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Research

# An individualised self-management exercise and education program did not prevent recurrence of low back pain but may reduce care seeking: a randomised trial

Tarcisio F de Campos [a], Natasha C Pocovi [a], Chris G Maher [b], Helen A Clare [c], Tatiane M da Silva [d], Mark J Hancock [a]

[a] Department of Health Professions, Faculty of Medicine, Health and Human Sciences, Macquarie University, Sydney, Australia; [b] Sydney School of Public Health, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia; [c] Helen Clare Physiotherapy, Sydney, Australia; [d] Master and Doctoral Programs in Physical Therapy, Universidade Cidade de Sao Paulo, Sao Paulo, Brazil

KEY WORDS

Low back pain
Prevention
Recurrence
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ABSTRACT

**Question**: What is the effect of a McKenzie-based self-management exercise and education program on the risk of recurrence of low back pain (LBP) and on the impact of LBP? **Design**: Randomised controlled trial with concealed allocation, blinded assessors and intention-to-treat analysis. **Participants**: 262 adults recently recovered from an episode of LBP. **Intervention**: The experimental group received a McKenzie-based self-management exercise and education program delivered over two individual sessions of 30 to 45 minutes with a physiotherapist, approximately 2 weeks apart. The control group received a single advice session over the phone. **Outcome measures**: The primary outcome was time to first recurrence of an episode of activity-limiting LBP. Secondary outcomes included time to recurrence of any LBP, time to a recurrence causing care seeking and a composite measure of pain and function ('impact of LBP'). Participants were followed-up monthly for $\geq$ 12 months. **Results**: The estimated effect of the experimental intervention on the risk of recurrence of an episode of: activity-limiting LBP was HR 1.11 (95% CI 0.80 to 1.54), any LBP was HR 0.95 (95% CI 0.72 to 1.26), and LBP for which care was sought was HR 0.69 (95% CI 0.46 to 1.04). The quarterly estimates of the experimental intervention's effect on impact of LBP and their 95% CIs were all within 4 points above or below 0 (no effect) on this scale from 8 to 50. **Conclusion**: This study's best estimate is that a McKenzie-based self-management exercise and education program does not produce a worthwhile reduction in the risk of an activity-limiting episode of LBP; however, modestly reduced or moderately increased risk cannot be ruled out. It may markedly reduce the risk of an episode of LBP resulting in care seeking, but does not have any worthwhile effect on the impact of LBP over 12 months. **Trial registration**: ACTRN12616000926437. **[de Campos TF, Pocovi NC, Maher CG, Clare HA, da Silva TM, Hancock MJ (2020) An individualised self-management exercise and education program did not prevent recurrence of low back pain but may reduce care seeking: a randomised trial. *Journal of Physiotherapy* 66:166–173]**



## Introduction

Low back pain (LBP) is a common condition and the leading cause of global disability according to the Global Burden of Disease studies.[1,2] Most people with an episode of LBP improve quickly;[3,4] however, recurrences within a year are common (40 to 69% depending on the definition used).[5,6] The recurrent nature of LBP is one of the major reasons why the condition carries such a large social and economic burden.[7] Despite the recurrent nature of LBP, few previous trials have investigated prevention strategies. Present evidence[8] shows that some future episodes of LBP can be prevented with exercise alone (35% risk reduction) or exercise in combination with education (45% risk reduction) for up to 1 year. The majority of the exercise programs in these trials are relatively costly, inflexible and time consuming (eg, 20 sessions over 13 weeks),[9] potentially making uptake of such programs difficult.[10]

To overcome these barriers, we developed a low-cost and flexible exercise and education program, based on the McKenzie method and emphasising self-management. The program involves simple and individualised exercises that require minimal time and can be performed independently on a daily basis. The exercises aim to balance/counteract everyday postures or positions adopted habitually, and to ameliorate any existing loss of lumbar spine movement. This exercise approach is different to that investigated in most previous prevention studies, where a combination of strength and aerobic exercises were used. One previous study investigated passive prone back extensions performed twice daily in military recruits and found these to be effective.[11] The exact mechanism by which any form of exercise

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prevents LBP is uncertain. Importantly, the McKenzie-based self-management approach investigated in the current study also provides strategies and education for self-management of mild episodes without seeking care. Therefore, this study was intended to estimate to what extent a McKenzie-based self-management exercise and educational approach, compared with a minimal-intervention control, prevents recurrences of LBP and future care seeking in people who have recently recovered from an episode of non-specific LBP. It also aimed to investigate whether the approach reduces the impact of LBP over 1 year.

Therefore, the research question for this randomised controlled trial was:

> What is the effect of a McKenzie-based self-management exercise and education program on the risk of recurrence of LBP and on the impact of LBP?

## Method

### Design

The SAFE trial was a two-group randomised controlled trial, with concealed allocation, intention-to-treat analysis and blinding of the outcome assessors and statistician. The study protocol was published in addition to being prospectively registered.[12]

People who had recently recovered from LBP and were willing and eligible to participate were randomised to either a McKenzie-based self-management exercise and education program or a minimal-intervention control group. A researcher, who was not otherwise involved in the study, developed a randomisation schedule and produced consecutively numbered, sealed, opaque envelopes containing the allocation schedule. The randomisation schedule used randomly permuted block sizes of 4, 6 and 8. Randomisation was stratified by history of previous episodes ($\leq$ 2 versus $>$ 2),[13] with balanced randomisation (1:1). To ensure that allocation was concealed, after collecting baseline data, the blinded researcher opened the next envelope to reveal the allocation number. Treatment providers and participants were not blind to group allocation.

Participants were followed for $\geq$ 12 months for the primary outcome: days to first self-reported recurrence of an activity-limiting episode of LBP.

The study was pragmatic in design. It investigated the effectiveness of the intervention in a real-world setting and incorporated most of the pragmatic design features presented in the PRECIS-2 tool. The trial included participants similar to those who would receive the intervention, was conducted in a setting similar to where it would be delivered in clinical practice and used outcomes that were directly relevant to participants.[14,15] The design of the SAFE trial is illustrated in Figure 1.

### Participants and therapists

The inclusion criteria were age $\geq$ 18 years and recent recovery (within the last 6 months) from an episode of non-specific LBP (with or without leg pain). An episode of non-specific LBP was defined as pain lasting $>$ 24 hours in the area between the 12th rib and buttock crease[16] not attributed to a specific diagnosis (eg, vertebral fracture or cancer). Recovery was defined as occurring after 7 consecutive days with pain no greater than 1 on a numeric pain scale from 0 to 10. Exclusion criteria were: previous spinal surgery; a co-morbidity restricting or preventing safe participation in exercise (eg, traumatic brain injury, psychological illness); inadequate English; previous exposure to a McKenzie-based approach as a method of preventing future LBP; and current pregnancy.

Participants were recruited through community advertising (eg, public noticeboards and social media websites) in Sydney, Australia. All potential participants were screened for eligibility. Eligible participants provided verbal consent and underwent a standardised baseline assessment over the phone.

All study physiotherapists were trained together in the study procedures in a single session. This session was led by an experienced McKenzie therapist instructor and the senior author, who had over 20 years of experience using the McKenzie approach. The session involved an explanation of the study design and purpose, followed by the step-by-step process of evaluating participants and delivering the intervention. This session lasted approximately 2 hours and included opportunity for clarification of any remaining questions. After this session all therapists were visited on one more occasion by the lead author to ensure that they were ready to deliver the intervention according to the study protocol. Regular contact was made with therapists during the study via newletters (approximately three per year) and one-to-one meetings to discuss any issues in delivering the intervention and to provide reminders of study procedures.

### Interventions

*Experimental: McKenzie-based self-management approach*

Participants allocated to the experimental group attended two individual face-to-face sessions, each with a duration of 30 to 45 minutes, delivered approximately 2 weeks apart, with a physiotherapist trained at least to level A (The Lumbar Spine module)[17] and level B (The Cervical and Thoracic Spine module)[18] of the McKenzie method. The study intervention sessions were performed at the physiotherapist's practice.

In the first session, participants were assessed using a modification of the McKenzie Lumbar Spine Assessment Form.[19] The history focused on developing a clear understanding of factors associated with previous episodes, and the individual's daily mechanical/postural stresses. The physical examination aimed to assess habitual postures and their relationship to symptoms, spinal movement loss and any effect of repeated spinal movements on symptoms and mobility. This assessment helped the therapists to gather information that guided prescription of an individualised prevention exercise program at home. All participants were provided with education and prescribed an individualised home exercise program focusing on those movements that balance/counteract everyday postures or positions adopted habitually, and on ameliorating any existing loss of lumbar spine movement. For instance, some participants were prescribed an exercise program involving lumbar extension to counterbalance the large amount of flexion activity/posture typical of most people's lives in either performing manual tasks or sitting. Each participant's home exercise program varied in frequency and duration based on the therapist's assessment of that participant's individual needs. Typically, exercises were prescribed to be performed multiple times per day and were of short duration.

At the follow-up session, the physiotherapists discussed with participants any barriers to participation in the program. Depending on this re-assessment the physiotherapist modified or progressed the home exercise program as required. Therapists emphasised the importance of continuing these exercises as a prevention strategy for LBP recurrence.

*Control: minimal intervention*

The control group received simple advice on prevention of LBP, delivered over the phone by a single physiotherapist. The key points were advice to maintain regular exercise, and education about lifting and handling objects safely; the phone call was approximately 10 to 15 minutes in duration. A copy of the *Managing Back Pain – Get Back on Track* booklet,[20] developed by Bupa Australia Pty Ltd, was posted to participants in this group. This booklet includes general advice about back pain prevention and self-management. If they required further clarification, participants in the control group had the opportunity to contact the physiotherapist on one further occasion, approximately 2 to 4 weeks after being randomised, by email or phone.

### Follow-up

Participants were followed-up monthly by a blinded researcher for $\geq$ 12 months, or until the study concluded. Participants received a

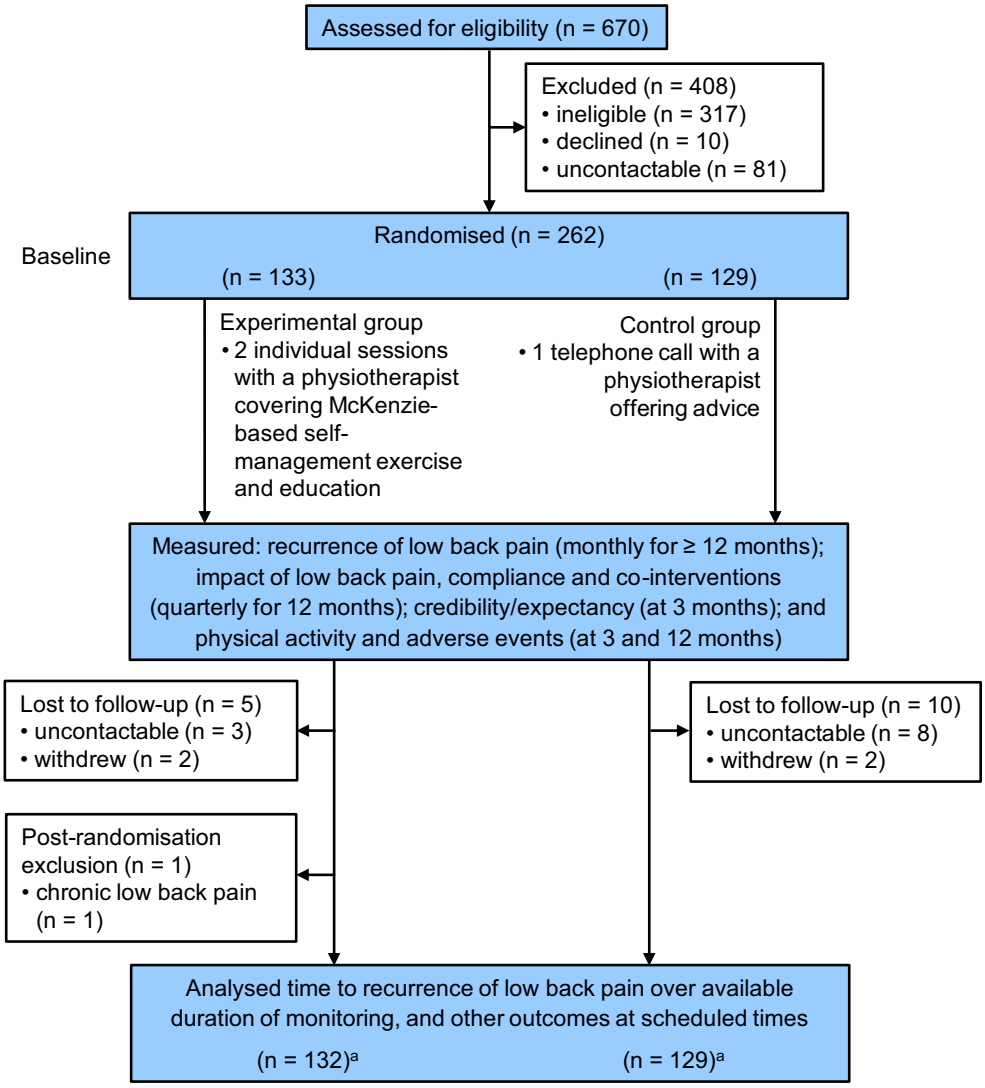


**Figure 1.** Flow of participants through the trial.
[a] Analyses used the available data from each participant's period in the trial.

monthly email or text message (based on preference) asking if they had experienced a recurrence of LBP with an intensity > 2 on a 0-to-10 pain rating scale and lasting ≥ 24 hours within the past 4 weeks or since the last contact from the research team. Participants who replied 'yes' were phoned by a researcher who collected further information about this recurrence, including whether it met the criteria for the primary outcome of activity-limitation due to LBP. In addition to the recurrence data, data were collected on the impact of LBP[21,22] at 3, 6, 9 and 12 months by phone or online survey[a].

### *Outcome measures*

*Primary outcome*

The primary outcome was time to recurrence of an episode of activity-limiting LBP. This was calculated as the number of days from randomisation to the first self-reported recurrence of an episode of activity-limiting LBP (intensity > 2 on a numeric pain rating scale from 0 to 10, lasting ≥ 24 hours, and subjectively interfering with day-to-day activities 'somewhat', 'quite a bit' or 'very much' using an adaptation of item PI9 of the PROMIS item bank to measure pain interference).[23]

*Secondary outcomes*

One secondary outcome was the time to recurrence of an episode of non-specific LBP. This was defined as the number of days from randomisation to the first reported recurrence of an episode of non-specific LBP (intensity > 2/10 on the numeric pain rating scale, lasting ≥ 24 hours).[24]

Time to recurrence of an episode of LBP leading to care seeking was also assessed. This was defined as the number of days from randomisation to the first reported LBP recurrence that resulted in a consultation with a healthcare provider.

The personal impact of LBP was measured using the impact score, as recommended by the NIH Task Force, which incorporates nine items of the 29-item PROMIS short form.[21,22] These items cover the domains of pain intensity, pain interference with normal activities and functional status. The total score ranges from 8 (least impact) to 50 (greatest impact). This measure was collected at 3, 6, 9 and 12 months, with participants being asked to respond about the impact of LBP over the previous 3 months regardless of whether they had experienced a recurrence.

*Process measures*

Some additional process measures were collected to help interpret trial results. These process measures included measures of physical activity, treatment compliance and treatment credibility.

Physical activity was measured using a modified version of the International Physical Activity Questionnaire (IPAQ) at baseline and at 3 and 12 months.[25]

Treatment compliance was monitored in two ways. Attendance at the two physiotherapy visits was recorded. Participants were asked to rate their compliance with the home program using the Brief Adherence Rating Scale, which ranges from 0 (not compliant at all) to 10 (very compliant), at 3, 6, 9 and 12 months.

Treatment credibility was measured by the Credibility Expectancy Questionnaire at 3 months.[26]

*Adverse events and use of co-interventions*

Adverse events and the use of any co-intervention were monitored during the study period. Adverse events were defined as any new medical condition or exacerbation of an existing condition as reported by the participants during the study. Serious adverse events were defined as any event resulting in death or hospital admission. Adverse events were assessed by directly asking participants at 3 and 12 months: 'Have you had a new medical condition or an exacerbation of an existing condition since the beginning of the study?' Information about any intervention for treatment or prevention of LBP (apart from the study program) was recorded in a free-text field at 3, 6, 9 and 12 months.

### *Data analysis*

Study sample size was calculated using commercial software[b], based upon the method of Lakatos.[27] At the beginning of the study, a 30% recurrence rate in the control group at 1 year was anticipated and it was initially calculated that a sample size of 198 participants per group would give 80% power to detect a 40% relative reduction in recurrence rates between the treatment group and control group. The sample size calculations were based on a 24-month accrual period and 12-month follow-up period. The study conservatively allowed for a monthly 1% loss to follow-up, and monthly 1% treatment non-compliance in both groups. However, 20 months after recruitment began (sample size 231), the sample size was re-assessed because, based on a cohort study[5] of a similar population, it was suspected that the control group recurrence rate was greater than the 30% used in the original calculations. Using a 40% recurrence rate at 1 year for the study control group (observed rate was 44% at 1 year in the control group at that time), the updated calculation indicated that a sample size of 131 participants per group would provide 80% power to detect a 40% relative reduction in recurrence rates with a two-sided alpha level of 0.05. This change to the study protocol was updated on the clinical trial registry.

All data were double-entered and analysed using the intention-to-treat principle.[28] For the primary and secondary outcomes, mean effects were estimated with 95% confidence intervals (CIs). Baseline comparability of the groups was analysed using key prognostic variables to assess for any chance imbalance that may have occurred; they were added as a confounder variable in the model if needed. The survival curves were inspected and the time-dependent covariate method was used to check if the proportional hazards assumption was violated.

Cox-regression was used to estimate the effects of experimental intervention on hazard ratios, which were reported with 95% CIs. For each group, the 25th percentile days to recurrence of activity-limiting LBP (ie, the number of days when 25% of participants had experienced a recurrence) was calculated. This analysis was used instead of the median days to recurrence, which was not calculable because $< 50\%$ of people had this event. Analogous survival analyses were conducted for the time to recurrence of non-specific LBP and time to an episode of care seeking for LBP. The effect of the experimental intervention on the secondary outcome, impact of LBP, was estimated with repeated measures linear models using data from 3, 6, 9 and 12 months. This was reported as a mean effect size over the 1-year period, with 95% CI.

Completeness of follow-up was calculated using the completeness index,[29] which quantifies the total observed person-time of follow-up as a percentage of the potential time of follow-up in the study. All analyses and interpretation of the results were performed by a blinded researcher. Analyses were performed using commercial software[c].

## Results

### *Flow of participants through the study*

Recruitment occurred from July 2016 to June 2018 with follow-up ending on the 30th of June, 2019. A total of 670 potential participants were screened for eligibility and 262 entered the study (Figure 1). Participants were followed for $\geq$ 12 months and $\leq$ 30 months. One participant, who was randomised to the experimental intervention group, was excluded after randomisation as the treating physiotherapist identified that the participant had ongoing chronic LBP and should not have been included. Two blinded researchers reviewed the case and recommended that the participant be excluded from the analyses. Of the 261 participants, 132 were assigned to the experimental intervention group and 129 to the control group. The reason for this mismatch in the total number of participants allocated in each group was due to the use of randomly permuted block sizes of 4, 6 and 8. In the experimental group, 127 participants received the allocated intervention, while six participants did not receive the allocated intervention (one post-randomisation exclusion and five could not attend the sessions). In the control group, 128 participants received the advice about prevention strategies, while one participant could not be contacted to receive the minimal intervention. In total, 246 participants (94%) either reached the study primary outcome or were censored at the end of the study follow-up period. The remaining 15 participants (five in the experimental group and ten in the control group) either were lost to follow-up or withdrew and were censored early. The completeness index was 94% for the study primary outcome.

### *Characteristics of study participants and therapists*

The demographic and baseline clinical characteristics of participants included in this trial are presented in Tables 1 and 2. The mean age was 42 years (SD 13) and approximately half (49%) were female. The median number of previous episodes of LBP across both groups was 6 (IQR 3 to 15). Participants in the two groups were similar at baseline. Nine physiotherapists credentialed in the McKenzie method delivered the McKenzie-based intervention.

### *Compliance with the study protocol*

Self-reported intervention compliance was similar across both groups over the 1-year follow-up period (Table 3). Attendance at the

**Table 1**
Demographic characteristics of participants included in the analysis.

| Characteristic | All (n = 261) | Exp (n = 132) | Con (n = 129) |
|---|---|---|---|
| Age *(y)*, mean (SD) | 42 (13) | 41 (13) | 44 (12) |
| Gender, n female (%) | 129 (49) | 68 (52) | 61 (47) |
| Weight *(kg)*, mean (SD) | 74.4 (16) | 73.8 (17) | 75.0 (15) |
| Height *(cm)*, mean (SD) | 170.7 (9) | 170.6 (9) | 170.8 (10) |
| Body mass index *($kg/m^2$)*, mean (SD) | 25.5 (5) | 25.3 (5) | 25.7 (5) |
| Education level, n (%) | | | |
| some secondary school | 2 (1) | 2 (2) | 0 (0) |
| completed secondary school | 17 (7) | 11 (8) | 6 (5) |
| some additional training | 38 (15) | 20 (15) | 18 (14) |
| undergraduate university | 104 (40) | 47 (36) | 57 (44) |
| postgraduate university | 100 (38) | 52 (39) | 48 (37) |
| Current work status, n (%) | | | |
| full time | 154 (59) | 75 (57) | 79 (61) |
| part time | 53 (20) | 26 (20) | 27 (21) |
| unemployed | 11 (4) | 7 (5) | 4 (3) |
| students or homeworkers | 17 (7) | 12 (9) | 5 (4) |
| other | 26 (10) | 12 (9) | 14 (11) |
| Manual task involving heavy loads, n (%) | | | |
| very frequently | 18 (7) | 9 (7) | 9 (7) |
| frequently | 43 (16) | 24 (182) | 19 (15) |
| occasionally | 84 (32) | 43 (33) | 41 (32) |
| rarely | 54 (21) | 28 (21) | 26 (20) |
| very rarely | 49 (19) | 20 (15) | 29 (22) |
| never | 13 (5) | 8 (6) | 5 (4) |
| Manual task involving awkward position, n (%) | | | |
| very frequently | 10 (4) | 6 (5) | 4 (3) |
| frequently | 34 (13) | 20 (15) | 14 (11) |
| occasionally | 85 (25) | 30 (23) | 35 (27) |
| rarely | 65 (33) | 44 (33) | 41 (32) |
| very rarely | 48 (18) | 21 (16) | 27 (21) |
| never | 19 (7) | 11 (8) | 8 (6) |

Con = control group, Exp = experimental group.

**Table 2**
Baseline characteristics of participants included in the analysis.

| Characteristic | All (n = 261) | Exp (n = 132) | Con (n = 129) |
|---|---|---|---|
| General health, n (%) | | | |
| excellent | 46 (18) | 23 (17) | 23 (18) |
| very good | 111 (43) | 53 (40) | 58 (45) |
| good | 93 (36) | 52 (39) | 41 (32) |
| fair | 11 (4) | 4 (3) | 7 (5) |
| Low back pain | | | |
| previous episodes *(n)*, median (IQR) | 6 (3 to 15) | 6.5 (3 to 15) | 6 (3 to 15) |
| duration of last episode *(d)*, median (IQR) | 7 (3 to 21) | 7 (3 to 19.5) | 7 (4 to 21) |
| time since last episode *(d)*, median (IQR)[a] | 31 (17 to 65) | 31.5 (18 to 62.75) | 31 (16 to 72) |
| perceived risk of recurrence *(0 to 10)*, mean (SD)[b] | 6.5 (2.3) | 6.6 (2.3) | 6.5 (2.3) |
| Physical activity *(min/wk)*, median (IQR)[c] | | | |
| walking | 180 (90 to 330) | 192 (92 to 358) | 180 (90 to 305) |
| moderate/vigorous | 90 (15 to 240) | 90 (0 to 240) | 120 (27 to 240) |
| Time sitting *(hr)*, mean (SD)[d] | 7.6 (3.2) | 7.7 (3.2) | 7.5 (3.3) |
| Smoking, n (%) | | | |
| never | 196 (75) | 98 (74) | 98 (76) |
| ex-smoker | 54 (21) | 28 (21) | 26 (20) |
| current smoker | 11 (4) | 6 (5) | 5 (4) |
| DASS-21 *(0 to 21)*, mean (SD)[e] | | | |
| depression | 4.4 (6) | 5.0 (6.8) | 3.8 (5.0) |
| anxiety | 4.0 (5) | 4.3 (4.9) | 3.7 (4.4) |
| stress | 10.1 (8) | 10.5 (8.8) | 9.7 (7.8) |
| Sleep quality, n (%) | | | |
| very good | 55 (21) | 29 (22) | 26 (20) |
| fairly good | 144 (55) | 67 (51) | 77 (60) |
| fairly bad | 56 (21) | 31 (23) | 25 (19) |
| very bad | 6 (2) | 5 (4) | 1 (1) |

Con = control group, DASS-21 = 21-item Depression Anxiety Stress Scale, Exp = experimental group.
[a] Days from the date of the end of last episode of LBP to the randomisation date.
[b] Perceived risk of recurrence over the next 12 months, scored from 0 (no risk) to 10 (very high risk).
[c] Self-rated total time spent doing the activity (at least 10 minutes at a time) over the previous 7 days.
[d] Hours spent sitting on an average weekday in the last week.
[e] Each domain score ranges from 0 (normal) to 21 (extremely severe).

two physiotherapy sessions in the intervention group was: 117 (89%) attended two sessions, 10 (7%) attended the initial session only, and five (4%) did not attend any sessions. Further details of study process measures are presented in Table 3.

### *Effects of the intervention*

*Primary outcome*

For the primary outcome of number of days from randomisation to first reported recurrence of activity-limiting LBP, the preventive effect of the experimental intervention was estimated as HR 1.11 (95% CI 0.80 to 1.54). The 25th percentile time from randomisation to activity-limiting recurrence of LBP (number of days when 25% of participants had experienced a recurrence) was 101 days (95% CI 74 to 127) in the experimental group and 127 (95% CI 44 to 210) in the control group. Figure 2 presents the Kaplan-Meier survival curves for days to first recurrence of an episode of activity-limiting LBP.

*Secondary outcomes*

The preventive effect of the experimental intervention on the secondary outcome of any recurrence of LBP was estimated as HR 0.95 (95% CI 0.72 to 1.26). The 25th percentile time to a recurrence of any episode of LBP was 58 days (95% CI 41 to 75) in the experimental group and 59 (95% CI 33 to 85) in the control group. Figure 3 presents the Kaplan-Meier survival curves for days to first recurrence of any episode of LBP.

The preventive effect of the experimental intervention on the secondary outcome of a recurrence of an episode of LBP leading to care seeking was estimated as HR 0.69 (95% CI 0.46 to 1.04), indicating a point estimate of a 31% reduction in care seeking in the experimental group compared with the control group. The 25th percentile time to a recurrence of LBP leading to care seeking was 344 days (95% CI 197 to 491) in the experimental group and 238 (95% CI 134 to 342) in the control group. Figure 4 presents the Kaplan-Meier survival curves for days to first recurrence of LBP leading to care seeking.

The experimental intervention did not have a worthwhile effect on the secondary outcome of impact of LBP over the 12-month period. The mean effect sizes and their confidence intervals at 3, 6, 9 and 12 months were all within 4 points above or below 0 (no effect) on the scale from 8 to 50 (Table 4).

Individual participant data are presented in Tables 5 and 6 on the eAddenda.

## Discussion

The purpose of this study was to estimate the effect of two sessions of McKenzie-based self-management exercise and an education program on people who had recently recovered from an episode of LBP. The primary outcome of this study was the risk of recurrence of activity-limiting LBP. The estimate of the effect on this outcome was HR 1.11 (95% CI 0.80 to 1.54). The best estimate was that a McKenzie-based self-management exercise and education program does not produce worthwhile reductions in the risk of an activity-limiting episode of LBP; however, modestly reduced or moderately increased risk could not be ruled out. This confidence interval indicates that the true effect of the experimental intervention on this outcome in the general population might be anywhere between increasing the hazard ratio by 54% or decreasing it by 20%. Further research could be undertaken to try to decrease this uncertainty about the effect on activity-limiting LBP.

Similarly, the best estimate suggested that the experimental intervention does not produce worthwhile reductions in risk for the secondary outcome of any LBP recurrence (HR 0.95, 95% CI 0.72 to 1.26). The confidence interval for the secondary outcome of recurrence of any LBP extended from 0.72 to 1.26, indicating that the experimental intervention might increase the hazard ratio by 26% or decrease it by 28%. Again, this finding does not exclude the possibility of important effects in either direction, so further research could be undertaken to try to decrease this uncertainty.

**Table 3**
Process measures.

| Measures | Exp (n = 132) | Con (n = 129) |
|---|---|---|
| Physical activity *(min/wk)*, median (IQR)[a] | | |
| Walking | | |
| baseline | 192 (92 to 358) | 180 (90 to 305) |
| 3 months | 150 (90 to 300) | 180 (82 to 307) |
| 12 months | 180 (90 to 300) | 180 (90 to 303) |
| Moderate/vigorous | | |
| baseline | 90 (0 to 240) | 120 (27 to 240) |
| 3 months | 90 (40 to 200) | 90 (17 to 245) |
| 12 months | 90 (20 to 205) | 90 (30 to 180) |
| Program compliance | | |
| Physiotherapy first session only, n (%) | 10 (8) | NA |
| Physiotherapy both sessions, n (%) | 117 (89) | NA |
| Home exercise program between sessions *(0 to 10)*, mean (SD)[b] | 7.3 (2.1) | NA |
| Compliance over 12 months *(0 to 10)*, mean (SD)[b] | | |
| 3 months | 6.8 (2.3) | 5.9 (2.5) |
| 6 months | 5.5 (2.6) | 5.7 (2.8) |
| 9 months | 5.2 (2.7) | 5.3 (2.8) |
| 12 months | 5.1 (2.8) | 5.2 (2.8) |
| Credibility/expectancy *(4 to 36)*, mean (SD)[c] | 29.5 (6.0) | 24.5 (9.0) |
| Adverse events, n[d] | | |
| serious adverse events | 9 | 6 |
| adverse events | 29 | 41 |
| Co-interventions, n[e] | | |
| overall | 153 | 210 |
| physiotherapy | 45 | 57 |
| chiropractic | 24 | 52 |
| massage | 21 | 37 |
| Pilates | 21 | 11 |
| acupuncture | 10 | 17 |
| yoga | 6 | 9 |
| others | 26 | 27 |
| Pregnancy, n | 1 | 3 |

Con = control group, Exp = experimental group, NA = not applicable.
[a] Self-rated total time spent doing the activity (at least 10 minutes at a time) over the previous 7 days.
[b] Brief Adherence Rating Scale, scored from 0 (not compliant at all) to 10 (very compliant).
[c] Credibility/expectancy, scored from 4 (low credibility/expectancy) to 36 (high credibility/expectancy).
[d] Number of adverse events reported in the study over two time-points (3 and 12 months).
[e] Number of additional co-interventions reported in the study over four time-points (3, 6, 9 and 12 months).

On the other hand, the estimates for the secondary outcome of recurrence of LBP causing care seeking gave a more helpful indication of what the true effect might be (HR 0.69, 95% CI 0.46 to 1.04). The best estimate was that the experimental intervention produces worthwhile reductions in risk for this outcome. The CI excluded the possibility that the experimental intervention increases the hazard ratio to any important extent (ie, $\leq$ 4%) and included the possibility that the effect is very worthwhile (ie, decreased the HR by 54%). This promising result suggests that this effect is worthy of further investigation. However, the experimental intervention clearly had a negligible effect on the impact of LBP, with effect sizes and their confidence intervals all lying within 4 points above or below 0 (no effect) on the scale from 8 to 50.

Current evidence from a systematic review of randomised trials on prevention of LBP suggests that exercise in combination with education has a protective effect for up to 1 year (RR 0.55, 95% CI 0.41 to 0.74).[8] Most trials in this review included group-based strength and aerobic exercises that were quite different from our experimental intervention. However, one of the included trials by Larsen et al[11] investigated the effect of passive prone back extensions performed twice daily and education based on the McKenzie method in male military conscripts. This study reported a relative risk reduction of a new LBP episode of around 60% (RR 0.36, 95% CI 0.18 to 0.73). In contrast, the best estimates from our trial suggest that a McKenzie-based self-management and education program did not produce worthwhile reductions in the risk of a recurrence and did not generate precise enough estimates to confidently

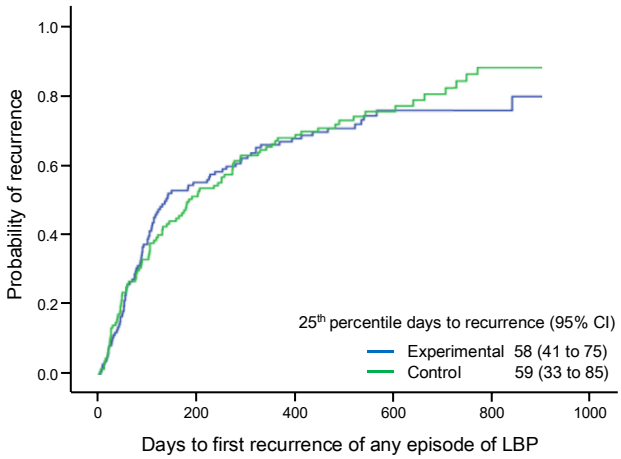


**Figure 3.** Kaplan-Meier survival curves for days to first recurrence of any episode of LBP. Recurrence is defined as a new episode of LBP of intensity > 2/10, lasting at least 24 hours.
LBP = low back pain.

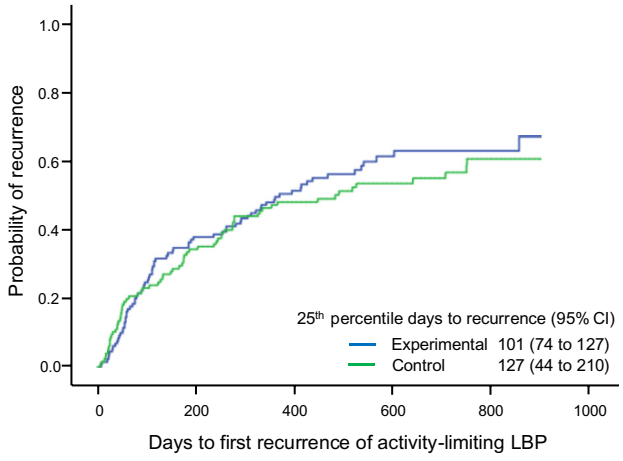


**Figure 2.** Kaplan-Meier survival curves for days to first recurrence of an episode of activity-limiting LBP.
Recurrence is defined as a new episode of LBP of intensity > 2/10, lasting at least 24 hours.
LBP = low back pain.

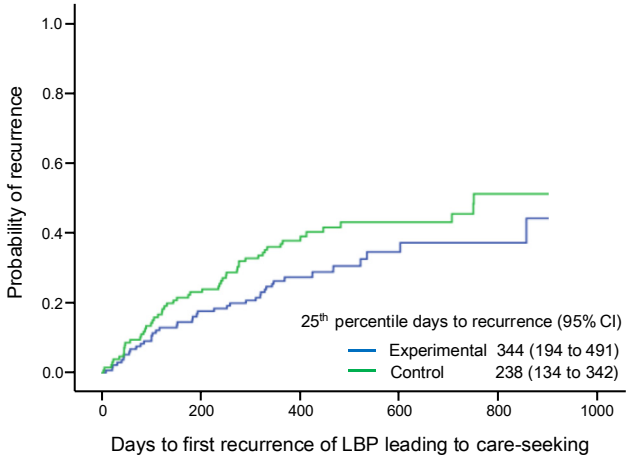


**Figure 4.** Kaplan-Meier survival curves for days to first recurrence of LBP leading to care seeking.
Recurrence is defined as a new episode of LBP of intensity > 2/10, lasting at least 24 hours.
LBP = low back pain.

**Table 4**
Modelled estimates of the Personal Impact of Back Pain over 12 months.

| Time-point | Exp | | Con | | MD (95% CI)[a] |
|---|---|---|---|---|---|
| | n | Mean (SD) | n | Mean (SD) | |
| Baseline | 132 | 21.7 (8.1) | 129 | 21.7 (8.9) | NA |
| 3 months | 129 | 13.0 (4.7) | 125 | 13.2 (5.8) | −0.1 (−1.8 to 1.5) |
| 6 months | 129 | 12.6 (5.3) | 120 | 13.8 (6.1) | −1.1 (−3.0 to 0.7) |
| 9 months | 126 | 13.0 (5.0) | 122 | 14.5 (7.3) | −1.3 (−3.3 to 0.6) |
| 12 months | 125 | 13.6 (6.8) | 117 | 13.4 (6.2) | 0.1 (−1.8 to 2.1) |

Personal Impact of Back Pain was based on nine items of the 29-item PROMIS short form and scored from 8 (least impact) to 50 (greatest impact).
Con = control group, Exp = experimental group, NA = not applicable.
[a] Mean between-group difference based on modelled estimates. A negative value of the MD estimate represents an effect in favour of the experimental group.

recommend whether or not it should be used in preventing recurrences of LBP. Important differences between our randomised trial and the trial by Larsen et al[11] could explain the different findings. We recruited a broad community population, whereas Larsen et al recruited male military conscripts. We recruited participants who had recovered from a previous episode of LBP within the past 6 months, whereas Larsen et al included a mixed population with and without LBP. We followed participants for between 12 and 30 months, whereas Larsen et al followed participants for 10 months.

Some strengths of our study were a pre-specified published protocol,[12] regular follow-ups to avoid recall bias and use of three definitions of a recurrence. We recruited an inception cohort of people recovered from an episode of LBP within the last 6 months and our results are most relevant to this population. We followed participants for between 12 months and 30 months, and achieved very high follow-up rates (completeness index of 94%).

A limitation of our trial was that it was not possible to blind clinicians and participants to group allocation due to the nature of the intervention. A single therapist delivered the minimal intervention to the control group, which could impact the generalisability of findings. The confidence intervals for the primary outcome are relatively wide; however, they clearly exclude the 40% reduction in risk that we powered the study to investigate.

It is unclear why the best estimates from our trial suggest that the intervention did not produce worthwhile reductions in risk of a recurrence, when exercise and education interventions have been effective in most previous trials. It is possible this is due to the imprecision of our estimates, but also suggests that future research should investigate whether it is the exercise type, dosage or both that is required for a protective effect. Our promising findings regarding reduction in care seeking require further testing in larger randomised trials that are fully powered for this less common but important event. Future mechanistic research to better understand how interventions might reduce care seeking would help with development of interventions that optimally target reduced care seeking.

What should clinicians make of this study's findings? The imprecise estimates on the first few outcomes should not be interpreted as evidence that the experimental intervention is ineffective for those outcomes. Further evidence may clarify that the intervention's effect is beneficial, negligible or harmful. Clinicians should keep an open mind about those outcomes until more precise estimates are available. For the time being, those estimates narrow our idea of what the true average effect of the intervention on those outcomes might be, but not enough to indicate whether the treatment should be used. The estimate of the effect on recurrence of LBP that leads to care seeking is more promising and does exclude the possibility of any important harm, but it still includes the possibility of no effect, so the study cannot be used to recommend the experimental intervention to prevent care seeking. Where the study was able to provide clear evidence was on the impact of LBP, with very narrow confidence intervals centred close to 0 (ie, no effect). Clinicians can conclude that the experimental approach has a negligible effect on the impact of LBP.

Given the strong trend evident on the 'care seeking' outcome and the clear indication of negligible effect on the 'impact of LBP', it is interesting to speculate whether a treatment could prevent care seeking even though it does not affect the impact of LBP. Although both interventions in this study offered strategies for self-management, the more intensive experimental intervention may have reinforced this message more effectively. Perhaps the experimental intervention does not delay the recurrence of LBP, but it does effectively teach patients to self-manage well enough so that they do not need to seek care from a healthcare practitioner when LBP recurs.

In conclusion, this study provided believable but imprecise estimates about whether a McKenzie-based self-management exercise and education program affects recurrence of LBP. The best estimate was that a McKenzie-based self-management exercise and education program does not produce worthwhile reductions in the risk of an activity-limiting episode of LBP but may produce worthwhile reductions in recurrence of an episode of LBP leading to care seeking. We also found clear evidence that any effect on the impact of LBP over 1 year is negligible. Further research should investigate the promising trend that this experimental intervention might delay care seeking when LBP recurs.

**What was already known on this topic:** Current evidence from randomised controlled trials suggests that exercise combined with education reduces the risk of a new episode of LBP; however, the evidence from these trials is mostly based on relatively costly, inflexible and time-consuming exercise programs.
**What this study adds:** This study provided robust but imprecise estimates about whether a McKenzie-based self-management exercise and education program affects recurrence of LBP, but it provided clear evidence that any effect on the impact of LBP over 1 year is negligible. Further research should investigate the promising trend that this intervention might prevent people from seeking healthcare when LBP recurs.

***Footnotes*:** [a] Qualtrics®, Qualtrics, Provo, USA. [b] PASS Software, NCSS, Kaysville, USA. [c] SPSS® version 25, IBM, Armonk, USA.

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***Correspondence:*** Mr Tarcisio F de Campos, Department of Health Professions, Macquarie University, NSW 2109, Australia. Email: tarcisio.de-campos@hdr.mq.edu.au

## References

1. Vos T, Barber RM, Bell B, Bertozzi-Villa A, Biryukov S, Bolliger I, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2015;386:743–800.
2. Vos T, Allen C, Arora M, Barber RM, Bhutta ZA, Brown A, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet*. 2016;388:1545–1602.
3. Downie AS, Hancock MJ, Rzewuska M, Williams CM, Lin CW, Maher CG. Trajectories of acute low back pain: a latent class growth analysis. *Pain*. 2016;157:225–234.
4. Costa LdCM, Maher CG, Hancock MJ, McAuley JH, Herbert RD, Costa LO. The prognosis of acute and persistent low-back pain: a meta-analysis. *CMAJ*. 2012;184:E613–E624.
5. da Silva T, Mills K, Brown BT, Herbert RD, Maher CG, Hancock MJ. Recurrence of low back pain is common: a prospective inception cohort study. *J Physiother*. 2019;65:159–165.
6. da Silva T, Mills K, Brown BT, Herbert RD, Maher CG, Hancock MJ. Risk of recurrence of low back pain: a systematic review. *J Orthop Sports Phys Ther*. 2017;47:305–313.
7. Wasiak R, Kim J, Pransky G. Work disability and costs caused by recurrence of low back pain: longer and more costly than in first episodes. *Spine*. 2006;31:219–225.
8. Steffens D, Maher CG, Pereira LS, Stevens ML, Oliveira VC, Chapple M. Prevention of low back pain: a systematic review and meta-analysis. *JAMA*. 2016;176:199–208.
9. Soukup MG, Lönn J, Glomsröd B, Bö K, Larsen S. Exercises and education as secondary prevention for recurrent low back pain. *Physiother Res Int*. 2001;6:27–39.
10. Stevens ML, Lin C-WC, Hancock MJ, Wisby-Roth T, Latimer J, Maher CG. A physiotherapist-led exercise and education program for preventing recurrence of low back pain: a randomised controlled pilot trial. *Physiotherapy*. 2018;104:217–223.
11. Larsen K, Weidick F, Leboeuf-Yde C. Can passive prone extensions of the back prevent back problems? A randomized, controlled intervention trial of 314 military conscripts. *Spine*. 2002;27:2747–2752.
12. de Campos TF, Maher CG, Clare HA, da Silva TM, Hancock MJ. Effectiveness of McKenzie method–based self-management approach for the secondary prevention of a recurrence of low back pain (SAFE Trial): protocol for a pragmatic randomized controlled trial. *Phys Ther*. 2017;97:799–806.
13. Stanton TR, Henschke N, Maher CG, Refshauge KM, Latimer J, McAuley JH. After an episode of acute low back pain, recurrence is unpredictable and not as common as previously thought. *Spine*. 2008;33:2923–2928.
14. Ford I, Norrie J. Pragmatic trials. *N Engl J Med*. 2016;375:454–463.
15. Sedgwick P. Explanatory trials versus pragmatic trials. *BMJ*. 2014;349:g6694.
16. Anderson JA. Epidemiological aspects of back pain. *J Soc Occup Med*. 1986;36:90–94.
17. The McKenzie Institute Australia: Part A – The Lumbar Spine; 2019. https://www.mckenzieinstituteaustralia.org/education/courses-overview/part-a-the-lumbar-spine/. Accessed 19 June, 2020.
18. The McKenzie Institute Australia: Part B – The Cervical and Thoracic Spine; 2019. https://www.mckenzieinstituteaustralia.org/education/courses-overview/part-b-the-cervical-and-thoracic-spine/. Accessed 19 June, 2020.
19. McKenzie R. The McKenzie Institute Lumbar Spine Assessment; 2006. http://www.mckenzieinstituteusa.org/forms/2006MIIAssessmentFormLumbar.pdf. Accessed 19 June, 2020.
20. BUPA. Guide to Positively Managing Back Pain. *Managing back Pain - Get Back on Track (pdf file)*. 2014 http://www.bupa.com.au/health-and-wellness/programs-and-support/member-support-programs/member-support-back-pain. Accessed 19 June, 2020.
21. Deyo R, Dworkin S, Amtmann D, Andersson G, Borenstein D, Carragee E, et al. Report of the NIH Task Force on Research Standards for chronic low back pain. *J Pain*. 2014;15:569–585.
22. Deyo RA, Ramsey K, Buckley DI, Michaels L, Kobus A, Eckstrom E, et al. Performance of a patient reported outcomes measurement information system (PROMIS) short form in older adults with chronic musculoskeletal pain. *Pain Med*. 2016;17:314–324.
23. Amtmann D, Cook KF, Jensen MP, Chen WH, Choi S, Revicki D, et al. Development of a PROMIS item bank to measure pain interference. *Pain*. 2010;150:173–182.
24. Stanton TR, Latimer J, Maher CG, Hancock MJ. A modified Delphi approach to standardize low back pain recurrence terminology. *Eur Spine J*. 2011;20:744–752.
25. Craig C, Marshall AL, Sjostrom M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc*. 2003;35:1381–1395.
26. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry*. 2000;31:73–86.
27. Lakatos E. Sample sizes based on the log-rank statistic in complex clinical trials. *Biometrics*. 1988;44:229–241.
28. Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. *BMJ*. 1999;319:670–674.
29. Clark TG, Altman DG, Stavola BLD. Quantification of the completeness of follow-up. *Lancet*. 2002;359:1309–1310.