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Effect of Intensive Patient Education vs Placebo Patient Education on Outcomes in Patients With Acute Low Back Pain
A Randomized Clinical Trial

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IMPORTANCE Many patients with acute low back pain do not recover with basic first-line care (advice, reassurance, and simple analgesia, if necessary). It is unclear whether intensive patient education improves clinical outcomes for those patients already receiving first-line care.

OBJECTIVE To determine the effectiveness of intensive patient education for patients with acute low back pain.

DESIGN, SETTING, AND PARTICIPANTS This randomized, placebo-controlled clinical trial recruited patients from general practices, physiotherapy clinics, and a research center in Sydney, Australia, between September 10, 2013, and December 2, 2015. Trial follow-up was completed in December 17, 2016. Primary care practitioners invited 618 patients presenting with acute low back pain to participate. Researchers excluded 416 potential participants. All of the 202 eligible participants had low back pain of fewer than 6 weeks' duration and a high risk of developing chronic low back pain according to Predicting the Inception of Chronic Pain (PICKUP) Tool, a validated prognostic model. Participants were randomized in a 1:1 ratio to either patient education or placebo patient education.

INTERVENTIONS All participants received recommended first-line care for acute low back pain from their usual practitioner. Participants received additional 2 × 1-hour sessions of patient education (information on pain and biopsychosocial contributors plus self-management techniques, such as remaining active and pacing) or placebo patient education (active listening, without information or advice).

MAIN OUTCOMES AND MEASURES The primary outcome was pain intensity (11-point numeric rating scale) at 3 months. Secondary outcomes included disability (24-point Roland Morris Disability Questionnaire) at 1 week, and at 3, 6, and 12 months.

RESULTS Of 202 participants randomized for the trial, the mean (SD) age of participants was 45 (14.5) years and 103 (51.0%) were female. Retention rates were greater than 90% at all time points. Intensive patient education was not more effective than placebo patient education at reducing pain intensity (3-month mean [SD] pain intensity: 2.1 [2.4] vs 2.4 [2.2]; mean difference at 3 months, −0.3 [95% CI, −1.0 to 0.3]). There was a small effect of intensive patient education on the secondary outcome of disability at 1 week (mean difference, −1.6 points on a 24-point scale [95% CI, −3.1 to −0.1]) and 3 months (mean difference, −1.7 points, [95% CI, −3.2 to −0.2]) but not at 6 or 12 months.

CONCLUSIONS AND RELEVANCE Adding 2 hours of patient education to recommended first-line care for patients with acute low back pain did not improve pain outcomes. Clinical guideline recommendations to provide complex and intensive support to high-risk patients with acute low back pain may have been premature.

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For the past 5 years, the Global Burden of Disease Study[1] has consistently ranked low back pain as the leading cause of disability worldwide. Low back pain is second only to the common cold as a reason for consulting a general practitioner.[2] A recent international review highlighted a global crisis in the mismanagement of low back pain, with high rates of guideline-discordant care in both high- and low-middle income countries.[3-5] In their call to action, the Lancet Low Back Pain Series Working Group authors recommended that researchers and policy makers: "Develop and implement strategies to ensure early identification and adequate education of patients with low back pain at risk for persistence of pain and disability."[3-5]

To manage uncomplicated acute low back pain (fewer than 6 weeks of pain duration), international guidelines recommend that general practitioners provide advice, education, reassurance, and simple analgesics, if necessary.[6] Although many patients receiving this care improve rapidly, 33% experience a recurrence in the next 12 months[7] and 20% to 30% develop chronic pain (defined as pain duration of 3 months or more).[8]

Patients who are at high risk of pain chronicity may require additional care, including second-line options such as physical (eg, spinal manipulation) and/or psychological therapies (eg, psychologically informed physiotherapy).[6] However, most trials that have evaluated adding second-line treatment options to standard guideline care for patients with acute low back pain have failed to demonstrate effectiveness compared with placebo (eg, addition of spinal manipulation, nonsteroidal antiinflammatory drugs, or both[9]; addition of structured exercises[10]; and addition of acupuncture, massage, or chiropractic care[11]). Patient education, a treatment that authors of a 2008 Cochrane review[12] concluded was effective for acute low back pain when applied in an intensive format and that every major clinical guideline recommends (but with little instruction on intensity),[13] has never been tested in a placebo-controlled trial. Any benefits observed in previous trials of patient education for acute low back pain could be explained by nonspecific effects of the clinical encounter or the characteristics of the usual care comparison.

Pain education, a form of intensive patient education that is often included in pain management programs, requires up to 2 hours during several encounters with a trained health practitioner. It involves detailed discussion of pain, including psychosocial contributors and advice about pacing and activity. Trials have found clinically meaningful effects of pain education on pain and disability in samples of patients with chronic pain.[14]

It is unknown whether intensive patient education, in addition to recommended first-line care, can improve outcomes for patients with acute low back pain. To address this gap in the literature, we conducted, to our knowledge, the first randomized, placebo-controlled trial of patient education for acute low back pain (Preventing Chronic Low Back Pain [PREVENT] Trial).[15]

Key Points

Question Is intensive patient education effective as part of first-line care for patients with acute low back pain?

Findings In this randomized clinical trial of 202 adults with acute low back pain from Sydney, Australia, adding intensive patient education to first-line care of patients was no better at improving pain outcomes than a placebo intervention.

Meaning Intensive patient education should not be offered to patients with acute low back pain who are receiving first-line care.

Methods

Study Design

This was an assessor-blinded, 1:1 parallel group, randomized, placebo-controlled trial. We published a study protocol prior to enrolling participants[15] (the original trial protocol is available in Supplement 1). The trial was prospectively registered. The University of New South Wales Human Research Ethics Committee, Sydney, New South Wales, Australia, approved the study on February 5, 2013 (reference number: HC12664). We obtained written, informed consent from all participants before they enrolled in the trial.

Treatments took place at physiotherapy clinics, general practices, or clinic rooms at a research institute (Neuroscience Research Australia) in Sydney, Australia. One of 2 trial clinicians (A.C.T. and I.W.S.) provided the treatment at participating centers. We recruited participants between September 10, 2013, and December 2, 2015. Trial follow-up was completed on December 17, 2016.

Participants

We sought to recruit participants aged 18 to 75 years who were seeking care for acute low back pain with or without referred leg pain. Participants with signs of radiculopathy (spinal nerve root compromise) were included. All participants were referred from general practitioners or physiotherapists. We excluded potential participants if they had the following: (1) chronic low back pain (more than 1 on a 11-point pain intensity numeric rating scale for more than 3 months), (2) less than 3 of 10 on the pain intensity numeric rating scale over the past week, (3) low risk of pain chronicity (less than 30% absolute risk of chronic pain according to the Predicting Inception of Chronic Pain (PICKUP) Tool[8] [eMethods 1 in Supplement 2]), (4) clinical features of serious spinal pathology (eg, cauda equina syndrome, infection, fracture, or cancer) assessed by a clinician, (5) poor command of the English language, (6) previous spinal surgery, or (7) a mental health condition that would preclude study participation. Referring clinicians were trained to provide all recruited participants with guideline-based care (advice to stay active, avoid bed rest, option of spinal manipulation, and/or simple analgesics). Staff were reimbursed per participant recruited for time spent on the study.

Randomization and Masking

We randomized participants in a 1:1 ratio to either intensive patient education or placebo patient education. The allocation schedule was generated by a researcher not involved in any other aspect of the study. That researcher used a computerized random number table to generate the allocation sequence in random block sizes of 4, 6, 8, and 10. The same re-

searcher who generated the allocation sequence placed allocation codes into sequentially numbered, sealed, opaque envelopes.

Before randomization, all participants completed baseline data collection and received a standardized short history and physical examination (approximately 10-minute length) with the trial clinicians (A.C.T. and I.W.S.). The short history and physical examination were standardized using pro forma documents (eMethods 2 in Supplement 2). The trial clinicians opened the envelope containing the group allocation. The allocation was concealed from participants, referring clinicians, other trial staff, and outcome assessors.

All treatment was provided during the acute phase of low back pain within 6 weeks of pain onset. Each participant received 2 × 1-hour individual, face-to-face sessions of either patient education or placebo patient education. The trial clinicians (A.C.T. and I.W.S.) who provided the patient education sessions were the same clinicians who provided the placebo patient education. An expert in pain education (G.L.M.) trained both trial clinicians to deliver the patient education intervention. An expert clinical psychologist in pain management (M.K.N.) trained both trial clinicians in the placebo patient education intervention. Training for the patient education intervention took approximately 16 hours, with 6 to 8 hours allocated for practicing role-play scenarios. Training for the placebo patient education took approximately 4 hours and was supplemented with 4 online 45-minute videos demonstrating techniques for providing a credible consultation that did not include advice or education.

Interventions

Intensive Patient Education

We adapted the information and advice provided in the patient education group from the book *Explain Pain*,[16] a text typically used for people with chronic pain. The intervention is described in full and according to the template for intervention description and replication (TIDieR) checklist in eMethods 3 in Supplement 2. In short, participants in the patient education group were provided with a detailed explanation about the biopsychosocial nature of pain in the format of diagrams, metaphors, and stories. The patient education intervention involved 3 main components: (1) reframing unhelpful beliefs about low back pain, (2) presenting information about the biologic basis and protective nature of both acute and chronic low back pain, and (3) evaluating understanding of new concepts and discussing techniques to promote recovery. Content was tailored to the individual according to specific concerns (eg, "I am worried I will have this back problem forever") and misconceptions (eg, "I can't work because my back is permanently damaged") that participants expressed during the consultation. Trial clinicians encouraged all participants to self-manage their low back pain by remaining active and avoiding bed rest. Trial clinicians also instructed participants on behavioral therapy techniques such as pacing.

Placebo Patient Education

We designed the placebo patient education sessions to control for time with an expert clinician. The sessions mimicked all aspects of the patient education sessions (listening, showing interest, and attention of the clinician) but without the education component. Participants in the placebo patient education group received no information, advice, or education about low back pain from the trial clinician. Participants were encouraged to talk about any topic that they desired. Trial clinician responses were aimed to maintain the discussion for the duration of the session. We included additional detail on the placebo intervention in eMethods 4 in Supplement 2.

Outcomes and Measurements

We collected self-reported data from participants at baseline (the first intervention session); 1 week after the 2 intervention sessions were complete; and 3, 6, and 12 months after the date of low back pain onset. Participants used online forms to complete outcome assessments. Baseline data included age, sex, duration of episode, number of previous episodes, other painful areas, and work status. An assessor who was masked to treatment allocation arranged the collection of outcome data using online forms. Participants completed the credibility and expectancy questionnaire[17] in paper format immediately after the trial clinician explained the rationale for the study and before randomization. Trial staff monitored adherence to the 2 intervention sessions using a study calendar. The trial clinician audio recorded all intervention sessions, with the participants' verbal consent, to monitor treatment fidelity. Treatment fidelity was evaluated by 2 researchers (G.L.M. and M.K.N.), who listened to the first and second sessions from 10 randomly selected participants and judged whether the sessions were patient education or placebo patient education. We used κ to determine agreement.

The primary outcome was mean pain intensity during the past week (reported on an 11-point pain intensity numeric rating scale), assessed 3 months after the onset of low back pain. Secondary outcomes and process measures are described in eMethods 5 of Supplement 2.

Statistical Analysis

We published our statistical analysis plan before analyzing our results.[18] A sample of 202 participants was required to ensure 80% power to detect a mean difference of 1 point on an 11-point numeric rating scale for pain intensity. Our power calculation assumed an SD of 2.3 and a 2-sided α of .05 and was adjusted with 15% loss to follow-up. We estimated the effect of the intervention on the primary outcome using a mixed model for repeated measures. We treated time as a categorical variable (1 week and 3, 6, or 12 months) and included group × time interactions to determine treatment effects at each time point. As an exploratory sensitivity analysis, we calculated *P* values from mixed models for repeated measures comparing between-group difference during the full 12-month trial, controlling for baseline and including all time points as categorical. We determined statistical significance to be $P < .05$ for a 2-sided test. We did not include study site (physiotherapy practice, general practice, or research institute) in the model because there was no evidence of site differences between groups (χ^2 test, $P = .14$). Details of the analysis of secondary outcomes is provided in eMethods 5 of Supplement 2 and the complete mediation analysis[19] in eResults 1 of Supplement 2. Two authors (S.L. and H.L.) performed the statistical analyses.

Results

Between September 10, 2013, and December 2, 2015, we screened 618 potential participants. **Figure 1** shows the flow of participants through the trial. The main reasons for participant exclusion included low risk of pain chronicity (n = 146), chronic pain (n = 79), declined participation (n = 75), or could not be contacted after initial referral from the primary care practitioner (n = 75). Other reasons for exclusion are shown in Figure 1. One potential participant was excluded in error because of pregnancy.

The 2 groups had similar demographic and clinical characteristics at baseline (**Table 1**). Of 202 participants randomized for the trial, 103 (51.0%) were female. Participants were middle-aged (mean [SD] age, 45.1 [14.5] years), had fewer than 2 weeks of low back pain, and had experienced 3 previous episodes of low back pain. Physiotherapists referred most participants (83%). Half of the sample (52%) felt there was a need for further investigation of their symptoms. Psychological characteristics were similar between groups; scores for depression and catastrophizing scales were lower and scores for self-efficacy were higher than those seen in samples from patients with chronic pain who attended tertiary care.[20]

All participants completed both trial sessions. Treatment credibility scores were not different between groups (mean [SD] credibility and expectancy questionnaire score for patient education vs placebo patient education: 36.6 [8.8] vs 35.3 [10.5]; mean difference, -1.3; 95% CI, -4.0 to 1.4). For our treatment fidelity check, raters correctly categorized all recordings as patient education or placebo patient education. There was perfect agreement between raters (κ = 1).

The primary analysis (**Table 2**) showed that patient education was not more effective than placebo patient education at reducing pain intensity at our primary end point (3-month follow-up mean difference, -0.3 points on an 11-point scale; 95% CI, -1.0 to 0.3; P = .31). Mean (SD) pain intensity decreased from 6.3 [2.4] at baseline to 2.1 [2.4] at 3 months in the patient education group and from 6.1 [2.2] at baseline to 2.4 [2.2] at 3 months in the placebo patient education group. (**Figure 2**).

There was a small effect of treatment group on disability, with patient education lower than placebo patient education at 1 week (mean difference, -1.6 points on a 24-point scale;

Figure 1. Flowchart of the Preventing Chronic Low Back Pain (PREVENT) Randomized Placebo-Controlled Trial

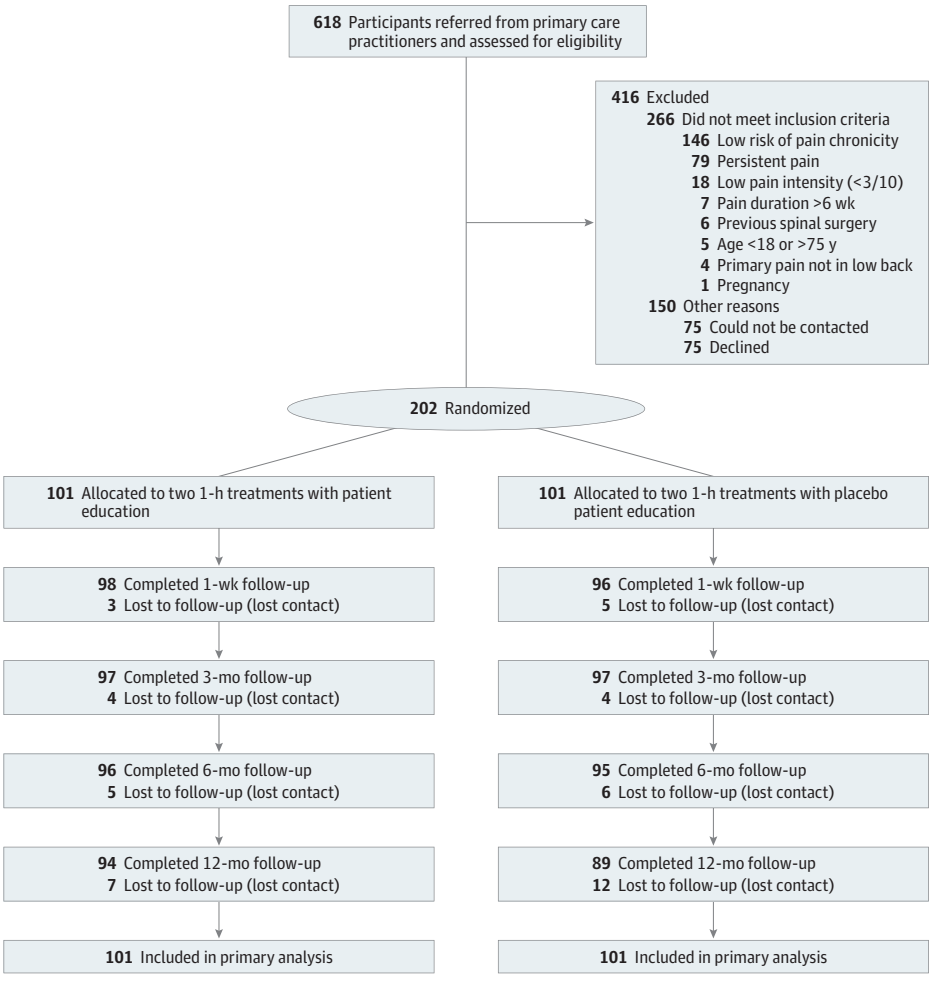


Table 1. Baseline Characteristics[a]

Characteristic	Patient Education (n = 101)	Placebo Patient Education (n = 101)
Age, mean (SD), y	46.5 (14.7)	43.8 (14.1)
Female sex	53 (52.5)	50 (49.5)
Clinical characteristic		
Pain duration, mean (SD), d	12.5 (7.7)	13.5 (8.7)
No. of previous episodes, median (IQR)	3 (5)	3 (7)
No. of other pain sites, mean (SD)	1.0 (1.2)	1.1 (1.3)
Referred by general practitioner	19 (18.8)	16 (15.8)
Referred by physiotherapist	82 (81.2)	85 (84.2)
First episode of back pain	21 (20.8)	18 (17.8)
Pain referred to leg	47 (46.5)	57 (56.4)
Pain in areas other than back or leg	57 (56.4)	55 (54.5)
Work absence or reduced hours	22 (21.8)	31 (30.7)
Receiving pain medication	50 (49.5)	54 (53.5)
Outcome scores at baseline		
Pain intensity, mean (SD)[b]		
Week	6.3 (2.4)	6.1 (2.2)
Current	4.0 (2.2)	4.0 (2.3)
Pain interference, mean (SD)[c]	6.0 (2.5)	6.4 (2.6)
Disability, mean (SD)[d]	11.0 (5.4)	11.7 (5.8)
Depressive symptoms, mean (SD)[e]	4.1 (3.7)	5.1 (5.0)
Reassurance		
Nothing seriously wrong, mean (SD)[f]	5.6 (2.7)	5.4 (2.7)
Yes, perceive a need for further tests	51 (50.5)	55 (54.5)
Process measures at baseline, mean (SD)		
Neuroscience knowledge[g]	6.0 (1.8)	5.9 (1.6)
Pain attitudes: pain is sign of damage[h]	2.3 (1.2)	2.5 (1.1)
Pain self-efficacy[i]	35.5 (13.1)	33.1 (13.0)
Catastrophizing[j]	18.3 (12.0)	19.9 (11.2)
Back beliefs[k]	27.7 (6.8)	28.3 (6.4)

Abbreviation: IQR, interquartile range.

[a] Data are presented as number (percentage) of patients unless otherwise indicated.

[b] Numeric rating scale with range from 0 (no pain) to 10 (worst pain possible).

[c] Numeric rating scale with range from 0 (no interference) to 10 (highest interference possible).

[d] Roland Morris Disability Questionnaire with range from 0 (no disability) to 24 (high disability).

[e] Depression severity scale of Depression, Anxiety and Stress Scale with range from 0 (no depressive symptoms) to 42 (high depressive symptoms).

[f] "How reassured do you feel that there is no serious condition causing your back pain?" Range from 0 (not reassured at all) to 10 (completely reassured).

[g] Neurophysiology of Pain Questionnaire with range from 0 (no knowledge) to 19 (highest knowledge).

[h] Survey of Pain Attitudes, question 3 from 1-item version: "The pain I feel is a sign that damage is being done." Range from 0 (very untrue for me) to 4 (very true for me).

[i] Pain Self-Efficacy Questionnaire with range from 0 (low pain self-efficacy) to 60 (high pain self-efficacy).

[j] Pain Catastrophizing Scale with range from 0 (low catastrophizing) to 52 (high catastrophizing).

[k] Back Beliefs Questionnaire with range from 9 (maladaptive or pessimistic beliefs) to 45 (helpful or positive beliefs).

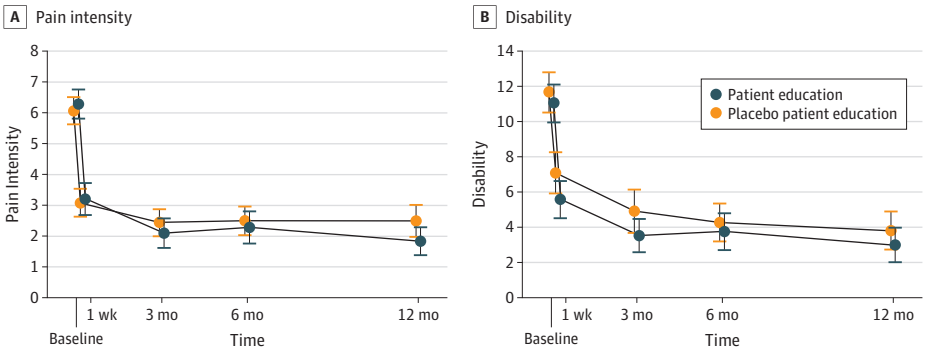
Table 2. Primary Outcomes for the Patient Education and Placebo Patient Education Groups at 1 Week and 3, 6, and 12 Months

Variable	Point Estimates, Mean (SD)		Mean Difference (95% CI)	*P* Value
	Patient Education	Placebo Patient Education		
Pain intensity during the past week				
1 wk	3.2 (2.4)	3.1 (2.2)	0.1 (−0.5 to 0.8)	.69
3 mo	2.1 (2.4)	2.4 (2.2)	−0.3 (−1.0 to 0.3)	.31
6 mo	2.3 (2.6)	2.5 (2.3)	−0.2 (−0.8 to 0.5)	.59
12 mo	1.8 (2.2)	2.5 (2.4)	−0.6 (−1.3 to 0.1)	.07
Overall intervention effect[a]	NA	NA	NA	.26

Abbreviation: NA, not applicable.

[a] *P* value is from mixed models for repeated measures comparing between-group difference during the full 12-month trial, controlling for baseline and including time points as a categorical variable.

Figure 2. Treatment Effects of Intensive Patient Education on Pain and Disability



A, Mean pain intensity score (primary outcome) using a numeric rating scale ranging from 0 (no pain) to 10 (worst pain possible). B, Mean disability outcomes score at 1 week and 3, 6, and 12 months using the Roland Morris Disability Questionnaire ranging from 0 (no disability) to 24 (high disability). Whiskers indicate 95% CIs.

95% CI, -3.1 to -0.1; P = .03) and at 3 months (mean difference, -1.7 points; 95% CI, -3.2 to -0.2; P = .03) (**Table 3**). There were no between-group differences in disability at 6- or 12-month follow-up.

There were some significant between-group differences in secondary outcomes (Table 3). The odds of having a recurrence of low back pain at 12 months were lower in the patient education group than in the placebo patient education group (odds ratio, 0.44; 95% CI, 0.24-0.82). Pain interference and the odds of seeking health care were also lower in the patient education group at 3 months (pain interference: mean difference, -0.8; 95% CI, -1.5 to -0.1; P = .02; health care seeking: odds ratio, 0.43; 95% CI, 0.19-0.93), but results for these variables were not lower at 6 or 12 months. Pain attitudes and reassurance at 1 week were higher in the patient education group (pain attitudes: mean difference, -0.9; 95% CI, -1.2 to -0.5; P < .001; reassurance ["How reassured do you feel that there is no serious condition causing your back pain?"]: mean difference, 1.2; 95% CI, 0.4-2.0; P = .003), and the effect on pain attitudes persisted at 12 months.

Patient education was not more effective than placebo patient education for reducing depressive symptoms, the incidence of chronic low back pain, or global perceived change (Table 3). The causal mediation analysis confirmed that patient education reduced catastrophizing and unhelpful beliefs (primary treatment targets), but these psychologic mechanisms did not reduce pain intensity (full results of mediation analysis reported in eResults 1, eTables 1 and 2, and eFigures 1-3 in Supplement 2). There were no reported adverse events in either treatment group. There was no evidence that out-of-trial therapy confounded treatment effects (eResults 2 and eTable 2 in Supplement 2).

Discussion

Our study provides evidence that intensive patient education is not effective compared with placebo for patients with acute low back pain. Two 1-hour sessions of patient education were no more effective than a placebo intervention for improving pain at our primary end point of 3 months or at 1 week, 6 months, or 12 months after the onset of acute low back pain. Disability was significantly lower in the intervention group compared with the placebo group at 1 week and 3 months but not at 6 months or 12 months. The short-term effects on disability, although consistent with those from similar trials,[21] were below published guidance on clinically meaningful effects (2 points on a 24-point Roland Morris Disability Questionnaire and 1 point on a 10-point numeric rating scale).[22] Our results suggest that offering more intensive patient education to patients with acute low back pain than that provided as part of standard practice does not reduce pain intensity or lead to meaningful reductions in disability.

Our results challenge a widespread belief that patient education is an effective strategy for treatment of acute low back pain. For example, every clinical guideline recommends patient education to manage acute low back pain.[13] These recommendations are, however, often unaccompanied by an evidence statement (eg, neither US[23] nor UK[22] guidelines cite evidence for patient education) or instruction on how patient education interventions should be conducted.[24] Two systematic reviews have concluded that primary care-based patient education is effective for acute low back pain.[12,25] The available Cochrane review[12] of individual patient education included 6 trials of patient education compared with usual care: 3 trials of brief interventions (<20 minutes) and 3 trials of intensive interventions (>2 hours). The authors concluded that intensive patient education may be more effective at increasing return-to-work rates compared with usual care based on 2 trials (n = 1432). However, those trials did not include pain or disability outcomes. Although a more recent review of 14 trials found that brief patient education could reduce back pain-related distress (n = 4872),[25] it was unclear whether these interventions could improve other clinical outcomes such as pain.[26] Of importance, our mediation analysis (eResults 1 in Supplement 2) suggests that interventions aimed at reducing pain-related distress (eg, catastrophization) are unlikely to influence the pain experience as much as previously thought.

Strengths and Limitations

This trial[15] had several strengths. It was the first trial, to our knowledge, to test a patient education intervention against a credible placebo (ie, a professional consultation without any information or advice) in patients with acute low back pain.

Table 3. Secondary Outcomes for the Patient Education and Placebo Patient Education Groups at 1 Week and 3, 6, and 12 Months[a]

Variable	Patient Education	Placebo Patient Education	Effect Measure Mean Difference or OR (95% CI)	*P* Value
Chronic low back pain at 3 mo, No./total No. (%)[b]	33/96 (34.4)	42/93 (45.1)	0.63 (0.32 to 1.14)	.13
Disability[c]				
1 wk	5.6 (5.2)	7.1 (5.8)	−1.6 (−3.1 to −0.1)	.03
3 mo	3.5 (4.6)	4.9 (6.0)	−1.7 (−3.2 to −0.2)	.03
6 mo	3.8 (5.2)	4.3 (5.2)	−0.8 (−2.4 to 0.7)	.28
12 mo	3.0 (4.7)	3.8 (5.1)	−0.8 (−2.4 to 0.7)	.29
Overall intervention effect[d]	NA	NA	NA	.17
Pain interference[e]				
1 wk	2.8 (2.7)	2.9 (2.5)	−0.1 (−0.8 to 0.6)	.71
3 mo	1.5 (2.1)	2.3 (2.4)	−0.8 (−1.5 to −0.1)	.02
6 mo	1.8 (2.6)	1.9 (2.3)	−0.1 (−0.8 to 0.6)	.87
12 mo	1.6 (2.4)	2.0 (2.5)	−0.4 (−1.1 to 0.3)	.30
Overall intervention effect[d]	NA	NA	NA	.16
Depressive symptoms[f]				
1 wk	2.6 (4.1)	3.3 (4.3)	−0.7 (−1.8 to 0.5)	.26
3 mo	2.1 (3.9)	2.5 (4.1)	−0.5 (−1.7 to 0.6)	.36
Overall intervention effect[d]	NA	NA	NA	.89
Current pain intensity[g]				
1 wk	2.3 (2.1)	2.2 (2.1)	0.1 (−0.5 to 0.7)	.69
3 mo	1.5 (2.0)	2.1 (2.1)	−0.6 (−1.2 to −0)	.04
6 mo	1.8 (2.5)	1.8 (1.9)	−0.1 (−0.7 to 0.5)	.78
12 mo	1.4 (2.1)	1.7 (2.1)	−0.3 (−0.9 to 0.3)	.33
Overall intervention effect[d]	NA	NA	NA	.13
Seeking health care for low back pain, No./total No. (%)				
3 mo	73/96 (76.0)	82/93 (88.2)	0.43 (0.19 to 0.93)	.03
6 mo	44/95 (46.3)	48/91 (52.7)	0.77 (0.43 to 1.38)	.38
12 mo	32/91 (35.2)	38/87 (43.7)	0.70 (0.38 to 1.28)	.25
Global change at 3 mo[h]	8.1 (1.7)	7.8 (2.0)	−0.3 (−0.9 to 0.2)	.11
Recurrence at 12 mo, No./total No. (%)[i]	26/91 (28.6)	41/87 (47.1)	0.44 (0.24 to 0.82)	.01
Pain attitudes				
1 wk	1.3 (1.2)	2.2 (1.3)	−0.9 (−1.2 to −0.5)	<.001
12 mo	1.2 (1.2)	1.6 (1.3)	−0.4 (−0.7 to 0)	.03
Overall intervention effect[d]	NA	NA	NA	.16
Nothing seriously wrong (0-10) at 1 wk[j]	7.6 (2.5)	6.5 (2.9)	1.2 (0.4 to 2.0)	.003
Yes, perceive a need for further tests at 1 wk, No./total No. (%)	25/98 (25.5)	36/96 (37.5)	0.57 (0.31 to 1.05)	.07

Abbreviations: NA, not applicable; OR, odds ratio.

[a] Data are presented as mean (SD) unless otherwise indicated.

[b] Reporting 2 or more on an 11-point pain intensity numeric rating scale during the past week and no periods of recovery at that time.

[c] Roland Morris Disability Questionnaire with range from 0 (no disability) to 24 (high disability).

[d] *P* value is from mixed models for repeated measures comparing between-group difference during the full 12-month trial, controlling for baseline and including time points as a categorical variable.

[e] Numeric rating scale with range from 0 (no interference) to 10 (highest interference possible).

[f] Depression severity scale of Depression, Anxiety, and Stress Scale with range from 0 (no depressive symptoms) to 42 (high depressive symptoms).

[g] Numeric rating scale with range from 0 (no pain) to 10 (worst pain possible).

[h] Global Back Recovery Scale.

[i] Recurrence was defined as answering yes to both of the following questions: (1) "In the last 6 months/12 months, has your lower back pain gone away completely for a period of more than 30 days, only to return later on?" and (2) "If yes, did the return of low back pain last at least 24 hours with a pain intensity of more than 2/10?"

[j] "How reassured do you feel that there is no serious condition causing your back pain?" Range from 0 (not reassured at all) to 10 (completely reassured).

This strategy allowed us to determine the specific effects of patient education and control for effects produced by a clinical encounter, for example, those from the attention of a health professional or from the credibility of an impending treatment. We trained 2 trial clinicians to ensure treatment fidelity. Retention rates were high (>90% at all time points). We followed a published trial protocol[15] and statistical analysis plan.[18] Data were collected and analyzed by researchers who were masked to group allocation.

We used PICKUP, a validated prognosis model,[8] to exclude people with acute low back pain who were at lower than average risk of pain chronicity. Approximately 40% of included participants developed chronic low back pain, a rate twice that of other trials on acute low back pain conducted in the same geographical area of Sydney (approximately 15%-20%).[9,27] We are therefore confident that we included participants who were at high risk of pain chronicity.

This study also has limitations. First, trial clinicians could not be blinded to treatment allocation. However, results of our audit suggested that there were no systematic differences in treatment credibility or treatment fidelity. Second, interventions in the PREVENT trial[15] were provided by trial physiotherapists, and it is unclear whether our results would have been the same if the participant's health practitioner provided the intervention. Third, we performed a number of statistical comparisons, which although planned, increased the

risk of Type I error. Interpretation of the statistically significant effects of intensive patient education on some secondary outcomes, such as pain interference and recurrence and odds of seeking health care (Table 3), must consider this potential limitation. Finally, because both groups received basic patient education as part of recommended first-line care and many recovered despite being classified as being high risk, the potential for between-group differences may have been reduced.

Conclusions

For patients with acute low back pain who received first-line care, intensive patient education was no more effective than a placebo intervention. Adding complex, time-consuming treatments to primary-care based advice and reassurance is likely to be unnecessary for most patients with acute low back pain.

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