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BMJ Open Pain education to prevent chronic low back pain: a study protocol for a randomised controlled trial

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ABSTRACT

Introduction: Low back pain (LBP) is the leading cause of disability worldwide. Of those patients who present to primary care with acute LBP, 40% continue to report symptoms 3 months later and develop chronic LBP. Although it is possible to identify these patients early, effective interventions to improve their outcomes are not available. This double-blind (participant/outcome assessor) randomised controlled trial will investigate the efficacy of a brief educational approach to prevent chronic LBP in 'at-risk' individuals. Methods/analysis: Participants will be recruited from primary care practices in the Sydney metropolitan area. To be eligible for inclusion participants will be aged 18-75 years, with acute LBP (<4 weeks' duration) preceded by at least a 1 month pain-free period and at-risk of developing chronic LBP. Potential participants with chronic spinal pain and those with suspected serious spinal pathology will be excluded. Eligible participants who agree to take part will be randomly allocated to receive 2×1 h sessions of pain biology education or 2×1 h sessions of sham education from a specially trained study physiotherapist. The study requires 101 participants per group to detect a 1-point difference in pain intensity 3 months after pain onset. Secondary outcomes include the incidence of chronic LBP, disability, pain intensity, depression, healthcare utilisation, pain attitudes and beliefs, global recovery and recurrence and are measured at 1 week post-intervention, and at 3, 6 and 12 months post LBP onset.

Ethics/dissemination: Ethical approval was obtained from the University of New South Wales Human Ethics Committee in June 2013 (ref number HC12664). Outcomes will be disseminated through publication in peer-reviewed journals and presentations at international conference meetings.

Trial registration number: https://www.anzctr.org.au/ Trial/Registration/TrialReview.aspx? ACTRN=12612001180808

INTRODUCTION

Low back pain (LBP) is very common^{1 2} and the leading cause of disability worldwide.³ Not everyone who gets LBP will develop chronic LBP

Strengths and limitations of this study

- This randomised controlled trial will investigate a new, simple and inexpensive approach to treating patients at-risk of developing chronic low back pain (LBP).
- A sham-controlled design is being implemented to control for non-specific effects of therapist patient interaction.
- Only those individuals identified as being at-risk of chronic LBP will be included to minimise the potential influence of natural recovery on the estimation of treatment effect.
- Therapist blinding is not possible.

(more than 3 months' duration), in fact, most do not.⁴ Although 60% of people who have LBP recover in a few weeks,⁵ and often with minimal intervention,⁶ for the other 40%, recovery is slow and the risk of long-term symptoms, or chronic LBP, is high. For patients who develop chronic LBP,⁷ research has consistently shown that treatments are seldom effective in returning them to a pain-free or productive life.^{8–11} These people face a downward spiral of increasingly lengthy periods of pain and disability with substantial social and personal disadvantage.¹ Most of the costs associated with LBP can be attributed to patients with chronic symptoms.¹²

Evidence for preventing chronic LBP

Attempts to prevent chronic LBP have typically treated all patients with acute LBP with the same intervention focused on either biomechanics, ¹³ fear avoidance, ¹⁴ work and social factors ¹⁵ or exercise. ¹⁶ ¹⁷ That these approaches have not been successful ¹⁸ may be due, at least in part, to the positive natural history of acute LBP for the majority of patients, resulting in a large Number Needed to Treat (NNT). A more logical approach would be to target interventions to patients 'at-risk' (elevated risk) of poor outcome. ¹⁹

Identifying patients at-risk of chronic LBP

A number of prospective cohort studies have identified characteristics of patients who are at-risk of developing chronic LBP. Screening tools have been developed so that treatments can be targeted towards those at-risk of developing chronic LBP, and have shown promising results. However, the predictive validity of these tools is often reduced when applied to samples which are different from that in which the tool was developed. Indeed, the relative contribution of each factor and the validity of cut-off scores for classifying at-risk individuals appears to vary substantially between study samples. Considering these limitations data from the same target population, acute LBP in Australian primary care, were used to identify those patients who are at-risk of developing chronic LBP.

Pain biology education

International guidelines recommend educating patients with acute LBP to reduce fear and concern about their LBP, and to promote an active recovery.²⁷ Education is a treatment option that is simple, inexpensive and readily used by primary care practitioners.

One educational approach that has not been tested to prevent chronic LBP is pain biology education, or 'explaining pain'. Explaining pain aims to reconceptualise pain as a protective output of the brain, rather than an accurate measure of tissue damage. It presents a conceptual framework that is based on biological processes that are accepted in the pain science community, but only recently introduced to people in pain. This framework integrates the various cognitive, social and contextual factors that modulate pain, and the appropriateness of a biopsychosocial approach to management and rehabilitation.²⁸

Experimental studies have shown that pain biology education changes pain-related attitudes and beliefs² and reduces catastrophising (holding a overly pessimistic interpretation of one's symptoms and prognosis) in people with chronic or sub-acute pain and in pain-free individuals.^{30–33} A blinded randomised experiment showed that pain biology education increased pain threshold during a straight leg raise test, in contrast to explaining lumbar spine physiology and anatomy, which decreased pain threshold during the same test.²⁹ Pain biology education can also reduce pain and disability in people with chronic pain. 33 34 These findings have been replicated in distinct chronic pain disorders in different language and cultural groups by independent researchers, 33 35 36 and are supported by systematic review and meta-analysis level evidence.³⁴

OBJECTIVES Primary objective

The primary *hypothesis* of this study is that the addition of pain biology education to clinical guideline-based care for acute LBP will reduce the intensity of LBP at 3 months.

Secondary objectives

Secondary objectives are to determine whether pain biology education (a) increases recovery and decreases disability, depression, pain-related beliefs and healthcare utilisation (b) effects can be maintained at 6 and 12 months.

METHODS Setting

Participants will be recruited from primary care (general practitioner and physiotherapy) practices in the Sydney metropolitan area.

Target population

Participants identified in primary care will be eligible for the study if they fulfill the following criteria:

Inclusion criteria

- ▶ Aged 18–75 years;
- ► The primary symptom is LBP with or without leg pain;
- ► A new episode of LBP,³⁷ ie, current pain preceded by >1 month without LBP;
- ► Average pain intensity $\ge 3/10$ on numeric rating scale (NRS)⁷ during the past week;
- ▶ The duration of current symptoms <6 weeks;
- ▶ At-risk of developing chronic LBP (at-risk status will be determined using responses to seven questions found to be predictive of chronic LBP by Henschke *et al*⁵: self-rated general health, presence of leg pain, previous episodes, compensation status, current pain intensity, depressive feelings and self-perceived risk of persistence);
- ► Sufficient fluency in English language to understand and respond to English language and questionnaires Exclusion criteria
- ► Chronic (ie, >3 months' duration) spinal pain (intensity NRS>1/10);
- ► Known or suspected serious spinal pathology (eg, cauda equina syndrome, inflammatory arthritis, malignancy etc.);
- Previous spinal surgery;
- ▶ Uncontrolled mental health condition (eg, schizophrenia, bipolar disorder, major depressive disorder) that precludes successful participation.

Recruitment

A primary care practitioner will provide a potential participant with an information sheet containing details of the study and contact study researchers with the contact details. Study researchers will contact the potential participant within 24 h to screen for study eligibility.

Eligible participants will then be given an appointment with the study physiotherapist at either the referring practitioners' rooms, a physiotherapy practice or at Neuroscience Research Australia. On the morning of the first appointment with the study physiotherapist, participants will be given a reminder phone call to check

they still have LBP (ie, average pain intensity ≥3/10 in the past week⁷). The intervention will take place within 6 weeks of LBP onset. Immediately before treatment, time will be given for any questions to be addressed, written informed consent will be obtained, and all participants will be reminded to continue with the care provided by their primary care clinician for their LBP. The second session will be scheduled no more than 2 weeks after the first session, so that study treatment will be completed while participants are in the 'acute' phase of LBP (less than 6 weeks' pain duration). Participants will be contacted to remind them of their appointments.

Treatment allocation and randomisation

A block randomisation schedule will be created using a computer-generated random number table, to allocate participants to one of the two treatment arms: 'pain biology education' or 'sham education'. The schedule will be generated by a statistician who is not involved in any other aspect of the study, and all researchers will be blinded to block size(s) and randomisation list. Sealed, sequentially numbered opaque envelopes will be used to ensure allocation concealment. A member of staff, not involved in the trial, will prepare the envelopes. Once the study physiotherapist will obtain informed consent and baseline data, the participant will be given a study number, an explanation of the study and a short history and physical examination. The randomisation envelope with the same study number of the participant will then be opened. Participants in both treatment arms will continue to receive guideline care from their primary care practitioner. Participant progress through the study is shown in figure 1.

Blinding

All outcome assessors and participants will be blinded to group allocation. The statistician conducting the primary data analysis will also be blinded to group allocation. The study physiotherapist delivering the intervention will not be blinded to group allocation due to the nature of the intervention being tested.

Interventions

Features of brief pain education and sham education are compared with the 'traditional' and guideline approach in online supplementary appendix A. ³⁸ ³⁹

Guideline care

All participants will receive current guideline care from their primary care providers in addition to the study interventions. Participating clinicians will be given a booklet and trained on the delivery of care based on the Australian National Medical and Research Council guideline for recent onset LBP. In general, the guideline recommends that after performing diagnostic triage, first-line care should consist of advice, reassurance and analgesic medication. Participants will be reassured of the benign nature of LBP, advised to remain

active and avoid bed rest and instructed in the use of simple analysesics to manage their symptoms. The practitioner may consider second-line options such as spinal manipulation if the participant does not respond to first-line care.

Physical examination

The study physiotherapist will conduct a physical examination of all participants prior to group allocation. The examination will involve active movement assessment, palpation and neurological testing. Findings, for example, movement restriction, tenderness and/or neurological signs will be used as discussion points during the education intervention.

Pain education

Participants randomised to the pain education intervention will participate in 2× 1 h sessions of pain education by the specifically trained study physiotherapist. The educational programme includes the following three broad components: (i) reframe any unhelpful beliefs about the nature of LBP; (ii) present key concepts of pain biology; (iii) evaluate understanding and discuss recovery.

Part (i). Reframe any unhelpful beliefs about the nature of LBP

The study physiotherapist will identify any unhelpful beliefs, those that have been found to be associated with poor recovery from LBP, such as poor recovery expectations, intentions to avoid activity due to fear of damage and beliefs concerning a reliance on passive treatment approaches.²⁶ These beliefs will be addressed by discussing any potentially unhelpful diagnostic, prognostic or therapeutic conclusions that the participant might have made. For example, a participant may express concern about a 'disc slipping out' with bending tasks at work. This belief will be identified to the participant as understandable, but inaccurate and unhelpful. Less threatening, evidence-based information will then be provided about the nature of the intervertebral disc, its inability to 'slip' and its relationship to LBP. The inherent strength and stability of spinal structures will be emphasised.41

Part (ii). Present key concepts of pain biology

Part (ii) introduces the key aspects of pain biology and is designed to complement part (i) as well as explanations given by the primary care provider. Topics have been adapted for the acute LBP population from previous work on pain education. ²⁹ Pain will be presented as being a protective output of the brain that is influenced by many factors, rather than being a robust signal of tissue damage. More specifically, participants will be taught that: nociceptive input is modulated at the tissues, spinal cord and brain; the brain evaluates many inputs before selecting a response; pain is the conscious part of the response. This explanation provides support for current guideline instructions. For example, instructions such as 'hurt doesn't equal harm', 'stay active' and

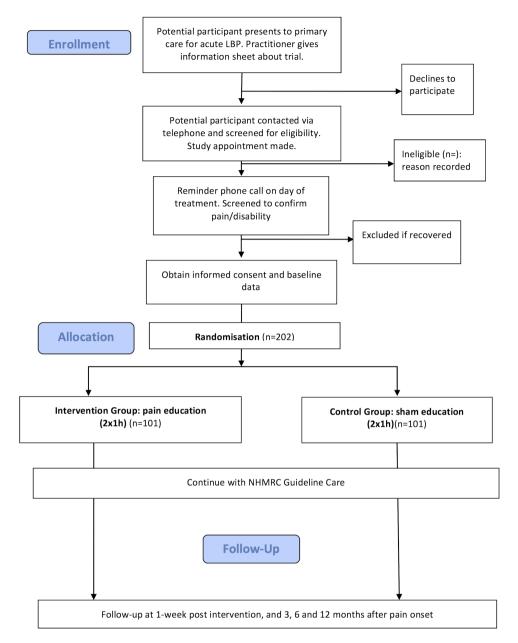


Figure 1 Trial design.

'return to work as soon as possible',²⁷ will be discussed in the context of evidence from pain biology.

Research has shown that the concepts of pain education can be understood by participants from a widerange of socioeconomic and educational backgrounds³¹ and that metaphors and stories are a useful way to present complex and new information.⁴² Metaphors are meant to provoke contemplation and increase the potential for re-organisation of previous thoughts about pain. Metaphors will be used to both reframe unhelpful beliefs (part i) and present new concepts, in accordance with established principles of conceptual change (see ref. ⁴³ for review).

In summary, the key concepts to be presented by the pain education are:

1. Pain is a protective mechanism, not necessarily a symptom of damage

- 2. In acute LBP, the system can become overprotective (sensitisation)
- 3. How one makes sense of their pain is an important factor for recovery

Part (iii). Evaluate understanding and discuss recovery

The final component of the intervention reinforces the concepts outlined in part (i) and (ii), and discusses recovery within these concepts. Understanding the cause of the symptoms and their variable relationship to tissue damage is discussed as the most important starting point for a good recovery. Emphasis is placed on the reliability of the tissue healing process, and the necessity of gradually returning to all activities. The explanation of pain biology in part (ii) provides evidence that rehabilitation approaches such as pacing are safe and effective. The participant is encouraged to discuss more specific

	Domain	Measures	Time point*
rimary	Pain	Pain intensity: 0–10 NRS average pain in the past week ⁷	12
Secondary	Chronic LBP	≥2/10 pain intensity (yes/no); no periods of recovery (yes/no)	12
	Disability	Roland Morris Disability Questionnaire ⁴⁶	0, 1, 12, 26, 52
	·	Disability NRS: 0–10 current and average disability in the past week ⁷	0, 1, 12, 26, 52
	Depression	Depression, Anxiety and Stress Scale ⁴⁷	0, 1, 12
	Pain	Pain Intensity NRS: current and average disability in the past week ⁷	0, 1, 26, 52
	Catastrophising	Pain Catastrophising Scale ⁴⁸	0, 1
	Credibility	Credibility and Expectancy Questionnaire ⁴⁹	1
	Healthcare utilisation	Medication	12, 26, 52
		Visits for LBP	12, 26, 52
		Treatment type	12, 26, 52
	Global change	Global Back Recovery Scale ⁵⁰	12
	Pain-free and disability-free periods	Periods >1 week no pain or disability	12
	Recurrence	>2 episodes lasting >24 h, >2/10 pain intensity, and 30 days pain free in between ³⁷	26, 52
	Neuroscience knowledge	Neurophysiology of Pain Questionnaire ⁵¹	0, 1
	Attitudes and beliefs	Survey of Pain Attitudes Two-item Version ⁵²	0, 1, 12, 26, 52
		Back Beliefs Questionnaire ⁵³	0, 1
		Orebro Musculoskeletal Pain Questionnaire ²¹	0, 1
	Self efficacy	Pain Self-Efficacy Questionnaire ⁵⁴	0, 1
	Reassurance	Nothing seriously wrong ⁵⁵	0, 1
		Further investigations required ⁵⁶	0, 1

aspects of rehabilitation (eg, goal setting) with their primary care provider.

Sham education

Participants randomised to the control intervention will receive 2× 1 h treatment sessions of sham education based on a 'reflective, non-directive approach described in our previous study'. 44 This approach uses active listening techniques such as paraphrasing, 45 and is designed to control for time with a health professional and the empathy that occurs within a consultation. Participants randomised to this intervention will be given the opportunity to discuss their LBP and any other problems that they may have. The study physiotherapist will respond in an empathic way, but will not offer advice or information on pain, their condition or any other matter. Any questions the participant may have about the management of their LBP will be referred back to the primary care provider. We have shown that study participants find this approach to be equally as credible as advice.⁴⁴

Baseline and outcome measures

In addition to clinical/ demographic data assessed at baseline (age, sex, duration of current LBP episode, number of previous episodes, other painful areas, compensation status) outcome measures and their measurement time points are outlined in table 1.

After the final study treatment, participants will be given a package containing all follow-up questionnaires. They will be contacted via SMS, email or telephone prior to the follow-up assessments to remind them to complete the questionnaires. They will be telephoned at 2 weeks post-treatment, then 3, 6 and 12 months after the reported date of pain onset to transcribe the results of the questionnaires over the phone. Alternatively questionnaires will be available for participants to complete online.

Primary outcome

The *primary* outcome will be self-reported pain intensity (NRS)⁷ at 3 months following the reported onset of symptoms. The 3 month follow-up time point was chosen for the primary outcome as this is the most common definition of chronic LBP⁵⁷ 58 and reflects the time when a clear change in prognosis occurs.

Secondary outcomes

The *secondary* outcomes will include the proportion of participants who have chronic LBP at 3 months. A participant will be determined as having chronic LBP if he or she has pain intensity ('In the past week, on average, how intense was your pain on a 0–10 scale where 0 is 'no pain' and 10 is 'pain as bad as it could be'') $\geq 2/10$ and no periods of recovery in the last 3 months.⁶

Additional secondary outcomes to be assessed via self-report questionnaire will be disability (Roland Morris Disability Questionnaire, ⁴⁶ Disability NRS: 0–10 current and average disability in the past week⁷), depression (Depression, Anxiety and Stress Scale⁴⁷), catastrophisa-Catastrophising Scale⁴⁸), credibility (Credibility and Expectancy Questionnaire 49), healthcare utilisation, global change (Global Back Recovery Scale⁵⁰), pain- and disability-free periods (periods >1 week no pain or disability), recurrence (>2 episodes of low back pain lasting >24 h, >2/10 pain intensity and at least 30 days pain free between³⁷), neurobiology knowledge (Neurophysiology of Pain Questionnaire⁵¹), painrelated attitudes and beliefs (Survey of Pain Attitudes Two-item Version; 52 Back Beliefs Questionnaire; 53 Orebro Musculoskeletal Pain Questionnaire²¹), self-efficacy (Pain Self-Efficacy Questionnaire⁵⁴) and reassurance (nothing seriously wrong;⁵⁵ further investigations required⁵⁶).

Data and treatment integrity

Trial data integrity will be monitored by regularly scrutinising data files for omissions and errors. All data will be double entered and the source of any inconsistencies will be explored and resolved. Treatment integrity will be checked by audio recording interventions. Ten per cent of recordings will be randomly selected and integrity determined by two independent assessors who are experts in the field.

Sample size calculations

Sample size was calculated using the Stata sample size calculation method for cluster randomised trials. With four repeated observations, an estimated intra-cluster correlation (correlation between the observations) of 0.4, α set at 5%, and allowing for 15% loss to follow-up, 101 participants are required in each group to have 80% power to detect a difference in pain intensity of 1 point (SD of 3) on the NRS at 3 months. In these calculations the increase in statistical power conferred by baseline covariates has been conservatively ignored.

Statistical analysis

The data will be analysed by intention-to-treat and by a statistician blinded to group allocation. The effect of treatment will be analysed separately for each outcome using linear mixed models with random intercepts for individuals to account for correlation of repeated measures. Estimates of the effect of the intervention and 95% CI will be estimated by constructing linear contrasts to compare the adjusted difference in means or proportions at each time point between the treatment and control groups.

CONCLUSION

This trial has been designed to provide robust data on the efficacy of a brief educational treatment aimed at preventing chronic LBP. The results have the potential to change how LBP is managed in primary care.

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Contributors JHM and GLM conceived the idea for the trial. GLM, JHM, ACT and MKN were responsible for developing the interventions. The trial was designed by JHM, MH, HL and ACT. ACT prepared the first draft of the manuscript. Successive drafts were contributed by ACT, GLM, MH, HL, IWS, NH, JMH, KMR and JHM. The final version of the manuscript was approved by all authors.

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Competing interests None.

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