Effectiveness and cost-effectiveness of an individualised, progressive walking and education intervention for the prevention of low back pain recurrence in Australia (WalkBack): a randomised controlled trial

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Summary

Background Recurrence of low back pain is common and a substantial contributor to the disease and economic burden of low back pain. Exercise is recommended to prevent recurrence, but the effectiveness and cost-effectiveness of an accessible and low-cost intervention, such as walking, is yet to be established. We aimed to investigate the clinical effectiveness and cost-effectiveness of an individualised, progressive walking and education intervention to prevent the recurrence of low back pain.

Methods WalkBack was a two-armed, randomised controlled trial, which recruited adults (aged 18 years or older) from across Australia who had recently recovered from an episode of non-specific low back pain that was not attributed to a specific diagnosis, and which lasted for at least 24 h. Participants were randomly assigned to an individualised, progressive walking and education intervention facilitated by six sessions with a physiotherapist across 6 months or to a no treatment control group (1:1). The randomisation schedule comprised randomly permuted blocks of 4, 6, and 8 and was stratified by history of more than two previous episodes of low back pain and referral method. Physiotherapists and participants were not masked to allocation. Participants were followed for a minimum of 12 months and a maximum of 36 months, depending on the date of enrolment. The primary outcome was days to the first recurrence of an activity-limiting episode of low back pain, collected in the intention-to-treat population via monthly self-report. Cost-effectiveness was evaluated from the societal perspective and expressed as incremental cost per quality-adjusted life-year (QALY) gained. The trial was prospectively registered (ACTRN12619001134112).

Findings Between Sept 23, 2019, and June 10, 2022, 3206 potential participants were screened for eligibility, 2505 (78%) were excluded, and 701 were randomly assigned (351 to the intervention group and 350 to the no treatment control group). Most participants were female (565 [81%] of 701) and the mean age of participants was 54 years (SD 12). The intervention was effective in preventing an episode of activity-limiting low back pain (hazard ratio 0·72 [95% CI 0·60–0·85], p=0·0002). The median days to a recurrence was 208 days (95% CI 149–295) in the intervention group and 112 days (89–140) in the control group. The incremental cost per QALY gained was AU$7802, giving a 94% probability that the intervention was cost-effective at a willingness-to-pay threshold of $28 000. Although the total number of participants experiencing at least one adverse event over 12 months was similar between the intervention and control groups (183 [52%] of 351 and 190 [54%] of 350, respectively, p=0·60), there was a greater number of adverse events related to the lower extremities in the intervention group than in the control group (100 in the intervention group and 54 in the control group).

Interpretation An individualised, progressive walking and education intervention significantly reduced low back pain recurrence. This accessible, scalable, and safe intervention could affect how low back pain is managed.

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Introduction

Low back pain is a highly prevalent and disabling condition. Low back pain is the leading cause of years lived with disability and was estimated to affect 619 million people globally in 2020, with this number projected to increase to 843 million people by 2050.[1] Approximately 70% of individuals experience a recurrence of low back pain within 12 months following recovery from an episode.[2] Recurrences substantially contribute to the disease and economic burden on individuals and society. Individuals experiencing recurrences bear higher medical costs and longer work absenteeism than those without recurrence.[3]

The combination of exercise and education has been shown to help prevent the recurrence of low back pain, associated disability, and work absenteeism.[4–6]

Research in context

Evidence before this study
Almost seven in ten people who recover from an episode of low back pain will experience a recurrence within the following year. Evidence suggests that exercise alone or combined with education reduces the risk of recurrence; however, many investigated exercises require specialised equipment and close supervision and can incur high costs. Accessible and affordable forms of exercise that enable individuals to self-manage their back pain have not been evaluated as interventions to prevent low back pain recurrence. In 2022, we published a systematic review examining walking, cycling, and swimming to treat and prevent low back pain. We searched MEDLINE, Embase, CINAHL, PEDro, and CENTRAL databases for peer-reviewed, randomised controlled trials from database inception until April 14, 2021, with no language restrictions. The search strategy was based on the recommended search terms of the Cochrane Back and Neck Group for "randomised controlled trials" and "low back pain", combined with search terms for walking, cycling, and swimming. We identified no trials that assessed the effectiveness of these exercises for preventing recurrences of low back pain. Walking is an accessible and low-cost exercise that reduces pain and disability in chronic low back pain; however, its effectiveness and cost-effectiveness in preventing recurrences have not been explored.

Added value of this study
To our knowledge, WalkBack is a world-first trial, demonstrating that a walking and education intervention, compared with a no treatment control, can substantially reduce recurrences of low back pain. The total number of adverse events was similar across groups; however, the intervention group reported twice as many lower extremity injuries than were observed in the control group. The intervention also had a high probability of being cost-effective compared with a no treatment control.

Implications of all the available evidence
This walking and education intervention, delivered using a health coaching approach, significantly reduced the recurrence of low back pain. Being accessible and low cost, this intervention has a better potential of being successfully implemented at scale than previously investigated forms of exercise. These results indicate the importance of preventive management and could affect how low back pain is managed.

Exercise-based interventions explored to date have typically included group-based programmes, usually requiring close clinician supervision and use of equipment, and might incur a high cost.[4] These factors potentially limit the accessibility of these exercise programmes for patients with recurrent low back pain.[7–9]

Walking is a low-risk exercise that is adaptable to busy lifestyles and accessible to most people regardless of socioeconomic status or geographical location. Walking delivers a range of health benefits, including enhanced cardiovascular health, improved cognition and mood, and reduced risk of non-communicable diseases.[10–12] Although the health benefits of walking have been widely explored, no trial has examined whether walking is effective in preventing recurrences of low back pain.[13]

This study aimed to investigate the clinical effectiveness and cost-effectiveness of an individualised, progressive walking and education intervention compared with a no-treatment control group, to prevent recurrences of low back pain.

Methods

Study design

WalkBack was a two-armed, randomised controlled trial, for which the intervention was delievered by 25 private physiotherapy clinics across Australia. The trial protocol and statistical analysis plan have been published.[14,15] The study was approved by the Macquarie University Human Research Ethics Committee (HREC:5201949218164) and is reported as per the CONSORT and CONSORT Extension for RCTs Revised in Extenuating Circumstances guidelines. The trial was prospectively registered (Australian New Zealand Clinical Trials Registry, ACTRN12619001134112).

Participants

Eligible participants were adults (≥18 years) who had recovered from an episode of non-specific low back pain within the previous 6 months. An episode of non-specific low back pain was defined as pain in the area between the 12th rib and buttock crease not attributed to a specific diagnosis (eg, vertebral fracture, infection, or cancer) lasting at least 24 h, with a pain intensity greater than 2 on a 0–10 numerical pain rating scale, causing at least somewhat or greater interference with day-to-day activities on an adapted version of item PI9 of the PROMIS item bank ("How much did low back pain interfere with your day-to-day activities?" Not at all; A little bit; Somewhat; Quite a bit; Very much).[16] Recovery was defined as more than 7 consecutive days with pain no greater than 1 on a 0–10 scale.[17]

Exclusion criteria were: any comorbidity preventing participation in a walking programme; current walking for exercise three or more times per week (≥30 min daily); current regular participation in an exercise programme for the prevention of recurrent low back pain (eg, pilates); achieving more than 150 min of moderate or vigorous intensity physical activity weekly (across a minimum of 3 days per week); spinal surgery in the preceding 6 months; current pregnancy; and an inadequate level of English to complete study questionnaires.

Participants were recruited via community advertising (eg, social media and company newsletters) and clinician referrals (eg, general practitioner, physiotherapists). All advertising strategies directed potential participants to a preliminary online screening form on the trial website. Those who passed the initial screening underwent full screening over the telephone with a member of the research team. All eligible participants provided informed consent electronically before completing an online baseline questionnaire.

See Online for appendix

Randomisation and masking

After completing the baseline questionnaire, participants were randomly assigned to the individualised, progressive walking and education intervention or a no treatment control group in a 1:1 allocation ratio. The randomisation sequence was created by a senior research team member (C-WCL) who was not involved in screening, randomisation, or data collection. The randomisation schedule comprised randomly permuted blocks of 4, 6, and 8, stratified by history of more than two previous lifetime episodes of low back pain, which is the only consistently reported prognostic factor for low back pain recurrence,[2] and recruitment from community advertising versus clinician referral. The randomisation sequence was embedded within Research Electronic Data Capture (REDCap), and a member of the research team (NCP) randomly assigned participants to their groups and notified them of their allocation.

Physiotherapists delivered the intervention but played no role in data collection other than recording session attendance. All participant-reported outcome measures were collected via a web-based questionnaire (REDCap) or telephone by a research team member who was masked to group allocation, as per participant preference. Data analyses were conducted by a statistician and health economist who were masked to group allocation. All authors agreed upon the interpretation of the results before unmasking.

Procedures

At baseline, data on sex were collected via self-report, with options of male or female. We did not collect data on ethnicity. Participants received six sessions with a registered physiotherapist who acted as a health coach for the walking programme. The first five sessions occurred within 12 weeks of randomisation, with a final booster session at 6 months. The walking programme was completed by participants in their own time. The physiotherapist used a health coaching approach (key principles described below) to support an individualised and progressive walking programme, which was structured to optimise long-term adherence. A guiding target for the programme was to walk five times per week for at least 30 min daily by 6 months; however, this was individualised as appropriate.

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The initial consultation (approximately 45 min) involved history taking and a physical examination to help guide the initial dose of the walking programme. A prescription guide was developed to suggest an appropriate starting dose for the walking programme and appropriate progression, based on the participant's current level of walking, age, and body-mass index (appendix pp 2–3). Importantly, using a person-centred approach, the initial prescription and the progression was individualised in discussion with the participant based on individual participant characteristics (eg, comorbidities and self-efficacy), environmental barriers (eg, safety, lighting, or surfaces), time constraints, preferences, and participant goals. Participants were also provided with a pedometer (Yamax-SW200) and a walking diary (appendix p 4) to track their walking throughout the first 12 weeks of the programme. After 12 weeks, participants were encouraged to continue to use the pedometer and walking diary if they found them motivating.

Follow-up sessions with the physiotherapist were used to check adherence (including checking the walking diary), track engagement, and adjust the walking programme as required. These sessions were initially intended to be a combination of two face-to-face sessions (30-min consultations at 4 weeks and 3 months post-randomisation) and three over-the-phone sessions (15-min consultations at 2 weeks and 6 weeks, and a reinforcement session at 6 months). Due to the COVID-19 pandemic, temporary restrictions were placed on in-person consultations, and many participants received the intervention via telehealth (ie, video consultations). The decision to switch to telehealth was made after consulting with study clinicians who viewed this delivery method as feasible and as equally effective as face-to-face consultations.

Education was also provided alongside the walking programme (appendix p 5). The education aimed to provide a basic understanding of modern pain science and reduce fear associated with low back pain. Simple strategies to reduce the risk of a recurrence of low back pain and instructions on how to self-manage any minor recurrences were discussed. Participants in both groups were not restricted from seeking other care for their low back pain as required. Further information about the intervention is published elsewhere,[14] and the Template for Intervention Description and Replication checklist is provided in the appendix (p 6).

The trial physiotherapists were upskilled in the principles of health coaching. The training was provided to physiotherapists via five adapted online modules (approximately 3 h) developed by Wellness Coaching Australia. These modules covered the topics of health coaching communication (eg, using open-ended questions, active listening, and avoiding giving instruction), participant-led and clinician-assisted goal setting, promotion of self-efficacy, motivational interviewing, and implementing action. Additionally, physiotherapists were trained by a research team member (NCP) in trial intervention procedures during a single 90-min session. During this session, clinicians' understanding of the health coaching principles and application to the trial was assessed using case vignettes. Clinicians received updates and reminders on trial procedures and tips for optimal intervention delivery via email approximately every 3 months. The research team also hosted online meetings every 6 months during the trial for clinicians to discuss any challenges with delivery of the intervention.

In the control group, participants were not provided with any intervention. However, they could engage in any prevention strategies or seek treatment to manage any new recurrence of low back pain while enrolled in the trial. This control was selected because the research team and consumer representative (OC) agreed this was the most important, practical, real-world comparison to the intervention.

Outcomes

The primary effectiveness outcome was the number of days from randomisation to the first recurrence of activity-limiting low back pain. This was defined as a new recurrence of low back pain lasting at least 24 h, with a pain intensity greater than 2 on a 0–10 numerical pain rating scale, causing at least somewhat or greater interference with day-to-day activities based on an adapted version of PI9 of the PROMIS item bank ("How much did low back pain interfere with your day-to-day activities?" Not at all; A little bit; Somewhat; Quite a bit; Very much).[16]

Participants were contacted via email to complete a monthly questionnaire establishing whether they experienced a recurrence of low back pain. If they had a recurrence, the start date was clarified so the number of days from randomisation until the recurrence could be established. Participants who did not complete the questionnaire were sent a reminder email and contacted by phone within 48 h to collect data. All participants who were randomly assigned to each group were followed up for this outcome for a minimum of 12 months and up to a maximum of 36 months, depending on the date of enrolment.

Data on secondary outcomes were collected for all randomly assigned participants. We had different definitions of recurrence to those that were used in the primary outcome: (1) any recurrence, or (2) a care-seeking recurrence of low back pain. Any recurrence was defined as a new recurrence of low back pain lasting at least 24 h, with a pain intensity greater than 2 on a 0–10 numerical pain rating scale. This is the lowest threshold used to define a recurrence, based on a Delphi study by Stanton and colleagues.[18] A care-seeking recurrence was defined as a new recurrence of low back pain (matching the lowest threshold definition), with care sought from a health-care provider.

Additional prespecified secondary outcome measures that were collected at months 3, 6, 9, and 12 were disability (Roland Morris Disability Questionnaire [RMDQ], 0–24 scale, for which higher scores indicate higher levels of pain-related disability),[19] health-related quality of life (EuroQoL EQ-5D-5L, 0–1 utility index, for which a score of 1 indicates full health),[20,21] physical activity (Active Australia Survey, collected at months 3 and 12, which is a modified version of the International Physical Activity Questionnaire [IPAQ] with Australian benchmarking),[22] sedentary behaviour (collected at months 3 and 12, using the sitting item of the IPAQ),[23] co-intervention utilisation (participants were asked, "Apart from your involvement in the study have you received any additional treatment or prevention approach for back pain over the last 3 months?"), adverse and serious adverse events (coded according to the ICD-11 framework).[24] Adverse events were self-reported by participants during quarterly follow-up by responding to the question "Have you had a new medical condition or an exacerbation of an existing condition since the beginning of the study?"

All participants were instructed to wear a hip-worn triaxial accelerometer (ActiGraph GTX3-BT) for a 7-day window, 3 months after enrolment in the trial as this was the time when we expected to see the greatest differences between groups. The accelerometers measured daily step count, daily brisk-walking steps, and minutes of moderate to vigorous physical activity. The original protocol also included clinicians' collecting a timed 10 meter walking test for intervention group participants at baseline and 3 months; however, due to the COVID-19 pandemic and the decision to deliver the intervention via telehealth, this measure could no longer be collected in a valid way and was ceased.

Intervention adherence measures were collected throughout the trial, including session attendance, duration of walking documented in the 12-week walking diary, and self-reported adherence (Brief Adherence Rating Scale [BARS], which ranges from 0 [not at all compliant] to 10 [very compliant]) collected quarterly for 12 months.

The economic evaluation was performed from the societal perspective, using patient-level data and the outcomes quality-adjusted life-years (QALYs) and recurrence of activity-limiting low back pain (yes or no over 12 months). QALYs were calculated from the EQ-5D-5L questionnaire using the Australian tariff[21] and the area under the curve approach. Originally, the statistical analysis plan indicated the use of the Canadian tariff to calculate QALYs, but this was modified with the release of the new Australian tariff (2023).[21] Societal cost outcomes included costs attributed to the delivery of the intervention (eg, session attendance, pedometer, and printing costs associated with the diary), health-care costs associated with low back pain (eg, hospital admission, health-care services, and medications), and work absenteeism collected via patient questionnaires administered at 3, 6, 9, and 12 months. Health-care use was valued using prices derived from published standard rates, and work absenteeism was valued using sex-specific price weights based on data from the Australian Bureau of Statistics.[25] Costs were expressed in 2023 Australian Dollars. As the economic evaluation follow-up did not extend beyond 12 months, costs and effects were not discounted. More detailed information about the measurement and valuation of costs and effects can be found in the appendix (pp 13–19).

Statistical analysis

A detailed statistical analysis plan was published before trial completion.[15] A sample size of 349 participants per group was calculated to detect a 25% relative reduction (30% to 22·5%; equivalent to a hazard ratio [HR] of 0·71) in the proportion of participants who experienced the primary outcome (activity-limiting episode of low back pain) in the intervention versus the control, using a conservative estimate of a 30% recurrence rate at 12 months in the control group.[26] Specifications for the sample size calculation included a two-sided log-rank test, 80% power, type 1 error of 0·05, 24-month accrual period, and 12-month follow-up period. Sample size calculations allowed for 1% loss to follow-up per month.

Analyses followed the intention-to-treat principle. Baseline characteristics are presented as proportions for categorical variables and as means with SD or medians with IQRs for continuous variables. For the recurrence outcomes, Cox regression was used to assess the effect of group allocation, reported as HR and 95% CIs. Adjustment for prognostic factors in the Cox models was planned if these were unbalanced between groups despite randomisation.[15] The proportional hazard assumption was tested using the time-dependent covariate method and inspection of Kaplan–Meier curves. The median days to a recurrence (ie, the number of days when 50% of participants had experienced a recurrence) was calculated for each group unless 50% did not experience recurrence, in which case 25% was used.

Linear mixed-effects models were used to assess the effect of the intervention on change over time in continuous secondary outcomes. These models control for correlation induced by repeated measures on the same individual through a random intercept, and use a restricted maximum likelihood approach that incorporates all available data to produce unbiased estimates assuming that missing data are missing at random. Model assumptions were checked using standard diagnostics. For cases in which model assumptions failed, transformations such as natural logarithm or square root of the outcomes were employed. Estimates were then back-transformed for the presentation of results. Results are presented as between-group mean differences with 95% CI at each timepoint using a multivariate t-interval adjustment for multiple comparisons. In instances in which transformations could not resolve issues with assumptions, the linear model results were presented together with sensitivity analyses conducted using percentile bootstrapping on the interval contrasts (5000 replicates). Differences between the intervention and control groups for the ActiGraph data were analysed using Welch two-sample *t*-tests since they only used one timepoint. A sensitivity analysis was also conducted to account for missing values in the secondary outcomes by generating ten complete datasets using the Multivariate Imputation by Chained Equations (MICE) package in R. The imputation model included the outcome variables of interest together with some auxiliary variables (ie, work status, age, gender, body-mass index, self-perceived risk of recurrence, and duration of last low back pain episode). The mixed-effects models were re-run with the results pooled over the ten data sets. Additionally, a second post-hoc sensitivity analysis was conducted in which the baseline outcome measure was used as a predictor for the secondary outcome analyses.

The economic evaluation was conducted with a time horizon of 12 months, consistent with the minimum follow-up period. Ten complete datasets were generated to impute missing values using MICE. The imputation model included all available cost and effect values and the auxiliary variables listed in the previous paragraph. Seemingly unrelated regression analyses were performed

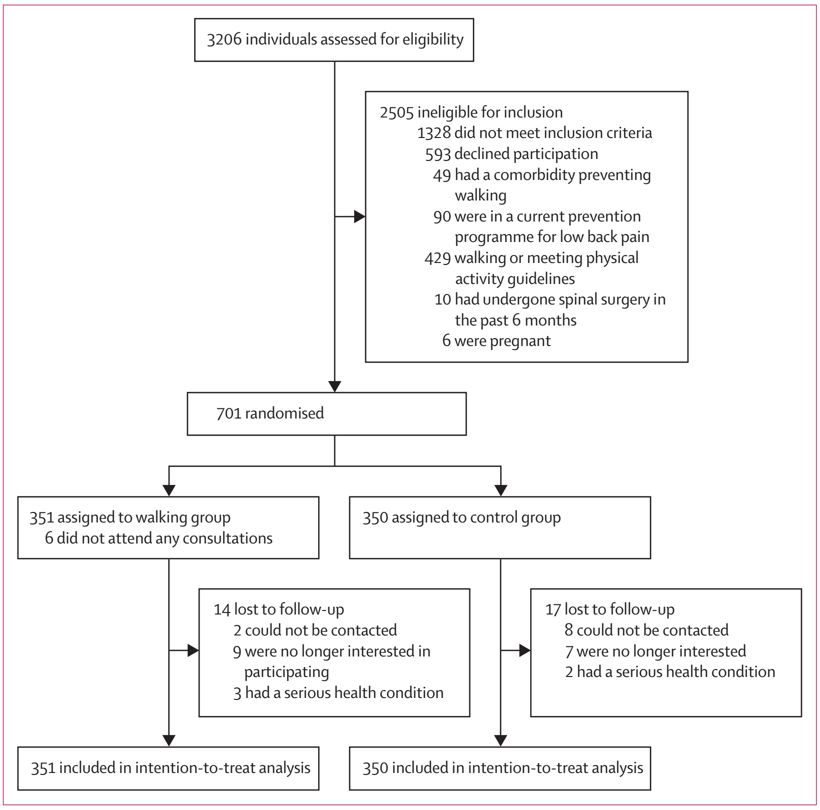

Figure 1: **Trial profile**

to assess differences in costs (ΔC) and effects (ΔE), which were subsequently used to estimate incremental cost-effectiveness ratios (ΔC/ΔE). Uncertainty surrounding cost differences was estimated using Bias Corrected and Accelerated bootstrapping (5000 replicates).[27] Cost-effectiveness planes and cost-effectiveness acceptability curves were constructed. Two sensitivity analyses were performed: (1) applying a health-care perspective and (2) using data from complete cases only. An independent data monitoring committee was not used due to the low-risk nature of the intervention. All analyses (clinical effectiveness and cost-effectiveness) were performed using R (version 4.2.2).

Role of the funding source

The funder of the study had no role in data collection, data analysis, data interpretation, or writing of the report.

Results

Between Sept 23, 2019, and June 10, 2022, 3206 potential participants were screened for eligibility, of whom 2505 (78%) were excluded for reasons including not meeting inclusion criteria, declining participation, having comorbidities preventing walking, or being currently in a prevention programme for low back pain. 701 participants from across Australia were randomly assigned to either the intervention group (n=351) or control group (n=350; figure 1). 670 (96%) participants (337 in the walking group and 333 in the control group) were successfully followed up until they experienced the primary outcome or were successfully followed up for a recurrence for at least 12 months (figure 1). The completeness index for the primary outcome was 87%.[28]

Baseline characteristics of participants are presented in table 1. The mean age of participants was 54 years (SD 12, range 20 to 82), and the majority were female (565 [81%] of 701). Participants reported a high number of previous episodes of low back pain (median 33 episodes) and a high perceived risk of recurrence over the next 12 months. The baseline characteristics were well-balanced between intervention and control and therefore no adjustments were made for these in any analyses.

24 physiotherapists with a median of 7 years' experience (range 1–35) acted as health coaches for the walking programme. In the intervention group, 345 participants attended at least one of the six available sessions with a physiotherapist (mean number of physiotherapy sessions attended was five [SD 1·6]), while six participants did not attend any sessions (figure 1). Self-reported adherence to the walking intervention reported with BARS was 7·3 (SD 2·5) out of 10 at 3 months, 6·6 (2·7) at 6 months, 6·0 (2·9) at 9 months, and 5·7 (3·0) at 12 months. Based on the 12-week walking diary completed by the intervention group, the median accumulated duration of intentional walking in week one was 80 min (IQR 52–125), and by week 12 was 130 mins (85–205). The walking diary also indicated that the

	Intervention (n=351)	Control (n=350)
Sex		
Male	71 (20%)	65 (19%)
Female	280 (80%)	285 (81%)
Age, years	54 (11)	54 (12)
Body-mass index (kg/m²)	30 (6)	31 (7)
Education level		
Primary school	0	1 (<1%)
Some secondary school	8 (2%)	10 (3%)
Completed secondary school	29 (8%)	16 (5%)
Some additional training	100 (28%)	123 (35%)
Undergraduate university	88 (25%)	96 (27%)
Postgraduate university	126 (36%)	104 (30%)
Current work status*		
Full-time	151 (43%)	147 (42%)
Part-time	90 (26%)	88 (25%)
Unemployed	13 (4%)	20 (6%)
Student	16 (5%)	8 (2%)
Homeworker	13 (4%)	11 (3%)
Sick leave, rehabilitation, or disability pension	3 (1%)	4 (1%)
Retired	72 (21%)	68 (19%)
Other	15 (4%)	21 (6%)
Gross annual household income, AU$		
No income	14 (4%)	15 (4%)
1–33 799	48 (14%)	38 (11%)
33 800 –88 399	122 (35%)	137 (39%)
88 400 –207 999	141 (40%)	139 (40%)
208 000 or more	26 (7%)	21 (6%)
Smoking status		
Never	193 (55%)	194 (55%)
Current smoker	18 (5%)	17 (5%)
Ex-smoker	140 (40%)	139 (40%)
Engagement in manual tasks involving heavy loads		
Very frequently	2 (1%)	5 (1%)
Frequently	25 (7%)	23 (7%)
Occasionally	124 (35%)	114 (33%)
Rarely	77 (22%)	88 (25%)
Very rarely	96 (27%)	96 (27%)
Never	27 (8%)	24 (7%)
Engagement in manual tasks involving awkward positions		
Very frequently	5 (1%)	3 (1%)
Frequently	36 (10%)	33 (9%)
Occasionally	117 (33%)	117 (33%)
Rarely	87 (25%)	95 (27%)
Very Rarely	85 (24%)	87 (25%)
Never	21 (6%)	15 (4%)
General health		
Excellent	22 (6%)	15 (4%)
Very good	90 (26%)	90 (26%)
Good	183 (52%)	179 (51%)
Fair	52 (15%)	61 (17%)
Poor	4 (1%)	5 (1%)

(Table 1 continues on next page)

	Intervention (n=351)	Control (n=350)
(Continued from previous page)		
Low back pain		
Number of previous episodes	30 (12–86)	36 (12–90)
Duration of last episode, days	5 (3–14)	4 (3–8)
Time since last episode, days	20 (13–39)	21 (14–51)
Perceived risk of recurrence (0 to 10)	7 (5–9)	7 (5–9)
Levels of physical activity measured by AAS, min per week		
Walking	60 (30–120)	60 (20–120)
Moderate	0 (0–38)	0 (0–60)
Vigorous	0 (0–0)	0 (0–0)
Sedentary behaviour measured by IPAQ-SF item		
Time sitting (min per weekday)	480 (300–600)	480 (300–600)
DASS-21 (0 to 21)		
Depression	2 (1–5)	2 (1–5)
Anxiety	1 (0–3)	1 (0–2)
Stress	4 (2–7)	4 (2–6)
Sleep quality		
Very good	32 (9%)	31 (9%)
Fairly good	183 (52%)	195 (56%)
Fairly bad	121 (34%)	114 (33%)
Very bad	15 (4%)	10 (3%)
Health status measured by Euro-QOL		
EQ-5D-5L Health State Index—Australian Tarif	0·93 (0·07)	0·93 (0·08)
EQ-VAS score (0–100)	72 (16)	72 (16)
Total number of previous episodes		
Two or fewer	13 (4%)	13 (4%)
More than two	338 (96%)	337 (96%)
Referral method		
Community	347 (99%)	345 (99%)
Clinician	4 (1%)	5 (1%)

Data are n (%), mean (SD), or median (IQR). AAS=Active Australia Survey. IPAQ-SF=International Physical Activity Questionnaire-Short Form. DASS-21=Depressions Anxiety Stress Scale. EQ-5D-5L=EuroQol 5-Dimension 5-Level. VAS=Visual Analogue Scale. *Participants could select multiple responses for this variable.

Table 1: **Baseline characteristics**

median of times walked per week by the intervention group was three times (IQR 3–4) in week one and four times (3–5) in week 12.

The intervention reduced the risk of an activity-limiting recurrence of low back pain compared with the control group (HR 0·72 [95% CI 0·60–0·85]; p=0·0002). The median days to a recurrence was 208 days (95% CI 149–295) in the intervention group and 112 days (89–140) in the control group (figure 2A).

The intervention also reduced the risk of any recurrences of low back pain and care-seeking recurrences of low back pain compared with the control group (HR 0·80 [95% CI 0·68–0·94], p=0·0066 and HR 0·57 [95% CI 0·44–0·74], p<0·0001; figure 2B and 2C). The proportional hazard assumption was violated for the outcome of a care-seeking recurrence of low back pain, so we split the time period as is common practice[29] and ran the analysis on only the first 12 months. Participants who had an event after 12 months were censored. The first 12 months were considered the most important study period and the period when most participants contributed data. The median days to any recurrence was 72 days (95% CI 62–92) in the intervention group and 56 days (48–66) in the control group. The median days to a care-seeking recurrence could not be calculated as fewer than 50% of participants in the intervention group experienced this event. The 25th percentile day to a care-seeking recurrence was 295 days (95% CI 215–380) in the intervention group and 116 days (89–147) in the control group.

The between-group estimated mean difference in disability (RMDQ) favoured the intervention group at all timepoints. The mean difference at 3 months was –1·41 (95% CI –2·26 to –0·55) and at 12 months was –1·28 (–2·01 to –0·55; table 2). The between-group estimated mean difference in health-related quality of life also favoured the intervention group (table 2; appendix p 8); however, model assumptions were not met due to left skewness in the data, and the results should be treated with caution. Conclusions from the bootstrap percentile intervals were consistent with the primary analysis results (appendix p 7).

ActiGraph measures at 3 months demonstrated greater total steps per day and brisk steps per day in the intervention than in the control group (mean difference of 611 [95% CI 183 to 1039] for steps per day and 616 [386 to 846] for brisk steps per day). There was no difference between groups in self-reported measures of moderate physical activity, vigorous physical activity, or time spent sitting. Total walking per week, based on the Active Australia Survey, was greater in the intervention group than the control group at 3 months (mean difference 51·09 mins [95% CI 22·32 to 79·87]), but this difference was not sustained at 12 months (mean difference 0·67 [–30·90 to 32·23]); table 2; appendix p 12). The sensitivity analyses for the secondary outcomes done using multiple imputations for missing data and baseline adjustment were consistent with the primary analysis (appendix pp 8–10).

A significantly higher percentage of participants in the control group sought a co-intervention than did participants in the intervention group (p=0·0005; 174 [49·7%] of 350 and 128 [36·5%] of 351, respectively). The co-interventions used by most participants were treatments provided by massage therapists, physiotherapists, and chiropractors. A summary of the co-interventions used by both groups during the first 12 months is provided in the appendix (p 11).

For the economic evaluation, the mean cost per participant from the societal perspective was higher in the intervention group than in the control group ($1005 [SEM 126] and $840 [129], respectively). When observed from the health-care perspective, the trend remained consistent, with the intervention group incurring higher costs than the control group ($862 [SEM 132] and $512 [$85], respectively). The cost of delivering the intervention was $414 per participant. A summary of aggregate and disaggregate cost differences is provided (appendix p 22). The intervention group gained more QALYs than the control group (mean difference 0·023 [95% CI 0·011 to 0·034]) and experienced fewer recurrences leading to activity-limitation than the control group in the first 12 months (mean difference –0·16 [95% CI –0·22 to –0·09]; appendix p 23).

For QALYs, the incremental cost-effectiveness ratio was 7802, indicating that the intervention's incremental cost per QALY gained was $7802 compared with a no-treatment control (appendix p 21). The cost-effectiveness acceptability curve showed that the intervention has a high (94%) probability of being cost-effective compared with a no treatment control, at a willingness-to-pay of $28 000 per QALY (figure 3).[30]

For recurrence, the incremental cost-effectiveness ratio was 1120, indicating that the intervention's incremental cost per participant prevented from having a recurrence leading to activity-limitation was $1120 compared with a no treatment control (appendix p 21). The cost-effectiveness acceptability curve shows that if decision makers are unwilling to pay for this outcome, the intervention has a 24% probability of being cost-effective compared with a no treatment control; however, the probability increases rapidly with increasing willingness-to-pay. Sensitivity analyses resulted in different point estimates but did not change the study's overall conclusion. A detailed description of results from the economic evaluation is available (appendix pp 13–23).

A similar number of participants experienced at least one adverse event across the intervention and control groups over 12 months (183 [52%] of 351 and 190 [54%] of 350, respectively, Fisher's exact test p=0·60). The number of participants who reported serious adverse events was also similar in the intervention and control groups over 12 months (39 [11%] of 351 and 35 [10%] of 350, respectively). In the intervention, there was a trend towards a greater number of adverse events related to the lower extremities and fewer events related to low back pain than in the control group (table 3). A detailed description of adverse events is available in the appendix (pp 24–31).

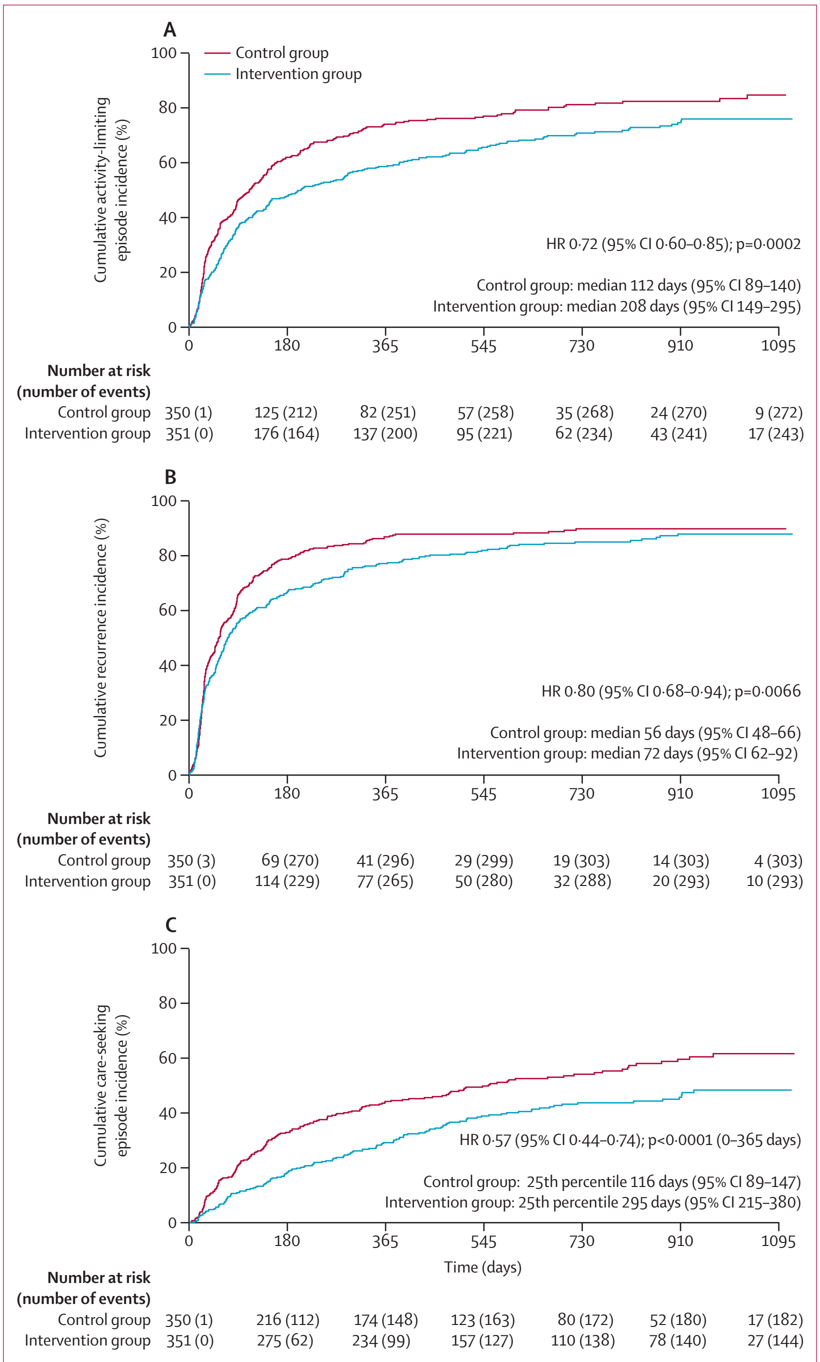

Figure 2: **Kaplan–Meier curves for each of the three recurrence outcomes**
(A) Activity-limiting recurrence (primary outcome). (B) Any recurrence. (C) Care-seeking recurrence. HR=hazard ratio.

Discussion

An individualised, progressive walking and education intervention substantially reduced low back pain recurrence compared with a no treatment control group in adults who were not previously engaging in regular physical activity. This finding was consistent across the primary and two secondary recurrence outcomes. There were also reductions in back pain-related disability in the intervention group for up to 12 months, and the intervention had a high probability of being cost-effective from the societal perspective compared with a no treatment control.

In 2018, *The Lancet* published a three-part Low Back Pain Series highlighting the scarcity of research for the prevention of low back pain, calling for the identification of effective and affordable strategies targeting prevention.[31] A recent systematic review by our team identified no randomised controlled trials assessing the effectiveness of walking, cycling, or swimming for low back pain

	Intervention (n=351)	Control (n=350)	Mean difference (95% CI)	p value
Disability measured by RMDQ*				
3 months	2·46 (0·22)	3·87 (0·28)	–1·41 (–2·26 to –0·55)	0·0003
6 months	2·12 (0·21)	3·16 (0·25)	–1·03 (–1·83 to –0·24)	0·0055
9 months	1·69 (0·18)	3·15 (0·25)	–1·46 (–2·22 to –0·70)	<0·0001
12 months	1·60 (0·18)	2·87 (0·24)	–1·28 (–2·01 to –0·55)	<0·0001
Health-related quality of life measured by EQ-5D-5L†				
Baseline	0·93 (0·01)	0·93 (0·01)	–0·00 (–0·02 to 0·02)	0·99
3 months	0·92 (0·01)	0·89 (0·01)	0·03 (0·01 to 0·05)	0·0015
6 months	0·92 (0·01)	0·91 (0·01)	0·02 (–0·01 to 0·04)	0·23
9 months	0·92 (0·01)	0·89 (0·01)	0·03 (0·01 to 0·05)	0·0087
12 months	0·92 (0·01)	0·89 (0·01)	0·03 (0·00 to 0·05)	0·016
ActiGraph measure at 3 months‡				
Steps per day (mean [SD])	6551 (2668)	5939 (2057)	611 (183 to 1039)	0·0052
Brisk steps per day§ (mean [SD])	1473(1529)	857 (972)	616 (386 to 846)	<0·0001
Moderate to vigorous physical activity, min per day (mean [SD])	24 (19)	18 (15)	6·4 (3·4 to 9·4)	<0·0001
Self-reported physical activity measured by AAS				
Walking (min per week)¶				
Baseline	70·30 (5·86)	67·20 (5·74)	3·10 (–16·40 to 22·60)	0·97
3 months	164·80 (9·30)	113·71 (7·75)	51·09 (22·32 to 79·87)	0·0001
12 months	160·08 (9·36)	159·41 (9·42)	0·67 (–30·90 to 32·23)	1·00
Moderate physical activity (min per week)¶				
Baseline	9·15 (2·10)	11·52 (2·36)	–2·38 (–9·90 to 5·14)	0·82
3 months	18·54 (3·10)	24·88 (3·60)	–6·34 (–17·65 to 4·96)	0·44
12 months	24·13 (3·61)	30·31 (4·09)	–6·18 (–19·16 to 6·80)	0·57
Vigorous physical activity (min per week)†				
Baseline	19·35 (4·75)	15·58 (4·75)	3·77 (–12·27 to 19·82)	0·92
3 months	32·59 (4·94)	34·23 (4·95)	–1·64 (–18·34 to 15·06)	0·99
12 months	43·21 (5·06)	37·46 (5·11)	5·75 (–11·41 to 22·92)	0·81
Self-reported sitting measured by IPAQ-SF item (min per weekday)				
Baseline	467·32 (10·04)	458·35 (10·06)	8·97 (–24·62 to 42·57)	0·87
3 months	408·22 (10·37)	418·67 (10·38)	–10·45 (–45·13 to 24·22)	0·82
12 months	391·54 (10·55)	397·70 (10·63)	–6·16 (–41·55 to 29·23)	0·96

Data are mean (SE), unless otherwise specified. All analyses are the result of linear mixed-effects models except for ActiGraph results, which used Welch's two-sample t tests. RMDQ=Roland–Morris Disability Questionnaire. EQ-5D-5L=EuroQol 5-Dimension 5-Level. AAS=Active Australia Survey. IPAQ-SF=International Physical Activity Questionnaire (only sitting item). *RMDQ data were not collected at baseline. RMDQ is a disability measure, which was collected at 3, 6, 9, and 12 months. A square root transformation was required to meet assumptions. The results presented were back-transformed to the original scale. †Assumptions were not met, and the results should be treated with caution. No transformations were available that enabled the meeting of assumptions. ‡ActiGraph data represent a minimum 4-day and maximum 7-day wear period. Only data for participants whose dataset met the minimum wear time requirement of 10 h per day are included (intervention n=244, control n= 232). §Brisk walking is defined as a cadence of more than 100 steps per minute. ¶A square root transformation was applied to the data in order to meet assumptions. The results presented were back-transformed to the original scale.

Table 2: **Repeated measures analysis of secondary outcomes**

prevention, reinforcing the evidence gap.[13] To our knowledge, WalkBack is the first randomised controlled trial assessing the effectiveness of a walking-based intervention to prevent low back pain recurrence. The prevention effects we identified appear similar in magnitude to group-based programmes requiring close clinician supervision and greater costs.[4,6] Our results suggest that this intervention could substantially reduce the personal and societal burden due to low back pain if widely implemented.

This study has several strengths. This trial was prospectively registered, with a published prespecified trial protocol and statistical analysis plan.[14,15] Participants were contacted regularly to reduce recall bias and ensure precise estimates of time-to-event data. Participants were followed up for at least 12 months and up to 36 months, achieving excellent follow-up rates for our primary outcome.

This trial commenced before the COVID-19 pandemic, and the intervention was intended to be delivered as a combination of in-person and telephone-based consultations. In response to the pandemic and stay-at-home orders enforced within Australia, the research team switched the intervention to a telehealth model (video consultations, replacing in-person consultations) within the first 6 months of the trial. This deviation from the original protocol was, in some ways, fortuitous. Due to this change, we recruited participants from across Australia, including rural and remote locations, that were only possible with telehealth delivery.

The limitations of this study include generalisability and a lack of masking. Most participants were female, 68% were aged between 43 years and 66 years, and had many previous episodes of low back pain, which should be considered when extrapolating our findings to the general population. However, we would note that low back pain is more prevalent in females and the prevalence increases with age.[1] Additionally, the questionnaires used were in English, presumably limiting participation of individuals from some ethnic backgrounds. Although we did not collect data related to ethnicity, we did sample from metropolitan and regional areas across Australia, including areas with low socioeconomic status, and high cultural and linguistic diversity. A large proportion of screened patients (n=2505 [78%]) were not included. The most common reason for potential participants not meeting the inclusion criteria was having chronic low back pain. However, we excluded a substantial number (n=429) of potential participants who were already walking regularly or who achieved more than 150 min per week of moderate to vigorous physical activity, so our results do not generalise to active adults. Physiotherapists with additional training in health coaching delivered the intervention; therefore, the effect of the delivery by other clinicians is unknown. Several outcomes were self-reported by participants who were not masked to group allocation, so it is possible that this lack of masking introduced some bias.

Findings from this trial have important implications, demonstrating that a small number of health coaching sessions with a trained physiotherapist who supports the adoption of a walking programme and provides education reduces recurrences of low back pain. The focus on empowering patients with back pain to self-manage their condition is strongly aligned with guideline recommendations.[31] This intervention should be relatively easy to scale up and could substantially reduce the burden due to low back pain, including reducing the costs associated with care. Although the total number of participants experiencing at least one adverse event was similar between groups, we did find a trend towards a greater number of adverse events related to the lower extremities in the intervention group (ie, 100 in the intervention group and 54 in control group). Clinicians should discuss this potential risk with patients, progress programmes carefully, and monitor for early symptoms.

A notable finding of our study is that while walking volume (minutes per week) in the intervention group roughly doubled over the first 3 months, it remained similar at 12 months. Additionally, although the intervention group walked more than the control group at 3 months (51 min [95% CI 22·32 to 79·87]), this difference was no longer present at 12 months (0·67 min [–30·90 to 32·23]). One contributing factor is that the walking reported by the control group increased over time, which might have been a result of lack of masking and could have diluted the treatment effect, or might have been a result of the effect that the COVID-19 pandemic had on engagement with walking. The lack of difference in walking at 12 months might also have been attributed to no ongoing support from the clinician, not continuing with the walking diary after 12 weeks, and by the presence of lower extremity injuries in the intervention group.

Future research should assess the implementation of this intervention, ideally as part of discharge planning following an acute episode of low back pain. It would also be important to test if the intervention remains effective when delivered in fewer sessions or by other clinicians (eg, exercise physiologists). There is little existing guidance on the smallest worthwhile effect to inform interpretation of the effect size for the primary outcome in our study. Future research should assess if the 28% reduction we identified for the primary outcome is large enough for patients, clinicians, and funders to consider this worthwhile. The exact mechanisms by which the intervention had its effect are unclear, as is the relative importance of the walking programme, and the education. We believe it is likely the two components complement each other, with education helping to overcome avoidance and fear of movement, while the health coaching and walking programme resulted in behaviour change. Finally, although the current trial focused on walking, future trials can explore whether other forms of recreational exercise (eg, swimming or cycling) can provide similar benefits.

In conclusion, the WalkBack intervention effectively reduced the risk of low back pain recurrence through an individualised, progressive walking and education intervention. Additionally, the intervention had a high probability of being cost-effective at established willingness-to-pay thresholds. By encouraging active self-management using health coaching principles, the

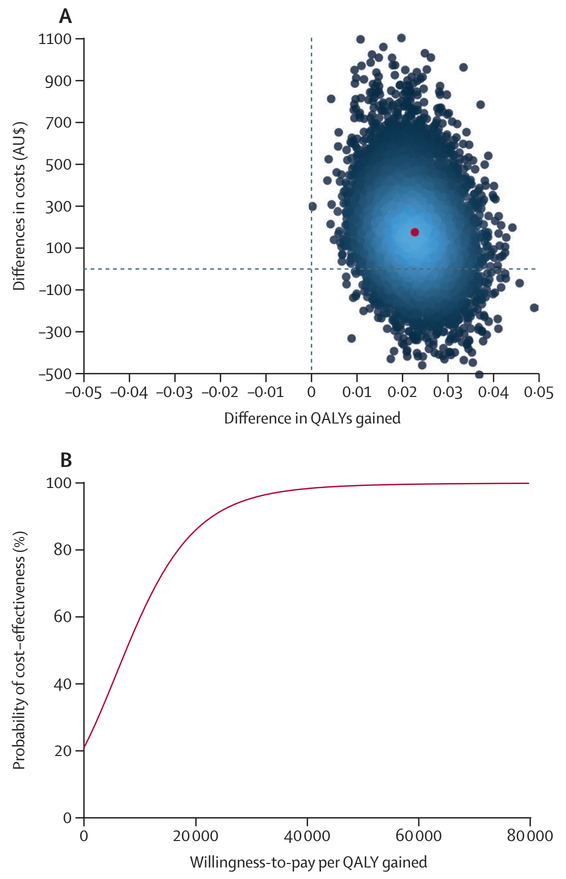

Figure 3: **Economic efficiency results for the outcome of QALY, based on the societal perspective**
(A) Cost-effectiveness plane. (B) Cost-effectiveness acceptability curve. QALY=quality-adjusted life-years.

	Intervention group (n=351)		Control group (n=350)		p value
	Events	Participants	Events	Participants	
Serious adverse events					
Total	52	39 (11%)	40	35 (10%)	0·71
Low back pain related*	6	3 (1%)	4	3 (1%)	··
Cardiovascular related*	3	2 (1%)	1	1 (<1%)	··
Musculoskeletal related*	11	10 (3%)	13	11 (3%)	··
Other	32	24 (7%)	22	20 (6%)	··
Adverse events†					
Total	371	183 (52%)	373	190 (54%)	0·60
Low back pain related*	61	50 (14%)	112	85 (24%)	··
Lower extremity related*	100	72 (21%)	54	41 (12)	··
Falls related*	9	9 (3%)	6	6 (2%)	··
Other	201	52 (15%)	201	58 (17%)	··

Data are absolute values or n (%), unless otherwise specified. The number of participants do not necessarily sum to the total as one participant could have more than one type of adverse event. p values are from a Fisher's exact test comparing the proportion of participants who experienced at least one event between intervention and control. Statistical comparison was only conducted for total numbers of serious adverse events and total numbers of adverse events. *These categories represent the events most likely related to the intervention. †Data represent all serious and non-serious adverse events reported within the first 12 months of the trial.

Table 3: **Adverse and serious adverse events**

WalkBack intervention might be able to reduce the prevalence of recurrent low back pain and associated burden on health-care systems.

Contributors

MJH, C-WCL, JL, DM, AT, OC, and CGM acquired funding for the conduct of this trial. NCP, MJH, C-WCL, JL, DM, AT, OC, and CGM conceived and designed the study. MJH, NCP, and SYKT were involved in data curation and project administration. PLG, JMvD, MJH, and NCP were involved in data analysis. PLG, MJH, and NCP had full access to and verified the data. NCP, MJH, C-WCL, and SDF wrote the first draft of the manuscript. All authors critically revised the manuscript for important intellectual content. All authors had an opportunity to provide input into the study protocol, access the data, contribute to the interpretation of the results, and to critically revise the manuscript for important intellectual content. All authors accept responsibility for the decision to submit for publication.

Declaration of interests

The Australia & New Zealand Musculoskeletal (ANZMUSC) Clinical Trials Network endorsed the WalkBack trial. NCP was on scholarships during her PhD candidature, which were funded by the National Health and Medical Research Council Low Back Pain Centre of Research Excellence (ANZBACK) and Macquarie University (Sydney, Australia). C-WCL and CGM are supported by National Health and Medical Research Council fellowships (APP1193939, awarded to C-WCL; and APP1194283, awarded to CGM). All other authors declare no competing interests.

Data sharing

The de-identified data and statistical code will be made available on request to the corresponding author. A data sharing agreement will require a commitment to using the data only for specified research purposes, to securing the data appropriately, and to destroying the data after a nominated period.

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