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Author/s:

Farragher, JB;Pranata, A;Williams, G;El-Ansary, D;Parry, SM;Kasza, J;Bryant, A

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Effects of lumbar extensor muscle strengthening and neuromuscular control retraining on disability in patients with chronic low back pain: A protocol for a randomised controlled trial

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BMJ Open Effects of lumbar extensor muscle strengthening and neuromuscular control retraining on disability in patients with chronic low back pain: a protocol for a randomised controlled trial

Joshua Brodie Farragher,¹ Adrian Pranata,² Gavin Williams,¹ Doa El-Ansary,² Selina M Parry,¹ Jessica Kasza,³ Adam Bryant¹

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For numbered affiliations see end of article.

Correspondence to

Joshua Brodie Farragher;
jffarragher@student.unimelb.edu.au

ABSTRACT

Introduction Chronic low back pain (CLBP) is the leading cause of disability worldwide. However, there is no consensus in the literature regarding optimal management. Exercise intervention is the most widely used treatment as it likely influences contributing factors such as physical and psychological. Literature evaluating the effects of exercise on CLBP is often generalised, non-specific and employs inconsistent outcome measures. Moreover, the mechanisms behind exercise-related improvements are poorly understood. Recently, research has emerged identifying associations between neuromuscular-biomechanical impairments and CLBP-related disability. This information can be used as the basis for more specific and, potentially more efficacious exercise interventions for CLBP patients.

Methods and analysis Ninety-four participants (including both males and females) with CLBP aged 18–65 who present for treatment to a Melbourne-based private physiotherapy practice will be recruited and randomised into one of two treatment groups. Following baseline assessment, participants will be randomly allocated to receive either: (i) strengthening exercises in combination with lumbar force accuracy training exercises or (ii) strengthening exercises alone. Participants will attend exercise sessions twice a week for 12 weeks, with assessments conducted at baseline, midway (ie, 6 weeks into the trial) and at trial completion. All exercise interventions will be supervised by a qualified physiotherapist trained in the intervention protocol. The primary outcome will be functional disability measured using the Oswestry Disability Index. Other psychosocial and mechanistic parameters will also be measured.

Ethics and dissemination This study was given approval by the University of Melbourne Behavioural and Social Sciences Human Ethics Sub-Committee on 8 August 2017, reference number 1 749 845. Results of the randomised controlled trial will be published in peer-reviewed journals.

Trial registration number ACTRN12618000894291.

Strengths and limitations of this study

- Both the assessor and participants are blinded to their group allocation. The treating therapists are not blinded.
- This is the first randomised controlled trial to investigate the efficacy of neuromuscular control exercise specifically targeting lumbar muscle force accuracy.
- The novel assessment of biomechanical parameters such as whole body kinematics during lifting and variable force accuracy of the lumbar extensors.
- There is no long-term follow-up.
- The trial protocol is dependent on specific equipment for replication or generalisation.

INTRODUCTION

Chronic low back pain (CLBP) is the leading cause of disability worldwide.¹ In 2015, ~540 million² or 7.3% of the world's population had CLBP-related disability.³ The ability to carry out daily activities is an important outcome for patients with CLBP.⁴ Patient-reported outcome measures are ideal tools for measuring disability. The most frequently utilised condition-specific disability measure for people with CLBP is the Oswestry Disability Index (ODI).^{5,6}

CLBP is a complex and multifactorial condition with both disability and pain linked to physical, neurophysiological, psychological and social factors.⁷ Physical and neurophysiological factors that have been found to associate with CLBP-related disability include lumbar extension strength deficits⁸ and decreased lumbar multifidus (LM) size.⁹ Moreover, novel measures of lumbar extensor force accuracy and control¹⁰ and

lifting-related inter-joint coordination^{11 12} have been associated with CLBP-related disability.

Diminished movement coordination between the trunk and the lower limbs during lifting has been associated with the development of CLBP.^{13 14} Moreover, people with higher CLBP-related disability have demonstrated kinematic and kinetic mal-adaptations during lifting.^{12 15} Indeed, a positive weak correlation ($r=0.30$, $p=0.048$) has been identified between trunk and hip movement coordination and self-reported disability.¹¹ Furthermore, functional tasks such as lifting often use sub-maximal force of the lumbar extensor muscles¹⁶; thus, there may be functional relevance in examining sub-maximal lumbar extension force accuracy. In support, a recently developed lumbar extensor force accuracy test demonstrated that it may predict up to 19% of the variance in CLBP-related disability.¹⁰

While the abovementioned factors are more associated with CLBP-related disability, muscle morphology of the lumbar spine has a moderate positive relationship with pain duration ($F=6.34$, $p=0.016$).¹⁷ No association has been established with self-reported CLBP-related disability^{17 18}; however, these studies participants had minimal disability, which may not be representative of a more disabled population. LM is a significant contributor to control and segmental stabilisation of the lumbar spine.^{19 20} In CLBP patients, a number of imaging studies have reported altered morphology and decreased size of the LM compared with matched healthy individuals.^{9 21–23} Moreover, people with unilateral CLBP display significantly reduced size of the LM on the symptomatic side of the lumbar spine compared with the asymptomatic side.⁹

In addition to lumbar muscle morphology, architectural differences in lumbar muscle tissue have been demonstrated in CLBP patients. MRI studies have demonstrated that CLBP patients have increased fat infiltration and decrease in cross-sectional area of their erector spinae and LM muscles.²⁴ Fat infiltration, a sign of lumbar muscle deconditioning, may increase the echogenicity (ie, 'whiteness') on real-time ultrasound (US) images.²⁵ The erector spinae muscles, in particular the more muscular lateral bands that connect the ilium, lumbar and lower thoracic region known as the iliocostalis lumborum (IL), are important in maintaining static and dynamic posture (ie, during lifting).^{26–28} Considering this, future studies should evaluate morphological and architectural parameters of the IL in addition to the LM and how these muscles respond to resistance training in people with CLBP.

Awareness of the psychosocial factors associated with CLBP has increased dramatically in recent years.²⁹ In particular, there have been a number of studies investigating the relationship between kinesiophobia and pain self-efficacy among CLBP patients.^{30–34} The Tampa Scale for Kinesiophobia (TSK) and Pain Self-Efficacy Questionnaire (PSEQ) should be considered when investigating this population, as they are associated with CLBP-related chronicity.³⁵ Thus, these measures may help explain

the mechanism(s) for improvements in CLBP-related disability.⁷

Despite the numerous studies investigating the effects of various types of exercise on disability in people with CLBP,^{36–38} the underlying mechanisms behind how and why people do/don't improve remain unknown. Previous CLBP-related interventional studies have focused on improving some of the abovementioned parameters.^{37 39 40} However, no previous randomised controlled trial (RCT) has investigated force accuracy and lifting-related inter-joint coordination that, of the biomechanical-neuromuscular factors, have a demonstrated stronger association with CLBP-related disability.^{10–12}

Objectives

The primary objective of this study is to determine in patients with CLBP whether the addition of lumbar neuromuscular control retraining exercises to a 12-week programme of general and back-specific strengthening exercises result in significant improvements in disability compared with 12 weeks of general and back-specific strengthening alone.

The secondary objective of this study is to: investigate the neuromuscular, biomechanical and psychosocial mechanisms in which neuromuscular control retraining and muscle strengthening may influence CLBP-related disability.

Hypothesis

It is hypothesised that CLBP participants receiving neuromuscular control exercise targeted at improving lumbar extensor force accuracy in addition to strengthening exercise will demonstrate a greater reduction in perceived disability compared with those only receiving strengthening exercises.

METHODS

Design and setting

The design is a two-arm randomised-controlled trial, which will be conducted at a single primary care physiotherapy centre in Melbourne, Australia and will be conducted over approximately 15 months (between July 2018 and October 2019). A total of 94 participants with CLBP will be recruited from a Melbourne-based private physiotherapy clinic. New patients presenting to the clinic with CLBP will be screened by a physiotherapist for eligibility into the study. Participants will be randomly allocated to receive either: (i) 12 weeks of global and isolated strengthening exercises or; (ii) 12 weeks of global and isolated strengthening exercises and a neuromuscular control exercise. The trial design is outlined in [figure 1](#).

Recruitment and participants

A physiotherapist will individually screen CLBP participants who present to the physiotherapy centre. A limitation of this recruitment strategy is that we will not be capturing people from the community who do not seek

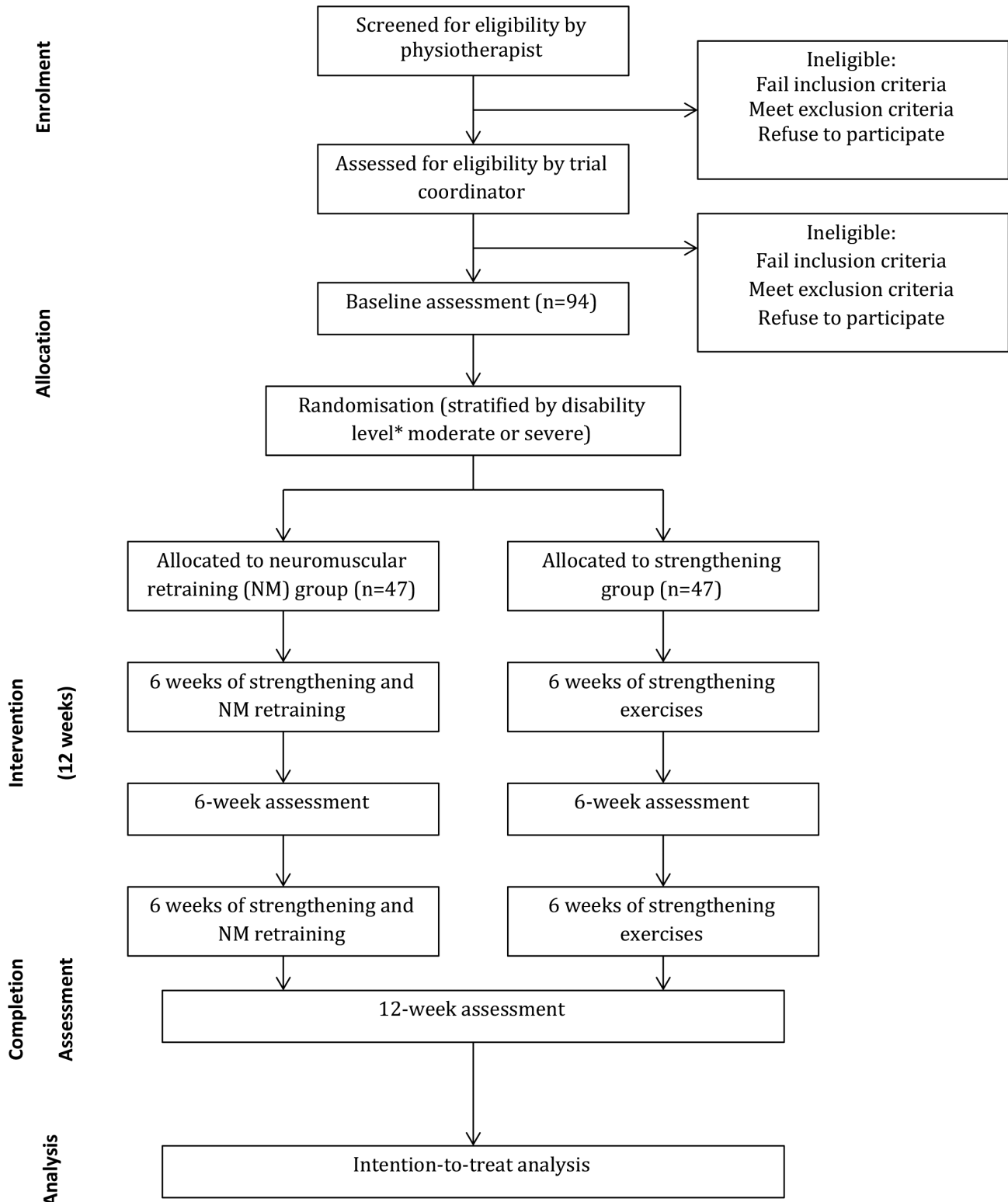


Figure 1 Study flow chart. *Disability is measured using the ODI; scores between 21% and 40% are classified as moderate disability and scores $\geq 41\%$ are classified as severe disability.

physiotherapy treatment and may manage their back pain via other professionals or self-means. Participants who meet the eligibility criteria will be presented with written information about the study, including its procedures. Those interested in participating will provide written informed consent prior to randomisation. The inclusion

and exclusion criteria are outlined in [table 1](#). Only participants with moderate or greater perceived disability (as per the ODI) will be included, as people with minimal CLBP-related disability have demonstrated similar results with a healthy population for the force accuracy assessment task.¹⁰

Table 1 Study inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Aged between 18 and 65 years	1. Medication managed psychological illness
2. Report chronic low back pain with or without pain radiating into the lower limbs for at least 3 months ^{67 68}	2. Previous spinal and lower limb surgery
3. Demonstrate moderate or greater disability on the ODI (ie, 21% or greater)	3. Diagnosed spinal osteoporosis/osteopaenia
	4. Diagnosed unstable spondylolisthesis/spondylolysis
	5. Diagnosed active systemic/inflammatory joint disease
	6. Diagnosed neurological and developmental disorders
	7. Overt neurological sign (absence of lower limb reflex or motor paralysis)
	8. Diagnosed significant medical conditions such as cancer or major cardiac diseases
	9. History of abdo-pelvic organ prolapse
	10. Use of medications that may influence balance
	11. Patients funded by a compensable body
	12. Inability to understand written/spoken English
	13. Pregnant
	14. <6 months postpartum

ODI, Oswestry Disability Index.

INTERVENTIONS

Participants from both treatment groups will participate in 12 weeks of machine-based resistance exercise sessions supervised in a one-to-one setting by qualified physiotherapists (1–5 years of experience). Each week, participants will attend two 30 min exercise sessions. The treating physiotherapists have been trained to deliver standardised interventions. All physiotherapists have undergone at least 15 hours of formal training in how to use the exercise machines (Delphex Kraeftigungstechnik). With respect to the novel neuromuscular control exercise, physiotherapists have undergone two one-to-one 30 min training sessions with the primary investigator (JBF) involved in the development of the exercise. On-site support will also be given to physiotherapists by one of the investigators (JBF) involved in the development of the exercise intervention.

During the 12-week programme, participants may also receive manual therapy and/or education by the treating physiotherapist. The type and dosage of co-interventions will be documented.

Control group

All participants enrolled in the RCT will undergo resistance training. Strengthening exercises will include a lumbar extension resistance exercise (figure 2A) together with one of the other resistance exercises (figure 2B–D) during each exercise session. The lumbar extension strength exercise is performed before any other strength exercise. Prior to completing the lumbar strength exercise, participants will complete a warm-up consisting of two lumbar extensions performed with no weight, as well



Figure 2 (A) Lumbar extension exercise. (B) Hip extension exercise. (C) Trunk flexion exercise. (D) Leg press exercise.

Table 2 Training parameters and the progression of the force accuracy task for the entirety of the trial

	Sets	Duration	Rest	Wave frequency	Force
Weeks 1–4	3 (excluding the warm-up)	60s for each sinusoidal frequency	30s between each set (including the warm-up)	Slow (0.05 Hz), medium (0.08 Hz) and fast (0.14 Hz) randomly ordered	20%–50% of MVIC. MVIC re-assessed at the beginning of each session
Weeks 5–6	3 (excluding the warm-up)	90s for each sinusoidal frequency	30s between each set (including the warm-up)	Slow (0.05 Hz), medium (0.08 Hz) and fast (0.14 Hz) randomly ordered	20%–50% of MVIC. MVIC re-assessed at the beginning of each session
Weeks 7–8	3 (excluding the warm-up)	120s for each sinusoidal frequency	30s between each set (including the warm-up)	Slow (0.05 Hz), medium (0.08 Hz) and fast (0.14 Hz) randomly ordered	20%–50% of MVIC. MVIC re-assessed at the beginning of each session
Weeks 9–12	3 (excluding the warm-up)	120s	30s between each set (including the warm-up)	Each set will contain a random mixture of each frequency (slow, medium, fast)	20%–50% of MVIC. MVIC re-assessed at the beginning of each session

Hz, hertz; MVIC, maximum voluntary isometric contraction.

as a 1 min set of the lumbar extension exercise (figure 2) at 50% of their training weight.

Participants in the control group will complete additional time on the lumbar extension exercise, at 50% of their maximum voluntary isometric contraction (MVIC), that is equivalent to the time (table 2) participants in the experimental group are performing the force accuracy exercise to control for work, that is if participants in the experimental group are completing 4 min of lumbar extensor force accuracy training, then the control participants will complete 4 min of lumbar extensor strength exercise performed at 50% of MVIC intensity.

Any other strengthening exercises (other than figure 2) prescribed to participants will be at the discretion of the supervising physiotherapist and will be documented in a training log.

Strength exercises image

Participants will complete a MVIC on each machine they use throughout the study. The starting training weight will be set at 85% of the MVIC. Each strengthening exercise is to be completed for 90–120s with one-to-one supervision. Participants will perform continuous repetitions with a 3-s concentric and eccentric phase and a 2-s isometric phase throughout this time. Once the participant can complete the exercise for 120s, the physiotherapist will increase the resistance by 5% for the next session. This resistance training protocol conforms to the current American College of Sports Medicine guidelines.⁴¹ The treating therapist will assess participant's pain intensity before, during and after performing each exercise using the Numerical Rating Scale (NRS). If a participant's pain increases by a value of 3 out of 10, then participants will cease the exercise.

Experimental group

In addition to resistance training, the intervention group will complete a neuromuscular control retraining exercise at the beginning of each training session. Specifically, participants will be seated on a MedX dynamometer (MedX) and will be instructed to push isometrically against the backrest with maximum voluntary effort. This MVIC data will be used to calculate the range of force required for the rest of the exercise. Participants will then be required to push back against the backrest to match a sinusoidal target force varying between 20% and 50% of their lumbar extension MVIC.¹⁰ The frequencies of the sinusoidal wave are 0.05 Hz, 0.08 Hz and 0.14 Hz (figure 3). Table 2 outlines the progression of the force accuracy exercise over the 12-week training programme.

Before beginning the force control exercise, all participants will complete a 1 min warm-up at a frequency of 0.08 Hz (medium). Following the warm-up, each session of force control exercise will involve participants completing three sets; each set will incorporate a different frequency (fast, medium or slow; see figure 3) that will be completed in a random order. A rest period of 30s between each set of force control exercise will remain constant throughout the 12-week intervention.

Outcome measures

All primary, secondary and additional outcome measures will be assessed at baseline (prior to randomisation), after 6 weeks of treatment and at completion (12 weeks).

Primary outcome

Oswestry Disability Index (ODI)

The primary outcome of interest will be perceived functional disability and will be assessed using the ODI.⁴² The ODI comprises of a pain scale and nine categories pertaining to activities of daily living. Each component

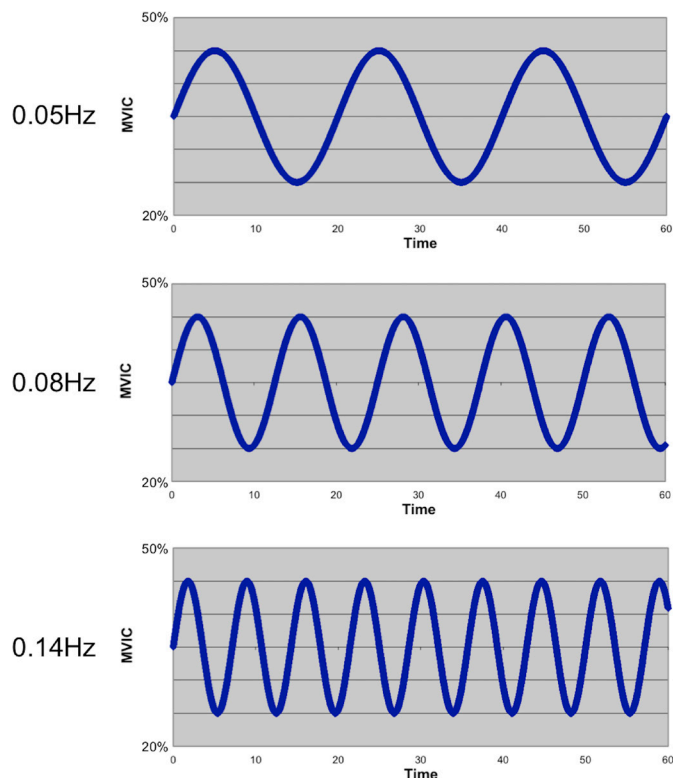


Figure 3 Sinusoidal waves for slow (0.05 Hz), medium (0.08 Hz) and fast (0.14 Hz) frequencies for the force accuracy assessment and training.

is scored from 0 to 5. Overall scores are calculated as a percentage with higher values indicative of worse perceived disability. The ODI is reliable (intraclass correlation coefficient (ICC)=0.94), has good construct validity ($r=0.99$)⁴³ and is sensitive to change in people with CLBP.^{44 45}

Secondary outcomes

Numerical Rating Scale (NRS)

Pain severity will be recorded using the NRS. Participants will be asked to rate their average low back pain over the past week on an 11-point scale ranging from 0 (no pain) to 10 (worst imaginable pain). The NRS has demonstrated good construct validity and reliability in people with CLBP.^{46 47}

Tampa Scale for Kinesiophobia (TSK-17)

The TSK-17 aims to measure pain-related fear beliefs about movement and re-injury⁴⁸; it is scored using 17 questions about fear of pain and/or movement. Scores range from 17 to 68; higher scores indicate greater fear of movement. The TSK-17 has been demonstrated to have good construct validity and be a reliable (Cronbach's $\alpha=0.81$)^{49 50} measure for pain-related fear and pain catastrophising in a CLBP cohort.

Pain Self-Efficacy Questionnaire (PSEQ)

The PSEQ asks 10 questions regarding pain and physical activity; Scores range from 0 to 60; lower scores indicate less confidence in recovering from CLBP. The PSEQ has good

construct validity⁴ and is a reliable (ICC=0.92)⁵¹ measure in people with CLBP. It is also a useful tool to explain variability in perceived disability in this population.³³

International Physical Activity Questionnaire (IPAQ) Short Form

The IPAQ Short Form will be used to evaluate participant's physical activity levels. Participants will provide information on their week's vigorous and moderate physical activity as well as walking time to calculate their metabolic equivalent in exercise testing. The IPAQ Short Form has demonstrated good reliability (ICC=0.80).⁵²

Additional outcomes

A series of additional outcomes will be collected for the purposes of answering related questions about biomechanical effects of force accuracy and strength training, and for subsequent analyses of potential mediating effects on primary and secondary outcomes. These measures will be used to determine treatment efficacy.

Lumbar extension strength

Assessment of isometric lumbar extension strength using the MedX dynamometer has demonstrated good construct validity⁵³ and reliability ($r=0.57-0.93$)⁵⁴ in people with CLBP.

Participants will be seated on the MedX dynamometer (figure 4) with their trunk in 12° flexion and lower limbs fixed. Using their lumbar extensor muscles, participants will then be required to push into the back force detection pad placed at the level of their thoracic spine with maximum voluntary effort.^{55 56} The force exerted on the load cell is measured as torque using custom developed LabView software.¹⁰

Lumbar extension force accuracy

Force accuracy assessment quantifies a person's ability to control and accurately produce sub-maximal, isometric force into a lumbar extension direction. This assessment has been demonstrated to be reliable (ICC=0.88) and have good construct validity in people with CLBP.¹⁰

While seated on the MedX dynamometer (as per earlier description), participants will then be asked to isometrically push against the backrest to match a fluctuating force trace (minimum and maximum thresholds of 20% MVIC and 50% MVIC, respectively) displayed in real time on a computer tablet (figure 5). The sub-maximal range is based on lumbar extensor activity during daily tasks such as pushing a shopping cart.⁵⁷

Participants will perform this force accuracy task at 0.08 Hz (medium speed) for 60 s as a warm-up. Participants will then perform three, 60-s assessments at three different frequencies in this order: (i) 0.08 Hz (five waves per minute; as per the warm-up), (ii) 0.05 Hz (three waves per minute; slow speed) and (iii) 0.14 Hz (8.4 waves per minute; fast speed). Participants will receive 30-s rest between the warm-up and each of the three assessments at different frequencies.



Figure 4 A participant seated on the MedX machine at 12° lumbar flexion. The MedX restraint system includes the pelvic restraint (A), lap belt (B), thigh restraint (C) and foot plate (D).

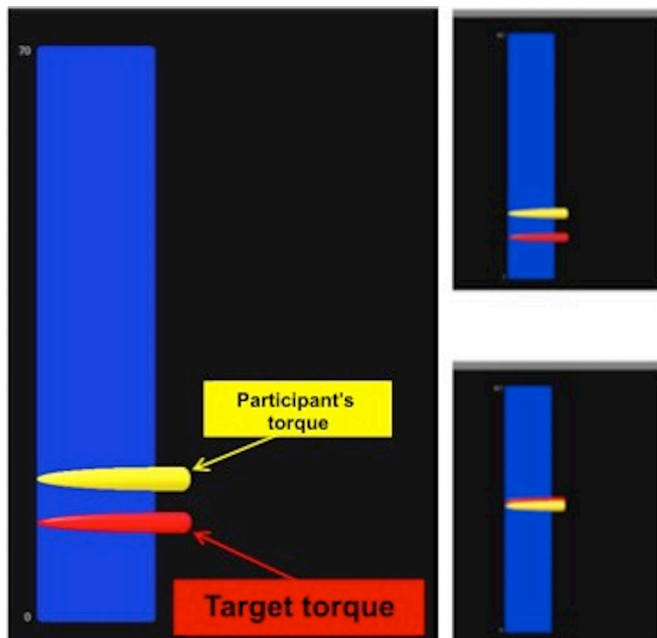


Figure 5 A screenshot of the muscle force accuracy assessment process as seen on the tablet by the participants. The red marker will move up and down at a speed depending on the frequency while the participant attempts to match this with the real-time yellow force marker. Reproduced with permission.

Lifting kinematics and kinetics

Kinetic and kinematic assessment during lifting has been demonstrated to be reliable (ICC=0.98) and has good construct validity for people with CLBP.¹¹

For kinematic and kinetic analyses, participants will be assessed barefoot while wearing shorts. Non-reflective markers will be placed on the skin overlying specific vertebrae, as well as the head, pelvis, upper and lower limbs. Balance and force distribution through each lower limb will be assessed using Nintendo Wii Balance Boards (WBB, Nintendo) while three-dimensional mapping of anatomical landmarks will be performed using a 12-camera optoelectric motion analysis system (Optitrack Flex 13, NaturalPoint) sampling at 120 Hz. Data from the WBBs will be collected on a laptop computer running custom software via a wireless Bluetooth connection. The WBB have demonstrated good construct validity against the appropriate gold-standard, laboratory-grade force platform.⁵⁸ The Optitrack system has demonstrated good accuracy and reliability compared with the more expensive and widely used Vicon 612.⁵⁹

Participants will start the test standing upright with arms by their sides. An 8-kg weight was selected for functional relevance as this has been defined as the average weight of a bag of groceries.⁶⁰ They will be given a standardised instruction to bend down and lift the weight with both hands from the ground to the level of their abdomen using a self-selected technique. They will then turn to their left and place the weight on a table at the height of their greater trochanter.¹² They will then be instructed to place the weight back on the floor using a self-selected technique. The same assessment will also be performed on the right side. Four lifting trials will be conducted per side, the first serves as a practice trial. The average of the three remaining trials will be used for data analysis (total of 8 trials).

The kinematic data will be labelled, cleaned and gap-filled using Optitrack Motive software (NaturalPoint) and then passed through a custom written analysis pipeline (Visual3D v5.01.6, C-Motion). Angular displacement and angular velocity data will then be derived using custom written LabVIEW 2009 (National Instruments) software.

Ultrasonography of lumbar multifidus (LM) and iliocostalis lumborum (IL) muscles

Ultrasonography is a non-invasive reliable means of assessing muscle quantity and quality (including echogenicity)²⁵ and has been used in CLBP populations.^{9 12 25 61 62} Within this study, participants will lie in a prone position on a plinth with a pillow placed under their pelvis to avoid excessive lumbar lordosis. Images will be acquired using a Sonosite Turbo Edge machine (SonoSite, Fujifilm) with a linear transducer (6–13 MHz). To ensure consistency and reproducibility, bony landmarks including the spinous and transverse processes of L3, 4 and 5 will be palpated and marked using a water-soluble marker. Detection of the spinous processes was determined manually using the

iliac crests as landmark guides. This has been previously demonstrated to be a reliable method for obtaining LM images.⁶³ Transverse images of the LM will be taken adjacent to the spinous processes on both sides. Transverse images of the IL will be taken in line with the L3 spinous process on both sides. Images of the LM will be collected while resting and also during active contraction of the muscles. Active contraction images will be procured as participants perform a prone ipsilateral straight leg extension without bending their knee to the point where their knee is off of the plinth. To ensure consistency between test sessions, the angle of the participant's thigh relative to horizontal will be measured using a smart phone running inclinometer software (iHandy Level, V.1.70.3, iHandy) attached to the participant's thigh.

All US images will be measured using Image J software (NIH). Measures of muscle thickness will be determined by measuring the distance between the superior fascial border and the inferior fascial border of the muscle at the thickest point. Echogenicity will be measured via a circumferential trace of the inner fascial border of the muscle. The resting transverse images of the LM and IL will be measured for thickness and echogenicity, whereas the active images of the LM will only be measured for thickness. All measurements will be performed three times and an average will be calculated post image acquisition. For each side, the mean difference in LM thickness between the resting and contracted state will be compared.

Sample size calculation

The aim is to detect a 10-point difference in the primary outcome (ie, ODI), which corresponds to the minimal clinically important difference.⁶⁴ With a SD of 15, this difference corresponds to an effect size of 0.67, and the between-group ODI minimal clinical important difference can be detected with 80% power and a significance level of 0.05 with 37 participants per group. Allowing for 20% dropout, recruitment of 47 ($=37/(1-0.2)$) participants per group is required.

Randomisation and allocation concealment

Following baseline assessment, participants will be randomised to one of the two treatment arms, using a computer-generated randomisation sequence, consisting of random permuted blocks of sizes 6–12, stratified by baseline ODI level (moderate or severe/greater). The schedule will be stored on a password-protected website (REDCap, Vanderbilt University) maintained by an off-site co-investigator not involved in either participant recruitment or administration of primary/secondary outcome measures. This same co-investigator will reveal group allocation to the treating physiotherapists.

Blinding

Participants will be blinded to group allocation by the process of limited disclosure. Participants will not be informed about the exercises to be completed by

participants in the other group. In addition, participants will not be informed about the study hypotheses, or which group they were allocated to, until study completion at which time they will be provided a summary of the study purpose, hypotheses and findings. The primary investigator will be conducting all the assessments and statistical analyses (in consultation with a biostatistician) and will not be involved in the random allocation process or treatment delivery and therefore, will not be privy to which group participants are allocated. As the primary and secondary outcomes are participant-reported, and participants are blinded, as well as the assessor conducting the biomechanical assessments is blinded, this study is also considered assessor-blinded. The statistician assisting with statistical analyses will not be involved in treatment delivery or assessment, nor with the randomisation process directly. A researcher not involved in the assessment, treatment or statistical analysis of participants will randomise and inform the treating physiotherapists, who are not blinded to the participant's group allocation.

Data management

All study data will be stored at the University of Melbourne for 15 years after the completion of the trial. All paper-based documents and data will be stored in a locked filing cabinet. All electronic data will be secured on a password-protected laptop and network drive. All documents that contain names or personal identifying information will be stored separately from other study data and identified by code number. Access to files will be limited to research staff involved in the study.

Statistical analysis

The principal investigator will analyse blinded data under the supervision of a biostatistician. Main comparative analyses between groups will be performed using intention-to-treat. If the proportion of missing outcome data is greater than 5%, multiple imputations will be used to account for missing outcome data. Data missing at baseline will be imputed using single mean imputation. Complete-case analyses will also be conducted. For the primary hypothesis, differences in mean change in disability index (baseline minus follow-up) will be compared between groups using linear regression modelling adjusted for baseline values and the stratifying variable of ODI level. Similar analyses will be conducted for continuous secondary outcomes. Standard diagnostic plots will be used to check the model assumptions of linearity and of constant variance and normality of residuals. All statistical analyses will be performed using SPSS V.21.0 (IBM) with significance level set at 0.05. A sensitivity analysis will be conducted in the case where one group receives more co-interventions than the other group.

Adverse events

The neuromuscular control exercise has been piloted to minimise risk of pain exacerbation. While this novel neuromuscular control exercise has not been previously

used for training people with CLBP, a similar protocol for assessment has been used in this population with no reports of pain exacerbation.¹⁰ The strengthening exercises and equipment utilised in this study have been previously used in people 2 weeks post lumbar discectomy.⁶⁵ Of the 80 participants recruited, two dropped out due to increased pain with training. The risk of pain exacerbation is likely to be less, as this study does not recruit acute postoperative patients. In addition, previous studies and the American College of Sport Medicine recommendations^{41 56} have used/prescribed similar intervention protocols, in similar settings and cohorts. An RCT investigating exercises of similar muscle groups reported a symptom exacerbation rate of 5.7%.⁶⁶ The treatment protocols in this study involve constant close monitoring of participants.

Physiotherapists and the primary investigator will record any adverse events. Participants will also be asked to contact the primary investigator at their discretion by phone or email to report adverse events. If an adverse event is reported, the primary investigator, treating physiotherapists will liaise with local health service providers (eg, patients general practitioner (GP) or paramedics). All adverse events will be documented in the final written report of this study.

Auditing

A member of the research team not involved in determining eligibility, assessment or treatment of participants will perform fidelity checks to ensure the assessment and treatment of participants throughout the trial conforms to this protocol. Fidelity checks will be conducted every 3 months to ensure strict adherence. These checks will include observation of clinician's treatment of participants, hand-checks of the training logs describing the exercises completed for each session as well as online database (REDCap, Vanderbilt University) checks for assessment data storage. Breaches of protocol will be reported and further training to the assessor or therapist involved will be provided. A follow-up check of the breaching party will be conducted 2 weeks later to ensure the protocol is strictly adhered to.

Ethical considerations

Any amendment requiring modifications to the protocol, which may impact on the study, will be agreed on by the research team and will be submitted to the ethics committee for approval. Minor changes to the protocol will be agreed on by the research team and will be documented in a memorandum. All changes will be documented with the relevant trial registry.

Written informed consent will be obtained from all participants enrolled in the study. Participants will be informed that they have no obligation to participate in the study and are free to withdraw at any time, without any negative consequences on their future care. Participant's names and personal information will remain confidential at all times. This will be achieved by identifying

data by the participant code and not using identifiable information; any identifiable information will be kept separate from study data.

Patient and public involvement

Patient priorities heavily impacted our decision to primarily investigate perceived disability in people with CLBP. While there are other mechanistic outcomes, understanding the impact that the interventions are having on a meaningful outcome for patients was paramount.

Patients were involved when developing and piloting the study assessment and intervention protocols. Patient's feedback regarding duration, difficulty and pain levels informed the protocol.

Patients presenting for treatment to a Melbourne-based physiotherapy clinic will be recruited for the proposed RCT. Trial participants will be able to obtain anonymous overall study results as well as their individual results from the trial after the completion of the study.

DISSEMINATION

Results of the RCT will be published in peer-reviewed journals. Data may be made available on request to the primary investigator, post-publication of all study results. The results of the trial will also be disseminated via conference presentations, professional organisations, media, social media and consumer organisations.

CONCLUSION

This will be the first RCT to compare the effects of neuromuscular control training with strength exercises on CLBP-related disability. The study results will provide valuable information about the physical and psychosocial mechanisms behind improvements in disability for people with CLBP.

Author affiliations

¹Physiotherapy, School of Health Sciences, The University of Melbourne, Melbourne, Victoria, Australia

²Health Professions, Swinburne University of Technology, Hawthorn, Victoria, Australia

³Epidemiology and Preventative Medicine, Monash University, Melbourne, Victoria, Australia

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Contributors JBF is a musculoskeletal physiotherapist who is undertaking his PhD. He is leading the randomised controlled trial (RCT), managing budget, managing clinicians involved in the intervention, performing assessments and responsible for outcomes. He is also responsible for publishing the trial protocol and the findings of the trial. AP has assisted with the development of data collection and intervention protocols and data analysis of lumbar extensor force control, lifting movement coordination kinematics and kinetics. He has also assisted with the development of the intervention protocol, participant randomisation, trial fidelity assessment

and manuscript preparation. GW has contributed to all aspects of RCT planning and implementation and publication, specifically helping to develop the novel force accuracy training protocol. DE-A has assisted with the study design, in particular the rationale and measurement protocol for ultrasound. She has also contributed to all aspects of the RCT planning, data analysis and publication. SMP has contributed to all aspects of RCT planning and publication, specifically developing the measurement protocol using ultrasound. JK has assisted with the sample size calculation and formulated data analysis plan. JK has mentored the corresponding author, JBF, in analysis and statistical calculations at the completion of the trial. AB has contributed to all aspects of RCT planning, implementation and publication. He has assisted with the development of data collection and intervention protocols and data analysis of lumbar extensor force control, lifting movement coordination kinematics and kinetics.

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