Individualised exercise for patients with persistent low back pain and lateral abdominal muscle impairments: a randomised feasibility study

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Abstract

Background: This parallel randomised control trial assessed feasibility of an exercise intervention for individuals with low back pain and maladaptive changes in lateral abdominal muscle contraction. Feasibility was assessed considering participant retention, program adherence and a preliminary evaluation of intervention efficacy.

Methods: Sixty adults (40 female, 20 male, average 54.2 years of age) with persistent low back pain and maladaptive changes in lateral abdominal muscle contraction were randomly assigned to fully or partially individualised versions of the 12 week program. All participants

received motor control and graded activity exercise individualised to their low back pain symptoms, impairments and functional goals. Additionally, participants in the fully individualised group were asked what types of exercise they enjoy, and this informed the graded activity prescription. Lateral abdominal outcome measures included endurance and ultrasound imaging (muscle thickness at rest and during contraction, transversus abdominis slide), manual palpation and pressure biofeedback unit measures of contraction. Clinical outcomes included pain intensity (Numeric Rating Scale), disability (Roland Morris Disability Questionnaire), function (Pain Specific Functional Scale), physical activity (International Physical Activity Questionnaire) and lumbar instability (Lumbar Instability Questionnaire). Outcomes were measured at baseline, at the end of the intervention and clinical outcomes were measured again three months after the intervention concluded. Linear mixed effects models were used to compare the effects of the intervention within and between groups.

Results: Retention and exercise compliance rates were 81% and >85% (86% control group, 87% experimental group) respectively. Participants in both groups achieved improved lumbar instability, disability, pain intensity, function, physical activity, lateral abdominal muscle endurance and contraction post intervention. The fully individualised group demonstrated greater between group improvements in function (mean [95%CI]: -2.577 [-3.239, -1.915] 12 weeks, -2.592 [-3.254, -1.930] 3 months) and physical activity (mean [95%CI]: -790.834 [-1712.05, 130.382] 12 weeks, -1080.748 [-2001.964, -159.532] 3 months).

Conclusions: The intervention demonstrated improvements in clinical outcomes, and acceptable exercise compliance. However, the intervention did not meet retention feasibility criteria to proceed to an adequately powered trial. Modifications to improve

retention including incorporating group activities are required. Following modifications, an adequately powered trial is required to determine the efficacy of the intervention.

Trial registration: This trial was prospectively registered on the Australian and New Zealand Clinical Trial Registry (ACTRN12622001284752 30 September 2022)

Keywords: lumbar, physical activity, motor control

Key messages regarding feasibility

What uncertainties existed regarding the feasibility?

Uncertainties existed regarding participant engagement with the program and the potential effect of the program on clinical and lateral abdominal muscle outcomes.

What are the key feasibility findings?

Participant retention was slightly below the threshold for the study being considered 'feasible'. However, the program met feasibility criteria for exercise compliance. Preliminary data suggested the program may demonstrate changes in clinical outcomes. It is unclear whether the between group differences in outcomes post intervention were due to baseline differences.

What are the implications of the feasibility findings for the design of the main study?

This study provides information about participant engagement and responses to an intervention designed for individuals with low back pain and maladaptive changes in lateral abdominal muscle contraction. In the following study, we will undertake an adequately powered study to have a greater understanding of the intervention effectiveness. Several strategies have been suggested to improve participant retention.

Background

Some individuals with persistent low back pain (pain ≥3 months; PLBP) present with maladaptive changes in trunk muscle activation, endurance, contraction and morphology.(1) Such motor control changes have been associated with PLBP recurrence.(1) (2) Hence, exercise may be prescribed to address maladaptive motor control changes. However, the evidence remains unclear regarding whether there is a superior type of exercise for individuals with maladaptive changes in lateral abdominal muscle activation, endurance, contraction or morphology (LAM; transversus abdominis [TrA], internal [IO] and external oblique [EO]).(3)

Two meta-analyses (Shanbehzadeh 2022 13 studies, 766 participants; Zhang 2021 18 studies, 1333 participants)) investigated the effectiveness of exercise types for improving abdominal muscle contraction and thickness in participants with PLBP.(4, 5) However, both concluded that various exercise programs (motor control, abdominal resistance, general and McKenzie exercises) may improve these measures.(4, 5) To the best of our knowledge, no reviews have examined the effectiveness of exercises for improving other measures of the LAM such as endurance.

The evidence is also inconclusive when comparing the effectiveness of exercise prescriptions for PLBP clinical outcomes including pain intensity, disability and function.(4-12) Some meta-analyses indicate motor control exercises were more effective for reducing pain intensity(4-8), disability(4, 5, 7, 13) and function(8) than other exercise interventions. However, other meta-analyses and systematic reviews have found various types of exercises to have comparable effects on such outcomes.(5, 9-12)

There are several potential reasons for why the evidence is inconclusive regarding the effectiveness of various exercise prescriptions for improving LAM and clinical outcomes. Firstly, sample populations often comprise patients with non-specific PLBP without further subgrouping.(14) Considering different mechanisms may contribute to non-specific PLBP, it is unlikely that individuals will respond to the same exercise program in the same way.(3) For example, preliminary evidence suggested that self-report lumbar instability significantly modified treatment response to a motor control or graded exercise program (interaction: 2.72; 95% confidence interval=1.39 to 4.06).(15) Additionally, motor control exercise programs have demonstrated greater effectiveness when applied to specific subgroups (for example acute unilateral LBP group, spondylolisthesis and pregnancy related pelvic girdle pain).(16) To more accurately understand whether different exercise programs are effective for individuals with PLBP and maladaptive LAM changes, samples should be comprised of individuals with maladaptive LAM changes.

Even if studies recruited participants based on specific clinical characteristics, interventions should be individualised.(17) Motor control exercise programs have demonstrated larger effects for reducing pain intensity where interventions have progressed to incorporating individualised functional exercises.(4) However, one systematic review examining various exercise programs for people with PLBP found that, of their included studies, 19% of exercise programs were individualised, 36% somewhat individualised and 45% were standardised.(10)

Recently, the authors of this article developed an individualised exercise intervention for patients with PLBP and maladaptive LAM muscle changes based upon the findings of a systematic review(18), scoping review (manuscript in preparation) and Delphi study(19) in

consultation with clinical practice guideline recommendations(20-40). The intervention aligns with many concepts outlined in previous motor control exercise prescription frameworks such as Motor Control Training and the Integrated Systems Framework. However, this intervention has greater emphasis on the incorporation of patient preferences and following a graded activity approach.

Prior to exploring the effectiveness of the intervention, ideally through a randomised controlled trial (RCT), it was necessary to undertake a feasibility study to inform the design of a RCT in the future and if the intervention needed further refinement. Specifically, this study sought to 1) evaluate the acceptability and suitability of an intervention in reference to participant retention and adherence and 2) to gain a preliminary understanding of the effect of the intervention on LAM and clinical outcomes. Additionally, this study aimed to investigate the influence of individualisation on the outcomes, by comparing a more standardised and more individualised version of the intervention.

Method

This parallel randomised control trial follows CONSORT reporting guidelines for feasibility studies(41) (Additional file 1), was prospectively registered on the Australian and New Zealand Clinical Trial Registry (ACTRN12622001284752, Additional file 2) and approved by The University of South Australia Human Research Ethics Committee (204929).

Participants

Sixty people with PLBP (40 female, 20 male; average age 54.2 years) were recruited via convenience sampling using word of mouth, website, and social media advertisements according to the following eligibility criteria (Table 1).

Table 1 Eligibility criteria

Inclusion	Having pain for at least 12 weeks, located between the buttock crease and lower ribs, with or without pain in one or both legs.[42] Aged 18 years or above. Able to speak English to communicate with a physiotherapist. Considered 'ready to exercise'* based on screening with the Physical Activity Readiness Questionnaire.[43] Demonstrated maladaptive changes in LAM contraction and/or thickness^
Exclusion	Demonstrated two or more symptoms of nerve root compromise for the same nerve root (weakness, loss of sensation or changes in reflexes)(44). Were pregnant or had given birth within the last year. Had potential or diagnosed serious pathology (cancer, cauda equina syndrome, fractures, infections)~. Had systemic inflammatory conditions such as rheumatoid arthritis. Had abdominal skin conditions which would preclude participants from having LAM ultrasound imaging. Had comorbidities which prevented participants from participating in exercise e.g. spinal cord injury, or an assessment by a general practitioner found that the participant was unsuitable to participate in the exercise program. Participants were advised to seek medical assessment if required from the results of the Physical Activity Readiness Questionnaire.[43]

* Participants were advised to seek medical clearance prior to participation if required from the results of the Physical Activity Readiness Questionnaire. This requires a medical assessment where participants may/have: osteoporosis, difficulty controlling heart or cardiovascular conditions, an irregular heartbeat, chronic heart failure, difficulty controlling high blood pressure, a resting blood pressure ≥160/90mmHg, symptoms of undiagnosed diabetes, difficulty controlling diabetes, difficulty controlling any respiratory conditions, low blood oxygen, requiring supplemental oxygen therapy, use of asthma medication more than twice per week, low blood pressure causing dizziness, light headedness or fainting on a regular basis, previously having had a stroke, or, if the individual has cardiovascular disease and have not participated in regular exercise recently.
^Please see below for the criteria used to assess LAM contraction and thickness
~Participants were verbally screened for 'red flags' indicating potential cancer or cauda equina syndrome. Participants with 'red flags' required medical clearance before participation in this study.

Maladaptive changes in LAM contraction were defined as, a deficiency in one or more of the following assessments measuring the ability to contract TrA: 1. Deep Muscle Contraction scale (score less than 10 which is considered optimal)[45]; 2. Prone Pressure biofeedback unit testing (exhibiting substitution strategies such as spinal/pelvic movement and/or a change in pressure outside the optimal range which is a reduction of 4-10mmHg)[46]; 3. USI ratios (suboptimal abdominal drawing in manoeuvre as measured using the TrA, preferential activation and preferential activation modified ratios). To the best of our knowledge,

definitive 'optimal' and 'suboptimal' scores for TrA, preferential activation and preferential activation modified ratios during the abdominal drawing in manoeuvre have yet to be defined. However, a higher ratio is indicative of increased TrA contraction(45), while lesser or negative ratios indicate insufficient use of TrA and/or increased oblique contraction depending on the ratio used.(45) Therefore, for this study, suboptimal USI ratios were defined as being 0 or negative. For LAM thickness, measures were required to be outside of 95% confidence intervals for previously published normative data: Male IO 6.1-17.3mm, EO 5.4-13.8mm, TrA 2.5-7.7mm; Female IO 3.5-12.7mm, EO 4.4-10.4mm, TrA 1.7-5.7mm.[47]

Procedures

Eligible participants provided informed consent and were then randomised into control or experimental treatment groups by the researcher (CP) using simple randomisation (Random Allocation Software © Version 1.0 2004 M Saghaei).(48) The intervention and data collection was conducted by one physiotherapist (CP) at the University of South Australia Clinical Trial Facility. Control and experimental groups undertook their intervention in parallel.

Participants were blinded to treatment groups as the participant information sheet only provided limited disclosure about the nature of the research study: participants were not informed that only the experimental group would have their exercise preferences incorporated into the program. It was not possible to blind the physiotherapist to baseline results or intervention study group allocation as they conducted data collection and randomisation.

In the first session, the physiotherapist completed a standard subjective examination to understand the patient's history and goals for the program. The physiotherapist then

observed the participant's standing and seated posture, and movement during activities identified by the participant during the subjective examination as problematic, such as sit to stand and bending over.

The physiotherapist and participant then collaboratively developed the exercise program consisting of daily motor control exercises (posture, movement +/- muscle activation) and graded activity exercises to complete a set number of times per week (cardiovascular + resistance).

Motor control exercise consisted of muscle activation, movement and posture exercises. Muscle activation exercises aimed to increase and/or decrease LAM activation according to results of the baseline assessment.(14) Participants were encouraged to practice corrected posture and movement strategies in activities they described as aggravating (e.g. sitting posture/sit to stand). Such exercises aimed to improve alignment/movement which was associated with improvements in participants' symptoms. Thus, prescription of motor control exercise was individualised considering the symptoms, impairments in posture, movement and/or muscle activation that were objectively assessed and participants' functional goals. Progression of the motor control exercise consisted of a transition from static (if required) to dynamic and functional exercises and was based upon the protocol described by Hodges et al (14).

Participants in the control group were asked to perform walking for cardiovascular exercise and resistance exercises were centred around functional goals e.g. sit to stand. Participants in the experimental group were asked what type/s of exercise they enjoy, and their resistance and cardiovascular exercises were developed integrating these preferences in addition to consideration of their functional goals. In both groups, the frequency of sessions

and time dedicated to exercise was adjusted to suit the individual's lifestyle. All other factors described below were consistent across both intervention groups.

For the graded activity component, cardiovascular exercise was progressed by either increasing the exercise frequency (adding 1 session), duration (increase of no more than 10 mins per session) or intensity (moderate or vigorous) towards World Health Organisation exercise prescription guidelines.(49) Resistance exercises were progressed by increasing session frequency (adding 1 session, up to non-consecutive days) and/or by using more challenging versions of exercises e.g. sit to stand -> squat. Only motor control exercises and cardiovascular OR resistance exercises would be progressed, never all three at once. Only one progression strategy (e.g. increased frequency) was used for each type of exercise at a time. Participants were not progressed if they could not demonstrate correct exercise technique to the physiotherapist, were having difficulty complying with the current exercise regime or reported their physical activity/function/pain goals were met. If participants reported difficulty in complying with the current regime, the physiotherapist discussed how it could be integrated into their lifestyle or made adjustments accordingly. Through targeting both motor control and graded activity, it aimed to reduce pain intensity, improve maladaptive LAM changes, functional capacity and education. See Table 2 for an overview of the intervention.

Table 2 Exercise prescription intervention

Components	Motor control exercise	Resistance exercise (Endurance and strength)	Cardiovascular exercise	Education
Aims	Improve movement and motor control	Improve global strength (and specific muscle strength if required)	Incorporate moderate/vigorous physical activity	Understand importance of exercise/staying active
Prescription	Posture, movement	Begin with simple, functional, low resistance	Progress towards exercise	Pain neuroscienc

	and or specific muscle activation re-training Progress from specific muscle exercise (e.g. learn to control deep muscles independently from superficial muscles) to functional activities	global strengthening exercises with good movement quality If required, incorporate trunk stabilisation exercises such as bridging, planks and bird dogs once motor control during functional positions/activities achieved. Endurance: Progress towards 2-3 sets of 15-25 reps Strength: Progress towards 3 sets of 8-12 reps ~3x per week	prescription guidelines e.g. World Health Organisation, American College of Sports Medicine	e education
Principles	Individualise the program considering the patient's preferences, lifestyle, impairments, and symptoms The program does not necessarily require equipment The program should improve patient's functional capacity and pain intensity Paced progression based on principles of graded activity and/or ability to maintain control Reduce fear avoidance and improve self-efficacy			Do not include in-depth biomedical explanations

During each appointment, the physiotherapist discussed pain science education according to the "Explain Pain" workbook.(50) This describes the biology of pain and concepts that may lead to the continuation of pain, such as central sensitisation. The physiotherapist used this information to explain the need for and prescription of graded activity.

Participants met with the physiotherapist individually: weekly during the first month, fortnightly during the second month and once in the final month of the 12-week program. The decreased frequency of appointments was planned to provide participants with greater autonomy. After the first appointment, participants could choose to conduct the follow-up appointments in person or via Telehealth using Zoom©. Participants were asked to record how often and what exercises they completed each week in an electronic or paper 'diary' (Additional file 3). Participants could choose which type of diary they preferred to use. This was brought to each appointment for discussion with the physiotherapist.

Feasibility outcome measures

Outcomes used in this study included: participant retention and compliance with the exercise regime, pain intensity, disability, function, physical activity, and LAM thickness/contraction/endurance. Intra-rater reliability testing was conducted by the examiner, finding moderate to excellent reliability across the LAM measures.(51)

Self-report outcomes questionnaires were completed and recorded using REDCap © electronic data capture tools (Vanderbilt) hosted at the University of South Australia. The questionnaires were sent to participants via an emailed or posted survey. Participants that did not complete the survey within a week were reminded via email/phone and if they did not respond within another week, they were contacted once more. A description of the

outcome measures used in this study and when they were collected is documented in Table 3.

Table 3 Outcome measures collected at each time point across the feasibility study

Data point / outcome measure	Timepoint collected	Psychometric properties
Anthropometric characteristics (Age, sex, height, weight, body mass index, pain duration, occupation)	Baseline	N/A
Pain intensity (measured using 0 to 10 Numeric Rating Scale) (52)	Baseline and 12 weeks (end intervention) and 3 months post intervention	Evidence for reliability (ICC 0.92) and construct validity (moderate association between numeric rating scale and pain intensity and disability scores) in PLBP population(53) (54) Minimally Clinically Important Difference: 2 (absolute value) or >30% change from baseline.(52)
Disability (measured using the Roland Morris Disability Questionnaire) (55)		Evidence for reliability (ICC 0.9) and content validity (Content validity confirmed via semi-structured interviews with participants with PLBP. Interviews explored the impact of low back pain on daily living and participants understanding and beliefs on the appropriateness of the Roland Morris Disability Questionnaire)(53) (56) Minimally Clinically Important Difference: 5 (absolute value) or >30% change from baseline. (52)
Lumbar instability (LISQ) (15)		Evidence for reliability (ICC 0.84), unclear construct validity in PLBP population when compared with the pain detect questionnaire (57)
Function (Pain Specific Function Scale) (58)		Evidence for reliability (ICC 0.91) and construct validity in PLBP population (moderate to good correlation with the global perceived effect scale, moderate to strong correlations with Oswestry disability index, global rating of change, functional rating index and Roland Morris Disability Questionnaire) (53, 59) Minimally Clinically Important Difference: 2.3 (absolute value).(53)
IPAQ – short form (60)		Evidence for reliability (75% of correlation coefficients above 0.65 across multiple countries in adults aged between 18 and 65), concurrent and criterion validity (fair to moderate agreement with accelerometers) in PLBP population (60)
LAM USI*	Baseline and 12 weeks (end intervention)	Evidence for reliability (ICC 0.7) and construct validity with electromyography in PLBP population.(51, 61) (45, 62)
LAM Pressure biofeedback		Evidence for reliability (ICC 0.69 to0.97) and some

unit*(46)		evidence for concurrent validity with electromyography in PLBP population. (51, 63) (64)
LAM Deep Muscle Contraction scale*(45)		Evidence for reliability (ICC 0.7) and some evidence for concurrent validity with USI in PLBP population. (45, 51)
LAM endurance (side plank holding time) (65)		Evidence for reliability (ICC 0.95) in PLBP population(66)
Survey about physical activity and low back pain (Likert scale)	3 months post intervention	N/A – developed for this intervention

Participant retention: Percentage of participants that attended all in-person appointments of the 12-week program. Only inclusive of those who completed baseline measurements. Reasons for attrition were noted.

Compliance with the exercise regime: Percentage of prescribed sessions completed (where participants completed all prescribed exercises) according to a self-report exercise diary during the intervention.

Abbreviations: DMC, Deep muscle contraction scale; ICC, intra-class correlation coefficient; IPAQ, international physical activity questionnaire; LSIQ, lumbar instability questionnaire; NRS, numeric pain rating scale; PBU, pressure biofeedback unit; PLBP, persistent low back pain; PSFS, pain specific functional scale; RMDQ, Roland Morris disability questionnaire; USI, ultrasound imaging

*All contraction measures were assessed during the abdominal drawing in manoeuvre. USI was also used to measure resting LAM thickness

Data analysis

Statistical analyses were performed using SPSS V.29 ©computer software. Retention and exercise compliance outcomes were assessed using the following assumptions: 1. Retention: Feasible if: At least 85% of people enrolled in the study are retained. Not feasible if: Less than 70% of people enrolled in the study are retained. These criteria were developed considering attrition bias is unlikely to affect the study where attrition does not exceed 20% and 15% respectively.(67, 68)

2. Exercise compliance: Feasible if: Participants complete on average at least 85% of scheduled exercise sessions. Not feasible if: Participants complete on average less than 65% of their scheduled exercise sessions. These assumptions were generated considering compliance with prescribed exercise in participants with PLBP has been demonstrated to range between 15 and 95%.(69, 70) As the program was designed to be individualised to

participants' lifestyle with regular monitoring and modification, the researchers hypothesised that exercise compliance would be at the higher end of that spectrum. The authors determined that the program would be considered 'feasible with modifications' if feasibility outcomes fell between the feasible and not feasible thresholds for both participant retention and exercise compliance.

Participant characteristics were described with descriptive statistics. Analyses of the effect of the intervention on clinical and LAM outcomes were conducted using linear mixed models. Group and time were fixed effects, with time modelled as a repeated measure and the group x time interaction was analysed. Within-person correlation was modelled as a random effect. All analyses were adjusted for participants' baseline data and using a Bonferroni correction. All analyses were conducted by intention to treat and reported using 95% confidence intervals. Pressure biofeedback data being a categorical variable was analysed between groups using a Chi-Squared test.

Odds ratios were calculated to compare the odds of achieving minimally clinically important difference (MCID) changes in pain intensity, disability and function between groups and reported using 95% confidence intervals.

The Likert scale three month follow up survey responses were exported from REDCap© and analysed descriptively using medians and interquartile ranges. Additionally, the percentage of agreement with each statement was calculated. Responses between groups were analysed using Chi-Squared tests.

Sample size

Sample size calculations were conducted according to the framework Lewis et al(71) proposed for feasibility studies. The required sample size assuming an alpha of 0.05 and power of 80% for the feasibility assumptions described above were as follows: retention – 56, exercise compliance – 34 (for experimental arm, therefore a total of 68 participants). It was decided to use the criterion requiring the highest numbers (exercise compliance). Assuming potential attrition of up to 15%, it was aimed to recruit 80 people.

Results

Recruitment occurred between January – April 2023 (Figure 1). Nine participants withdrew (81% retention from enrolment) for reasons unrelated to the study. Two adverse events occurred, but these were unrelated to the study. One participant sustained a hip injury during a home renovation. One participant attended the final session of data collection and reported extreme dizziness on arrival. The participant was hospitalised but completed data collection on a separate day (nine days later) after receiving medical clearance.

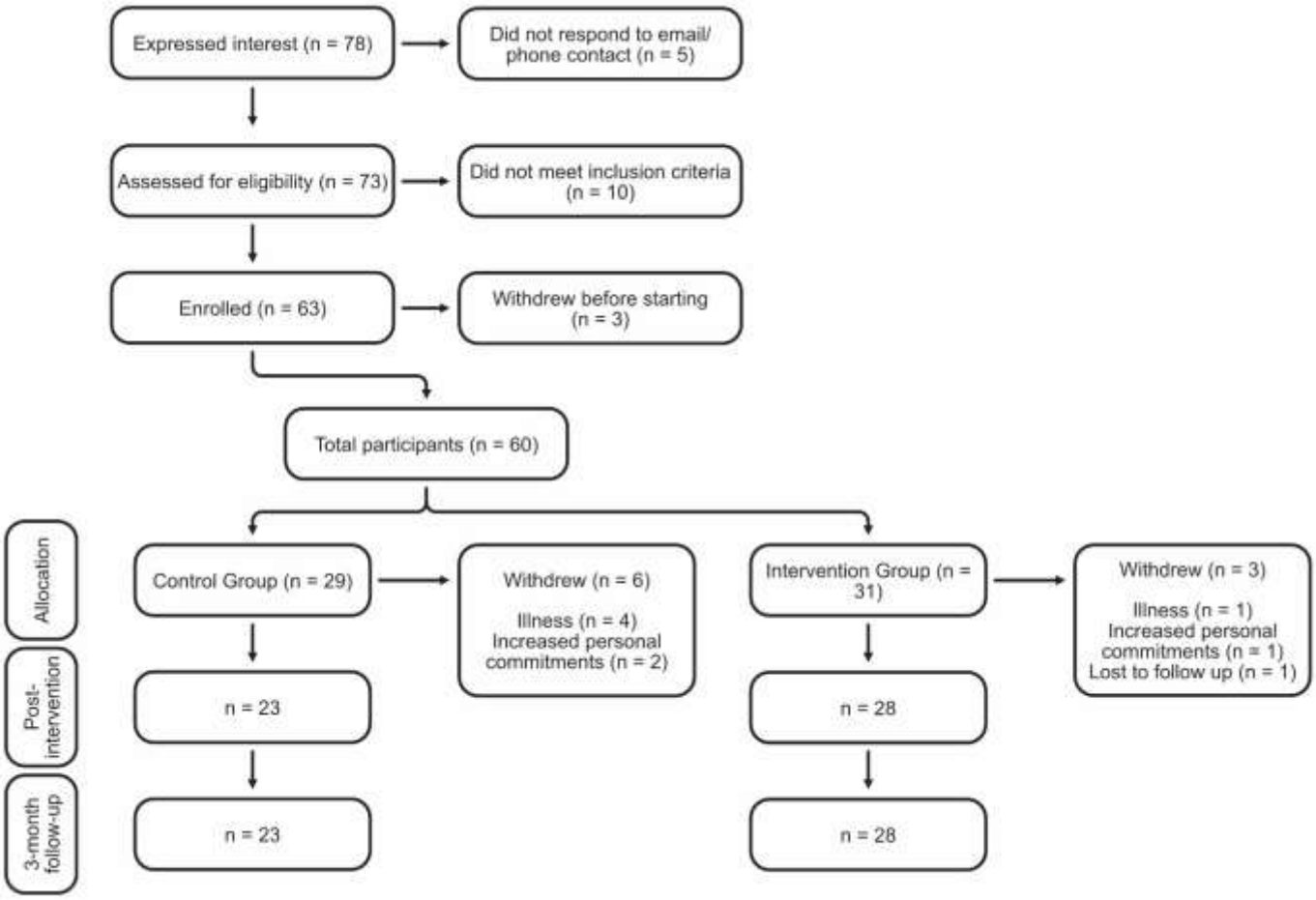


Figure 1 Participant recruitment and progress through the feasibility study

Participants in control and experimental groups were comparable for baseline characteristics except age, for which the intervention group were younger (Table 4). Type of intervention attendance (face-to-face versus telehealth) was similar between groups. Most participants attended the intervention face-to-face (16 in control group and 19 in experimental group). Four participants in each group attended via a combination of telehealth and face-to-face visits. Five participants in the experimental group and three participants in the control group attended via telehealth only. Physical activity levels and time holding a side bridge were greater in the experimental group at baseline. Baseline

LAM thickness was within 95% CI of normative data for most participants, with only three participants' EO thickness and two participants' IO thickness below normative data ranges. One participant's TrA thickness was above normative data ranges.

Table 4 Baseline participant characteristics

Characteristic	Control group (n = 29)	Experimental Group (n = 31)
Sex	20 F, 9 M	20 F, 11 M
Age	59.17 (11.1)	50.52 (15.79)
BMI	27.91 (5.82)	27.05 (6.78)
Symptom duration (years)	12.88 (10.51)	12.86 (9.06)
Previous back surgery[+]	28 N, 1 Y	29 N, 2 Y
Number of health professionals seen about low back pain[+]	2.39 (1.23)	2.62 (1.21)
Pain areas according to the Nordic Body Chart[+]	2.30 (1.1)	2.17 (1.1)
Number of participants with unilateral low back pain[+]	22 N, 6 Y	25 N, 4 Y
Number of participants with unilateral pain spanning to above knee[+]	23 N, 5 Y	26 N, 3 Y
Number of participants with unilateral pain spanning to below knee[+]	24 N, 4 Y	25 N, 4 Y
Number of participants with bilateral low back and lower limb pain (above or below knee) [+]	25 N, 3 Y	26 N, 3 Y
Number of participants with central low back pain[+]	6 N, 22 Y	4 N, 25 Y
Number of participants with referred pain (lower limb) [+]	16 N, 12 Y	17 N, 12 Y
Number of patients with anaesthesia/paraesthesia[+]	23 N, 5 Y	24 N, 6 Y
Do you think this intervention will help your low back pain? (5 Yes, 4 Possibly, 3 Unsure, 2 Possibly not, 1 No)	4.41 (0.78)	4.16 (1.13)
Exercise compliance	87.16%	86.25%

+ Back pain characteristics obtained during the subjective examination.

Note all values are presented as mean (standard deviation) unless stated otherwise.

Distribution of pain and presence referred pain and anaesthesia/paraesthesia was not reported by one participant in the control group and two participants in the intervention group. This could not be followed up as these participants subsequently withdrew.

Exercise compliance was comparable for the control and experimental groups and met the feasibility criteria (Table 4).

Participants in both groups achieved improvements over time in lumbar instability, disability, pain intensity, function, physical activity levels, time holding a side bridge, IO thickness and LAM contraction as measured by TrA slide, preferential activation, preferential activation modified and TrA ratios, the Deep Muscle Contraction Scale and Pressure Biofeedback Unit and LAM endurance (Table 5, Figure 2). The experimental group

demonstrated greater improvements in function (95% CI -2.05, -0.18 time point 1, -2.33, -0.46 time point 2) and physical activity (95% CI -2401.85, -248.54 time point 1, -2451.06, -297.75 time point 2) at both time points. Both groups were comparable for all other self-report outcomes. The percentage of participants achieving MCID changes in such outcomes were similar between groups (Table 6).

For the LAM, the control group demonstrated greater improvements in the DMC, TrA ratio, and TrA slide compared to the experimental group. In contrast, the experimental group demonstrated greater improvements in TrA and EO thickness as well as the left side bridge. LAM thickness largely remained within 95% confidence intervals for normative data.

Table 5 here (see table 5 at the end of PDF – was unable to include here due to journal guidelines as it is longer than one page)

Table 6 Percentage of participants who achieved a minimally clinically important difference in clinical outcomes post intervention

Outcome	Criteria for achieving minimally clinically important change	Control Group	Experimental Group
Pain intensity	Absolute minimally clinically important difference (improvement 2 or more)	52%	42%
	30% improvement from baseline score	55%	48%
Disability	Absolute minimally clinically important difference (improvement of 5 or more)	34%	26%
	30% improvement from baseline score	62%	65%
Function	Absolute minimally clinically important difference (improvement of 2.3 or more)	41%	58%

Three months post the intervention, 74% and 89% of participants in the control group and experimental groups respectively reported continuing with the exercises prescribed in the intervention. Five participants in the experimental group and one participant in the control group reported health changes which impacted their ability to exercise following the intervention. Such changes, for example, respiratory illness, were unrelated to the

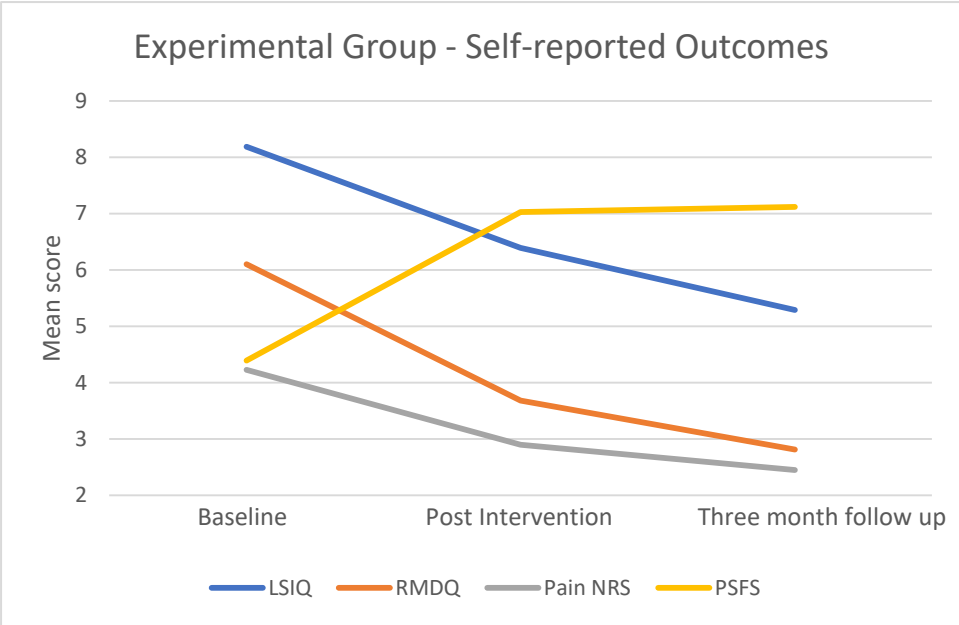
intervention. Despite this, the follow up Likert scale questions revealed the experimental group had greater agreement (median scores) with statements regarding continuation with physical activity and confidence to manage PLBP (Table 7).

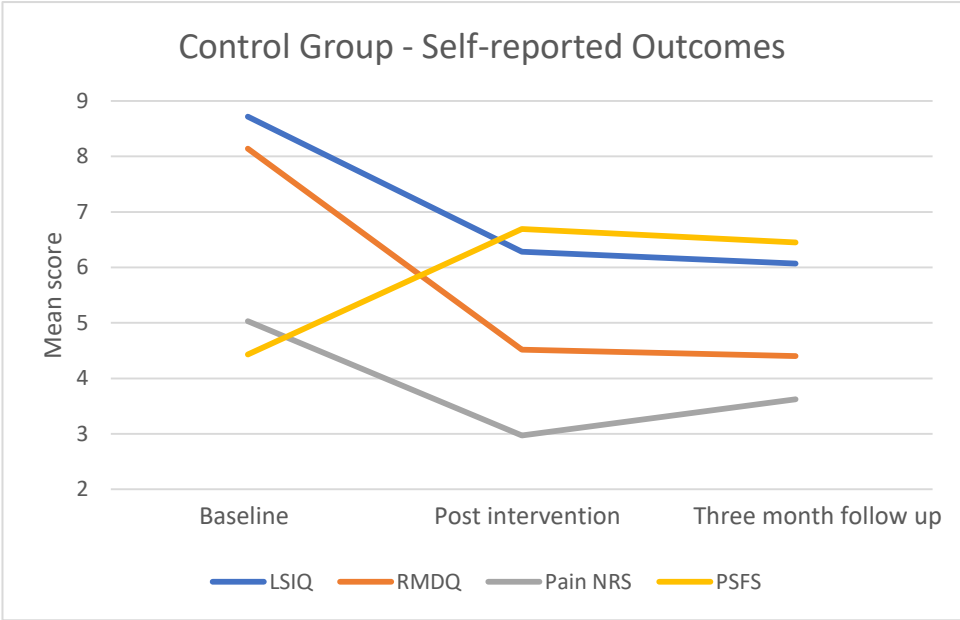
Table 7 Three month follow up survey results

Statement	Control Group n = 23		Experimental Group n = 28	
	Percentage of Agreement	Median (Q1, Q3)	Percentage of Agreement	Median (Q1, Q3)
I can effectively fit physical activity into my life	87.0%	5 (4, 5.5)	96.4%	6 (5, 6)
I have continued with regular physical activity since completing the intervention	91.3%	5 (4, 5)	89.3%	6 (5, 6)
I feel confident to continue with regular physical activity without the supervision of a physiotherapist	95.7%	5 (4, 5)	92.9%	6 (5, 6)
I feel confident to manage and or prevent my back pain	87%	5 (4, 5)	92.9%	5 (4, 6)
My back pain has improved in the 3 months after finishing the program	78.3%	5 (4, 5)	78.6%	5 (4, 6)
Other questions	Yes	No	Yes	No
Have you continued with the exercises prescribed as part of the intervention?	17	6	25	3
Since completing the intervention have you had any changes in your health which have limited your ability to exercise?	1	22	5	23

Abbreviations: IPAQ, international physical activity questionnaire; LSIQ, lumbar spine instability questionnaire; PSFS, pain specific functional scale; NRS, numeric rating scale; N/A, not applicable; 3M F/U, 3 Month follow up.

Note all data are presented as means (standard deviations) unless reported otherwise.





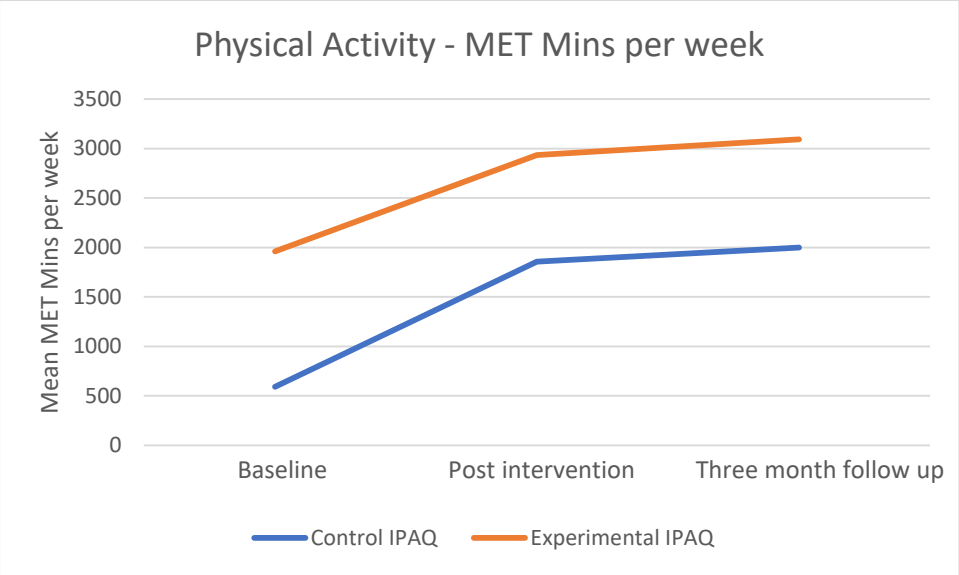


Figure 2 Mean changes in outcomes across the intervention for the experimental and control groups

Abbreviations: IPAQ: International Physical Activity Questionnaire, LSIQ: Lumbar Instability Questionnaire, MET: Metabolic Equivalent, NRS: Numeric Rating Scale, PSFS: Patient Specific Functional Scale, RMDQ: Roland Morris Disability Questionnaire

Discussion

This study aimed to determine the preliminary effectiveness and feasibility of an exercise and educational intervention for participants with PLBP and maladaptive changes in LAM contraction. Retention and exercise compliance rates were above 80%. Participants in both groups achieved improved lumbar instability, disability, pain intensity, function, physical activity, lateral abdominal muscle endurance and contraction post intervention. The fully individualised group demonstrated greater between-group improvements in function and physical activity at the end of the intervention and 3 months after the intervention finished.

Retention met the 'feasible with modifications criterion'. Attrition was due to participants developing unrelated and unpreventable illnesses, and increased family/work commitments. Due to the individualised nature of the program and options for telehealth, it was anticipated that time dedicated to exercise would be sustainable for participants with changing commitments. However, participants that withdrew did so after session one, so did not have the opportunity to trial adapting the program to their new circumstances. Previous pilot and feasibility studies assessing exercise programs for patients with PLBP have reported lower rates of attrition then the current study.(70, 72) One non-individualised program with 7% attrition required had less frequent appointments and patients were provided a mobile app to monitor compliance.(72) This model would reduce the intervention's time burden however, fewer sessions with the physiotherapist may decrease opportunity for participants' progression. Another program trialling group yoga sessions with a combined sample of participants with PLBP and neck pain showed 86% retention at 12 weeks.(70) Potentially the peer aspect of the program provided an incentive to continue.

The present intervention could incorporate a mobile app and/or peer activities to reduce attrition.

Exercise compliance met the feasibility criteria (≥85% compliance). A cross-sectional study found self-report exercise compliance to be 39%, physiotherapist perceived exercise compliance to be 16% and the ability to accurately remember and demonstrate prescribed exercises to be 15% in patients with PLBP.(69) Higher rates of compliance in the present study may be due to bias, as, recruitment for this exercise intervention may have attracted people who were more interested in exercising.(73) In comparison, Peek's study was retrospectively analysing data from patients that had attended treatments for PLBP. However, compliance of up to 95% compliance has been reported in other studies.(70) Reviews of the literature have examined factors influencing participants' with PLBP adherence to exercise.(74, 75) Factors associated with higher adherence incorporated into the present program included: patient education, supervision/feedback on exercise performance, individualisation, and telehealth options.(74, 75) Additional factors identified in those reviews such as incorporating behavioural change motivational strategies may further improve exercise compliance.(75) Some behavioural change from the intervention was noted, with greater physical activity levels post intervention and at the three month follow up in the experimental group. This suggests the experimental variable of incorporating participant exercise preferences may improve short term exercise compliance. However, this assumption may be confounded by the experimental group having greater physical activity levels at baseline compared to the control group. Thus, it remains unclear whether the differences post intervention were due to the experimental condition or baseline physical activity.

This study also measured the effect of the program on LAM outcomes, disability, function, pain intensity, perceived lumbar instability and physical activity. The lack of between group differences post intervention for most outcomes suggests that the incorporation of patient preferred exercise did not impact intervention effectiveness. Between group differences in physical activity and function outcomes are limited considering the experimental groups' greater physical activity levels at baseline and use of an underpowered sample. It is hypothesised that the incorporation of preferred physical activity may have facilitated a sustained increase in physical activity for the experimental group which led to sustained improvements in function. However, further research is required to confirm this.

Average changes in pain intensity, disability and function were comparable to previous motor control exercise interventions(76-82), suggesting this intervention was not superior. The effects did not consistently achieve minimum clinically important differences, but most participants achieved a 20% reduction in pain intensity which is considered a minimal worthwhile effect for an individualised exercise program.(83) Future studies should compare this protocol with a no intervention control group to determine clinical relevance using the smallest worthwhile effect threshold. As there are a range of definitions for what is considered a clinically important difference, clinicians should discuss likely outcomes of this treatment with patients based on current evidence so they can make an informed decision of whether this is appropriate for them. It is unlikely that patients would make a full recovery from this program.

Participants in both groups demonstrated improvements in Pressure Biofeedback Unit, Ultrasound imaging and Deep Muscle Contraction Scale measures of TrA contraction, triangulating these findings. While the normative values for TrA slide are unknown, baseline

slide for this sample was lower than previous samples of participants with PLBP: 0.44(84), 0.76(85) and 1.1cm(86) which may be due to purposive sampling used in this study. Changes in slide, however, were comparable, suggesting this intervention was not superior. As these studies had similar program durations, potentially there is a ceiling effect for change that can be achieved within a time period. For the Deep Muscle Contraction scale, the improvement was slightly lower than what has been achieved in a previous study.(45) However, the present study's participants baseline scores were higher than those of Oliveira et al 2017[45], potentially limiting capacity for change. Two other trials have reported on TrA contraction using pressure biofeedback in the prone position. Both demonstrated significantly improved TrA contraction(87, 88), with specific muscle activation exercises being superior to abdominal strengthening.(88) These findings support the use of motor control exercises if TrA contraction is reduced.

Endurance improved in both groups post intervention. On average, participants did not demonstrate an imbalance between right and left side endurance at baseline. A non-significant trend towards asymmetry in side bridge holding times has been demonstrated in a previous sample of participants with a history of PLBP.(2) Compared to asymptomatic samples endurance times (54 to 97 seconds)(65, 89), baseline side bridge holding times for participants in this chapter were considerably lower. While baseline data is comparable to other PLBP samples(66, 90), normative data for side bridge endurance in PLBP samples has not been determined. A previous randomised controlled trial found both motor control and abdominal resistance exercises to improve side bridge endurance.(90) This supports the inclusion of both types of exercises in the present protocol if clinicians are aiming to improve LAM endurance.

While LAM thickness demonstrated some changes over the intervention, at baseline this was within normative data ranges for most participants. Therefore, achieving hypertrophy was likely irrelevant for most participants. Hence, it remains unknown how individuals with muscle atrophy may respond to this program. For the few participants' whose LAM thickness was outside of normative data ranges at baseline, the intervention did not consistently increase and or decrease LAM thickness into normative ranges. Previous literature has found some samples of people with PLBP demonstrate significantly decreased thickness of LAM compared to asymptomatic samples(91, 92) which may be associated with increased LBP.(92) However, other samples demonstrate no differences compared to asymptomatic samples.(93) Perhaps such inconsistent evidence supports the need for individualisation and inclusion of strength/hypertrophy exercises only if atrophy is found as recommended in the intervention.

Limitations

There were several limitations of this study. Firstly, due to attrition and recruitment resources (time and funding), the study was underpowered to test feasibility of exercise compliance. Additionally, statistical results on intervention efficacy were mostly underpowered, meaning findings must be replicated in an adequately powered study to draw conclusions on efficacy. However, it was sufficiently powered to examine participant retention. Secondly, while the Deep Muscle Contraction scale, TrA ratio, TrA slide and EO and TrA thickness indicated between group differences after the intervention, the changes were not greater than the minimal detectable change calculated by the authors from reliability data. Therefore, it is plausible that these differences may be due to normal measurement variability. While reliability was moderate to excellent, further research

should aim to improve reliability of these outcome measures. Otherwise, it remains unclear how effective interventions are for improving LAM contraction. Thirdly, the experimental group had greater physical activity levels at baseline, therefore it is uncertain whether increased physical activity after the intervention was related to the intervention, or baseline physical activity levels. Fourthly, providing the option for participants to access the program via telehealth may be a confounding factor to assessing the feasibility of the intervention. While the use of telehealth was comparable between groups, the literature is unclear regarding its effectiveness compared to other interventions for patients with PLBP. One systematic review found telehealth based interventions were not more effective than educational interventions.(94) However, a more recent randomised controlled trial found remotely delivered physiotherapy to be comparable to usual care for musculoskeletal conditions.(95) Thus, it is unclear whether delivering the program via different means may have affected the outcomes presented in this chapter. Finally, the researcher was not blinded to participants' group allocation or data collection.

Conclusion

This exercise program may improve motor control and muscle endurance (relevant to LAM), pain intensity, disability, function and physical activity levels. The trial was below feasibility criteria for participant retention but met feasibility criteria for exercise compliance in both intervention groups. Preliminary data indicated the incorporation of patient preferred general exercise may be associated with increased function and physical activity at the three month follow up. Further research should trial the program using an adequately powered sample to determine whether group differences were related to baseline physical activity or the use of patient preferred exercise.

Tables longer than one page

Table 5 Effect of exercise intervention on outcome measures

		Unadjusted mean score (SD)		**Adjusted between group difference**	**Adjusted mean difference over time – all participants (all values compared against time 0)**
Variable	Time	Control Group	Experimental Group	Mean (95% CI)	Mean (95% CI)
LSIQ	0	8.72 (2.67)	8.19 (3.21)		
	1	6.28 (3.15)	6.39 (2.91)	-1.269 (-2.714, 0.176)	2.351 (1.292, 3.409)
	2	6.07 (3.53)	5.29 (3.33)	-0.443 (-1.888, 1.003)	2.805 (1.747, 3.863)
RMDQ	0	8.14 (4.27)	6.10 (4.70)		
	1	4.52 (4.11)	3.68 (4.13)	0.162 (-1.098, 1.422)	2.792 (1.891, 3.692)
	2	4.4 (3.8)	2.81 (4.14)	0.93 (-0.330, 2.190)	3.658 (2.757, 4.558)
NRS	0	5.03 (1.64)	4.23 (2.05)		
	1	2.97 (2.03)	2.90 (1.97)	0.069 (-1.05, 1.187)	1.575 (0.768, 2.383)
	2	3.62 (1.80)	2.45 (1.80)	0.656 (-0.462, 1.775)	1.503 (0.695, 2.311)
PSFS	0	4.43 (1.91)	4.39 (2.36)		
	1	6.69 (2.17)	7.03 (2.47)	-1.113 (-2.045, -0.180)	-2.577 (-3.239, -1.915)
	2	6.45 (2.07)	7.12 (2.74)	-1.394 (-2.326, -0.461)	-2.592 (-3.254, -1.930)
IPAQ	0	590.66 (485.18)	1959.48 (1462.16)		
	1	1857.80 (1706.83)	2934.89 (2562.15)	-1325.197 (-2401.851, -248.542)	-790.834 (-1712.05, 130.382)
	2	1998.96 (2434.15)	3094.06 (2580.51)	-1374.407 (-2451.061, -297.752)	-1080.748 (-2001.964, -159.532)
DMC	0	6.86 (1.41)	7.17 (1.40)		
	1	8.52 (1.3)	8.73 (1.26)	1.043 (0.496, 1.59)	-1.852 (-2.251, -1.452)
PA ratio	0	0.033 (0.04)	0.034 (0.03)		
	1	0.054 (0.05)	0.04 (0.03)	0.016 (-0.004, 0.036)	-0.014 (-0.024, -0.003)
PAM ratio	0	0.034 (0.06)	0.042 (0.04)		
	1	0.061 (0.06)	0.05 (0.04)	0.014 (-0.011, 0.039)	-0.017 (-0.03, -0.003)
TrA ratio	0	1.40 (0.26)	1.40 (0.33)		
	1	1.57 (0.36)	1.41 (0.23)	0.198 (0.049, 0.347)	-0.088 (-0.165, -0.012)
Oblique ratio	0	1.19 (0.19)	1.16 (0.12)		
	1	1.19 (0.22)	1.15 (0.12)	0.068 (-0.015, 0.15)	0.000 (-0.043, 0.042)

Table 5 Effect of exercise intervention on outcome measures

		Unadjusted mean score (SD)		**Adjusted between group difference**	**Adjusted mean difference over time – all participants (all values compared against time 0)**
Variable	Time	Control Group	Experimental Group	Mean (95% CI)	Mean (95% CI)
TrA slide	0	4.3 (3.40)	2.7 (3.50)		
	1	7.9 (5.10)	5.5 (4.60)	0.244 (0.032, 0.457	-0.032 (-0.440, -0.201)
TrA thickness	0	4.4 (1.20)	4.3 (1.30)		
	1	4.4 (1.20)	4.7 (1.40)	-0.073 (-0.132, -0.013	-0.014 (-0.034, 0.006)
IO thickness	0	7.1 (2.50)	7.8 (2.80)		
	1	7.3 (2.50)	8.1 (3.00)	0.005 (-0.096, 0.106)	-0.027 (-0.052, -0.002)
EO thickness	0	4.4 (1.00)	4.6 (1.30)		
	1	4.3 (0.90)	4.8 (1.50)	-0.095 (-0.148, -0.042)	0.000 (-0.016, 0.017)
Right side bridge	0	20.64 (18.73)	35.92 (22.03)		
	1	41.90 (23.70)	56.29 (23.29)	-4.439 (-12.297, 3.419)	-19.035 (-24.36, -13.71)
Left side bridge	0	20.80 (19.57)	35.36 (21.73)		
	1	36.00 (24.38)	55.00 (21.30)	-15.956 (-20.663, -11.249)	-16.239 (-19.408, -13.07)

Abbreviations: DMC, Deep Muscle Contraction; EO, External Oblique; IO, Internal Oblique; IPAQ, International Physical Activity Questionnaire; LSIQ, Lumbar Spine Instability questionnaire; MET, Metabolic Equivalent of Task; NRS, pain Numerical Rating Scale; PA, Preferential Activation; PAM, Preferential Activation Modified; PSFS, Patient Specific Functional Scale; RMDQ, Roland Morris Disability Questionnaire; SMD, standard mean difference; TrA, Transversus Abdominis

Additional material

Additional file 1: CONSORT checklist guidelines for feasibility studies

Additional file 2: Trial registration protocol

Additional file 3: Exercise compliance diary

All additional files are located in the one PDF.

List of abbreviations:

EO: external oblique

IO: internal oblique

LAM: lateral abdominal muscles

PLBP: persistent low back pain

TrA: transversus abdominis

USI: ultrasound imaging

Declarations:

Ethics approval and consent to participate: This study was approved by The University of South Australia Human Research Ethics Committee (204929). Participants provided informed consent prior to participation.

Consent for publication: Not applicable

Availability of data and materials: The datasets generated and/or analysed during the current study are not publicly available due to privacy or ethical restrictions but are available from the corresponding author on reasonable request.

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