The role of patient education materials in supporting guideline implementation and improving outcomes for patients with low back pain in primary care

by

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Abstract

Patients lack knowledge and have unhelpful beliefs about low back pain (LBP) that are associated with worse outcomes and overuse of diagnostic imaging. Physicians report that the drivers of imaging overuse include patient expectations for imaging and not having a reliable and concise method to explain why imaging is not needed to diagnose most LBP. This dissertation explores whether patient education materials (PEMs) can support physicians in providing education to patients to improve patient outcomes and, in particular, reduce unnecessary LBP imaging in primary care.

First, I conducted a systematic review and meta-analysis on the effectiveness of PEMs for LBP, but few trials measured knowledge, beliefs, imaging rates, or intervention fidelity. Furthermore, details about the tested PEMs were mostly unavailable, so this review reveals little is known about PEMs' mechanisms of action, how their content was developed, and what this content entails.

Second, patients want education about LBP treatment options, but the evidence around LBP treatments is continuously changing. Therefore, I conducted a systematic review and meta-analysis to investigate the analgesic effects of conservative treatments for LBP compared with placebo. Out of 56 treatments, none showed reliable evidence of large effects and the majority (86%) had inconclusive evidence. These findings underscore the need for better resource prioritization in this field.

Third, I set out to assess the content of PEMs, but no tool had been developed to assess if PEMs contain information about patients' needs. I created a checklist outlining

21 patient information needs (i.e., what patients want to know) and education needs (i.e., what clinicians and researchers want patients to know) about LBP. Using this checklist and other tools I assessed PEMs for their understandability, actionability, readability, quality, accuracy, comprehensiveness, and coverage of information about patients' needs. PEMs scored poorly across most outcomes and none were actionable or comprehensive.

Overall, my thesis reveals that little is known about if and how PEMs might work to help manage LBP in practice and exposes the systemic issues in their development and testing. More work is required before disregarding PEMs as an intervention for LBP.

General summary

Studies show that patients lack knowledge about low back pain (LBP) diagnosis and management. Imaging cannot detect the cause of pain for most people with LBP. Despite this, patients frequently request imaging, and family doctors struggle to explain why imaging is not necessary. This results in unnecessary imaging in practice, which can be harmful to patients (e.g., radiation exposure) and healthcare systems (e.g., increased spending). This thesis explores if PEMs can help physicians better educate patients about LBP to improve patient outcomes and reduce unnecessary imaging requests.

I reviewed the literature for any studies assessing the effectiveness of PEMs for LBP on patient outcomes. However, few studies measured important outcomes like knowledge and imaging requests, highlighting that more research is needed to determine if PEMs can increase patients' knowledge about LBP diagnosis and management and reduce their expectations for unnecessary imaging.

Second, patients want education about LBP management, but the evidence around LBP treatments is continuously changing. To provide patients with up-to-date information on treatments, I reviewed the literature for any studies assessing the effects of non-surgical interventions on pain levels in patients with LBP. I found 56 different treatments, but none showed reliable evidence of large effects, and it is unclear if the majority (86%) of treatments are effective. More work must be done to determine if most tested treatments for LBP are effective or not effective.

Third, I developed a checklist to see if PEMs contain information about 21 patient information needs (i.e., what patients want to know) and education needs (i.e., what LBP experts want patients to know) about LBP. Using this checklist and other tools I assessed PEMs for their understandability, actionability, readability, quality, accuracy, and comprehensiveness, and whether they contain information about patients' needs. PEMs scored poorly across most outcomes, and none were actionable or comprehensive.

My thesis reveals that we do not know enough about if and how PEMs might work to help manage LBP in practice and highlights many issues with how PEMs have been developed and tested in the literature.

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List of Abbreviations

4DSQ; Four-Dimensional Symptom Questionnaire

ADLQ; Activities of Daily Living Questionnaire

ALBDS; Aberdeen Pain and Function Scale

APA; American Psychological Association

AQoL-8D; Assessment of Quality of Life 8-Dimension

BACK-PAQ; Back Pain Attitudes Questionnaire

BBQ; Back Beliefs Questionnaire

BPI; Brief Pain Inventory

CBT; cognitive behavioral therapy

CENTRAL; Cochrane Central Register of Controlled Trials

CI; confidence interval

CPCI-42; 42-Item Chronic Pain Coping Inventory

CPGS; Chronic Pain Grade Scale

CSQ; Coping Strategies Questionnaire

Dartmouth CO-OP; Dartmouth Primary Care Cooperative Information Project

DASS-21; 21-Item Depression Anxiety Stress Scale

DDS; Descriptor Differential Scale

EQ-5D; the EuroQol 5-dimension health-related quality of life instrument

EQ5D-3L; the EuroQol 5-dimension, 3-level health-related quality of life instrument

FABQ; Fear-Avoidance Beliefs Questionnaire

FABQwork; Fear Avoidance Beliefs Questionnaire (Work subscale)

FFbH-R; Hannover Functional Ability Questionnaire

FKGL; Flesch-Kincaid Grade-Level

FRE; Flesh-Kincaid Grade Ease

GABAA; g-aminobutyric acid type A

GP; general practitioner

GPE; Global Perceived Effect scale

GRADE; Grades of Recommendation, Assessment, Development and Evaluation

HAD; Hospital Anxiety and Depression scale

HONcode; Health on the Net Code of Conduct

JAMA; Journal of American Medical Association

LBP; low back pain

LBP-MSBQ; Low Back Pain Medical Scans Beliefs Questionnaire

LKQ; Low Back Pain Knowledge Questionnaire

MAOIs; monoamine oxidase inhibitors

mFABQ; Modified Fear-Avoidance Beliefs Questionnaire;

NDRIs; noradrenaline-dopamine reuptake inhibitors

NL SUPPORT; Newfoundland and Labrador Support for People and Patient-Oriented Research and Trials

NRS; Numeric Rating Scale

NSAIDs; non-steroidal anti-inflammatory drugs

ODI; Oswestry Disability Index

OEQ; Outcome Evaluation Questionnaire

PCS; Pain Catastophizing Scale

PEMAT; Patient Education Materials Assessment Tool

PEMAT-A/V; Patient Education Materials Assessment Tool for Audiovisual materials

PEMAT-P; Patient Education Materials Assessment Tool for Printable materials

PEMs; patient education materials

PENs; patient education needs

PGIC; Patients Global Impression of Change scale

PHQ-8; 8-item Patient Health Questionnaire

PICO; participants, interventions, comparator, outcome

PINE-LBP; Patient Information and Education Needs Checklist for Low Back Pain

PINs; patient information needs

PIRFT; Percutaneous intradiscal radiofrequency thermocoagulation

PNF; proprioceptive neuromuscular facilitation

PPQ; Patient Pain Questionnaire

PRESS; Peer Review of Electronic Search Strategies

PRISMA; Preferred Reporting Items for Systematic reviews and Meta-Analyses

PROMIS; Patient-Reported Outcomes Measurement Information System

PSEQ; Pain Self-Efficacy Questionnaire

PSEQ-2; 2-Item Pain Self-Efficacy Questionnaire

PSS; Perceived Stress Scale

QBPDS; Quebec Back Pain Disability Scale

RCT; randomized controlled trial

RevMan; Review Manager

RF; radiofrequency

RIMAs; reversible inhibitors of monoamine oxidase A

RMDQ; Roland Morris Disability Questionnaire

RR; risk ratio

SARIs; serotonin antagonist and reuptake inhibitors

SAS; Zung Self-Rating Anxiety Scale

SBS; Symptom Bothersomeness scale

SD; standard deviation

SDS; Zung Self-Rating Depression Scale

SF-12; 12-Item Short Form Survey

SF-36; 36-Item Short Form Survey

SMD; standardized mean difference

SMT; Spinal Manipulative Therapy

SNRIs; selective noradrenaline reuptake inhibitors

SSRIs; selective serotonin reuptake inhibitors

TCAs; tricyclic antidepressants

TENS; Transcutaneous Electrical Nerve Stimulation

TIDieR; Template for Intervention Description and Replication

TRPV1; transient receptor potential vanilloid 1

TSK; Tampa Scale of Kinesiophobia

TSK-4; 4-item Tampa Scale for Kinesiophobia

TSK-G; The Tampa Scale for Kinesiophobia - General

TSK-SV = Tampa Scale for Kinesiophobia Short Version

UTs; unvalidated tools

VAS; Visual Analogue Scale

VNS; Visual Numeric Scale

WLQ; Work Limitations Questionnaire

List of Appendices

Knowledge Translation

Oral presentations

Cashin, A.* and Furlong, B.* (co-first authors), Kamper, S., De Carvalho, D., Machado, L., Davidson, S., Bursey, K., Abdel Shaeed, C., Hall, A. (2023). Analgesic Effects of Conservative Treatments for Low Back Pain: A Systematic Review and Meta-Analysis of Placebo-Controlled Randomised Trials. 18th International Forum for Back and Neck Pain Research, Groningen, Netherlands.

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Peer-Reviewed Publications

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CHAPTER 1: Introduction

1.1 Overview

This dissertation aims to investigate the potential of patient education materials (PEMs) as an intervention to improve outcomes for patients with low back pain (LBP). I also sought to determine if they are a plausible intervention to support family physicians to reduce unnecessary LBP imaging in primary care. I was interested in PEMs as a means to reduce unnecessary imaging in primary care because (i) patients' desire for imaging is rooted in their belief that imaging is needed to diagnose LBP, and (ii) family physicians' lack of a reliable and concise method to explain why imaging is not needed to diagnose most LBP are among the most commonly reported reasons for unnecessary imaging requests. Patient education that includes a reliable way of explaining the role of imaging may help to correct this belief and, in turn, reduce unnecessary imaging requested for these reasons. To undertake this work, I sought to understand the effectiveness of PEMs on LBP outcomes and assess the content of available PEMs from the literature to determine which PEMs are best for use in practice. Because there are also widespread misconceptions amongst both patients and providers about the effectiveness of the many available treatments for LBP, I conducted a review to determine the analgesic effects of all available conservative treatments for LBP, which could be used to update treatment information provided in PEMs. This chapter provides a comprehensive overview of all the concepts that underpin the scope of my thesis and inform my research objectives. It provides an overview of (i) clinical low back pain, including guideline recommendations for its diagnosis and management; (ii) why imaging for LBP is unnecessary for most people and how it is being overused in practice; (iii) currently available behaviour change interventions used to reduce unnecessary LBP imaging; (iv) the barriers and facilitators to

reducing unnecessary LBP imaging; and (v) what is known about patient education for LBP and, more specifically, the potential role of PEMs for LBP in addressing the barriers and facilitators to reducing unnecessary LBP imaging.

1.2 Clinical Low Back Pain

1.2.1 Burden

LBP affects people of all ages, including children and adolescents [1–3], in low, middle, and high-income countries alike [4]. It is the leading cause of disability in the world [5] affecting over 500 million people at any one time in 2017 [6] – a number that is projected to rise to 843 million by 2050 [5]. People with LBP experience pain, loss of function, psychological distress, social isolation, and work and activity limitations [4,7,8]. They accumulate a lower value of personal wealth compared to those without LBP [9] and more people report premature retirement due to LBP than any other chronic health condition [10]. The all-cause direct medical costs associated with spine-related conditions in the United States was an estimated $315 billion per year from 2012-2014 [11]. LBP is a worsening global health concern with consequences for both the individual person and societies as a whole.

1.2.2 What is it?

There are two overarching types of LBP: non-specific and specific. The vast majority (90-95%) of people have “non-specific” LBP, which is defined as pain occurring below the rib cage and above the gluteal folds that is not reliably attributable to a specific pathoanatomical cause [12,13]. The remaining proportion (5-10% [14]) has “specific” LBP, meaning there is a definitive nociceptive cause to their pain [4]. Most people with

specific LBP have “radicular syndromes” (often referred to as “sciatica”) where pain radiates downward through the legs, usually due to some nerve root compromise [15,16]. Only about 1% of people with specific LBP have other, often more severe, spinal pathologies such as vertebral fracture or infection [14]. Non-specific LBP is the primary focus of this thesis; there are three subtypes classified by symptom duration: acute, subacute, and chronic.

1.2.3 Acute and subacute non-specific LBP

Acute LBP is a new episode of LBP occurring within the past 6 weeks, while subacute LBP is LBP that has persisted for 6 to 12 weeks [17]. Acute LBP has a favourable prognosis for most people, with rapid improvements in pain and disability after 4-6 weeks [18,19], while subacute LBP is thought of as a higher-risk transition period between acute and chronic LBP [20]. Both physical and psychosocial risk factors, such as heavy lifting and job dissatisfaction, are associated with an increased risk of an acute LBP episode [21,22], and people who have had LBP in the past have a higher rate of recurrence, with up to 33% experiencing a flare-up within a year [23]. Subacute LBP is thought to be more highly associated with psychosocial factors. For example, a systematic review of 21 observational studies found that increased fear avoidance beliefs were associated with worse work-related outcomes (i.e., not returning to work and a higher number of sick days) in people with subacute LBP compared to those with acute (< 2 weeks) and chronic (> 3 months) LBP [24].

1.2.4 Chronic non-specific LBP

Chronic LBP is LBP that has persisted for 12 weeks or more [25]. It is characterized by lowered quality of life and functional limitations that may interfere with daily activities and work [4,26]. Estimates vary, but up to 1 in 5 adults have chronic LBP [25,27]; it is more prevalent in women, and the risk of chronicity substantially increases for adults aged 50 years and older [25]. Similar to acute and subacute LBP, chronic LBP is associated with both physical (e.g., higher body weight and physically demanding work) and psychosocial (e.g., general anxiety and depression) risk factors [28], and is more than twice as likely to occur in working populations than those who do not work [29]. There is no reliable cure for chronic LBP and the benefits of most interventions on pain and disability are modest [30].

1.2.5 Diagnosis

In the past decade, two overviews of clinical practice guidelines were conducted to inform the diagnosis and management of LBP. The first, by Oliveira et al. [31], updated Koes et al.'s [32] overview to synthesize current diagnosis and management recommendations for non-specific LBP in primary care. The second and more recent overview, by Zaina et al. [33], aimed to identify effective rehabilitation interventions for non-specific LBP presenting with or without radiculopathy. Both overviews have slightly different, but useful, objectives and outputs and were used to identify clinical practice guidelines for LBP. I also conducted a literature search for clinical practice guidelines and found one additional guideline by Pangarkar et al. [34] that was not included in either of these overviews. In total, 19 clinical practice guidelines for LBP were identified from

these sources and are used in the following discussions of the diagnosis and management of LBP [15,34–51].

Nearly all of the clinical practice guidelines provide recommendations for diagnosing patients with LBP. They suggest classifying patients as having either non-specific or specific LBP, and, where appropriate, most also recommend classifying patients into a distinct third radiculopathy group. To accurately classify someone with LBP into one of these three categories, the guidelines primarily recommend an initial physical exam and patient history, and many specifically recommend neurologic exams (e.g., straight leg raise test and strength, reflex, or sensation assessments) to identify possible nerve root irritation. Palpation, posture assessments, and spinal range of movement assessments are less commonly recommended. Nearly all of the guidelines recommend assessment of yellow flags, or psychosocial barriers to recovery (e.g., negative beliefs about pain and activity, sickness behaviours such as prolonged bed rest, or societal withdrawal [43]) that may be associated with worse LBP outcomes. These factors may influence prognosis, and most guidelines recommend assessing for them within the first two consultations. Nearly all of the guidelines recommend against the use of routine diagnostic imaging for non-specific LBP. Instead, they recommend using imaging only when red flags (i.e., more serious risk factors such as trauma, severe neurological deficit, and fever that are indicative of specific spinal pathologies [43]) are present or when the results of imaging would likely inform treatment. People with non-specific LBP typically do not present with any red flags; therefore, routine use of imaging for this population is not recommended.

1.2.6 Management

Management of both acute and chronic non-specific LBP typically involves non-pharmacological treatments like education, exercise, and manual therapies (e.g., spinal manipulative therapy and massage) as well as pharmacological therapies such as NSAIDs. In addition to these treatments, cognitive behavioural therapy, multidisciplinary rehabilitation, and antidepressants are commonly recommended for patients with chronic LBP. Though the evidence remains uncertain, injections and surgery may be useful for select patients with chronic LBP. However, there has been a progressive shift to approaching LBP treatment with a biopsychosocial model rather than a biomedical model, as guidelines more commonly recommend conservative physical and psychological therapies over pharmacological and non-conservative therapies [17,31]. Accordingly, one of the most commonly recommended and rarely disputed first-line treatments for LBP is education, discussed further in section 1.6.

Though the above treatments are currently the most widely recommended for LBP, it should be noted that these recommendations are continuously changing and there is no gold standard treatment for LBP since most have only small to moderate effects on pain and disability [52]. As a result, a substantial number of treatments continue to be tested in the literature. For example, in a 2009 review of the analgesic effects of treatments for non-specific LBP compared with placebo, Machado et al. [53] identified 34 unique treatments. Fifteen years later, in 2024, it is likely that the number of available treatments is even higher; this amount of information is very difficult for stakeholders to manage. In practice, there are also widespread misconceptions about the effectiveness of

treatments for LBP amongst both patients and providers because the use of low value (i.e., ineffective or harmful) treatments is widespread [54]; additionally, treatment recommendations continue to vary between clinical practice guidelines (e.g., acupuncture is recommended by the American College of Physicians [46], but not by the National Institute for Health and Care Excellence [15]). To address these issues in the literature, I updated the review by Machado et al. [53] to determine the efficacy of all conservative treatments for LBP on pain intensity in Chapter 3. This review will aid guideline producers in synthesizing this information and can be used to inform future patient education interventions for LBP with the most up-to-date and comprehensive treatment information.

1.3 The overuse of diagnostic imaging for low back pain

As noted, clinical practice guidelines recommend against the use of routine diagnostic imaging for non-specific LBP. Table 1.1 outlines some of the evidence behind this recommendation. Failing to comply with this recommendation is a concern because the harms of this diagnostic technique outweigh the benefits for patients with non-specific LBP. It means wasteful spending for individual patients and societies, direct harms such as radiation, and indirect harms such as opportunity cost which further strain healthcare systems [55,56]. Studies show that LBP imaging is overused in practice, as five percent or less of patients with LBP have serious spinal pathology requiring imaging, but about one quarter of all patients with LBP presenting to family practice settings are referred for imaging [57–59] and over one third of patients in ED settings [58]. Furthermore, systematic reviews investigating the appropriateness of LBP imaging found that one-third

to one-half of LBP images performed were inappropriate based on guideline recommendations [60,61]. Reducing unnecessary LBP imaging is a priority that would not only reduce healthcare costs, but allow for re-allocation of these resources to higher-value services, thereby improving patients' quality of care [62,63]. Behaviour change interventions could improve physician adherence to guideline-recommended imaging practices. Below, I introduce and summarize interventions to reduce unnecessary imaging that have been used to date.

Table 1.1 Reasons for why guidelines recommend against the routine use of diagnostic imaging for non-specific low back pain

- **There is no evidence that routine imaging improves LBP outcomes.** Two systematic reviews investigating imaging for LBP found imaging was not associated with better outcomes [64] and may in fact be associated with worse outcomes [65].
- **Imaging findings are not a definitive source of patients' LBP.** Many "abnormalities" (e.g., disc herniations) found through imaging are no longer considered to be abnormal. That is, they have been shown not to be associated with LBP in multiple studies [66,67] and are common enough in asymptomatic populations that they have been referred to as a natural part of aging [68].
- **Imaging findings often do not inform further diagnosis and management** [69–71]. That is, even when "abnormalities" are identified, the patient's diagnosis and associated management plans often remain the same.
- **Conversely, when imaging findings are used to inform further management, this can lead to unnecessary and more aggressive treatment.** Indeed, imaging can lead to more low value procedures as it is easy for these visually identifiable and interpretable "abnormalities" to be targets of unnecessary treatment, even surgery [72], which is supported by studies showing correlations between imaging and surgery rates [73].
- **Imaging can lead to patient labeling.** This can cause patients to perceive themselves to be sick or more fragile when in actuality the abnormal finding may not be associated with, nor a cause of, their pain [69]. This "labeling" may be associated with fear-avoidance and catastrophizing and may prolong recovery [74,75].
- **Imaging exposes patients to unnecessary radiation.** X-ray and CT scans expose patients to radiation, which can increase the risk of cancer [76].
- **The imaging overuse problem is increasing and the financial impact is significant.** LBP imaging has been increasing in the last two decades [58]. In the U.S. alone, costs associated with CT and x-ray imaging nearly doubled from $2.686 billion in 2000 to $4.656 billion in 2006 [77].

1.4 Behaviour change interventions to reduce unnecessary imaging for low back pain

To date, many interventions have been developed to reduce unnecessary imaging for LBP with little success. Jenkins et al. [78] conducted a systematic review to investigate these interventions and their effectiveness. They found no effect for passive guideline dissemination and education workshops, and uncertain effectiveness of audit and feedback for reducing LBP imaging. Clinical decision support and reminder interventions were effective for reducing LBP imaging, but only one study investigated each of these interventions so the strength of this evidence was low. A more recent systematic review on the same topic was conducted by Belavy et al. [79], who included three additional randomized controlled trials published after the review by Jenkins et al. [78]. These additional interventions included use of the STarT Back tool (i.e., a tool used to stratify LBP patients into different management pathways based on their level of psychosocial risk), and two multifaceted interventions including (i) education sessions, audit and feedback, fast-track referral systems and non-opioid pain management and (ii) education, feedback, and focus groups. These interventions were found to have no effect on reducing LBP imaging. Finally, a systematic review was conducted to determine the effectiveness of interventions to decrease LBP image ordering in the emergency department, but they found only controlled before-after studies and no randomized controlled trials so more work is required in this area as well [80]. As a result, there remains a need to investigate interventions to reduce unnecessary imaging for LBP.

1.5 Barriers to reducing unnecessary imaging for low back pain

Before designing a behaviour change intervention, it is important to understand the reasons for why the target behaviour is or is not occurring in the first place so that the intervention can be developed to address these reasons. Many studies have been conducted to investigate why physicians order unnecessary imaging tests for patients with LBP, and these studies reveal many barriers to changing this behaviour. For example, two systematic reviews of qualitative studies on this topic identified the following clinician-reported barriers to reducing unnecessary imaging requests in practice [81,82]: (i) patient pressure for an image or concrete diagnosis, (ii) ordering an image to avoid conflict or maintain trust with patients who expect an image or concrete diagnosis, (iii) ordering an image to reassure patients, (iv) using imaging as a means of managing the consultation when there is not enough time to explain to patients why scans are not needed, (v) ordering an image in fear of litigation (e.g., due to missing potential red flags during a physical exam), and (vi) lack of confidence in their ability to convince the patient that imaging is not necessary or in their ability to conduct a physical exam. Of these, the most commonly reported barrier was patient pressure for imaging, which suggests that patients' lack of knowledge about LBP diagnosis and the purpose of diagnostic imaging is a primary driver for imaging overuse. Indeed, many studies confirm this from the patient's perspective, showing that 50% or more of the patient population reports expectations for LBP imaging [83–87] and a concrete diagnosis that will explain the cause of their LBP [86,87]. Systematic reviews of qualitative data support this notion, as patients report asking for imaging when physicians do not provide a specific diagnosis for their LBP [88–90].

Changing behaviour to reduce unnecessary imaging is a complex issue involving multiple barriers from both the patient and physician perspective and no interventions have been designed to target all of these barriers [81]. This was confirmed in a follow-up study by Hall et al. [91], who conducted a systematic review to determine which behaviour change techniques have been used in interventions to reduce unnecessary LBP imaging. Behavior change techniques are defined as the *"smallest components compatible with retaining the proposed active ingredients with the minimum of overlap"* [92]. In essence, the researchers coded which components of these interventions targeted the barriers identified in their previous review. Of the 38 studies they included, only 10 and 5 studies, respectively, tested interventions with behaviour change techniques to target the most commonly reported barriers of (i) patient pressure for imaging and (ii) ordering an image to reassure patients that nothing is wrong. This review highlighted that most of the previously tested interventions to reduce unnecessary image ordering were not developed to target the primary drivers of this behaviour, which may contribute to their lack of effectiveness.

Overall, the main physician- and patient-reported barriers to increase physician compliance with LBP image ordering recommendations revolve around patients' lack of understanding about their condition. Patients commonly lack knowledge about non-specific LBP diagnosis and therefore continue seeking a concrete diagnosis to identify the exact origins of their pain, which is most often not possible. In lieu of a satisfactory diagnosis, patients put pressure on clinicians to order an image of their spine to obtain said diagnosis, which is the most common physician-reported barrier. Most interventions that have been designed to reduce LBP imaging to date have been directed towards the

physician and not the patient [81]. However, since one of the primary drivers of unnecessary image ordering comes from patients' lack of knowledge, patient-facing education is well-poised to address this gap in practice.

1.6 Patient education for low back pain

Patient education involves providing information to patients about their condition, including information about diagnosis, prognosis, and treatment options, to increase their knowledge and enable them to make informed decisions about their health behaviours and increase their willingness to adhere to treatments that may improve the course of their condition [93]. Education is an important part of LBP management and is nearly universally recommended as a first-line treatment for LBP (i.e., it is recommended by 17 of 19 clinical practice guidelines [15,34–36,38–46,48–51]). Ten years apart, in both 2008 and 2018, two Lancet series papers stressed the importance of improving public knowledge about LBP [54,94]. This is because evidence from many surveys around the world show that both the general public and people with LBP lack knowledge [95–97] and have unhelpful beliefs [83,88,98] about LBP. Unhelpful beliefs about LBP (also known as "negative beliefs" or "misconceptions") refer to any beliefs that people have about LBP (e.g., LBP management, diagnosis, prognosis, prevention) that conflict with best available evidence. These include fear avoidance (i.e., avoiding movement due to fear of pain or injury) and believing avoiding activity is good, believing that diagnostic imaging will identify the root cause of pain, and that LBP has inevitable negative consequences. Each of these examples conflicts with best available evidence, and unhelpful beliefs like these have been associated with worse LBP outcomes and increased

risk of onset [24,74,98–101], while more positive beliefs are associated with improved outcomes for patients [102,103]. For example, if one associates movement with heightened LBP, they may become fearful of carrying out that movement again [104]. In other words, they have developed a fear of movement (i.e., a fear-avoidance belief). Best evidence suggests that staying active is imperative to LBP recovery [31,33] and fear-avoidance beliefs increase the risk of delayed recovery and greater work absence [104].

Some may argue that knowledge alone is not enough to change behaviour and question the usefulness of patient education as an intervention on its own [105]. This conclusion may be valid in many scenarios for other health conditions. However, a substantial amount of literature over the past two decades indicates that patients with LBP have inaccurate knowledge that may lead to unhelpful beliefs, and that unhelpful beliefs are associated with worse LBP outcomes. In addition, recent systematic reviews using behaviour change theory (e.g., the Theoretical Domains Framework [106] and the Behaviour Change Techniques Taxonomy [107]) have found that one of the primary drivers of unnecessary image ordering comes from patients' lack of knowledge [81,91]. Therefore, if patient education is able to improve patients' knowledge and modify their unhelpful beliefs and expectations for unnecessary imaging, it could be a useful first step in changing physician image-ordering behaviours. Once patients' knowledge is improved, other barriers to image-ordering can be addressed. However, before suggesting patient education as an intervention to address this gap, it is important to review the literature to determine how it is being used in practice and if it is generally effective.

1.6.1 The effectiveness of patient education for low back pain

To inform my research questions I searched the literature to find systematic reviews investigating the effectiveness of patient education for low back pain. I found that many patient education interventions such as individual patient education (i.e., one-on-one health appointments between provider and patient where education about LBP is provided to the patient [108]), back schools (i.e., education programs, typically in the form of didactic lectures on LBP management and prevention, between a therapist and a group of patients with LBP [109]), and pain neuroscience education (i.e., education specifically on the neurophysiology of pain as opposed to general LBP information [110]) have been tested. The evidence shows these patient education interventions are potentially effective for improving various clinical, process, and health system outcomes (Table 1.2). Though some of these reviews show that patient education may be a viable intervention to influence patient behaviour, such as by reducing LBP-related primary care visits [111] and sick leave [112], none investigated the effectiveness of PEMs alone. In addition, though no systematic review has investigated PEMs alone, a recent randomised controlled trial found that provision of a PEM about LBP significantly decreased imaging rates after one year [113]. That being said, it seems there are difficulties with implementing patient education in practice. Recent systematic reviews identified that only 1 in 5 patients receive education from their family practitioner [59] and that, though patients have information needs for which they actively seek education, they find it difficult to find clear and consistent information to address these needs in practice [88]. Patients also report receiving conflicting information from different health providers [88]. These issues are probably complicated by clinical practice guidelines, which lack detail about what

specific types of information clinicians should provide to their patients (Table 1.3). For example, four guidelines recommend providing 'tailored' education to patients, but do not elaborate on how to do this. Others recommend providing education about the 'nature' of LBP, 'neurophysiology,' and/or 'body mechanics' but they do not specify what these mean or what information clinicians should provide about these topics. In addition, only two guidelines recommend providing information to patients about the usefulness of imaging, which perhaps exacerbates the imaging overuse problem. Lancet series papers confirm this issue more generally, stating that guidelines sometimes do not contain sufficient detail for clinicians to follow in order to adhere to best practices [55] and that when guidelines do not suggest explicit ways to implement its recommendations (and they often do not), the effects on clinical practice are minimal or non-existent [17].

Table 1.2 Previous systematic reviews assessing the effectiveness of patient education interventions on low back pain outcomes for patients with non-specific low back pain

Author (Year)	Question(s)	Population	Intervention	Comparison	Outcomes	Findings
Ainpradub (2016) [114]	Effect of education for prevention and treatment of LBP, and to find most effective educational content	Acute, chronic	Education programs	No education program	Pain, disability, fear-avoidance beliefs, quality of life, work absenteeism, prevalence, incidence, work limitations	No effect on any outcome. Conflicting evidence for prevention of LBP.
Barbari (2020) [115]	Effectiveness of communicative and education strategies on awareness and knowledge about LBP and behaviour change	Chronic	Communicative and education strategies	Waiting list, usual care, placebo, no intervention, active/passive treatments	Modification of maladaptive behaviour (e.g., fear-avoidance beliefs, catastrophizing), exercise compliance, LBP awareness and knowledge	Pain science education, either on its own, or in combination with other interventions, significantly improved maladaptive behaviour modification in most studies (5/7 RCTs) at short, mid and long-term compared to other interventions
Brox (2008) [116]	Effectiveness of back schools, brief education, fear-avoidance training	Chronic	Back schools, brief education, fear-avoidance training	Waiting-list control, placebo, usual care, other conservative treatments	Pain, disability, sick leave, cost-effectiveness, recurrence	Back schools & fear-avoidance training: conflicting evidence Brief education: effective for reducing sick leave and disability compared to UC
Clarke (2011) [117]	Determine benefits of pain neurophysiology education on pain intensity, physical function, psychological and social function	Chronic	Pain neurophysiology education	Other education	Pain intensity, physical function, attitudes, catastrophizing, social functioning (work status)	Pain neurophysiology education beneficial for all outcomes compared to other education interventions
Du (2017) [118]	Effectiveness of self-management programs on pain and disability for chronic LBP	Chronic	Self-management programs	Waiting list control, active controls, usual care	Pain, disability	Effective for decreasing pain and disability from immediate to long-term follow-up
Engers (2008) [108]	Effect of individual patient education on pain, global improvement, functioning and return-to-work	Acute, chronic	Individual patient education	No intervention, other interventions, other education interventions	pain, global improvement, functioning, return-to-work	Improves return to work and may improve function for patients with acute/subacute LBP (note no meta-analysis was conducted)

Nicholl (2017) [119]	Effect of digital self-management interventions on LBP outcomes and what are the key components of these interventions	Acute, chronic	Any digital, interactive, self-management intervention where information/materials provided	Usual care, non-digital interventions, non-interactive interventions	Pain, disability, quality of life, depression, fear-avoidance beliefs, catastrophizing, physical activity, medication use, healthcare utilization, cost, knowledge, self-efficacy	There were largely no differences between groups for most studies (note no meta-analysis was conducted)
Oliveira (2012) [120]	Effectiveness of self-management LBP interventions	Acute, chronic	Self-management or self-care interventions	Minimal interventions such as usual care, waiting list control, or written information, as well as other conservative interventions	Pain, disability	Self-management more effective for improving pain and disability than minimal interventions
Parreira (2017) [121]	Effect of back schools for chronic LBP on pain and disability	Chronic	Back schools	Usual care, waiting list, other interventions	Pain, disability, work status, adverse events	Weak evidence that back school reduces pain and disability when compared to usual care or no intervention
Straube (2016) [122]	Effect of back schools on chronic LBP	Chronic	Back schools	Any intervention, no intervention	Pain, sick leave, pain interference with work and activities of daily living	Back schools reduced pain and disability in short term when compared to no treatment
Tegner (2018) [123]	Effectiveness of neurophysiological pain education for chronic LBP	Chronic	Neurophysiological pain education	Usual care, no intervention	Pain, disability, behavioral attitudes	Neurophysiological pain education reduced pain and disability compared to usual care and no intervention
Traeger (2015) [124]	Effectiveness of patient education in primary care to increase reassurance in patients with acute and subacute LBP	Acute	Individual patient education	Usual care, attention control, placebo booklets	Reassurance (pooled measures of fear-avoidance beliefs, anxiety, worry, distress, catastrophizing, healthcare utilization)	Individual patient education increased reassurance in both short- and long-term follow-ups, and reduced LBP-related healthcare visits in long-term

Zahari (2020) [125]	Effectiveness of patient education for elderly LBP patients	Not specified	Patient education	Before and after	Pain, disability, quality of life	Authors concluded that patient education improves pain, disability and quality of life, but this should be interpreted with caution as they do not perform a meta-analysis and only comment on before and after scores

Abbreviations: LBP = low back pain

Table 1.3. Recommendations for education in clinical practice guidelines for low back pain

Author/institution (year, location)	**Guideline name**	**LBP Population**	**Education recommendations copied verbatim from each guideline**
Philippine Academy of Rehabilitation Medicine (2011, the Philippines) [34]	Low back pain management guideline	Acute, subacute, chronic	ACUTE, SUBACUTE, CHRONIC: *Education to avoid bed rest (no more than two days if needed), stay active, continue usual activities including work, education about risk factors (e.g., limit activities that causes spread of symptoms such as lifting or gardening)*
Toward Optimized Practice (2015, Canada) [39]	Evidence-informed primary care management of low back pain	Prevention, acute, subacute, chronic	PREVENTION: *Information on how to care for your back and emphasize patient responsibility and workplace ergonomics, information on prognosis (benign nature, generally gets better within 6 weeks), recommend against providing education based on biomedical/biomechanical model as this can convey negative messages about LBP.* ACUTE, SUBACUTE: *education about prognosis (benign, long-term course of LBP), advice to stay active and continue usual activities including work, recommend physical exercise, self-management strategies, limit activity that causes peripheralization.* CHRONIC: *provision of low back pain information, advice to stay active, education to reduce fear and catastrophizing*
Chenot et al. (2017, Germany) [36]	Non-specific low back pain	Any duration	*Tailored education based on patient's individual risk profile, discuss patient's psychosocial risk factors and advise self-management, advice to stay or become physically active and advise against bed rest*
Elleuch et al. (2015, Africa) [38]	Formalized consensus: clinical practice recommendations for the management of acute low back pain of the African patient	Any duration	*Reassure about good prognosis (improvement usually within less than a month), education about risk factors and hypothetical causes*

Guevara-López et al. (2011, Mexico) [40]	Practice guidelines for the management of low back pain	Acute, Subacute, Chronic	ACUTE, SUBACUTE: *education to avoid bed rest* CHRONIC: none
Malaysian association for the study of pain (2016, Malaysia) [41]	Malaysian low back pain management guideline	Acute, Chronic	ACUTE: *Advice to stay active (reassure them that it is fine to stay active despite the pain), continue usual activities, avoid bed rest, education about posture and body mechanics* CHRONIC: none
Marques (2006, Spain) [42]	The treatment of low back pain and scientific evidence	Acute, Subacute, Chronic	ACUTE, SUBACUTE, CHRONIC: *Avoid bed rest, information about prognosis (spontaneous recovery within 2-6 weeks, reassurance that pain is not due to serious illness), discuss how pain can emanate from structures of the spine, suggest physical activity including work if possible, provide positive reinforcement to patient*
National Institute for Health and Care Excellence (2017, United Kingdom) [15]	Low back pain and sciatica in over 16s: assessment and management	Any duration	*Provide tailored information based on individual needs and capabilities to help patient self-manage their LBP. Include information on the nature of low back pain and sciatica, and encouragement to continue with normal activities*
NSW Agency for Clinical Innovation (2016, Australia) [43]	Management of people with acute low back pain: model of care	Acute	*Reassure that LBP is a symptom, not a serious disease that should cause long-term disability, reassure about good prognosis (e.g., most LBP gets better quickly), avoid patient labeling (e.g., labeling LBP as an injury, disc trouble, degeneration or wear and tear), advice to stay active and continue daily activities including work, information about recurrent symptoms and how to deal with them, avoid 'let pain be your guide,' encourage patients to take responsibility and self-manage, use phrases like "backache should not cripple you unless you let it."*
Pohjolainen et al. (2015, Finland) [45]	Update on current care guideline: low back pain	Acute, Subacute, Chronic	*Could not obtain translation, however, Oliveira et al. [31] report that this guideline recommends avoiding bed rest, advice to maintain normal activities, and reassurance. These recommendations were for any duration of symptoms.

American College of Physicians (2017, United States) [46]	Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians	Acute, Subacute, Chronic	ACUTE, SUBACUTE: *inform of generally favorable prognosis (usually improves within the first month, improves over time regardless of treatment), and patient's expected course, advice to remain active as tolerated, information about effective self-care options* CHRONIC: *advice to remain active as tolerated*
Rached et al. (2013, Brazil) [47]	Lombalgia inespecífica crônica: reabilitação	Chronic	None provided
Stochkendahl et al. (2018, Denmark) [48]	National Clinical Guidelines for non-surgical treatment of patients with recent onset low back pain or lumbar radiculopathy	Acute	*Advice to remain physically active, reassurance to reduce worries and fears of illness, provide actionable recommendations*
Van Tulder et al. (2010, the Netherlands) [50]	Ketenzorgrichtlijn aspecifieke lage rugklachten	Acute, Chronic	ACUTE, CHRONIC: *recommendation to use brochures provided within the guideline that cover information about what is non-specific LBP (e.g., no indications of pinched nerve, disease, or damage), prognosis (goes away on its own within a few days or weeks), usefulness of imaging, advice to stay active and continue usual daily activities even with pain, maintain good posture, causes of LBP (e.g., lifting too quickly, too heavy, etc.), and things to avoid (e.g., avoid standing or sitting in same position for long periods of time, avoid bending over quickly, avoid lifting heavy things, avoid twisting with the lower back)*
Belgian Health Care Knowledge Centre (2017, Belgium) [51]	Low back pain and radicular pain: assessment and management	Any duration	*Provide tailored advice and information to help them self-manage their LBP. Provide information on the benign nature of low back pain and radicular pain, encouragement to continue with normal activities (including exercise), and reassurance*

Institute for Clinical Systems Improvement (2018, United States) [49]	Adult Acute and Subacute Low Back Pain	Acute, subacute	ACUTE, SUBACUTE: *Tailored information on treatment and recovery expectations; education to specifically address fear-avoidance, catastrophizing, or anxious behaviours; reassurance of good prognosis, that pain does not equal harm, and that most LBP cannot be attributed to specific cause; education about imaging and how it is not helpful for non-specific LBP (i.e., where the provider is not concerned about a serious underlying cause such as infection, fracture or cancer); education about the role of medications for LBP; advice to remain active and continue with daily activities even with discomfort; education about warning signs of underlying pathology which may require follow-up*
American Pain Society (2009, United States) [37]	Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society	Subacute, chronic	None provided, however the intended focus of this guideline was on interventional therapies, surgery, and interdisciplinary rehabilitation, so education may have been outside the scope of this guideline
Canadian chiropractic guideline initiative (2018, Canada) [35]	Spinal manipulative therapy and other conservative treatments for low back pain: a guideline from the Canadian chiropractic guideline initiative	Acute, chronic	ACUTE: *advice on posture and physical activity* CHRONIC: *advice, educational material*

United States Department of Veterans Affairs and Department of Defense (2019, United States) [34]	VA/DoD clinical practice guideline: diagnosis and treatment of low back pain	Acute, subacute, chronic	ACUTE, SUBACUTE, CHRONIC: *Education on nature of LBP, importance of staying active, self-care treatments such as weight loss and smoking/tobacco cessation, education about neurophysiology*

1.6.2 Patient education materials to address barriers for reducing unnecessary LBP imaging

PEMs are a potential solution to facilitate the provision of clear, consistent, and evidence-based information because they are relatively inexpensive, quick to provide to patients in practice, and unlikely to cause harm. They can address many barriers for improving physician compliance with LBP imaging recommendations and are potentially useful resources for clinicians who may find it difficult to provide education in practice due to the ambiguity of guideline recommendations. In Table 1.4, I provide more detail as to how PEMs may be able to address many of the barriers described in section 1.5. It is important to note, however, that the systematic reviews by Slade et al. [82] and Hall et al. [81] identified additional barriers that PEMs may not be able to address, such as (i) ordering an image out of fear of missing red flags on a physical exam, (ii) lack of confidence in ability to conduct a physical exam, or (iii) ordering an image because it is a requirement for the patient's sick certification. Therefore, PEMs do not target every known barrier for LBP imaging overuse, but they target many of them. Further, PEMs can easily be incorporated into other interventions that target the remaining barriers.

Table 1.4. Reasons for why patient education materials may address physician and patient-oriented barriers to improving physician compliance with guideline-recommended imaging ordering practices for low back pain

Barriers identified from the literature	**How can patient education materials address this barrier?**
Patient pressure to get an image or concrete diagnosis	Providing patients with clear, consistent, and accurate information about LBP diagnosis (e.g., 'physicians are trained to identify red flags during physical exams,' 'imaging is only needed in the presence of red flags and does not detect anything useful in the absence of red flags,' or 'the way we manage your low back pain will most likely be the same with and without imaging') may reduce patient expectations to get an unnecessary image, thereby reducing the likelihood they will put pressure on the physician by requesting an unnecessary image
Ordering an image to avoid conflict or maintain trust with patients who expect an image or concrete diagnosis	As described above, if patients receive education that addresses their misconceptions about diagnostic imaging for LBP, it is possible that this may reduce their likelihood of requesting an image, which would avoid putting providers in a difficult position where they feel obliged to request the image in order to maintain trust or avoid conflict
Ordering images to reassure patients	If patients are properly educated about their LBP, including information that could reassure them about their condition (e.g., 'LBP has a favourable prognosis and usually gets better within a few weeks for most people,' 'the vast majority of people have 'simple' LBP which means there is nothing seriously wrong with their back'), they may no longer require additional reassurance from diagnostic imaging, especially if they are provided with information to increase their understanding of the intended use of diagnostic imaging for LBP
Ordering images as a means of managing the consultation due to lack of time (e.g., not enough time to explain to patient why scans not needed)	Physicians do not have enough time to provide in-depth explanations about why LBP imaging is not helpful to every patient, so perhaps putting all the relevant information in a patient education material that they can quickly provide to their patients and use as a supplement to very brief verbal education would be a potential solution for this
Lack of confidence in ability to convince patients that imaging is not necessary	Physicians can use the patient education material as a guide for what important information to tell patients regarding LBP imaging, referring to the material as a credible source that corroborates what they are saying. Some materials also contain prescription pads that can support the physician in providing detailed management and diagnostic plans to patients

Abbreviations: LBP = low back pain

1.6.3 Content and design of patient education materials

A large number of systematic reviews have investigated the effectiveness of educational interventions for LBP (Table 1.2) but comparatively little research investigated the content of these interventions. To our knowledge, only two studies specifically assessed PEMs for LBP in terms of their content by investigating the accuracy of their treatment recommendations [126,127]. Furthermore, no studies to determine the specific information PEMs for LBP should contain have been conducted and no one has assessed existing PEMs to determine whether they contain this information. Indeed, amongst the systematic reviews (Table 1.2) that tested the effectiveness of a broader array of educational interventions for LBP, many noted that there was considerable variation in the content among these interventions [111,112,128–130] and that more work is required to determine what content should be included [13,112]. These findings, combined with the ambiguity of guideline recommendations for LBP education discussed in section 1.6.1, suggest that the literature remains uncertain about what content should be included in educational interventions for LBP. This is an important gap to address because a recent systematic review identified that patients have many information needs for which they actively seek education, but have difficulty finding clear and consistent information to address these needs in practice [88]. Thus, perhaps the best place to start in addressing this gap would be to determine if PEMs for LBP contain information that relates to concepts that are important to both patients and providers. To my knowledge, no such assessment tool is available in the literature and therefore I sought to develop one in Chapter 4 of this thesis.

Little is known about how PEMs have been developed. For example, in their Cochrane review to investigate the effectiveness of individual patient education interventions on clinical LBP outcomes, Engers et al. [13] state that none of the included studies reported using a theoretical model to develop their intervention. Further, though some reviews extracted data on additional intervention characteristics such as frequency and duration, none used the TIDieR checklist (a 12-item reporting guideline for intervention characteristics to enhance the description and replicability of interventions) [131] to guide data extraction of intervention characteristics. Therefore, very little is known about how these interventions were designed (e.g., the rationale or theory behind them), nor is much known about other important elements described in the TIDieR checklist such as the fidelity of these interventions (i.e., if the intervention was delivered as planned). It is also unclear whether these interventions were co-developed with patients, as this has not been investigated thoroughly by any of the existing reviews. Co-developing educational interventions with patients is important because patients are the end-users of these interventions. Involving their perspectives in intervention design can make these interventions more relevant to patients and their local context and better address their needs [132]. Therefore, in our Chapter 2 systematic review on the effectiveness of PEMs on various LBP outcomes, I also included a detailed description of all included PEMs using the twelve TIDieR checklist elements to gain a better understanding of how these interventions were developed, and whether they were co-developed with patients.

1.6.4 Patient education materials' readiness for use in practice

In addition to evaluating the content of PEMs for LBP, it is important to assess their readiness for use in practice in terms of how the content is written and presented. This can be done by using evidence-based and validated assessment tools designed specifically to evaluate PEMs and other health information such as the Patient Education Material Assessment Tool (PEMAT) to assess whether the information is understandable (i.e., patients can process and describe the information) and actionable (i.e., patients can carry out some action based on the information) [133], as well as the DISCERN tool to assess whether the information is of high-quality (i.e., the information is reliable or trustworthy) [134]. The Flesch Reading Ease (FRE) and Flesch-Kincaid Grade-Level (FKGL) algorithms can also be used to assess whether the information contained in PEMs is readable (i.e., patients can easily read or understand the information) [135]. However, only two studies have assessed the readability [127] and quality [126,127] of websites about LBP identified through the Google search engine and reported that these websites scored poorly in both areas. No study to date has evaluated PEMs for LBP identified through peer-reviewed literature, which is a potentially higher-quality source of PEMs that are ready for use in practice. Additionally, no study has assessed the understandability or actionability of PEMs for LBP using the PEMAT [133], which is a validated [133,136] assessment tool for PEMs commonly used in the literature for other health conditions such as laryngectomy [137], breast cancer risk assessment [138], hypertension [139], and Zenker's Diverticulum [140] with moderate to high inter-rater reliability. Therefore, I assessed PEMs for LBP identified from synthesized, peer-

reviewed literature in Chapter 5 with a battery of these evidence-based and validated assessment tools in order to find the best available PEMs for use in practice.

1.7 Research objectives

Overall, patient education is nearly universally recommended as a first-line treatment for patients with LBP [15,34–36,38–46,48–51] because patients across the world lack knowledge [95–97] and have unhelpful beliefs or misconceptions about LBP [83,88,98]. These misconceptions include expectations for unnecessary imaging, which physicians report is a primary driver of imaging overuse [81,91]. Education can address these problems by providing accurate information about LBP to increase knowledge, which may thereby influence patients' unhelpful beliefs that are associated with poor LBP outcomes. However, patients report finding it difficult to obtain clear and consistent information in practice [88] and they also report rarely receiving education from their family physician [59]. PEMs for LBP are a potential solution to facilitate the provision of clear, consistent, and evidence-based education because they are relatively inexpensive and easy to provide. Further, as outlined in Table 1.4, they may address many patient- and physician-oriented barriers to reducing unnecessary imaging. However, little is known about PEMs for LBP because no systematic review has been conducted to determine their effectiveness alone. We also know little about other educational interventions in terms of their design and content because most research on these interventions has focused on testing their effectiveness rather than investigating these important content and design elements (e.g., [108,116–120,122–125,128–130]). Therefore, the goal of this thesis was to gain a better understanding of PEMs for LBP in terms of their effectiveness, content, and

readiness for use in practice in order to determine their potential as a tool to support family physicians in reducing unnecessary imaging for LBP. In addition, since the evidence suggests that patients and providers have misconceptions about LBP treatments, I aimed to determine the analgesic effects of all conservative treatments for LBP, which can also be used to supply patient education interventions with the most up-to-date and comprehensive evidence around LBP treatments. To achieve my thesis objectives, I conducted four studies (Chapters 2-5), which provide a basis of evidence to determine whether existing PEMs for LBP suffice or if they require improvement to more effectively improve LBP outcomes in practice. Below, I outline the specific objectives of each study I conducted to achieve this goal.

Chapter 2: In order to better understand how PEMs have been used to improve LBP outcomes, I conducted a literature search to identify systematic reviews investigating PEMs for LBP. I identified numerous systematic reviews on various educational interventions for LBP [13,111,112,128–130,141–147] (Table 1.2), but none assessed the effectiveness of PEMs alone. Instead, they investigated individual patient education [13,111], specific delivery methods of education such as communicative education strategies [128,147], select educational topics such as neurophysiological pain education [141,147], or more intensive formats of education such as multi-session or multi-component education programs [112,129,130,142–146]. The goal of Chapter 2 was to address this gap in the literature by conducting a systematic review and meta-analysis to investigate the effectiveness of PEMs for LBP alone compared to no intervention and other interventions on various clinical (e.g., pain and disability), process (e.g., knowledge

and pain self-efficacy), and health system (e.g., days off work, imaging rates) outcomes for acute and chronic LBP.

Chapter 3: The content in PEMs for LBP typically includes information about diagnosis, prognosis, and treatment. Diagnosis and prognosis information for LBP have remained largely unchanged in recent literature, but evidence around LBP treatments is continuously changing and the use of low-value treatments remains widespread [54]. The goal of Chapter 3 is to provide up-to-date information about LBP treatments so that we can include it in future PEMs. To do this, I conducted a systematic review and meta-analysis to investigate the analgesic effects of conservative treatments for acute and chronic LBP compared with placebo.

Chapter 4: A substantial amount of literature has been conducted to determine the effectiveness of various educational interventions on LBP outcomes, but comparatively little research has been done to evaluate the content of these interventions. This is likely due, in part, to the fact that there are no evidence-based assessment tools to assess LBP-related content, nor are there any standardized lists of learning objectives outlining what patients with LBP should know. This gap is apparent in clinical practice guidelines, which often recommend providing education to patients with LBP without detailing what specific types of information to provide. The goal of Chapter 4 is to address this evidence gap by developing a novel, evidence-based checklist outlining patient information needs (i.e., what patients want to know) and patient education needs (i.e., what clinicians and researchers want patients to know).

Chapter 5: Few systematic assessments on PEMs for LBP have been conducted and the best available PEMs that clinicians can use in practice is, therefore, unclear. It is also unclear how most PEMs for LBP were developed and none have been assessed to determine if their content is relevant to patients' needs. The goal of Chapter 5 was to find the best available PEMs for use in practice and whether they require improvement. To do this, I conducted a study using the checklist developed in Chapter 4 alongside a comprehensive battery of evidence-based and validated assessment tools to assess PEMs in terms of their content (i.e., is their content accurate, comprehensive, and does it contain information about patients' needs) and readiness for use in practice (i.e., is the information understandable, actionable, readable, and of high-quality).

CHAPTER 2: Patient education materials for non-specific low back pain and sciatica: A systematic review and meta-analysis

Preface

This manuscript has been published in PLoS One. Furlong, B., Etchegary, H., Aubrey-Bassler, K., Swab, M., Pike, A., & Hall, A. (2022). Patient education materials for non-specific low back pain and sciatica: A systematic review and meta-analysis. PLoS One, 17(10), e0274527. doi:10.1371/journal.pone.0274527.

Co-authorship statement: BF, AH, HE, and KAB conceptualized the idea for this project. BF read relevant literature and reporting guidelines, narrowed the research questions, specified the inclusion and exclusion criteria, drafted the protocol, and then had it reviewed by the broader team. BF worked with MS in specifying the search criteria. MS conducted the searches. BF conducted all study selection, data extraction, quality appraisal, and data analysis. BF interpreted all data and wrote the first draft of the manuscript. All authors reviewed the manuscript and have read and approved of the final version.

Abstract

Introduction: Guidelines recommend patient education materials (PEMs) for low back pain (LBP), but no systematic review has assessed PEMs on their own. We investigated the effectiveness of PEMs on process, clinical, and health system outcomes for LBP and sciatica.

Methods: Systematic searches were performed in MEDLINE, EMBASE, CINAHL, PsycINFO, SPORTDiscus, trial registries and grey literature through OpenGrey. We included randomized controlled trials of PEMs for LBP. Data extraction, risk of bias, and quality of evidence gradings were performed independently by two reviewers. Standardized mean differences or risk ratios and 95% confidence intervals were calculated, and effect sizes pooled using random-effects models. Analyses of acute/subacute LBP were performed separately from chronic LBP at immediate, short, medium, and long-term (6, 12, 24, and 52 weeks, respectively).

Results: 27 studies were identified. Compared to usual care for chronic LBP, we found moderate to low-quality evidence that PEMs improved pain intensity at immediate (SMD = -0.16 [95% CI: -0.29, -0.03]), short (SMD = -0.44 [95% CI: -0.88, 0.00]), medium (SMD = -0.53 [95% CI: -1.01, -0.05]), and long-term (SMD = -0.21 [95% CI: -0.41, -0.01]), medium-term disability (SMD = -0.32 [95% CI: -0.61, -0.03]), quality of life at short (SMD = -0.17 [95% CI: -0.30, -0.04]) and medium-term (SMD = -0.23 [95% CI: -0.41, -0.04]) and very low-quality evidence that PEMs improved global improvement ratings at immediate (SMD = -0.40 [95% CI: -0.58, -0.21]), short (SMD = -0.42 [95% CI: -0.60, -0.24]), medium (SMD = -0.46 [95% CI: -0.65, -0.28]), and long-term (SMD = -

0.43 [95% CI: -0.61, -0.24]). We found very low-quality evidence that PEMs improved pain self-efficacy at immediate (SMD = -0.21 [95% CI: -0.39, -0.03]), short (SMD = -0.25 [95% CI: -0.43, -0.06]), medium (SMD = -0.23 [95% CI: -0.41, -0.05]), and long-term (SMD = -0.32 [95% CI: -0.50, -0.13]), and reduced medium-term fear-avoidance beliefs (SMD = -0.24 [95% CI: -0.43, -0.06]) and long-term stress (SMD = -0.21 [95% CI: -0.39, -0.03]). Compared to usual care for acute LBP, we found high to moderate-quality evidence that PEMs improved short-term pain intensity (SMD = -0.24 [95% CI: -0.42, -0.06]) and immediate-term quality of life (SMD = -0.24 [95% CI: -0.42, -0.07]). We found low to very low-quality evidence that PEMs increased knowledge at immediate (SMD = -0.51 [95% CI: -0.72, -0.31]), short (SMD = -0.48 [95% CI: -0.90, -0.05]), and long-term (RR = 1.28 [95% CI: 1.10, 1.49]) and pain self-efficacy at short (SMD = -0.78 [95% CI: -0.98, -0.58]) and long-term (SMD = -0.32 [95% CI: -0.52, -0.12]). We found moderate to very low-quality evidence that PEMs reduced short-term days off work (SMD = -0.35 [95% CI: -0.63, -0.08]), long-term imaging referrals (RR = 0.60 [95% CI: 0.41, 0.89]), and long-term physician visits (SMD = -0.16 [95% CI: -0.26, -0.05]). Compared to other interventions (e.g., yoga, Pilates), PEMs had no effect or were less effective for acute/subacute and chronic LBP.

Conclusions: There was a high degree of variability across outcomes and time points, but providing PEMs appears favorable to usual care as we observed many small, positive patient and system impacts for acute/subacute and chronic LBP. PEMs were generally less effective than other interventions; however, no cost effectiveness analyses were

performed to weigh the relative benefits of these interventions to the likely less costly PEMs.

2.1 Introduction

Low back pain (LBP) accounts for more disability than any other musculoskeletal condition [148] and is among the five most common reasons why patients visit their family physicians [149]. It represents a substantial economic burden resulting from both direct (e.g., health care costs) and indirect costs [150] (e.g., productivity loss and compensation claims) [151,152].

International, evidence-based guidelines for the treatment and management of LBP [153–157] recommend that for non-specific LBP (LBP that is not attributable to a recognizable, specific pathology) [53] investigations such as imaging are not required. Instead, they recommend that management should include reassurance, simple analgesics, self-care strategies, and advice and education. Patient education materials (PEMs) for LBP are intended to transfer accurate knowledge about diagnosis, prognosis, and ways to manage pain and aid recovery in order to correct false/unhelpful beliefs, reassure patients about prognosis, and manage their expectations of recovery. We hypothesized that by modifying beliefs and expectations, PEMs may reduce fear or concern related to pain, modify patients' experience of pain and expectation for unnecessary tests or other referrals, and increase patients' self-efficacy to engage in recommended strategies to manage pain which should facilitate recovery.

Indeed, Lim et al. [158] recently showed that people living with LBP want education – specifically, clear and consistent information about their LBP presented in language they can follow that includes self-management strategies and treatment options. Other systematic reviews have assessed patient education for LBP [111,112,128–

130,141–147,159] as discussed in our protocol [160]. The most relevant review was published in 2008 [13], but variation in the education interventions of the 24 studies precluded meta-analysis limiting our understanding of the effectiveness of PEMs. Subsequent reviews have focused on clinical outcomes or broader interventions and therefore, none have fully assessed outcomes that would test our hypothesis.

This is the first systematic review and meta-analysis to investigate the effect of PEMs alone on a comprehensive set of outcomes for non-specific LBP and sciatica. The primary aim of this review is to provide up-to-date evidence on the effectiveness of these materials on immediate process outcomes such as knowledge, attitudes, and fear-avoidance beliefs; clinical outcomes such as pain and physical disability; and health system outcomes such as healthcare utilization and cost effectiveness in patients with acute and chronic non-specific LBP or sciatica.

2.2 Methods

We published our protocol for this systematic review and meta-analysis [160] (Appendix 2.1).

2.2.1 Search strategy

A professional librarian adapted the search strategy (Appendix 2.2) used by Engers et al., [13] which was later peer-reviewed following the Peer Review of Electronic Search Strategies (PRESS) guidelines [161]. They searched MEDLINE, EMBASE, CINAHL, PsycINFO, and SPORTDiscus from inception to March 24, 2022, as well as trial registries and grey literature using OpenGrey.

2.2.2 Study selection

Results from the electronic database search were de-duplicated in Endnote [162] and imported to Covidence systematic review software [163]. Google translate was used for all non-English articles and study authors were contacted for clarification if needed. Title and abstract and full-text review were conducted by two reviewers (BF, one of GD, AS, SG; see acknowledgements) using a screening form that included pre-specified inclusion and exclusion criteria (Appendix 2.3); conflicts were resolved by a third reviewer (AH). Reference lists of relevant studies were hand-searched, and authors of conference abstracts or ongoing trials were contacted to identify additional studies. If a paper related to a study identified in a conference abstract could not be found, it was excluded.

2.2.3 Data extraction

Two reviewers (BF, one of AS, SG; see acknowledgements) independently extracted data for all studies using standardized data extraction forms in Microsoft Excel, and conflicts were resolved by a third reviewer (AH). Data items included study information (authors, year of publication, country of data collection, LBP type and duration, sample size, outcome measures, study design, intervention group description, comparison group description), intervention details using the 12 variables in the TIDieR checklist [131] and outcome information (measurement tools, measurement scales, scoring methods and interpretation, means, and standard deviations).

2.2.4 Risk of bias assessment

Risk of bias was assessed using the PEDro scale [164]. A study was at high risk of bias if 0-3 criteria on the scale were satisfied, moderate if 4-6 criteria were satisfied, and low if 7-10 criteria were satisfied. However, if randomization was not appropriate (e.g., quasi-randomization) or there was less than 85% follow-up, the study was considered to be at high risk of bias. PEDro scores were extracted from the PEDro database if available (BF); otherwise, two reviewers (BF, AH) independently assessed risk of bias for each study. Conflicts were discussed and, if necessary, reviewed with a third author (AP) to reach consensus.

2.2.5 Data synthesis

We included the following contrasts:

1. PEMs alone vs. no intervention
2. PEMs alone vs. another intervention
3. PEMs + another intervention vs. the same intervention without PEMs

Analyses were conducted separately for acute/sub-acute (pain<12 weeks) and chronic (pain≥ 12 weeks) populations for all outcomes at immediate, short, medium, and long-term (defined as the closest follow-up time point to 6, 12, 24 and 52 weeks, respectively). For immediate-term follow-up only, if a study measured more than once during our defined timeframe (e.g., at both 2 weeks and 6 weeks), we chose the closest follow-up measure after the intervention was provided to get a more accurate depiction of the intervention's "immediate" effect. For other time points, if a study measured more

than once within our specified timeframe, we chose the time point closest to 12, 24, or 52 weeks.

2.2.6 Effectiveness analysis

Point estimates of effect size and 95% confidence intervals were used to estimate the treatment effect. Review Manager (RevMan) 5.4.1 (The Cochrane Collaboration) was used for the analysis [165]. Since different measurement tools were used for each outcome, we used the standardized mean difference for all analyses of continuous outcomes. Risk ratios were used for dichotomous outcomes. Where outcome data from multiple studies was pooled but the measurement scales pointed in different directions (e.g., one scale increased with disease severity while the others did not), we multiplied the point estimates by –1 to reverse the direction as described in the Cochrane handbook [166]. Where data for the same outcome were reported continuously and dichotomously between studies, we transformed dichotomous data into the SMD where possible using the methods described in the Cochrane handbook [167] to allow for pooling of treatment effects. Otherwise, SMD and RR were reported separately. A random-effects model was used for each contrast since variation between each intervention was likely. We pooled the results if the participants, interventions, and outcomes were sufficiently homogenous, allowing for a small degree of clinical heterogeneity in the types of PEMs (e.g., content or delivery of the intervention) and populations assessed (e.g., duration of low back pain). If $I^2 > 75\%$, which represents potential for considerable statistical heterogeneity [168], we investigated both the level of clinical heterogeneity as well as the magnitude and direction

of the differences in effect sizes across studies to determine if it remained reasonable to pool the results.

2.2.7 Certainty of the evidence

To assess the level of certainty of the evidence, a summary of findings table was developed for each outcome using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach [169]. GRADE was assessed independently by two reviewers (BF, AH); our process for downgrading each of the five domains can be found in our published protocol [160] (Appendix 2.1) and in Appendix 2.3. Conflicts were discussed and, if necessary, reviewed with a third author (AP) to reach consensus.

2.2.8 Sensitivity and subgroup analyses

Our primary analyses included all studies, but we excluded studies judged to be at high risk of bias due to concerns about the randomization process in a sensitivity analysis to determine if these studies influenced the results.

2.2.9 Missing data

In cases where only the between group mean difference was provided in a study and we could not obtain the individual group summary data from the study's authors, we used the generic inverse variance method to pool this data with that of the other studies [170]. A more complete explanation of missing data treatment is described in our protocol [160].

2.2.10 Protocol deviations

We made minor deviations (further described in Appendix 2.3) to our published protocol [160] (Appendix 2.1). Of note, due to small number of studies with physician-provided PEMs, we expanded our criteria to include studies where a member of the study's research team was responsible for providing the PEMs.

2.3 Results

2.3.1 Description of included trials (Table 2.1)

Of the 6435 unique records identified, 537 full texts were reviewed, and 27 included in the review (Figure 2.1). Most trials were conducted in the United States [171–180], followed by three in the United Kingdom [181–183], two each in Spain [184,185], Sweden [186,187], and Thailand [188,189], and one each in Australia [190], Croatia [191], Finland [113], Germany [192], Iran [193], the Netherlands [194], and New Zealand [195]. One trial was conducted in both Denmark and Norway [196]. There were 21 RCTs [171–181,183–188,190–192,196] and six cluster RCTs [113,182,189,193–195], and participants were recruited largely through primary care [113,173,174,177–185,191,192,194–196]. Twelve trials included participants with acute LBP [113,171,173,181–183,186,187,189,192,194,195] and 15 with chronic LBP [172,174–180,184,185,188,190,191,193,196]. PEMs interventions were compared to usual care in 14 studies [113,171,180–183,185,187,190,192–196] and other interventions in 13 studies including Pilates [184], Yoga [177–179,191], exercise [189], stretching [172], proprioceptive neuromuscular facilitation [188], massage [174], walking [176], chiropractic manipulation [173], and cognitive behavioral therapy [175,186].

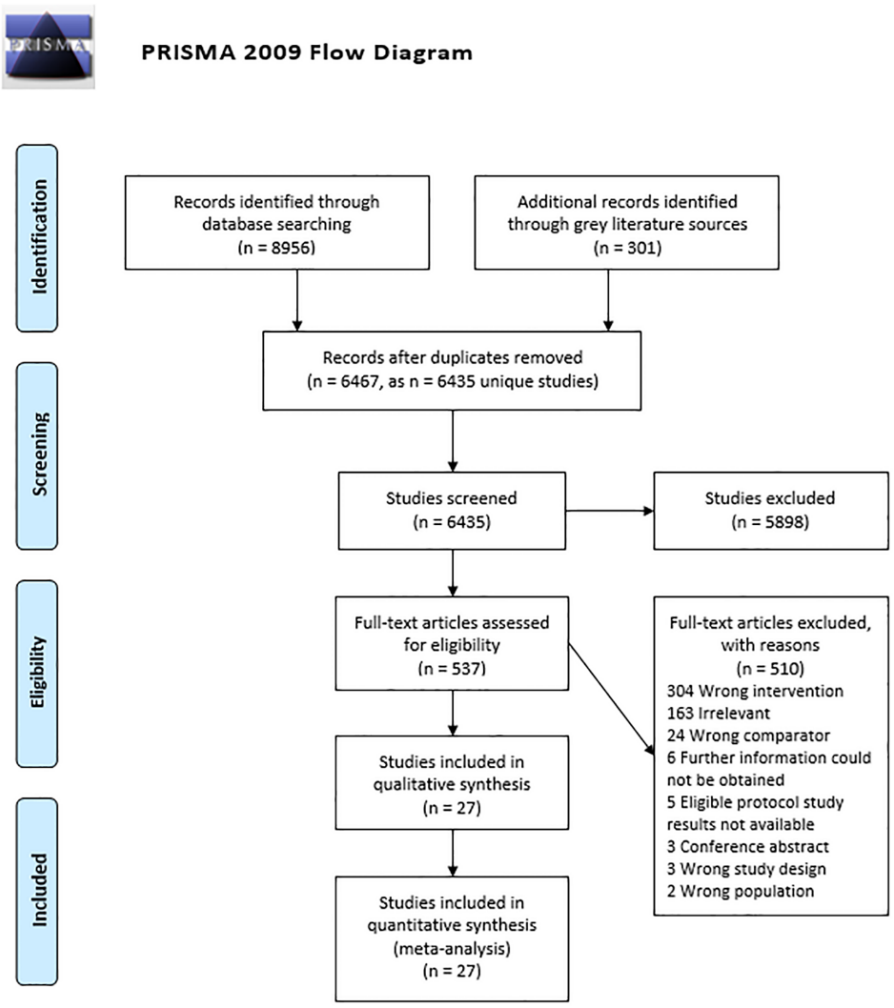

Figure 2.1. PRISMA flow diagram of the systematic literature search

Table 2.1. Study characteristics

Study Year, Country	Age, M (SD)	Recruitment[+]	Education group (n)	Comparison (n)	Knowledge	Self-efficacy	Attitudes	General beliefs	Fear-avoidance	Catastrophizing	Coping	Anxiety	Stress	Depression	Pain	Disability	Quality of life	Global	Function	Days off work	Imaging	Physician visits	Referrals	Cost	Risk of Bias
ACUTE																									
Bucker 2010, DE	I: 45.8 (14.3) C: 43.1 (12.4)	Primary care	Booklet[¥] (n=128)	Unrelated booklet (n=61)	Y				Y							Y	Y								High
Cherkin 1998, US	I: 40.1 (11.2) C: 39.7 (9.4)	Primary care	Booklet (n=66)	Chiropractic manipulation (n=122)											Y	Y				Y					Low
Darlow 2019, NZ	I: 46.2 (14.5) C: 45.9 (14.4)	Primary care	Booklet (n=126)	Usual care (n=100)		Y			Y	Y		Y			Y	Y								Y	Low
Irvine 2015, SE	NR	Community	Website (n=199)	Usual care (n=199)	Y	Y				Y					Y	Y	Y								Mod
Jellema 2005, NL	I: 43.4 (11.1) C: 42.0 (12.0)	Primary care	Booklet (n=143)	Usual care (n=171)					Y	Y		Y			Y	Y	Y	Y		Y					Mod
Linton 2000, SE	I: 44.0 (NR) C: 44.0 (NR)	Mixed	Booklet (n=70)	CBT (n=107)					Y	Y		Y		Y	Y	Y				Y		Y			Low
Little 2001, UK	I: 42.0 (14.0) C: 47.0 (17.0)	Primary care	Booklet (n=81)	Usual care (n=78)	Y											Y									High
Lorig 2002, US	I: 47.0 (11.6) C: 45.0 (0.9)	Community	Booklet, video (n=190)	Usual care (n=231)		Y						Y			Y	Y						Y			High
Roberts 2002, UK	I: 39.2 (10.9) C: 39.3 (9.7)	Primary care	Booklet (n=36)	Usual care (n=28)	Y	Y										Y									Mod
Roland 1989, UK	O: 38.0 (NR)	Primary care	Booklet (n=483)	Usual care (n=453)	Y															Y		Y	Y		High
Sihawong 2021, TH	I: 40.2 (10.3) C: 41.6 (12.5)	Community	Booklet (n=20)	Exercise program (n=11)											Y	Y									Mod
Simula 2021, FI	I: 41.4 (12.8) C: 44.6 (12.6)	Primary care	Booklet (n=215)	Usual care (n=203)											Y	Y	Y			Y	Y	Y			High
CHRONIC																									

Areeudom-wong 2017, TH	I: 35.4 (10.3) C: 36.2 (9.9)	Community	Booklet (n=21)	PNF (n=21)											Y	Y	Y								High
Brodsky 2019, US	I: 48.0 (10.1) C: 49.9 (8.7)	Community	Booklet (n=35)	Stretching exercise (n=43)											Y	Y									High
Cherkin 2001, US	I: 43.8 (11.7) C: 45.7 (11.4)	Primary care	Booklet, videos (n=90)	Massage (n=78)											Y	Y	Y			Y					Low
Chiauzzi 2010, US	O: 46.1 (12.0)	Community	Digital booklet (n=105)	CBT website (n=104)		Y			Y	Y	Y	Y	Y	Y	Y	Y		Y							Mod
Ferrell 1997, US	I: 72.7 (3.8) C: 72.3 (3.4)	Mixed	Booklet (n=10)	Walking program (n=9)											Y		Y		Y						Mod
Hodges 2021, AU	I: 48.1 (14.0) C: 47.8 (14.1)	Community	Website (n=214)	Unguided care (n=226)											Y	Y	Y								High
Kazemi 2021, IR	I: 37.0 (5.7) C: 37.0 (7.8)	Community	Website (n=60)	Usual care (n=60)											Y	Y	Y								High
Kuvacic 2018, HR	O: 34.2 (4.52)	Primary care	Booklet (n=15)	Yoga (n=15)								Y		Y	Y	Y									High
Sandal 2021, DK & NO	I: 48.3 (15.0) C: 46.7 (14.4)	Primary care	Mobile app (n=232)	Usual care (n=229)		Y			Y				Y	Y	Y	Y	Y	Y							Low
Saper 2017, US	I: 44.2 (10.8) C: 46.4 (10.4)	Primary care	Booklet (n=64)	Yoga (n=127)											Y	Y	Y	Y							Low
Sherman 2005, US	I: 45 (11) C: 44 (12)	Primary care	Booklet (n=30)	Yoga (n=36)											Y	Y	Y								Low
Sherman 2011, US	I: 50.8 (9.1) C: 46.6 (9.8)	Primary care	Booklet (n=45)	Yoga (n=92)											Y	Y		Y							Low
Valenza 2017, ES	I: 38 (12) C: 40 (16)	Primary care	Booklet (n=27)	Pilates (n=27)											Y	Y									Low
Valenzuela-Pascual 2019, ES	I: 47.0 (11.1) C: 45.7 (8.8)	Primary care	Website (n = 26)	Usual care (n = 22)					Y						Y	Y									Mod
Weiner 2020, US	I: 71.3 (7.5) C: 67.2 (5.5)	Primary care	Aging back clinic (n = 25)	Usual care (n = 30)											Y	Y	Y								Low

NR = not reported, I = intervention group, C = control group, O = overall study sample, CBT = cognitive behavioral therapy, PNF = proprioceptive neuromuscular facilitation, Mod = moderate risk of bias. ¥Booklet refers to any type of written educational material such as a book, leaflet, brochure, pamphlet, etc. ⁺Recruitment refers to

the location participants were recruited from (community recruitment was any recruitment not performed in a primary care family practice or emergency department setting, and mixed recruitment involved both primary care and community recruitment).

2.3.2 Description of the interventions using the TIDieR Checklist (Table 2.2)

PEMs were provided by physicians [180–183,191,192,194,195] or researchers [171–179,184–190,193,196] via a hard copy booklet, leaflet or pamphlet [113,171–174,176–184,186,188,189,191,192,194,195] with several newer studies using digital formats [175,185,187,190,193,196]. PEMs content was similar across studies and included anatomy, causes of LBP, posture and movement, proper lifting techniques, exercises, how to manage flare-ups, pain management, importance of staying active, self-management strategies, and treatment options. Six studies intended to and/or measured delivery of the PEMs to the patient by audio-recording GP consultations [195], asking participants if they read the materials [174,178,186,194] or recording participant activity in a mobile application [196].

Table 2.2. Description of the patient education material interventions using the TIDieR checklist

Study year	Education material	Study purpose[¥]	Education content	Procedure	Mode of delivery (provider)	Consult? [+] (n)	Co-interventions	Comparator description	Measured adherence/ fidelity?
ACUTE									
Bucker 2010	Booklet*	Effect of written education materials on functional capacity, fear of movement, general health, and knowledge	Booklet (NR) with information on LBP diagnosis, advice to remain active, self-management strategies	GP discussed LBP with the patient and provided the leaflet at end of consult	Face to face (GP)	Yes (1)	None	Unrelated booklet with no information about LBP	No
Cherkin 1998	Booklet	Compare effect and cost of physical therapy, chiropractic manipulation, and educational booklet on LBP outcomes	Booklet (*Back in Action: A Guide to Understanding Your Low Back Pain and Learning What You Can Do About It*) with information on LBP causes, prognosis, self-management strategies, returning to normal activity, appropriate use of imaging	Booklet was mailed to participants and no further advice/consultation was provided	Mailed (researcher)	No (0)	None	Short-lever high-velocity chiropractic manipulation (up to 8 times over 4 weeks)	No
Darlow 2019	Booklet	Effect and cost of consult with GP trained in FREE approach on attitudes, knowledge, confidence, and clinical behaviour	Booklet *(Free for People with Back Pain)* with information about LBP anatomy, causes, and prognosis, fear-avoidance beliefs, appropriate use of imaging, self-management strategies, returning to normal activity, acknowledgment of the difficulties of living with LBP	Booklet provided during consult with GP trained in the FREE approach (training focused on behavior change approaches to reduce provision of unhelpful LBP information)	Face to face (GP)	Yes (1)	Advice from GP trained in FREE approach	Usual care	Audio-recorded the sessions to assess FREE approach but did not report fidelity of booklet provision
Irvine 2015	Website	Effect of self-management website for improving pain, quality of life, well-being, and helpful behaviours	Website *(FitBack)* with both text- and video-based information on LBP, self-management and prevention strategies, and LBP exercises supported by weekly	Participants were given access to the website at start of study (no further advice/consultation was provided)	Online (researcher)	No (0)	weekly email reminders to track pain management activities	Usual care	No

		for LBP and determine correlation with behaviour change mediators	reminders and self-care messages						
Jellema 2005	Booklet	Effect of minimal intervention strategy for reducing fear-avoidance beliefs, pain catastrophizing, and distress	Booklet based on the *Back Book* (*Omgaan met lage rugpijn)* with information on LBP causes, prognosis, and treatments	Two GP consults: (1) provided advice and pain medication if necessary; (2) provided tailored information based on psychosocial prognostic factors, then provided booklet	Face to face (GP)	Yes (2)	None	Usual care	85% of participants reported reading the booklet
Linton 2000	Booklet	Effect of cognitive behavioural therapy for improving coping and reducing sick leave and healthcare utilization	Booklet (*Back Pain—Don't Suffer Needlessly*) with information on self-management strategies with an emphasis coping strategies and confronting fear-avoidance beliefs	Participants were given the booklet (no further advice/consultation was provided)	NR (researcher)	No (0)	None	Cognitive behavioral therapy (120 min sessions 1x/week for 6 weeks)	83% of participants reported reading the booklet "word for word" at least once
Little 2001	Booklet	Effect of booklet + advice on pain, function, satisfaction, and knowledge compared to pain medication + advice to stay active	Booklet (*Back Home*) with information on the LBP causes, proper lifting techniques, self-management strategies, advice to stay active and minimize bed rest, and sources for further reading	GP provided the booklet during a consult while giving supporting statements and encouragement to read the booklet	Face to face (GP)	Yes (1)	None	Usual care	No
Lorig 2002	Booklet + videotape	Effect of education intervention for improving disability, pain, quality of life, role function, psychological distress, and reducing	Booklet (*The Back Pain Helpbook*) and Videotape (*Easing Back: Taking Control of Your Back Problem*) with information on LBP causes, self-management strategies, flare-ups, advice to stay active, proper walking/ posture, and	Participants were given the booklet and videotape, then added to the email discussion group	NR (researcher)	No (0)	email discussion group to discuss experiences with other LBP patients and content experts	Usual care	No

		healthcare utilization	supportive messages from other LBP patients						
Roberts 2002	Booklet	Develop and test effect of booklet on knowledge, attitude, behaviour, and function	Booklet (*Back Home*) with information on the LBP causes, proper lifting techniques, self-management strategies, advice to stay active and minimize bed rest, and sources for further reading	GP provided the booklet during a consult while giving supporting statements and encouragement to read the booklet	Face to face (GP)	Yes (1)	None	Usual care	No
Roland 1989	Booklet	Effect of booklet on healthcare utilization and knowledge	Booklet (*Back Book*) with information on the anatomy of the back, self-management strategies, LBP exercises, how to prevent of chronification, and when to seek care	GP provided the booklet during a consult	Face to face (GP)	Yes (1)	None	Usual care	No
Sihawong 2021	Booklet	Effect of risk factor education on pain and disability in office workers with neck and LBP	Booklet (NR) contained information from the *Back Book* that addressed LBP risk factors and provided information on spine function, coping with LBP, and self-management strategies	Completed a checklist of LBP risk factors, then asked to reflect on their answers using information in the booklet	Face to face (researcher)	No (0)	Completed risk factor checklist at each follow-up	Home-based stretching, strengthening, and endurance exercises (up to 5x/week)	No
Simula 2021	Booklet	Effect of booklet on reducing imaging, days off work, healthcare visits, and disability, and improving function and quality of life	Booklet (*Understanding Low Back Pain*) with information on LBP causes, prevalence, self-management strategies, appropriate imaging use, advice to stay active	Provider provided booklet during a consult	Face to face (GP, physio, nurse)	Yes (1)	None	Usual care	No
CHRONIC									
Areeudomwong 2017	Booklet	Effect of proprioceptive neuromuscular facilitation on pain, disability, quality of life, satisfaction, and	Booklet (NR) with information on LBP anatomy, causes, self-management strategies	Researcher provided the booklet, advised patients how to use it and recommended to perform exercises in the booklet	Face to face (researcher)	Yes (1)	None	Proprioceptive neuromuscular facilitation training (30 min sessions 5x/week for 4 weeks)	No

		lumbar erector spinae muscle activity							
Brodsky 2019	Booklet	Pilot to investigate feasibility of a larger RCT and compare data with recent similar studies	Booklet (*The Back Pain Helpbook*) with information on LBP causes, self-management strategies, managing flare-ups, importance of staying active, and targeted the role of emotions for LBP.	Researcher provided the booklet (no further advice/consultation was provided)	Face to face (researcher)	No (0)	None	Stretching exercise program (30 min sessions 1x/week for 12 weeks) + take-home stretching exercise manual	No
Cherkin 2001	Booklet + videotapes	Effect and cost of acupuncture, massage, and booklet (booklet provided to control group in an effort to reduce attrition, as opposed to just providing usual care)	Booklet (*The Back Pain Helpbook*) and videotapes with information on LBP causes, self-management strategies, managing flare-ups, importance of staying active, and advice on how to cope with emotional and interpersonal problems resulting from LBP	Materials were mailed to participants (no further advice/consultation was provided)	Mailed (researcher)	No (0)	None	Soft tissue massage (60 min sessions, up to 10 sessions over 10 weeks)	55% of participants reported reading more than 2/3 of booklet and 73% watched the videotapes
Chiauzzi 2010	Booklet	Effect of cognitive behavioural therapy website for reducing distress and pain, and increasing self-efficacy, physical functioning, global impression of positive change, and use of coping strategies	Booklet (*Back Pain Guide* by the National Institute of Neurological Disorders and Stroke) with information on LBP anatomy, causes, treatment, and self-management strategies	Electronic copy of booklet emailed to participants and asked to read it over 4 weeks (no further advice/ consultation was provided)	E-mailed (researcher)	No (0)	None	Cognitive-behavioural therapy website *("painACTION")* (content provided 2x/week over 4 weeks)	No
Ferrell 1997	Booklet	Effect of walking program on improving pain management for elderly people	Booklet (NR) with general information about pain and pain management	Researcher provided the booklet (no further advice/ consultation was provided)	Face to face (researcher)	No (0)	Weekly telephone call (to reduce attrition)	Supervised, low-intensity walking program with stretching exercises (10-	No

								45 min sessions 4x/week over 6 weeks)	
Hodges 2021	Website	Effect of website on improving health literacy, treatment choice, and clinical outcomes compared to unguided internet use	Website *(MyBackPain)* with text- and video-based information about LBP prognosis, treatment, self-management strategies, advice to stay active, and other tailored content to increase self-efficacy and reduce negative LBP beliefs	Participants given access to website, shown how to use it, and encouraged to use it	Online (researcher)	Yes (1)	Could opt-in to emails with key messages about LBP	Self-directed LBP information seeking; asked to use the internet on their own to find information about LBP and keep diary of websites visited	No
Kazemi 2021	Website	Effect of website on reducing occupational LBP in nurses compared to no intervention	Website (NR; based on the PRECEDE-PROCEED model), with information on LBP anatomy, prognosis, risk factors, exercises, ergonomics, and correct positioning of the spine	Participants given access to website and shown how to use it. Different educational topics were uploaded to the website on two separate days	Online (researcher)	Yes (1)	Weekly reminders to use website and perform exercises	Usual care	No
Kuvacic 2018	Booklet	Effect of yoga and an education intervention on reducing disability, anxiety, depression, and pain	Booklet (NR) with information on LBP anatomy, ergonomics, correct posture, movement, breathing mechanisms.	GP provided booklet during consult	Face to face (GP)	Yes (1)	Newsletters (2x/ week for 8 weeks) reiterating information from booklet	Yoga (2x/week for 8 weeks) with focus on breathing techniques and emotional control	No
Sandal 2021	Mobile application	Effect of mobile application on facilitating self-management of LBP, reducing disability, and improving other LBP-related outcomes	Mobile application (*selfBACK*) with general text- and video-based information about LBP, LBP exercises, self-management strategies, goal setting	Researchers provided access to the application, showed participants how to use it, and recommended using it to supplement LBP care	Online (researcher)	Yes (1)	Step counting wristband, reminders with self-management recommendations, and gamification (rewards/badges)	Usual care	78% participants adhered to the intervention (defined as creating 6+ 'self-management plans' in the app in

									the first 12 weeks)
Saper 2017	Booklet	To determine if yoga is noninferior to physical therapy	Booklet (*The Back Pain Helpbook*) and videotapes with information on LBP causes, self-management strategies, managing flare-ups, importance of staying active, and advice on how to cope with emotional and interpersonal problems resulting from LBP	Researcher provided the booklet (no further advice/ consultation was provided)	NR (researcher)	No (0)	Newsletter (summarizing main points from booklet) and check-in call every 3 weeks	Yoga (75 mins, 1x/week for 12 weeks) with relaxation, meditation, and breathing techniques, and take-home yoga supplies and instructions	No
Sherman 2005	Booklet	To determine the effectiveness and safety of yoga	Booklet (*The Back Pain Helpbook*) and videotapes with information on LBP causes, self-management strategies, managing flare-ups, importance of staying active, and advice on how to cope with emotional and interpersonal problems resulting from LBP	Researcher provided the booklet (no further advice/ consultation was provided)	NR (researcher)	No (0)	None	*Viniyoga* yoga classes (75 mins, 1x/week for 12 weeks) with breathing and relaxation techniques, and take-home instructions	100% reported reading at least part of book, 30% said they read 1/3-2/3 book, 57% reported reading more than 2/3
Sherman 2011	Booklet	To compare the effects of yoga, stretching exercises, and self-care education	Booklet (*The Back Pain Helpbook*) and videotapes with information on LBP causes, self-management strategies, managing flare-ups, importance of staying active, and advice on how to cope with emotional and interpersonal problems resulting from LBP	Researcher provided the booklet (no further advice/ consultation was provided)	NR (researcher)	No (0)	None	*Viniyoga* yoga classes (75 mins, 1x/week for 12 weeks) with breathing and relaxation techniques, and take-home instructions	No
Valenza 2017	Booklet	Effect of Pilates on improving disability, pain, mobility,	Booklet (NR) with information on fear of movement and the importance of remaining	Researcher provided the booklet (no further advice/ consultation was provided)	NR (researcher)	No (0)	None	Pilates (45 mins, 2x/week for 8 weeks) with floor exercises (using	No

		flexibility, and balance	active, postural care, lifting weights, and false beliefs.					55-cm ball) and relaxation session with rubber roller	
Valenzuela-Pascual 2019	Website	Effect of website on decreasing pain, disability, and fear-avoidance beliefs in primary care	Website with text- and video-based information about LBP anatomy, causes, common negative LBP beliefs, appropriate imaging use, neurophysiology of pain, and pain modulation	Researcher provided access to the website (no further advice/ consultation was provided)	Face to face (researcher)	No (0)	Online discussion to share and discuss LBP experiences	Usual care	No
Weiner 2020	Booklet	Feasibility and effect of guided treatment on reducing pain and improving function	NR	Geriatrician used series of screening questionnaires to tailor treatment approach for each patient and provided booklet during consult	Face to face (geriatrician)	Yes (1)	Pre-screening questionnaire to tailor treatment	Usual care	No

*Booklet refers to any type of written educational material such as a book, leaflet, brochure, pamphlet, or handbook. [+]We omitted frequency and duration from the TIDieR table as the education material was provided one time in all trials. Instead, since some trials provided the education material during a consultation and others did not, we included this observation in the table along with the number of consultations held (a consultation was defined as not just the provision of the patient education material, but also verbal discussion including advice and education about LBP, how to access/used the material, or recommendations to use the material. [¥]As discussed in the manuscript, the education materials were used as a control or usual care group in some studies, so the purpose of these studies may not relate to education materials.

2.3.3 Risk of bias (Table 2.3)

10 studies had high risk of bias [113,171,172,181,183,188,190–193], eight had moderate risk of bias [175,176,182,185,187,189,194,195], and nine had low risk of bias [173,174,177–180,184,186,196]. The most common source of bias was lack of blinding. Due to the nature of the intervention, none of the 27 included studies satisfied the criteria for blinding of subjects or providers and only nine of 27 studies reported blinding of outcome assessors. Nine of 10 high risk of bias studies [113,171,172,181,188,190–193] were the result of insufficient follow-up. Only one of six cluster RCTs [113,182,189,193–195] adequately reported adjusting for clustering [113].

Table 2.3. Risk of bias

Author Year	1. Eligibility Criteria	2. Random Allocation	3. Allocation Concealment	4. Similar at Baseline	5. Blind (Subjects)	6. Blind (Administered)	7. Blind (Outcome Assessor)	8. At least 85% Complete	9. ITT Analysis	10. Between Group Stats	11. Point Measures/Variability	Total Score	Risk of bias*
Areeudomwong 2017	Y	Y	Y	Y	N	N	Y	N	N	Y	Y	6	High
Brodsky 2019	Y	Y	N	Y	N	N	Y	N	N	Y	Y	5	High
Bucker 2010	Y	Y	N	N	N	N	N	N	Y	Y	Y	4	High
Cherkin 1998	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	Low
Cherkin 2001	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	7	Low
Chiauzzi 2010	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	6	Mod
Darlow 2019	Y	Y	Y	Y	N	N	N	Y	Y	Y	N	6	Mod
Ferrell 1997	Y	Y	N	Y	N	N	N	Y	N	Y	Y	5	Mod
Hodges 2021	Y	Y	N	Y	N	N	Y	N	Y	Y	Y	6	High
Irvine 2015	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	6	Mod
Jellema 2005	Y	Y	N	Y	N	N	N	Y	Y	Y	N	5	Mod
Kazemi 2021	Y	Y	Y	Y	N	N	N	N	N	Y	N	4	High
Kuvacic 2018	N	Y	N	Y	N	N	N	N	N	Y	Y	4	High
Linton 2000	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	7	Low
Little 2001	Y	Y	Y	N	N	N	N	N	N	Y	Y	4	High
Lorig 2002	Y	Y	N	Y	N	N	N	N	Y	Y	Y	5	High
Roberts 2002	Y	Y	Y	N	N	N	Y	Y	N	Y	N	5	Mod

Roland 1989	Y	N	N	N	N	N	N	Y	N	Y	Y	3	High
Sandal 2021	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	7	Low
Saper 2017	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	7	Low
Sherman 2005	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	7	Low
Sherman 2011	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	7	Low
Sihawong 2021	Y	Y	N	Y	N	N	N	Y	Y	Y	N	5	Mod
Simula 2021	Y	Y	N	Y	N	N	N	N	N	Y	Y	4	High
Valenza 2017	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	Low
Valenzuela-Pascual 2019	Y	Y	Y	Y	U	U	U	Y	N	Y	Y	6	Mod
Weiner 2020	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	Low

*A study was deemed to have a high risk of bias if 0-3 criteria on the scale were satisfied, moderate if 4-6 criteria were satisfied, and low if 7-10 criteria were satisfied. However, if studies did not follow proper randomization methods, or did not reach 85% follow-up, we judged the study to be at high risk of bias regardless of the overall PEDro score. If cluster RCTs did not adjust for clustering we indicated this source of bias by reporting "No" for criterion #11 (Point Measures/Variability), regardless of the original judgment for this criterion.

2.3.4 Effectiveness of patient education materials for acute/subacute LBP

2.3.4.1 Patient education materials alone vs. no intervention or usual care

Nine trials [113,171,181–183,187,192,194,195] compared the effect of PEMs to usual care on LBP-related outcomes for acute/subacute LBP patients. In the usual care arm, patients could carry on with any LBP care as they normally would outside of the study. In one study [192], the usual care group also received a booklet with information unrelated to LBP as a control intervention. The most commonly measured outcome was disability (n=8), followed by measures of pain intensity (n=5), pain self-efficacy (n=4), knowledge (n=4), quality of life (n=4), fear-avoidance beliefs (n=3), catastrophizing (n=3), anxiety (n=3), days off work (n=3), and physician visits (n=3). Single studies measured global improvement, cost, imaging, and referrals. No studies measured function, general beliefs, attitudes, coping, stress, or depression. A summary of findings for eight key outcomes are presented in Table 2.4 (a summary of all other outcomes and forest plots for all analyses are presented in Appendices 2.4 and 2.5, respectively).

Table 2.4. Summary of findings: education materials compared with no intervention (usual care) for acute/subacute low back pain

Outcome (# studies) Time points	Outcome measurement tools[a]	SMD[b] (95% CI) or $RR^{+,-}$ (95% CI)	Participants (# studies)	Quality of Evidence[c] (GRADE)
Knowledge (n = 5):				
• Immediate-term (1-8 wks)	UTs (4)	-0.51 [-0.72, -0.31]	699 (4)	⊕⊕⊖⊖ Low[1,4]
• Short-term (13-16 wks)	UTs (2)	-0.48 [-0.90, -0.05]	502 (2)	⊕⊕⊖⊖ Low[1,4]
• Medium-term	-	-	0 (0)	No evidence
• Long-term (52 wks)	UTs (1)	RR^{+} = 1.28 [1.10, 1.49]	777 (1)	⊕⊖⊖⊖ Very low[6]
Self-efficacy (n = 4):				
• Immediate-term (2-8 wks)	PSEQ-2 (1), UTs (3)	-0.28 [-0.63, 0.07]	650 (3)	⊕⊕⊕⊖ Moderate[4]
• Short-term (16 wks)	UTs (1)	-0.78 [-0.98, -0.58]	398 (1)	⊕⊖⊖⊖ Very low[6]
• Medium-term	-	-	0 (0)	No evidence
• Long-term (52 wks)	UTs (1)	-0.32 [-0.52, -0.12]	421 (1)	⊕⊖⊖⊖ Very low[6]
Pain (n = 5):				
• Immediate-term (2-8 wks)	NRS (2), UTs (1)	-0.13 [-0.27, 0.01]	910 (3)	⊕⊕⊕⊕ High
• Short-term (12-16 wks)	NRS (3), UTs (1)	-0.24 [-0.42, -0.06]	1101 (4)	⊕⊕⊕⊕ High
• Medium-term (26 wks)	NRS (2)	-0.03 [-0.20, 0.15]	515 (2)	⊕⊕⊕⊕ High
• Long-term (52 wks)	NRS (2), VNS (1)	-0.11 [-0.24, 0.02]	892 (3)	⊕⊕⊕⊖ Moderate[1]
Disability (n = 8):				
• Immediate-term (1-8 wks)	RMDQ (2), ALBDS (2), FFbH-R (1), WLQ (1)	-0.05 [-0.17, 0.06]	1220 (6)	⊕⊕⊕⊕ High
• Short-term (13-16 wks)	RMDQ (2), ALBDS (1), FFbH-R (1), WLQ (1), ODI (1)	-0.06 [-0.18, 0.05]	1272 (6)	⊕⊕⊕⊕ High
• Medium-term (26 wks)	RMDQ (2), ALBDS (1)	0.09 [-0.08, 0.27]	563 (3)	⊕⊕⊕⊕ High
• Long-term (52 wks)	RMDQ (2), ALBDS (1), ODI (1)	-0.09 [-0.27, 0.08]	938 (4)	⊕⊕⊕⊖ Moderate[1]
Quality of Life (n = 4):				
• Immediate-term (1-8 wks)	SF-36 (1), Dartmouth CO-OP (1)	-0.24 [-0.42, -0.07]	524 (2)	⊕⊕⊕⊖ Moderate[4]
• Short-term (13-16 wks)	SF-36 (1), Dartmouth CO-OP (1), UTs (1)	-0.20 [-0.43, 0.03]	804 (3)	⊕⊕⊕⊕ High
• Medium-term (26 wks)	UTs (1)	0.00 [-0.23, 0.23]	286 (1)	⊕⊖⊖⊖ Very low[6]
• Long-term (52 wks)	EQ5D-3L (1), UTs (1)	0.01 [-0.17, 0.19]	470 (2)	⊕⊕⊕⊖ Moderate[1]

Global improvement (n = 1):				
• Immediate-term (6 wks)	UTs (1)	RR^{-} = 1.07 [0.80, 1.43]	305 (1)	⨁⊖⊖⊖ Very low[6]
• Short-term (13 wks)	UTs (1)	RR^{-} = 1.03 [0.75, 1.42]	305 (1)	⨁⊖⊖⊖ Very low[6]
• Medium-term (26 wks)	UTs (1)	RR^{-} = 1.05 [0.75, 1.47]	299 (1)	⨁⊖⊖⊖ Very low[6]
• Long-term (52 wks)	UTs (1)	RR^{-} = 1.15 [0.81, 1.65]	288 (1)	⨁⊖⊖⊖ Very low[6]
Days off work (n = 3):				
• Immediate-term (6 wks)	% with days off work (1)	RR^{-} = 0.83 [0.49, 1.42]	248 (1)	⨁⊖⊖⊖ Very low[6]
• Short-term (13 wks)	% with days off work (1), mean days off work (1)	-0.35 [-0.63, -0.08]	612 (2)	⨁⨁⊖⊖ Low[1,4]
• Medium-term (26 wks)	% with days off work (1)	RR^{-} = 0.33 [0.10, 1.16]	244 (1)	⨁⊖⊖⊖ Very low[6]
• Long-term (52 wks)	% with days off work (1), mean days off work (2)	-0.10 [-0.32, 0.12]	1535 (3)	⨁⨁⨁⊖ Moderate[1]
Imaging (n = 1):				
• Immediate-term	-	-	0 (0)	No evidence
• Short-term (13 wks)	% receiving LBP imaging (1)	RR^{-} = 0.64 [0.38, 1.09]	364 (1)	⨁⊖⊖⊖ Very low[6]
• Medium-term	-	-	0 (0)	No evidence
• Long-term (52 wks)	% receiving LBP imaging (1)	RR^{-} = 0.60 [0.41, 0.89]	364 (1)	⨁⊖⊖⊖ Very low[6]

[a]See legend in Appendix 2.4 for a complete list of non-abbreviated names of all measurement tools. [b]Data are presented as standardized mean differences (SMD) and 95% confidence intervals (95% CI) unless otherwise indicated (negative SMD favors education materials). Risk ratios are indicated with RR^{+} (RR > 1 favors education) and RR^{-} (RR < 1 favors education). [c]Quality of evidence was downgraded for risk of bias,[1] imprecision,[2] inconsistency,[3] indirectness,[4] publication bias,[5] or downgraded to very low if there was one study[6] (more details provided in Appendix 2.3).

Pain Intensity (n=5). We found high-quality evidence that PEMs were significantly more effective for reducing pain intensity compared to usual care at short-term (4 RCTs, n = 1101; SMD = -0.24; 95% CI: -0.42, -0.06; p = 0.01; I^2 = 55%). We found high-quality evidence that PEMs had no effect on pain intensity compared to usual care at immediate (3 RCTs, n = 910; SMD = -0.13; 95% CI: -0.27, 0.01; p = 0.07; I^2 = 14%) and medium-term (2 RCTs, n = 515; SMD = -0.03 95% CI: -0.20, 0.15; p = 0.77; I^2 = 0%), and moderate-quality evidence of no effect at long-term (3 RCTs, n = 892; SMD = -0.11; 95% CI: -0.24, 0.02; p = 0.11; I^2 = 0%).

Disability (n=8). We found high-quality evidence that PEMs had no effect on disability compared to usual care at immediate (6 RCTs, n = 1220; SMD = -0.05; 95% CI: -0.17, 0.06; p = 0.35; I^2 = 0%), short (6 RCTs, n = 1272; SMD = -0.06; 95% CI: -0.18, 0.05; p = 0.30; I^2 = 7%), and medium-term (3 RCTs, n = 563; SMD = 0.09; 95% CI: -0.08, 0.27; p = 0.31; I^2 = 6%) and moderate-quality evidence of no effect at long-term (4 RCTs, n = 938; SMD = -0.09; 95% CI: -0.27, 0.08; p = 0.28; I^2 = 37%).

Quality of Life (n=4). We found moderate-quality evidence that PEMs are significantly more effective than usual care for improving quality of life at immediate-term (2 RCTs, n = 524; SMD = -0.24; 95% CI: -0.42, -0.07; p = 0.006; I^2 = 0%). We found high-quality evidence that PEMs had no effect on quality of life compared to usual care at short-term (3 RCTs, n = 804; SMD = -0.20; 95% CI: -0.43, 0.03; p = 0.09; I^2 = 58%). We found very low-quality evidence of no effect at medium-term (1 RCT, n = 286; SMD = 0.00; 95% CI: -0.23, 0.23; p = 1.00) and moderate-quality evidence of no effect at long-term (2 RCTs, n = 470; SMD = 0.01; 95% CI: -0.17, 0.19; p = 0.94; I^2 = 0%).

Global Improvement (n=1). We found very low-quality evidence that PEMs had no effect compared to usual care on global improvement at immediate (1 RCT, $n = 305$; RR = 1.07; 95% CI: 0.80, 1.43; $p = 0.64$), short (1 RCT, $n = 305$; RR = 1.03; 95% CI: 0.75, 1.42; $p = 0.85$), medium (1 RCT, $n = 299$; RR = 1.05; 95% CI: 0.75, 1.47; $p = 0.76$), and long-term (1 RCT, $n = 288$; RR = 1.15; 95% CI: 0.81, 1.65; $p = 0.43$), where RR > 1 favors usual care.

Knowledge (n=5). We found low-quality evidence that PEMs are significantly more effective than usual care for improving knowledge in the immediate (4 RCTs, $n = 699$; SMD = -0.51; 95% CI: -0.72, -0.31; $p < 0.00001$; $I^2 = 47\%$) and short-term (2 RCTs, $n = 502$; SMD = -0.48; 95% CI: -0.90, -0.05; $p = 0.03$; $I^2 = 71\%$). We found very low-quality evidence that PEMs are significantly more effective than usual care for improving long-term knowledge (1 RCT, $n = 777$; RR = 1.28; 95% CI: 1.10, 1.49; $p = 0.001$)

Pain Self-Efficacy (n=4). We found moderate quality evidence that PEMs had no effect on pain self-efficacy compared to usual care at immediate-term (3 RCTs, $n = 650$; SMD = -0.28; 95% CI: -0.63, 0.07; $p = 0.12$; $I^2 = 73\%$). We found very low-quality evidence that PEMs are significantly more effective than usual care for improving self-efficacy at short (1 RCT, $n = 398$; SMD = -0.78; 95% CI: -0.98, -0.58; $p < 0.00001$) and long-term (1 RCT, $n = 421$; SMD = -0.32; 95% CI: -0.52, -0.12; $p = 0.002$)

Fear-Avoidance Beliefs (n=3). We found high quality evidence that PEMs had no effect on fear-avoidance beliefs compared to usual care at immediate-term (3 RCTs, $n = 611$; SMD = -0.14; 95% CI: -0.36, 0.09; $p = 0.23$; $I^2 = 44\%$), and very low-quality

evidence of no effect at short (1 RCT, n = 114; SMD = 0.00; 95% CI: -0.38, 0.38; p = 1.00) and long-term (1 RCT, n = 150; SMD = 0.10; 95% CI: -0.15, 0.35; p = 0.43).

Catastrophizing (n=3). We found high quality evidence that PEMs had no effect on catastrophizing compared to usual care at immediate-term (3 RCTs, n = 879; SMD = -0.01; 95% CI: -0.22, 0.20; p = 0.92; I^2 = 60%), and very low-quality evidence of no effect at short (1 RCT, n = 398; SMD = -0.12; 95% CI: -0.31, 0.07; p = 0.22) and long-term (1 RCT, n = 248; SMD = 0.07; 95% CI: -0.18, 0.32; p = 0.58).

Anxiety (n=3). We found moderate-quality evidence that PEMs had no effect on anxiety compared to usual care at immediate-term (2 RCTs, n = 485; SMD = -0.01; 95% CI: -0.45, 0.43; p = 0.98; I^2 = 83%) and low-quality evidence of no effect at long-term (2 RCTs, n = 673; SMD = -0.13; 95% CI: -0.52, 0.26; p = 0.53; I^2 = 85%).

Days off Work (n=3). We found low-quality evidence that PEMs were significantly more effective for reducing days off work compared to usual care at short-term (2 RCTs, n = 612; SMD = -0.35; 95% CI: -0.63, -0.08; p = 0.01; I^2 = 22%). We found very low-quality evidence that PEMs had no effect on days off work compared to usual care at immediate (1 RCT, n = 248; RR = 0.83; 95% CI: 0.49, 1.42; p = 0.50) and medium-term (1 RCT, n = 244; RR = 0.33; 95% CI: 0.10, 1.16; p = 0.08) and moderate-quality evidence of no effect at long-term (3 RCTs, n = 1535; SMD = -0.10; 95% CI: -0.32, 0.12; p = 0.37; I^2 = 62%). Sensitivity analysis for long-term follow-up revealed no difference when removing one study [183] due to concerns about their randomization method (SMD = -0.23; 95% CI: -0.46, 0.00; p = 0.05; I^2 = 11%).

Imaging (n=1). We found very low-quality evidence that PEMs are significantly more effective for reducing imaging for LBP compared to usual care at long-term (1 RCT, n = 364; RR = 0.60; 95% CI: 0.41, 0.89; p = 0.01). We found very low-quality evidence that PEMs had no effect on imaging compared to usual care at short-term (1 RCT, n = 364; RR = 0.64; 95% CI: 0.38, 1.09; p = 0.10).

Physician visits (n=3). We found moderate-quality evidence that PEMs are significantly more effective for reducing physician visits compared to usual care at long-term (3 RCTs, n = 1721; SMD = -0.16; 95% CI: -0.26, -0.05; p = 0.003; I^2 = 0%). We found very low-quality evidence of no effect at short-term (1 RCT, n = 364; SMD = -0.07; 95% CI: -0.27, 0.13; p = 0.49). Sensitivity analysis for long-term follow-up revealed no difference when removing one study [183] due to concerns about their randomization method (SMD = -0.16; 95% CI: -0.31, -0.02; p = 0.03; I^2 = 0%).

Referrals (n=1). We found very low-quality evidence that PEMs are significantly more effective than usual care for reducing specialist referrals at long-term (1 RCT; n = 936; RR = 0.85; 95% CI: 0.58, 1.23; p = 0.38).

Cost (n=1). We found very low-quality evidence that PEMs had no effect on cost compared to usual care at medium-term (1 RCT, n = 226; SMD = -0.11; 95% CI: -0.37, 0.16; p = 0.43).

2.3.4.2 Patient education materials alone vs. other interventions

Three trials [173,186,189] compared the effect of PEMs to other interventions on LBP-related outcomes for acute/subacute LBP patients. The comparator interventions

were cognitive behavioural therapy [186], chiropractic manipulation [173], and an exercise program [189]. The studies included measures of pain intensity (n=3), disability (n=3), and days off work (n=2), and one study measured fear-avoidance beliefs, catastrophizing, anxiety, depression, and physician visits. No studies measured quality of life, global improvement, function, knowledge, self-efficacy, attitudes, general beliefs, coping, stress, imaging, referrals, or cost. A summary of findings for eight key outcomes are presented in Table 2.5 (a summary of all other outcomes and forest plots for all analyses are presented in Appendices 2.4 and 2.5, respectively).

Table 2.5 Summary of findings: education materials compared with another intervention for acute/subacute low back pain

Outcome (# studies) Time points	Outcome measurement tools[a]	SMD[b] (95% CI) or RR[+,-] (95% CI)	Participants (# studies)	Quality of Evidence[c] (GRADE)
Knowledge: no evidence				
Self-Efficacy: no evidence				
Pain (n = 3):				
• Immediate-term (4 wks)	SBS (1)	0.51 [0.20, 0.83]	178 (1)	⊕⊖⊖⊖ Very low[6]
• Short-term (12 wks)	VAS (1), SBS (1)	0.07 [-0.81, 0.95]	212 (2)	⊕⊕⊖⊖ Low[2,3]
• Medium-term (26 wks)	VAS (1)	-0.89 [-1.66, -0.11]	31 (1)	⊕⊖⊖⊖ Very low[6]
• Long-term (52 wks)	OEQ (1)	0.04 [-0.28, 0.36]	155 (1)	⊕⊖⊖⊖ Very low[6]
Disability (n = 3):				
• Immediate-term (4 wks)	RMDQ (1)	0.27 [-0.04, 0.58]	178 (1)	⊕⊖⊖⊖ Very low[6]
• Short-term (12 wks)	RMDQ (2)	0.23 [-0.06, 0.51]	212 (2)	⊕⊕⊕⊖ Moderate[2]
• Medium-term (26 wks)	RMDQ (1)	-0.15 [-0.88, 0.58]	31 (1)	⊕⊖⊖⊖ Very low[6]
• Long-term (48-52 wks)	ADLQ (1), % with reduced activity (1)	0.20 [-0.04, 0.43]	343 (2)	⊕⊕⊖⊖ Low[2,4]
Quality of Life: no evidence				
Global Improvement: no evidence				
Days off work (n = 2):				
• Immediate-term	-	-	0 (0)	No evidence
• Short-term	-	-	0 (0)	No evidence
• Medium-term	-	-	0 (0)	No evidence
• Long-term (48-52 wks)	% with days off work (1), mean days off work (1)	0.36 [0.09, 0.63]	343 (2)	⊕⊕⊖⊖ Low[2,4]
Imaging: no evidence				

[a]See legend in Appendix 2.4 for a complete list of non-abbreviated names of all measurement tools. [b]Data are presented as standardized mean differences (SMD) and 95% confidence intervals (95% CI) unless otherwise indicated (negative SMD favors education materials). Risk ratios are indicated with RR^{+} (RR > 1 favors education) and RR^{-} (RR < 1 favors education). [c]Quality of evidence was downgraded for risk of bias,[1] imprecision,[2] inconsistency,[3] indirectness,[4] publication bias,[5] or downgraded to very low if there was one study[6] (more details provided in Appendix 2.3).

Pain Intensity (n=3). We found very low-quality evidence that PEMs are more effective for reducing pain intensity compared to other interventions at medium-term (1 RCT, n = 31; SMD = -0.89; 95% CI: -1.66, -0.11; p = 0.02). We found very low-quality evidence that PEMs are less effective than other interventions at immediate-term (1 RCT, n = 178; SMD = 0.51; 95% CI: 0.20, 0.83; p = 0.001), low-quality evidence that PEMs have no effect on pain intensity when compared to other interventions at short-term (2 RCTs, n = 212; SMD = 0.07; 95% CI: -0.81, 0.95; p = 0.88; I^2 = 79%), and very low-quality evidence of no effect at long-term (1 RCT, n = 155; SMD = 0.04; 95% CI: -0.28, 0.36; p = 0.81).

Disability (n=3). We found very low-quality evidence that PEMs had no effect on disability compared to other interventions at immediate (1 RCT, n = 178; SMD = 0.27; 95% CI: -0.04, 0.58; p = 0.09) and medium-term (1 RCT, n = 31; SMD = -0.15; 95% CI: -0.88, 0.58; p = 0.69), moderate-quality evidence of no effect at short-term (2 RCTs, n = 212; SMD = 0.23; 95% CI: -0.06, 0.51; p = 0.12; I^2 = 0%), and low-quality evidence of no effect at long-term (2 RCTs, n = 343; SMD = 0.20; 95% CI: -0.04, 0.43; p = 0.10; I^2 = 0%).

Fear-Avoidance Beliefs (n=1). We found very low-quality evidence that PEMs had no effect on fear-avoidance beliefs compared to other interventions at long-term (1 RCT, n = 155; SMD = 0.17; 95% CI: -0.16, 0.49; p = 0.31).

Catastrophizing (n=1). We found very low-quality evidence that PEMs had no effect on catastrophizing compared to other interventions at long-term (1 RCT, n = 155; SMD = -0.06; 95% CI: -0.38, 0.27; p = 0.73).

Anxiety (n=1). We found very low-quality evidence that PEMs had no effect on anxiety compared to other interventions at long-term (1 RCT, n = 155; SMD = -0.05; 95% CI: -0.37, 0.27; p = 0.74).

Depression (n=1). We found very low-quality evidence that PEMs had no effect on depression compared to other interventions at long-term (1 RCT, n = 155; SMD = 0.00; 95% CI: -0.32, 0.32; p = 1.00).

Days off Work (n=2). We found low-quality evidence that PEMs are significantly less effective than other interventions for reducing days off work at long-term (2 RCTs, n = 343; SMD = 0.36; 95% CI: 0.09, 0.63; p = 0.01; I^2 = 0%).

Physician Visits (n=1). We found very low-quality evidence that PEMs were less effective than other interventions on reducing physician visits (1 RCT, n = 155; SMD = 0.53; 95% CI: 0.20, 0.85; p = 0.002) at long-term.

2.3.4.3 Intervention vs. intervention + patient education materials (additive effect)

No studies measured the additive effect of PEMs with other interventions.

2.3.5 Effectiveness of patient education materials for chronic LBP

2.3.5.1 Patient education materials alone vs. no intervention or usual care

Five trials [180,185,190,193,196] compared the effect of PEMs to usual care on LBP-related outcomes for chronic LBP patients. A protocol for usual care was not described in four of these studies; rather, patients could continue any LBP care as they normally would outside of the study. In one study [190], the comparator group was

unguided internet use where participants were asked to seek out information about LBP on their own; we considered this similar to usual care. Outcomes measured included pain intensity (n=5), disability (n=5), quality of life (n=4), fear-avoidance beliefs (n=2), and one study measured global improvement, self-efficacy, stress, and depression. No studies measured function, knowledge, attitudes, general beliefs, catastrophizing, coping, anxiety, days off work, imaging, physician visits, referrals, or cost. A summary of findings for eight key outcomes are presented in Table 2.6 (a summary of all other outcomes and forest plots for all analyses are presented in Appendices 2.4 and 2.5, respectively).

Table 2.6. Summary of findings: education materials compared with no intervention (usual care) for chronic low back pain

Outcome (# studies) Time points	Outcome measurement tools[a]	SMD[b] (95% CI) or RR[+,-] (95% CI)	Participants (# studies)	Quality of Evidence[c] (GRADE)
Knowledge: no evidence				
Self-Efficacy (n = 1):				
• Immediate (6 wks)	PSEQ (1)	-0.21 [-0.39, -0.03]	461 (1)	⊕⊖⊖⊖ Very low[6]
• Short-term (13 wks)	PSEQ (1)	-0.25 [-0.43, -0.06]	461 (1)	⊕⊖⊖⊖ Very low[6]
• Medium-term (26 wks)	PSEQ (1)	-0.23 [-0.41, -0.05]	461 (1)	⊕⊖⊖⊖ Very low[6]
• Long-term (39 wks)	PSEQ (1)	-0.32 [-0.50, -0.13]	461 (1)	⊕⊖⊖⊖ Very low[6]
Pain (n = 5):				
• Immediate (2-6 wks)	VAS (2), NRS (1), UTs (1)	-0.16 [-0.29, -0.03]	890 (4)	⊕⊕⊕⊖ Moderate[1]
• Short-term (12-13 wks)	VAS (2), NRS (1), UTs (1)	-0.44 [-0.88, 0.00]	925 (4)	⊕⊕⊖⊖ Low[1,3]
• Medium-term (24-26 wks)	VAS (2), NRS (1), UTs (1)	-0.53 [-1.01, -0.05]	907 (4)	⊕⊕⊖⊖ Low[1,3]
• Long-term (39-52 wks)	VAS (1), NRS (1)	-0.21 [-0.41, -0.01]	757 (2)	⊕⊕⊕⊖ Moderate[1]
Disability (n = 5):				
• Immediate (2-6 wks)	RMDQ (4)	-0.12 [-0.31, 0.07]	919 (4)	⊕⊕⊕⊖ Moderate[1]
• Short-term (12-13 wks)	RMDQ (3), QBPDS (1)	-0.23 [-0.48, 0.03]	964 (4)	⊕⊕⊕⊖ Moderate[1]
• Medium-term (24-26 wks)	RMDQ (3), QBPDS (1)	-0.32 [-0.61, -0.03]	939 (4)	⊕⊕⊕⊖ Moderate[1]
• Long-term (39-52 wks)	RMDQ (2)	-0.12 [-0.27, 0.02]	770 (2)	⊕⊕⊕⊖ Moderate[1]
Quality of Life (n = 4):				
• Immediate (4-6 wks)	AQoL-8D (1), SF-12 (1), EQ-5D (1)	-0.04 [-0.18, 0.09]	839 (3)	⊕⊕⊕⊖ Moderate[1]
• Short-term (12-13 wks)	AQoL-8D (1), SF-12 (1), SF-36 (1), EQ-5D (1)	-0.15 [-0.28, -0.03]	934 (4)	⊕⊕⊕⊖ Moderate[1]
• Medium-term (24-26 wks)	AQoL-8D (1), SF-12 (1), SF-36 (1), EQ-5D (1)	-0.23 [-0.41, -0.04]	902 (4)	⊕⊕⊕⊖ Moderate[1]
• Long-term (39-52 wks)	AQoL-8D (1), EQ-5D (1)	-0.13 [-0.28, 0.01]	748 (2)	⊕⊕⊕⊖ Moderate[1]
Global Improvement				
• Immediate (6 wks)	GPE (1)	-0.40 [-0.58, -0.21]	461 (1)	⊕⊖⊖⊖ Very low[6]
• Short-term (13 wks)	GPE (1)	-0.42 [-0.60, -0.24]	461 (1)	⊕⊖⊖⊖ Very low[6]
• Medium-term (26 wks)	GPE (1)	-0.46 [-0.65, -0.28]	461 (1)	⊕⊖⊖⊖ Very low[6]
• Long-term (39 wks)	GPE (1)	-0.43 [-0.61, -0.24]	461 (1)	⊕⊖⊖⊖ Very low[6]
Days off work: no evidence				

Imaging: no evidence

[a]See legend in Appendix 2.4 for a complete list of non-abbreviated names of all measurement tools. [b]Data are presented as standardized mean differences (SMD) and 95% confidence intervals (95% CI) unless otherwise indicated (negative SMD favors education materials). Risk ratios are indicated with RR^+ (RR > 1 favors education) and RR^- (RR < 1 favors education). [c]Quality of evidence was downgraded for risk of bias,[1] imprecision,[2] inconsistency,[3] indirectness,[4] publication bias,[5] or downgraded to very low if there was one study[6] (more details provided in Appendix 2.3).

Pain Intensity (n=5). We found moderate-quality evidence that PEMs were significantly more effective for reducing pain intensity compared to usual care at immediate (4 RCTs, n = 890; SMD = -0.16; 95% CI: -0.29, -0.03; p = 0.02; I^2 = 0%) and long-term (2 RCTs, n = 757; SMD = -0.21; 95% CI: -0.41, -0.01; p = 0.04; I^2 = 47%), and low-quality evidence of the same observation at short (4 RCTs, n = 925; SMD = -0.44; 95% CI: -0.88, 0.00; p = 0.05; I^2 = 89%) and medium-term (4 RCTs, n = 907; SMD = -0.53; 95% CI: -1.01, -0.05; p = 0.03; I^2 = 90%).

Disability (n=5). We found moderate-quality evidence that PEMs are significantly more effective for reducing disability compared to usual care at medium-term (4 RCTs, n = 939; SMD = -0.32; 95% CI: -0.61, -0.03; p = 0.03; I^2 = 74%). We found moderate-quality evidence of no effect at immediate (4 RCTs, n = 919; SMD = -0.12; 95% CI: -0.31, 0.07; p = 0.23; I^2 = 38%), short (4 RCTs, n = 964; SMD = -0.23; 95% CI: -0.48, 0.03; p = 0.08; I^2 = 68%), and long-term (2 RCT, n = 770; SMD = -0.12; 95% CI: -0.27, 0.02; p = 0.09; I^2 = 0%).

Quality of Life (n=4). We found moderate-quality evidence that PEMs are significantly more effective for increasing quality of life compared to usual care at short (4 RCTs, n = 934; SMD = -0.15; 95% CI: -0.28, -0.03; p = 0.02; I^2 = 0%) and medium-term (4 RCT, n = 902; SMD = -0.23; 95% CI: -0.41, -0.04; p = 0.02; I^2 = 39%). We found moderate-quality evidence of no effect at immediate (3 RCT, n = 839; SMD = -0.04; 95% CI: -0.18, 0.09; p = 0.55; I^2 = 0%) and long-term (2 RCT, n = 748; SMD = -0.13; 95% CI: -0.28, 0.01; p = 0.07; I^2 = 0%).

Global Improvement (n=1). We found very low-quality evidence that PEMs were significantly more effective at increasing global improvement ratings compared to usual care at immediate (1 RCT, $n = 461$; SMD = -0.40; 95% CI: -0.58, -0.21; $p < 0.0001$), short (1 RCT, $n = 461$; SMD = -0.42; 95% CI: -0.60, -0.24; $p < 0.00001$), medium (1 RCT, $n = 461$; SMD = -0.46; 95% CI: -0.65, -0.28; $p < 0.00001$), and long-term (1 RCT, $n = 461$; SMD = -0.43; 95% CI: -0.61, -0.24; $p < 0.00001$).

Self-efficacy (n=1). We found very low-quality evidence that PEMs were significantly more effective at increasing self-efficacy compared to usual care at immediate (1 RCT, $n = 461$; SMD = -0.21; 95% CI: -0.39, -0.03; $p = 0.02$), short (1 RCT, $n = 461$; SMD = -0.25; 95% CI: -0.43, -0.06; $p = 0.009$), medium (1 RCT, $n = 461$; SMD = -0.23; 95% CI: -0.41, -0.05; $p = 0.01$), and long-term (1 RCT, $n = 461$; SMD = -0.32; 95% CI: -0.50, -0.13; $p = 0.0007$).

Fear-Avoidance Beliefs (n=2). We found very low-quality evidence that PEMs were significantly more effective for reducing fear-avoidance beliefs compared to usual care at medium-term (1 RCT, $n = 461$; SMD = -0.24; 95% CI: -0.43, -0.06; $p = 0.01$). We found high-quality evidence that PEMs had no effect on fear-avoidance beliefs compared to usual care at immediate-term (2 RCTs, $n = 505$; SMD = -0.15; 95% CI: -0.33, 0.02; $p = 0.09$; $I^2 = 0\%$), and very low-quality evidence of no effect at short (1 RCT, $n = 461$; SMD = -0.09; 95% CI: -0.27, 0.09; $p = 0.33$) and long-term (1 RCT, $n = 461$; SMD = -0.16; 95% CI: -0.34, 0.02; $p = 0.08$).

Stress (n=1). We found very low-quality evidence that PEMs were significantly more effective at decreasing stress compared to usual care at long-term (1 RCT, $n = 461$;

SMD = -0.21; 95% CI: -0.39, -0.03; p = 0.02). We found very low-quality evidence that PEMs had no effect on stress compared to usual care at immediate (1 RCT, n = 461; SMD = -0.13; 95% CI: -0.32, 0.05; p = 0.15), short (1 RCT, n = 461; SMD = -0.13; 95% CI: -0.31, 0.06; p = 0.18), and medium-term (1 RCT, n = 461; SMD = -0.15; 95% CI: -0.33, 0.03; p = 0.11).

Depression (n=1). We found very low-quality evidence that PEMs had no effect on depression compared to usual care at immediate (1 RCT, n = 461; SMD = -0.18; 95% CI: -0.36, 0.01; p = 0.06), short (1 RCT, n = 461; SMD = -0.09; 95% CI: -0.27, 0.09; p = 0.35), medium (1 RCT, n = 461; SMD = -0.11; 95% CI: -0.29, 0.07; p = 0.24), and long-term (1 RCT, n = 461; SMD = -0.15; 95% CI: -0.33, 0.03; p = 0.10).

2.3.5.2 Patient education materials alone vs. other interventions

Ten trials [172,174–179,184,188,191] compared the effect of PEMs to other interventions (Table 2.7) on LBP-related outcomes for chronic LBP patients. The most commonly measured outcome was pain intensity (n=10), followed by disability (n=9), quality of life (n=5), global improvement (n=3), anxiety (n=2), and depression (n=2). Single studies measured function, pain self-efficacy, fear-avoidance beliefs, catastrophizing, coping, stress, days off work. No studies measured knowledge, attitudes, general beliefs, imaging, physician visits, referrals, or cost. A summary of findings for eight key outcomes are presented in Table 2.7 (a summary of all other outcomes and forest plots for all analyses are presented in Appendices 2.4 and 2.5, respectively).

Table 2.7. Summary of findings: education materials compared with another intervention for chronic low back pain

Outcome (# studies) Time points	Outcome measurement tools[a]	SMD[b] (95% CI) or RR[+,-] (95% CI)	Participants (# studies)	Quality of Evidence[c] (GRADE)
Knowledge: no evidence				
Self-Efficacy (n = 1):				
• Immediate-term (4 wks)	PSEQ (1)	0.05 [-0.23, 0.33]	199 (1)	⊕⊖⊖⊖ Very low[6]
• Short-term (12 wks)	PSEQ (1)	0.06 [-0.22, 0.34]	199 (1)	⊕⊖⊖⊖ Very low[6]
• Medium-term (24 wks)	PSEQ (1)	0.04 [-0.24, 0.32]	199 (1)	⊕⊖⊖⊖ Very low[6]
• Long-term	-	-	0 (0)	No evidence
Pain (n = 10):				
• Immediate-term (4-8 wks)	SBS (3), VAS (1), NRS (1), BPI (1), PPQ (1), UTs (1)	0.30 [0.03, 0.56]	732 (8)	⊕⊕⊕⊕ High
• Short-term (9-12 wks)	NRS (3), SBS (2), BPI (1), UTs (1)	0.54 [0.20, 0.88]	815 (7)	⊕⊕⊕⊕ High
• Medium-term (24-26 wks)	SBS (2), BPI (1), UTs (1)	0.22 [-0.25, 0.69]	450 (4)	⊕⊕⊕⊖ Moderate[3]
• Long-term (52 wks)	SBS (1)	0.18 [-0.12, 0.48]	168 (1)	⊕⊖⊖⊖ Very low[6]
Disability (n = 9):				
• Immediate-term (4-8 wks)	RMDQ (6), ODI (1)	0.47 [0.12, 0.83]	714 (7)	⊕⊕⊕⊕ High
• Short-term (9-12 wks)	RMDQ (6), ODI (2)	0.64 [0.25, 1.02]	881 (8)	⊕⊕⊕⊕ High
• Medium-term (24-26 wks)	RMDQ (3), ODI (1)	0.29 [-0.09, 0.67]	450 (4)	⊕⊕⊕⊕ High
• Long-term (52 wks)	RMDQ (1)	-0.07 [-0.37, 0.23]	168 (1)	⊕⊖⊖⊖ Very low[6]
Quality of Life (n = 5):				
• Immediate-term (4-8 wks)	SF-36 (3), SF-12 (1)	1.25 [0.14, 2.36] Two studies did not provide usable data but found no difference between groups	62 (2) 221 (2)	⊕⊕⊖⊖ Low[1,2]
• Short-term (10-12 wks)	SF-36 (3), SF-12 (1)	1.01 [-0.99, 3.01] Two studies did not provide usable data but found (i) no difference between groups or (ii) education to be less effective than other interventions	228 (2) i. 66 (1) ii. 168 (1)	⊕⊕⊖⊖ Low[2,3]
• Medium-term (26 wks)	SF-36 (1)	One study did not provide usable data but found no difference between groups	63 (1)	⊕⊖⊖⊖ Very low[6]

• Long-term (52 wks)	SF-12 (1)	One study did not provide usable data but found no difference between groups	159 (1)	⨁⨀⨀⨀ Very low[6]
Global Improvement (n = 3):				
• Immediate-term (4-6 wks)	PGIC (1), UTs (1)	0.53 [0.21, 0.84]	327 (2)	⨁⨁⨁⨀ Moderate[2]
• Short-term (12 wks)	PGIC (1), UTs (2)	0.60 [0.16, 1.04]	509 (3)	⨁⨁⨁⨁ High
• Medium-term (24-26 wks)	PGIC (1), UTs (1)	0.55 [0.19, 0.91]	327 (2)	⨁⨁⨁⨀ Moderate[2]
• Long-term	-	-	0 (0)	No evidence
Days off work (n = 1):				
• Immediate-term		-	0 (0)	No evidence
• Short-term (10 wks)	% with days off work (1)	One study did not provide usable data but found no difference between groups	168 (1)	⨁⨀⨀⨀ Very low[6]
• Medium-term		-	0 (0)	No evidence
• Long-term		-	0 (0)	No evidence
Imaging: no evidence				

[a]See legend in Appendix 2.4 for a complete list of non-abbreviated names of all measurement tools. [b]Data are presented as standardized mean differences (SMD) and 95% confidence intervals (95% CI) unless otherwise indicated (negative SMD favors education materials). Risk ratios are indicated with RR^+ (RR > 1 favors education) and RR^- (RR < 1 favors education). [c]Quality of evidence was downgraded for risk of bias,[1] imprecision,[2] inconsistency,[3] indirectness,[4] publication bias,[5] or downgraded to very low if there was one study[6] (more details provided in Appendix 2.3).

Pain Intensity (n=10). We found high-quality evidence that PEMs are less effective than other interventions for decreasing pain intensity at immediate (8 RCT, n = 732; SMD = 0.30; 95% CI: 0.03, 0.56; p = 0.03; I^2 = 63%) and short-term (7 RCT, n = 815; SMD = 0.54; 95% CI: 0.20, 0.88; p = 0.002; I^2 = 80%). We found moderate and very-low quality evidence that PEMs had no effect on pain intensity compared to other interventions at medium (4 RCT, n = 450; SMD = 0.22; 95% CI: -0.25, 0.69; p = 0.35; I^2 = 81%) and long-term (1 RCT, n = 168; SMD = 0.18; 95% CI: -0.12, 0.48; p = 0.24), respectively.

Disability (n=9). We found high-quality evidence that PEMs are less effective than other interventions for decreasing disability at immediate (7 RCTs, n = 714; SMD = 0.47; 95% CI: 0.12, 0.83; p = 0.009; I^2 = 79%) and short-term (8 RCT, n = 881; SMD = 0.64; 95% CI: 0.25, 1.02; p = 0.001; I^2 = 85%). We found high and very-low quality evidence that PEMs had no effect on disability compared to other interventions at medium (4 RCT, n = 450; SMD = 0.29; 95% CI: -0.09, 0.67; p = 0.13; I^2 = 72%) and long-term (1 RCT, n = 168; SMD = -0.07; 95% CI: -0.37, 0.23; p = 0.65), respectively.

Quality of Life (n=5). We found low-quality evidence that PEMs were less effective than other interventions for improving quality of life at immediate-term (2 RCTs, n = 62; SMD = 1.25; 95% CI: 0.14, 2.36; p = 0.03; I^2 = 73%). Two studies (2 RCTs; n = 221) could not be pooled in the analysis but both found no difference of effect. We found low-quality evidence that PEMs had no effect on quality of life compared to other interventions at short-term (2 RCTs, n = 228; SMD = 1.01; 95% CI: -0.99, 3.01; p = 0.32; I^2 = 96%). Two studies (2 RCTs; n = 221) could not be pooled, but one found there

to be no difference of effect (n = 66), and the other found PEMs to be significantly less effective than other interventions (n = 168). Finally, we found very low-quality evidence that PEMs had no effect on quality of life compared to other interventions medium (1 RCT; n = 63) and long-term (1 RCT; n = 159).

Global Improvement (n=3). We found moderate-quality evidence that PEMs are less effective than other interventions on global improvement ratings at immediate (2 RCTs, n = 327; SMD = 0.53; 95% CI: 0.21, 0.84; p = 0.001; I^2 = 22%) and medium-term (2 RCTs, n = 327; SMD = 0.55; 95% CI: 0.19, 0.91; p = 0.003; I^2 = 44%), and high-quality evidence of the same observation at short-term (3 RCTs, n = 509; SMD = 0.60; 95% CI: 0.16, 1.04; p = 0.008; I^2 = 75%).

Function (n=1). We found very low-quality evidence that PEMs are significantly less effective than other interventions for improving performance-based function measures on the 6-Minute Walk test (1 RCT, n = 19; SMD = 1.34; 95% CI: 0.32, 2.36; p = 0.01) and Sit-to-Stand test (1 RCT, n = 17; SMD = 1.26; 95% CI: 0.18, 2.34; p = 0.02) at immediate-term. We found very low-quality evidence that PEMs had no effect compared to other interventions on the Sit-and-Reach test (1 RCT, n = 19; SMD = 0.95; 95% CI: -0.02, 1.91; p = 0.05) at immediate-term.

Pain Self-Efficacy (n=1). We found very low-quality evidence that PEMs had no effect on pain self-efficacy compared to other interventions at immediate (1 RCT, n = 199; SMD = 0.05; 95% CI: -0.23, 0.33; p = 0.74), short (1 RCT, n = 199; SMD = 0.06; 95% CI: -0.22, 0.34; p = 0.67), and medium-term (1 RCT, n = 199; SMD = 0.04; 95% CI: -0.24, 0.32; p = 0.77).

Fear-Avoidance (n=1). We found very low-quality evidence that PEMs had no effect on fear-avoidance beliefs compared to other interventions at immediate (1 RCT, n = 199; SMD = 0.13; 95% CI: -0.15, 0.41; p = 0.35), short (1 RCT, n = 199; SMD = 0.08; 95% CI: -0.20, 0.36; p = 0.57), and medium-term (1 RCT, n = 199; SMD = 0.00; 95% CI: -0.28, 0.28; p = 1.00).

Catastrophizing (n=1). We found very low-quality evidence that PEMs are significantly less effective than other interventions for reducing catastrophizing thoughts at immediate (1 RCT, n = 199; SMD = 0.50; 95% CI: 0.21, 0.78; p = 0.0006), short (1 RCT, n = 199; SMD = 0.42; 95% CI: 0.14, 0.70; p = 0.003), and medium-term (1 RCT, n = 199; SMD = 0.44; 95% CI: 0.15, 0.72; p = 0.002).

Coping (n=1). We found very low-quality evidence that PEMs had no effect on coping compared to other interventions at immediate (1 RCT, n = 199; SMD = 0.13; 95% CI: -0.14, 0.41; p = 0.34), short (1 RCT, n = 199; SMD = 0.22; 95% CI: -0.05, 0.50; p = 0.12), and medium-term (1 RCT, n = 199; SMD = 0.17; 95% CI: -0.10, 0.45; p = 0.22).

Anxiety (n=2). We found very low-quality evidence that PEMs had no effect on anxiety compared to other interventions at immediate (1 RCT, n = 199; SMD = 0.07; 95% CI: -0.20, 0.35; p = 0.60), and medium-term (1 RCT, n = 199; SMD = 0.13; 95% CI: -0.15, 0.40; p = 0.38), and low-quality evidence of no difference in effect at short-term (1 RCT, n = 199; SMD = 0.65; 95% CI: -0.58, 1.87; p = 0.30; I^2 = 88%).

Stress (n=1). We found very low-quality evidence that PEMs had no effect on stress compared to other interventions immediate (1 RCT, n = 199; SMD = 0.17; 95% CI:

-0.10, 0.45; $p = 0.22$) and medium-term (1 RCT, $n = 199$; SMD = 0.26; 95% CI: -0.02, 0.54; $p = 0.07$). We found very low-quality evidence that PEMs are significantly less effective than other interventions for decreasing stress at short-term (1 RCT, $n = 199$; SMD = 0.31; 95% CI: 0.03, 0.59; $p = 0.03$).

Depression (n=2). We found very low-quality evidence that PEMs had no effect on depression compared to other interventions at immediate (1 RCT, $n = 199$; SMD = 0.03; 95% CI: -0.25, 0.31; $p = 0.84$) and medium-term (1 RCT, $n = 199$; SMD = 0.18; 95% CI: -0.10, 0.46; $p = 0.21$), and low-quality evidence of no effect at short-term (1 RCT, $n = 199$; SMD = 0.79; 95% CI: -0.56, 2.14; $p = 0.25$; $I^2 = 90\%$).

Days off Work (n=1). We found very low-quality evidence that PEMs had no effect on days off work compared to other interventions at short-term (1 RCT, $n = 168$). No summary data for this outcome was provided in the study so no point estimate can be provided.

2.3.5.3 Intervention vs. intervention + patient education materials (additive effect)

No studies measured the additive effect of PEMs with other interventions.

2.4 Discussion

We found 27 trials that evaluated the effectiveness of PEMs for acute or chronic LBP. Most were at moderate to high risk of bias (most commonly due to insufficient follow-up). We hypothesized that knowledge provided by PEMs would modify beliefs, expectations, and pain self-efficacy, and these changes would positively influence

patients' experience or perception of pain, expectations for unnecessary tests or other referrals, and adherence to advice to facilitate recovery compared to those who did not receive PEMs. Compared to usual care for acute LBP, PEMs appear to have at least some positive impacts both for patients and health systems, such as improved short-term pain intensity and immediate-term quality of life. Though the evidence was fairly low quality, knowledge appears to increase with the provision of PEMs across all measured time periods, as well as pain self-efficacy in the short to long-term. For health systems, the evidence was again fairly low quality, but PEMs reduced the short-term number of days off work and long-term physician visits and imaging. Compared to usual care for chronic LBP, PEMs were associated with improved pain intensity, global improvement ratings, and pain self-efficacy across all time periods, and quality of life from short to medium-term with variable levels of very low to moderate evidence. At medium-term, PEMs decreased disability but showed no impact at any other time measurement. The effect of PEMs on fear-avoidance beliefs and stress was more variable: fear-avoidance beliefs decreased in the medium-term, while stress decreased in the long term, with no other measurable impact in the other time periods. PEMs had no impact on depression.

Compared to other interventions, PEMs appear to have limited effectiveness in acute LBP. Though there were only one to two studies in all analyses and the quality of evidence was low to very low, PEMs were less effective in reducing immediate-term pain intensity and the number of long-term days off work and physician visits, with no effect on fear-avoidance beliefs, anxiety, depression, and disability. PEMs showed only a small impact on reducing pain intensity in the medium-term, but not short or long-term.

Compared to other interventions in chronic LBP, PEMs had no effect or were less effective for every outcome measured.

2.4.1 Comparison with existing literature

Though we are the first to assess PEMs alone, our results are supported by and expand on previous literature investigating the effectiveness of patient education for LBP. We found many under-assessed outcomes in the LBP patient education literature, including knowledge. Nevertheless, we did find improvements in knowledge across all measured time points, and we provide the first evidence of effect on this outcome for LBP. Looking to the wider literature, we find similar results for PEMs on knowledge for other conditions like diabetes [197] and cancer [198]. Imaging was another under-assessed outcome measured by only one study in our review. However, we found LBP PEMs can reduce imaging rates, which is consistent with studies where PEMs are used as part of larger multi-component interventions to reduce imaging [199–201].

Our findings differ from those of Traeger et al., [111] who found that individual patient education (with or without PEMs) improved reassurance for acute/subacute LBP. Despite including many of the same studies, we did not find any measures of reassurance. Looking more closely at their methods, we see they combined several proxy outcomes (e.g., anxiety, fear-avoidance, and catastrophizing) as their measure of reassurance. We included these outcomes but analysed them as separate constructs and while many favoured PEMs, they were mostly not statistically significant. This highlights the importance of using validated measures of outcomes.

Our results also expanded on those of Engers et al., [13] who found no studies comparing individual patient education to usual care for chronic LBP. We updated this literature with five recent studies and found PEMs were effective on several clinical and process outcomes. Compared to usual care for acute LBP, they found patient education was significantly more effective in some studies but not others. We had similar findings in this comparison, but since we pooled the results in meta-analyses, we were able to find a trend towards a benefit of PEMs over usual care for most clinical outcomes at most time points. Compared to other interventions, we had similar findings that PEMs had no effect or were less effective for chronic LBP.

2.4.2 Implications for practice

Our review showed that offering PEMs to patients is preferable to usual care for both acute and chronic LBP. Given that PEMs are relatively inexpensive to produce, easy to provide, and unlikely to cause harm, clinicians may find them an effective adjunct to care. Unfortunately, we could not obtain copies of many of the PEMs that were the focus of the papers in our review despite reaching out to all authors. Additional work will be required to effectively translate these materials into practice and realize their potential.

2.4.3 Implications for research

Overall, we were disappointed to find that many of the studies included in our review used unvalidated and modified outcome measures (especially for process outcomes) despite the existence of validated measurement tools. This clouds our understanding of the effectiveness of interventions and we recommend that researchers use unmodified, validated tools to measure all outcomes. In addition, many key outcomes

were rarely measured (e.g., quality of life, knowledge, pain self-efficacy) or not measured at all (e.g., attitudes, general beliefs). To standardize reporting in clinical trials, we recommend that researchers more frequently assess quality of life as it is a core clinical outcome for LBP alongside pain and disability [202], and suggest developing a similar set of core domains for important process outcomes related to LBP (e.g., fear-avoidance beliefs, catastrophizing, coping, pain self-efficacy) since measures of these outcomes varied substantially across LBP trials. Researchers should work with patients with LBP to choose a core set of prioritized, patient-reported outcomes. Finally, PEMs literature lacks adequate reporting on material development as well as measures of intervention adherence and other outcomes related to intervention fidelity, making it difficult to fully understand their effectiveness. We recommend that researchers assess and report these outcomes to determine if the interventions are being provided and received as planned by following intervention reporting guidelines such as the TIDieR checklist [131].

2.4.4 Future research

PEMs compared to usual care for chronic LBP appear to have more success than those for acute LBP, perhaps because the majority were comprehensive digital interventions (as opposed to the physical booklets most often used for acute LBP) with one or often more of the following: (i) co-development with patients, (ii) text- and video-based information, (iii) instant, tailored feedback based on automated questions, (iv) interactive or gamification components including quizzes and rewards, (v) reminders to use the material and follow recommendations, and (vi) could be accessed anywhere at any time. We recommend future studies compare these newer PEMs to other guideline-

recommended interventions (e.g., exercise therapies, massage, CBT) since most studies we found in this comparison used standard physical booklets. Furthermore, most of these studies treated the PEMs group as a control or usual care group, which may have introduced bias to the comparison and hindered our ability to interpret the results.

2.4.5 Strengths and limitations

The primary strengths of this review were our adherence to best practices for conducting systematic reviews. We followed all guidance provided in the Cochrane [203] and GRADE [169] handbooks, conducted a sensitive search strategy that adhered to the PRESS guidelines [161], and followed the TIDieR recommendations [131] for reporting of intervention details, which allowed for a more thorough assessment of PEMs. Additionally, we included a comprehensive list of outcomes that are important to all stakeholders, including patients, policymakers, researchers, and clinicians, and compared PEMs to other interventions that are commonly used in practice to provide relative effectiveness. We also sought and obtained additional data from authors who did not report the data within their study. Limitations to this review include the use of unvalidated and modified outcome measures and the conversion of dichotomized data to SMDs where it was necessary to pool the results. Both decisions could have influenced the resulting effect sizes and increased the degree of variability across outcome measures and time periods.

2.5 Conclusion

Due to the degree of variability in the impact of PEMs on all outcomes and across all time periods (likely a result of the heterogeneity of measures and definitions across

studies), it is difficult to succinctly and concisely state conclusions for all outcomes. However, it certainly appears that providing PEMs is better than doing nothing (i.e., usual care) as we observed small positive patient and system impacts for both acute and chronic LBP. Given their low cost and relative ease of provision, PEMs appear preferable to usual care, although the quality of evidence is fairly low for this conclusion. Compared to other interventions, PEMs had no effect or were less effective for almost every outcome measured; however, cost effectiveness was not assessed in any of these studies, and it is likely that PEMs were substantially less costly than all other studied interventions. Additionally, in recent years more comprehensive digital PEMs have been developed, and we recommend these are compared to other interventions before making conclusions about their relative usefulness.

2.6 Acknowledgements

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2.8 Competing interests

The authors have declared that no competing interests exist.

CHAPTER 3: Analgesic effects of non-surgical and non-interventional treatments for low back pain: A systematic review and meta-analysis of placebo-controlled randomised trials

Preface

This manuscript is currently under review at BMJ Evidence-Based Medicine.

Bradley M Furlong* and Aidan G Cashin,* Steven J Kamper, Diana De Carvalho, Luciana A. C. Machado, Simon RE Davidson, Krystal K Bursey, Christina Abdel Shaheed, Amanda M Hall. *Co-first author – authors contributed equally.

Co-authorship statement: AH and SK conceived the idea for the project. BF updated the protocol from the original review, then had it reviewed by the broader team. A health research librarian conducted the initial search and BF conducted the updated searches. AH, BF and KB conducted the study selection, BF, KB and SD conducted data extraction and SK, BF, SD and KB conducted quality appraisal. BF managed all data throughout the project and led team discussions on questions regarding study inclusion, quality appraisal, and data analysis. BF analysed all the data. BF and AGC had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. AGC wrote the first full draft of the manuscript. All authors provided substantive feedback on the manuscript and have read and approved the final version. The corresponding author (the manuscript's guarantor) attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Abstract

Objectives: To investigate the efficacy of non-surgical and non-interventional treatments for adults with low back pain compared with placebo.

Eligibility criteria: Randomised controlled trials evaluating non-surgical and non-interventional treatments compared with placebo or sham in adults (≥18 years) reporting non-specific low back pain.

Information sources: MEDLINE, CINAHL, EMBASE, PsychInfo and Cochrane Central Register of Controlled Trials were searched from inception to 14 April 2023.

Risk of bias: Risk of bias of included studies was assessed using the 0 to 10 PEDro Scale.

Synthesis of results: Random effects meta-analysis was used to estimate pooled effects and corresponding 95% confidence intervals on outcome pain intensity (0 to 100 scale) at first assessment post treatment for each treatment type and by duration of low back pain; (sub)acute (< 12 weeks) and chronic (≥ 12 weeks). Certainty of the evidence was assessed using the Grading of Recommendations Assessment (GRADE) approach.

Results: A total of 301 trials (377 comparisons) provided data on 56 different treatments or treatment combinations. One treatment for acute (NSAIDs), and 5 treatments for chronic (exercise, spinal manipulative therapy, taping, antidepressants, TRPV1 agonists) low back pain were efficacious, effect sizes were small and of moderate certainty. Three treatments for acute (exercise, glucocorticoid injections, paracetamol), and two treatments for chronic (antibiotics, anaesthetics) low back pain were not efficacious and are unlikely to be suitable treatment options; moderate certainty evidence. Evidence is inconclusive for remaining treatments due to small samples, imprecision, or low and very low certainty evidence.

Conclusions: The current evidence shows that one in ten non-surgical and non-interventional treatments for low back pain are efficacious, providing only small analgesic effects beyond placebo. The efficacy for majority of treatments is uncertain due to the limited number of randomised participants and poor study quality. Further high-quality, placebo-controlled trials are warranted to address remaining uncertainty in treatment efficacy along with greater consideration for placebo-control design of non-surgical and non-interventional treatments.

Registration: OSF Registries; https://osf.io/2dk9z

What is already known on this topic

- Placebo-controlled randomised trials are the best method for evaluating efficacy of treatments. There is a limited but growing evidence base of placebo-controlled randomised trials investigating the analgesic effects of non-surgical and non-interventional treatments for non-specific low back pain.

What this study adds

- This is the most comprehensive systematic review of placebo-controlled randomised trials investigating non-surgical and non-interventional treatments for non-specific low back pain; including 301 trials on 56 different treatments or treatment combinations.
- Most non-surgical and non-interventional treatments for low back pain were not efficacious. Around ten percent of non-surgical and non-interventional treatments provided small analgesic effects beyond placebo.

- For acute low back pain, there is moderate certainty evidence that NSAIDs are efficacious. For chronic low back pain, there is moderate certainty evidence that exercise, spinal manipulative therapy, taping, antidepressants, TRPV1 agonists are efficacious.

How this study might affect research, practice or policy

- This study supports the efficacy of several non-surgical and non-interventional treatments for reducing pain intensity compared to placebo in low back pain. Further high-quality, placebo-controlled trials to reduce uncertainty in remaining efficacy estimates are warranted as well as greater consideration for the design of placebos of many non-surgical and non-interventional treatments.

3.1 Introduction

Low back pain is a common [204] and burdensome problem [205] characterised by debilitating pain, impaired function, societal withdrawal and financial impacts [206]. The majority (80-90%) of low back pain is categorised as non-specific based on the fact that a nociceptive cause cannot be reliably identified clinically [207]. The global burden of low back pain is projected to increase in coming decades highlighting the need for efficacious and safe treatments for patients, clinicians, and policy makers [208].

Non-surgical and non-interventional treatments are recommended as first-line care for low back pain [209,210]. These include a large and heterogenous collection of treatments options with many new treatments continuing to be developed and implemented in clinical practice. With an increasing number of treatment options, it is difficult for key stakeholders to remain updated with what treatments are available much less understand their analgesic efficacy. It is essential to understand which treatment options are most promising to provide sound recommendations for healthcare providers, funders and patients.

Our group published a systematic review in 2008 that included 76 trials of 34 treatments which provides the most recent evidence of the analgesic effects of all non-surgical and non-interventional treatments in placebo-controlled randomised trials in a single review [211]. Since then the evidence base has grown substantially with many new treatments investigated using a placebo-controlled design. While systematic reviews for some of these treatments have been published, they only provide evidence on a single treatment. Variability in scope and quality of recent systematic reviews also makes use of

the evidence difficult for clinicians, patients, and policy makers. Synthesizing the evidence of non-surgical and non-interventional treatments for low back pain in a single review will provide much needed clarity on the effectiveness of available interventions compared to placebo.

The objective of this study is to provide an up-to-date evidence synthesis of the efficacy of non-surgical and non-interventional treatments compared with placebo or sham in adults with low back pain. We expect this review to form an essential part of a body of research that identifies which treatments can be recommended for care, which should be discouraged, and which are promising but require further research.

3.2 Methods

The review protocol was prospectively registered on Open Science Framework [212] (Appendix 3.1) and reported following the PRISMA guidelines [213]. Appendix 3.2 reports the minor deviations from the protocol and original review [211].

3.2.1 Eligibility criteria

3.2.1.1 Study Type

We included published randomised placebo-controlled trials of non-surgical and non-interventional treatments for people with non-specific low back pain. Investigating treatments in randomised, placebo or sham controlled trials is an important first step to determine the effectiveness of treatments. Doing so helps identify which treatments have effects beyond the contextual and non-specific effects of receiving care (placebo effects) [214], while also minimising the risk of bias (e.g., allocation, attention, detection,

performance and attrition biases) [215]. Evidence generated from placebo-controlled trials can support promotion of effective treatments and de-implementation of those that are no more effective than placebo. This information cannot be determined from other designs that use no-treatment or other-treatment comparison.

We translated non-English studies with Google Translate except for one study whose full text file was incompatible (e.g., JPEG). We excluded trials investigating primary prevention of low back pain (that included pain-free participants) and cross-over trials unless data were provided for the first phase before the crossover period. We also excluded unpublished records or trials for pragmatic reasons due to resource restraints in a review of this size.

3.2.1.2 Participants

Participants were adults with non-specific low back pain. Non-specific low back pain was defined as pain between the lower rib cage and gluteal folds, with or without non-radicular spine-related leg pain [216], for which no evidence of specific spinal pathology could be reliably detected [207,217]. Lumbar osteoarthritis, spondylolisthesis, disc protrusion, herniation, or prolapse, and facet syndrome were considered as non-specific low back pain and included [218]. Studies that included spine-related leg pain [216] were included unless the sample met our criteria for radiculopathy (positive neurological exam for sensory or motor deficits, e.g., dermatomal hypoesthesia or anaesthesia, myotomal weakness, or reduced or absent reflexes). We excluded studies that primarily recruited patients with low back pain due to specific spinal pathologies (e.g., cauda equina syndrome, infection, neoplasm, vertebral fracture including spondylolysis,

inflammatory disease including axial spondyloarthropathies), lumbar radicular syndromes, spinal stenosis, pregnancy, or recent spinal surgery (≤12 months). Trials reporting mixed populations (e.g., non-specific low back pain, upper back pain, and neck pain) were included if ≥ 75% of the sample had non-specific low back pain.

3.2.1.3 Interventions

We included non-surgical and non-interventional treatments that aimed to improve pain in people with low back pain. This included conservative (non-invasive) pharmacological (eg NSAIDs, muscle relaxants) and non-pharmacological (eg exercise, massage) treatments that could be provided in primary care. A detailed description of eligible treatment types is provided in Appendix 3.3. We included studies comparing combination medicines (e.g., muscle relaxants + NSAIDs) to a placebo and studies that reported standardized co-interventions (i.e., the same adjunct therapy provided to both the experimental and placebo groups). Surgical, interventional, and minimally invasive procedures, including laminectomy, posterior fusion, intradiscal electrothermal therapy, chemonucleolysis, radiofrequency denervation, prolotherapy, spinal cord stimulation, and intraspinal, interspinous and supraspinous injections were excluded [219].

3.2.1.4 Comparison

We included studies if the control intervention was described as a placebo or sham by the study's authors. We excluded studies compared with waitlist, no treatment, and usual care, and studies where it was not possible to isolate the effectiveness of the target intervention. For example, studies comparing a multicomponent non-pharmacological

intervention (e.g., heat + acupuncture) to the same multicomponent placebo group (e.g., sham heat + sham acupuncture).

3.2.1.5 Outcome

We included studies reporting a continuous measure of pain intensity. Pain intensity is considered a core outcome [220] and primary treatment target [221] for low back pain research, and is considered essential for recovery by people with low back pain [222]. Data on pain intensity was extracted at the first assessment after the end of treatment at the time which treatment was hypothesised to exert the greatest effect. We excluded studies reporting proxy measures (e.g., symptom bothersomeness, pain-related disability). We did not extract data on harms (adverse events), disability or other patient reported outcomes because this was beyond the scope of this review.

3.2.2 Data sources and searches

The search strategy was developed in collaboration with a health research librarian. We combined terms for randomised controlled trials and low back pain (as described by the Cochrane Back Review Group [223]), and additional terms including placebo, sham, attention-control, and minimal intervention (Appendix 3.4). We updated the search from the previous review [211] from January 2005 to April 2023 using MEDLINE, CINAHL, EMBASE, APA PsycInfo and Cochrane Central Register of Controlled Trials (Central). Authors of conference abstracts or ongoing trials identified in the search were contacted to determine if these studies had since been published. In addition, the reference lists of relevant systematic reviews were screened for potentially relevant trials. We did not search clinical trials registries or grey literature.

3.2.3 Study selection

All records identified by the search strategy were de-duplicated and imported to Covidence for screening. The review team independently screened all titles and abstracts. We retrieved full length records of potentially eligible titles and screened these in duplicate to determine inclusion. Disagreements between reviewers were resolved through discussion, or when necessary, through consultation with a third reviewer. All studies previously included in the original review [211] were screened against our inclusion criteria.

3.2.4 Data Extraction

Two independent reviewers extracted data from eligible studies using a standardised, piloted, data extraction form in Microsoft Excel. We extracted data on the study characteristics, participants, interventions, comparisons, co-interventions and pain outcome from each trial (Appendix 3.5). Outcome data (i.e., mean and standard deviation of pain scores) closest to the end of treatment were extracted in duplicate. When end of treatment scores were not reported, we extracted data according to the hierarchy of pre-treatment to post-treatment within group change scores for each eligible treatment arm first, then between group differences and corresponding 95% confidence intervals at follow-up. If pain outcome data was only provided graphically, we estimated the data using the WebPlotDigitizer (version 4.6) software. Where necessary we estimated the standard deviation using a relevant statistic provided in the study (e.g., confidence interval, standard error, interquartile range) [224]. When no measure of variance was reported, we imputed the standard deviation from the largest trial in the same analysis that

used the same measurement tool or used the standard deviation from another study included in the review using the same measurement tool with similar population characteristics [224]. We resolved disagreements regarding data extraction through discussion (BF, SD, KB), or with arbitration by a third reviewer if necessary (AH). Study authors were contacted when data were not reported.

3.2.5 Risk of bias and certainty of the evidence

When they were available, we extracted ratings for trials from the PEDro database (pedro.org.au), otherwise two trained independent raters scored the trials using the 0 to 10 PEDro scale (Appendix 3.6) [225,226]. Disagreements were resolved by discussion or, where necessary with a third reviewer. The PEDro scale has acceptable clinimetric properties and convergent validity with earlier versions of the Cochrane Risk of Bias Scale [226]. We considered the PEDro scale items for random allocation, concealed allocation, and adequate follow-up (>85%) as critical domains due to potential to bias treatment effect estimates in placebo-controlled randomised trials [227]. Studies with a PEDro score of ≤6/10 or one of the critical items marked as no/unclear, were classified as high risk of bias. Studies with a PEDro score of ≥7 and no critical items marked no/unclear were classified as low risk of bias [226]. Methodological quality was not an inclusion criterion.

Two independent reviewers assessed the certainty of the evidence for each analysis using the GRADE system classified as high, moderate, low, or very low certainty [228,229]. Disagreements were resolved by consensus. We downgraded the certainty of the evidence from ‘high’ certainty by one level if serious flaws were present in each the

five domains: risk of bias, inconsistency, indirectness, imprecision, publication bias (Appendix 3.7).

3.2.6 Data synthesis and analysis

All analyses were grouped by intervention class (pharmacological or non-pharmacological intervention) due to different challenges designing and implementing appropriate placebo controls [230]. Analyses were further stratified by treatment type based on descriptions provided in Appendix 3.3, and the duration of low back pain in the included trials; (sub)acute (< 12 weeks) and chronic (≥ 12 weeks) [223]. When a study included a mix of participants with acute and chronic low back pain, we classified the study as acute when either ≥ 75% of the population had acute low back pain or if the mean or median symptom duration of the sample was ≤ 30 days. We classified the study as chronic low back pain when either ≥ 75% of the population had chronic low back pain or the mean or median symptom duration of the sample was ≥ 12 months. Studies not meeting the above criteria were not included in our primary analysis, and are reported separately. We conducted meta-analyses where there was more than one study that reported pain intensity. For studies with multiple eligible comparisons, we either treated each comparison as an individual trial if considered in different meta-analyses, or divided the control group sample size by the number of trial arms in the same meta-analysis [224]. To facilitate the interpretation, we converted pain scores to a common 0-100 point scale, with 0 denoting no pain and 100 the worst possible pain [231,232]. To ensure the direction of effect was consistent between studies reporting between group differences and changes scores, we multiplied the point estimates by -1 when necessary [224]. For

each comparison, we classified findings as either efficacious, not efficacious, or inconclusive [233] (Appendix 3.8). We interpreted the size of the mean between group difference based on the definitions from the American College of Physicians and the American Pain Society [234]. A difference of 5 to 10 points was considered small, >10 to 20 points moderate and >20 points large.

Random effects meta-analytic models were fit using the inverse variance method in Review Manager (RevMan; version 5.4.1). We expressed effects for pain intensity using the mean between group difference and accompanying 95% confidence intervals. Meta-analyses were summarised using forest plots and I^2 statistics were calculated to assess the percentage of the total variance due to heterogeneity between trials. We created heat maps to simultaneously visualise the certainty of evidence and the magnitude of the effect. Due to the large number of included studies, we did not perform narrative synthesis on studies with unusable pain intensity data. We conducted sensitivity analyses to assess the potential impact of risk of bias in individual studies on the results of the meta-analysis. This involved examining how results vary with the exclusion of studies judged to be at high risk of bias.

3.3 Results

The flow of studies through the review is summarised in Figure 3.1. Overall, 6258 records were identified, 1547 duplicates were removed, and 4651 titles and abstracts screened. A total of 301 trials (377 treatment arms of interest) were included; 218 new trials plus 83 from the previous review. Twenty-one trials were not included in the

quantitative synthesis because they included participants of mixed low back pain duration (e.g., acute and chronic low back pain) (Appendix 3.16).

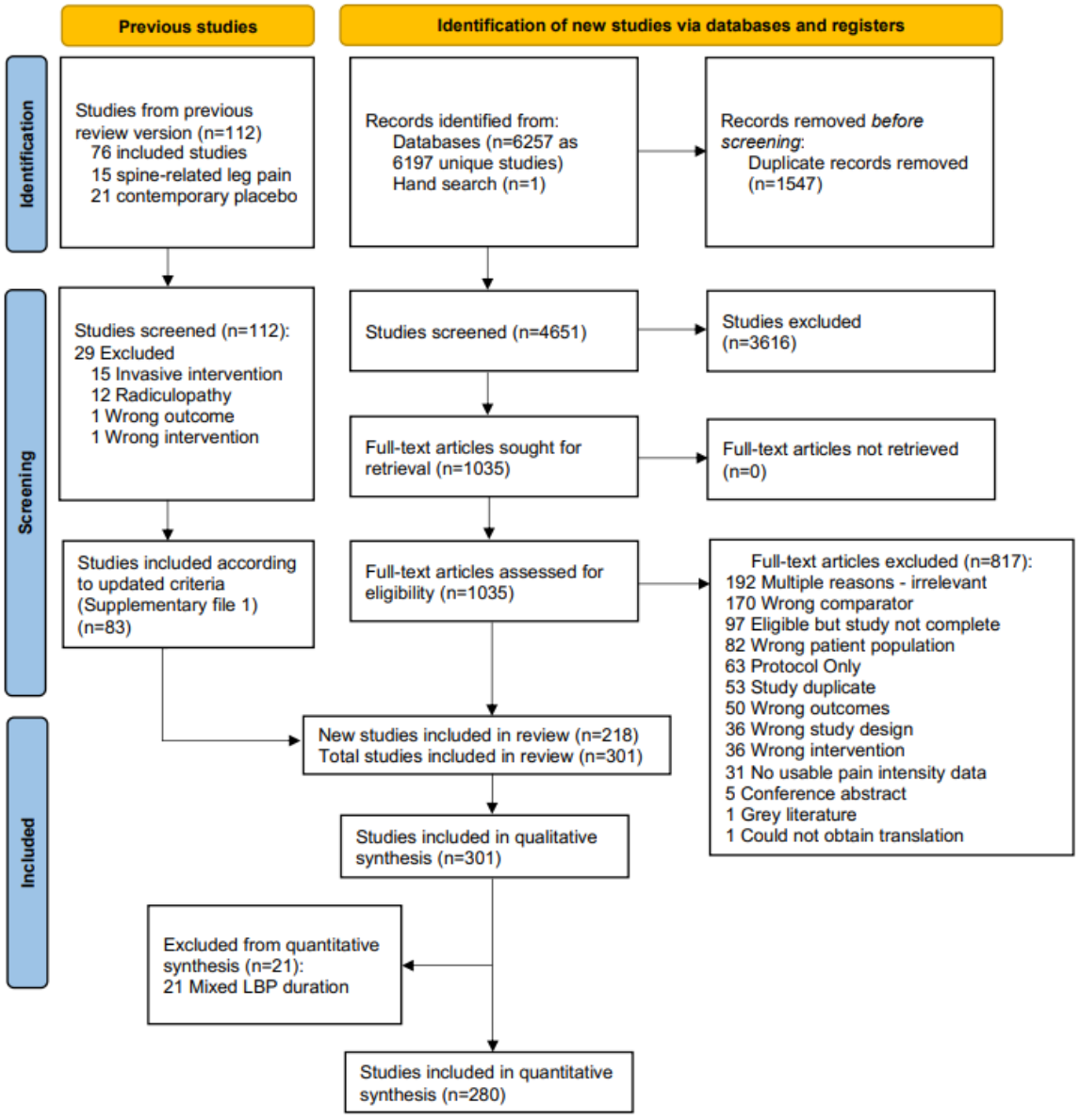


Figure 3.1. Flow of record selection process

3.3.1 Study characteristics

The 377 treatment arms of interest investigated 56 different treatments or treatment combinations. Most common were NSAIDs (n=27), opioids (n=26), laser and light (n=25), acupuncture (n=24) and mobilisation (n=19). Fifty-two trials sampled participants with acute low back pain, 228 trials with chronic low back pain, and 21 trials sampled participants with both acute and chronic low back pain (mixed duration). Trials were conducted on 6 continents (Africa, North America, South America, Asia, Australia, and Europe), in 44 countries. Pain intensity was most often assessed using the Visual Analogue Scale or the Numeric Rating Scale. Study characteristics are reported in Appendices 9-11.

3.3.2 Study quality

The median score (interquartile range) on the 0 to 10 PEDro scale for the included trials was 8 (6, 9). Of the 301 trials, 187 (62%) were considered at high risk of bias (Appendix 12). The most common risks of bias related to not blinding the therapist (209 trials, 69%), not performing analysis by intention-to-treat (149 trials, 50%), and not concealing allocation (138 trials, 46%).

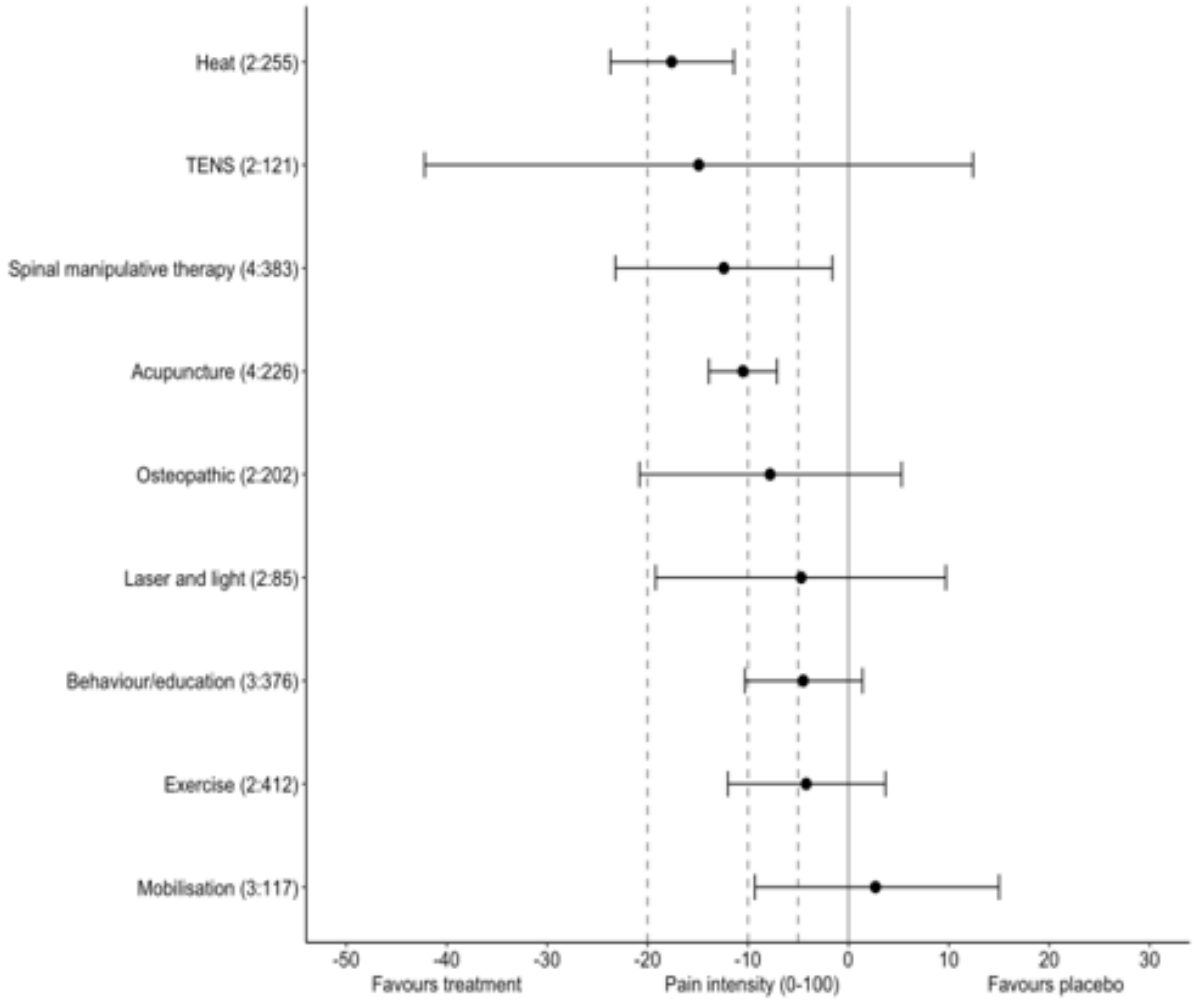
3.3.3 Certainty of the evidence

Of the 69 treatment comparisons, the certainty of the evidence was moderate for 11 (16%), low for 25 (36%), and very low for 33 (48%). There were no treatment comparisons where the certainty of the evidence was high. The main reasons for downgrading certainty of the evidence were inconsistency (n=52, 75%), risk of bias (n=47, 68%) and imprecision (n=47, 68%).

3.3.4 Analgesic efficacy

Tables 3.1-3.3 summarise the analgesic efficacy for all non-surgical and non-interventional treatments for acute and chronic low back pain. Efficacy estimates are presented as a Mean Difference on a 0-100 point pain scale. Figures 3.2 and 3.3 display the effect size and 95% confidence interval (from most to least effective) for treatment comparisons including two or more study or study arms. Appendices 3.18 and 3.19 display effect size and certainty (GRADE rating) of the evidence together. Detailed analysis for all treatments including the GRADE evidence profile is presented in Appendices 3.13-3.16.

A


Heat (2:255)
TENS (2:121)
Spinal manipulative therapy (4:383)
Acupuncture (4:226)
Osteopathic (2:202)
Laser and light (2:85)
Behaviour/education (3:376)
Exercise (2:412)
Mobilisation (3:117)
-50
-40
-30
-20
-10
0
10
20
30
Favours treatment
Pain intensity (0-100)
Favours placebo

B

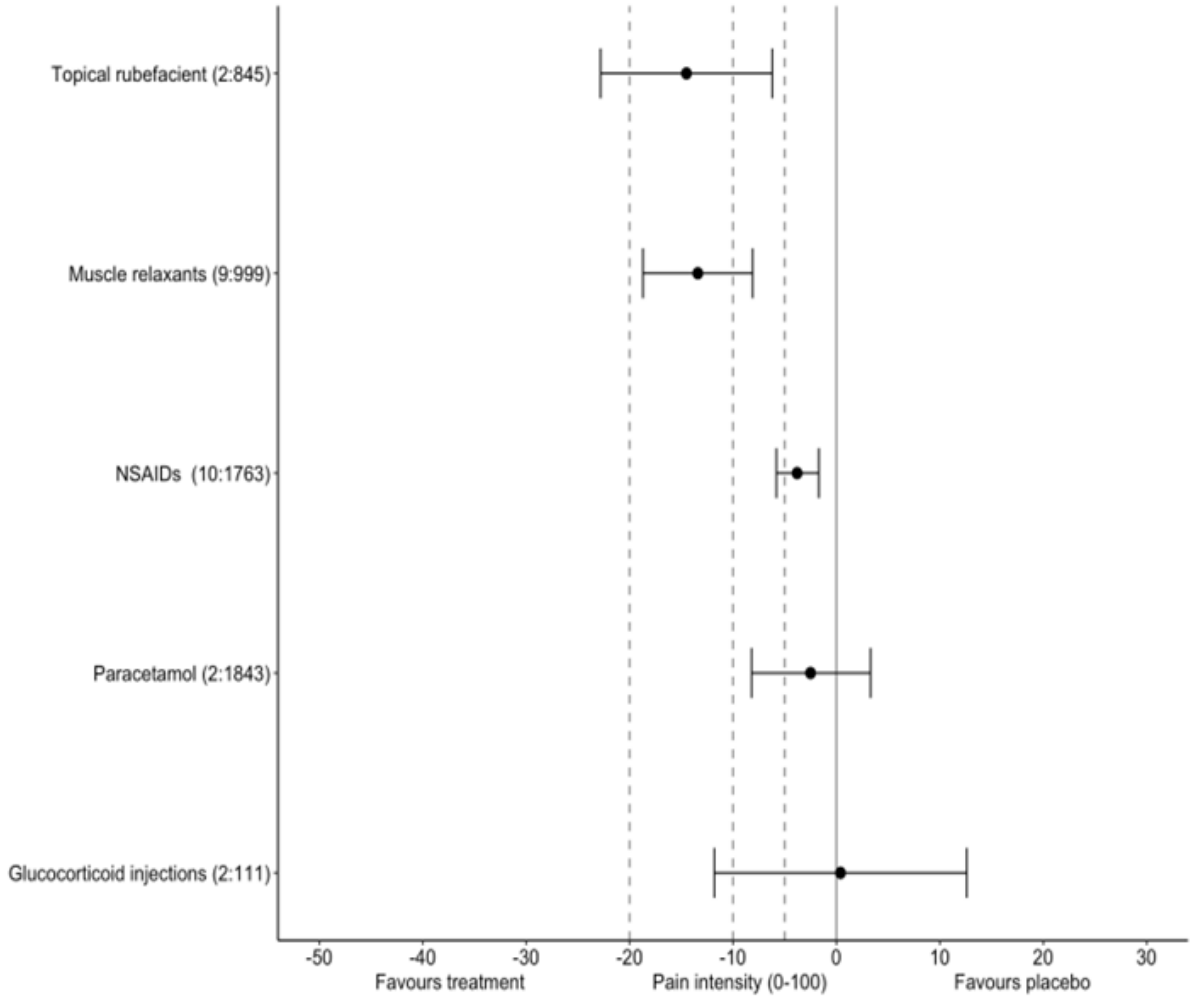
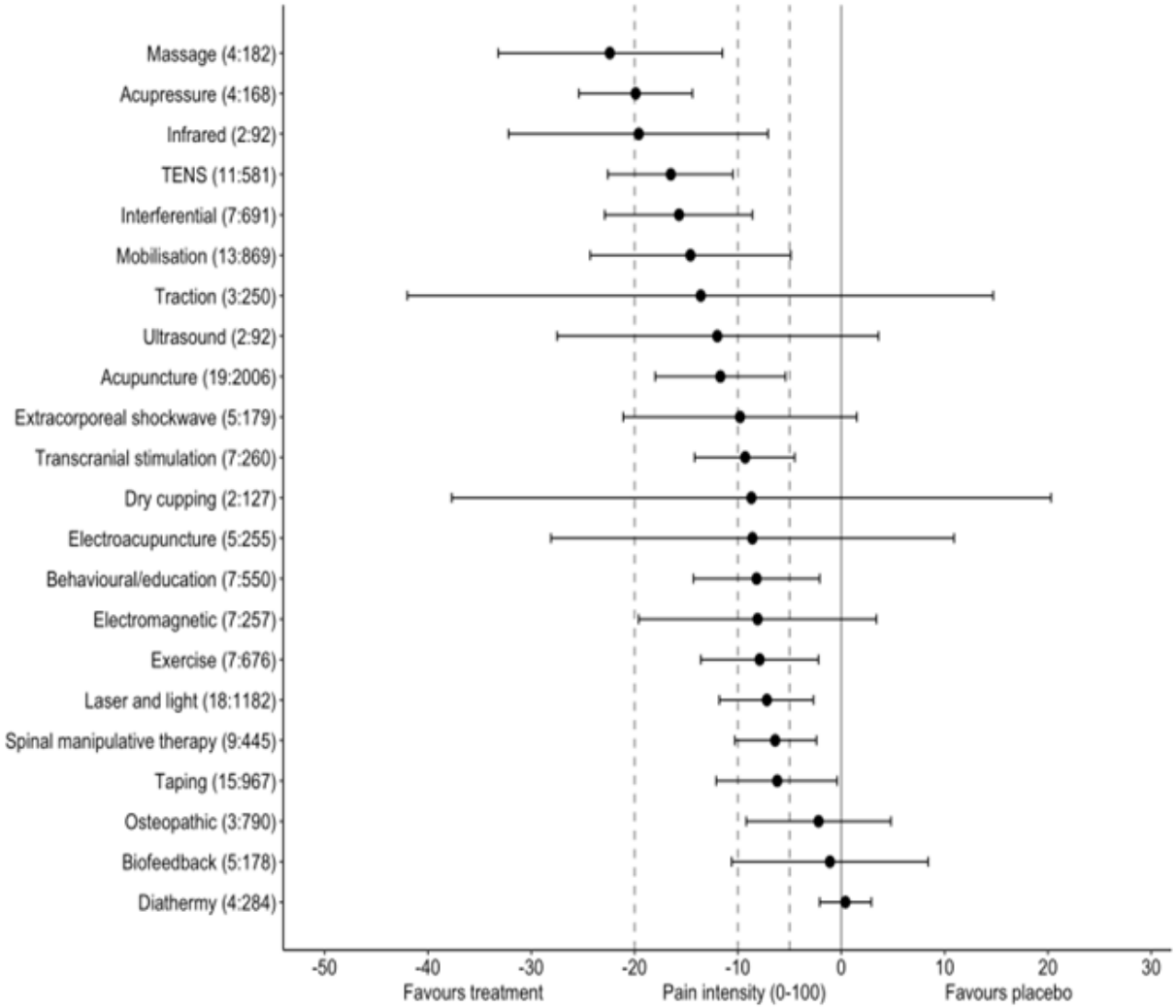

Topical rubefacient (2:845)
Muscle relaxants (9:999)
NSAIDs (10:1763)
Paracetamol (2:1843)
Glucocorticoid injections (2:111)
-50
-40
-30
-20
-10
0
10
20
30
Favours treatment
Pain intensity (0-100)
Favours placebo

Figure 3.2. Analgesic efficacy of non-pharmacological (panel A) and pharmacological (panel B) treatments including two or more trial or trial arms for acute low back pain. Circles represent pooled estimates of random effects and error bars represent 95% CIs. Negative values favour treatment. In parentheses: number of trials; total number of participants. The dotted lines define the magnitude of effects: large (>20 points); moderate (>10–20 points); small (5-10 points), and solid line defines the null

A


Massage (4:182)
Acupressure (4:168)
Infrared (2:92)
TENS (11:581)
Interferential (7:691)
Mobilisation (13:869)
Traction (3:250)
Ultrasound (2:92)
Acupuncture (19:2006)
Extracorporeal shockwave (5:179)
Transcranial stimulation (7:260)
Dry cupping (2:127)
Electroacupuncture (5:255)
Behavioural/education (7:550)
Electromagnetic (7:257)
Exercise (7:676)
Laser and light (18:1182)
Spinal manipulative therapy (9:445)
Taping (15:967)
Osteopathic (3:790)
Biofeedback (5:178)
Diathermy (4:284)
-50
-40
-30
-20
-10
0
10
20
30
Favours treatment
Pain intensity (0-100)
Favours placebo

B

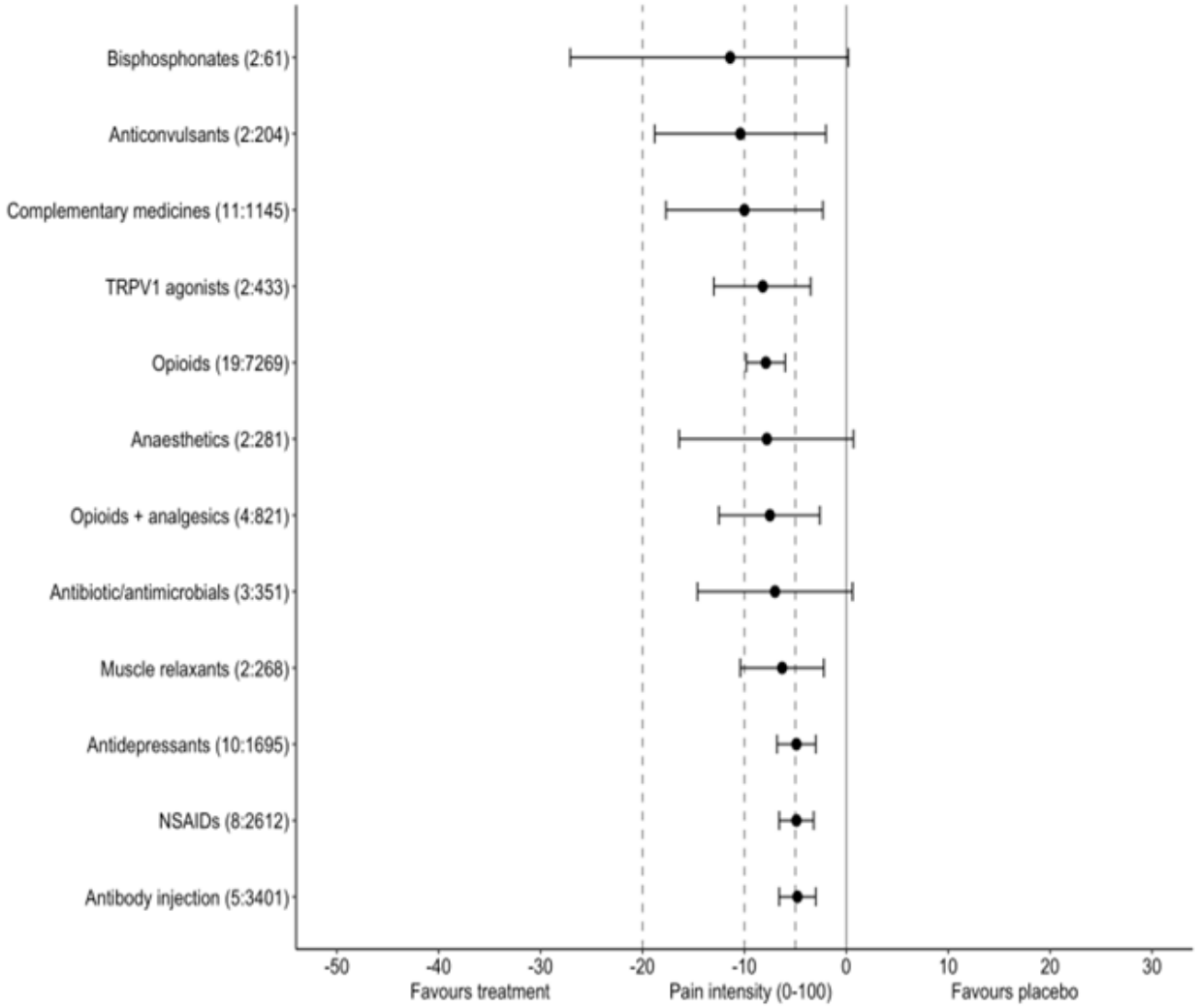

Bisphosphonates (2:61)
Anticonvulsants (2:204)
Complementary medicines (11:1145)
TRPV1 agonists (2:433)
Opioids (19:7269)
Anaesthetics (2:281)
Opioids + analgesics (4:821)
Antibiotic/antimicrobials (3:351)
Muscle relaxants (2:268)
Antidepressants (10:1695)
NSAIDs (8:2612)
Antibody injection (5:3401)
-50
-40
-30
-20
-10
0
10
20
30
Favours treatment
Pain intensity (0-100)
Favours placebo

Figure 3.3. Analgesic efficacy of non-pharmacological (panel A) and pharmacological (panel B) treatments including two or more trial or trial arms for chronic low back pain. Circles represent pooled estimates of random effects and error bars represent 95% CIs. Negative values favour treatment. In parentheses: number of trials; total number of participants. The dotted lines define the magnitude of effects: large (>20 points); moderate (>10–20 points); small (5-10 points), and solid line defines the null.

3.3.5 Evidence for efficacious interventions

3.3.5.1 Acute low back pain

No non-pharmacological treatments and one pharmacological treatments (NSAIDs; moderate certainty evidence) was found to be efficacious for acute low back pain (Table 3.1).

3.3.5.2 Chronic low back pain

Three non-pharmacological treatments (exercise, spinal manipulative therapy, taping; moderate certainty evidence) and two pharmacological treatments (antidepressants, TRPV1 agonists; moderate certainty evidence) were found to be efficacious for chronic low back pain (Table 3.1).

Table 3.1. Summary of findings table for efficacious interventions.

For (P) patients with low back pain, what is the effect of the (I) intervention listed below, (C) compared to placebo on the (O) outcome of pain at the (T) timepoint closest to the end of treatment				
Intervention	**Mean difference 0-100 (95% CI)**	**No of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
Acute low back pain				
Pharmacological intervention				
NSAIDs	-3.8 (-5.8 to -1.8)	1763 (10)	⨁⨁⨁⊖ Moderate[a]	Probably provide slight reductions in pain
Chronic low back pain				
Non-pharmacological intervention				
Exercise	-7.9 (-13.6 to -2.2)	676 (7)	⨁⨁⨁⊖ Moderate[a]	Probably provides small reductions in pain
Spinal manipulative therapy	-6.4 (-10.3 to -2.5)	445 (9)	⨁⨁⨁⊖ Moderate[a]	Probably provides small reductions in pain
Taping	-6.3 (-12.1 to -0.4)	967 (15)	⨁⨁⨁⊖ Moderate[b]	Probably provides small reductions in pain
Pharmacological interventions				
Antidepressants	-4.9 (-6.8 to -2.9)	1695 (10)	⨁⨁⨁⊖ Moderate[a]	Probably provide slight reductions in pain
TRPV1 agonists	-8.2 (-13.0 to -3.5)	433 (2)	⨁⨁⨁⊖ Moderate[a]	Probably provide small reductions in pain

[a] Downgraded by one level for serious risk of bias
[b] Downgraded by one level for serious inconsistency due to heterogeneity or single trial comparison

3.3.6 Evidence for not efficacious interventions

3.3.6.1 Acute low back pain

One non-pharmacological treatment (exercise; moderate certainty evidence) and two pharmacological treatments (glucocorticoid injections, paracetamol; moderate certainty evidence) were not efficacious for acute low back pain (Table 3.2).

3.3.6.2 Chronic low back pain

No non-pharmacological treatments and two pharmacological treatments (anaesthetics, antibiotics; moderate certainty evidence) were not efficacious for chronic low back pain (Table 3.2).

Table 3.2. Summary of findings table for not efficacious interventions.

For (P) patients with low back pain, what is the effect of the (I) intervention listed below, (C) compared to placebo on the (O) outcome of pain at the (T) timepoint closest to the end of treatment?				
Intervention	**Mean difference 0-100 (95% CI)**	**No of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
Acute low back pain				
Non-pharmacological intervention				
Exercise	-4.1 (-12.0 to 3.7)	412 (2)	⨁⨁⨁⊖ Moderate[a]	Probably provides little to no difference in pain
Pharmacological intervention				
Glucocorticoid injections	0.4 (-11.8 to 12.6)	111 (2)	⨁⨁⨁⊖ Moderate[b]	Probably provides little to no difference in pain
Paracetamol	-2.5 (-8.2 to 3.3)	1843 (2)	⨁⨁⨁⊖ Moderate[a]	Probably provides little to no difference in pain
Chronic low back pain				
Pharmacological interventions				
Anaesthetics	-7.8 (-16.4 to 0.7)	281 (2)	⨁⨁⨁⊖ Moderate[b]	Probably provide small reductions in pain
Antibiotic/antimicrobials	-7.0 (-14.6 to 0.6)	351 (3)	⨁⨁⨁⊖ Moderate[b]	Probably provide small reductions in pain

[a] Downgraded by one level for serious inconsistency due to heterogeneity or single trial comparison
[b] Downgraded by one level for imprecision due to < 400 participants in the analysis

3.3.7 Interventions for which evidence is inconclusive

3.3.7.1 Acute low back pain

Ten non-pharmacological treatments (acupuncture, behaviour/education, extracorporeal shockwave, heat, laser and light, massage, mobilisation, osteopathic, spinal manipulative therapy, TENS; low to very low certainty evidence) and ten pharmacological treatments (cannabinoid, colchicine, immunoglobulin, muscle relaxants, muscle relaxants + NSAIDs, nucleoside, opioids, ozone injections, pyrazolone derivatives, topical rubefacient; low to very low certainty evidence) had inconclusive evidence about their efficacy for acute low back pain (Table 3.3).

3.3.7.2 Chronic low back pain

Twenty two non-pharmacological treatments (acupressure, acupuncture, behaviour/education, biofeedback, diathermy, dry cupping, electroacupuncture, electromagnetic, extracorporeal shockwave, foot orthotics, infrared, interferential, laser and light, massage, mobilisation, osteopathy, radiotherapy, reflexology, TENS, traction, transcranial stimulation, ultrasound; low to very low certainty evidence) and 16 pharmacological treatments (allosteric modulator of the g-aminobutyric acid type A (GABAA) receptor, antibody injections, anticonvulsants, antidepressants + paracetamol, bee venom, bisphosphonates, Bushen Huoxue formula, complementary medicines, endogenous steroids, hypnotic medicines, muscle relaxants, muscle relaxants + NSAIDs, NSAIDs, opioids, opioids + analgesics, probiotics; low to very low certainty evidence) had inconclusive evidence about their efficacy for chronic low back pain (Table 3.3).

Table 3.3. Summary of findings table for interventions for which evidence is inconclusive

For (P) patients with low back pain, what is the effect of the (I) intervention listed below, (C) compared to placebo on the (O) outcome of pain at the (T) timepoint closest to the end of treatment?				
Intervention	**Mean difference 0-100 (95% CI)**	**No of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
Acute low back pain				
Non-pharmacological intervention				
Acupuncture	-10.5 (-13.9 to -7.1)	226 (4)	⨁⨁⨀⨀ Low[a,d]	May provide moderate reductions in pain
Behaviour/education	-4.4 (-10.3 to 1.4)	376 (3)	⨁⨀⨀⨀ Very low[a,b,d]	May provide little to no difference in pain (evidence is very uncertain)
Extracorporeal shockwave	14.6 (2.0 to 27.2)	53 (1)	⨁⨀⨀⨀ Very low[a,b,d]	May provide moderate increases in pain (evidence is very uncertain)
Heat	-17.6 (-23.7 to -11.4)	255 (2)	⨁⨀⨀⨀ Very low[a,d,e]	May provide moderate reductions pain (evidence is very uncertain)
Laser and light	-4.7 (-19.2 to 9.7)	85 (2)	⨁⨀⨀⨀ Very low[a,b,d]	May provide little to no difference in pain (evidence is very uncertain)
Massage	-22.0 (-34.4 to -9.6)	40 (1)	⨁⨀⨀⨀ Very low[a,b,d]	May provide large reductions in pain (evidence is very uncertain)
Mobilisation	2.9 (-9.3 to 15.0)	117 (3)	⨁⨀⨀⨀ Very low[a,b,d]	May increase pain (evidence is very uncertain)
Osteopathic	-7.7 (-20.6 to 5.2)	202 (2)	⨁⨀⨀⨀ Very low[a,b,d]	May provide small reductions in pain (evidence is very uncertain)
SMT	-12.4 (-23.2 to -1.6)	383 (4)	⨁⨁⨀⨀ Low[b,d]	May provide moderate reductions in pain
TENS	-14.9 (-42.2 to 12.4)	121 (2)	⨁⨀⨀⨀ Very low[a,b,d]	May provide moderate reductions in pain (evidence is very uncertain)
Pharmacological intervention				
Cannabinoid	4.0 (-6.0 to 14.0)	100 (1)	⨁⨁⨀⨀ Low[b,d]	May increase pain
Colchicine	15.0 (-10.6 to 40.6)	15 (1)	⨁⨀⨀⨀ Very low[a,b,d]	May moderately increase pain (evidence is very uncertain)
Immunoglobulin	-34.4 (-56.4 to -12.5)	41 (1)	⨁⨀⨀⨀ Very low[a,b,d]	May provide moderate reductions in pain (evidence is very uncertain)
Muscle relaxants	-13.4 (-18.7 to -8.0)	999 (9)	⨁⨁⨀⨀ Low[a,b]	May provide moderate reductions in pain
Muscle relaxants + NSAIDs	-6.0 (-18.8 to 6.8)	105 (1)	⨁⨀⨀⨀ Very low[a,b,d,e]	May provide small reductions in pain (evidence is very uncertain)
Nucleoside	-4.0 (-11.5 to 3.5)	161 (1)	⨁⨀⨀⨀ Very low[a,b,d,e]	May provide little to no difference in pain (evidence is very uncertain)
Opioids	-24.5 (-30.0 to -19.1)	200 (1)	⨁⨀⨀⨀ Very low[b,c,d]	May provide large reductions in pain (evidence is very uncertain)
Ozone injections	-13.0 (-20.0 to -6.0)	41 (1)	⨁⨀⨀⨀ Very low[a,b,d]	May provide moderate reductions in pain (evidence is very uncertain)
Pyrazolone derivatives	-12.3 (-18.5 to -6.1)	168 (1)	⨁⨀⨀⨀ Very low[b,d,e]	May provide moderate reductions in pain (evidence is very uncertain)
Topical rubefacient	-14.5 (-22.7 to -6.2)	845 (2)	⨁⨁⨀⨀ Low[b,e]	May provide moderate reductions in pain
Chronic low back pain				
Non-pharmacological intervention				
Acupressure	-19.9 (-25.4 to -14.4)	168 (4)	⨁⨁⨀⨀ Low[a,d]	May provide moderate reductions in pain
Acupuncture	-11.7 (-18.0 to -5.4)	2006 (19)	⨁⨁⨀⨀ Low[b,e]	May provide moderate reductions in pain
Behavioural/education	-8.2 (-14.3 to -2.1)	550 (7)	⨁⨁⨀⨀ Low[a,b,]	May provide small reductions in pain
Biofeedback	-1.1 (-10.5 to 8.4)	178 (5)	⨁⨀⨀⨀ Very low[a,b,d]	May provide little to no difference in pain (evidence is very uncertain)
Diathermy	0.4 (-2.1 to 2.9)	284 (4)	⨁⨀⨀⨀ Very low[a,b,d]	May provide little to no difference in pain (evidence is very uncertain)

Dry cupping	-8.7 (-37.7 to 20.3)	127 (2)	⨁⨁⨀⨀ Low[b,d]	May provide small reductions in pain
Electroacupuncture	-8.6 (-28.1 to 10.9)	255 (5)	⨁⨀⨀⨀ Very low[a,b,d]	May provide small reductions in pain (evidence is very uncertain)
Electromagnetic	-8.1 (-19.6 to 3.4)	257 (7)	⨁⨀⨀⨀ Very low[a,b,d]	May provide small reductions in pain (evidence is very uncertain)
Extracorporeal shockwave	-9.8 (-21.1 to 1.5)	179 (5)	⨁⨀⨀⨀ Very low[a,b,d]	May provide small reductions in pain (evidence is very uncertain)
Foot orthotics	-34.7 (-44.3 to -25.1)	51 (1)	⨁⨀⨀⨀ Very low[a,b,d]	May provide large reductions in pain (evidence is very uncertain)
Infrared	-19.6 (-32.2 to -7.1)	92 (2)	⨁⨀⨀⨀ Very low[a,b,d,e]	May provide moderate reductions in pain (evidence is very uncertain)
Interferential	-15.7 (-22.9 to -8.6)	691 (7)	⨁⨀⨀⨀ Very low[a,b,e]	May provide moderate reductions in pain (evidence is very uncertain)
Laser and light	-7.2 (-11.8 to -2.7)	1182 (18)	⨁⨁⨀⨀ Low[a,b]	May provide small reductions in pain
Massage	-22.4 (-33.2 to -11.6)	182 (4)	⨁⨀⨀⨀ Very low[a,b,d]	May provide large reductions in pain (evidence is very uncertain)
Mobilisation	-14.6 (-24.3 to -4.9)	869 (13)	⨁⨁⨀⨀ Low[a,b]	May provide moderate reductions in pain
Osteopathic	-2.2 (-9.2 to 4.8)	790 (3)	⨁⨁⨀⨀ Low[a,b]	May provide little to no difference in pain
Radiotherapy	-1.3 (-16.6 to 14.0)	32 (1)	⨁⨁⨀⨀ Low[b,d]	May provide little to no difference in pain
Reflexology	-8.0 (-19.2 to 3.2)	15 (1)	⨁⨀⨀⨀ Very low[a,b,d]	May provide small reductions in pain (evidence is very uncertain)
TENS	-16.5 (-22.5 to -10.5)	581 (11)	⨁⨁⨀⨀ Low[a,b]	May provide moderate reductions in pain
Traction	-13.6 (-42.0 to 14.8)	250 (3)	⨁⨁⨀⨀ Low[b,d]	May provide moderate reductions in pain
Transcranial stimulation	-9.3 (-14.2 to -4.5)	260 (7)	⨁⨁⨀⨀ Low[a,d]	May provide small reductions in pain
Ultrasound	-12.0 (-27.5 to 3.6)	92 (2)	⨁⨀⨀⨀ Very low[a,b,d]	May provide moderate reductions in pain (evidence is very uncertain)
Pharmacological interventions				
GABAA receptor modulator	1.6 (-3.7 to 6.9)	148 (1)	⨁⨀⨀⨀ Very low[b,d,e]	May increase pain (evidence is very uncertain)
Antibody injection	-4.8 (-6.6 to -3.0)	3401 (5)	⨁⨁⨀⨀ Low[a,e]	May provide slight reductions in pain
Anticonvulsants	-10.4 (-18.8 to -2.0)	204 (2)	⨁⨀⨀⨀ Very low[a,b,c,d]	May provide moderate reductions in pain (evidence is very uncertain)
Antidepressants + paracetamol	5.7 (-4.3 to 15.7)	63 (1)	⨁⨀⨀⨀ Very low[a,b,d]	May increase pain (evidence is very uncertain)
Bee Venom	-9.3 (-18.7 to 0.1)	54 (1)	⨁⨁⨀⨀ Low[b,d]	May provide small reductions in pain
Bisphosphonates	-11.4 (-22.9 to 0.2)	61 (2)	⨁⨁⨀⨀ Low[d,e]	May provide small reductions in pain
Bushen Huoxue formula	-11.6 (-16.3 to -6.9)	66 (1)	⨁⨁⨀⨀ Low[b,d]	May provide moderate reductions in pain
Complementary medicines	-10 (-17.7 to -2.3)	1145 (11)	⨁⨀⨀⨀ Very low[a,b,e]	May provide moderate reductions in pain (evidence is very uncertain)
Endogenous steroids	-5.5 (-13.3 to 2.3)	83 (1)	⨁⨀⨀⨀ Very low[a,b,d]	May provide small reductions in pain (evidence is very uncertain)
Hypnotic medicines	-19.9 (-31.5 to -8.3)	52 (1)	⨁⨀⨀⨀ Very low[b,d,e]	May provide moderate reductions in pain (evidence is very uncertain)
Muscle relaxants	-6.3 (-10.4 to -2.2)	268 (2)	⨁⨁⨀⨀ Low[a,d]	May provide small reductions in pain
Muscle relaxants + NSAIDs	-10.0 (-56.0 to 36.0)	18 (1)	⨁⨁⨀⨀ Low[b,d]	May provide moderate reductions in pain
NSAIDs	-4.9 (-6.6 to -3.1)	2612 (8)	⨁⨁⨀⨀ Low[a,e]	May provide slight reductions in pain
Opioids	-7.9 (-9.8 to -6.0)	7269 (19)	⨁⨀⨀⨀ Very low[a,b,e]	May provide small reductions in pain (evidence is very uncertain)
Opioids + analgesics	-7.5 (-12.5 to -2.5)	821 (4)	⨁⨁⨀⨀ Low[a,e]	May provide small reductions in pain
Probiotic	1.0 (-8.0 to 10.0)	88 (1)	⨁⨁⨀⨀ Low[b,d]	May provide little to no difference in pain

[a] Downgraded by one level for serious risk of bias

[b] Downgraded by one level for serious inconsistency due to heterogeneity or single trial comparison
[c] Downgraded by one level for indirectness due to > 50% of trials included participants with spine-related leg pain
[d] Downgraded by one level for imprecision due to < 400 participants in the analysis
[e] Downgraded by one level for publication bias due to evidence of funnel plot asymmetry or >50% of participants were from industry funded trials with potential conflicts of interest

3.3.8 Sensitivity analyses

Appendix 3.17 presents detailed results for sensitivity analyses exploring the effect of risk of bias. The results did not substantially vary through statistically different non-overlapping confidence intervals by removing studies at high risk of bias.

3.4 Discussion

This review provides the most comprehensive summary of evidence for non-surgical and non-interventional treatments for low back pain. We included 301 placebo-controlled trials with data on an additional 21 treatments or treatment combinations compared to the earlier review version [211]. For this review we separated analyses by intervention class (non-pharmacological and pharmacological) and duration of low back pain (acute and chronic) to provide specific evidence to support clinical decisions and policy recommendations. We also assessed the certainty of the evidence using GRADE to assess the confidence in the proximity of the estimated effect to the true population mean effect.

Only one treatment for acute low back pain and 5 treatments for chronic low back pain had at least moderate certainty evidence for providing statistically significant reductions in pain intensity compared to placebo. Effect estimates for efficacious treatments for acute pain (NSAIDs) and chronic pain (exercise, spinal manipulative therapy, taping, antidepressants, TRPV1 agonists) were small. We identified three treatments for acute low back pain (exercise, glucocorticoids, paracetamol) and two treatments for chronic low back pain (anaesthetics, antibiotics/antimicrobials) for which there is at least moderate quality evidence of no effect. Evidence is inconclusive for other

treatments due to few participants, imprecision, or being of low or very low certainty. Further large, high-quality trials may help reduce the uncertainty in the evidence for these treatments.

This systematic review was prospectively registered [235] and reported following recommended guidance [213]. We included all non-surgical and non-interventional treatments evaluated in placebo-controlled randomised trials and published in any language. We assessed the methodological quality of trials using the PEDro scale [226] and evaluated the certainty of the evidence using GRADE [228,229]. Finally, to support clinical and policy interpretation of findings, we provided a visual summary of results organising the findings by the magnitude and certainty of effects as well as classified the findings for each comparison as either efficacious, not efficacious, or inconclusive based on both statistical significance and the certainty of the evidence.

Our review has limitations. The eligibility criteria relied on the comparator being described as a placebo or sham in the identified trials to be included in the review, the definition for what constitutes the placebo or sham group varies between trials. We decided to group similar treatments (e.g., selective and non-selective NSAIDs) regardless of route of administration to reduce the number of comparisons reported and support the interpretation for clinical and policy decision making. This is commonly done in the field (e.g., [236,237]). We included trials in which participants in both groups received the same standardised co-intervention. It is unlikely the inclusion of trials with standardised co-interventions influenced the interpretation of findings. Finally, we did not include

unpublished records or trials for pragmatic reasons. The impact of including these studies is uncertain and not routinely considered in low back pain research [238].

Placebo comparators are an important tool in evidence-based medicine because they separate the specific from non-specific effects of treatments and reduce the risk of common biases. In low back pain research, meta-analyses have demonstrated that placebo interventions have a small analgesic effect (8/100 points) compared to no intervention in the short term [239]. Despite their importance, placebo controlled trials are uncommon in low back pain research, with most trials compared against another treatment or against usual care [227]. For example, there are a lack of placebo-controlled trials of common psychological treatments (e.g., cognitive behavioural therapy) for low back pain [240]. Without evidence from placebo-controlled trials, the specific effects of common treatments are unknown. The absence of placebo controlled trials may result from difficulty in design for non-pharmacological interventions [230,241], confusion with common terminology [215,242], and challenges in interpretation by consumers [243].

Interpretation of these findings should consider the challenges in designing and implementing credible and matched placebo controls for all treatment options considered in this review. For example, the participatory and often complex nature of non-pharmacological treatments (e.g., exercise and psychological therapies) makes it difficult to design and implement suitable placebo controls [230]. In comparison methods for placebo controls for medications and unimodal treatments such as acupuncture and electro-physical agents are well-established and straight-forward. This may result in higher certainty and more precise estimates of efficacy for treatments such as medications

and acupuncture, than for exercise, psychological and behavioural interventions. For this reason, clinicians and policy-makers should consider evidence from trials with other types of control interventions in decision making.

Our findings are broadly comparable to those of recent high-quality systematic reviews of single treatment classes (e.g., exercise therapy [237], acupuncture [244], and antidepressants [245]), overview of pharmacological treatments investigated in Cochrane systematic reviews [246], and clinical practice guideline recommendations [209]. Discrepancies in findings with other reviews are likely due to differences in: 1) inclusion criteria (e.g., PICO elements) including use of recent terminology to classify spine-related leg pain [216]; 2) data sources (e.g., inclusion of trial registry data [247]), 3) choice of tool and method to assess risk of bias and certainty of evidence; and 4) combination of the above (e.g., muscle relaxants [248]). Identified discrepancies related to minor differences in the size of the effect or certainty of the evidence that would not substantially change clinical decisions. The increasing publication of overlapping and low-quality systematic reviews across low back pain research makes direct comparisons across all investigated treatments difficult [249].

Our review did not find reliable evidence of large effects for any of the included treatments which is consistent with clinical guidelines and our previous review. While we would like to provide more certain recommendations for where to invest and disinvest in treatments it's not possible at this time. Certainty in our findings is limited by many of the available trials including few participants and reporting inconsistent results. Further complicating the interpretation of findings is the heterogenous type and quality of some

of the placebos used in the included trials. These findings from our review provide important insights for the broader, ongoing conversation about “where to next” for placebo-controlled trials of low back pain treatments.

Our review identified several unanswered questions for future research. There is a clear need for large, high-quality, placebo-controlled trials to reduce uncertainty in efficacy estimates for many non-surgical and non-interventional treatments. For example, many of the included treatments had only a single trial with less than 100 participants per group. Additional high-quality trials will support the investigation of potential heterogeneity of treatment effects including relevant subgroups. There are also common treatments for which no placebo-controlled trials have been conducted despite being commonly recommended in clinical practice guidelines [209,250]. Finally, there is a need for better consideration around the design of placebos for complex interventions such as behavioural, psychological and exercise treatments with opportunities to draw on recently published guidance [251].

3.5 Conclusion

Best available evidence shows that one in ten common non-surgical and non-interventional treatments for low back pain are efficacious, providing small analgesic effects beyond placebo. Further high-quality, placebo-controlled trials are warranted to address the remaining uncertainty in treatment efficacy along with greater consideration for designing placebos of non-surgical and non-interventional treatments.

3.6 Acknowledgments

We acknowledge Lindsay Alcock for running the updated search. We acknowledge the following graduate students who helped with initial screening and data extraction but were not able to continue for the duration of the review; Gabrielle Logan, Emily Devereaux, and Keisha Whelan.

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3.8 Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

3.9 Ethical approval

Not required.

3.10 Data sharing

The dataset used and analysed during this study, and the accompanying code is available from the corresponding author upon reasonable request.

3.11 Transparency

All authors affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted; and any discrepancies from the study as originally planned (and, if relevant, registered) have been explained.

3.12 Dissemination to participants and related patient and public communities

We will disseminate our findings to patient organisations and traditional media and social media outlets.

3.13 Patient consent for publication

Not required.

3.14 Patient and public involvement

No patients or members of the public were directly involved in setting the research question or in developing plans for the design of this study because of a lack of

funding. We asked patients and members of the public to read the draft manuscript and advise on the writing and interpretation of results. We plan to disseminate the results of this review to relevant patient organisations.

CHAPTER 4: Does your patient education material for low back pain meet patients' information and education needs? Development of a new checklist

Preface

This manuscript is currently under review at PLoS One. Bradley Furlong, Holly Etchegary, Andrea Pike, Kris Aubrey-Bassler, Simon Davidson, Amanda Hall

Co-authorship statement: BF conceptualized the idea for this study based on the literature as no tool had been developed to assess whether patient education materials contained information about patients' needs. BF reviewed the broader literature to develop the protocol and define the checklist domain, then had it reviewed by the broader team before proceeding. BF conducted the literature searches for all data to inform our content analysis. BF, AH, and AP conducted the content analysis. BF, AH, and HE coordinated the patient engagement activities and face validity checks. BF prepared all materials for these meetings and led each discussion. BF made all necessary changes to the checklist based on feedback from these meetings. SD pre-tested the checklist. BF wrote the first draft of the manuscript. All authors reviewed the manuscript and have read and approved of the final version.

Abstract

Introduction: Patient education aims to enable patients to make more knowledgeable decisions about their health behaviours. Though there are many validated tools to assess the understandability, actionability, quality, and readability of patient education materials, no tool has been developed to assess whether patient education materials contain information about the information needs of patients with low back pain.

Objectives: To synthesize a comprehensive list of patients' information and education needs about low back pain and design a checklist that can be used to assess if patient education materials for low back pain contain information about these needs.

Methods: We reviewed the literature to inform our working definitions of patients' information needs (i.e., what patients have said they want to know more about) and education needs (i.e., what clinicians and researchers have identified that patients lack knowledge about). Using these definitions, we found two recent systematic reviews investigating patients' information needs, attitudes, and beliefs about low back pain. We used the constant comparative method to conduct a content analysis of the data from these reviews into codes and categories relating to patients' needs, from which we generated checklist items. Patient partners and clinician researchers who are members of our wider research team helped us to assess the face validity of the items. An experienced clinician researcher pre-tested the checklist to minimize misunderstandings and measurement error.

Results: We developed a checklist comprising 21 patient information and education needs relating to prognosis, diagnosis, treatment, causes, aetiology, prevention, functional

anatomy, activities of daily living, and pain neuroscience education. The checklist was determined to have acceptable face validity by content experts.

Conclusion: We developed the first checklist that can be used to assess if patient education materials for low back pain contain information about patients' information and education needs. Though further validation is required, we expect the checklist will be useful for developing future educational content for low back pain.

4.1 Introduction

Patient education is an integral part of any healthcare exchange that aims to enable patients to make more knowledgeable decisions about their health behaviours [93]. Providing information about important health topics including assessment, diagnosis, prognosis, treatment options, required follow-up, and when to seek further care may increase patients' willingness to adhere to treatments and improve the course of their condition [93].

As part of a larger project, we are intending to use patient education (via a patient education material) as part of a multicomponent intervention for improving evidence-based treatment for patients with low back pain (LBP) [252]. In a related preparatory study, we developed a protocol to conduct a comprehensive assessment of patient education materials for LBP with a battery of evidence-based and validated assessment tools including the Patient Education Materials Assessment Tool (PEMAT) [133], the DISCERN tool [253], the Flesh-Kincaid Grade Ease and Flesch-Kincaid Grade-Level algorithms [135], and methods developed by Ferreira et al. [254] to assess their understandability, actionability, quality, readability, accuracy, and comprehensiveness [255].

In our literature review of assessment tools, we identified that none had been rigorously designed to assess if patient education materials contain information about the information needs of patients with LBP. Only one similar tool exists [256], but (i) it was informed by data from a single qualitative study, (ii) it was designed specifically for

evaluating websites and not for other types of patient education materials, (iii) its items were not assessed to determine if they had acceptable face validity, and (iv) it does not consider other types of information-related needs, such as what information health providers think patients with LBP should know. Therefore, we set out to explore how we might develop a more comprehensive checklist that accounts for both patient- and provider-identified needs, that can be used on any patient education materials and not just websites, is informed by a more comprehensive dataset available from the wider literature, and is evaluated for face validity by expert judges.

We reviewed the literature for a definition of patient information needs and identified a literature review published in 2011 [257] which outlines two types of information requirements relevant to patients: patient information needs (PINs) and patient education needs (PENs). A PIN is a realization that one lacks knowledge to achieve a goal [257]. A PEN, on the other hand, is informed by other measures of knowledge deficit, often by someone other than the individual with the knowledge deficit [258]. For example, patients with LBP often express a need for more information about LBP prognosis [88], which would be considered a PIN. In contrast, evidence shows that people have many incorrect beliefs about LBP including beliefs that bed rest is beneficial and that diagnostic imaging is required to identify the root cause of pain [83,85,98]. Since these knowledge gaps were identified by LBP experts, these would be considered PENs. Differentiating between PINs and PENs is important because information in patient education materials is typically based on what health providers wish to convey to patients (i.e., PENs) and not necessarily on information that patients have expressed interest in

learning more about (i.e., PINs). Though providing information about PENs is an essential component of LBP education, if patient education materials fail to provide information about PINs they are less likely to address patients' needs.

Using these definitions of PINs and PENs, we found two recent systematic reviews that were conducted to determine (i) the information needs and expectations of patients with LBP [88] and (ii) patients' beliefs and attitudes about LBP [98]. These reviews formed a good foundation of evidence from which to identify PINs and PENs about LBP. The objectives of this study are two-fold (i) to identify a comprehensive list of items that describe the types of information that patients want to know about and educators want patients to know about related to low back pain and (ii) to organize them into a draft checklist with a coding scheme for future pilot testing.

4.2 Methods

We were unable to identify a standardized method for developing a checklist. As a result, we used guidance from Boetang et al. [259], a paper outlining best practices for developing measurement tools for health research, and followed a series of steps to develop our checklist. Specifically, we (i) described the domains of interest, (ii) generated items for the checklist, (iii) assessed their face validity, and (iv) pre-tested the items. The protocol for this development study was registered on Open Science Framework [260] (Appendix 4.1).

4.2.1 Domains description

We used the literature review conducted by Ormandy [257] as the basis on which we conceptualized and developed a working definition of PINs and PENs. We used these definitions to develop a checklist to assess patient education materials for LBP for the presence or absence of any information about each PIN and PEN. The checklist is intended to measure how many PINs and PENs the patient education material contained any information about. It is not intended to measure the accuracy of this information, nor how likely this information is to subjectively satisfy patients' needs. Upon a thorough review of the literature, we determined that more work would be required in this area to develop a tool capable of properly assessing these more complex constructs.

4.2.2 Item generation

We conducted a content analysis of data from two recently published and relevant systematic reviews [98,158] whereby we (i) familiarized ourselves with the data, (ii) divided up the text into meaning units, (iii) formulated codes, and (iv) developed categories [261,262]. To familiarize ourselves with the data, we extracted all relevant data from our data sources and re-read them multiple times before analysis. After extracting the data, we divided the text into meaning units (i.e., quotes and existing questionnaire items representing single concepts [262]). Using the constant comparison method [263], we continuously compared between and among all data elements to formulate the codes and categories, referring back to our domain definition to ensure all codes and categories related to PINs and/or PENs. We organized codes into pre-existing categories based on common information types found in PEMs from the NHS database (e.g.,

https://www.nhs.uk/conditions/) including diagnosis, treatment, and causes. Additional categories were added based on the data. An item was generated for each code, and codes were further reviewed alongside the items generated from them in an iterative process involving the research team, patients, and clinicians as further described below and in Figure 4.1. We further describe our data sources and how we analyzed the data related to PINs and PENs below.

4.2.2.1 Patient information needs (PINs)

Our initial review of the literature did not identify any existing tools for the assessment of PINs for LBP. Fortunately, Lim et al. [88] recently published a systematic review of qualitative data regarding PINs and identified 14 themes (11 related to information content, and 3 related to mode of delivery), which served as the basis for our analysis. To supplement these themes, we engaged with nine patient partners, some of whom were living with chronic LBP, to gain feedback regarding their understanding and agreement with each theme and to determine if any themes were missing. All patient partners are members of our wider research team formed for the De-implementing Wisely Project sponsored by the Canadian Institutes of Health Research Strategy for Patient Oriented Research [264]. Originally, we had planned to generate items based on the themes identified in Lim et al. [88]. However, we were unable to proceed without further analyzing the data presented in the review for two reasons: 1) Some of the identified themes had overlapping concepts (e.g., the "general information content related to LBP" theme describes that patients want information about the nature and course of LBP, but this is also covered by the "prognosis, including future disability and effect on work

capacity" theme); 2) Some of the identified themes were based on patient expectations, rather than PINs, such as the "perceived needs for imaging" theme, which described patients' incorrect beliefs about the purposes of diagnostic imaging for LBP. Fortunately, Lim et al. [88] provided a comprehensive list of the data used to generate the themes reported in their paper, which we were able to reanalyze into codes with non-overlapping concepts relating solely to PINs rather than expectations and/or beliefs.

4.2.2.2 Patient education needs (PENs)

Many questionnaires for the assessment of patients' knowledge, beliefs, and attitudes about LBP have been used and reported in the literature. Most of these were included in a recent systematic review investigating beliefs and attitudes about LBP by Morton et al. [98]. We also completed an electronic search of PubMed and Google Scholar for key words related to knowledge, attitudes, beliefs, expectations, and low back pain from 2014-2024 to identify any questionnaires that may have been missed in the review by Morton et al. [98]. The search strategy for each database is presented in Appendix 4.2. We included any study using a questionnaire to assess these outcomes for LBP. Since these questionnaires are typically developed by teams of clinicians and researchers, we considered each item on the questionnaires to represent a PEN (i.e., information that clinicians and researchers think patients with LBP should know more about). We extracted these items to contribute to the initial pool of possible items to be used in our checklist. We considered each individual item to be a meaning unit for our content analysis, and rearranged similar items into common codes. We engaged with clinical and academic LBP experts who are members of our wider research team to

determine if any items appeared to be missing from our list or if any tools to assess these constructs were missed in our literature search.

4.2.3 Question and response option development

Once codes and categories were generated, we drafted the checklist. The domain specifies developing a checklist to assess PEMs for the presence or absence of information about each PIN and PEN. Thus, we framed each code in a question format to best reflect if PEMs contained any information about it. A simple binary (i.e., yes/no) response option was used since this is a checklist, and detailed descriptions of what might constitute a yes or no response for each item are supplied in the final checklist.

4.2.4 Face validity

Face validity is the degree to which end users of a tool judge the items to be relevant to the domain of interest [265]. The primary goal of this activity was to review the checklist to determine if the items accurately represented the PINs and PENs we identified from the literature and confirmed during the process of item generation. To do this, we held three discussion groups [266] with content experts - one each with patient partners and members of the research team to assess the face validity of items relating to PINs and another with clinical and academic LBP experts to assess the face validity of items relating to PENs. All content experts were members of our wider research team that was formed for the De-implementing Wisely Project sponsored by the Canadian Institutes of Health Research Strategy for Patient Oriented Research [264]. In total, nine patient

partners, two experienced clinician researchers, and three members of the research team were engaged for the face validity checks.

Each discussion group followed the same general procedure; we emailed content experts a brief summary of the tool with the items relevant to their expertise before convening virtually with each group. In these meetings, the lead investigator delivered a short summary of the checklist and how it was developed before each item was reviewed, one-by-one, to determine if they accurately reflected the PINs or PENs identified from the literature and confirmed during item generation. Content experts were asked to provide feedback for each item on the checklist and to review those items against PINs or PENs to make sure the checklist adequately covered all identified needs. We encouraged open-ended discussion but asked the following two questions as prompts: (1) Looking at the existing questionnaire items, do you think we grouped them appropriately (i.e., do you think they all represent the same information/education need); (2) Do you think the question we generated from the existing questionnaire items accurately represents this information/education need?

4.2.5 Pre-testing

Pre-testing the tool aims to minimize misunderstanding of the questions and subsequent measurement error by highlighting and eliminating poorly worded or double-barrelled questions [259]. This process should result in a revision of phrasing to be maximally understood by all future users of the tool. Pre-testing was completed by end users of the tool, which in this case are people who intend to evaluate or develop patient education materials for LBP such as clinicians or researchers. Pre-testing was conducted

by a clinician and academic researcher (SD) experienced with LBP on two patient education materials for LBP. We asked the pre-tester for feedback on the wording of the items and response options, overall formatting of the checklist, and their general experience with using the tool in terms of its feasibility for use in practice.

4.2.6 Ethics

Ethics review is not required by the Newfoundland and Labrador Health Research Ethics Authority for engagement activities. The work conducted in this study is considered an engagement activity because (i) the expert judges (i.e., patient partners, academic and clinical low back pain experts) were members of our wider research team that was formed for the De-implementing Wisely Project sponsored by the Canadian Institutes of Health Research Strategy for Patient Oriented Research [264] and (ii) all members were engaged in a collaborative role and they were not being studied as research participants, nor was any study data collected about them [267].

4.3 Results

4.3.1 Item generation

4.3.1.1 Patient information needs (PINs)

We identified nine distinct codes, each representing a PIN, from the qualitative data obtained from Lim et al. [88]. We excluded data corresponding to the "Information about support services for LBP" and "Tailored information regarding LBP management" themes identified by Lim et al. [88] as we considered information that is tailored to individual patients and contexts to be impractical to include in standardized patient

education materials. We also excluded data corresponding to codes relating to the mode of delivery of information (i.e., "Need for high quality information," "Need for health information to be delivered in a suitable tone and understandable language," and "Where to find credible information") as assessing understandability, quality, or credibility of information content is similarly outside the scope of this checklist and other validated tools have been designed to assess these constructs (e.g., PEMAT [133], DISCERN [253]). Finally, we considered their "perceived needs for imaging" theme, which described patients' incorrect beliefs about the purposes of diagnostic imaging for LBP, to represent PENs rather than PINs, and thus did not include this data in our content analysis related to PINs. Appendix 4.3 has a list of all codes that were excluded and why, and we further discuss this issue in the implications for research and practice section of this study. The content analysis with all supporting data for each code and category is presented in Appendix 4.4. An additional two flow diagrams depicting our step-by-step content analysis are available in Appendices 4.5-4.6.

4.3.1.2 Patient education needs (PENs)

We investigated the individual items of questionnaires identified in the Morton et al. review [98] and 15 additional studies identified through our literature search [85,95–97,268–278]. The questionnaires reported in these studies included the Tampa Scale of Kinesiophobia (TSK) [279], the Fear-Avoidance Beliefs Questionnaire (FABQ) [280], the Back Beliefs Questionnaire (BBQ) [281], the Back Pain Attitudes Questionnaire (BACK-PAQ) [282], the Low Back Pain Medical Scans Beliefs Questionnaire (LBP-MSBQ) [269], and the Low Back Pain Knowledge Questionnaire (LKQ) [283]. We also

included various stand-alone items (i.e., single items used in studies that were not part of an identifiable questionnaire) that were identified by Morton et al. [98]. We extracted and coded 118 items from these sources. We identified 18 codes from this data, representing 18 distinct PENs. We omitted items related to work safety since work is a broad concept and it would not be feasible for patient education materials to tailor information to every reader's work context. Three miscellaneous items from existing questionnaires were omitted because they were outside the scope of the checklist. Appendix 4.3 outlines a list of the items that were excluded and why, and we further discuss this issue in the implications for research and practice section of this study. The content analysis with all supporting data for each code and category is presented in Appendix 4.4. An additional two flow diagrams depicting our step-by-step content analysis are available in Appendices 4.5-4.6.

4.3.2 Question and response development

We transformed the codes identified above into a question format with binary "Yes" or "No" response options and example descriptions of what types of information may warrant either response. An answer of "Yes" indicates that the material contains information about the corresponding need and an answer of "No" indicates that the material does not contain any information about the corresponding need. For items with an answer of "Yes," the rater is asked to extract, verbatim, any information from the material that is related to the corresponding need. Ultimately, this resulted in a 19-item checklist consisting of two items relating to PINs, 10 items relating to PENs, and seven items relating to both PINs and PENs, which we used for our face validity checks.

4.3.3 Face validity

4.3.3.1 Patient information needs (PINs)

Members of the research team (BF, AP, AH) iteratively reviewed and modified the nine items relating to PINs. Items were continuously modified to improve the clarity, focus, and relevance of items to the identified PINs. For example, we modified the item "Does the material contain any information about exact diagnosis and the relationship between exact diagnosis and treatment" to "Does the material contain any information about the relationship between exact diagnosis and treatment" since it was initially double-barreled. We also added an additional item “Does the material contain any information about general exercise or sports for low back pain?” because it was unclear if treatment information about exercise programs such as yoga, tai chi, or Pilates were related to the item about self-management strategies or the item about provider-based non-pharmacological treatments. Patient partners, whom we considered to be content experts for PINs, similarly reviewed the items relating to PINs. The majority of comments were positive, with all patients valuing the purpose of the checklist and agreeing that it could have beneficial implications for patients with LBP. Minor changes to wording and clarification of key definitions were suggested but no threats to face validity were identified. More details about the changes made at this stage are presented in Figure 4.1.

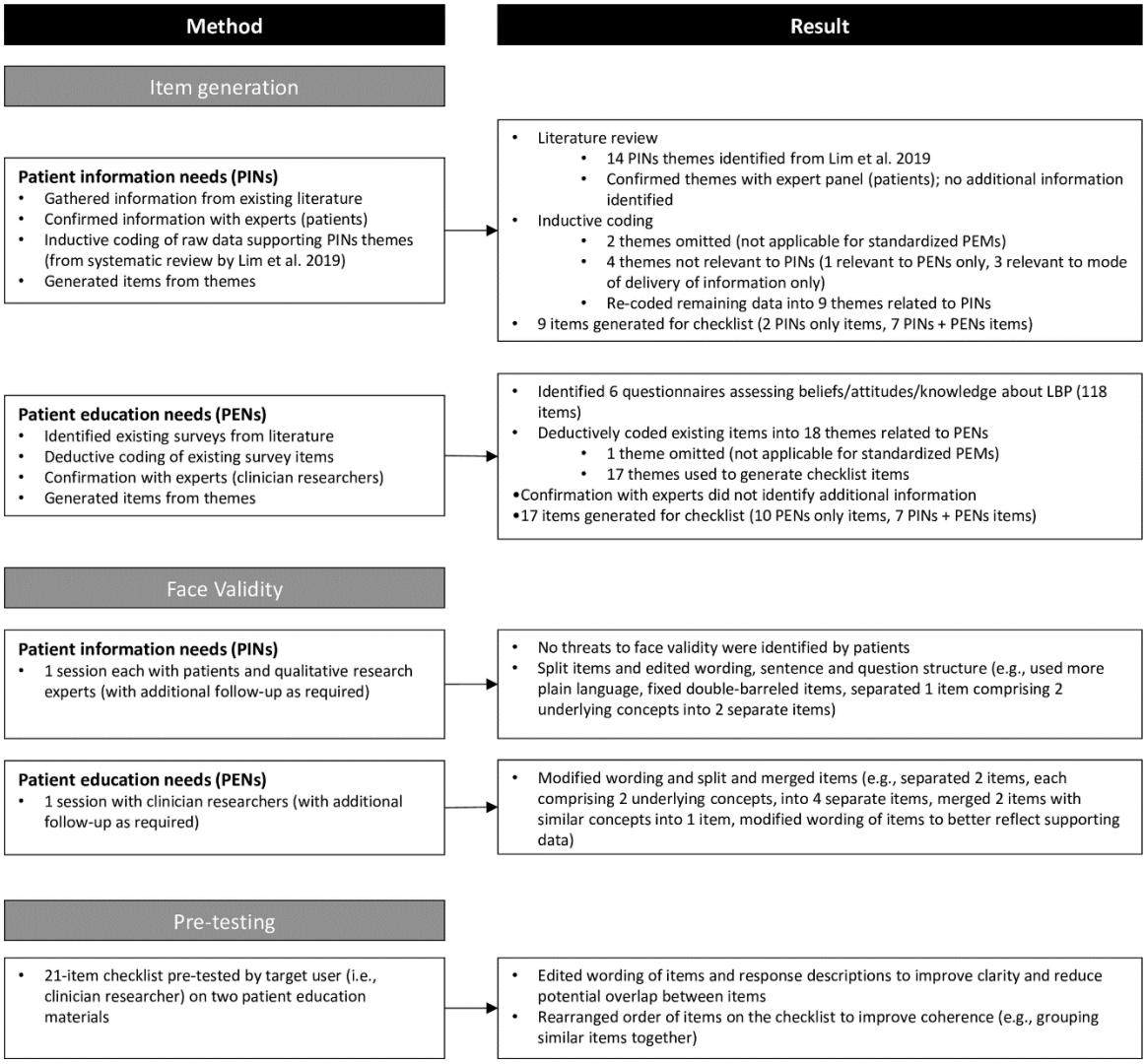

Figure 4.1. Flow diagram showing the stepped approach for methods and results.

4.3.3.2 Patient education needs (PENs)

All 17 items relating to PENs were assessed, one-by-one, by two experienced clinician researchers to determine if they accurately reflected the PENs identified from the literature and confirmed during item generation. They provided detailed feedback, including suggestions to modify the wording of items, to split items consisting of more

than one concept into separate items, and to merge items with similar concepts together as one item so that they better reflected PENs. For example, they suggested separating our item *"Does the material contain any information about diagnosis, causes, or aetiology for low back pain?"* into two separate items: one for LBP diagnosis and another for LBP causes and aetiology, since these represent two distinct PENs. They also commented on how our initial item *"Does the material contain any information about specific beliefs about sitting, lifting, carrying, bending, and positioning?"* consisted of concepts that would be more succinctly defined in separate items as 'functional tasks' (i.e., lifting, carrying, bending) and 'postures' (i.e., positioning, sitting, standing). More details about the changes made at this stage are presented in Figure 4.1.

4.3.4 Pre-testing

Modifications to the checklist based on the face validity discussion groups resulted in a 21-item checklist, which was pre-tested by an experienced clinician researcher (SD) who used the checklist to rate two patient education materials for LBP [284–286] (note: we combined and rated the Choosing Wisely Canada materials as one because they provide complimentary information on LBP diagnosis [286] and treatment [285]). The pre-tester commented that the checklist was easy to use and provided feedback on formatting as well as the wording of items and corresponding response descriptions. Firstly, they noted that there was little coherence in how the checklist items were ordered. For example, there were five items related to LBP treatment but they were not grouped together in succession in the checklist. We therefore re-arranged all similar items together to make the rating process more coherent for future raters. Secondly,

various changes to wording were made to improve the clarity of items and to minimize misunderstanding. For example, in the item "*Does the material contain any information about leg pain?"* we originally included information about leg pain only, omitting other important leg symptoms such as loss of sensation, numbness, or weakness. We revised the item to "*Does the material contain any information about leg pain/symptoms?"* and in the response descriptions we further specified that this could include any information about "leg symptoms such as loss of sensation, numbness, or weakness" and not just pain. Other modifications to wording were made to various items to reduce potential overlap between items and to increase their clarity for future raters. These changes are further detailed in Figure 4.1. The checklist items are presented in Table 4.1 and the full version of the checklist is available in Appendix 4.7.

Table 4.1. Patient information and education needs checklist for low back pain items.

Item #	Item	PIN?*	PEN?*
Prognosis, causes and aetiology			
#1	Does the material contain any information about prognosis for low back pain?	X	X
#2	Does the material contain any information about low back pain flare-ups and/or recurrence?	X	X
#3	Does the material contain any information about low back pain causes or aetiology?	X	X
#4	Does the material contain any information about the influence of psychological factors on low back pain?		X
Prevention			
#5	Does the material contain any information about the prevention of low back pain?	X	
Functional anatomy			
#6	Does the material contain any information about the functional anatomy of the spine?		X
Diagnosis			
#7	Does the material contain any information about low back pain diagnosis?	X	X

#8	Does the material contain any information about the types of tests, investigations, and/or exams required or not required to diagnose low back pain?		X
#9	Does the material contain any information about leg pain/symptoms?	X	
#10	Does the material contain any information about the relationship between exact diagnosis and treatment?		X
Treatment			
#11	Does the material contain any information about pharmacological treatment for low back pain?	X	X
#12	Does the material contain any information about provider-based non-pharmacological treatment for low back pain?	X	X
#13	Does the material contain any information about general exercise or sports for low back pain?	X	X
#14	Does the material contain any information about self-management strategies for low back pain?	X	X
#15	Does the material contain any information about the role of surgery as a treatment option for low back pain?		X
#16	Does the material contain any information about the management of low back pain flare-ups and/or recurrence?	X	X
#17	Does the material contain any information to promote staying active and/or not resting?		X
Activities of daily living			
#18	Does the material contain any information about functional tasks in relation to low back pain?		X
#19	Does the material contain any information about postures in relation to low back pain?		X
Pain neuroscience education			
#20	Does the material contain any information about the relationship between pain and injury?		X
#21	Does the material contain any information about the safety of physical activity and/or exercise and/or sport?		X

*PIN = patient information need; PEN = patient education need.

4.4 Discussion

4.4.1 Statement of principal findings

We developed a novel, 21-item checklist that can be used to assess if patient education materials for LBP contain information about 21 PINs and PENs about prevention, leg symptoms, diagnostic methods, staying active, safety of movement, functional tasks, functional anatomy, postures, surgical treatment, the relationship between pain and injury, the influence of psychological factors on LBP, the relationship between exact diagnosis and treatment, diagnosis, causes and aetiology, prognosis, flare-ups, the management of flare-ups, pharmacological treatment, provider-based non-pharmacological treatment, general exercise and sport, and self-management strategies. The checklist was determined to have acceptable face validity through iterative group discussions with patients, members of the research team, and clinical and academic LBP experts. Pre-testing with an experienced clinician researcher revealed many needed modifications to improve clarity and ease of use. The items consist of two PINs, 10 PENs, and nine combined PINs and PENs, suggesting that while many PINs and PENs overlap, patients have information requirements about additional topics (i.e., PINs about leg pain and prevention) outside of those identified by clinicians and researchers in the literature (i.e., PENs). The final version of the checklist is available in Appendix 4.7.

4.4.2 Strengths and weaknesses of the study

Though we were unable to find guidelines for checklist development, we followed the best practices for scale development [259] and content analysis [261–263] which we consider to be a strength of this study. This included conducting a literature search to

inform the description of our domain, analyzing a comprehensive set of published, peer-reviewed data using the constant comparative method to inform item generation, and involving a representative population of expert judges (i.e., patients and academic and clinical LBP experts) to verify face validity. We followed best practices for patient engagement by offering flexibility and choice in the activities patients could engage in, as well as the levels with which they could choose to participate in these activities (i.e., inform, consult, involve, or collaborate) [287,288]. We offered flexibility regarding the mode and frequency of communication in that we used patients' preferred communication methods (e.g., e-mail, video conferencing software, pre-recorded presentations that can be accessed anytime, etc.) and met as many times as they wanted to continue to work together. Our patient engagement lead (HE) gave advance notice about the details of this project to all patient partners, who committed to working with the team to create and refine the checklist.

This study also had limitations. Due to a lack of resources we were unable to follow all the scale development procedures outlined in Boateng et al. [259]. For example, we did not conduct formal content analysis using the Delphi method or formal statistical procedures such as the content validity ratio to statistically verify content validity. Second, the sample size of expert judges used for assessing validity and pre-testing was small and we therefore cannot be sure that all items are fully representative of the PINs and PENs we identified from the literature and confirmed during the process of item generation. Third, the existing questionnaires we used for our analysis were not designed and validated with our domain in mind. It is therefore possible that additional

PENs were missed during this process. Fourth, we omitted three broad PIN and PEN topic areas (i.e., information about support services, tailored information regarding LBP management, the role of work in making LBP worse or harming your back) from our checklist because they were deemed unfeasible for inclusion in standardized patient education materials for use in different contexts. However, we would recommend these topics be considered in additional local or site-specific materials and recognize that further research in this area may find ways of distilling these topics into content that is manageable for inclusion in standardized patient education materials. Finally, we did not ground the questions we asked during the face validity checks in theory and they are potentially leading. This may have impeded the open discussion we had hoped to generate during the discussion groups. Thus, further work with a more robust focus group and a theory-based question guide would provide a more rigorous assessment of face validity.

4.4.3 Comparison with other literature

This is a novel checklist for LBP, and we are unaware of similar checklists being developed for any other health condition. However, similar to how Lim et al. [88] investigated the PINs of patients with LBP in their systematic review, investigations of PINs and PENs have been conducted for other health conditions such as diabetes [289], cancer [290], and stroke [291]. Similar checklists could be developed for these health conditions in an effort to improve the educational content being provided to patients.

4.4.4 Implications for practice

Compared to no intervention, usual care, or placebo, systematic reviews investigating the effectiveness of patient education materials and individual patient

education (which often involves the provision of patient education materials) find education to be at least somewhat effective for improving process outcomes (e,g., reassurance and knowledge) [124,292], clinical outcomes (e.g., pain and disability) [292–294], and health system outcomes (e.g., imaging, primary care visits, and sick leave) [124,292,294]. However, recent evidence shows that patients who seek education to satisfy their PINs have difficulty accessing clear and consistent information to address these needs [88], and none of the available patient education materials identified from these systematic reviews have been assessed to determine if they contain information about PINs and PENs. Our checklist can be used to assess if patient education materials for LBP contain information about these needs and we expect it will be a useful resource for stakeholders who want to identify the best available patient education materials for use in practice. This may have positive implications for practice because providing patients with patient education materials containing more information about their needs may more effectively improve their knowledge and beliefs about LBP. Furthermore, many recent systematic reviews suggest that knowledge and/or beliefs are associated with clinical outcomes such as disability [295,296], pain [96,296], quality of life [96,297], and others suggest patients' lack of knowledge contributes to imaging overuse [81,82]. We therefore hypothesize that improving patients' knowledge and beliefs about LBP by providing them information about their needs would subsequently improve their clinical and health system outcomes as well.

4.4.5 Implications for research

Our checklist provides a comprehensive list of the known PINs and PENs about LBP, which we would consider to be the minimum elements of education that should be provided to patients with LBP. Therefore, it is not only useful for assessing information content, but also for developing future patient education materials or other educational resources for LBP. This has positive implications for research because the literature is still uncertain about the specific types of information that should be provided to patients with LBP in practice. For example, the National Institute for Health and Care Excellence [15] broadly recommends provision of tailored information about the nature of LBP and advice to stay active – but what is the "nature" of LBP, what exactly constitutes "staying active," and how do clinicians tailor this information to their patients? These ambiguous recommendations are common across published guidelines [31,33] and, though more work is to be done, our checklist may act as an initial step to informing more specific guideline recommendations for LBP education in the future.

4.4.6 Unanswered questions and future research

This was a preliminary development study and additional research is required in this area. First, it is important to confirm the list of PINs or PENs we have identified. We recommend conducting a validation study with a larger sample size of expert judges and to conduct additional rounds of pre-testing. Second, once a comprehensive list of PINs and PENs has been confirmed, it would be useful to investigate what specific types of information would be sufficient to satisfy each need from the patient's perspective. If patients with LBP feel satisfied by the information they receive, it is possible that this

information would improve their knowledge and beliefs about LBP more effectively. However, additional studies would be required to validate these hypotheses. Third, it would also be useful for content experts to convene and rank which PINs and PENs are most important. This would have implications for how educational content developers might structure content and key messages about LBP. Finally, our checklist is not intended to assess other factors that might contribute to improving knowledge or satisfying PINs and PENs, such as the understandability, actionability, reliability, quality, readability, accuracy, and comprehensiveness of the information. However, tools have already been developed to measure many of these factors such as the PEMAT [133], DISCERN [253], and the Flesh-Kincaid Grade Ease algorithm [135]. We recommend a formal assessment of patient education materials with these tools in addition to our checklist to determine the best available patient education materials for use in practice.

4.5 Conclusion

We developed a novel checklist comprising 21 distinct PINs and PENs about LBP. The checklist can be used to assess if patient education materials for LBP contain information about these needs and, though further validation is required, we expect the checklist will be useful for developing future educational content for low back pain.

4.6 Acknowledgements

The authors would like to thank the patient partners from the Patient Partnership Council and Diana De Carvalho and Daphne To for their engagement in the face validity checks.

CHAPTER 5: Assessing patient education materials about low back pain for their understandability, actionability, quality, readability, accuracy, comprehensiveness, and coverage of information about patients' needs: a systematic review

Preface

This manuscript has not been submitted to a journal. Bradley Furlong, Mona Frey, Simon Davidson, Giovanni Ferreira, Holly Etchegary, Kris Aubrey-Bassler, Amanda Hall

Co-authorship statement: BF conceptualized the idea for this study. BF reviewed relevant literature, developed the protocol (e.g., specified inclusion and exclusion criteria, identified which tools would be used to assess the materials, defined how to interpret the tool scores) then had it reviewed by the broader team. BF conducted the search. BF managed the project, and together with MF, SD, and GF conducted the assessments. BF conducted all data analysis and interpretation of results. BF wrote the first draft of the manuscript. All authors reviewed the manuscript and have read and approved of the final version.

Abstract

Background: Patients with low back pain (LBP) lack knowledge about their condition and have unhelpful beliefs about LBP diagnosis and management, which have been associated with worse LBP outcomes. Education can potentially modify these beliefs, but patients rarely receive education in practice despite its nearly universal recommendation in clinical practice guidelines. Patient education materials (PEMs) for LBP are a quick and inexpensive intervention that can address this gap by supporting the provision of accurate, clear, and consistent information to patients with LBP.

Objective: Conduct a systematic review to identify and assess PEMs for LBP for their understandability, actionability, quality, readability, accuracy, comprehensiveness, and coverage of information about patients' needs in order to identify the best available PEMs for LBP that clinicians can use in practice.

Methods: To identify PEMs we searched MEDLINE, EMBASE, CINAHL, PsycINFO, and SPORTDiscus from inception to April 2024 for systematic reviews evaluating the effectiveness of PEMs on clinical, process, or health system outcomes. We also conducted a hand search for PEMs recommended in clinical practice guidelines. We used the Patient Education Materials Assessment Tool (PEMAT) to assess their understandability and actionability, the DISCERN tool to assess their quality, the newly developed Patient Information and Education Needs Checklist for Low Back Pain (PINE-LBP) to assess if they contain information about patients' needs, and the Flesch Reading Ease (FRE) and Flesch-Kincaid Grade-Level (FKGL) algorithms to assess their readability. Accuracy was assessed as the proportion of treatment recommendations in

PEMs that clearly aligned with guideline recommendations and comprehensiveness was assessed as the proportion of guideline recommendations that were correctly covered by the PEM. We also conducted a qualitative synthesis of information provided in PEMs that related to the 21 information and education needs outlined in the PINE-LBP.

Results: 19 PEMs were included in this study and most scored poorly across most outcomes. There were large proportions of inaccurate treatment recommendations and no PEMs were considered actionable or comprehensive. Our qualitative synthesis revealed considerable variation in the content provided across PEMs, even for the most common topics like prognosis and diagnosis. Some content on the same topics directly conflicted across PEMs and there were concerns about whether some information was evidence-based. Only one PEM, the My Back Pain website, met the acceptable standards for more than half (four of seven) outcomes.

Conclusion: PEMs for LBP identified from peer-reviewed, published literature and clinical practice guidelines require improvement in many areas. Of the PEMs we assessed, the My Back Pain website ranked highest, but failed to meet acceptable standards for actionability, readability, and comprehensiveness; we therefore recommend the creation of a new PEM that meets acceptable standards on all the assessments we included.

5.1 Introduction

Low back pain (LBP) is a global problem that has become progressively more common and burdensome over the past three decades. Its prevalence increased by 54% from 1990 to 2015 [298], affecting over 500 million people globally by 2017 [6]. It occurs in people of all ages [3] in low, middle, and high-income countries [299] and is now the leading cause of disability in the world [3].

Eighty to 90% of patients with LBP have "non-specific" LBP, meaning their pain is not attributable to a specific pathoanatomical cause [12] and is instead a complex symptom influenced by biophysical, psychological, and social factors [299]. It has a favorable prognosis for most people [102], but surveys of the general population find many individuals have unhelpful beliefs about LBP including concerns about its inevitable negative consequences, misconceptions about diagnosis and management, and expectations for unnecessary diagnostic imaging [83,98]. These beliefs have been associated with worsened outcomes and increased risk of onset [24,74,98–101], while more optimistic beliefs such as pain self-efficacy and positive recovery expectations have been associated with improved outcomes [102,103]. In addition, misconceptions about etiology and diagnosis may give rise to patient expectations for unnecessary imaging [88], which, according to physicians, are a primary driver for imaging overuse [81]. In a recent Lancet series paper, Buchbinder et al. [54] call for action to address these widely held misconceptions and Choosing Wisely Canada is actively seeking ways to reduce low-value imaging for LBP in routine practice [300]. In accordance with these initiatives, there is a need for interventions that can modify unhelpful LBP beliefs and expectations.

Education for LBP is intended to facilitate recovery by transferring accurate information about diagnosis, prognosis, and self-management strategies to increase knowledge, modify beliefs and expectations, and increase self-efficacy to engage in self-management strategies. Sixteen of 18 clinical practice guidelines for LBP [31,33] recommend providing education to patients with LBP. However, recent systematic reviews have found that patients with LBP have specific health information needs for which they actively seek education, but have difficulty accessing clear and consistent information to address these needs [88]. In addition, only about 20% of patients with LBP receive education from their family practitioner [59]. Patient education materials (PEMs) are a relatively inexpensive and quick option to address this gap. They can support clinicians in providing clear, consistent, and credible information during health encounters, and we have recently completed a systematic review that found PEMs alone were generally more effective than usual care across various clinical (e.g., pain, disability), process (e.g., knowledge, pain self-efficacy), and health system (e.g., imaging, days off work) outcomes [292] for people with acute and chronic LBP. Particularly, though the quality of evidence was low, PEMs increased knowledge and self-efficacy, suggesting they could be a practical first step to modifying beliefs. However, no systematic assessments have been conducted to determine the quality of the PEMs included in our systematic review and details about how most of these PEMs were developed was scarce. Other studies have assessed websites about LBP identified through the Google search engine [126,127,301,302], but no study to date has evaluated PEMs for LBP identified through peer-reviewed literature. Additionally, no study has assessed the understandability or actionability of PEMs for LBP using the validated Patient Education

Material Assessment Tool (PEMAT) [133], nor have they assessed the content of these PEMs to determine if they provide information about patients' needs.

To determine the best available PEMs that should be used in practice and if they can be improved, we conducted a systematic review of the literature to identify and assess PEMs in terms of their content (i.e., do they contain information about patients' needs and is the information accurate and comprehensive) and readiness for use in practice (i.e., is the information understandable, actionable, readable, and of high-quality) using evidence-based and validated tools.

5.2 Methods

We prospectively registered the protocol for this study on Open Science Framework [255] (Appendix 5.1).

5.2.1 Search strategy

We defined PEMs as an intervention where information about LBP (e.g., diagnosis, prognosis, treatments) is provided using an evidence-based supplement (e.g., pamphlets, booklets, links to online resources, audio files, videos, apps) intended for use by patients with LBP. As there are many resources that could meet this definition, we narrowed our inclusion to only those PEMs found in published literature that (i) were recommended in clinical practice guidelines and (ii) had been evaluated for effectiveness on clinical, process or health system outcomes. In addition, as an overall aim of this work is to reduce unnecessary imaging for LBP, we also hand searched PEMs pertaining to

LBP produced by Choosing Wisely, which is an internationally recognized body for producing recommendations to reduce unnecessary tests and treatments [303].

To find clinical practice guidelines for LBP we referred to the two most recent overviews of clinical practice guidelines for LBP by Oliveira et al. [304] and Zaina et al. [33]. To find PEMs that have been evaluated for effectiveness on clinical, process, or health system outcomes, we searched the literature to find systematic reviews investigating PEMs for LBP and conducted a hand search of the studies included in these reviews. To find relevant systematic reviews, we replicated the search strategy from Furlong et al. [292] to search MEDLINE, EMBASE, CINAHL, PsycINFO, and SPORTDiscus from inception to April 11th, 2024. We screened records retrieved from this search using Covidence systematic review software [305].

5.2.2 Inclusion criteria

The overall goal of this study was to find the best available PEMs to provide to patients in practice. It is likely that PEMs recommended for use by clinical practice guidelines and Choosing Wisely are feasible for use in practice, but systematic reviews of educational interventions for LBP vary greatly and the provision of PEMs is often not the primary focus of these reviews [160]. Therefore, we included systematic reviews that focused primarily on the provision of PEMs and, more specifically, PEMs that could be provided feasibly in a primary care setting (e.g., user-friendly, short pamphlets instead of longer textbook-style booklets that would be difficult to produce and distribute). We also included systematic reviews investigating individual patient education (i.e., education provided during an individual health appointment) as this often involves the provision of

PEMs that are feasible for use in primary care (e.g., [108,124,294]). We excluded systematic reviews where the PEMs were (i) provided in a group-based setting (e.g., back schools) as we believe one-on-one appointments are much more common in primary care; (ii) provided as part of multidisciplinary interventions, as PEMs are often not the primary focus of these studies; (iii) provided over multiple sessions, as it is often not feasible to provide multi-session interventions in primary care settings; and (iv) based on specific types of education, such as pain neuroscience education, because patients with LBP have various health information needs outside of these specific topics [88]. After obtaining PEMs from these sources, we screened them according to our inclusion criteria outlined in Appendix 5.2. We contacted study authors and guideline producers to request PEMs where necessary.

5.2.3 Study selection

Systematic reviews identified from the search were uploaded to Covidence systematic review software [305] where duplicates were automatically removed. Title and abstract and full text review was conducted by one reviewer (BF) according to our pre-specified eligibility criteria. The studies included in eligible systematic reviews were hand searched to identify PEMs that were tested for effectiveness on clinical, process, or health system outcomes. Choosing Wisely websites identified via the Google search engine, and clinical practice guidelines identified by Zaina et al.[33] and Oliveira et al.[304], were similarly hand searched for PEMs that were recommended for use in practice. PEMs from these sources were then screened according to our pre-specified eligibility criteria by one author (BF). Authors were contacted to obtain additional information where necessary.

5.2.4 Outcomes

5.2.4.1 Understandability and Actionability

The Patient Education Materials Assessment Tool (PEMAT) is an instrument developed to assess if PEMs are understandable (i.e., patients can process and describe the information) and actionable (i.e., patients can carry out some action based on the information) for people of different backgrounds or health literacy levels [133]. English and Japanese versions are available, and both are reliable and valid [133,136,306]. There are two versions of the PEMAT, one intended for use on printable (PEMAT-P) materials, and another for audiovisual (PEMAT-A/V) materials [133]. The PEMAT produces a score for understandability and another for actionability, which are interpreted separately. Response options are binary (i.e., 1 for "Agree" and 0 for "Disagree"), and the overall scores are calculated as the total points accumulated divided by the total possible points, multiplied by 100% to achieve a score between 0% and 100%. PEMs scoring above 70% on the understandability or actionability scales are determined to be understandable or actionable, respectively [133]. We developed a detailed codebook for the PEMAT assessments conducted for this study, which is presented in Appendix 5.3.

5.2.4.2 Information Quality

The DISCERN tool is a reliable and valid tool developed to assess the quality of text-based information about treatment choices [134,307,308]. It consists of 16 items, each scored on a 5-point Likert-type scale ranging from 1 ("No") to 5 ("Yes"), where higher scores reflect greater quality of health information. The items are subdivided into

three sections. Section 1 (items 1-8) includes questions about the PEM's aims, evidence sources, and sources of potential bias. Section 2 (items 9-15) includes questions about treatment choices (e.g., what treatment options are available, how they work, and their benefits and risks). Section 3 (item 16) consists of a single item, which asks the user for their overall interpretation of information quality. Audiovisual PEMs were excluded from the DISCERN assessments. The DISCERN Handbook [253] provides little information on how to interpret its scores, so we will use the interpretation commonly used in previous studies [309–313]: very poor (< 27 points), poor (27 to 38 points), fair (39 to 50 points), good (51 to 62 points), and excellent (> 62 points) quality. We developed a detailed codebook for the DISCERN tool assessments conducted for this study, which is presented in Appendix 5.3.

5.2.4.3 Readability

The Flesch Reading Ease (FRE) and Flesch-Kincaid Grade-Level (FKGL) are two algorithms for measuring readability [135]. Both tools use the same variables (i.e., total words, syllables, and sentences) but apply different weightings to these variables. The FRE is scored on a 0-100 scale, where higher scores represent easier reading, and the FKGL provides a score that corresponds to the grade school levels in the United States, where a lower grade level represents easier reading. Readability scores were based on plain text only, excluding any non-related text (e.g., acknowledgements, references, developer and publisher information, links) and non-textual elements (e.g., images, figures, videos). Audiovisual PEMs were excluded from the readability assessments. The American Medical Association recommends that health education materials should be

written at a sixth grade level or lower [314], which corresponds to scores of 80 or greater on the FRE and lower than 7 on the FKGL.

5.2.4.4 Coverage of information about patients' needs

Quantitative summary. The Patient Information and Education Needs Checklist for Low Back Pain (PINE-LBP) was developed by our research team [260] and comprises a comprehensive list of 21 information and education needs about LBP identified from the literature. Patient information needs (PINs) are defined as one's subjective realization that they lack knowledge to achieve a goal [257] and patient education needs (PENs) are informed by other measures of knowledge deficit [258]. The checklist can, therefore, be used to determine if PEMs contain information that patients have indicated they wish to know more about (i.e., PINs) and information that clinicians and researchers have identified as knowledge deficits among patients with LBP (i.e., PENs). Each item on the checklist corresponds to a distinct PIN or PEN. It comprises binary responses options where a response of "Yes" indicates that the material contains information about the corresponding need and an answer of "No" indicates that the material does not contain any information about the corresponding need. We converted the score to a percentage score out of 100% by dividing the number of "Yes" answers by the total number of items (n = 21) for each PEM. The checklist was judged to have acceptable face validity by expert judges (i.e., patient partners, qualitative content experts, and clinician researchers), but further validity testing is required to determine the optimal cut-offs for this checklist. To facilitate interpretation we considered scores of 75% or greater to indicate a PEM that had sufficient information about PINs and PENs.

Qualitative summary. For all items with an answer of "Yes" on the PINE-LBP, the rater was asked to extract, verbatim, any information from the material that was related to the corresponding need. We coded and qualitatively summarized this information for each PIN and PEN.

5.2.4.5 Information accuracy

We assessed the accuracy of information about LBP treatments using the method developed by Ferreira et al. [126]. We defined information accuracy as the number and proportion of clear and accurate recommendations for treatments provided in PEMs that were in concordance with clinical practice guideline recommendations. Since recommendations vary between guidelines, we chose to base our assessment off of two separate guidelines, coding what treatments for LBP (i) are endorsed by at least one guideline, (ii) are dismissed by at least one guideline, and (iii) have conflicting recommendations between the two guidelines. From a pragmatic perspective, we chose guidelines based on transparency and comprehensiveness of the guideline review process. Our primary source for this assessment was the National Institute for Health and Care Excellence [15] guideline and our secondary source was the American College of Physicians [46] guideline, particularly because it is widely used and recognized with reach to the general population. Both guidelines are also freely available to the public. To define what treatments described in PEMs were in concordance with guideline recommendations, we used the following codes:

- Appropriate endorsement: the PEM recommends to use a treatment that is endorsed by at least one guideline.

- Appropriate dismissal: the PEM recommends to avoid a treatment that is dismissed by at least one guideline.
- Inappropriate endorsement: the PEM recommends to use a treatment that is dismissed by at least one guideline.
- Inappropriate dismissal: the PEM recommends to avoid a treatment that is endorsed by at least one guideline.
- Endorsed: the PEM recommends to use a treatment that is not mentioned in either guideline.
- Dismissed: the PEM recommends to avoid a treatment that is not mentioned in either guideline.

Accurate recommendations for treatments were coded as those that were appropriately endorsed, appropriately dismissed, or dismissed by the PEM, and inaccurate recommendations for treatments were coded as those that were inappropriately endorsed, inappropriately dismissed, or endorsed by the PEM. We considered endorsements of any treatment with conflicting recommendations between guidelines to be an inaccurate recommendation, and dismissals of these treatments to be an accurate recommendation. Unclear recommendations for treatments were coded as recommendations that vaguely described a treatment. For example, a recommendation to use "over-the-counter medications" would be considered an unclear endorsement since it does not specify which over-the-counter medications should be taken. Information accuracy was calculated by dividing the number of clear and accurate recommendations made by the PEM by the total number of recommendations provided by the PEM. No pre-determined cut-offs have

been set for what constitutes a sufficiently accurate PEM. However, to facilitate interpretation of this data we considered scores of 75% or greater to indicate a PEM that was sufficiently accurate. We developed a detailed codebook for the accuracy assessments conducted for this study, which is presented in Appendix 5.3.

5.2.4.6 Comprehensiveness

We assessed the comprehensiveness of information about LBP treatments using the method developed by Ferreira et al. [126]. Comprehensiveness was defined as the proportion of guideline recommendations correctly covered by the PEM. This was calculated by dividing the sum of appropriate endorsements and appropriate dismissals made by the PEM by the total number of recommendations provided by the guidelines. No pre-determined cut-offs have been set for what constitutes a sufficiently comprehensive PEM. However, to facilitate interpretation of this data we considered scores of 75% or greater to indicate a PEM that was sufficiently comprehensive.

5.2.5 Assessment procedure and data synthesis

One author (BF) extracted information on the characteristics of each PEM including its developer, country, purpose, LBP type, format, and length, where applicable. Included PEMs were rated using each of the assessment tools described above by one of four authors (BF, MF, SD, GF). Raters met regularly to discuss and resolve any questions encountered during the rating process, involving a senior author (AH) to come to consensus where necessary. All data relevant to the PINE-LBP, PEMAT, DISCERN, accuracy, and comprehensiveness assessments were entered into Microsoft Excel [315]. Data for the FRE and FKGL assessments were entered into Microsoft Word [316].

5.2.6 Data synthesis

Statistics for the PINE-LBP, PEMAT, DISCERN tool, accuracy, and comprehensiveness assessments were calculated using Microsoft Excel [315]. FRE and FKGL scores were calculated using the built-in readability statistics in Microsoft Word [316]. Data were interpreted using the cut-off scores described above. Using the PINE-LBP, we also conducted a synthesis of the qualitative data extracted from PEMs to describe what types of information related to PINs and PENs were used.

5.2.7 Ethics

Ethical approval is not required for this study.

5.3 Results

5.3.1 Patient Education Material Characteristics

Of the 83 potential PEMs identified from our search, 19 were included in this study (Figure 5.1). The PEMs were developed in Australia [284,317–322], Canada [285,286,323–326], New Zealand [327–329], the United States [330–332], and the United Kingdom [333]. Two PEMs did not specify their country of origin [334,335]. The Choosing Wisely organizations from Canada, New Zealand, and the United States each developed two PEMs with complimentary information about LBP diagnosis [286,327,330] and treatment [285,329,332]. We therefore combined and rated these together (i.e., as one PEM per organization). Most were printable PDF booklets [284,285,317,320,323–328,330,331,333], followed by websites [318,319,321,322], a video [334], and a digital smartphone application [335]. Additional details on the included PEMs are presented in Table 5.1.

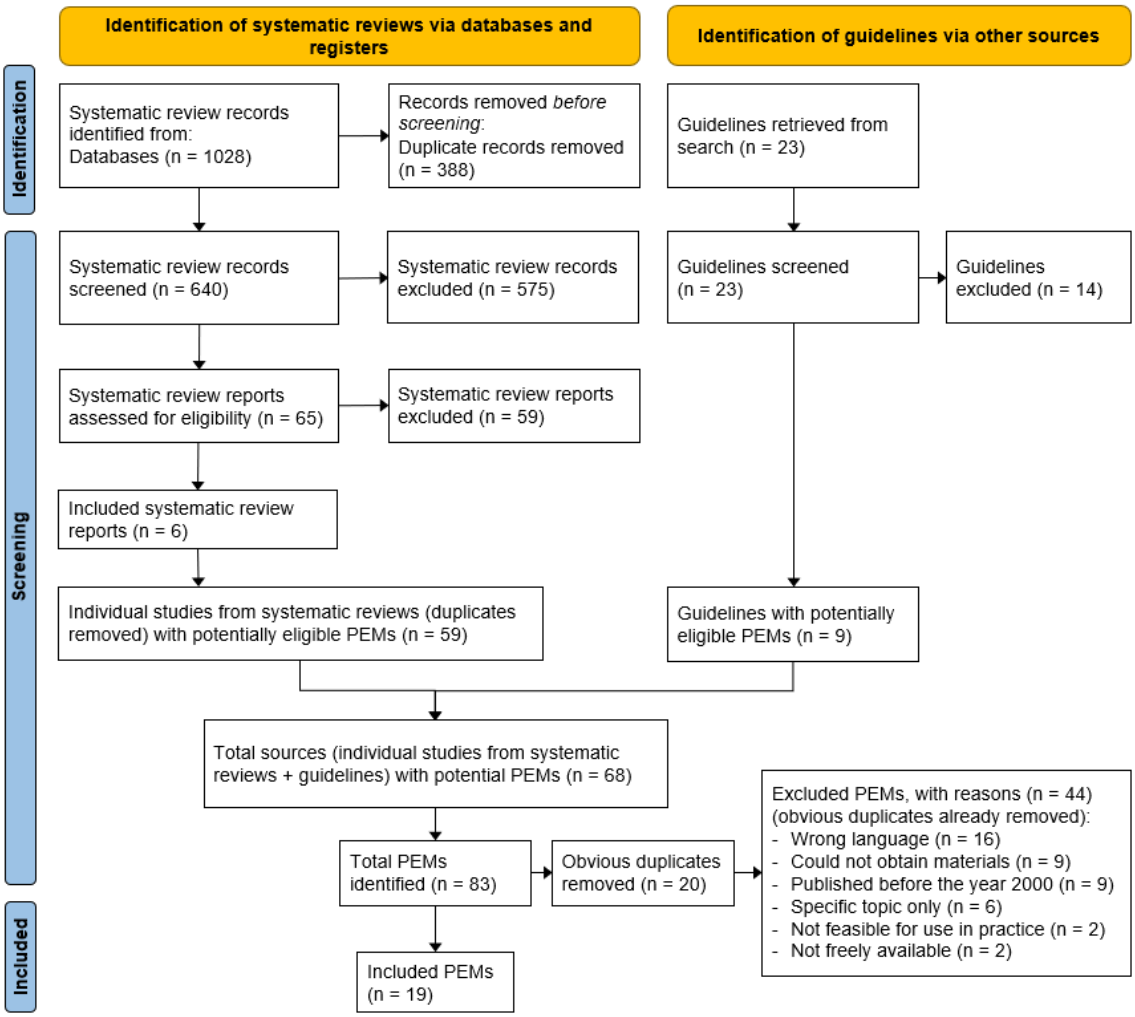

Figure 5.1. PRISMA-style flow chart of the identification of patient education materials and assessment of their eligibility

Table 5.1. Patient education material characteristics

Name	Publication year	Developers	Country	Purpose	Low back pain type	Format	Length (pages)
LBP (PainHealth) [322]	2023	Western Australia Department of Health, Curtin University, University of Western Australia, Musculoskeletal Health Network	Australia	To provide people with musculoskeletal pain access to evidence-based information that can help them manage their condition	n/a	Website	n/a
Managing LBP [320]	2022	New South Wales Agency for Clinical Innovation and State Insurance Regulatory Authority	Australia	n/a	Acute	Booklet (PDF)	2
Best practice care [317]	2019	Agency for Clinical Innovation Musculoskeletal Network	Australia	To describe best practice care for acute low back pain	Acute	Booklet (PDF)	12
Treating/Imaging LBP (US) [330,332]	2019 & 2017	Choosing Wisely (ABIM Foundation)	United States	To be used while talking to a healthcare provider	n/a	Booklet (PDF)	4
Patient Handout [331]	2018	Institute for Clinical Systems Improvement	United States	n/a	n/a	Booklet (PDF)	1
Truth about LBP [335]	2018	Clinically Relevant Technologies	n/a	To provide useful knowledge to help recovery	n/a	App	n/a
Understanding LBP [284]	2018	Macquarie University	Australia	n/a	n/a	Booklet (PDF)	8

Physio for Acute LBP [321]	2017	Australian Physiotherapy Association	Australia	n/a	Acute	Website	n/a
Physio for Persistent LBP [319]	2017	Australian Physiotherapy Association	Australia	n/a	Chronic	Website	n/a
Free for People With LBP [328]	2016	Researchers from University of Otago	New Zealand	n/a	n/a	Booklet (PDF)	20
My Back Pain [318]	2016	The University of Queensland, Arthritis Australia, Cochrane Back and Neck Group	Australia	To provide trustworthy and up to date information to help people with low back pain	Acute and chronic	Website	n/a
So Your Back Hurts (Acute) [325]	2015	Institute of Health Economics	Canada	To improve readers' understanding of acute low back pain	Acute	Booklet (PDF)	20
So Your Back Hurts (Chronic) [326]	2015	Institute of Health Economics	Canada	To improve readers' understanding of acute low back pain	Chronic	Booklet (PDF)	16
Should Know (Acute) [324]	2015	Institute of Health Economics	Canada	n/a	Acute	Booklet (PDF)	1
Should Know (Chronic) [323]	2015	Institute of Health Economics	Canada	n/a	Chronic	Booklet (PDF)	1
LBP (DocMikeEvans) [334]	2014	Michael Evans and Reframe Health Films Inc.	n/a	n/a	n/a	Video	n/a

Back Book [333]	2002	Multidisciplinary team of experts	United Kingdom	To provide accurate and effective information about low back pain	n/a	Booklet (PDF)	28
Managing/Imaging LBP (NZ) [327,329]	n/a	Choose Wisely New Zealand	New Zealand	n/a	Acute	Booklet (PDF)	2
Treating/Imaging LBP (CA) [285,286]	n/a	Choosing Wisely Canada	Canada	To be used while talking to a healthcare provider	n/a	Booklet (PDF)	4

5.3.2 Understandability and Actionability

For printable PEMs (n=18), understandability scores ranged from 50.0% to 70.6% (Table 5.2). One PEM [317] was considered understandable based on the pre-determined cut-off score of 70%. Most were successful in not expecting the user to perform calculations (18/18) and presented information using plain language (18/18), the active voice (17/18), informative headers (17/18), and visual cues (17/18). Few PEMs clearly stated their purpose (3/18) or refrained from including information that distracts from their purpose (2/18). Actionability scores for printable PEMs ranged from 0% to 66.7%; therefore, none were considered actionable based on the pre-determined cut-off score of 70%. Approximately half identified at least one action the user can take (13/18) and addressed the user directly when describing actions (10/18), but few provided tangible tools to help the user take action (2/18) or broke actions down into manageable steps (1/18), and none used visual aids to make it easier to act on instructions (Appendix 5.4).

For audiovisual PEMs (n=3), understandability scores ranged from 50.0% to 75.0% (Table 5.2). One PEM [318] was considered understandable based on the pre-determined cut-off score. All used plain language, the active voice, visual cues, and presented information in a logical sequence, but none broke information down into short sections to make the content easier to understand. Actionability scores for audiovisual PEMs ranged from 0% to 33.3%, therefore none were considered actionable based on the pre-determined cut-off score. Most clearly identified at least one action the user can take (2/3), but none addressed the user directly when describing these actions or broke them down into manageable steps (Appendix 5.4).

Table 5.2. Assessment tool scores for patient education materials

Patient Education Material	PINE-LBP (0-100%) ≥ 75%[1]	PEMAT Understandability (0-100%) ≥ 70[1]		PEMAT Actionability (0-100%) ≥ 70[1]		DISCERN (16-80) > 62[1]	FRE (0-100) ≥ 80[1]	FKGL (0-18) < 7[1]	Accuracy *n* (0-100%) ≥ 75%[1]	Comprehensiveness (0-100%) ≥ 75%[1]
		P	AV	P	AV					
Low Back Pain (PainHealth) [322]	71.4	50.0	-	20.0	-	47	58.3	9.2	7 (70.0)	19.4
Managing LBP [320]	52.4	58.8	-	66.7	-	30	69.3	**6.7***	**6 (85.7)***	12.9
Best practice care [317]	66.7	**70.6***	-	16.7	-	52	62.6	8.3	**5 (100)***	12.9
Treating/Imaging LBP (US) [330,332]	42.9	56.3	-	40.0	-	30	73.7	**6.0***	**3 (75.0)***	6.5
Patient Handout [331]	57.1	58.3	-	40.0	-	26	**83.0***	**4.1***	2 (20.0)	3.2
Truth about LBP [335]	66.7	68.8	66.7	20.0	33.3	24	49.2	10.8	5 (41.7)	16.1
Understanding LBP [284]	57.1	62.5	-	33.3	-	34	71.4	**6.4***	3 (33.3)	6.5
Physio for Acute LBP [321]	52.4	62.5	-	0	-	31	52.9	10.1	**6 (75.0)***	16.1
Physio for Persistent LBP [319]	52.4	56.3	-	0	-	24	49.3	10.5	8 (61.5)	22.9
Free for People with LBP [328]	**76.2***	62.5	-	33.3	-	40	**80.6***	**5.0***	**2 (100)***	6.5
My Back Pain [318]	**100***	62.5	**75.0***	20.0	33.3	**65***	61.4	8.3	**A: 32 (78.0)*,[2]** C: 36 (73.5)[2]	A: 64.5[2] C: 68.6[2]
So Your Back Hurts (Acute) [325]	71.4	69.2	-	0	-	54	61.3	8.6	12 (70.6)	32.3
So Your Back Hurts (Chronic) [326]	66.7	69.2	-	0	-	51	58.1	9.1	11 (50.0)	25.7
Should Know (Acute) [324]	47.6	61.5	-	40.0	-	32	75.0	**4.7***	**4 (80.0)***	9.7
Should Know (Chronic) [323]	42.9	61.5	-	40.0	-	32	64.7	**6.4***	6 (66.7)	11.4
LBP (DocMikeEvans) [334]	**81.0***	-	50.0	-	0	-	-	-	6 (42.9)	17.1
Back Book [333]	**95.2***	50.0	-	40.0	-	38	73.8	**5.9***	7 (58.3)	19.4
Managing/Imaging LBP (NZ) [327,329]	42.9	61.5	-	40.0	-	25	60.3	9.4	2 (33.3)	3.2

Treating/Imaging LBP (CA) [285,286]	57.1	50.0	-	40.0	-	32	61.8	8.2	**6 (75.0)***	16.1
Number (%) of PEMs meeting cut-off	4 (21.1)	1 (5.6)	1 (33.3)	0 (0)	0 (0)	1 (5.6)	2 (11.1)	8 (44.4)	8 (42.1)	0 (0)

Abbreviations: PINE-LBP = Patient Information and Education need checklist for Low Back Pain; PEMAT = Patient Education Materials Assessment Tool; FRE = Flesh Reading Ease; FKGL = Flesch-Kincaid Grade-Level; P = Printable materials; AV = Audiovisual materials; A = Acute; C = Chronic; PEM = patient education material

*Bolded and underlined values represent those that have met the cut-off score for the respective outcome

[1]Cut-off score descriptions: DISCERN scores are interpreted as follows: very poor (< 27 points), poor (27 to 38 points), fair (39 to 50 points), good (51 to 62 points), and excellent (> 62 points) quality health information. PEMs with DISCERN scores of higher than 62 are considered to be of sufficiently high quality. PEMAT scores of 70% or greater on the understandability and/or actionability subscales indicate an understandable and/or actionable PEM, respectively. PEMs with FRE scores of 80 or greater are considered sufficiently readable (i.e., at a sixth-grade level or lower). PEMs with FKGL scores of lower than 7 are considered sufficiently readable (i.e., at a sixth-grade level or lower). PEMs with 75% or more clear accurate recommendations are considered to be sufficiently accurate. PEMs with 75% or more comprehensiveness are considered to be sufficiently comprehensive.

[2]The My Back Pain website provided separate recommendations for acute and chronic LBP so we conducted two information accuracy and comprehensiveness analyses on this PEM – one for acute LBP and one for chronic LBP. This is further described in the accuracy analysis codebook presented in Appendix 5.3.

5.3.3 Information Quality

DISCERN scores ranged from 24 to 65 (Table 5.2). Based on the pre-determined cut-off scores, four PEMs had very poor quality information [319,327,329,331,335], eight had poor quality information [284–286,320,321,323,324,330,332,333], two had fair quality information [322,328], three had good quality information [317,325,326], and one had excellent quality information [318]. PEMs generally provided information that (i) achieved its aims when the aims were clearly stated, (ii) was relevant to the target population, (iii) made it clear that there is more than one possible treatment choice, and (iv) facilitated shared decision-making. However, the average score of all other items was relatively poor (i.e., less than 3 on the 1 to 5 scale). Particularly problematic areas involved not providing sufficient information about (i) how treatment choices affect overall quality of life, (ii) what would happen if no treatment were used, (iii) how each treatment works, and (iv) what sources of information were used to develop the content (Appendix 5.5).

5.3.4 Readability

FRE scores ranged from 49.2 to 83.0 and FKGL scores ranged from 4.1 to 10.8 (Table 5.2). Two PEMs [328,331] met the cut-off score (≥ 80.0) for acceptable readability on the FRE while eight PEMs [284,320,323,324,328,330–333] met the cut-off score (< 7.0) for acceptable readability on the FKGL.

5.3.5 Coverage of information about patients' needs

5.3.5.1 Quantitative summary

PINE-LBP scores ranged from 42.9% to 100% (Table 5.2). The content from four PEMs [318,328,333,334] had sufficient information about patients' needs based on the cut-off score of 75%. Approximately 90% of PEMs included information about diagnosis, prognosis, pharmacological treatment options, self-management strategies, diagnostic methods, leg pain, and advice to stay active and/or recommendations against bed rest (Table 5.3). Less than half included information about prevention, causes and aetiology, flare-ups, management of flare-ups, general exercise and sports, the relationship between exact diagnosis and treatment, functional tasks, functional anatomy, postures, and surgery. Coverage of PINs and PENs was relatively even. Of the 11 items relating to PINs, six (54.5%) were covered by more than half of the PEMs. Of the 19 items relating to PENs, 11 (57.9%) were covered by more than half of the PEMs.

Table 5.3. Patient information and education needs checklist for low back pain (PINE-LBP) scores by item with additional qualitative interpretations

Patient education materials																								
PIN	PEN	Item (Does the material contain any information about…)	LBP (PainHealth) [322]	Managing LBP [320]	Best practice care [317]	Treating /Imaging LBP (US) [330]	Patient Handout [331]	Truth About LBP [335]	Understanding LBP [284]	Physio for Acute LBP [321]	Physio for Persistent LBP [319]	Free for People with LBP [328]	My Back Pain [318]	So Your Back Hurts (Acute) [325]	So Your Back Hurts (Chronic) [326]	Should Know (Acute) [324]	Should Know (Chronic) [323]	LBP (DocMikeEvans) [334]	Back Book [333]	Managing/Imaging LBP (NZ) [327]	Treating /Imaging LBP (CA) [285]	TOTAL	Were the information points similar across PEMs?*	Did the content across PEMs agree?*	Was the information across PEMs evidence-based?*
X	X	1. LBP prognosis	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	18			
X	X	2. LBP flare-ups and/or recurrence	N	N	N	N	Y	Y	Y	N	N	Y	Y	Y	N	Y	N	Y	Y	N	N	9			
X	X	3. LBP causes or aetiology	Y	N	N	N	N	Y	N	Y	Y	N	Y	Y	Y	N	N	N	Y	N	N	8			
	X	4. Influence of psychological factors on LBP	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	14			
X		5. Prevention of LBP	N	Y	N	N	Y	Y	N	N	N	Y	Y	Y	N	Y	N	N	Y	N	N	8			
	X	6. Functional anatomy of the spine	Y	N	Y	N	N	N	N	N	N	Y	Y	N	N	N	N	Y	Y	N	N	6			
X	X	7. LBP diagnosis	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	18			
	X	8. Tests, investigations, exams for diagnosis	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	19			
X		9. Leg pain/symptoms	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	17			
	X	10. Relationship between diagnosis and Rx	N	Y	Y	N	Y	Y	N	Y	Y	Y	Y	N	Y	N	N	N	Y	N	N	10			
X	X	11. Pharmacological Rx for LBP	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	17			
X	X	12. Provider-based non-pharmacological Rx	Y	Y	Y	N	N	N	N	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	N	Y	13			
X	X	13. General exercise or sports for LBP	N	N	N	N	N	N	Y	N	N	N	Y	N	Y	N	Y	Y	Y	N	Y	7			
X	X	14. Self-management strategies for LBP	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	17			
	X	15. Role of surgery as a Rx for LBP	Y	N	N	Y	N	N	N	N	N	N	Y	N	Y	N	N	Y	Y	Y	Y	8			
X	X	16. Managing LBP flares/recurrence	N	N	N	N	N	N	N	N	N	Y	Y	Y	N	N	N	Y	N	N	N	4			
	X	17. Promoting staying active/not resting	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	19			
	X	18. Functional tasks in relation to LBP	Y	N	Y	N	N	N	N	Y	N	Y	Y	N	N	N	N	Y	Y	N	N	7			

	X	19. Postures in relation to low back pain	N	N	N	N	N	N	Y	N	N	Y	Y	N	Y	N	N	Y	Y	Y	N	7			
	X	20. Relationship between pain and injury	Y	Y	Y	N	Y	Y	Y	N	N	Y	Y	Y	Y	N	N	Y	Y	N	Y	13			
	X	21. Safety of physical activity/exercise/sport	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	N	N	N	Y	N	Y	13			
		TOTAL	15	11	14	9	12	14	12	11	11	16	21	15	14	10	9	17	20	9	12				

PIN = patient information need; PEN = patient education need; LBP = low back pain; Rx = treatment

*These 3 variables are an overarching high-level summary of the information presented in PEMs that related to the 21 PINs and PENs outlined in the PINE-LBP. Green cell = answer of "Yes" indicating no real concerns; Orange cell = answer of "Sometimes" indicating concerns for some information points; Red cell = answer of "No" indicating concerns on most information points, or possibly a big concern on one information point. A more detailed qualitative synthesis of the information related to all PINs and PENs is presented in Appendix 5.6.

5.3.5.2 Qualitative summary

Across PEMs for LBP there was considerable variation in the content related to most (18/21) PINs and PENs (Table 5.3). Though many typical statements were made about commonly covered topics like prognosis (e.g., 'low back pain gets better in a few weeks') and diagnosis (e.g., 'low back pain is pain below the ribs and above the bottom'), additional information was often provided with little consistency across PEMs. Furthermore, the information related to some (6/21) PINs and PENs conflicted across PEMs. For example, some PEMs commented on the safety of lifting, while others reported that lifting can increase the risk of LBP. Other PEMs commented on the uncertainty around the effectiveness of treatments like acupuncture, massage, spinal manipulation, and electrical stimulation while others stated these are effective treatments for LBP. Finally, there were concerns about whether the information related to some (5/21) PINs and PENs was evidence-based. For example, some PEMs recommended various sitting and standing tips (e.g., using lumbar supports, tilting pelvis to flatten spinal curve), which to our knowledge are not clearly supported by research evidence. We present a high-level summary of these potential concerns in Table 5.3 and a more detailed qualitative synthesis of this information in Appendix 5.6.

5.3.6 Information accuracy

Information accuracy ranged from 20.0% to 100% and seven PEMs [285,286,317,318,320,321,324,328,330,332] had sufficient accuracy based on the cut-off score of 75% (Table 5.2). The proportion of clear accurate recommendations to use a treatment (51.6%) was lower than the proportion of clear accurate recommendations to

avoid a treatment (84.3%). Among the 15 PEMs coded for acute LBP, the most commonly recommended treatments were advice to stay active (n=14), exercise (n=10), use NSAIDs (n=9), and apply heat (n=9). Seven PEMs provided recommendations for paracetamol, five of which inappropriately endorsed this treatment. Among the five PEMs coded for chronic LBP, the most commonly recommended treatments were exercise (n=5) and advice to stay active (n=4). These PEMs inappropriately endorsed acupuncture (n=3), paracetamol (n=2), and/or opioids (n=1) (Appendices 5.7-5.9).

5.3.7 Comprehensiveness

Comprehensiveness ranged from 3.2% to 68.6%. No PEMs were sufficiently comprehensive based on the cut-off score of 75% (Table 5.2) and only one PEM [318] correctly covered more than 50% of guideline recommendations. On average (± SD), PEMs for acute LBP correctly covered 5.1 (4.8) of 31 guideline recommendations for acute LBP. PEMs for chronic LBP correctly covered an average (± SD) of 10.2 (8.0) of 35 guideline recommendations for chronic LBP (Appendix 5.9).

5.4 Discussion

5.4.1 Statement of principal findings

To our knowledge, this is the first study to systematically catalog and assess PEMs for LBP used in published synthesized literature. It is also the first to assess PEMs for LBP in terms of their understandability and actionability (using the PEMAT) and coverage of information about patients' needs (using the PINE-LBP). Most PEMs failed to meet the cut-offs for most outcomes and none were considered actionable or comprehensive. The highest ranking PEM was the My Back Pain website [318], which is

the only PEM to meet the cut-off scores for more than half (4 of 7) of these important outcomes. Though it did not meet the cut-off for comprehensiveness, it is also the only PEM to correctly cover more than 50% of guideline recommended treatments for both acute and chronic LBP. More importantly, this study identified numerous areas where PEMs for LBP, including the My Back Pain website, can be improved for future use in practice.

5.4.2 Strengths and weaknesses of the study

We used a comprehensive search strategy developed by a professional librarian to systematically identify PEMs from published synthesized literature. We screened PEMs using pre-determined inclusion and exclusion criteria outlined in our prospectively registered protocol [255] and outlined the selection process in a PRISMA-style flow chart for added transparency. We conducted our assessments with evidence-based and validated assessment tools and developed detailed codebooks, which we make available in Appendix 5.3.

This study had limitations. Assessments were not conducted in duplicate by two independent raters, rather they were conducted by only one rater. Conducting assessments in duplicate can minimize the risk of errors, therefore it may have resulted in different assessment tool scores. However, our team met frequently to discuss any uncertainties that arose during the rating process and we developed codebooks to improve consistency of ratings between PEMs. In addition, we omitted other potential sources of PEMs such as Google, YouTube, and smartphone app stores so our sample of PEMs is not representative of all available PEMs for LBP. However, other studies have already

conducted similar assessments on PEMs from these sources (e.g., [126,127,301,302,336]) and we hypothesized that PEMs utilized in peer-reviewed literature would be of higher quality and more feasible for use in practice. We also excluded non-English language PEMs so it is possible that PEMs developed in other languages are of higher quality than those found in our sample. Finally, two PEMs [318,335] had interactive sections where tailored information was generated based on the user's responses to questions. We did not include this information in our assessments because it would have been difficult to ensure we generated all the information from all possible combinations of responses to questions. We therefore only included static, non-interactive information provided in PEMs for LBP. Omitting this information may have impacted assessment tool scores for these PEMs.

5.4.3 Comparison with other literature

We identified four similar studies [126,127,301,302] that assessed the credibility or quality (n = 4), accuracy (n = 3), readability (n = 3), and comprehensiveness (n = 1) of PEMs for LBP. These studies included English [126,127,302] or Portuguese [301] language websites identified primarily via Google and one sought PEMs specifically designed for adolescent populations [302]. Credibility or quality were measured using the Journal of American Medical Association (JAMA) benchmark criteria [337] and the Health on the Net Code of Conduct (HONcode) [338], both of which comprise similar questions to the DISCERN tool. Accuracy and comprehensiveness were measured using similar methods of judging the concordance of treatment recommendations with guideline recommendations. Readability was assessed with the FKGL for English-language PEMs

and the Portuguese version of the Flesch-Kincaid index [339] for Portuguese-language PEMs. Findings were comparable to the current study, where low levels of credibility or quality, accuracy, readability, and comprehensiveness were generally reported. Accuracy data were particularly similar to that found in Ferreira et al. [126], such as for the proportions of clear accurate recommendations to use a treatment (50.0% vs. 51.6% in the current study) and to avoid a treatment (82.7% vs. 84.3% in the current study). Interestingly, the interpretation of readability across studies varied depending on what cut-off score was used. When using the 6th grade level as the cut-off score for acceptable readability, our study had the highest proportion of PEMs meeting this criterion (i.e., 42% compared to 14-19%). However, when using the 8th grade level as the cut-off, which corresponds to the average reading level of American adults [340], findings were more comparable across studies (i.e., 50-65% of PEMs met this cut-off across studies).

5.4.4 Implications for future practice

Based on the results of this study, we would recommend the My Back Pain website [318] for use in practice since it met the cut-offs for more outcomes and was more comprehensive than all other PEMs. However, we have identified many clear problem areas across PEMs that, when addressed, may improve the effectiveness of PEMs for LBP and have beneficial implications for practice. For example, PEMs should contain a clear statement of aims and content that is relevant to its aims. They should provide sources and clearly outline the date the content was produced. Treatment information should refer to evidence, including areas of uncertainty, and comprise a description of their benefits, risks, and potential mechanisms of action, as well as how

they might affect overall quality of life. Medical terms should be avoided unless necessary and, if used, should be clearly defined. PEMs should address the user directly, provide actionable statements, and include tangible tools to help the user take action. They should include visual aids that help readers understand the content and make it easier to act on instructions, and information should be broken down into short sections. They should also contain information about each of the 21 PINs and PENs outlined in the PINE-LBP. Finally, developers should be cognisant of sentence length and multi-syllabic words to ensure acceptable readability and refer to up-to-date clinical practice guidelines when writing recommendations for LBP treatments. Implementing these recommendations should result in higher quality and more understandable, actionable, and readable PEMs with content that is more accurate, comprehensive, and covers more information about patients' needs. We hypothesize that PEMs meeting the acceptable standards on all these important outcomes would more effectively improve patients' knowledge, attitudes, and beliefs about LBP, which may thereby improve other downstream clinical (e.g., pain and disability) and health system (e.g., days off work, imaging rates) outcomes compared to PEMs not meeting these standards.

5.4.5 Implications for research

We have added to previous research conducted in this area by demonstrating that PEMs identified through published synthesized literature also have unacceptable levels of quality, accuracy, comprehensiveness, and readability. We have also conducted the first assessment of understandability, actionability, and coverage of information about patients' needs and found that PEMs for LBP are generally inadequate in these areas as

well. Through our qualitative synthesis of information content, we observed considerable variation in what information is provided even for the most common topics like diagnosis, prognosis, and treatment options. This observation has been made elsewhere, such as in the recently published clinical practice guideline for LBP by the World Health Organization, which states there was *"heterogeneity in the education topics included in the trials … making it difficult to judge which topics are most effective, for whom and when"* [341]. A substantial amount of research has been conducted to determine if PEMs and other education interventions are effective for LBP (e.g., [108,116,124,292–294,342]), but comparatively little research has been done to assess or inform the specific content provided in these interventions. It is clear that more work is required to address this evidence gap.

5.4.6 Unanswered questions and future research

There are many unanswered questions in this area which require further research. First, to improve the specificity and consistency of educational content for LBP, we recommend that leading experts and patients with LBP convene to establish a clear set of learning objectives for LBP with a rubric outlining what specific types of information are required to realize each objective (e.g., what information is required to satisfy patients' needs). The PINE-LBP is an initial attempt at outlining such topics but further work is required to validate them. Since it is unlikely that any one PEM could contain all the information that every patient would want to know, we also recommend involving patients in considering the most important learning objectives. This would be helpful to inform (i) the structure and key content of PEMs and other educational interventions for

LBP and (ii) time-constrained providers about the educational topics they should focus on during short health encounters. Once a PEM for LBP is developed with these objectives, and other important domains such as understandability, actionability, readability, quality, accuracy, and comprehensiveness in mind, it would be useful to test it in a mixed methods study both to (i) investigate patient and provider experiences with using the PEM and preferences for PEM mode of delivery (e.g., hard vs. soft copy) and (ii) investigate its mechanisms of action to determine if it satisfies patients' needs, improves their knowledge, attitudes, and beliefs about LBP, and translates into important clinical benefits. Mixed methods is a useful design to allow for a deeper understanding of complex issues. While knowledge may seem a simple enough outcome, I have come to understand it to be quite complex with the potential for many influencing factors along the path from information to knowledge to beliefs to behavior, thus understanding PEMs using a mixed methods approach may help understand the interaction of a PEM and knowledge acquisition more fully. Finally, some items on the PEMAT and DISCERN tools have elements of subjectivity. Therefore, before conducting our assessments we searched the literature to see how other research groups were coding these items. While we found many studies using the PEMAT (e.g., [137,138,343–345]) and DISCERN tool (e.g., [343,346–348]), many of which commented on the subjective nature of these tools or on developing a standardized coding procedure, none provided a copy of their codebook or any details about these coding procedures. We provided our own codebooks to be as transparent as possible, but are unable to comment on how our coding decisions may have affected the results because we had no reference to compare them to. We recommend researchers be transparent in outlining their coding procedures, preferably by

providing a detailed codebook to enhance interpretability and to allow other researchers to build upon or modify their coding decisions in future assessments.

5.5 Conclusion

PEMs for LBP identified from published synthesized literature failed to meet acceptable standards for most tested outcomes and none were considered actionable or comprehensive. They have large proportions of inaccurate treatment information and vary considerably in the information they provide. Of the PEMs we assessed, the My Back Pain website ranked highest but it was still deficient in many areas; we therefore recommend the creation of a new PEM that meets acceptable standards on all the assessments we included.

5.6 Competing interests

None declared.

5.7 Funding

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CHAPTER 6: Discussion

The aim of this thesis was to understand the use of PEMs as an intervention to improve outcomes for LBP with a specific focus on how they might support reducing unnecessary LBP imaging. I conducted four studies to realize this aim, which are outlined in Chapters 2-5. Each of these individual chapters have an in-depth discussion which includes sections on how the findings compare to the literature and the strengths and limitations of each study design. In this overall discussion of my thesis, I summarize each of the studies included in my thesis that address my overall thesis objectives (tempered by study limitations) and discuss what my findings add to the literature, considerations for future research, and the main implications of this work for practice followed by an overall conclusion.

6.1 Summary of findings

My thesis included four different studies: two systematic reviews with comprehensive meta-analyses, the development of a checklist, and a systematic review to identify and assess PEMs for LBP. I prospectively registered [255,260,349] or published [160] protocols for each study and involved patients in Chapters 2, 4 and 5 while following best practices for patient engagement. The systematic reviews were conducted following guidelines by Cochrane [203], PRISMA [350], GRADE [351], PRESS [161], and/or TIDieR [131]. Other strengths of these designs include the use of two reviewers during all stages of screening, data extraction and data analysis, including only randomized controlled trials, and the use of sensitivity analysis for studies with high risk of bias. As a result of using these methods, there is moderate to high confidence that the results produced are of high validity and reliability. There are two main limitations with

respect to the checklist development and systematic assessment of PEMs for LBP. First, I recruited a small sample of expert judges for face validity checks and pre-testing of the PINE-LBP and I only used existing data to inform item generation. Further testing is required to confirm the checklist is fully representative of the PINs and PENs I identified and to determine whether any are missing. Second, assessments of PEMs for LBP were conducted by a single rater, which may increase the likelihood of errors. This limitation may be emphasized by the subjective nature of some of the assessment tools, so it is possible that if two raters were to conduct the same ratings in duplicate, it would have resulted in different final scores. In an attempt to address this limitation, I reviewed the literature for other studies using the PEMAT (e.g., [87–91]) and DISCERN tool (e.g., [87,92–94]) to gain a better understanding of how to address the subjective items. Though these studies often commented on the subjective nature of these tools or on developing a standardized coding procedure, none provided a copy of their codebook or any details about these coding procedures. I therefore developed and provided codebooks in our study to be as transparent as possible, but I am unable to comment on how the coding decisions may have affected the results because I had no reference against which to compare them.

In Chapter 2, I conducted a systematic review and meta-analysis on the effectiveness of PEMs for LBP on 20 clinical, process, and health system outcomes for LBP. I found that, when compared to usual care, PEMs had positive impacts across various outcomes. However, very few trials measured process and health system outcomes, which resulted in mostly low and very low quality evidence (or no evidence)

for these outcomes. For example, only five of 27 trials measured knowledge, one measured imaging rates, and none measured general attitudes or beliefs about LBP. Additionally, process outcomes were often measured using bespoke scales or modified versions of validated scales, further muddling the evidence. Moreover, only five of 27 trials reported measures of fidelity, so it is unclear if the patients in most trials received the PEMs as planned or if they read them. I therefore cannot conclude that PEMs influence the outcomes that they are primarily intended to act upon. Finally, I was unable to obtain copies of most PEMs used in these trials and details of their content and how they were developed were mostly unavailable. This review demonstrates that PEMs are a potentially effective intervention for LBP, but little is known about their mechanisms of action, how their content was developed, and what this content entails. Though one of the goals of this thesis was to investigate how PEMs might support clinicians in reducing unnecessary imaging in primary care, I was unable to confirm my hypothesis that PEMs would increase knowledge and modify beliefs, thereby reducing patients' expectations for unnecessary imaging. Since only one of 27 studies measured imaging rates, I am unable to comment further on the effectiveness of PEMs for LBP on reducing unnecessary LBP imaging. However, this review uncovered many evidence gaps that can be used to inform future research on this topic. I will discuss these further below.

In Chapter 3, I conducted a systematic review and meta-analysis on the analgesic effects of conservative treatments for LBP. I included 301 randomised placebo-controlled trials which provided data on 56 different treatments or treatment combinations. I found no reliable evidence of large effects for any treatment, which is consistent with clinical

practice guidelines, and the evidence for the majority (86%) of treatments was inconclusive. Certainty in our findings was limited as many trials included few participants, reported inconsistent results, and used heterogenous placebos. This is a concerning finding that highlights the need for better prioritisation of resources in this field because we are neither able to confirm nor refute the efficacy of the vast majority of tested treatments for LBP. More work is required to make sense of this information for clinical practice and to update the content around treatment recommendations in PEMs for LBP.

In Chapter 4, I developed a checklist outlining 21 distinct PINs (i.e., what patients want to know) and PENs (i.e., what clinicians and researchers want patients to know) for LBP. The checklist includes 9 overlapping PINs and PENs, 10 PENs, and 2 PINs, demonstrating that patients want to know about two additional topics (i.e., leg pain and prevention) that are not accounted for in the literature informed by clinicians and researchers alone. I developed the checklist so that we could evaluate whether PEMs contain information about patients' needs about LBP, but predict that it will be a useful tool for developers of educational interventions as it comprises a list of evidence-based topics (vetted by a sample of patients) that can inform future educational content. However, this was a preliminary development study and further validation is required to confirm the PINs and PENs I identified and whether any are missing.

In Chapter 5, I conducted a systematic assessment of PEMs for LBP using a comprehensive battery of evidence-based and validated assessment tools to determine their understandability, actionability, readability, quality, accuracy, comprehensiveness,

and coverage of information about patients' needs. This was the first study to include PEMs identified from published literature including those identified from our systematic review in Chapter 2, as well as those recommended in clinical practice guidelines for LBP. The PEMs scored poorly across most outcomes and no PEMs were considered to be actionable or comprehensive. Our qualitative synthesis of content revealed considerable variation in the information provided, even for the most common topics of diagnosis, prognosis, and treatment options, and our accuracy assessment revealed a large proportion of inaccurate treatment recommendations. The My Back Pain website [318] was the highest-scoring PEM, which met acceptable standards for four of seven outcomes. I recommend this PEM for use in practice above the others, but encourage modifications so that it can meet acceptable standards on the remaining outcomes as well (i.e., comprehensiveness, actionability, and readability).

6.2 What this thesis adds to the literature

My thesis has added to the literature by providing the most comprehensive assessment of PEMs for LBP to date. It has also identified that PEMs as a stand-alone intervention to reduce unnecessary imaging seems to have been disregarded when, in actual fact, little is known about the effectiveness of PEMs due to a lack of adequate testing on important mechanistic and fidelity-based outcomes. Most notably, almost nothing is known about the effects PEMs have on their primary mechanisms of action (i.e., knowledge and beliefs). In addition, little is known about their effects on secondary outcomes along the clinical outcome pathway (e.g., anxiety, fear, coping strategies, self-efficacy, treatment engagement, pain, disability, and quality of life). Further, there is

almost no information on the fidelity of interventions using PEMs; we do not know if patients received or read them in most studies. This is astonishing given the millions of research dollars that have been spent on dozens of other treatments for LBP (as evidenced in the second review where I found 56 unique treatments or treatment combinations that have been tested in placebo-controlled randomized controlled trials, which are one of the most expensive study designs). Furthermore, in terms of the assessment of PEMs in chapter 5, I found that the PEMs that have been tested in the literature fail to meet acceptable standards on various important outcomes, highlighting the dire need for developers to consider these outcomes, which are based on evidence-based tools and resources, when developing PEMs. Failing to do so will result in further oversaturation of the literature with PEMs that do not meet evidence-based standards.

6.3 Implications for Research.

6.3.1 The field overall

As demonstrated in Chapters 2 and 3 of this thesis, my work revealed an abundance of gaps in the literature. Problems identified in Chapter 2 include evidence of (i) developing and testing PEMs without considering their theoretical mechanisms (i.e., testing downstream clinical endpoints instead of the process outcomes they are primarily intended to modify), (ii) using unvalidated and modified outcome measures despite the existence of validated measurement tools, (iii) omitting measures of intervention fidelity, which are necessary to confirm if the observed changes in outcomes are due to the intervention or some other variable, and (iv) providing insufficient details about the PEMs that were tested. Chapter 3 revealed that a substantial number of treatments are

being investigated for LBP, often in small, low-quality trials that are not sufficient to meaningfully contribute to decision making and that many new treatments continue to be tested without first establishing the evidence on previously tested treatments. Due to these factors, little is known about the clinical utility of PEMs and the analgesic effects of the majority (86%) of conservative treatments for LBP. Both chapters demonstrate that it is of utmost importance for researchers and/or funders to (i) inform the planning, development, and testing of interventions for LBP using theoretical frameworks such as the Theoretical Domains Framework [106], the Behaviour Change Techniques Taxonomy [92], and/or the Behaviour Change Wheel [352]; (ii) measure intervention fidelity and use validated measurement tools to assess LBP-related outcomes to facilitate a more reliable interpretation of research findings; (iii) enhance reporting of intervention details by following reporting guidelines such as the TIDieR checklist [131]; and (iv) better prioritize funding for LBP research or else research dollars will continue to be wasted.

6.3.2 Specific areas

My thesis has also identified several unanswered questions for future research. Broadly, it reveals that the majority of tested conservative treatments for LBP have uncertain efficacy, in part due to the conduct of small trials and the use of unstandardized, heterogenous placebos for non-pharmacological interventions. Using placebo controls is important for determining if the treatment has effects beyond the contextual and non-specific effects of receiving care (i.e., placebo effects). Developing placebos for certain interventions is difficult and other types of controls (e.g., usual care, waiting list controls) can provide us with evidence in their absence. However, these controls do not provide us

with evidence about the efficacy of an intervention (i.e., the specific effects of the intervention on top of the placebo effects). It is true that it is much more difficult to design placebos for non-pharmacological complex interventions like psychological and physical therapies since there are often many different components to control for. However, the idea is to control for all components except for the ones we are interested in measuring the effects of. This is easier with pharmacological interventions because we can, for example, provide participants with a placebo pill that looks, tastes, and smells the same as the true intervention. For multimodal or complex non-pharmacological interventions, it is often not that simple; though the premise is the same: thinking about the mechanisms of interest and how to control for all other components except for these mechanism(s) of interest is necessary. Luckily, there is recently published guidance by Hohenschurz-Schmidt et al. [353] on developing control interventions in efficacy and mechanistic trials of physical, psychological, and self-management therapies (i.e., the COPPS statement). They provide a detailed checklist for the development and implementation of control interventions for physical, psychological, and self-management therapies that prompt researchers to think about many important questions in the planning of their control intervention. For example, they recommend (i) rationalizing the need for an efficacy trial, (ii) clearly defining the mechanism of interest, and (iii) replicating as many components of the experimental intervention as possible while (iv) ensuring the control intervention does not include the active components of interest. Going forward, I recommend researchers follow this guidance and conduct large, high-quality trials, which would likely reduce the uncertainty in the estimates of future meta-analyses.

More specific to education for LBP, it became clear from our literature searches that there are problems with the implementation of LBP education in practice. Recent systematic reviews have identified that most patients do not receive education about their LBP from their family doctor [354] and those that receive education in practice report receiving conflicting information from different providers [355]. In addition, most clinical practice guideline recommendations to provide education are accompanied by vague descriptions of what this education should entail [33,356] (see also Table 1.2). I also found no tools to assess the specific educational content in PEMs or other educational interventions for LBP so I developed a checklist to assess this information in Chapter 4. Utilizing this checklist to extract and synthesize the information from these PEMs revealed that inconsistent and conflicting information about these topics was provided across PEMs. Taken together, my thesis reveals that we do not know specifically what information to provide to patients with LBP. We know that patients should be provided information about topics like diagnosis, prognosis, and treatment options, but the extent of these recommendations are generally to tell patients they do not have anything seriously wrong with their backs, that their LBP is likely to get better in a few weeks, and that they should avoid bed rest and stay active. To address this gap in the literature, I recommend leading LBP experts and patients with LBP convene to develop a standardized, evidence-based list of learning objectives for patients with LBP using our checklist as a foundation to inform this effort. I recommend that this list of learning objectives come with detailed descriptions of what specific types of information would address each learning objective (e.g., what information is required to satisfy patients'

needs) so that future educational content and guidelines for LBP may be updated with this more specific information.

Finally, this thesis identified a number of problems with the way that PEMs for LBP have been developed and tested. I found that they are often developed without considering their understandability, actionability, quality, readability, accuracy, comprehensiveness, and coverage of information about patients' needs and suggest developers refer to each outcome measurement tool as a guide going forward. I also found few trials measuring the effectiveness of PEMs on process outcomes (e.g., knowledge, beliefs) or fidelity outcomes (e.g., did patients receive the PEM as planned, did they read it), which limits our understanding of whether PEMs for LBP are effective and how they work. Therefore, once a PEM has been developed or modified to meet acceptable standards for understandability, actionability, quality, readability, accuracy, comprehensiveness, and coverage of information about patients' needs, I recommend testing it in a large, high-quality trial that assesses these important process and fidelity outcomes using evidence-based and validated measurement tools. Only then can we make any claims about the causal mechanisms and effectiveness of this intervention.

6.4 Implications for Practice

This thesis has identified that we lack clear tools that healthcare professionals can use to support the provision of education in practice. Many PEMs for LBP are available in peer-reviewed, published literature or are recommended by clinical practice guidelines, but none meet acceptable standards for all the important, evidence-informed outcomes that I tested including readability, understandability, actionability, quality, accuracy,

comprehensiveness, and coverage of information about patients' needs. Most PEMs have large proportions of inaccurate treatment recommendations, a finding that is perhaps unsurprising when interpreted alongside our systematic review on the analgesic effects of conservative treatments for LBP, which found no large effects for any treatment and uncertain efficacy for 86% of treatments. I also found there to be inconsistent messaging across PEMs, even for the most common topics like diagnosis and prognosis. Ultimately, I identified that PEMs for LBP require improvement in many areas and better prioritization of research is essential to make sense of whether the majority of tested treatments are useful for LBP. Until these gaps are addressed, clinicians will have little choice but to use PEMs that provide inconsistent and inaccurate information to patients, much of which is irrelevant to what patients are seeking care about. This failure to provide consistent and accurate information is likely to complicate how patients understand and manage their LBP. It may potentially frustrate patients and exacerbate their unhelpful beliefs and attitudes about LBP, thereby worsening other downstream clinical (e.g., pain, disability) and health system (e.g., imaging, days off work) outcomes in practice. Until a new PEM meeting standards on all of our assessment criteria is developed, I would recommend use of the My Back Pain website [318], as it scored highly on more outcomes than all other tested PEMs.

Conclusion

My thesis used a variety of research methods, including systematic reviews and meta-analyses, the development of a checklist, and a systematic assessment of PEMs for LBP to obtain a better understanding of the potential use of PEMs as an intervention to

improve patient outcomes with a specific focus on how they might support reducing unnecessary LBP imaging in primary care. It reveals that the LBP research community has not yet done its due diligence in the development and assessment of PEMs, a potentially safe, cost-effective, and easy-to-implement intervention. Little is known about the effects PEMs have on their primary mechanisms of action (i.e., knowledge and beliefs) and no PEMs available in the literature meet acceptable standards for all evidence-based outcomes including understandability, actionability, quality, readability, accuracy, comprehensiveness, and coverage of information about patients' needs. Going forward, I recommend a PEM be modified or developed to meet these evidence-based standards, then tested in a large, high-quality trial to determine its effectiveness on knowledge and beliefs and other secondary outcomes along the clinical outcome pathway such as fear, self-efficacy, pain, and disability before we close the door on this potentially useful intervention.

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Appendices

Appendix 2.1. Protocol for Chapter 2

Preface

This protocol has been published in BMJ Open. Furlong, B., Aubrey-Bassler, K., Etchegary, H., Pike, A., Darmonkow, G., Swab, M., & Hall, A. (2020). Patient education materials for non-specific low back pain and sciatica: a protocol for a systematic review and meta-analysis. BMJ open, 10(9), e039530. doi: 10.1136/bmjopen-2020-039530

Co-authorship statement: AH and BF conceptualised and designed this systematic review and meta-analysis. BF and AH drafted the protocol. BF, AH and MS developed the search strategy and conducted the search. AH, KA-B and HE provided feedback on the manuscript for both content and clarity. All authors reviewed and provided feedback on the methods and analysis as well as the manuscript. BF and GD will perform study selection and data extraction. AH is the guarantor of this review.

Abstract

Introduction Low back pain accounts for more disability than any other musculoskeletal condition and is associated with severe economic burden. Patients commonly present with negative beliefs about low back pain and this can have detrimental effects on their health outcomes. Providing evidence-based, patient-centered education that meets patient needs could help address these negative beliefs and alleviate the substantial low back pain burden. The primary aim of this review is to investigate the effectiveness of patient education materials on immediate process, clinical, and health system outcomes.

Methods and analysis The search strategy was developed in collaboration with a librarian and systematic searches will be performed in MEDLINE, EMBASE, CINAHL, PsycINFO, and SPORTDiscus. We will also search trial registries and grey literature through the OpenGrey database. Study selection will include a title and abstract scan and full text review by two authors. Only randomized controlled trials will be included in this review. Trials must include patients with low back pain or sciatica and investigate educational interventions with at least one of the following contrasts: (1) education alone vs. no intervention; (2) education alone vs. another intervention; (3) education in addition to another intervention vs. the same intervention with no education. Data extraction, risk of bias, and grading of the quality of evidence will be performed independently by two reviewers. Risk of bias will be assessed using the PEDro scale, and the quality of evidence will be assessed with the Grades of Recommendation, Assessment, Development and Evaluation approach. A random-effects model will be used for each contrast, and results will be pooled if the participants, interventions, and outcomes are

homogenous. If heterogeneity is high ($I^2 > 75\%$), we will evaluate the magnitude and direction of the differences in effect sizes across studies to determine if it remains reasonable to pool the results. Analyses of acute and subacute low back pain (less than 12 weeks duration) will be performed separately from chronic low back pain (12 weeks or greater duration). Likewise, analyses of short-term (less than 6 months) and long-term (6 months or greater) follow-up will be performed separately. Subgroup analyses will be performed on non-specific low back pain, sciatica, and mixed populations.

Ethics and dissemination Ethical approval is not required for this review. This study, along with its results, will be published in a peer-reviewed journal.

Article Summary

Strengths and limitations of this study

- Broad and comprehensive search strategy in several databases that will follow the Peer Review of Electronic Search Strategies guidelines, peer-reviewed by two librarians
- There will be no language restriction for relevant studies
- This review will be limited to evidence from randomized controlled trials
- Heterogeneity between interventions may prevent us from conducting a meta-analysis

Introduction

Non-specific low back pain (LBP) is pain occurring below the rib cage and above the gluteal folds that is not due to a specific, identifiable cause [1,2]. It is a very common condition from which many will recover within a few weeks; however, an estimated 23% of these patients tend to develop chronic LBP, defined as consistent LBP for three months or more [3], and up to 33% will likely experience a recurrence within a year [4]. Recent data indicate that non-specific LBP accounts for more disability than any other musculoskeletal condition [5] and multiple studies show that the direct costs (e.g., health care costs) and indirect costs (e.g., industry productivity loss and compensation claims) [6] associated with the disorder have a severe economic burden [7,8]. Indeed, non-specific LBP is one of the leading causes of work absenteeism [8] and was associated with approximately 60.1 million years lived with disability in 2015 [9]. Katz [7] estimates the annual cost associated with the condition to be $100-200 billion in the US alone.

LBP is one of the five most common reasons why patients visit their family physicians [10]. When visiting a doctor, most patients want information and reassurance about their LBP [11], but one study showed that participants were not satisfied with the information they received [12]. Previous research indicates that patients may be dissatisfied because (1) providing satisfying information is especially difficult for non-specific LBP since patients cannot be presented with a specific diagnosis [13]; (2) common treatments for non-specific LBP are not always effective [13]; (3) health professionals have time constraints and may not always provide a detailed explanation of the condition [14]; and (4) health professionals themselves may not be up to date with

information about the condition and treatments [14]. For these reasons, LBP care may become frustrating or confusing for patients, and may result in a spread of misinformation about LBP.

Though there are a limited amount of studies investigating the factors associated with negative beliefs about LBP, Bunzli et al [15] found that these beliefs are associated with (1) patients' previous experience with pain, (2) diagnostic uncertainty, (3) being provided with a diagnosis of a condition that could not be fixed, and (4) previous failed treatments. Negative beliefs are held despite the fact that non-specific LBP has a generally favourable prognosis [16] and is considered to be self-limiting [17]. A recent systematic review found that negative LBP beliefs are present in many populations and countries around the world [18]. For example, Gross et al [19] found that most individuals in Canada hold pessimistic beliefs about LBP. They express concern about the severity and long-term inevitably of LBP, and that it will most likely lead to disability in the future. Several studies show that negative patient beliefs about LBP, such as pain-related fear and pain catastrophizing, are associated with LBP-related disability [20] and may be more predictive of disability than pain intensity and duration [21]. For example, fear-avoidance beliefs, pain catastrophizing and beliefs/concern that non-specific back pain is a disabling condition are associated with low levels of physical activity and high levels of disability in patients with LBP [22,23]. Conversely, positive recovery expectations may lead to better outcomes [24] and interventions aimed at reforming negative LBP beliefs into positive ones have been shown to improve LBP recovery [25,26].

Patient education may be a helpful tool to increase satisfaction with care and mitigate the subsequent development of negative patient beliefs about LBP. Patient education involves providing advice and information to patients to help them better understand their condition(s). Doing so may help to modify negative beliefs that influence behaviour associated with the condition [27]. LBP patient education aims to heighten patients' understanding of LBP, to reassure patients of the condition's favorable prognosis, and to provide patients with helpful tools to self-manage their LBP to reduce recurrence and healthcare dependency [13]. Indeed, we know from a recent review by Lim et al [11] on the health information needs of people with LBP that patients want education – they want clear and consistent information about their LBP that is presented in language they can follow and include self-management strategies and treatment options. Given this information, developing and implementing standardized, evidence-informed educational materials may therefore be a time and cost-efficient way of (1) providing patient-centered information that meets patient information needs; (2) addressing negative LBP beliefs by helping patients develop realistic expectations for their diagnosis; and (3) relieving the healthcare system's LBP burden by providing healthcare professionals with evidence-informed tools that can be promptly provided to patients, and which also keep healthcare professionals up to date with current LBP information.

Engers et al [1] conducted one of the first reviews on patient education materials (e.g., an information booklet, pamphlet, leaflet or video) for low back pain in 2008 searching studies published up to 2006. They identified 10 studies that assessed education

vs. no intervention of which only four assessed pain, five assessed disability and six assessed return to work. This review only included a narrative synthesis of the results and the effect sizes were not reported across studies, making it difficult to interpret the overall effect of education. Since this review, there have been additional systematic reviews that have assessed some form of patient education [28–40]. However, most of these reviews have investigated more intensive formats of education or skills training programs (e.g., multi-session and multi-component education programs or self-management interventions) [28,30,32–37], or a specific delivery method of education (e.g., verbal and communicative education strategies) [29,38] rather than the provision of education materials. Similarly, some reviews only focused on a specific education topic such as neurophysiological pain education [31,38]. There were three reviews that explored the effectiveness of patient education that included studies involving education materials for various outcomes for LBP [28,39,40]. The most recent of these reviews was conducted by Zahari et al [40]. They investigated the effectiveness of patient education interventions that could range from an information booklet to a multi-session education program on pain, disability and quality of life in elderly people (> 60 years of age). While they found that these types of education interventions were moderately effective, this only provides us with an update for a specific portion of the population of interest and on only a subset of the outcomes we are interested in. In terms of outcomes, few reviews have investigated the effect of patient education materials on important process outcomes such as knowledge, skills, fear-avoidance, and self-efficacy. There are only two reviews to our knowledge that have focused on these outcomes and included studies that used patient education materials as an intervention [28,39]. Traeger et al [39] focused on the outcome

of reassurance (defined as reducing fear and concern) and Ainpradub et al [28] included fear-avoidance beliefs as an outcome. While Traeger et al [39] found positive effects on reassurance, Ainpradub et al [28] found no effect on fear-avoidance beliefs. However, each of these reviews included different studies and both included interventions beyond the scope of patient education materials. Therefore, while there is currently a large breadth of evidence from available systematic reviews on patient education, none have focused specifically on the effectiveness of providing patient educational materials to patients on process, clinical and health system outcomes and thus the evidence remains out of date for this question.

Accordingly, the primary aim of this review is to provide up to date evidence on the effectiveness of patient education materials on immediate process outcomes such as knowledge, satisfaction, and expectations; clinical outcomes such as pain and physical disability; and health system outcomes such as healthcare utilization and cost effectiveness in patients with acute and chronic LBP.

Methods

Search strategy

The search strategy will be adapted from the comprehensive search strategy developed by the Back Pain Cochrane review group for the review by Engers et al [1]. This will be completed by an academic health sciences librarian with input from the project team, and will be peer reviewed by a second librarian following the Peer Review of Electronic Search Strategies (PRESS) guidelines [41]. The following databases will be

searched from inception to April 2020: MEDLINE, EMBASE, CINAHL, PsycINFO, and SPORTDiscus. A draft of the adapted Ovid MEDLINE search strategy is presented in Appendix 2.1A. We will also search trial registries as well as grey literature through the OpenGrey database.

Inclusion/exclusion criteria

For this review, there will be no language restrictions. We will use Google translate for non-english studies. The remainder of the criteria are as follows:

Study design

Only randomized controlled trials (RCTs) will be included. Pilot and feasibility studies will be included so long as participants were randomly allocated to groups.

Population

Eligible studies will investigate adults aged 16 years or older with acute, subacute, or chronic non-specific LBP or sciatica. Our definition of non-specific LBP will include populations with and without leg pain, but without nerve root compromise, as well as conditions such as spondylitis, spondylolysis, spondylolisthesis, disc protrusion, herniation or prolapse, and radicular syndrome. Sciatica will be defined as pain radiating downwards from the buttock due to pressure on the lumbosacral nerve root [42]. This nerve root compromise may involve inflammation or other immunological processes [43]. Studies will be excluded if subjects have a specific pathology such as cauda equina syndrome, infection, neoplasm, fracture, or inflammatory disease, or if a large portion of the included participants were pregnant or had spinal surgery in the previous 12 months

as the patient education for these patients are likely to differ from patients with non-specific LBP.

Interventions

In terms of intervention, any study that investigates the effect of patient education will be included. Patient education will be defined as interventions in which there is a health encounter between a patient and physician (delivered in a one-to-one setting or in a group-based medical appointment) in family practice and emergency department settings where information about LBP (e.g., diagnosis, prognosis, self-management or other treatment advice) is provided to the patient by using a standardized evidence-based supplement. An evidence-based supplement can include structured pamphlets, booklets, links to online resources, audio files, videos, or workbooks that are provided to the patient during or after consultation with the physician. Studies investigating education not delivered directly by a physician (e.g., media campaigns), or education aimed solely at teaching subjects how to perform exercises will be excluded. Interventions in which the education provided to the patient is only provided verbally from the physician without an evidence-based supplement as described above will also be excluded. Education materials are often provided as one component in a larger multi-component intervention; for this review, we are interested in interventions in which the educational material is the main component of the intervention. Therefore, interventions that include education, plus another conservative component such as physiotherapy which is considered to be the main component, will be excluded unless the comparison group allows us to isolate the effect of education.

Comparison

We will consider the effect of education compared to 2 main comparison groups (i) no other intervention and (ii) another conservative intervention. In cases where education is part of a multi-component intervention and is not the main component, they will be included if the effect of the education alone can be determined (i.e., education + other conservative components vs. the conservative components alone which allows for determining the additive effect of education). In cases where the comparison group is described as usual care but is not explicitly defined as to what this entails, we will assume it to be the absence of an active intervention and included in the first comparison group. For studies that have a usual care comparison group which is defined and does include other interventions such as seeking care from health professionals or exercise therapy, etc., this study will be included in the second comparison. Comparisons of non-conservative treatments (e.g., spinal cord stimulations or surgery) will be excluded.

Outcomes

For this review we are interested in assessing the effectiveness of education at three different levels. First, we are interested in the effect of education on process outcomes. These are the variables that are directly targeted by the education intervention and are thought to influence the clinical outcomes including knowledge, pain self-efficacy, reassurance, pain-related anxiety, depression, coping, expectations, and treatment satisfaction (these are also referred to as potential mediators of effect). Second, we are interested in the effect of education on clinical outcomes relevant to patients with low back pain including short and long-term measures of pain, physical disability, return

to work, and quality of life. Third, we are interested in the effect of education on health-system outcomes including healthcare utilization and cost effectiveness. Studies that evaluate any of these outcomes will be included in this systematic review.

Study selection

Titles and abstracts of studies found in the literature search will be downloaded and imported to Endnote [44]. Duplicates will be removed manually by the librarian and the resulting studies will be imported to Covidence systematic review software [45] to perform the remainder of study selection. Titles and abstracts will be reviewed independently by two authors (BF, GD) for relevance, starting with a 10-study trial period to determine if a revision to the inclusion and exclusion criteria is required. Any conflicts will be discussed by the reviewers, and when necessary, a third reviewer will be consulted to resolve the conflict (AH). The full texts of relevant studies will then be obtained, and full-text review will be performed by two independent reviewers (BF, GD). Conflicts will be discussed by the same reviewers and when necessary, a third reviewer to resolve the conflict (AH). Reference lists of relevant studies will be hand searched to find studies missed by the search, and authors will be contacted to identify additional studies when conference abstracts or ongoing trials are found. If the full study of a conference abstract cannot be found it will be excluded.

Data extraction

Two reviewers will independently extract and chart the data of all included studies using standardized data extraction forms in Microsoft Excel (BF, GD). The extraction

forms will include variables relating to study details (authors, year of publication, country of data collection), study characteristics (LBP type duration, sample size, outcomes measures, study design individual or cluster RCT, brief intervention group description, comparison group description). Intervention details will be extracted in accordance with the 12 variables outlined in the TIDieR checklist [46] (e.g. a description of the intervention procedures, who provided the intervention, how and where the intervention was provided, the frequency/dose and duration of the intervention, if and how adherence and fidelity were to be assessed, etc.). Lastly, specific information on each outcome will be extracted including measurement tools, measurement scales, scoring methods and interpretation, mean and standard deviation. Point estimates of effect size and 95% confidence intervals will be used to estimate the treatment effect. Review Manager 5 will be used for the analysis.

After data extraction is complete, two authors will make independent judgments to include or exclude relevant studies for the meta-analysis. If all relevant data points are obtained, the study will be included.

Risk of bias assessment

Risk of bias will be assessed at the outcome level using the PEDro scale [47]. The PEDro scale grades risk of bias on a 10-point scale. A study will be deemed to have a high risk of bias if 0-3 criteria on the scale are satisfied, moderate if 4-6 criteria are satisfied, and low if 7-10 criteria are satisfied. Two reviewers will independently assess risk of bias for all included studies (BF, GD). Conflicts will be discussed, and where necessary, will be resolved by a third reviewer (AH). Sensitivity analyses will be

performed to determine if data from studies judged to have a high risk of bias influence the overall effect size.

Data synthesis

Contrasts

We are interested in assessing the effects of education in the following three scenarios:

1. Education alone vs. no intervention

2. Education alone vs. another intervention

3. Education in addition to another intervention vs. the same intervention with no education

Effectiveness analysis

As it is likely that different measurement tools will be used for each outcome, we plan to use the standardized mean difference for the analysis. A random-effects model will be used for each contrast since variation between each intervention is likely. We plan to pool the results if the participants, interventions, and outcomes are homogenous. We anticipate there will be a small degree of clinical heterogeneity in the types of educational materials (e.g., content or delivery of the intervention) and populations assessed (e.g., duration of low back pain) for which we consider to be acceptable given our overall study question. If $I2 > 75\%$, which represents potential for considerable statistical heterogeneity, we will investigate both the level of clinical heterogeneity as well as the

magnitude and direction of the differences in effect sizes across studies to determine if it remains reasonable to pool the results. If heterogeneity is too high, or if there is only one study in the strata, we plan to develop a qualitative synthesis to describe the effect of the interventions. If meta-analyses are possible, we plan to perform subgroup analyses for hard copy (e.g., booklets, pamphlets) and soft copy (e.g., link to online resource, video) education material interventions. Subgroup analyses will also be performed for non-specific LBP, sciatica, and mixed populations. A study will be considered to have a population of non-specific LBP if people with nerve root compromise are excluded. If there is no exclusion for nerve root compromise, then the population will be considered to be a mixed population. If only those with nerve root compromise are included in the study the population will be considered to be a sciatica population. Analyses of acute and subacute LBP (less than 12 weeks duration) will be performed separately from chronic LBP (12 weeks or greater duration). Likewise, analyses of short-term (less than 6 months) and long-term (6 months or greater) follow-up will be performed separately. We also plan to perform a sensitivity analysis to determine if high risk of bias studies influence the results of the analysis.

To assess the level of certainty of the evidence, a summary of findings table will be developed for each outcome using the GRADE approach [48]. GRADE involves assessing each study using five domains, each of which are "downgraded" a level of evidence if they meet the following criteria:

1. Quality - studies with high risk of bias contain greater than 25% of all participants

2. Inconsistency - high heterogeneity is clear from visual inspection or $I^2>75\%$

3. Indirectness - over 50% of participants are not in the target group (i.e., if participants were subject to multicomponent interventions where the effect of education alone may not be interpretable)

4. Imprecision - the comparison for continuous data involves less than 400 participants, or there are less than 300 events for dichotomous data

5. Publication bias - (i) many included studies have a small sample size, (ii) studies are or are likely to be industry-sponsored, (iii) other conflicts of interest are present. Publication bias will also be assessed from visual inspection of a funnel plot. The treatment effect from each study will be plotted against the sample size of each study. If the plot does not resemble a cone, or if the regression line is not perpendicular to the x axis then there may be publication bias. If any of these criteria are present, we will consider downgrading the quality of evidence of studies.

These will be assessed independently by two reviewers (BF, GD). Conflicts will be discussed, and if necessary, will be reviewed with a third author to come to a consensus (AH). Studies will be considered to have high quality evidence, moderate quality evidence, low quality evidence, very low-quality evidence, or no evidence if there are zero to four downgrades, respectively.

Dealing with missing data

Authors will be contacted if data are missing from a study. Otherwise, the data will be obtained from graphs or calculated using other data in the study where possible. If a mean value cannot be obtained, the study will not be included in the meta-analysis, but

instead used for descriptive review. If a standard deviation is not provided it will be calculated or estimated using a relevant statistic provided in the study (e.g., from confidence intervals, standard errors, p values) [49]. If the standard deviation cannot be calculated in this way, it may be imputed by borrowing values from similar studies, as described in the Cochrane handbook [50].

Patient and public involvement

Patients and members of the public were involved in identifying and prioritizing this question as part of an "improving the management of low back pain" key stakeholder engagement session held at Memorial University. During that session, patient-identified outcomes were also recorded and informed the choice of outcomes for this review. Neither patients nor members of the public were involved in the development of the protocol. Patients will be consulted again to review and validate components of education interventions and outcomes identified through the review according to their lived experience. Finally, patients will be consulted to help translate key messages of the results for dissemination.

Ethics and dissemination

Ethical approval is not required for this review. This study, along with its results, will be published in a peer-reviewed journal and the results may be summarized and circulated in other formats as appropriate (e.g., infographics or evidence briefs). We have decided to publish rather than preregister this protocol as publishing has the added benefit

of receiving critical appraisal and gives us the ability to provide a more detailed description of the methods and background of the study.

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Competing interests statement

None declared.

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Appendix 2.1A. Search strategy

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to April 03, 2020>

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1 Back Pain/ (17459)

2 Low Back Pain/ (21473)

3 Sciatica/ (4973)

4 exp Spondylosis/ (7396)

5 back pain.ti,ab. (45684)

6 back ache.ti,ab. (100)

7 backache.ti,ab. (2466)

8 lumbar pain.ti,ab. (1453)

9 spine pain.ti,ab. (415)

10 spinal pain.ti,ab. (1430)

11 sciatica.ti,ab. (4170)

12 sciatic pain.ti,ab. (570)

13 spondylosis.ti,ab. (3198)

14 spondyloarthr*.ti,ab. (6453)

15 spondylolisthesis.ti,ab. (4981)

16 lumbago.ti,ab. (1333)

17 dorsalgia.ti,ab. (88)

18 or/1-17 (82854)

19 exp Health Education/ (240671)

20 exp Communications Media/ (316973)

21 Social Media/ (7278)

22 Internet/ (71717)

23 Mobile applications/ (5487)

24 Internet-Based Intervention/ (78)

25 exp Counseling/ (43379)

26 ed.fs. (275241)

27 education*.ti,ab. (527633)

28 psychoeducation*.ti,ab. (4772)

29 back school*.ti,ab. (290)

30 book*.ti,ab. (33489)

31 workbook*.ti,ab. (702)

32 (video or videos).ti,ab. (94724)

33 (audio or audiovisual*).ti,ab. (19979)

34 pamphlet*.ti,ab. (1923)

35 leaflet*.ti,ab. (21863)

36 brochure*.ti,ab. (2294)

37 (poster or posters).ti,ab. (6900)

38 (website* or web sites*).ti,ab. (28891)

39 (app or apps).ti,ab. (26854)

40 (application* adj2 (web or internet or online or mhealth or ehealth or digital or smartphone or cellphone or phone or ipad or iphone or android or mobile)).ti,ab. (10903)

41 infographic*.ti,ab. (298)

42 module*.ti,ab. (64302)

43 animation*.ti,ab. (2899)

44 ((patient or consumer or health) adj information).ti,ab. (29271)

45 ((biopsychosocial or psychosocial or psycho social or cognitive or behavioral or behavioural or psychological) adj2 (treatment* or intervention* or therapy or therapies or management or program* or training or approach* or counsel* or coach*)).ti,ab. (79187)

46 ((online or web or internet or e learning or elearning or ehealth or e health or telehealth or telephone or phone) adj2 (session* or program* or workshop* or training or coach* or counsel* or support*)).ti,ab. (11514)

47 ((group or individual or individuali* or personal or personali* or self) adj2 (session* or program* or workshop* or training or coach* or counsel* or support*)).ti,ab. (54884)

48 ((health or movement) adj coach*).ti,ab. (752)

49 advice.ti,ab. (47300)

50 reassurance.ti,ab. (5570)

51 or/19-50 (1605878)

52 ((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or randomised.ab. or placebo.ab. or drug therapy.fs. or randomly.ab. or trial.ab. or groups.ab.) not (exp animals/ not humans.sh.) (4063887)

53 18 and 51 and 52 (2406)

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Appendix 2.2. Search strategy

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily <1946 to March 24, 2022>

Search Strategy:

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1 Back Pain/ (18402)

2 Low Back Pain/ (24663)

3 Sciatica/ (5132)

4 exp Spondylosis/ (8214)

5 back pain.ti,ab. (52845)

6 back ache.ti,ab. (111)

7 backache.ti,ab. (2587)

8 lumbar pain.ti,ab. (1647)

9 spine pain.ti,ab. (488)

10 spinal pain.ti,ab. (1644)

11 sciatica.ti,ab. (4587)

12 sciatic pain.ti,ab. (594)

13 spondylosis.ti,ab. (3517)

14 spondyloarthr*.ti,ab. (7933)

15 spondylolisthesis.ti,ab. (5635)

16 lumbago.ti,ab. (1408)

17 dorsalgia.ti,ab. (107)

18 or/1-17 (93541)

19 exp Health Education/ (257076)

20 exp Communications Media/ (366614)

21 Social Media/ (12867)

22 Internet/ (78659)

23 Mobile applications/ (9696)

24 Internet-Based Intervention/ (889)

25 exp Counseling/ (47228)

26 ed.fs. (294215)

27 education*.ti,ab. (619610)

28 psychoeducation*.ti,ab. (5995)

29 back school*.ti,ab. (304)

30 book*.ti,ab. (37582)

31 workbook*.ti,ab. (812)

32 (video or videos).ti,ab. (118444)

33 (audio or audiovisual*).ti,ab. (25653)

34 pamphlet*.ti,ab. (2127)

35 leaflet*.ti,ab. (24353)

36 brochure*.ti,ab. (2570)

37 (poster or posters).ti,ab. (7881)

38 (website* or web sites*).ti,ab. (36982)

39 (app or apps).ti,ab. (36123)

40 (application* adj2 (web or internet or online or mhealth or ehealth or digital or smartphone or cellphone or phone or ipad or iphone or android or mobile)).ti,ab. (15794)

41 infographic*.ti,ab. (697)

42 module*.ti,ab. (80774)

43 animation*.ti,ab. (3370)

44 ((patient or consumer or health) adj information).ti,ab. (34919)

45 ((biopsychosocial or psychosocial or psycho social or cognitive or behavioral or behavioural or psychological) adj2 (treatment* or intervention* or therapy or therapies or management or program* or training or approach* or counsel* or coach*)).ti,ab. (94595)

46 ((online or web or internet or e learning or elearning or ehealth or e health or telehealth or telephone or phone) adj2 (session* or program* or workshop* or training or coach* or counsel* or support*)).ti,ab. (15121)

47 ((group or individual or individuali* or personal or personali* or self) adj2 (session* or program* or workshop* or training or coach* or counsel* or support*)).ti,ab. (65872)

48 ((health or movement) adj coach*).ti,ab. (1048)

49 advice.ti,ab. (54323)

50 reassurance.ti,ab. (6430)

51 or/19-50 (1849755)

52 ((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or randomised.ab. or placebo.ab. or drug therapy.fs. or randomly.ab. or trial.ab. or groups.ab.) not (exp animals/ not humans.sh.) (4626609)

53 18 and 51 and 52 (2912)

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Appendix 2.3. Inclusion, exclusion, and GRADE criteria, protocol deviations.

Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Language	Any language	-
Study design	Randomized controlled trials (RCTs) were included. Grey literature (e.g., theses), and pilot and feasibility studies were included so long as participants were randomly allocated to intervention and control groups.	All other non-RCT study designs.
Population	Adults aged 16 years or older with acute, subacute, or chronic non-specific LBP or sciatica. Our definition of non-specific LBP included populations with and without leg pain, but without nerve root compromise, as well as conditions such as spondylitis, spondylolysis, spondylolisthesis, disc protrusion, herniation or prolapse, and radicular syndrome. Sciatica was defined as pain radiating downwards from the buttock due to pressure on the lumbosacral nerve root. This nerve root compromise could involve inflammation or other immunological processes.	Subjects with specific pathology such as cauda equina syndrome, infection, neoplasm, fracture, or inflammatory disease, or if a large portion of the included participants were pregnant or had spinal surgery in the previous 12 months. There were no exclusion criteria based on care-seeking and non-care-seeking populations, so participants could be recruited either through physicians in a general practice setting or through the community (e.g., newspaper ads, online websites).
Intervention	Studies investigating the effect of patient education materials for LBP were included. Specifically, patient education materials were defined as interventions where any information about non-specific LBP or sciatica (e.g., diagnosis, prognosis, self-management or other treatment advice) was provided to the patient with a	Education delivered by other health professionals (e.g., chiropractors, physiotherapists) were not included. Studies where the education was solely aimed at teaching subjects how to perform exercises, or where the education was provided verbally from the physician or researcher without an evidence-based supplement were

	standardized evidence-based supplement (e.g., structured pamphlets, booklets, links to online resources, audio files, videos, or workbooks provided to the patient by a physician or member of the research team conducting the study. Education materials could be provided in person, via mail, or online.	not included. Education materials are often provided as one component in a larger multi-component intervention; for this review, we were interested in interventions in which the educational material is the main component of the intervention. Therefore, interventions that include education materials plus another conservative component such as physiotherapy were excluded unless the comparison group allowed us to isolate the effect of the education material.
Comparison	We considered the effect of education materials compared to two main comparison groups (i) no other intervention and (ii) another conservative intervention. In cases where education was part of a multi-component intervention and was not the main component, they were included if the effect of the education alone could be determined (i.e., education + other conservative components vs. the conservative components alone which allows for determining the additive effect of education).	Comparisons of non-conservative treatments (e.g., spinal cord stimulations or surgery) were excluded.
Outcomes	We included process outcomes (the variables that are directly targeted by the education intervention and are thought to influence the clinical outcomes such as knowledge, pain self-efficacy, reassurance, pain-related anxiety, depression, and coping), clinical outcomes (those relevant to patients with low back pain including measures of pain, physical disability, and quality of life) and health-system outcomes (healthcare utilization measures	We excluded a select few outcomes including flexibility and balance

	like physician visits and imaging, and cost effectiveness)	

Grades of Recommendation, Assessment, Development and Evaluation approach (GRADE)

GRADE involves assessing each study using five domains, each of which are "downgraded" a level of evidence if they meet the following criteria:

1. Quality - studies with high risk of bias contain greater than 25% of all participants

2. Inconsistency - high heterogeneity is clear from visual inspection or I^2>75%

3. Indirectness - over 50% of participants are not in the target group (i.e., if participants were subject to multicomponent interventions where the effect of education alone may not be interpretable)

4. Imprecision - the comparison for continuous data involves less than 400 participants, or there are less than 300 events for dichotomous data

5. Publication bias - (i) many included studies have a small sample size, (ii) studies are or are likely to be industry-sponsored, (iii) other conflicts of interest are present. Publication bias was also assessed from visual inspection of a funnel plot if the analysis included 10 or more studies, as recommended in the Cochrane handbook. The treatment effect from each study was plotted against the sample size of each study. If the plot did not resemble a cone, or if the regression line was

not perpendicular to the x axis, there may have been publication bias. If any of these criteria were present, we considered downgrading the quality of evidence of studies.

Studies were considered to have high quality evidence, moderate quality evidence, low quality evidence, very low-quality evidence, or no evidence if there were zero to four downgrades, respectively. When there was only one study in a comparison, it automatically received a very low-quality evidence assessment unless it was a large trial ($n > 1000$) with low risk of bias. In these cases, we would upgrade the assessment to low-quality evidence. For comparisons with studies that did not provide usable data for the meta-analysis (e.g., absence of summary data that we could not obtain after contacting authors), we provided a narrative synthesis of the studies alongside the analysis, and these studies were not included in GRADE assessment.

Protocol deviations

Modifications to inclusion and exclusion criteria: In our initial literature screening, we found few studies ($n = 9$) where a physician provided the education material in a primary care or emergency department setting. We expanded these criteria to include studies where a member of the study's research team could provide the education materials, rather than restricting this responsibility to a physician. Intuitively, to capture studies where PEMs were provided by a researcher, we allowed for inclusion of studies where participants were recruited outside of primary care or emergency department settings (e.g., through the community using online advertisements or local posters).

If a study's inclusion/exclusion criteria did not match with our criteria of acute/subacute or chronic LBP, we went by the authors' definition of LBP and included these studies in the respective analysis category. Where the authors did not specify the population as acute/subacute or chronic, we looked at the baseline demographic data to see if a distribution of LBP duration was provided. If the majority (>50%) of subjects had acute/subacute or chronic LBP, we included the study in the respective analysis category and accounted for this decision in our GRADE judgements (i.e., if more than half of the sample came from studies with unclear or mixed populations, we downgraded the quality of evidence for indirectness). There was a special case where a study included patients with a LBP duration of 6 weeks or greater and did not explicitly define their population as acute, subacute, or chronic. This fell between our two defined populations, but we included this study in the chronic LBP comparison because there would be no typical acute (< 6 weeks) LBP patients and we assumed there would be more chronic than subacute LBP patients due to the nature of these definitions. We accounted for this decision in our GRADE judgements of indirectness.

Modifications to the data synthesis: We originally planned to perform separate analyses for short (less than 6 months) and long-term (6 months or greater) follow-up time periods, but many studies had more than one follow-up during these timeframes. To better conform to the many follow-up time points and provide a more accurate depiction of how PEMs are effective over time, we included two additional time points (for a total of four) as described in our manuscript.

Modifications to sensitivity and subgroup analyses: We had planned to perform subgroup analyses on nonspecific LBP, sciatica, and mixed LBP populations based on exclusion or inclusion of patients with nerve root compromise, however, we found that in many studies this criterion was not specified, and no studies specifically stated they only included subjects with nerve root compromise. We therefore assumed the sciatica population to be minimal in included studies and considered all studies to have a population of non-specific LBP, so we could not perform this subgroup analysis. We also planned to perform subgroup analyses on hard vs. soft copy PEMs. Unfortunately, few studies used soft copy PEMs and most that did were isolated to one comparison. That is, four of five studies comparing PEMs to usual care for chronic LBP used soft copy PEMs, whereas only one study comparing PEMs to usual care for acute LBP used a soft copy PEM. Due to this imbalance between groups in the different comparisons, we did not see the value in performing this subgroup analysis.

Appendix 2.4. Summary of findings for all outcomes and comparisons

Legend: Non-Abbreviated Outcome Measures

- **4DSQ:** Four-Dimensional Symptom Questionnaire
- **ADLQ:** Activities of Daily Living Questionnaire
- **ALBDS:** Aberdeen Pain and Function Scale
- **AQoL-8D:** Assessment of Quality of Life 8-Dimension
- **BPI:** Brief Pain Inventory
- **CSQ:** Coping Strategies Questionnaire
- **CPCI-42:** 42-Item Chronic Pain Coping Inventory
- **Dartmouth CO-OP:** Dartmouth Primary Care Cooperative Information Project
- **DASS-21:** 21-Item Depression Anxiety Stress Scale
- **EQ-5D:** the EuroQol 5-dimension health-related quality of life instrument
- **EQ5D-3L:** the EuroQol 5-dimension, 3-level health-related quality of life instrument
- **FABQ:** Fear-avoidance beliefs questionnaire
- **FFbH-R:** Hannover Functional Ability Questionnaire
- **GPE:** Global Perceived Effect scale
- **HAD:** Hospital Anxiety and Depression scale
- **NRS:** Numeric Rating Scale
- **ODI:** Oswestry Disability Index
- **OEQ:** Outcome Evaluation Questionnaire
- **PCS:** Pain Catastophizing Scale
- **PGIC:** Patients Global Impression of Change scale
- **PHQ-8:** 8-item Patient Health Questionnaire
- **PPQ:** Patient Pain Questionnaire
- **PSEQ:** Pain Self-Efficacy Questionnaire
- **PSEQ-2:** 2-Item Pain Self-Efficacy Questionnaire
- **PSS:** Perceived Stress Scale
- **QBPDS:** Quebec Back Pain Disability Scale
- **RMDQ:** Roland Morris Disability Questionnaire
- **SAS:** Zung Self-Rating Anxiety Scale
- **SBS:** Symptom Bothersomeness scale
- **SDS:** Zung Self-Rating Depression Scale
- **SF-12:** 12-Item Short Form Survey
- **SF-36:** 36-Item Short Form Survey
- **TSK-4:** 4-item Tampa Scale for Kinesiophobia
- **UTs:** unvalidated tools (unspecified, bespoke, or unnecessary adaptations of already validated tools with insufficient information to determine their validity)
- **VAS:** Visual Analogue Scale

- **VNS:** Visual Numeric Scale
- **WLQ:** Work Limitations Questionnaire

Education materials compared with no intervention (usual care) for acute/subacute low back pain
P: adults aged 16+ with acute/subacute low back pain (<12 weeks duration)
I: education materials (typically provided during a single encounter with a physician or researcher in-person, via parcel, or over the internet)
C: no intervention or usual care

Outcome (# studies) Time points	Outcome measurement tools[a]	SMD[b] (95% CI) or RR[+,-] (95% CI)	Participants (# studies)	Quality of Evidence[c] (GRADE)
Knowledge (n = 5):				
• **Immediate-term (1-8 wks)**	UTs (4)	-0.51 [-0.72, -0.31]	699 (4)	⨁⨁⨀⨀ Low[1,4*]
• **Short-term (13-16 wks)**	UTs (2)	-0.48 [-0.90, -0.05]	502 (2)	⨁⨁⨀⨀ Low[1,4*]
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	UTs (1)	RR[+] = 1.28 [1.10, 1.49]	777 (1)	⨁⨀⨀⨀ Very low[6]
Self-efficacy (n = 4):				
• **Immediate-term (2-8 wks)**	PSEQ-2 (1), UTs (3)	-0.28 [-0.63, 0.07]	650 (3)	⨁⨁⨁⨀ Moderate[4*]
• **Short-term (16 wks)**	UTs (1)	-0.78 [-0.98, -0.58]	398 (1)	⨁⨀⨀⨀ Very low[6]
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	UTs (1)	-0.32 [-0.52, -0.12]	421 (1)	⨁⨀⨀⨀ Very low[6]
Attitudes: no evidence				
General beliefs: no evidence				
Fear-avoidance (n = 3):				
• **Immediate-term (1-6 wks)**	FABQ (2), UTs (1)	-0.14 [-0.36, 0.09]	611 (3)	⨁⨁⨁⨁ High
• **Short-term (13 wks)**	FABQ (1)	0.00 [-0.38, 0.38]	114 (1)	⨁⨀⨀⨀ Very low[6]
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	FABQ (1)	0.10 [-0.15, 0.35]	150 (1)	⨁⨀⨀⨀ Very low[6]
Catastrophizing (n = 3):				
• **Immediate-term (2-8 wks)**	TSK-4 (1), CSQ (1), UTs (1)	-0.01 [-0.22, 0.20]	879 (3)	⨁⨁⨁⨁ High
• **Short-term (16 wks)**	TSK-4 (1)	-0.12 [-0.31, 0.07]	398 (1)	⨁⨀⨀⨀ Very low[6]
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	CSQ (1)	0.07 [-0.18, 0.32]	248 (1)	⨁⨀⨀⨀ Very low[6]

Coping: no evidence				
Anxiety (n = 3):				
• **Immediate-term (2 wks)**	4DSQ (1), UTs (1)	-0.01 [-0.45, 0.43]	485 (2)	⨁⨁⨁⨀ Moderate[3]
• **Short-term**	-	-	0 (0)	No evidence
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	4DSQ (1), UTs (1)	-0.13 [-0.52, 0.26]	673 (2)	⨁⨁⨀⨀ Low[1,3]
Stress: no evidence				
Depression: no evidence				
Pain (n = 5):				
• **Immediate-term (2-8 wks)**	NRS (2), UTs (1)	-0.13 [-0.27, 0.01]	910 (3)	⨁⨁⨁⨁ High
• **Short-term (12-16 wks)**	NRS (3), UTs (1)	-0.24 [-0.42, -0.06]	1101 (4)	⨁⨁⨁⨁ High
• **Medium-term (26 wks)**	NRS (2)	-0.03 [-0.20, 0.15]	515 (2)	⨁⨁⨁⨁ High
• **Long-term (52 wks)**	NRS (2), VNS (1)	-0.11 [-0.24, 0.02]	892 (3)	⨁⨁⨁⨀ Moderate[1]
Disability (n = 8):				
• **Immediate-term (1-8 wks)**	RMDQ (2), ALBDS (2), FFbH-R (1), WLQ (1)	-0.05 [-0.17, 0.06]	1220 (6)	⨁⨁⨁⨁ High
• **Short-term (13-16 wks)**	RMDQ (2), ALBDS (1), FFbH-R (1), WLQ (1), ODI (1)	-0.06 [-0.18, 0.05]	1272 (6)	⨁⨁⨁⨁ High
• **Medium-term (26 wks)**	RMDQ (2), ALBDS (1)	0.09 [-0.08, 0.27]	563 (3)	⨁⨁⨁⨁ High
• **Long-term (52 wks)**	RMDQ (2), ALBDS (1), ODI (1)	-0.09 [-0.27, 0.08]	938 (4)	⨁⨁⨁⨀ Moderate[1]
Quality of Life (n = 4):				
• **Immediate-term (1-8 wks)**	SF-36 (1), Dartmouth CO-OP (1)	-0.24 [-0.42, -0.07]	524 (2)	⨁⨁⨁⨀ Moderate[4*]
• **Short-term (13-16 wks)**	SF-36 (1), Dartmouth CO-OP (1), UTs (1)	-0.20 [-0.43, 0.03]	804 (3)	⨁⨁⨁⨁ High
• **Medium-term (26 wks)**	UTs (1)	0.00 [-0.23, 0.23]	286 (1)	⨁⨀⨀⨀ Very low[6]
• **Long-term (52 wks)**	EQ5D-3L (1), UTs (1)	0.01 [-0.17, 0.19]	470 (2)	⨁⨁⨁⨀ Moderate[1]

Global improvement (n = 1):				
• **Immediate-term (6 wks)**	UTs (1)	RR^{-} = 1.07 [0.80, 1.43]	305 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (13 wks)**	UTs (1)	RR^{-} = 1.03 [0.75, 1.42]	305 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (26 wks)**	UTs (1)	RR^{-} = 1.05 [0.75, 1.47]	299 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term (52 wks)**	UTs (1)	RR^{-} = 1.15 [0.81, 1.65]	288 (1)	⨁⊖⊖⊖ Very low[6]
Function: no evidence				
Days off work (n = 3):				
• **Immediate-term (6 wks)**	% with days off work (1)	RR^{-} = 0.83 [0.49, 1.42]	248 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (13 wks)**	% with days off work (1), mean days off work (1)	-0.35 [-0.63, -0.08]	612 (2)	⨁⨁⊖⊖ Low[1,4*]
• **Medium-term (26 wks)**	% with days off work (1)	RR^{-} = 0.33 [0.10, 1.16]	244 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term (52 wks)**	% with days off work (1), mean days off work (2)	-0.10 [-0.32, 0.12]	1535 (3)	⨁⨁⨁⊖ Moderate[1]
Imaging (n = 1):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term (13 wks)**	% receiving LBP imaging (1)	RR^{-} = 0.64 [0.38, 1.09]	364 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	% receiving LBP imaging (1)	RR^{-} = 0.60 [0.41, 0.89]	364 (1)	⨁⊖⊖⊖ Very low[6]
Physician visits (n = 3):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term (13 wks)**	Mean physician visits (1)	-0.07 [-0.27, 0.13]	364 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	Mean physician visits (2), % with physician visit (1)	-0.16 [-0.26, -0.05]	1721 (3)	⨁⨁⨁⊖ Moderate[1]
Referrals (n = 1):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term**	-	-	0 (0)	No evidence
• **Medium-term**	-	-	0 (0)	No evidence

• **Long-term (52 wks)**	Proportion with specialist referral (1)	RR^{-} = 0.85 [0.58, 1.23]	936 (1)	⨁⊖⊖⊖ Very low[6]
Cost (n = 1):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term**	-	-	0 (0)	No evidence
• **Medium-term (26 wks)**	Quality-adjusted life years (1)	-0.11 [-0.37, 0.16]	226 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term**	-	-	0 (0)	No evidence

[a]See legend on first page of Appendix 2.4 for non-abbreviated names of measurement tools. [b]Data are presented as standardized mean differences (SMD) and 95% confidence intervals (95% CI) unless otherwise indicated (negative SMD favors education materials). Risk ratios are indicated with RR^{+} (RR > 1 favors education) and RR^{-} (RR < 1 favors education). [c]Quality of evidence was downgraded for risk of bias,[1] imprecision,[2] inconsistency,[3] indirectness,[4] publication bias,[5] or downgraded to very low if there was one study.[6] In this comparison, downgrades for risk of bias and inconsistency followed our pre-defined cut-offs (Appendix 2.3) and do not require further interpretation. *Where evidence for knowledge, pain self-efficacy, quality of life, and days off work were downgraded for indirectness, this was due to Irvine *et al.,* 2015 (they did not explicitly define their LBP population) or Simula *et al.,* 2021 (PEMs could be given by other providers and not just physicians, however, we decided to include this study since they provided a detailed breakdown of data for each provider and almost half of the sample saw a physician).

Education materials compared with another intervention for acute/subacute low back pain
P: adults aged 16+ with acute/subacute low back pain (<12 weeks duration)
I: education materials (typically provided during a single encounter with a physician or researcher in-person, via parcel, or over the internet)
C: any non-conservative intervention (e.g., yoga, massage, exercise, cognitive behavioural therapy, etc.)

Outcome (# studies) Time points	Outcome measurement tools[a]	SMD[b] (95% CI) or RR[+,-] (95% CI)	Participants (# studies)	Quality of Evidence[c] (GRADE)
Knowledge: no evidence				
Self-Efficacy: no evidence				
Attitudes: no evidence				
General beliefs: no evidence				
Fear-Avoidance (n = 1):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term**	-	-	0 (0)	No evidence
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	FABQ (1)	0.17 [-0.16, 0.49]	155 (1)	⨁⊖⊖⊖ Very low[6]
Catastrophizing (n = 1):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term**	-	-	0 (0)	No evidence
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	PCS (1)	-0.06 [-0.38, 0.27]	155 (1)	⨁⊖⊖⊖ Very low[6]
Coping: no evidence				
Anxiety (n = 1):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term**	-	-	0 (0)	No evidence
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	HAD (1)	-0.05 [-0.37, 0.27]	155 (1)	⨁⊖⊖⊖ Very low[6]
Stress: no evidence				

Depression (n = 1):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term**	-	-	0 (0)	No evidence
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	HAD (1)	0.00 [-0.32, 0.32]	155 (1)	⨁⊖⊖⊖ Very low[6]
Pain (n = 3):				
• **Immediate-term (4 wks)**	SBS (1)	0.51 [0.20, 0.83]	178 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (12 wks)**	VAS (1), SBS (1)	0.07 [-0.81, 0.95]	212 (2)	⨁⨁⊖⊖ Low[2,3]
• **Medium-term (26 wks)**	VAS (1)	-0.89 [-1.66, -0.11]	31 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term (52 wks)**	OEQ (1)	0.04 [-0.28, 0.36]	155 (1)	⨁⊖⊖⊖ Very low[6]
Disability (n = 3):				
• **Immediate-term (4 wks)**	RMDQ (1)	0.27 [-0.04, 0.58]	178 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (12 wks)**	RMDQ (2)	0.23 [-0.06, 0.51]	212 (2)	⨁⨁⨁⊖ Moderate[2]
• **Medium-term (26 wks)**	RMDQ (1)	-0.15 [-0.88, 0.58]	31 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term (48-52 wks)**	ADLQ (1), % with reduced activity (1)	0.20 [-0.04, 0.43]	343 (2)	⨁⨁⊖⊖ Low[2,4*]
Quality of Life: no evidence				
Global Improvement: no evidence				
Function: no evidence				
Days off work (n = 2):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term**	-	-	0 (0)	No evidence
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (48-52 wks)**	% with days off work (1), mean days off work (1)	0.36 [0.09, 0.63]	343 (2)	⨁⨁⊖⊖ Low[2,4*]
Imaging: no evidence				
Physician visits (n = 1):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term**	-	-	0 (0)	No evidence

• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term (52 wks)**	Mean physician visits (1)	0.53 [0.20, 0.85]	155 (1)	⨁⊖⊖⊖ Very low[6]
Referrals: no evidence				
Cost: no evidence				

[a]See legend on first page of Appendix 2.4 for non-abbreviated names of measurement tools. [b]Data are presented as standardized mean differences (SMD) and 95% confidence intervals (95% CI) unless otherwise indicated (negative SMD favors education materials). Risk ratios are indicated with RR^+ (RR > 1 favors education) and RR^- (RR < 1 favors education). [c]Quality of evidence was downgraded for risk of bias,[1] imprecision,[2] inconsistency,[3] indirectness,[4] publication bias,[5] or downgraded to very low if there was one study.[6] In this comparison, downgrades for imprecision and inconsistency followed our pre-defined cut-offs (Appendix 2.3) and do not require further interpretation. *Where evidence for disability and days off work were downgraded for indirectness, this was due to Linton *et al.,* 2000 (did not explicitly define their LBP population) and Cherkin *et al.,* 1998, (mixed LBP population: 72% acute, 28% chronic).

Education materials compared with no intervention (usual care) for chronic low back pain
P: adults aged 16+ with chronic low back pain (≥ 12 weeks duration)
I: education materials (typically provided during a single encounter with a physician or researcher in-person, via parcel, or over the internet)
C: no intervention or usual care

Outcome (# studies) Time points	Outcome measurement tools[a]	SMD[b] (95% CI) or RR[+,-] (95% CI)	Participants (# studies)	Quality of Evidence[c] (GRADE)
Knowledge: no evidence				
Self-Efficacy (n = 1):				
• **Immediate (6 wks)**	PSEQ (1)	-0.21 [-0.39, -0.03]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (13 wks)**	PSEQ (1)	-0.25 [-0.43, -0.06]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (26 wks)**	PSEQ (1)	-0.23 [-0.41, -0.05]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term (39 wks)**	PSEQ (1)	-0.32 [-0.50, -0.13]	461 (1)	⨁⊖⊖⊖ Very low[6]
Attitudes: no evidence				
General beliefs: no evidence				
Fear Avoidance (n = 2):				
• **Immediate (2-6 wks)**	FABQ (2)	-0.15 [-0.33, 0.02]	505 (2)	⨁⨁⨁⨁ High
• **Short-term (13 wks)**	FABQ (1)	-0.09 [-0.27, 0.09]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (26 wks)**	FABQ (1)	-0.24 [-0.43, -0.06]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term (39 wks)**	FABQ (1)	-0.16 [-0.34, 0.02]	461 (1)	⨁⊖⊖⊖ Very low[6]
Catastrophizing: no evidence				
Coping: no evidence				
Anxiety: no evidence				
Stress (n = 1):				
• **Immediate (6 wks)**	PSS (1)	-0.13 [-0.32, 0.05]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (13 wks)**	PSS (1)	-0.13 [-0.31, 0.06]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (26 wks)**	PSS (1)	-0.15 [-0.33, 0.03]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term (39 wks)**	PSS (1)	-0.21 [-0.39, -0.03]	461 (1)	⨁⊖⊖⊖ Very low[6]

Depression (n = 1):				
• **Immediate (6 wks)**	PHQ-8 (1)	-0.18 [-0.36, 0.01]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (13 wks)**	PHQ-8 (1)	-0.09 [-0.27, 0.09]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (26 wks)**	PHQ-8 (1)	-0.11 [-0.29, 0.07]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term (39 wks)**	PHQ-8 (1)	-0.15 [-0.33, 0.03]	461 (1)	⨁⊖⊖⊖ Very low[6]
Pain (n = 5):				
• **Immediate (2-6 wks)**	VAS (2), NRS (1), UTs (1)	-0.16 [-0.29, -0.03]	890 (4)	⨁⨁⨁⊖ Moderate[1]
• **Short-term (12-13 wks)**	VAS (2), NRS (1), UTs (1)	-0.44 [-0.88, 0.00]	925 (4)	⨁⨁⊖⊖ Low[1,3]
• **Medium-term (24-26 wks)**	VAS (2), NRS (1), UTs (1)	-0.53 [-1.01, -0.05]	907 (4)	⨁⨁⊖⊖ Low[1,3]
• **Long-term (39-52 wks)**	VAS (1), NRS (1)	-0.21 [-0.41, -0.01]	757 (2)	⨁⨁⨁⊖ Moderate[1]
Disability (n = 5):				
• **Immediate (2-6 wks)**	RMDQ (4)	-0.12 [-0.31, 0.07]	919 (4)	⨁⨁⨁⊖ Moderate[1]
• **Short-term (12-13 wks)**	RMDQ (3), QBPDS (1)	-0.23 [-0.48, 0.03]	964 (4)	⨁⨁⨁⊖ Moderate[1]
• **Medium-term (24-26 wks)**	RMDQ (3), QBPDS (1)	-0.32 [-0.61, -0.03]	939 (4)	⨁⨁⨁⊖ Moderate[1]
• **Long-term (39-52 wks)**	RMDQ (2)	-0.12 [-0.27, 0.02]	770 (2)	⨁⨁⨁⊖ Moderate[1]
Quality of Life (n = 4):				
• **Immediate (4-6 wks)**	AQoL-8D (1), SF-12 (1), EQ-5D (1)	-0.04 [-0.18, 0.09]	839 (3)	⨁⨁⨁⊖ Moderate[1]
• **Short-term (12-13 wks)**	AQoL-8D (1), SF-12 (1), SF-36 (1), EQ-5D (1)	-0.15 [-0.28, -0.03]	934 (4)	⨁⨁⨁⊖ Moderate[1]
• **Medium-term (24-26 wks)**	AQoL-8D (1), SF-12 (1), SF-36 (1), EQ-5D (1)	-0.23 [-0.41, -0.04]	902 (4)	⨁⨁⨁⊖ Moderate[1]
• **Long-term (39-52 wks)**	AQoL-8D (1), EQ-5D (1)	-0.13 [-0.28, 0.01]	748 (2)	⨁⨁⨁⊖ Moderate[1]
Global Improvement				
• **Immediate (6 wks)**	GPE (1)	-0.40 [-0.58, -0.21]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (13 wks)**	GPE (1)	-0.42 [-0.60, -0.24]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (26 wks)**	GPE (1)	-0.46 [-0.65, -0.28]	461 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term (39 wks)**	GPE (1)	-0.43 [-0.61, -0.24]	461 (1)	⨁⊖⊖⊖ Very low[6]
Function: no evidence				

Days off work: no evidence
Imaging: no evidence
Physician Visits: no evidence
Referrals: no evidence
Cost: no evidence

[a]See legend on first page of Appendix 2.4 for non-abbreviated names of measurement tools. [b]Data are presented as standardized mean differences (SMD) and 95% confidence intervals (95% CI) unless otherwise indicated (negative SMD favors education materials). Risk ratios are indicated with RR^{+} (RR > 1 favors education) and RR^{-} (RR < 1 favors education). [c]Quality of evidence was downgraded for risk of bias,[1] imprecision,[2] inconsistency,[3] indirectness,[4] publication bias,[5] or downgraded to very low if there was one study.[6] In this comparison, all downgrade decisions followed our pre-defined cut-offs (Appendix 2.3) and do not require further interpretation.

Education materials compared with another intervention for chronic low back pain
P: adults aged 16+ with chronic low back pain (≥ 12 weeks duration)
I: education materials (typically provided during a single encounter with a physician or researcher in-person, via parcel, or over the internet)
C: any non-conservative intervention (e.g., yoga, massage, exercise, cognitive behavioural therapy, etc.)

Outcome (# studies) Time points	Outcome measurement tools[a]	SMD[b] (95% CI) or RR[+,-] (95% CI)	Participants (# studies)	Quality of Evidence[c] (GRADE)
Knowledge: no evidence				
Self-Efficacy (n = 1):				
• **Immediate-term (4 wks)**	PSEQ (1)	0.05 [-0.23, 0.33]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (12 wks)**	PSEQ (1)	0.06 [-0.22, 0.34]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (24 wks)**	PSEQ (1)	0.04 [-0.24, 0.32]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term**	-	-	0 (0)	No evidence
Attitudes: no evidence				
General beliefs: no evidence				
Fear-Avoidance (n = 1):				
• **Immediate-term (4 wks)**	FABQ (1)	0.13 [-0.15, 0.41]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (12 wks)**	FABQ (1)	0.08 [-0.20, 0.36]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (24 wks)**	FABQ (1)	0.00 [-0.28, 0.28]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term**	-	-	0 (0)	No evidence
Catastrophizing (n = 1)				
• **Immediate-term (4 wks)**	PCS (1)	0.50 [0.21, 0.78]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (12 wks)**	PCS (1)	0.42 [0.14, 0.70]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (24 wks)**	PCS (1)	0.44 [0.15, 0.72]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term**	-	-	0 (0)	No evidence
Coping (n = 1):				
• **Immediate-term (4 wks)**	CPCI-42 (1)	0.13 [-0.14, 0.41]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (12 wks)**	CPCI-42 (1)	0.22 [-0.05, 0.50]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (24 wks)**	CPCI-42 (1)	0.17 [-0.10, 0.45]	199 (1)	⨁⊖⊖⊖ Very low[6]

• **Long-term**	-	-	0 (0)	No evidence
Anxiety (n = 2):				
• **Immediate-term (4 wks)**	DASS-21 (1)	0.07 [-0.20, 0.35]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (9-12 wks)**	DASS-21 (1), SAS (1)	0.65 [-0.58, 1.87]	229 (2)	⨁⨁⊖⊖ Low[2,3]
• **Medium-term (24 wks)**	DASS-21 (1)	0.13 [-0.15, 0.40]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term**	-	-	0 (0)	No evidence
Stress (n = 1):				
• **Immediate-term (4 wks)**	DASS-21 (1)	0.17 [-0.10, 0.45]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (12 wks)**	DASS-21 (1)	0.31 [0.03, 0.59]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term (24 wks)**	DASS-21 (1)	0.26 [-0.02, 0.54]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term**	-	-	0 (0)	No evidence
Depression				
• **Immediate-term (4 wks)**	DASS-21 (1)	0.03 [-0.25, 0.31]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Short-term (9-12 wks)**	DASS-21 (1), SDS (1)	0.79 [-0.56, 2.14]	229 (2)	⨁⨁⊖⊖ Low[2,3]
• **Medium-term (24 wks)**	DASS-21 (1)	0.18 [-0.10, 0.46]	199 (1)	⨁⊖⊖⊖ Very low[6]
• **Long-term**	-	-	0 (0)	No evidence
Pain (n = 10):				
• **Immediate-term (4-8 wks)**	SBS (3), VAS (1), NRS (1), BPI (1), PPQ (1), UTs (1)	0.30 [0.03, 0.56]	732 (8)	⨁⨁⨁⨁ High
• **Short-term (9-12 wks)**	NRS (3), SBS (2), BPI (1), UTs (1)	0.54 [0.20, 0.88]	815 (7)	⨁⨁⨁⨁ High*
• **Medium-term (24-26 wks)**	SBS (2), BPI (1), UTs (1)	0.22 [-0.25, 0.69]	450 (4)	⨁⨁⨁⊖ Moderate[3]
• **Long-term (52 wks)**	SBS (1)	0.18 [-0.12, 0.48]	168 (1)	⨁⊖⊖⊖ Very low[6]
Disability (n = 9):				
• **Immediate-term (4-8 wks)**	RMDQ (6), ODI (1)	0.47 [0.12, 0.83]	714 (7)	⨁⨁⨁⨁ High*
• **Short-term (9-12 wks)**	RMDQ (6), ODI (2)	0.64 [0.25, 1.02]	881 (8)	⨁⨁⨁⨁ High*
• **Medium-term (24-26 wks)**	RMDQ (3), ODI (1)	0.29 [-0.09, 0.67]	450 (4)	⨁⨁⨁⨁ High

• **Long-term (52 wks)**	RMDQ (1)	-0.07 [-0.37, 0.23]	168 (1)	⊕⊖⊖⊖ Very low[6]
Quality of Life (n = 5):				
• **Immediate-term (4-8 wks)**	SF-36 (3), SF-12 (1)	1.25 [0.14, 2.36] Two studies did not provide usable data but found no difference between groups	62 (2) 221 (2)	⊕⊕⊖⊖ Low[1,2]
• **Short-term (10-12 wks)**	SF-36 (3), SF-12 (1)	1.01 [-0.99, 3.01] Two studies did not provide usable data but found (i) no difference between groups or (ii) education to be less effective than other interventions	228 (2) i. 66 (1) ii. 168 (1)	⊕⊕⊖⊖ Low[2,3]
• **Medium-term (26 wks)**	SF-36 (1)	One study did not provide usable data but found no difference between groups	63 (1)	⊕⊖⊖⊖ Very low[6]
• **Long-term (52 wks)**	SF-12 (1)	One study did not provide usable data but found no difference between groups	159 (1)	⊕⊖⊖⊖ Very low[6]
Global Improvement (n = 3):				
• **Immediate-term (4-6 wks)**	PGIC (1), UTs (1)	0.53 [0.21, 0.84]	327 (2)	⊕⊕⊕⊖ Moderate[2]
• **Short-term (12 wks)**	PGIC (1), UTs (2)	0.60 [0.16, 1.04]	509 (3)	⊕⊕⊕⊕ High
• **Medium-term (24-26 wks)**	PGIC (1), UTs (1)	0.55 [0.19, 0.91]	327 (2)	⊕⊕⊕⊖ Moderate[2]
• **Long-term**	-	-	0 (0)	No evidence
Function (n = 1):				
• **Immediate-term (8 wks)**	6-min walk test Sit-to-stand test Sit-and-reach test	1.34 [0.32, 2.36] 1.26 [0.18, 2.34] 0.95 [-0.02, 1.91]	19 (1) 17 (1) 19 (1)	⊕⊖⊖⊖ Very low[6] ⊕⊖⊖⊖ Very low[6] ⊕⊖⊖⊖ Very low[6]
• **Short-term**	-	-	0 (0)	No evidence
• **Medium-term**	-	-	0 (0)	No evidence

• **Long-term**	-	-	0 (0)	No evidence
Days off work (n = 1):				
• **Immediate-term**	-	-	0 (0)	No evidence
• **Short-term (10 wks)**	% with days off work (1)	One study did not provide usable data but found no difference between groups	168 (1)	⨁⊖⊖⊖ Very low[6]
• **Medium-term**	-	-	0 (0)	No evidence
• **Long-term**	-	-	0 (0)	No evidence
Imaging: no evidence				
Physician visits: no evidence				
Referrals: no evidence				
Cost: no evidence				

[a]See legend on first page of Appendix 2.4 for non-abbreviated names of measurement tools. [b]Data are presented as standardized mean differences (SMD) and 95% confidence intervals (95% CI) unless otherwise indicated (negative SMD favors education materials). Risk ratios are indicated with RR^+ (RR > 1 favors education) and RR^- (RR < 1 favors education). [c]Quality of evidence was downgraded for risk of bias,[1] imprecision,[2] inconsistency,[3] indirectness,[4] publication bias,[5] or downgraded to very low if there was one study.[6] In this comparison, downgrades for risk of bias and imprecision followed our pre-defined cut-offs (Appendix 2.3) and do not require further interpretation, and there were no downgrades for indirectness. *Due to the nature of our question (i.e., pooling the data from studies with widely varying comparator interventions), we expected considerable heterogeneity in this comparison. Therefore, if $I^2 > 75\%$, we first sought to determine if the heterogeneity could be explained before downgrading the quality of evidence for inconsistency. Heterogeneity was high for short-term pain ($I^2 = 80\%$), and immediate ($I^2 = 79\%$) and short-term disability ($I^2 = 85\%$). However, we did not downgrade for inconsistency because comparator interventions varied substantially in these comparisons, and one noticeable outlier study had a consistently larger effect in favor of the comparator intervention throughout all three of these analyses. It was a small study (n = 42) with a much higher intensity comparator intervention than all other studies (i.e., proprioceptive neuromuscular facilitation 5x/week compared to most other comparator interventions provided 1x/week). Thus, we did not downgrade for inconsistency for these comparisons because the higher intensity explains the stronger effect, the study was small and contributed little weight to the pooled estimate, and the direction of effect was the same throughout all studies in all three comparisons, so the presence or absence of this outlier is unlikely to change the result. All other comparisons with $I^2 > 75\%$ were downgraded for inconsistency.

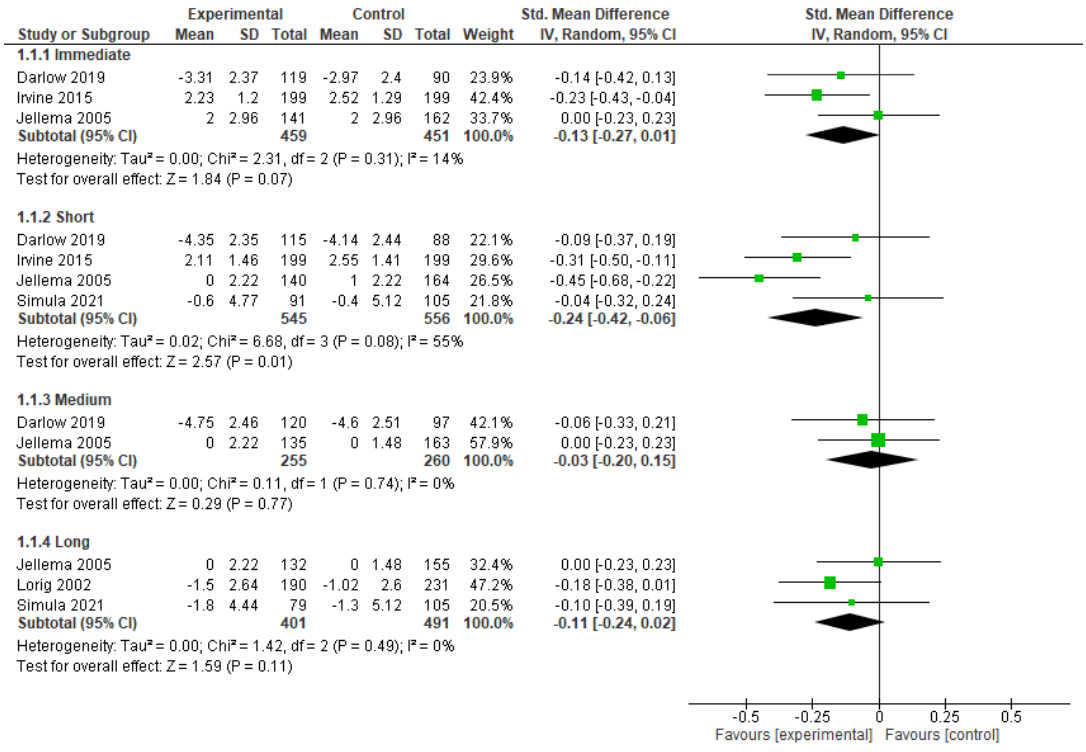
Appendix 2.5. Forest plots for all outcomes and comparisons

**In all forest plots, the experimental group refers to patient education materials and the control group refers to the comparator (i.e., usual care or other interventions depending on the comparison).*

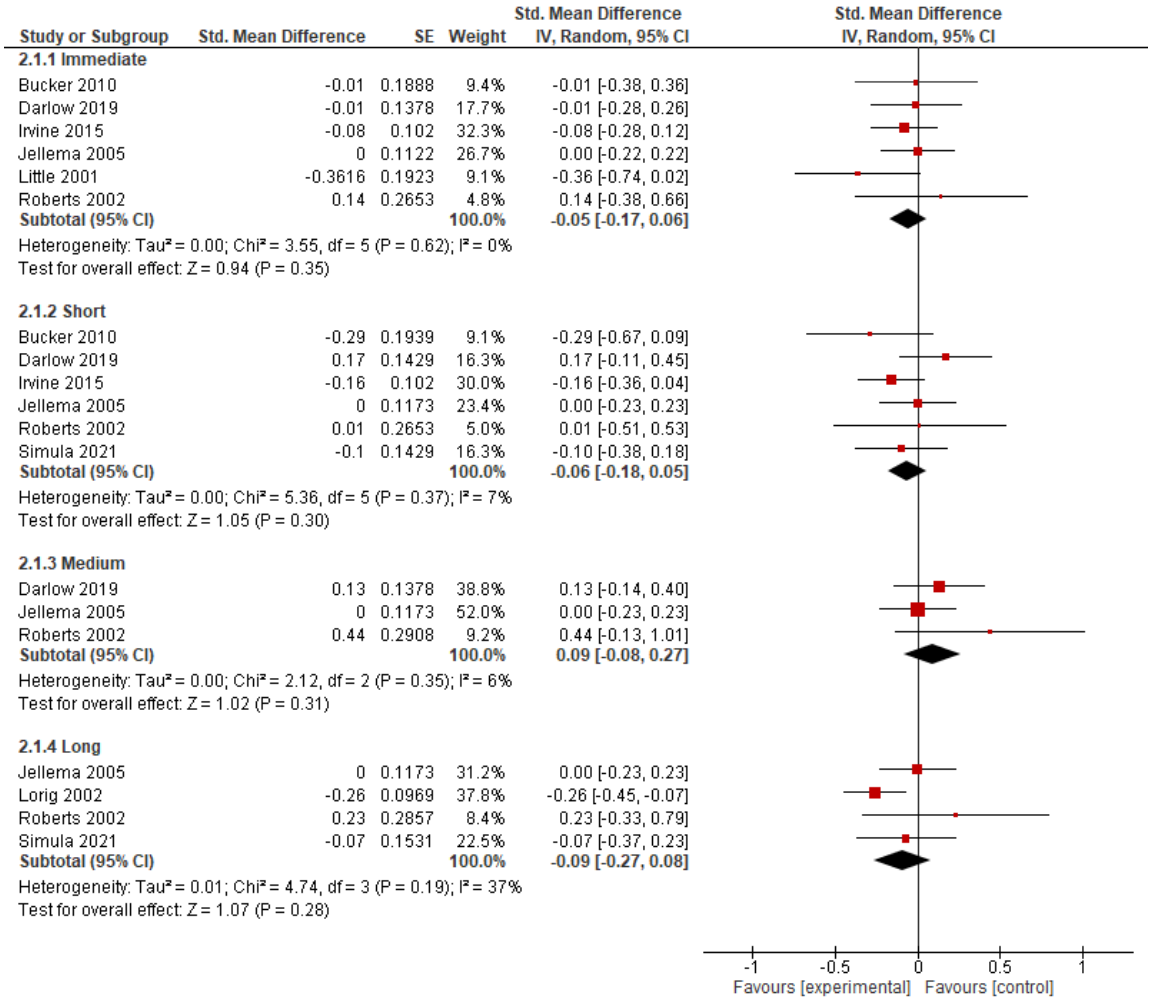
Acute/subacute LBP

Patient education materials alone vs. no intervention or usual care for acute/subacute LBP

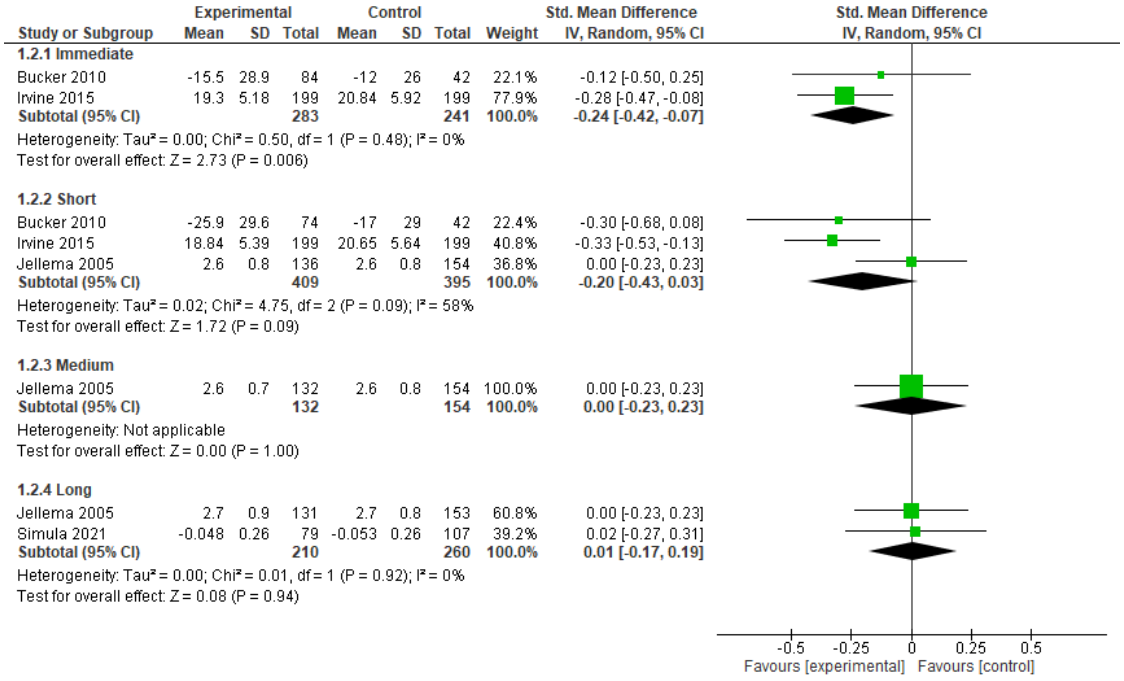
Pain Intensity (n=5)



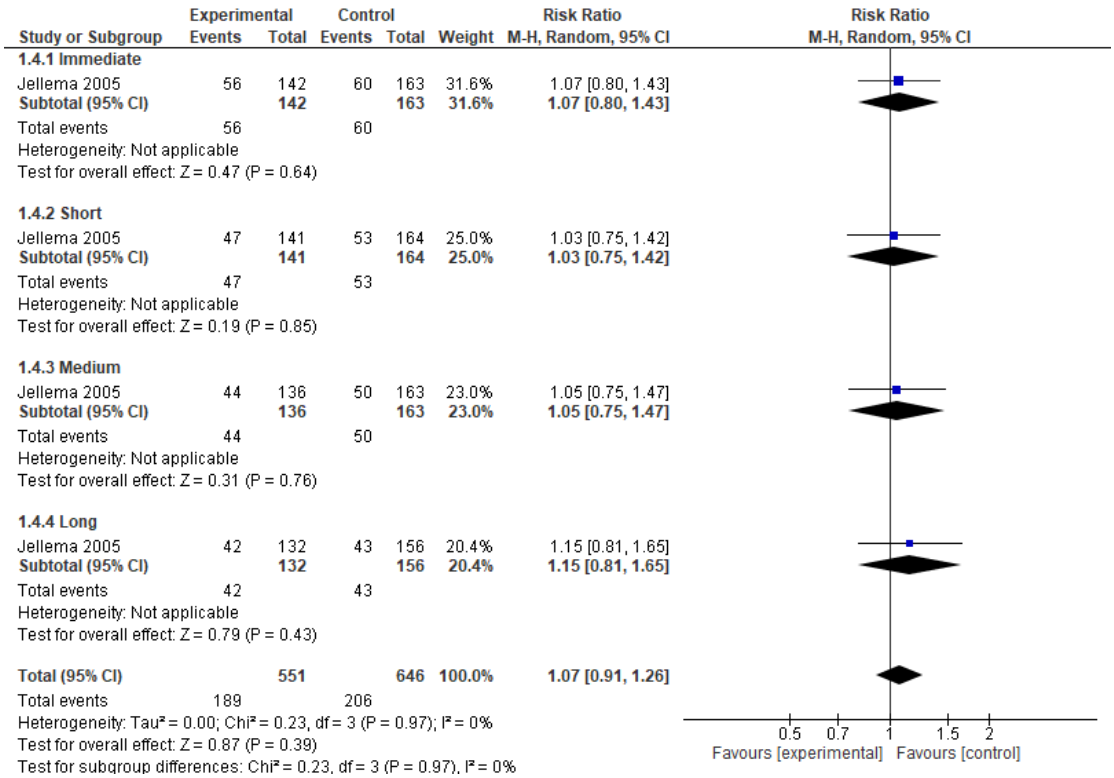
Disability (n=8)



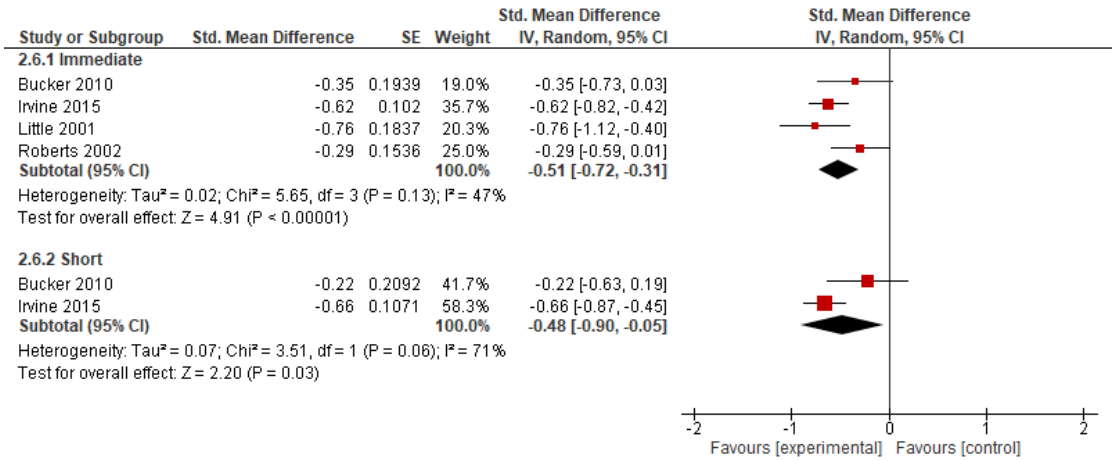
Quality of Life (n=4)

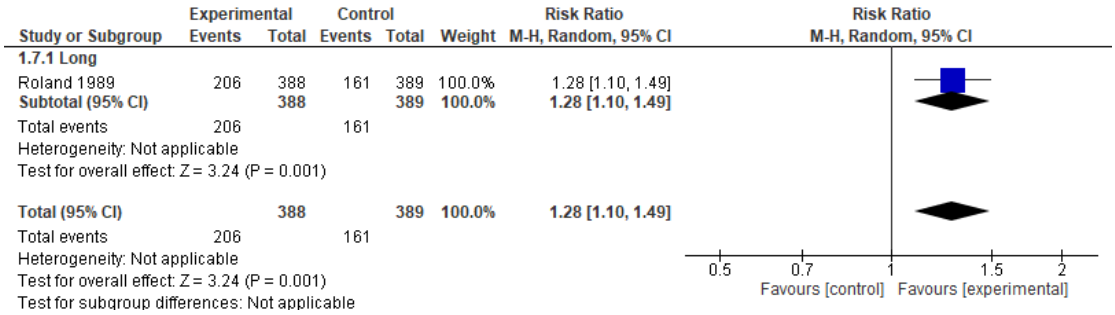


Global Improvement (n=1; RR < 1 favors education)

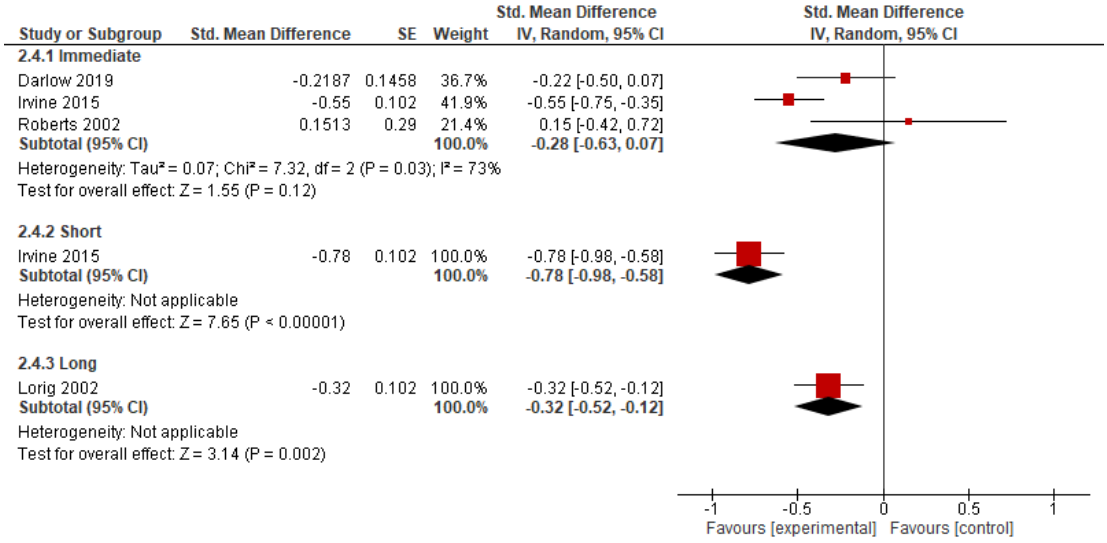


Knowledge (n=5; RR > 1 favors education in the long-term analysis)

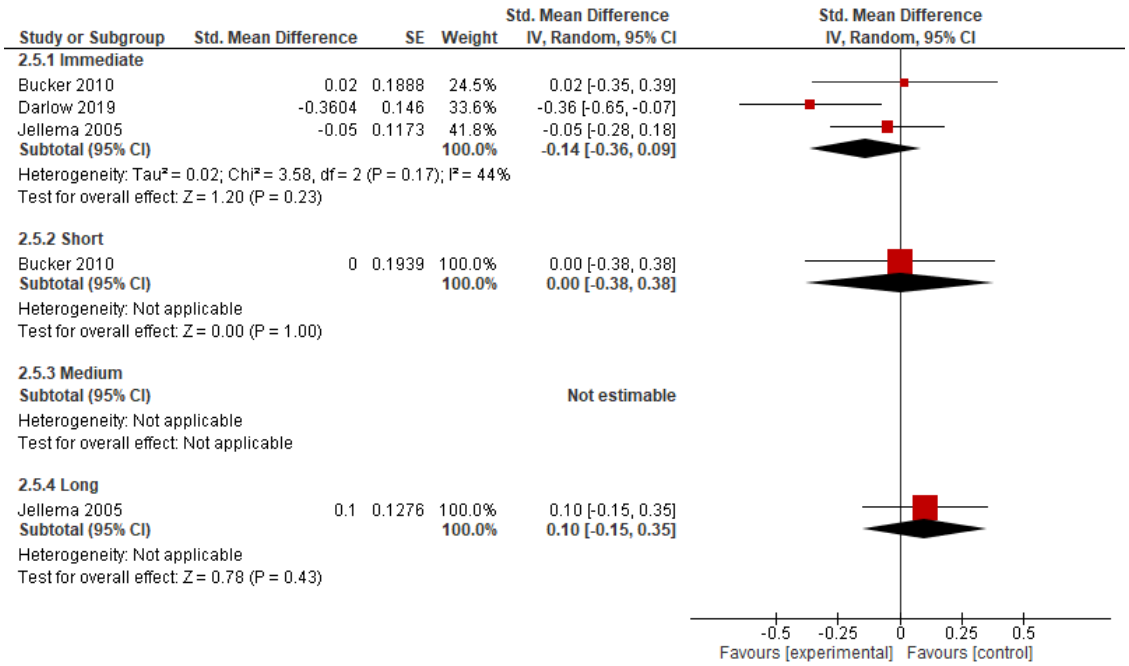




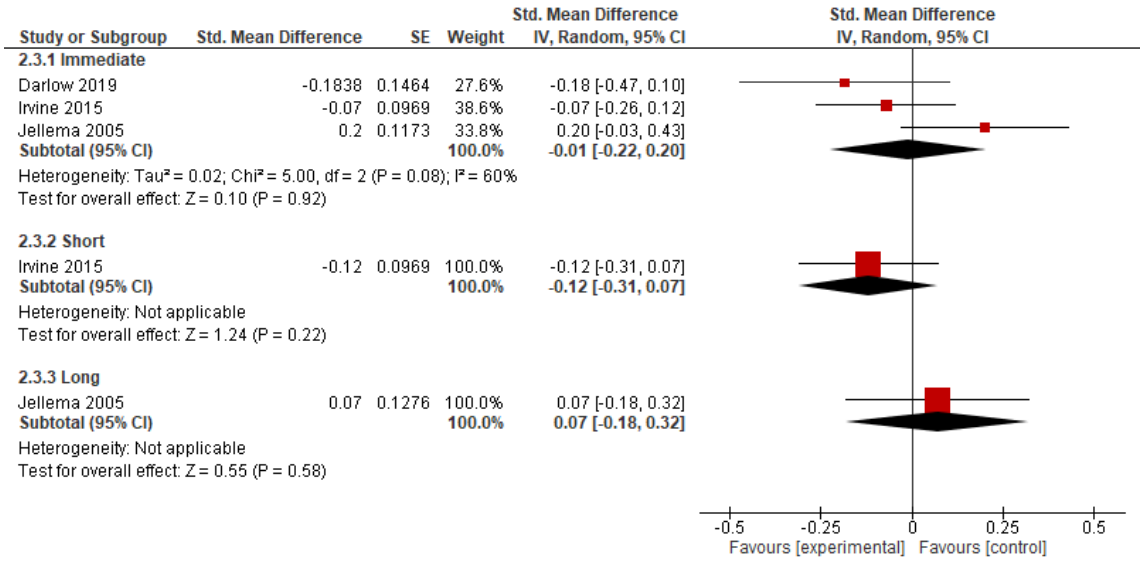
Pain Self-Efficacy (n=4)



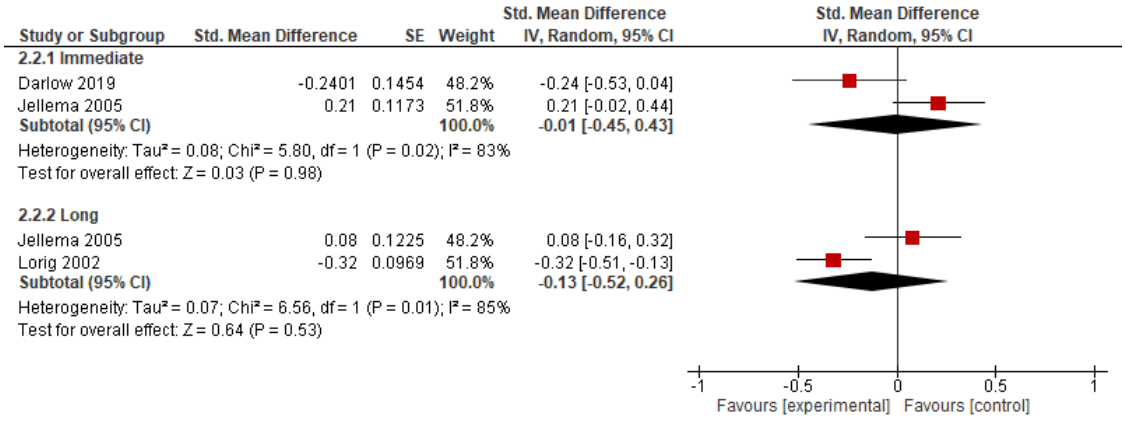
Fear-Avoidance Beliefs (n=3)



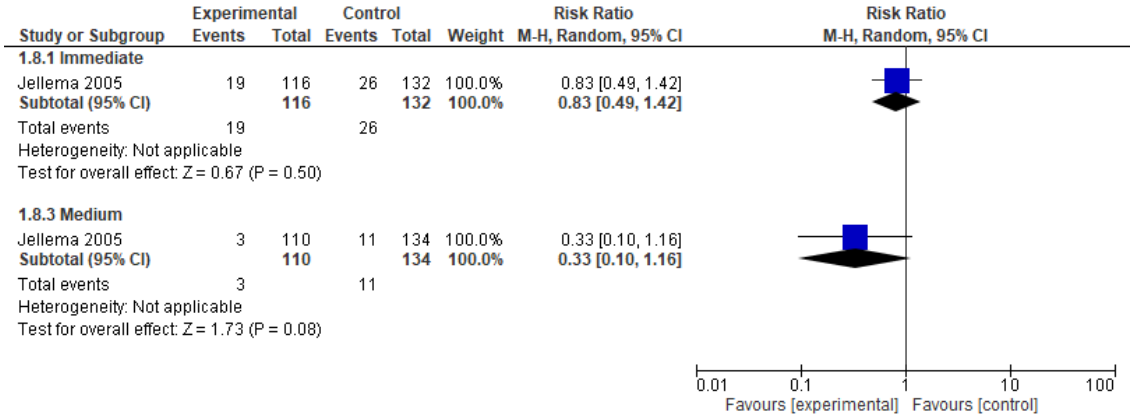
Catastrophizing (n=3)

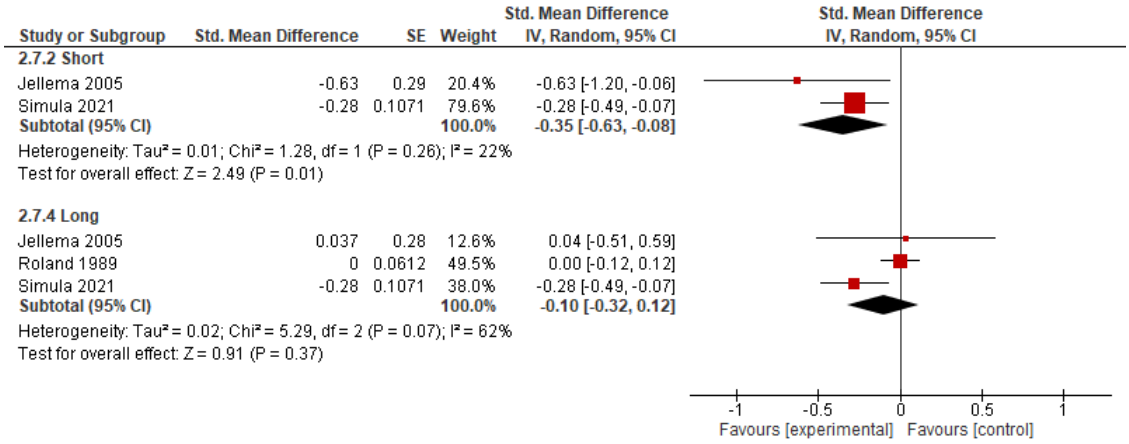


Anxiety (n=3)

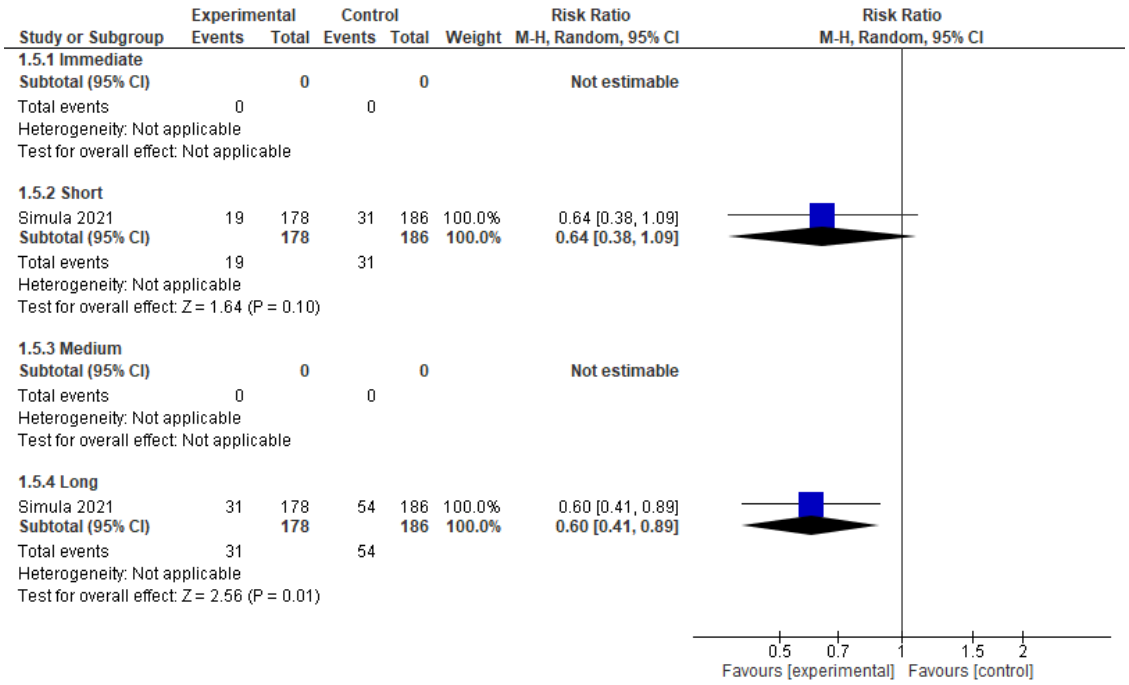


Days off Work (n=3; RR < 1 favors education for the immediate and medium-term analyses)

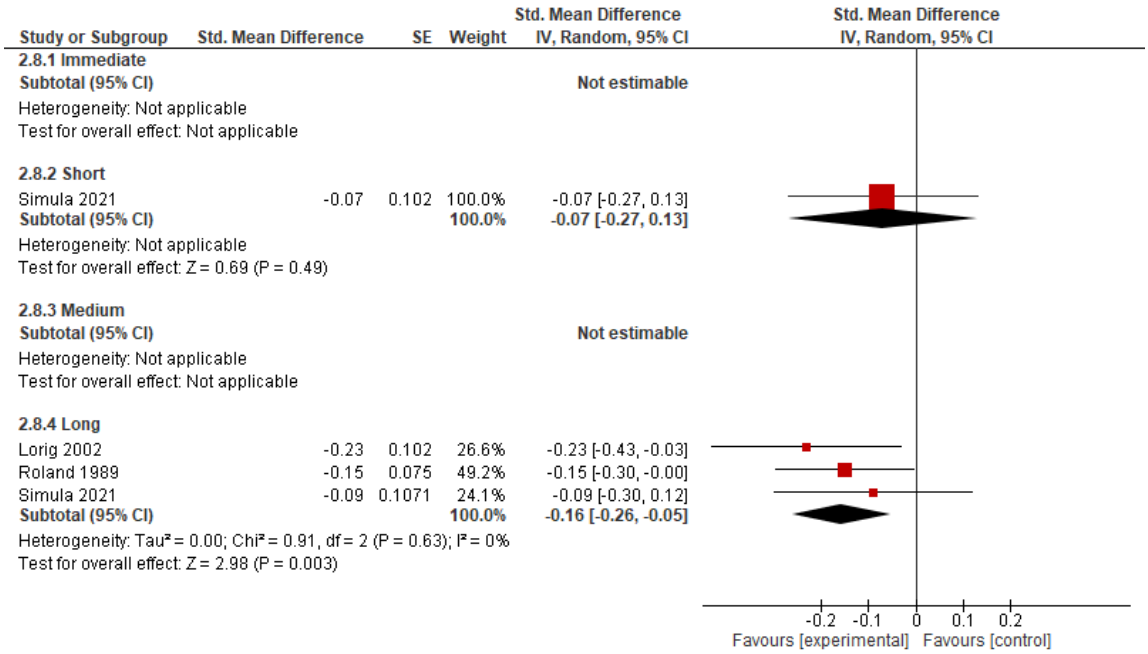




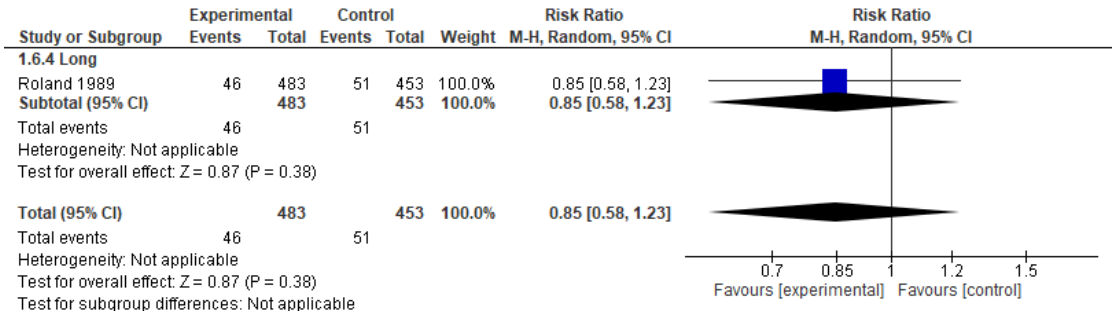
Imaging (n=1; RR < 1 favors education)



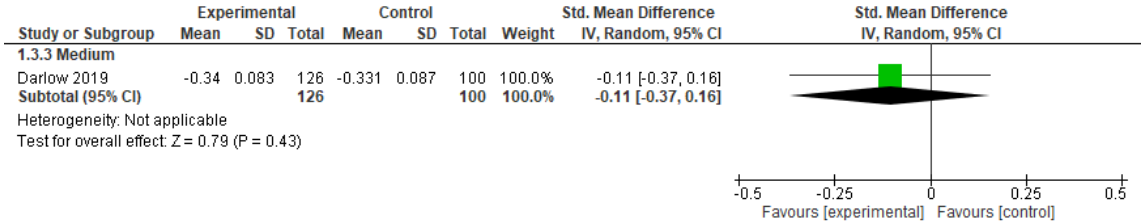
Physician visits (n=3)



Referrals (n=1)

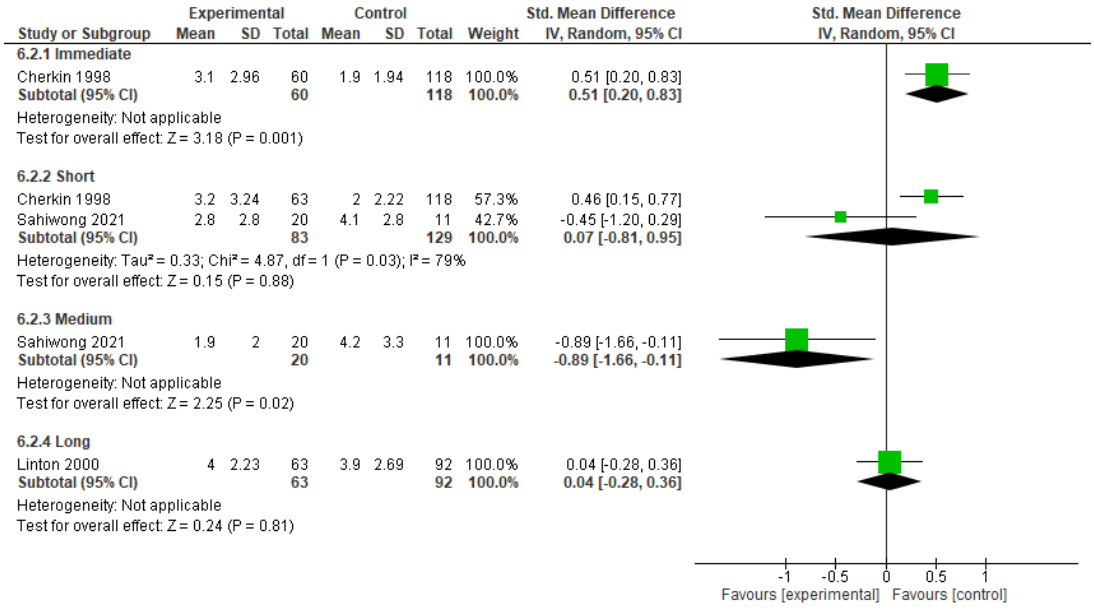


Cost (n=1)

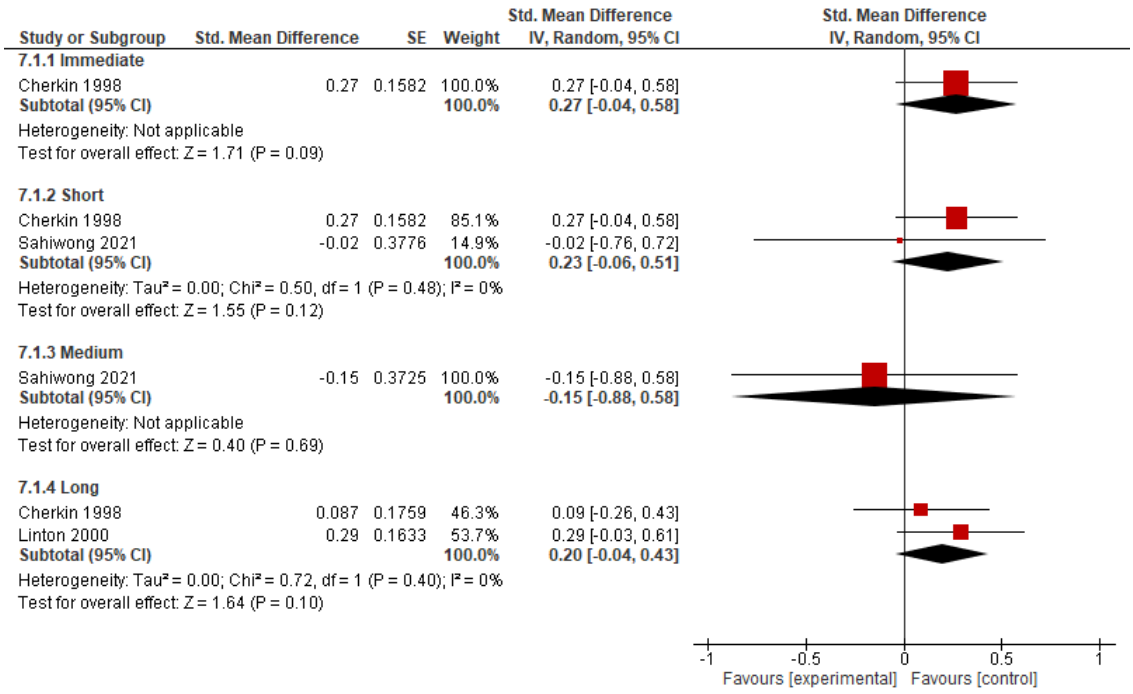


Patient education materials alone vs. other interventions for acute/subacute LBP

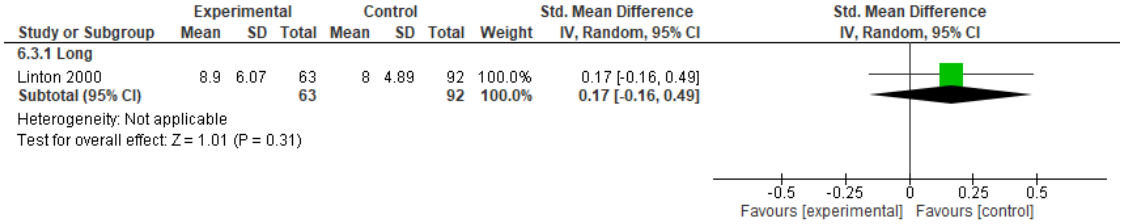
Pain Intensity (n=3)



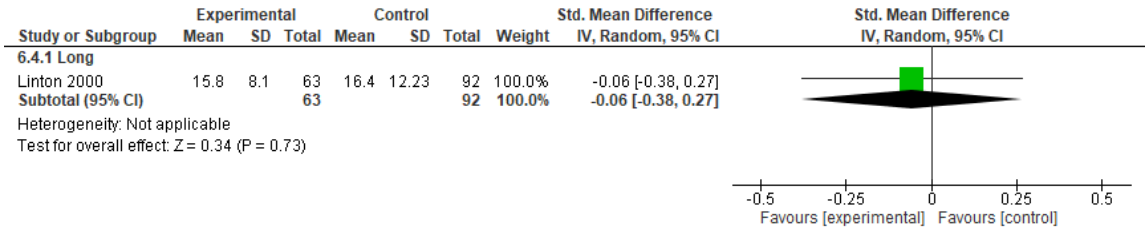
Disability (n=3)



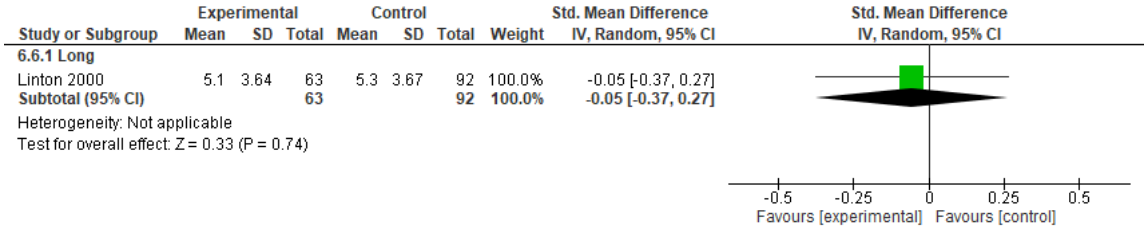
Fear-Avoidance Beliefs (n=1)



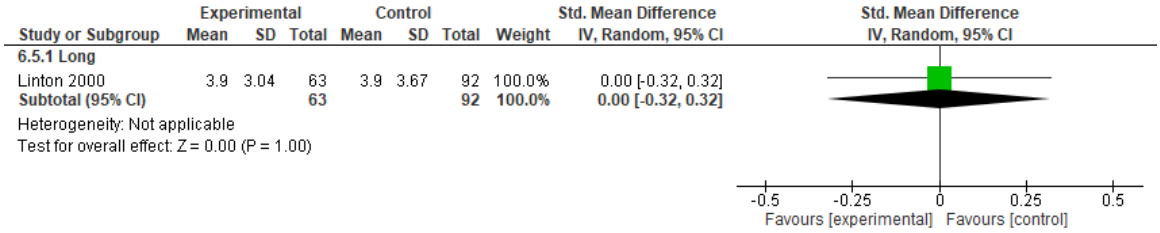
Catastrophizing (n=1)



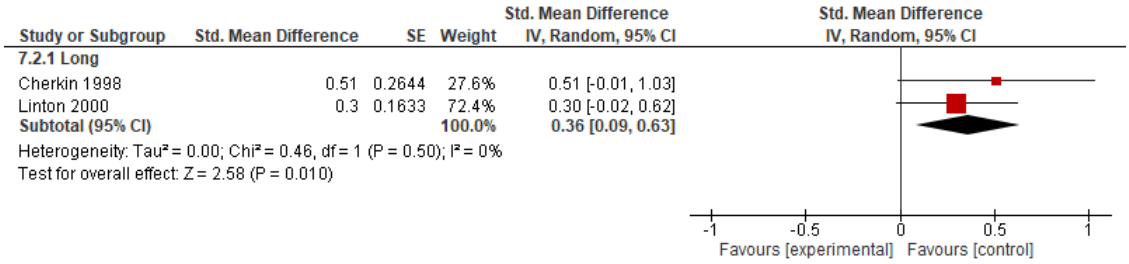
Anxiety (n=1)



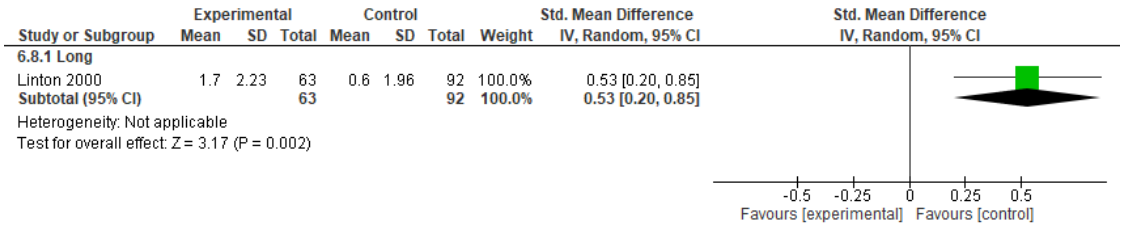
Depression (n=1)



Days off Work (n=2)



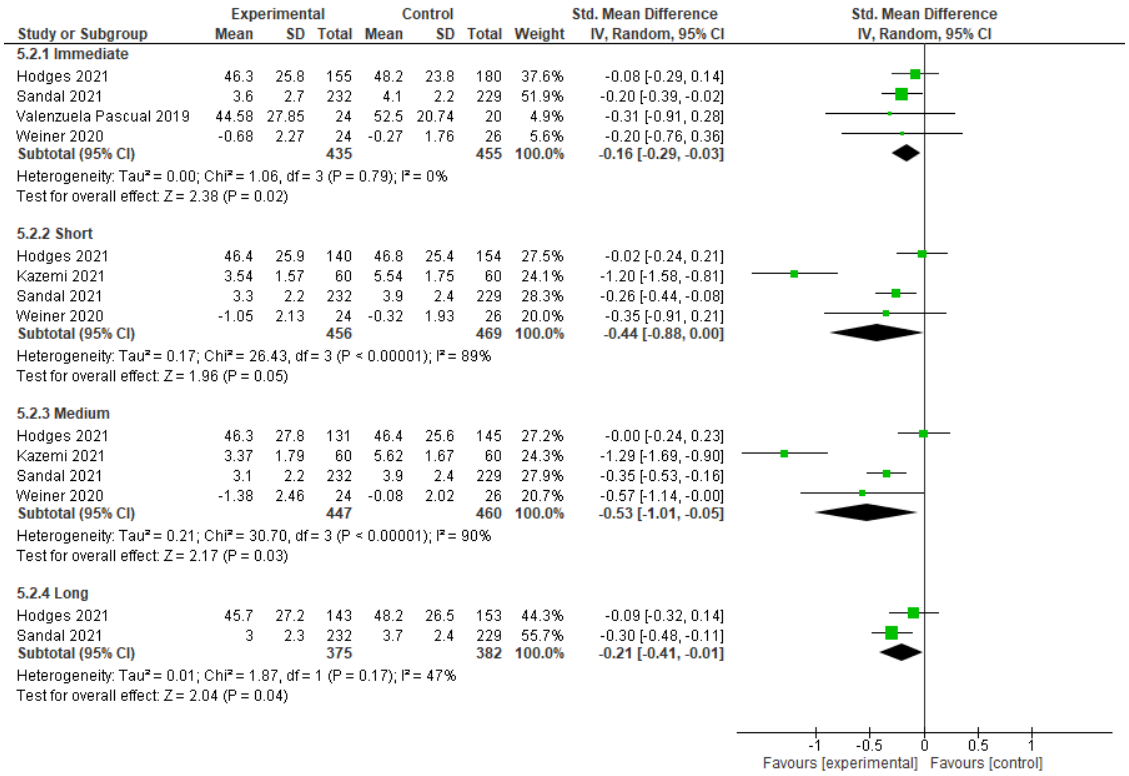
Physician Visits (n=1)



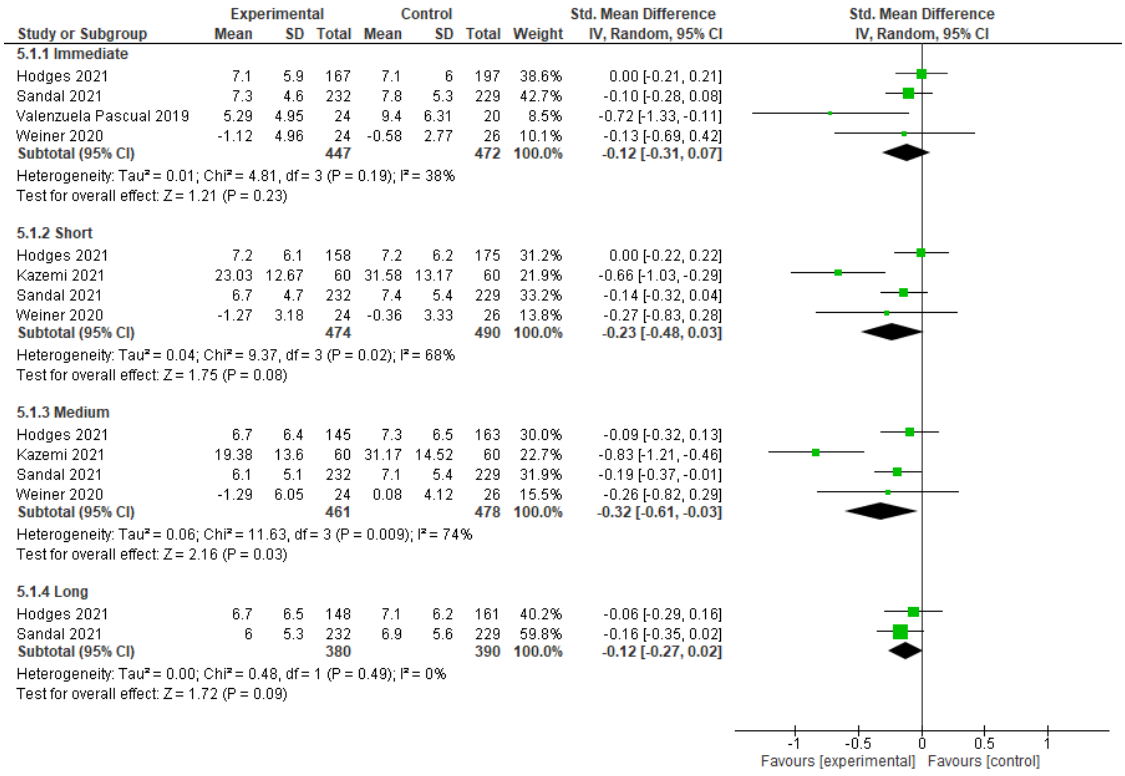
Chronic LBP

Patient education materials alone vs. no intervention or usual care for chronic LBP

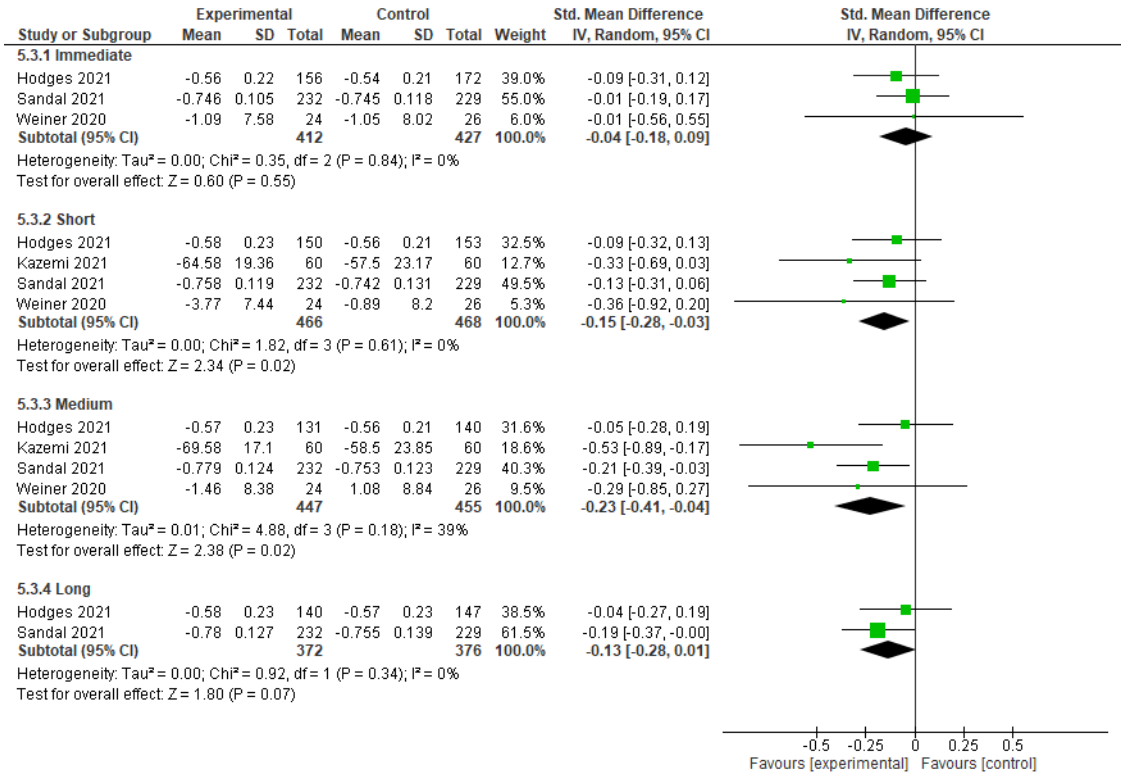
Pain Intensity (n=5)



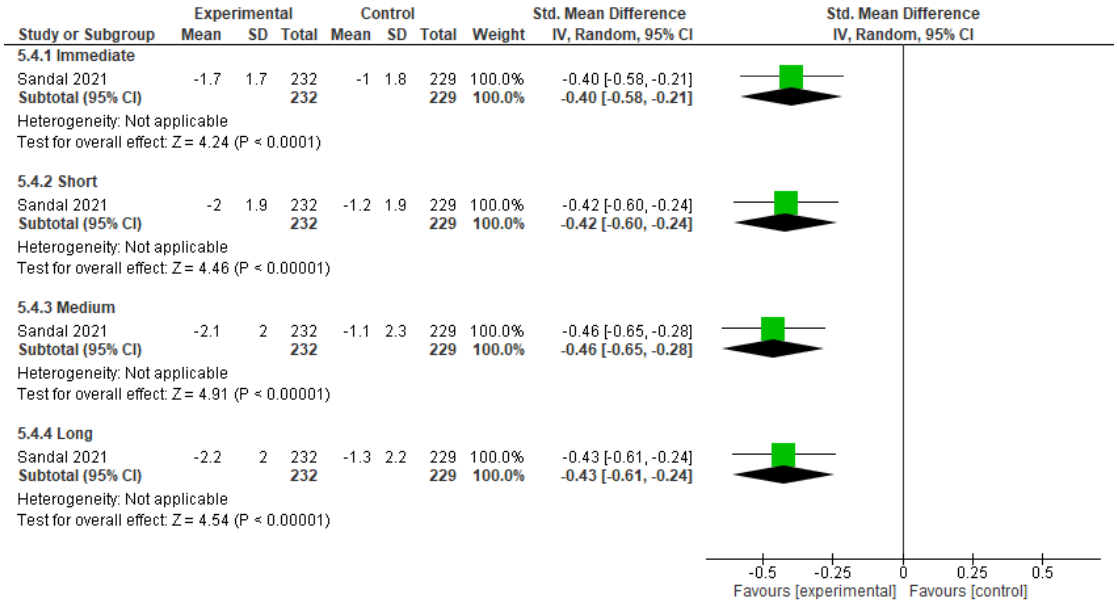
Disability (n=5)



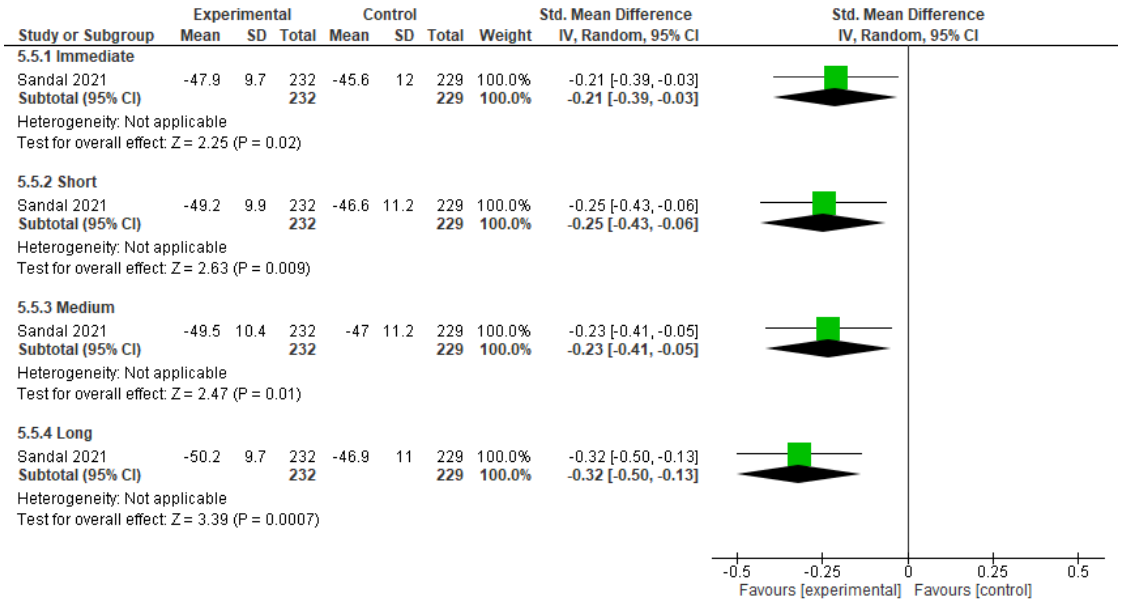
Quality of Life (n=4)



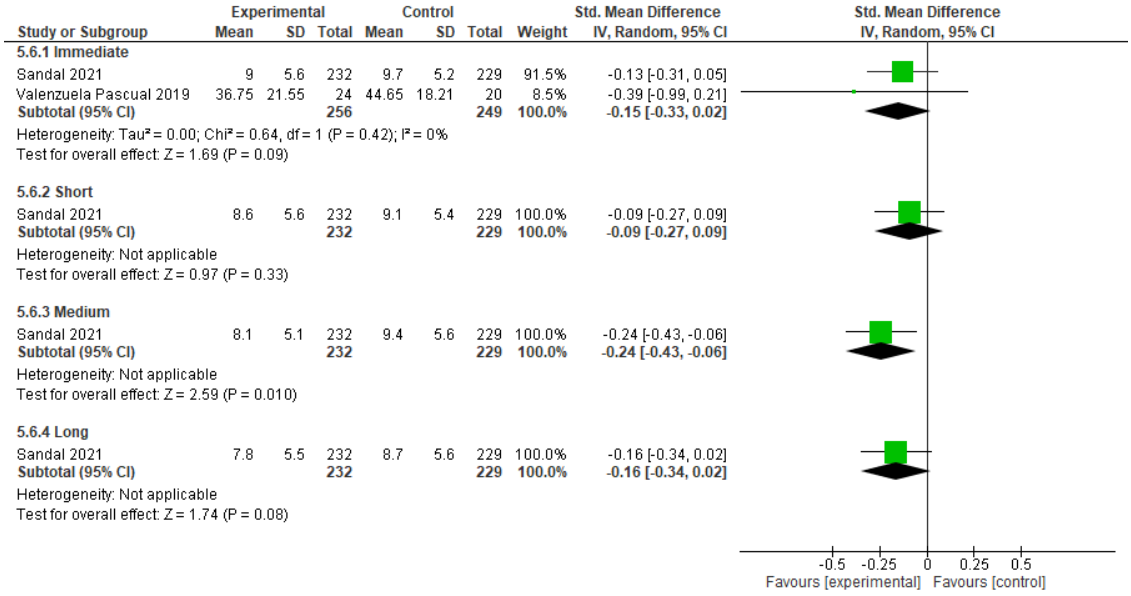
Global Improvement (n=1)



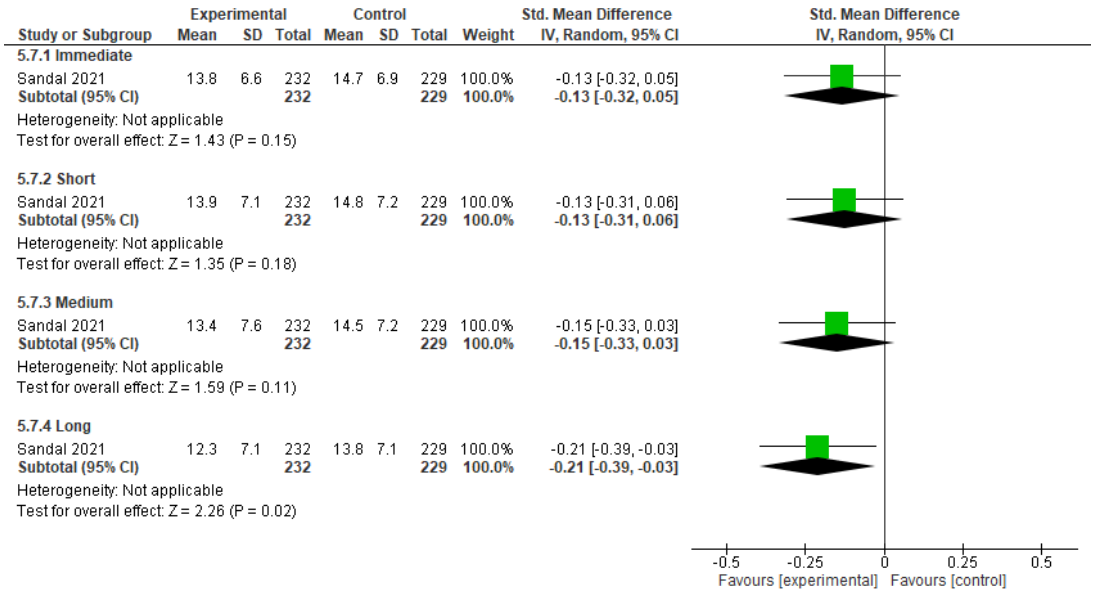
Self-efficacy (n=1)



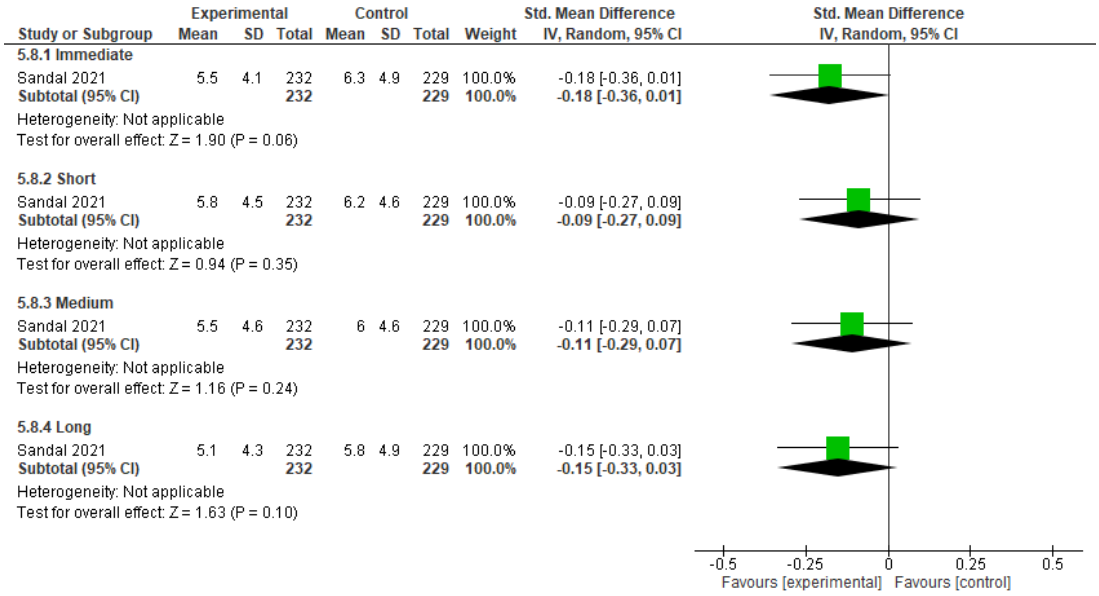
Fear-Avoidance Beliefs (n=2)



Stress (n=1)

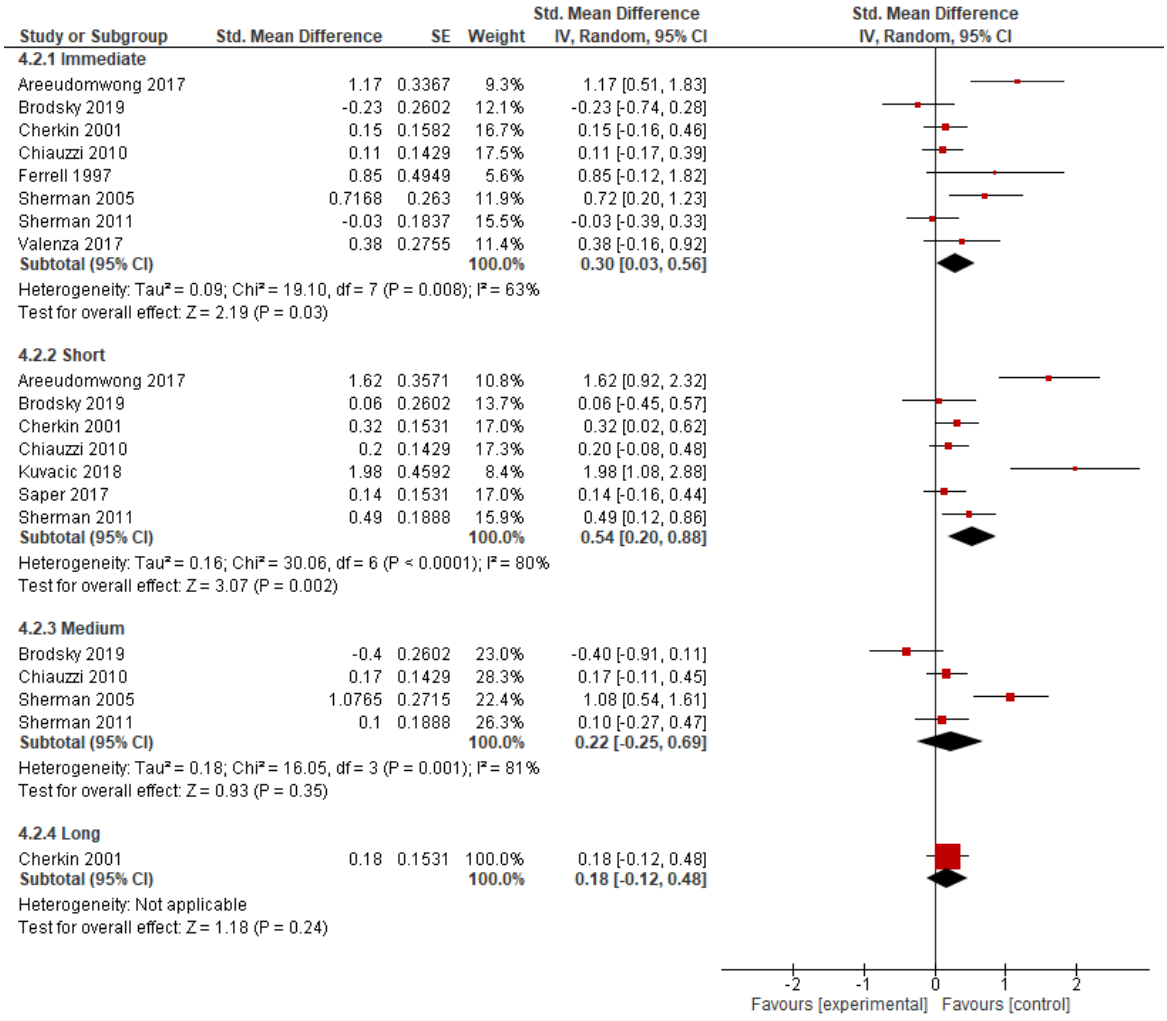


Depression (n=1)

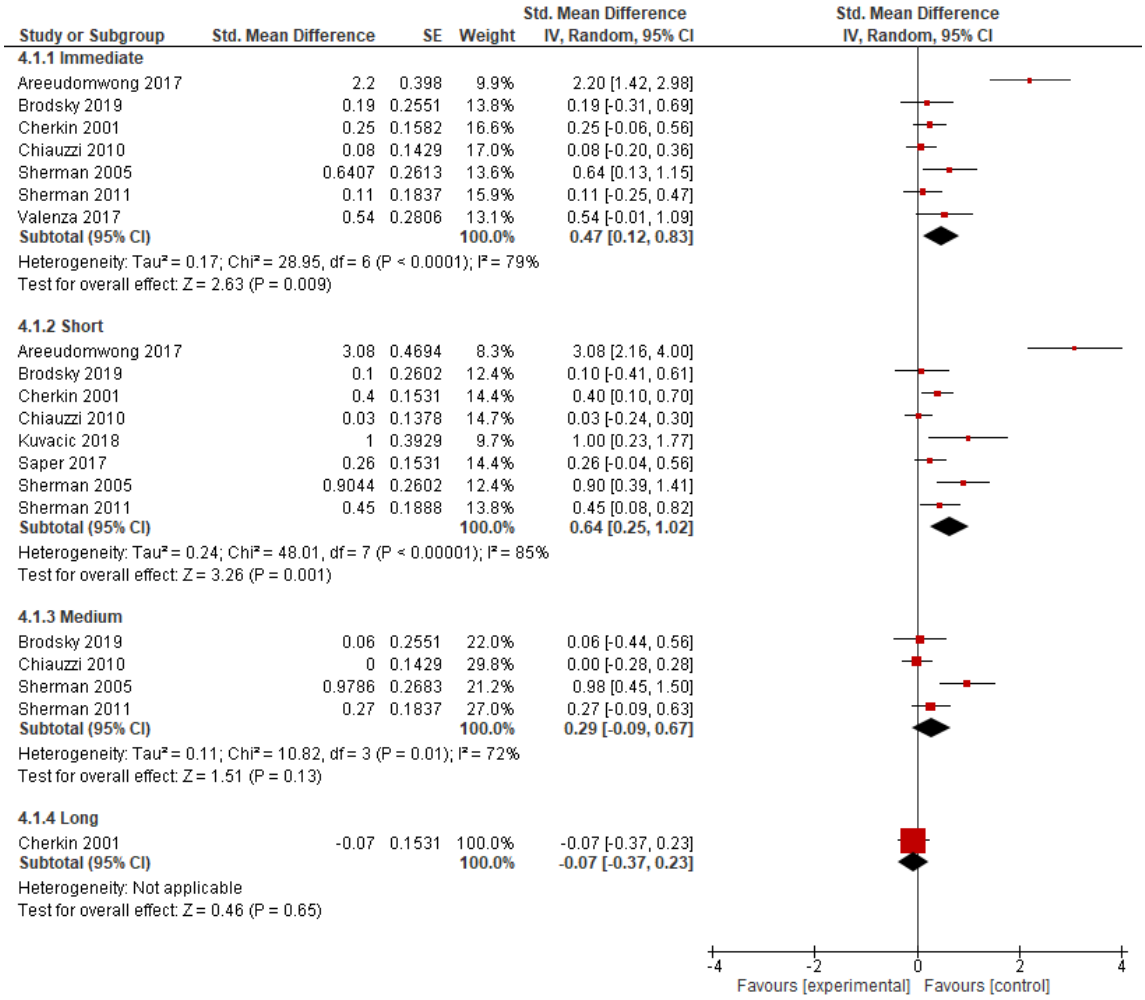


Patient education materials alone vs. other interventions for chronic LBP

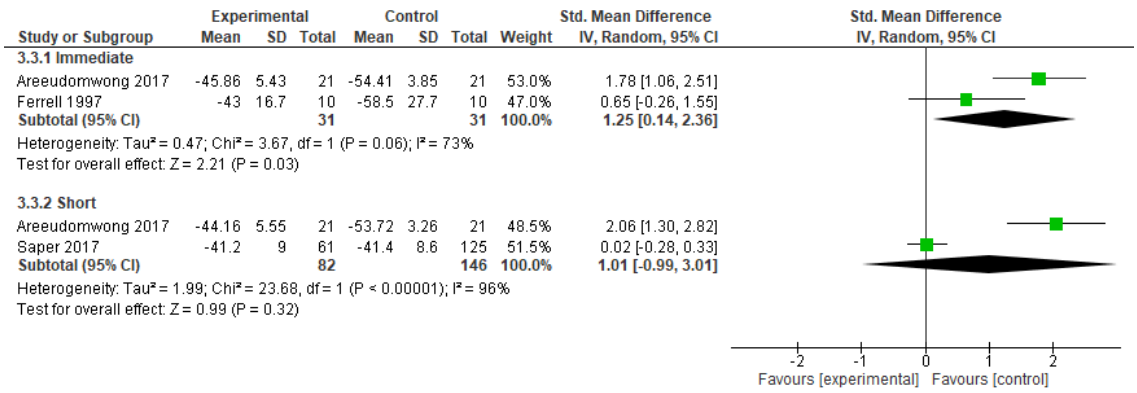
Pain Intensity (n=10)



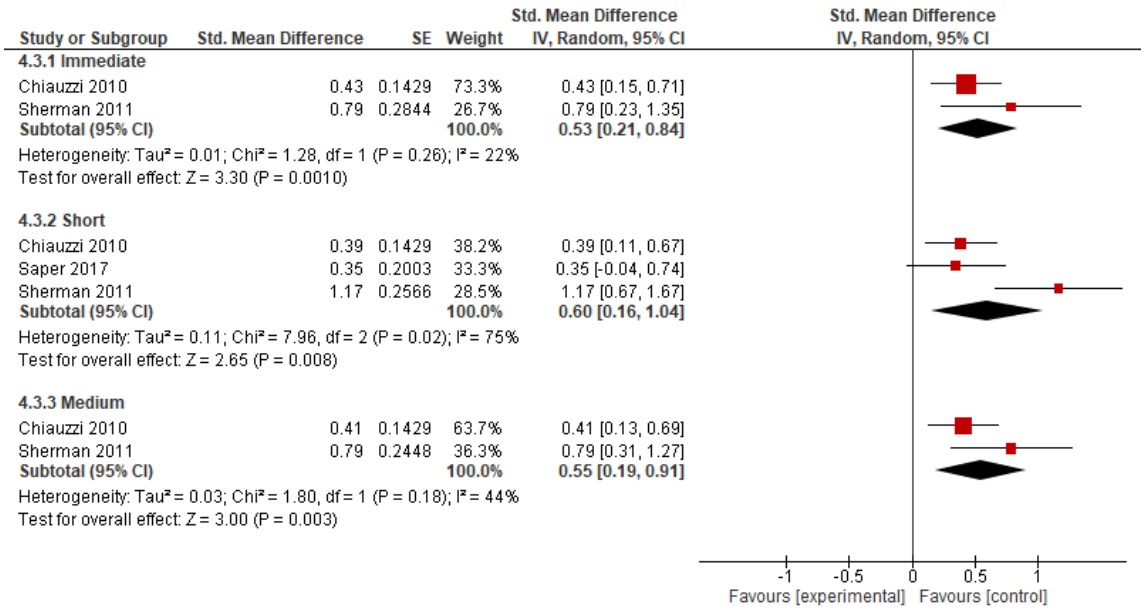
Disability (n=9)



Quality of Life (n=5, however, two studies did not provide usable data and were narratively synthesized)

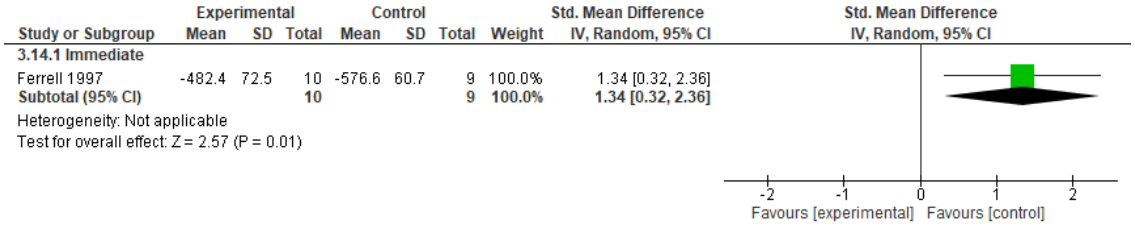


Global Improvement (n=3)

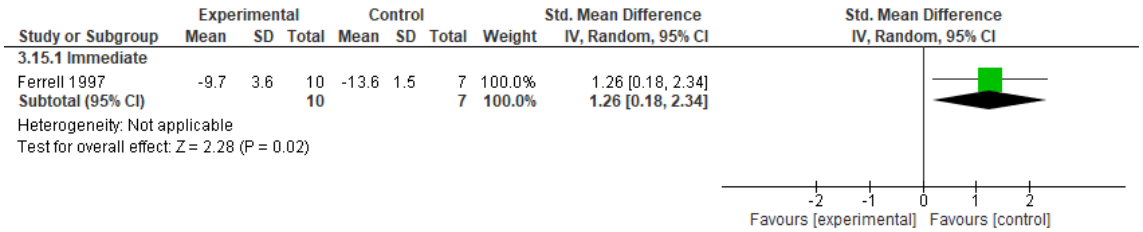


Function (n=1)

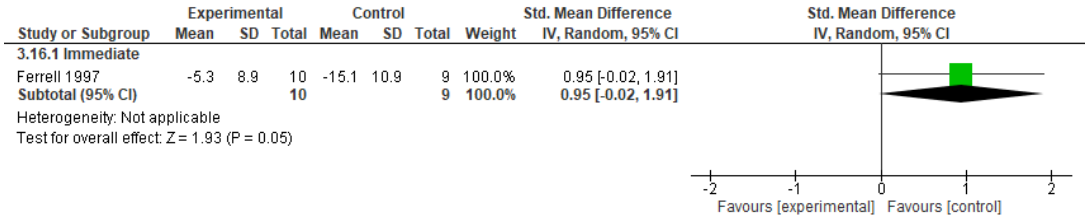
i. 6-min. walk:



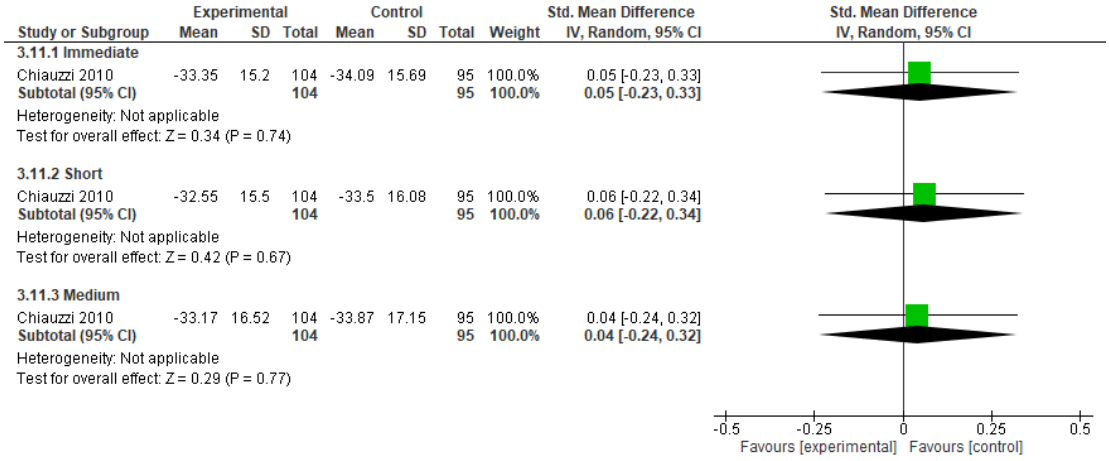
ii. Sit-to-stand:



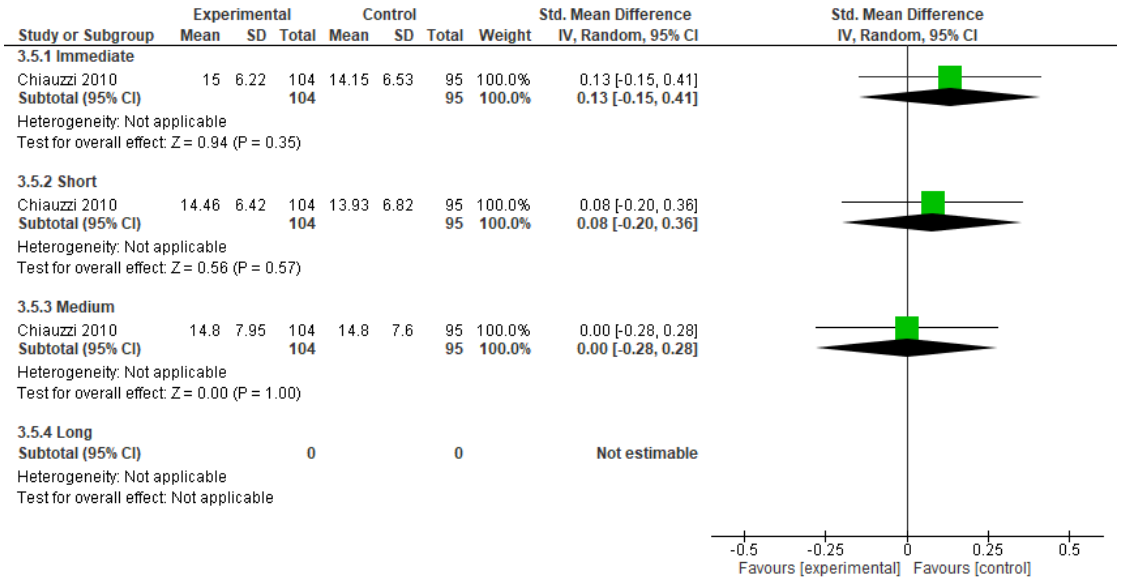
iii. Sit-and-reach:



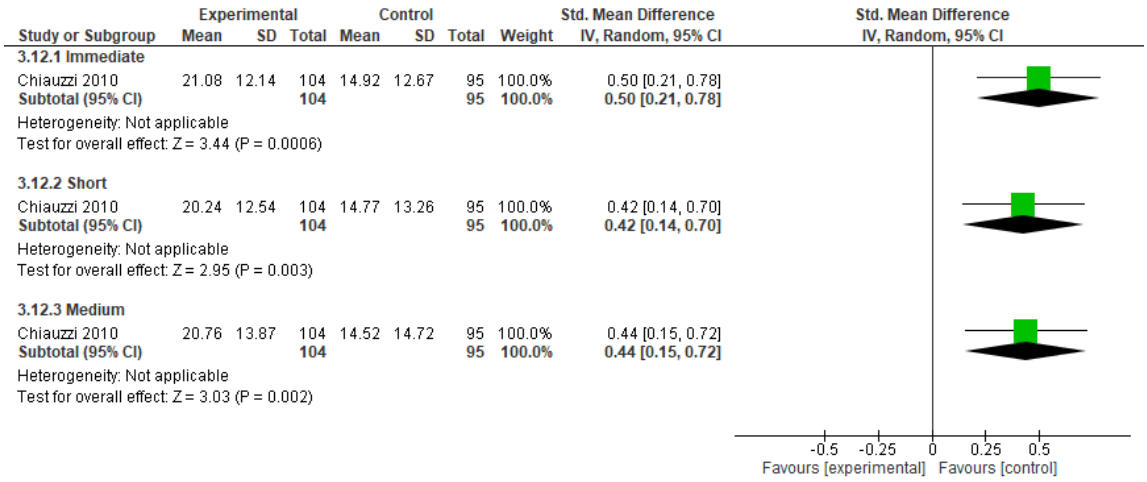
Pain Self-Efficacy (n=1)



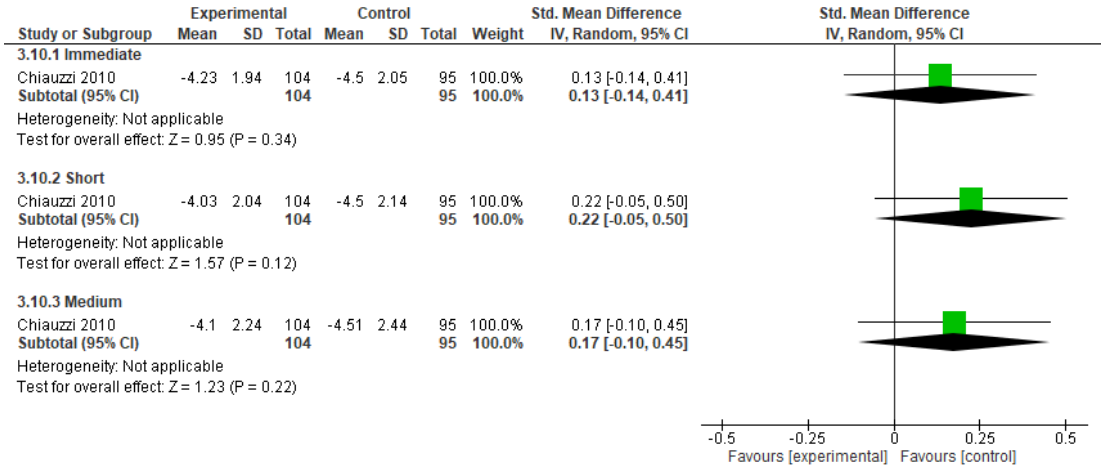
Fear-Avoidance (n=1)



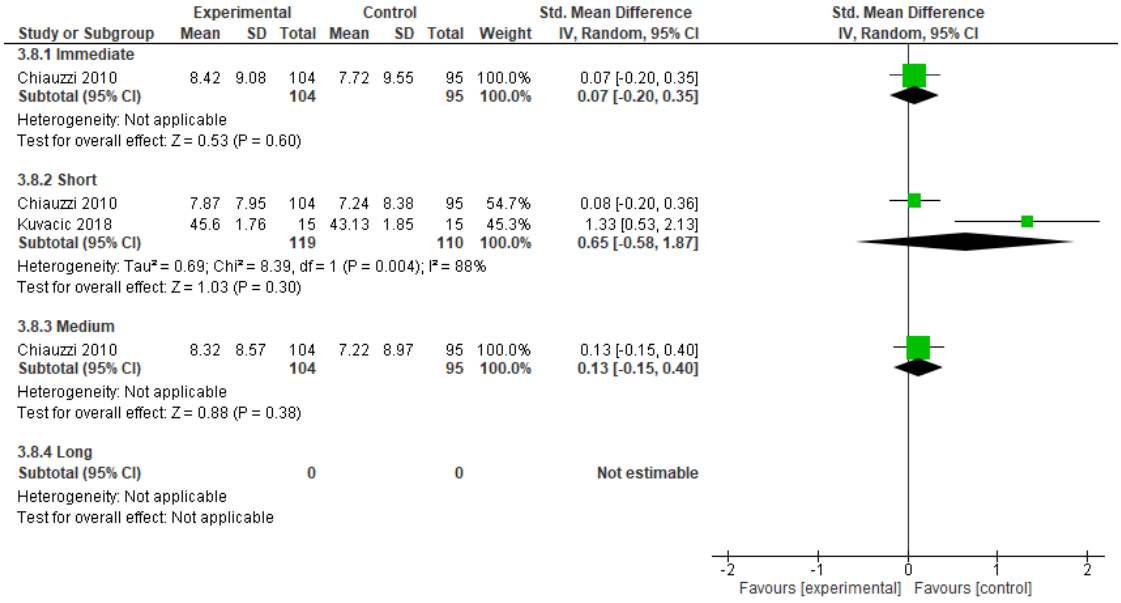
Catastrophizing (n=1)



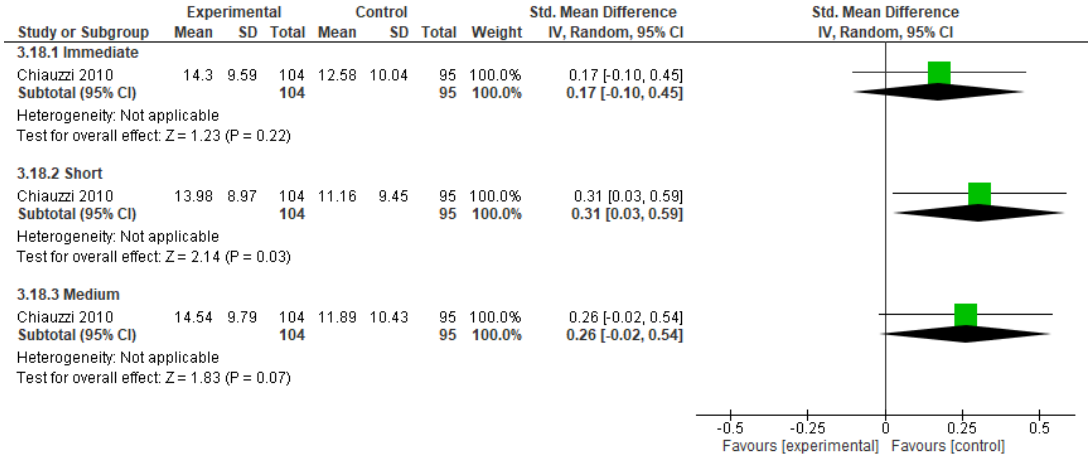
Coping (n=1)



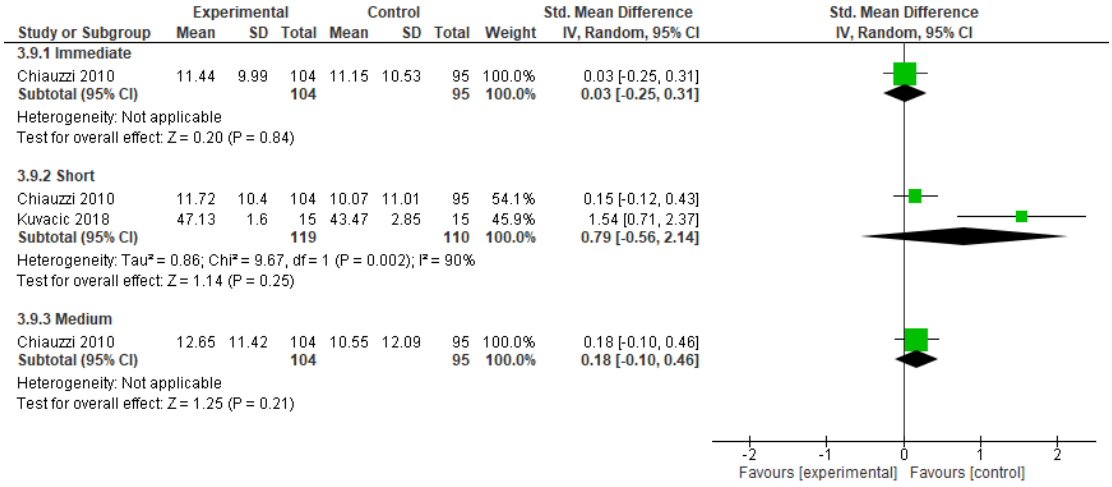
Anxiety (n=2)



Stress (n=1)



Depression (n=2)



Days off Work (n=1, however, the study did not provide usable data and was narratively synthesized)

Appendix 2.6. PRISMA checklist.

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	P34
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	P36
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	P39-40
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	P40
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	P41
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	P40
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix 2.2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	P41
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	P41
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	P41
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	P41
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	P42
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	P42-43

Section and Topic	Item #	Checklist item	Location where item is reported
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	P43
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	P44
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	P42
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	P43
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	P43
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	P44
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	P44
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	P44
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	P45
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	P46
Study characteristics	17	Cite each included study and present its characteristics.	P45-57
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	P58-59
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Appendix 2.4
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	P59-81
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	P59-81

Section and Topic	Item #	Checklist item	Location where item is reported
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Appendix 2.4
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	P59-81
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	P59-81, Appendix 2.4
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	P59-81, Appendix 2.4
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	P83
	23b	Discuss any limitations of the evidence included in the review.	P86
	23c	Discuss any limitations of the review processes used.	P86
	23d	Discuss implications of the results for practice, policy, and future research.	P84-86
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	P40
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	P40
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Appendix 2.3
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	P87
Competing interests	26	Declare any competing interests of review authors.	P87
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Appendix 2.5

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Appendix 3.1. Protocol for Chapter 3

This protocol was registered on Open Science Framework. Steve Kamper, Diana De Carvalho, Luciana A. C. Machado, Alicia Taylor, Bradley Furlong, Georgia Darmonkow, Emily Devereaux, Gabrielle Logan, Keisha Whelan, Amanda Hall (2020). Analgesic effects of conservative treatments for non-specific low back pain and sciatica: an updated meta-analysis of placebo-controlled randomized trials. https://osf.io/gk7fp

Background

The double-blind, randomized placebo-controlled trial is the gold-standard study design when assessing the specific effect (efficacy) of an intervention [1–3]. However, many randomized controlled trials (RCTs) of treatments for low back pain (LBP) do not employ a placebo group [4]. Instead, interventions are frequently compared with a control group that receives another type of treatment (e.g. exercise regime, medication, usual general practitioner care, etc). Results obtained from this approach may be difficult to interpret because the efficacy of some treatments used in these control groups is unclear.

In 2008, Machado and colleagues published the first systematic review and meta-analysis of the evidence from randomized, placebo-controlled trials on analgesic effects of treatments for non-specific LBP [5]. They identified 76 RCTs reporting on 34 conservative or surgical treatments, the most common of which were medications including muscle relaxants (n=9), anti-inflammatory drugs (NSAIDS, n=7), antidepressants (n=4), herbal medicines (n=4), and analgesics (n=3). Spinal manipulative therapy (SMT, n=6), transcutaneous electrical nerve stimulation (TENS, n=4) and acupuncture (n=4) were the most commonly studied non-medicamentous conservative treatments, and radiofrequency (RF) denervation was the most investigated invasive treatment (n=4). The remainder of the treatments (e.g. exercise, injections, massage, back school, etc.) were investigated by three or less studies. Overall, specific treatment effects were small (<10 points on a 100-point scale) or moderate (10-20 points on a 100-point scale). The few studies that found large effects (>20 points on a 100-point scale) were from a single trial; thus, the estimates are imprecise and would be likely to change with additional data.

Over the last decade, there has been an increase in the number of RCTs on conservative interventions for non-specific LBP employing a placebo group, so it is timely to update the study by Machado and colleagues [5]. The methods outlined in their original review will be followed, but a few adjustments will be made to include trials reporting on sciatica, a condition commonly associated with LBP, and to keep up to date with best practices since 2008, i.e. interpretation of the meta-analysis using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach [6].

Aim

To determine the efficacy of conservative interventions for the management of non-specific LBP and sciatica.

Methods

Eligibility criteria

Study Type. Randomized, placebo-controlled trials will be included. Trials in which the placebo group is a contemporary treatment for LBP (e.g. educational booklet) will be excluded. Non-English studies will be translated using Google Translate where possible.

Participants. Studies reporting on non-specific LBP or sciatica will be included. Other diagnoses (e.g. osteoarthritis, spondylolisthesis, disc protrusion/herniation/prolapse, facet syndrome) will be considered under the label "non-specific LBP" or "sciatica" only when the clinical description of trial participants correspond to the definitions described in Appendix 3.1A. Studies

reporting on serious spinal pathologies (cauda equina syndrome, infection, neoplasm, vertebral fracture and inflammatory disease), pregnancy or spinal surgery in the past 12 months, and trials on primary prevention (i.e., the subjects are currently pain-free), will be excluded.

Interventions. Studies investigating the effects of conservative (non-invasive) interventions for non-specific LBP or sciatica will be included.

Outcome Measures. Studies will be considered eligible for inclusion if they report a continuous measure of pain. Similarly to the review by Machado and colleagues,5 we will extract data on pain outcomes from the first assessment after the end of the therapy, as it may represent the time-point where the largest analgesic effects would be observed.

Search Strategy

Electronic database search. An electronic database search will be conducted from 2005 to June 2020 using MEDLINE, CINAHL, EMBASE, PsychInfo and Cochrane Central Register of Controlled Trials (Central). A combination of terms to search for RCTs and LBP (as described by the Cochrane Back Review Group [7]), and the terms placebo, sham, attention-control and minimal intervention will be used as search terms (Appendix 3.1B). Electronic databases will be searched to identify any relevant reviews previously published. The bibliographies of these reviews will be searched to identify trials missed by the electronic search process. Authors of conference abstracts or ongoing trials found in the search will be contacted to determine if these studies have since been published.

Assessment for trial inclusion

All articles identified by the search strategy will be downloaded to Endnote and duplicates removed [8]. The remainder of the studies will be title and abstract screened according to the eligibility criteria by two reviewers (DDC and either AH or GL) using Covidence Systematic Review software [9]. The full text of all potentially eligible trials will be retrieved and screened by two independent reviewers (AH, GL, AT, ED). Consensus will be used to resolve disagreements, and a third author (SK or LM) will be consulted if necessary.

Methodological Quality

The PEDro scale will be used to assess the quality of the included studies. Quality will be rated by two independent reviewers (AT, GL, BF, GD, ED and KW), and consensus will be used to solve disagreements. Whenever possible, PEDro scores will be extracted from the Physiotherapy Evidence Database (www.pedro.fhs.usyd.edu.au). No minimum score will be set for inclusion. Studies with a score of 7 or more will be classified as low risk of bias.

Data Extraction

Eligible studies will have relevant data extracted by two independent reviewers (AT, GL, BF, GD, ED and KW) using standardized data extraction forms in Microsoft Excel [10]. Consensus will be used to solve disagreements, and a third author (SK, AH or LM) will be consulted if necessary. Appendix 3.1C describes the list of data extraction elements. Study authors will be contacted if additional data is required. If a standard deviation is not provided it will be calculated or estimated using a relevant statistic provided in the study (e.g., confidence intervals, standard errors, or p values)

[11]. If the standard deviation cannot be calculated in this way, it may be imputed by borrowing values from similar studies, as described in the Cochrane handbook [12].

Data Analysis

Meta-analysis

The primary analysis will include populations of patients with non-specific LBP and sciatica for each treatment type. Where there is more than one trial that estimates the effect of a particular treatment, we will use a random effects model to obtain a pooled estimate of the effect (weighted mean difference) of that treatment. For each trial, the size of the treatment effect will be estimated by subtracting the mean pain in the treatment group from the mean pain in the placebo group. Means and standard deviations of the pain scores at the time point closest to the end of treatment will be used. Where necessary, pain scores will be rescaled to a 0- to a 100-point scale. The meta-analysis will be conducted using Review Manager 5.3 [13].

Sensitivity analysis

A prespecified analysis of the effect estimate will be performed based on the removal of studies that specifically included recruitment of patients with sciatica (as defined by the studies authors).

Sub-group analysis

A prespecified sub-group analysis will be performed to evaluate the efficacy of treatments in populations with acute and chronic symptoms (symptoms present for <3 months or ≥3 months, respectively). Trials that have a mix of patients with acute and chronic symptoms will not be included in the sub-group analysis.

Synthesis of results

To assess the level of certainty of the evidence, a summary of findings table will be developed for each meta-analysis using the GRADE approach [6]. GRADE involves assessing each study using five domains (quality, inconsistency, indirectness, imprecision and publication bias), each of which are "downgraded" by a level of evidence if they meet the following criteria:

Quality - studies with high risk of bias contain greater than 25% of all participants

Inconsistency - high heterogeneity is clear from visual inspection or I^2>50%

Indirectness - over 50% of participants are not in the target group (i.e., if participants were subject to multicomponent interventions where the effect of the target treatment alone may not be interpretable)

Imprecision - the comparison for continuous data involves less than 400 participants

Publication bias - (i) many included studies have a small sample size, (ii) studies are or are likely to be industry-sponsored, (iii) other conflicts of interest are present.

These domains will be assessed independently by two reviewers (SK, AH, LM, DDC, AT, GL, BF, GD) for each included trial. Conflicts will be discussed, and if necessary, will be reviewed with a third author to come to a consensus. Studies will be considered to have high-quality evidence, moderate-quality evidence, low-quality evidence, very low-quality evidence, or no evidence if there are zero to four downgrades, respectively.

References

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5. Machado LAC, Kamper SJ, Herbert RD, Maher CG, McAuley JH. Analgesic effects of treatments for non-specific low back pain: a meta-analysis of placebo-controlled randomized trials. Rheumatology. 2009;48(5):520-527.

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7. Furlan AD, Pennick V, Bombardier C, van Tulder M. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. Spine. 2009;34(18):1929-1941.

8. EndNote. Clarivate Analytics PLC; 2020. https://endnote.com/

9. Innovation VH. Covidence Systematic Review Software. Veritas Health Innovation; 2016.

10. Microsoft Excel. Microsoft Corporation; 2020. https://www.microsoft.com/en-us/microsoft-365/excel

11. Higgins JP, Deeks JJ. Chapter 7: Selecting studies and collecting data. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). Published 2008. www.handbook.cochrane.org

12. Higgins JP, Deeks JJ, Altman DG. Chapter 16: Special topics in statistics. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). Published 2011. www.handbook.cochrane.org

13. Review Manager (RevMan) [Computer Program]. The Cochrane Collaboration; 2014.

Appendix 3.1A. Eligibility criteria

Search #

Details of Publication:

1. First author:_____
2. Year:_____
3. Citation (journal, volume, pages)_____

Eligibility: (tick relevant box)

Criterion	**Yes**	**No**	**Uncertain**
Randomized?			
Placebo-controlled?			
Non-specific low back pain or Sciatica? All subjects must present pain between the lower rib cage and gluteal folds, with/without non-radicular leg pain; or sciatica (radicular syndrome). Osteoarthritis, spondylolisthesis, disc protrusion/herniation/prolapse or facet syndrome are eligible if participants' clinical			
Continuous measure of pain?			
Conservative intervention?			

Appendix 3.1B. Search Strategy

MEDLINE-OVID , CINAHL-OVID, PsycINFO and Cochrane Central Register of Controlled Trials (based upon July 2004 updated search strategies for Cochrane Back Review Group)

Part A: Generic search for randomized controlled trials and controlled clinical trials

1. randomized controlled trial.pt
2. controlled clinical trial.pt
3. Randomized Controlled Trials/
4. Random Allocation/
5. Double-Blind Method/
6. Single-Blind Method/
7. or/1-6
8. Animals/ not Human/
9. 7 not 8
10. clinical trial.pt
11. exp Clinical Trials/
12. (clin$ adj25 trial$).tw
13. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw
14. Placebos/
15. placebo$.tw
16. random$.tw
17. Research Design/
18. (latin adj square).tw
19. or/10-18

20. 19 not 18

21. 20 not 9

22. Comparative Study/

23. exp Evaluation Studies/

24. Follow-Up Studies/

25. Prospective Studies/

26. (control$ or prospective$ or Volunteer$).tw

27. Cross-Over Studies/

28. or/22-27

29. 28 not 8

30. 29 not (9 or 21)

31. 9 or 21 or 30

Part B: Specific search for low back pain

32. dorsalgia.ti,ab

33. exp Back Pain/

34. backache.ti,ab

35. (lumbar adj pain).ti,ab

36. sciatica.ti,ab

37. sciatica/

38. spondylosis.ti,ab

39. lumbago.ti,ab

40. or/32-39

41. 40 and 31

Part C: Specific search for placebo-controlled trials

42. placebo$.tw

43. sham$.tw

44. attention-control.tw

45. minimal intervention.tw

Appendix 3.1C. Criteria for data extraction

Study Author, Year
Rev Initials of the reviewer(s) responsible for data extraction.
Country
Funding Source
Condition LBP – Sciatica – Mixed
Duration of symptoms: Acute – Chronic – Mixed Acute (symptoms lasting less than 3 months) – Chronic (symptoms lasting 3 months or more) – Mixed (Study includes patients with acute and chronic symptoms)
Patient Demographics Age, gender, etc.
Conservative therapies Describe the type of therapy implemented in the experimental groups. Do not need to be specific about the name of the drug or dosage, just list the type of drug, type of modality, etc.
Name of the experimental intervention under investigation Eg. acupuncture; paroxetine 20 mg; mobilisation; etc

Intervention details according to elements of the TIDieR template Description of the intervention, frequency and dose, duration and provider
Description of the Placebo intervention Description of the intervention, frequency and dose, duration and provider
Non-standardised co-intervention: Y/N Yes if patients from any group were allowed to undergo other interventions or use analgesics, eg. rescue analgesia. Considered Yes if no attempt to control for co-interventions is described.
Non-standardised co-intervention type Describe the type of non-standardised co-intervention allowed.
Standardised co-intervention: Y/N Yes if patients from ALL groups received the SAME type of intervention as a baseline treatment, eg. usual care, booklet, analgesics.
Standardised co-intervention type Describe the type of standardised co-intervention allowed.
Pain Outcome Measure description Paient measurement tool name, scale range, if a higher score is better or worse,
Pain Outcome data For the data-point closest to end of treatment: mean and standard deviation and sample size for conservative and placebo group

Appendix 3.2. Deviations from protocol and original review

We deviated from our pre-registered protocol (access from https://osf.io/2dk9z).

The deviations are as follows:

- We did not conduct the planned sensitivity analyses removing studies specifically recruiting patients with spine-related leg pain because the reported eligibility criteria and definitions for nonspecific low back pain and spine-related leg pain were heterogenous and often overlapping.

We deviated from the original review (access from doi:10.1093/rheumatology/ken470).

The deviations are as follows:

- We followed updated guidance from the Cochrane handbook to include trials with multiple comparisons. This involved either treating each comparison as an individual trial if considered in different analyses or dividing the control group sample size by the number of trial arms if considered in the same analysis.
- We included trials which included participants with spine-related leg pain due to substantial overlap with non-specific low back pain.
- We included all trials which were self-reported as a placebo or sham control including trials previously considered as "contemporary treatment" (e.g., very low intensity shortwave diathermy, educational booklets, low-force spinal manipulation and soft-tissue massage, etc.).

- We followed updated definitions on conservative interventions which meant excluding studies which were considered as minimally invasive interventional therapies (e.g., radiofrequency denervation, percutaneous thermocoagulation intradiscal techniques, prolotherapy, facet joint and intradiscal injections).
- We conducted post-hoc sensitivity analyses investigating the impact of risk of bias in individual studies on the results of the meta-analysis.

Appendix 3.3. Treatment types

Pharmacological treatments:

- Anesthetics: a medication that blocks nerve signals to prevent pain
- Anticonvulsants: including gabapentinoids, barbiturates, hydantoins, iminostilbene, ozazolidinedione, Succinimide, Aliphatic carboxylic acids, Miscellaneous.
- Antidepressants: including selective noradrenaline reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs) selective serotonin reuptake inhibitors (SSRIs), noradrenaline-dopamine reuptake inhibitors (NDRIs), serotonin antagonist and reuptake inhibitors (SARIs), tetracyclic antidepressants, monoamine oxidase inhibitors (MAOIs), reversible inhibitors of monoamine oxidase A (RIMAs), melatonergic antidepressants
- Bee venom injection
- Glucocorticoids
- Monoclonal antibody injections (administered subcutaneously or intravenously)
- Muscle relaxants: including antispastic, non-benzodiazepine antispasmodic, benzodiazepines, and miscellaneous muscle relaxants
- Non-steroidal anti-inflammatory drugs (NSAIDs): including selective cyclooxygenase-2 inhibitors or non-selective NSAIDs
- Opioids
- Paracetamol (Acetaminophen)
- Other medicines that could not otherwise be categorised

Non-pharmacological treatments

- Acupressure: application of mechanical pressure to specified acupuncture points
- Acupuncture: insertion of fine needles into the skin at specified points
- Behavioural/Education: information about the condition and/or beliefs surrounding a person's condition plus or minus support for changing behaviours
- Biofeedback: real-time feedback to the person relevant to their back
- Diathermy: high frequency electrical current that produces heat in the muscles
- Electroacupuncture: application of electrical current to needles inserted in the skin
- Electromagnetic: application of electromagnetic energy to the back
- Exercise: specific body movements with the aim of increasing fitness, strength, mobility or motor control
- Extracorporeal Shockwave: high frequency, high energy pulsed sound waves delivered to the back tissues
- Heat: application of warmth to the back
- Interferential: application of electrical currents at two different frequencies that interfere with each other
- Laser and light: application of focused light or laser beams to the back
- Massage: manual rubbing or kneading of the back muscles and tissues
- Mobilisation: non-physiological movement of back joints using manual pressure

- Osteopathic: manual therapy according to osteopathic models, usually involving mobilisation, manipulation and/or massage
- Spinal Manipulative Therapy (SMT): high force, low amplitude thrusts to spinal joints delivered by manual pressure
- Taping: adhesive fabric applied to the back
- Transcutaneous Electrical Nerve Stimulation (TENS): application of electrical current to the skin over the back that causes gentle muscle contractions
- Traction: application of external force to stretch the back structures longitudinally
- Transcranial Stimulation: application of magnetic or electrical field to the head to stimulate nerve activity
- Ultrasound: application of low energy sound waves to the back
- Otherwise not categorised: e.g., dry cupping, foot orthotics, infrared, orthopedic device

Appendix 3.4. Search strategy

MEDLINE-OVID , CINAHL-OVID, EMBASE, APA PsycINFO and Cochrane Central Register of Controlled Trials (based upon July 2004 updated search strategies for Cochrane Back Review Group)

MEDLINE	
#1	placebo OR sham OR "supportive therapy" OR "supportive therapies" OR "credible attention placebo" OR "credible attention placebos" OR "relaxation training control" OR "relaxation training controls" OR "discussion group" OR "discussion groups" OR "modest contrast" OR "attention control" OR "minimal intervention"
#2	dorsalgia[tiab] OR backache[tiab] OR "lumbar pain"[tiab] OR sciatica[tiab] OR spondylosis[tiab] OR lumbago[tiab]
#3	"Back Pain"[Mesh] OR "Sciatica"[Mesh]
#4	#2 OR #3
#5	((((("Randomized Controlled Trial" [Publication Type]) OR "Random Allocation"[Mesh]) OR "Double-Blind Method"[Mesh]) OR "Single-Blind Method"[Mesh]) OR "Controlled Clinical Trial" [Publication Type]
#6	"single blind" OR "single blinded" OR "single mask" OR "single masked"
#7	"double blind" OR "double blinded" OR "double mask" OR "double masked"
#8	"treble blind" OR "treble blinded" OR "treble mask" OR "treble masked"
#9	"triple blind" OR "triple blinded" OR "triple mask" OR "triple masked"
#10	#6 OR #7 OR #8 OR #9
#11	placebo* OR random*
#12	control* OR prospective OR volunteer*
#13	#11 OR #12
#14	(((((("Clinical Trial" [Publication Type]) OR "Placebos"[Mesh]) OR "Research Design"[Mesh]) OR "Comparative Study" [Publication Type]) OR "Evaluation Study" [Publication Type]) OR "Follow-Up Studies"[Mesh]) OR "Prospective Studies"[Mesh]) OR "Cross-Over Studies"[Mesh]
#15	#5 OR #10 OR #13 OR #14

#16	#1 AND #4 AND #15
#17	#16 AND human

CINAHL	
S1	placebo OR sham OR "supportive therapy" OR "supportive therapies" OR "credible attention placebo" OR "credible attention placebos" OR "relaxation training control" OR "relaxation training controls" OR "discussion group" OR "discussion groups" OR "modest contrast" OR "attention control" OR "minimal intervention"
S2	TI (dorsalgia OR backache OR "lumbar pain" OR sciatica OR spondylosis OR lumbago) OR AB (dorsalgia OR backache OR "lumbar pain"OR sciatica OR spondylosis OR lumbago)
S3	(MH "Back Pain+") OR (MH "Sciatica")
S4	S2 OR S3
S5	((MH "Random Assignment") OR (MH "Double-Blind Studies") OR (MH "Single-Blind Studies")) OR PT randomized control trial OR PT controlled clinical trial
S6	"single blind" OR "single blinded" OR "single mask" OR "single masked"
S7	"double blind" OR "double blinded" OR "double mask" OR "double masked"
S8	"treble blind" OR "treble blinded" OR "treble mask" OR "treble masked"
S9	"triple blind" OR "triple blinded" OR "triple mask" OR "triple masked"
S10	S6 OR S7 OR S8 OR S9
S11	placebo* OR random*
S12	control* OR prospective OR volunteer*
S13	S11 OR S12
S14	(MH "Placebos") OR (MH "Study Design") OR (MH "Prospective Studies") OR (MH "Crossover Design") OR PT clinical trial OR PT comparative study OR PT evaluation study
S15	S5 OR S10 OR S13 OR S14
S16	S1 AND S4 AND S15
S17	S16 AND human

EMBASE	
1	'placebo'/exp OR placebo OR sham OR 'supportive therapy'/exp OR 'supportive therapy' OR 'supportive therapies' OR 'credible attention placebo' OR 'credible attention placebos' OR 'relaxation training control' OR 'relaxation training controls' OR 'discussion group'/exp OR 'discussion group' OR 'discussion groups' OR 'modest contrast' OR 'attention control'/exp OR 'attention control' OR 'minimal intervention'
2	dorsalgia:ab,ti OR backache:ab,ti OR 'lumbar pain':ab,ti OR sciatica:ab,ti OR spondylosis:ab,ti OR lumbago:ab,ti
3	'backache'/exp OR 'sciatica'/exp
4	#2 OR #3
5	'randomization'/exp OR 'double blind procedure'/de OR 'single blind procedure'/de OR 'randomized controlled trial'/exp OR 'controlled clinical trial'/exp
6	'single blind' OR 'single blinded' OR 'single mask' OR 'single masked'
7	'double blind' OR 'double blinded' OR 'double mask' OR 'double masked'
8	'treble blind' OR 'treble blinded' OR 'treble mask' OR 'treble masked'
9	'triple blind' OR 'triple blinded' OR 'triple mask' OR 'triple masked'
10	#6 OR #7 OR #8 OR #9
11	placebo* OR random*
12	control* OR prospective OR volunteer*
13	#11 OR #12
14	'placebo'/de OR 'study design'/de OR 'prospective study'/de OR 'crossover procedure'/de OR 'clinical trial'/exp OR 'comparative study'/de OR 'evaluation study'/exp
15	#5 OR #10 OR #13 OR #14
16	#1 AND #4 AND #15
17	#16 AND human

PsycInfo	
1	placebo OR sham OR "supportive therapy" OR "supportive therapies" OR "credible attention placebo" OR "credible attention placebos" OR "relaxation training control" OR "relaxation training controls" OR "discussion group" OR "discussion groups" OR "modest contrast" OR "attention control" OR "minimal intervention"
2	TI (dorsalgia OR backache OR "lumbar pain" OR sciatica OR spondylosis OR lumbago) OR AB (dorsalgia OR backache OR "lumbar pain" OR sciatica OR spondylosis OR lumbago)
3	DE Back Pain OR sciatica
4	S2 OR S3
5	(DE "Randomized Clinical Trials" OR DE "Randomized Controlled Trials") OR randomize*
6	("single blind" OR "single blinded" OR "single mask" OR "single masked") OR ("double blind" OR "double blinded" OR "double mask" OR "double masked") OR ("treble blind" OR "treble blinded" OR "treble mask" OR "treble masked") OR ("triple blind" OR "triple blinded" OR "triple mask" OR "triple masked")
7	S5 OR S6
8	placebo* OR random* OR control* OR prospective OR volunteer*
9	((DE "Placebo") OR (DE "Clinical Trials")) OR ("study design" OR "prospective study" OR "crossover study" OR "comparative study" OR "evaluation study")
10	S7 OR S8 OR S9
11	S1 AND S4 AND S10
12	S11 AND human

CENTRAL	
#1	placebo OR sham OR "supportive therapy" OR "supportive therapies" OR "credible attention placebo" OR "credible attention placebos" OR "relaxation training control" OR "relaxation training controls" OR "discussion group" OR "discussion groups" OR "modest contrast" OR "attention control" OR "minimal intervention"
#2	dorsalgia OR backache OR "lumbar pain" OR sciatica OR spondylosis OR lumbago OR "back pain"
#3	random allocation OR "randomized controlled trial" OR "controlled clinical trial" OR "single blind" OR "single blinded" OR "single mask" OR "single masked" OR "double blind" OR "double blinded" OR "double mask" OR "double masked" OR "treble blind" OR "treble blinded" OR "treble mask" OR "treble masked" OR "triple blind" OR "triple blinded" OR "triple mask" OR "triple masked"
#4	placebo* OR random* OR control* OR prospective OR volunteer*
#5	comparative study OR "evaluation study" OR "follow-up study" OR "cross-over study"
#6	#4 OR #5
#7	#1 AND #2 AND #6
#8	#7 AND human

Appendix 3.5. Criteria for data extraction

Study Author, Year
Country
Funding Source
Condition Low back pain – Spine-related leg pain (Sciatica) – Mixed
Duration of symptoms: Acute – Chronic – Mixed Acute (symptoms lasting less than 3 months) – Chronic (symptoms lasting 3 months or more) – Mixed (Study includes participants with acute and chronic symptoms)
Patient Demographics Age, gender, etc.
Conservative therapies Describe the type of therapy implemented in the experimental groups. Does not need to be specific about the name of the drug or dosage, just list the type of drug, type of modality, etc.
Name of the experimental intervention under investigation Eg. acupuncture; paroxetine 20 mg; mobilisation; etc
Intervention details according to elements of the TIDieR template Description of the intervention, frequency and dose, duration and provider
Description of the Placebo intervention Description of the intervention, frequency and dose, duration and provider
Standardised co-intervention: Y/N Yes if patients from ALL groups received the SAME type of intervention as a baseline treatment, eg. usual care, booklet, analgesics.
Standardised co-intervention type Describe the type of standardised co-intervention allowed.
Pain Outcome Measure description

Pain intensity measurement tool name, scale range, if a higher score is better or worse,
Pain Outcome data For the data-point closest to end of treatment: time point, data type (post or change score), mean and standard deviation and sample size for intervention and placebo groups (if mean or standard deviation was not provided, we extracted other relevant statistics such as median and interquartile range, confidence interval, or standard error)

Appendix 3.6. PEDro scale

The PEDro scale is a rating scale to assess the methodological quality and risk of bias of clinical trials.[1] The PEDro scale[2] consists of 11 items encompassing external validity (item 1), internal validity (items 2 to 9), and statistical reporting (items 10 to 11):

1. Eligibility criteria and source

"eligibility criteria were specified"

*2. Random allocation

"subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)"

*3. Concealed allocation

"allocation was concealed"

4. Baseline comparability

"the groups were similar at baseline regarding the most important prognostic indicators"

5. Blinding of participants

"there was blinding of all subjects"

6. Blinding of therapists

"there was blinding of all therapists who administered the therapy"

7. Blinding of assessors

"there was blinding of all assessors who measured at least one key outcome"

*8. Adequate follow-up (> 85%)

"measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups"

9. Intention-to-treat analysis

"all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by 'intention to treat'"

10. Between-group statistical comparisons

"the results of between-group statistical comparisons are reported for at least one key outcome"

11.Reporting of point measures and measures of variability

"the study provides both point measures and measures of variability for at least one key outcome"

Items are rated yes or no (1 or 0) according to whether the criterion is clearly satisfied in the study. A total PEDro score between 0 to 10 is achieved by adding the ratings of items 2 to 11. Higher scores indicate superior methodological quality. The 0 to 10 PEDro score can be considered to meet interval level measurement, allowing comparison of scores between studies.[3]

* Items considered as critical for overall trial risk of bias judgements.

References

1. Cashin AG, McAuley JH. Clinimetrics: Physiotherapy Evidence Database (PEDro) Scale. Journal of physiotherapy. 2019 Sep 11;66(1):59-
2. https://pedro.org.au/wp-content/uploads/PEDro_scale.pdf
3. De Morton NA. The PEDro scale is a valid measure of the methodological quality of clinical trials: a demographic study. Australian Journal of Physiotherapy. 2009 Jan 1;55(2):129-33.

Appendix 3.7. GRADE framework

We assessed the certainty in the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group methodology.[1]

The certainty of evidence was initially classified as 'high' (very certain that the true effect lies close to that of the estimate of the effect) and possibly downgraded to 'moderate' (moderately certain in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different), 'low' (certainty in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect), or 'very low' (very little certainty in the effect estimate: the true effect is likely to be substantially different from the estimate of effect).

We graded the evidence in the following recommended domains in the following manner:

- Risk of bias: limitations in the study design and execution. We downgraded by one level if > 25% of the participants in the analysis came from studies assessed as high risk of bias.[2]
- Inconsistency: unexplained heterogeneity of results. We downgraded by one level if we identified important heterogeneity from visual inspection of the forest plot or the proportion of study variance not due to sampling error I^2>50%. We also downgraded by one level for comparisons with only a single trial [3]

- Indirectness: the applicability of the evidence to the question of interest. We downgraded by one level if over 50% of the participants in the analysis were not from the target group.[4]
- Imprecision: the precision of the estimated treatment effect. We downgraded by one level if there were less than 400 participants in the analysis.[5]
- Publication bias: systematic under- or over-estimation of the underlying effect due to the selective publication of studies. We downgraded by only one level if we strongly detected publication bias through visually assessing funnel plots and considering study sources of funding or other conflicts of interest present.[6]

References

1. Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 2011;64(4):401-406
2. Guyatt GH, Oxman AD, Vist G, et al. GRADE guidelines: 4. Rating the quality of evidence - study limitations (risk of bias). J Clin Epidemiol. 2011;64(4):407-415.
3. Guyatt GH, Oxman AD, Kunz R, et al. GRADE guidelines: 7. Rating the quality of evidence - inconsistency. J Clin Epidemiol. 2011;64(12):1294-1302.
4. Guyatt GH, Oxman AD, Kunz R, et al. GRADE guidelines: 8. Rating the quality of evidence - indirectness. J Clin Epidemiol. 2011;64(12):1303-1310.
5. Guyatt GH, Oxman AD, Kunz R, et al. GRADE guidelines 6. Rating the quality of evidence - imprecision. J Clin Epidemiol. 2011;64(12):1283-1293.

6. Guyatt GH, Oxman AD, Montori V, et al. GRADE guidelines: 5. Rating the quality of evidence - publication bias. J Clin Epidemiol. 2011;64(12):1277-1282

Appendix 3.8. Classification of treatment findings

For each comparison, we classified findings as either efficacious, not efficacious, or inconclusive[1]:

Efficacious

A treatment was classified as efficacious when the difference between the treatment and placebo group was statistically significantly in favour of the treatment and the certainty of evidence was at least moderate.

Not efficacious

We classified a treatment as not efficacious when the difference between treatment and placebo group was not statistically significantly in favour of the treatment and the certainty of evidence was at least moderate.

Inconclusive

When the certainty of evidence was low and very low or a comparison had only one small trial (sample size <100 per arm)[2] or both, we considered the evidence of efficacy to be inconclusive regardless of statistical significance, magnitude, or direction of effect.

References

1. Ferreira GE, Abdel-Shaheed C, Underwood M, et al. Efficacy, safety, and tolerability of antidepressants for pain in adults: overview of systematic reviews. BMJ. Published online February 1, 2023:e072415. doi:10.1136/bmj-2022-072415

2. Nuesch E, Trelle S, Reichenbach S, et al. Small study effects in meta-analyses of osteoarthritis trials: meta-epidemiological study. BMJ. 2010;341(jul16 1):c3515-c3515. doi:10.1136/bmj.c3515

Appendix 3.9. Characteristics of included studies in the analysis by treatment class

Treatment class	Number of trials (participants)	Duration of low back pain (number of trials)	PEDro score (0-10), mean (SD)
Acupressure	4 (168)	Chronic (4)	6.8 (1.0)
Acupuncture	23 (2233)	Acute (4); Chronic (19)	6.9 (1.6)
Allosteric modulator of the g-aminobutyric acid type A (GABAA) receptor	1 (222)	Chronic(1)	10 (NA)
Anaesthetics	2 (281)	Chronic (2)	7 (0)
Antibiotic/antimicrobials	3 (351)	Chronic (3)	9.3 (0.6)
Antibody injection	5 (3401)	Chronic (5)	8.3 (1.2)
Anticonvulsants	2 (204)	Chronic (2)	8.5 (2.1)
Antidepressants	10 (1695)	Chronic (10)	7.9 (1.3)
Antidepressants + paracetamol	1 (63)	Chronic (1)	6 (NA)
Bee Venom	1 (54)	Chronic (1)	10 (NA)
Behavioural/education	10 (948)	Acute (3); Chronic (7)	6.5 (2.0)
Biofeedback	5 (178)	Chronic (5)	5.8 (1.5)
Bisphosphonates	2 (65)	Chronic (2)	9 (1.4)
Bushen Huoxue Formula	1 (70)	Chronic (1)	10 (NA)
Cannabinoid	1 (100)	Acute (1)	10 (NA)
Colchicine	1 (15)	Acute (1)	6 (NA)
Complementary medicines	11 (1151)	Chronic (11)	8 (1.2)
Diathermy	4 (284)	Chronic (4)	7 (2.9)
Dry cupping	2 (128)	Chronic (2)	8.5 (0.7)
Electroacupuncture	4 (280)	Chronic (4)	7.5 (1.3)
Electromagnetic	7 (257)	Chronic (7)	6.6 (1.3)
Endogenous steroids	1 (83)	Chronic (1)	6 (NA)
Exercise	9 (1098)	Acute (2); Chronic (7)	7.5 (1.7)
Extracorporeal shockwave	6 (236)	Acute (1); Chronic (5)	6.7 (1.5)
Foot orthotics	1 (51)	Chronic (1)	6 (NA)
Glucocorticoid injection	2 (111)	Acute (2)	8.5 (0.7)
Heat	2 (255)	Acute (2)	5 (0)
Hypnotic medicines	1 (52)	Chronic (1)	10 (NA)
Immunoglobulin	1 (41)	Acute (1)	7 (NA)
Infrared	2 (92)	Chronic (2)	5.5 (0.6)
Interferential	7 (691)	Chronic (7)	7.3 (1.7)
Laser and light	20 (1267)	Acute (2); Chronic (18)	7.5 (2.0)
Massage	5 (226)	Acute (1); Chronic (4)	6.6 (1.8)
Mobilisation	16 (986)	Acute (3); Chronic (13)	6.3 (1.6)
Muscle relaxants	11 (1267)	Acute (9); Chronic (2)	7.8 (1.0)
Muscle relaxants + NSAIDs	2 (123)	Acute (1); Chronic (1)	8.5 (0.7)
NSAIDs	16 (4449)	Acute (10); Chronic (8)	7.9 (2.0)
Nucleoside	1 (161)	Acute (1)	9 (NA)
Opioids	20 (7469)	Acute (1); Chronic (19)	7.6 (1.1)
Opioids + analgesics	4 (821)	Chronic (4)	8.5 (1.3)
Orthopedic device	1 (30)	Chronic (1)	9 (NA)
Osteopathic	5 (1194)	Acute (2); Chronic (3)	7.4 (1.7)
Ozone injections	1 (41)	Acute (1)	7 (NA)
Paracetamol	2 (1843)	Acute (2)	9.5 (0.7)
Probiotic	1 (88)	Chronic (1)	10 (NA)
Pyrazolone derivatives	1 (168)	Acute (1)	8 (NA)
Radiotherapy	1 (32)	Chronic (1)	7 (NA)
Reflexology	1 (15)	Chronic (1)	4 (NA)

Spinal manipulative therapy	13 (828)	Acute (4); Chronic (9)	7.2 (1.7)
Taping	15 (967)	Chronic (15)	7.4 (1.4)
TENS	13 (710)	Acute (2); Chronic (11)	6.6 (1.6)
Topical rubefacient	2 (845)	Acute (2)	8 (2.8)
Traction	3 (250)	Chronic (3)	7 (1.7)
Transcranial stimulation	7 (271)	Chronic (7)	7.1 (1.7)
TRPV1 agonists	2 (433)	Chronic (2)	8.5 (0.7)
Ultrasound	2 (92)	Chronic (2)	7 (1.4)

Appendix 3.10. Characteristics of individual included studies

Study, Year (Reference)	Study sample relevant to this review	Test intervention, n	Comparison intervention, n	Pain intensity outcome measure	Source of funding
Acupressure					
Kim, 2021(1)	62 participants with chronic low back pain from South Korea	Auricular acupressure, 31	Placebo acupressure at acupoints unrelated to low back pain, 31	VAS (0-10)	Not reported
Yeh, 2013(2)	21 participants with chronic low back pain from the US	Auricular acupressure, 11	Sham acupressure at acupoints unrelated to low back pain, 10	BPI short form NRS (0-10)	Center for Research and Evaluation Pilot/Feasibility Study Program, School of Nursing, University of Pittsburgh
Yeh, 2014(3)	37 participants with chronic low back pain from the US	Auricular acupressure, 19	Sham acupressure at acupoints unrelated to low back pain, 18	BPI NRS (0-10)	Aging Institute of the University of Pittsburgh Medical Center (UPMC), Senior Services and the University of Pittsburgh
Yeh, 2015(4)	61 participants with chronic low back pain from the US	Auricular acupressure, 30	Sham acupressure at acupoints unrelated to low back pain, 31	BPI NRS (0-10)	Center for Research and Evaluation (CRE) at the University of Pittsburgh (Pitt), School of Nursing (SON) and the Aging Institute at the University of Pittsburgh Medical Center (UPMC), Senior Services
Acupuncture					
Brinkhaus, 2006(5)	219 participants with chronic low back pain from Germany	Acupuncture, 146	Sham acupuncture consisting of superficial needling at non-acupuncture points, 73	VAS (0-100)	This trial was initiated because of a request from German health authorities (the Federal Committee of Physicians and Social Health Insurance Companies and the German Federal Social Insurance Authority) and sponsored by German social health insurance companies. The health authorities requested a randomized trial including a sham control condition with an observation period of at least 6 months.

					All other decisions on design, data collection, analysis, interpretation, and publication were the complete responsibility of the researchers.
Carlsson, 2001(6)	50 participants with chronic low back pain from Sweden	Acupuncture with electroacupuncture, 34	Detuned TENS, 16	VAS (0-100)	Supported in part by grant No. 05658 from the Swedish Medical Research Council project (to B.S.)
Cho, 2013(7)	130 participants with chronic low back pain from South Korea	Acupuncture plus exercise at home, 65	Sham acupuncture using semi-blunt needle on non-acupuncture points without penetration plus exercise at home, 65	VAS (0-10)	Korean Health Industry Development Institute
Del-Canto-Fernández, 2022(8)	20 participants with mixed duration low back pain from Spain	Acupuncture with deep dry needling, 10	Placebo acupuncture using sham acupuncture needles, 10	VAS (0-10)	None
Duplan, 1983(9)	30 participants with acute low back pain from France	Acupuncture, 15	Sham acupuncture using superficial needling at non-acupuncture points, 15	VAS (0-10)	Not reported
Haake, 2007(10)	774 participants with chronic low back pain from Germany	Verum acupuncture, 387	Sham acupuncture using superficial needling at non-acupuncture points, 387	CPGS	German public health insurance companies: Allgemeine Ortskrankenkasse, Betriebskrankenkasse, Innungskrankenkasse, Bundesknappschaft, Bundesverband der Landwirtschaftlichen Krankenkassen, and Seekasse
Hasegawa, 2014(11)	80 participants with acute low back pain from Brazil	Acupuncture, 40	Sham non-penetrating acupuncture, 40	VAS (0-10)	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior—Ministério da Educação do Governo do Brasil (MEC).
Huang, 2019(12)	46 participants with chronic low back pain from China	Acupuncture, 23	Sham non-penetrating acupuncture, 23	VAS (0-100)	None

Inoue, 2006(13)	31 participants with chronic low back pain from Japan	Acupuncture, 15	Sham acupuncture using a guide tube without needling, 16	VAS (0-100)	None
Itoh, 2006(14)	26 participants with chronic low back pain from Japan	Trigger point acupuncture, 13	Sham non-penetrating acupuncture, 13	VAS (0-10)	Ministry of Health and Welfare (H14-Choju-029)
Kennedy, 2008(15)	48 participants with acute low back pain from the UK	Verum acupuncture plus the back book, 24	Sham non-penetrating acupuncture plus the back book, 24	VAS (0-100)	Dr Park developed the Park Sham Device and supplied the samples for use in the study
Kerr, 2003(16)	60 participants with chronic low back pain from Ireland	Acupuncture plus educational leaflet, 30	Detuned TENS plus educational leaflet, 30	VAS (0-100)	Department of Health and Social Services for Northern Ireland
Koppenhaver, 2021(17)	60 participants with chronic low back pain from the US	Acupuncture dry needling, 30	Sham non-penetrating acupuncture dry needling, 30	NRS (0-10)	The Advanced Medical Technology Initiative (AMTI), through the Telemedicine and Advanced Technology Research Center (TATRC) at the U.S. Army Medical Research and Development Command (USAMRDC)
Kovacs, 1997(18)	78 participants with chronic low back pain from Spain	Neuroreflexotherapy, 41	Sham neuroreflexotherapy consisting of epidermal implants in adjacent points, 37	VAS (0-10)	Fundacion Kovacs and 'Fondo de Investigaciones Sanitarias' (no. 92/0037-00), Madrid, Spain
Leibing, 2002(19)	85 participants with chronic low back pain from Germany	Acupuncture plus physiotherapy, 40	Sham acupuncture consisting of superficial needling at non-acupuncture points plus physiotherapy, 45	VAS (0-10)	The Ministry of Education, Science, Research and Technology (BMBFT), Federal Republic of Germany (01 KT 9407)
Li, 2021(20)	73 participants with acute low back pain from China	Acupuncture, 37	Sham non-penetrating acupuncture, 36	VAS (0-100)	None
Makary, 2015(21)	56 participants with unclear low back pain duration from South Korea	Acupuncture, 33	Sham acupuncture consisting of acupuncture needling without somatosensory tactile stimulation, 23	VAS (0-10)	The National Research Foundation funded by the Ministry of Science, ICT and Future Planning (NRF-2013R1A1A1010318 and NRF-2014R1A2A1A11051355) and Korea Institute of Oriental Medicine (K17052)

Martín-Corrales, 2020(22)	46 participants with chronic low back pain from Spain	Acupuncture dry needling, 23	Sham non-penetrating acupuncture dry needling, 23	VAS (0-10)	None
Mendelson, 1983(23)	77 participants with chronic low back pain from Australia	Acupuncture, 36	Sham acupuncture consisting of superficial needling at non-acupuncture points, 41	VAS (0-100)	The National Health and Medical Research Council of Australia (grant 74/9158)
Mendonca, 2022(24)	36 participants with chronic low back pain from Brazil	Acupuncture, 18	Sham acupuncture consisting of immediate needle withdrawal after puncture	NRS (0-10)	The National Council for Technological and Scientific Development (CNPQ): Chamada MCTI/CNPq/MS - SCTIE - Decit N° 07/2013 - Política Nacional de Práticas Integrativas e Complementares (PICS) no Sistema Único de Saúde
Molsberger, 2002(25)	126 participants with chronic low back pain from Germany	Acupuncture, 65	Sham acupuncture consisting of superficial needling at non-acupuncture points, 61	VAS (0-100)	The German Ministry of Education, Science and Research
Moura, 2019(26)	73 participants with chronic low back pain from Brazil	Auricular acupuncture, 37	Placebo auricular acupuncture at acupoints unrelated to low back pain, 36	BPI (0-10)	Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG). Process APQ-02828-16
Rajfur, 2022(27)	40 participants with chronic low back pain from Poland	Acupuncture dry needling, 20	Sham non-penetrating acupuncture dry needling, 20	VAS (0-10)	The University of Opole in Poland and the Academy of Physical Education in Katowice subventions according to the number of FIZ/3/2022. Also supported by the Ministry of Health subventions according to the number of SUBZ.E060.22.099 from the IT Simple system of the Wroclaw Medical University in Poland.
Tu, 2019(28)	54 participants with chronic low back pain from the US	Acupuncture, 28	Placebo acupuncture using placebo needles, 26	PROMIS-29 pain intensity subscale (0-10)_	JK is supported by P01 AT006663, R01 AT008563, R61/R33 AT009310, R33AT009341, R21 AT008707 from NIH/NCCIH, and R34DA046635 from NIH/NIDA. JK has a disclosure to report (holding equity in a startup company, MNT, and pending patents to

					develop new neuromodulation devices) but declares no conflict of interest.
Ushinohama, 2016(29)	80 participants with chronic low back pain from Brazil	Acupuncture, 40	Detuned ultrasound, 40	NRS (0-10)	Not reported
Allosteric modulator of the g-aminobutyric acid type A (GABAA) receptor					
Gurrell, 2018(30)	148 participants with chronic low back pain from the US	Oral PF-06372865, 74	Oral placebo, 74	NRS (0-10)	Pfizer. All authors are or were employees of Pfizer at the time of this research and may own stock in the company.
Anaesthetics					
Hashmi, 2012(31)	30 participants with chronic low back pain from the US	Lidocaine patch, 15	Placebo treatment, 15	VAS (0-10)	Endo Pharmaceuticals and in part by National Institutes of Health R01 NS35115. Endo Pharmaceuticals provided financial aid, Lidocaine and placebo patches, but had no involvement in other aspects of the project.
Imamura, 2016(32)	251 participants with chronic low back pain from Brazil	Paraspinal lidocaine injection, 126	Placebo lidocaine injection, 125	VAS (0-10)	The Physical and Rehabilitation Medicine Institute, Clinics Hospital of University of Sao Paulo Medical School. Dr. Morales-Quezada received funding support from an Institutional National Research Service Award from the National Center for Complementary and Integrative Health grant T32AT000051, the Ryoichi Sasakawa Fellowship Fund, and by the Program in Placebo Studies at Beth Israel Deaconess Medical Center.
Antibiotic and Antimicrobial medicines					
Albert, 2013(33)	162 participants with chronic low back pain from Denmark	Oral Amoxicillin-clavulanate, 90	Oral placebo, 72	Low back pain rating scale (0-10)	IMK general foundation, The Danish Rheumatism Association, Svend Hansen and Ina Hansens Foundation, Ib Henriksen Foundation, Dagmar

					Marshalls Foundation, Karen Hansen Memory Foundation, Ing. K.A. Rohde and Wife's foundation
Bråten, 2019(34)	180 participants with chronic low back pain from Norway	Oral Amoxicillin, 89	Oral placebo, 91	NRS (0-10)	Helse Sør-Øst (grant No 2015090) and Helse Vest (grant No 911938 and 911891)
Schnitzer, 2016(35)	41 participants with chronic low back pain from the US	Oral D-cycloserine, 20	Oral placebo, 21	NRS (0-10)	None
Antibody injection					
Dakin, 2021(36)	563 participants with chronic low back pain from the US, Canada and Europe	Subcutaneous or IV fasinumab, 422	Placebo injection, 141	NRS (0-10)	Regeneron Pharmaceuticals and Teva Pharmaceutical Industries
Katz, 2011(37)	129 participants with chronic low back pain from the US	IV Tanezumab, 88	IV Placebo, 41	NRS (0-10)	Pfizer
Kivitz, 2013(38)	1052 participants with chronic low back pain from the US	IV Tanezumab, 822	Oral Placebo, 230	Pain intensity rating (0-10)	Pfizer
Markman, 2020(39)	1223 participants with chronic low back pain from the US	Subcutaneous injections Tanezumab, 815	Subcutaneous injections Placebo, 409	Low back pain intensity (0-10)	Pfizer, Eli Lilly and Company
Sanga, 2016(40)	389 participants with chronic low back pain from the US, Canada and Belgium	Subcutaneous injections Fulranumab, 311	Subcutaneous injections Placebo, 78	NRS (0-10)	Janssen Research &Development LLC.
Anticonvulsants					
Atkinson, 2016(41)	108 participants with chronic low back pain from the US	Oral Gabapentin, 55	Oral placebo, 53	NRS (0-10)	United States Department of Veterans Affairs, Office of Research and Development
Mathieson, 2017(42)	209 participants with mixed duration low back pain from Australia	Oral Pregablin, 108	Oral placebo, 101	NRS (0-10)	National Health and Medical Research Council of Australia grant (ID APP1042073)

Muehlbacher, 2006(43)	96 participants with chronic low back pain from Austria	Oral Topiramate, 48	Oral placebo, 48	McGill Pain Questionnaire	None
Antidepressants					
Atkinson, 1998(44)	78 participants with chronic low back pain from the US	Oral Nortriptyline, 38	Oral placebo, 40	DDS pain scale	The United States Department of Veterans Affairs, and by the National Institutes of Health Grant MO1-RR00827
Atkinson, 1999(45)	103 participants with chronic low back pain from the US	Oral Maprotiline, 33 Oral Paroxetine, 34	Oral placebo, 36	DDS pain scale	The United States Department of Veterans Affairs, and by the National Institutes of Health Grant MO1-RR00827
Dickens, 2000(46)	92 participants with chronic low back pain from the UK	Oral Paroxetine, 44	Oral placebo, 48	VAS (0-100)	SmithKline Beecham
Goodkin, 1990(47)	44 participants with chronic low back pain from the US	Oral Paroxetine, 22	Oral placebo, 22	VAS (0-10)	NIH grants MH18764 and MH16744 and NIMH Mental health Clinical Research Center grant MH41115, a grant from Procter & Gamble Company, a grant from the Stanford University Health Sciences Research and Development Fund, and a grant from the Western Research and Development Office of the Veterans Administration
Gould, 2020(48)	71 participants with chronic low back pain from the US	Oral Desipramine, 38	Oral placebo, 33	DDS pain scale	The Office of Research and Development, Clinical Sciences Research and Development, Department of Veterans Affairs
Katz, 2005(49)	54 participants with chronic low back pain from the US	Oral Bupropion, 26	Oral placebo, 28	NRS (0-10)	GlaxoSmithKline to R.H.D., who has also received research support, consulting fees, or lecture honoraria in the past year from Abbott Laboratories, Eli Lilly & Co., Endo Pharmaceuticals, EpiCept Corporation, NeurogesX,

					Novartis Pharmaceuticals, Organon, Ortho-McNeil Pharmaceutical, Pfizer, Purdue Pharma, Ranbaxy Corporation, Reliant
Konno, 2016(50)	458 participants with chronic low back pain from Japan	Oral Duloxetine, 232	Oral placebo, 226	BPI (0-10)	Shionogi & Co. Ltd., Eli Lilly Japan K.K., and Eli Lilly and Company
Skljarevski, 2009(51)	404 participants with chronic low back pain from the US	Oral Duloxetine, 287	Oral placebo, 117	BPI (0-10)	Eli Lilly and Company. Authors V. Skljarevski, M. Ossanna, H. Liu-Seifert, Q. Zhang, A. Chappell, S. Iyengar and M. Detke are or were at the time of submission employees of Eli Lilly and Company and may be minor shareholders
Skljarevski, 2010(52)	401 participants with chronic low back pain from the US	Oral Duloxetine, 198	Oral placebo, 203	BPI (0-10)	Eli Lilly and Company
Urquhart, 2018(53)	146 participants with chronic low back pain from Australia	Oral amitriptyline, 72	Oral active placebo, 74	VAS (0-100)	National Health and Medical Research Council (ID 1024401). Drs Urquhart, Wluka, and Wang are recipients of NHMRC Career Development Fellowships (Clinical Level 1 No. 1011975; Clinical Level 2 No. 1063574; Clinical Level 1 No. 1065464, respectively).
Antidepressant + paracetamol					
Kurniawati, 2020(54)	63 participants with chronic low back pain from Indonesia	Oral Amitriptyline + Acetaminophen, 33	Oral placebo + Acetaminophen, 30	VAS (0-10)	None
Bee Venom					
Seo, 2017(55)	54 participants with chronic low back pain from South Korea	Subcutaneous Bee Venom injections + NSAID (loxonin) + self-administration exercise education program, 27	Subcutaneous placebo injections + NSAID (loxonin) + self-administration exercise education program, 27	VAS (0-10)	Korea Institute of Oriental Medicine (K17121) and Spine Center of Kyung Hee University Hospital at Gang-Dong

Behavioural/educational					
Ashar, 2022(56)	101 participants with chronic low back pain from the US	Pain reprocessing therapy, 50	Subcutaneous open-label placebo injection, 51	BPI (0-10)	National Institutes of Health grants R01 DA035484 (Dr Wager), R01 MH076136 (Dr Wager), National Center for Advancing Translational Sciences grant TL1-TR-002386 (Dr Ashar), Radiological Society of North America (Dr Flood), German Research Foundation grant GE 2774/1-1 (Dr Geuter), the Psychophysiologic Disorders Association, the Foundation for the Study of the Therapeutic Encounter, and community donations
Bergquist-Ullman, 1977(57)	147 participants with acute low back pain from Sweeden	Back school, 72	Low intensity short-wave diathermy, 75	Pain index (0-70)	The Swedish Work Environment Fund & AB Volvo
Chenard, 1991(58)	26 participants with chronic low back pain from France	Back school, 14	Detuned TENS, 12	VAS (0-100)	La presente recherche a ete supportee par une subvention du fonds pour la formation des chercheurs et l'aide a la recherche du Gouvernement du Quebec (FCAR: EQ-3030)
Garcia, 2021(59)	188 participants with chronic low back pain from the US	Virtual reality pain relief skills program, 94	Sham virtual reality, 94	NRS (0-10)	AppliedVR, Inc
Oliveira, 2022(60)	160 participants with chronic low back pain from Brazil	Physical activity coaching, 80	Attentional control (active listening without providing therapeutic advice), 80	NRS (0-10)	The São Paulo Research Foundation (FAPESP; Grant 2014/14077-8) and the National Council for Scientific and Technological Development (CNPQ; Grant 408712/2016-3). CB Oliveira received a scholarship (Grant 2016/03826-5) from FAPESP, Brazil. CG Maher and A Tiedemann hold research fellowships funded by Australia's National Health and Medical Research Council.

Nicholas, 1992(61)	20 participants with chronic low back pain from Australia	Cognitive behavioural and relaxation therapy + physiotherapy, 10	Group discussion + physiotherapy, 10	Pain rating (0-5)	None
Pengel, 2007(62)	131 participants with acute low back pain from Australia and New Zealand	Advice and sham exercise, 63	Sham advice and sham exercise, 68	NRS (0-10)	National Health and Medical Research Council of Australia and the Australasian Low Back Pain Trial Committee
Snook, 1998(63)	85 participants with chronic low back pain from the US	Prevention of morning flexion, 42	"Ineffective" exercise, 43	NRS (0-10)	Liberty Mutual Insurance Company
Stuckey, 1986(64)	16 participants with chronic low back pain from the US	Relaxation training, 8	Encouragement to relax, 8	NRS (0-100)	Doctors Education and Research Fund at Orthopaedic Hospital, and the assistance of the late Homer C. Pheasant, M.D.. Director of the Adult Back Clinic.
Traeger, 2019(65)	202 participants with acute low back pain from Australia	Pain education, 101	Placebo education, 101	NRS (0-10)	The Australian National Health and Medical Research Council funded this trial (project identification number: 1047827), which was investigator initiated (chief investigator, Prof McAuley; coinvestigators, Dr Henschke and Prof Nicholas, Moseley, Main, Blyth, and Refshauge). Dr Traeger, Dr Lee, and Prof Moseley were supported by National Health and Medical Research Council research fellowships.
Biofeedback					
Kapitza, 2010(66)	42 participants with chronic low back pain from Germany	Contingent respiratory biofeedback, 21	Non contingent respiratory biofeedback, 21	VAS (0-10)	None
Kent, 2015(67)	112 participants with chronic low back pain from Australia	Motion-sensor biofeedback + usual care, 58	Placebo biofeedback + usual care, 54	VAS (0-100)	The Department of Business and Innovation (Market Validation Program), Victorian Government, Australia, and (ii) dorsaVi P/L (the

					Australian company who manufactures the ViMove motion-sensor system used in this study)
Krafft, 2017(68)	33 participants with chronic low back pain from Germany	Biofeedback, 18	Sham biofeedback, 15	NRS (0-10)	The Else Kroner-Fresenius-Stiftung € 2012_A197 to R.R., and the Graduate School of Systemic Neurosciences and the German Research Association (DFG) via the RTG 2175 "Perception in context and its Neural Basis", both Ludwig-Maximilians University Munich
Ryan, 2014(69)	30 participants with chronic low back pain from the UK	Tactile acuity stimulation, 15	Sham tactile acuity stimulation, 15	VAS (0-100)	University Research Fund Grant from Teesside University
Stuckey, 1986(64)	16 participants with chronic low back pain from the US	EMG biofeedback training, 8	Encouragement to relax, 8	NRS (0-100)	Doctors Education and Research Fund at Orthopaedic Hospital, and the assistance of the late Homer C. Pheasant, M.D.. Director of the Adult Back Clinic
Bisphosphonates					
Koivisto, 2014(70)	40 participants with chronic low back pain from Finland	IV Zoledronic acid injection, 20	IV placebo injection, 20	VAS (0-100)	Novartis Pharma
Shea, 2022(71)	25 participants with chronic low back pain from China	Oral Zoledronic acid, 13	Oral placebo, 12	NRS (0-10)	The Health and Medical Research Fund of Hong Kong
Bushen Huoxue Formula					
Zhan, 2022(72)	70 participants with chronic low back pain from China	Oral Bushen huoxue formula, 35	Oral placebo formula, 35	VAS (0-10)	National Natural Science Foundation of China (No. 81930118), Central Public Welfare Research Institutes (No. ZZ13-YQ-038), Innovation Team and Talents Cultivation Program of National Administration of Traditional Chinese Medicine (No. ZYYCXTD-C-202003),

					and National Key R & D Program of China (No. 2021YFC1712800)
Cannabinoids					
Bebee, 2021(73)	100 participants with acute low back pain from Australia	Oral Cannabidiol (CBD), 50	Oral placebo, 50	VRS (0-10)	The Robert C. Bulley Charitable Fund and the Austin Medical Research Foundation. Anselm Wong holds a National Health and Medical Research Council fellowship (1159907)
Colchicine					
Schnebel, 1988(74)	27 participants with chronic low back pain from the US	Oral colchicine, 15	Oral placebo, 12	VAS (0-10)	None
Complementary medicines					
Chiu, 2011(75)	60 participants with chronic low back pain from Malaysia	IM methylocobalamin injections, 33	IM placebo injection, 27	VAS (0-100)	International Medical University, Seremban, Malaysia
Chrubasik, 1999(76)	197 participants with chronic low back pain from Germany	Oral Harpagophytum WS 1531, 131	Oral placebo, 66	Arhus pain index (0-60)	Not reported
Chrubasik, 2000(77)	210 participants with chronic low back pain from Germany	Oral Salicin, 140	Oral placebo, 70	Arhus pain index (0-60)	The European Academy of Natural Medicine/Bad Schwalbach and by Plantina GmbH/Munich
Dzik, 2018(78)	24 participants with chronic low back pain from Poland	Oral Vitamin D, 14	Oral placebo, 10	VAS (0-100)	NCN UMO-2012/05/B/NZ7/02493
Mauro, 2000(79)	60 participants with chronic low back pain from Italy	IM Vitamin B12 injections, 30	IM placebo injections, 30	VAS (0-100)	None
Pach, 2011(80)	89 participants with chronic low back pain from the US	Subcutaneous Toxicodendron injections, 41	Subcutaneous placebo injections, 48	VAS (0-100)	WALA Heilmittel GmbH
Prakash, 2023(81)	55 participants with chronic low back pain from India	Individualized homeopathic medicines, 28	Matching placebo, 27	VAS (0-10)	None

Qin, 2022(82)	108 participants with chronic low back pain from China	Oral Jianyao Migu granules, 54	Oral placebo, 54	VAS (0-10)	The Shanghai Shenkang Hospital Development Project (16CR3074B), Longhua HospitalMinhang TCM Specialty Alliance construction project (2021-2023, LM03 Traditional Chinese Orthopedics &Traumatology), and the The fifth batch of dragon Medicine of Longhua Hospital affiliated to Shanghai University of Traditional Chinese Medicine (KC2022006)
Sandoughi, 2015(83)	53 participants with chronic low back pain from Iran	Oral Vitamin D + advice to exercise, 26	Oral placebo + advice to exercise, 27	VAS (0-10)	Not reported
Schrader, 1999(84)	60 participants with chronic low back pain from the US	Oral Magnesium oxide, 30	Oral placebo, 30	Likert pain scale (0-10)	The Uniformed Services University of the Health Sciences Protocol Number T06177-01
Shirzad-Siboni, 2022(85)	60 participants with mixed duration low back pain from Iran	Topical chamomile oil, 30	Topical placebo (paraffin oil), 30	BPI (0-10)	None
Wilkens, 2010(86)	250 participants with chronic low back pain from Norway	Oral Glucosamine sulfate, 125	Oral placebo, 125	NRS (0-10)	The Norwegian Foundation for Health and Rehabilitation through the Norwegian Low Back Pain Association, Norwegian Chiropractic Associations Research Fund, and Wilhelmsens Research Fund
Diathermy					
Amaral, 2023(87)	36 participants with chronic low back pain from Brazil	Short wave diathermy, 18	Detuned short wave diathermy, 18	McGill Pain Questionnaire	The Coordination for the Improvement of Higher Education Personnel - Brazil (CAPES; Finance Code 001)
Gibson, 1985(88)	68 participants with chronic low back pain from the UK	Short wave diathermy, 34	Detuned short wave diathermy, 34	VAS (0-100)	The Arthritis and Rheumatism Council
Karasel, 2021(89)	90 participants with chronic low back pain from Cyprus	Short wave diathermy, 60	Detuned short wave diathermy, 30	VAS (0-10)	None

Ku, 2018(90)	56 participants with chronic low back pain from Korea	Radiofrequency thermal stimulation + cupping, 28	Detuned radiofrequency thermal stimulation + cupping, 28	VAS (0-100)	Korean Institute of Medicine and Technology Innovation Program
Shakoor, 2008(91)	114 participants with chronic low back pain from Bangledesh	Short wave diathermy + NSAID + exercise	Detuned short wave diathermy + NSAID + exercise	VAS (0-100)	University Grants Commission
Dry cupping					
Almeida Silva, 2021(92)	90 participants with chronic low back pain from Brazil	Dry cupping, 45	Sham cupping, 45	NRS (0-10)	The Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), Master's degree scholarship, Financial code 001. Dr Bruno T Saragiotto is supported by the Sao Paulo Research Foundation (FAPESP).
De Melo Salemi, 2021(93)	38 participants with chronic low back pain from Brazil	Dry cupping, 19	Sham cupping, 19	VAS (0-10)	None
Electroacupuncture					
Leite, 2018(94)	43 participants with chronic low back pain from Brazil	Electroacupuncture, 21	Detuned electroacupuncture, 22	NRS (0-10)	Apoio a projetos de Pesquisa/Chamada MCTI/CNPq/MSSCTIE-Decit N∘ 07/2013-Pol´ıtica Nacional de Praticas Inte- ´grativas e Complementares (PICS) no Sistema Unico de ´Saude
Sator-Katzenschlager, 2004(95)	61 participants with chronic low back pain from Austria	Auricular electroacupuncture, 31	Detuned auricular electroacupuncture, 30	VAS (0-10)	None
Topuz, 2004(96)	30 participants with chronic low back pain from Turkey	Percutaneous neuromodulation therapy, 15	Detuned TENS, 15	VAS (0-10)	None
Torres, 2023(97)	100 participants with chronic low back pain from Brazil	Electroacupuncture, 75	Detuned electroacupuncture, 25	NRS (0-10)	The Coordination for the Improvement of Higher Education Personnel - Brazil (CAPES) - Finance Code 001.
Weiner, 2003(98)	34 participants with chronic low back pain from the US	Percutaneous electrical nerve stimulation + physiotherapy, 17	Detuned percutaneous electrical nerve stimulation + physiotherapy, 17	McGill Pain Questionnaire	USPHS Research Grants P60AR44811 and R01AG18299 from the National Institutes of Health
Electromagnetic					

Alzayed, 2020(99)	42 participants with chronic low back pain from Saudi Arabia	Pulsed electromagnetic field therapy + exercise, 20	Sham pulsed electromagnetic field therapy + exercise, 22	NRS (0-10)	Not reported
Elshiwi, 2019(100)	50 participants with chronic low back pain from Egypt	Pulsed electromagnetic field therapy, 25	Sham pulsed electromagnetic field therapy, 25	VAS (0-10)	None
Gyulai, 2015(101)	50 participants with chronic low back pain from Hungary	Bio-electro-magnetic-energy-restoration therapy + physiotherapy, 25	Sham bio-electro-magnetic-energy-restoration therapy + physiotherapy, 25	VAS (0-10)	Devices were made available by BEMER Medical Technic Ltd. for the completion of the study which subsequently were donated to the hospital
Harden, 2007(102)	40 participants with chronic low back pain from the US	Therapeutic electromagnetic fields, 20	Sham therapeutic electromagnetic fields, 20	VAS (0-100)	Not reported
Lee, 2006(103)	40 participants with chronic low back pain from South Korea	Pulsed electromagnetic field therapy, 20	Detuned pulsed electromagnetic field therapy, 20	NRS (0-10)	Not reported
Lisi, 2019(104)	42 participants with chronic low back pain from the US	Pulsed electromagnetic field therapy, 19	Detuned pulsed electromagnetic field therapy, 23	NRS (0-10)	Aerotel Ltd
Masse-Alarie, 2017(105)	21 participants with chronic low back pain from Canada	Repetitive peripheral magnetic stimulation + motor training, 11	Detuned repetitive peripheral magnetic stimulation + motor training, 10	VAS (0-100)	Canadian Foundation for Innovation (CFI, CS equipment), the Fonds de Recherche du Québec – Santé (FRQS, Province of Quebec, Canada – HMA and LDB PhD studentships) and the Canadian Institutes for Health Research (CIHR, HMA studentship)
Wachi, 2022(106)	30 participants with chronic low back pain from Japan	Capacitive and resistive electric transfer therapy, 15	Detuned capacitive and resistive electric transfer, 15	VAS (0-10)	None
Endogenous steroids					
Naylor, 2020(107)	100 participants with chronic low back pain from the US	Oral Pregnenolone, 48	Oral placebo, 52	NRS (0-10)	Department of Veterans Affairs (VA) Rehabilitation Research and Development Career Development Award (1lK2RX000908 to Dr Naylor),

					a VA Career Development Transition Award (Dr Marx), VA Merit Review Awards (Dr Marx), and the VA Mid-Atlantic Mental Illness Research Education and Clinical Center
Exercise					
Almhdawi, 2020(108)	41 participants with chronic low back pain from Jordan	Smartphone exercise and advice application, 21	Smartphone application without exercise or low back pain related advice, 20	VAS (0-10)	Jordan University of Science and Technology (Grant #20180429) and European Union)
Costa, 2009(109)	154 participants with chronic low back pain from Australia	Motor control exercise, 77	Detuned ultrasound, 77	NRS (0-10)	University of Sydney research grant
Faas, 1993(110)	318 participants with acute low back pain from the Netherlands	Exercise, 156	Ultrasound (lowest possible dose), 162	VAS (0-85)	Praeventie Fonds
Garcia, 2018(111)	148 participants with chronic low back pain from Brazil	McKenzie exercise, 74	Detuned ultrasound, 74	NRS (0-10)	Sao Paulo Research Foundation
Geisser, 2005(112)	51 participants with chronic low back pain from the US	Specific exercise + sham muscle energy technique, 26	Non-specific exercise + sham muscle energy technique, 25	VAS (0-10)	National Center for Medical Rehabilitation Research, National Institute of Child and Human Development, and the National Institutes of Health grant (R03-HD35893)
Goldby, 2006(113)	213 participants with chronic low back pain from the UK	Spinal stabilisation exercise + back school, 84 Manual procedures + exercise excluding spinal stabilisation + back school, 89	Educational booklet + back school, 40	NRS (0-100)	Professional organizational funds (not specified)
Hansen, 1993(114)	180 participants with mixed duration low back pain from Denmark	Intensive muscle training, 60 Pragmatic physiotherapy, 59	Semi hot pack + traction with 10% body weight, 61	Pain scale (0-9)	None

Pengel 2007	133 participants with acute low back pain from Australia and New Zealand	Individualised exercise + sham advice, 65	Sham exercise + sham advice, 68	NRS (0-10)	The National Health and Medical Research Council of Australia and the Australasian Low Back Pain Trial Committee
Preyde, 2000(115)	48 participants with mixed duration low back pain from Canada	Remedial exercise with posture education, 22	Sham laser therapy, 26	McGill Pain Questionnaire	The College of Massage Therapists of Ontario (CMTO)
Spratt, 1993(116)	56 participants with chronic low back pain from the US	Bracing/extension exercise, 18 Bracing/flexion exercises, 21	Abdominal wrap + general advice to walk, 17	VAS (0-10)	NIH grant #AR 34344-03 and Camp International, Inc (J. Weinstein, principle investigator).
Xu, 2021(117)	44 participants with chronic low back pain from China	Pressure biofeedback exercises for transverse abdominis, 29	Sham biofeedback exercise, 15	McGill Pain Questionnaire	National Key R&D Program of China (2018YFC1314700), Fok Ying-Tong Education Foundation of China (fund number: 161092), the Scientific and Technological Research Program of the Shanghai Science and Technology Committee (fund number: 19080503100), and the Shanghai Key Lab of Human Performance (Shanghai University of Sport, fund number: 11DZ2261100)
Extracorporeal shockwave					
Çelik, 2020(118)	50 participants with chronic low back pain from Turkey	Extracorporeal shockwave therapy, 25	Placebo extracorporeal shockwave therapy, 25	NRS (0-10)	None
Lange, 2021(119)	63 participants with acute low back pain from Germany	Radial extracorporeal shockwave therapy, 32	Placebo radial extracorporeal shockwave therapy, 31	VAS (0-100)	None
Moon, 2017(120)	30 participants with chronic low back pain from South Korea	Extracorporeal shockwave therapy, 15	Sham extracorporeal shockwave therapy, 15	NRS (0-10)	Soonchunhyang University Research Fund
Rajfur, 2022(121)	40 participants with chronic low back pain from Polan	Focused extracorporeal shockwave therapy, 20	Sham focused extracorporeal shockwave therapy, 20	VAS (0-10)	The University of Opole in Poland and the Academy of Physical Education in Katowice subventions according to the

					number of FIZ/3/2022. Also supported by the Ministry of Health subventions according to the number of SUBZ.E060.22.099 from the IT Simple system of the Wrocław Medical University in Poland.
Taheri, 2021(122)	38 participants with chronic low back pain from Iran	Extracorporeal shockwave therapy, 19	Sham extracorporeal shockwave therapy, 19	VAS (0-10)	School of Medicine, Isfahan University of Medical Sciences through grant No 395978
Walewicz, 2019(123)	40 participants with chronic low back pain from Poland	Radial extracorporeal shockwave therapy, 20	Sham Radial extracorporeal shockwave therapy, 20	VAS (0-10)	The Ministry of Science and Higher Education in Poland as a statutory research grant of the Opole Medical School (no. WPBWF1/18) and the Wroclaw Medical University (no. STM.E025.17.018)
Foot orthotics					
Castro-Mendez, 2013(124)	60 participants with chronic low back pain from Spain	Foot orthotic, 30	Sham foot orthotic, 30	VAS (0-100)	None
Glucocorticoid injections					
Friedman, 2006(125)	87 participants with acute low back pain from the US	IM Methylpredinosolone acetate injection, 44	IM placebo injection, 43	NRS (0-10)	None
Gastaldi, 2019(126)	34 participants with acute low back pain from France	IV Methylpredinosolone injection, 17	IV placebo injection, 17	VAS (0-100)	Direction de la Recherche Clinique et de l'innovation of CHU Grenoble Alpes
Heat					
Nadler, 2003(127)	191 participants with acute low back pain from the US	Wearable heatwrap, 95	Oral placebo, 96	Pain relief (0-5)	Procter & Gamble Co
Nadler, 2003(128)	67 participants with acute low back pain from the US	Wearable heatwrap, 33	Oral placebo, 34	NRS (0-100)	Procter & Gamble Co
Hypnotic					

Goforth, 2014(129)	52 participants with chronic low back pain from the US	Oral Eszopiclone, 32	Oral placebo, 20	VAS (0-100)	Sunovion Corporation (then Sepracor Corporation)
Immunoglobulin					
Ginsberg, 1987(130)	44 participants with acute low back pain from Belgium	Intradermal immunoglobulin injection, 22	Intradermal placebo injection, 22	NRS (0-5)	Not reported
Infrared					
Gale, 2006(131)	39 participants with chronic low back pain from Canada	Infrared radiation wrap, 21	Sham wrap, 18	NRS (0-10)	MSCT Infrared Wraps Inc for provided the IR wraps
Ricci, 2022(132)	54 participants with chronic low back pain from Italy	Far infrared technology (FIT) therapy patches, 36	Sham patches, 18	VAS (0-10)	The plasters were given for free by the D.Fensec srl to test them on selected patients
Siems, 2010(133)	43 participants with mixed duration low back pain from Germany	Infrared radiation, 32	Placebo infrared radiation, 11	VAS (0-10)	None
Interferential					
Almeida, 2022(134)	63 participants with chronic low back pain from Brazil	Interferential current therapy, 42	Sham, interferential current therapy, 21	NRS (0-10)	None
Corrêa, 2016(135)	150 participants with chronic low back pain from Brazil	Interferential current therapy, 100	Placebo interferential current therapy, 50	Verbal NRS (0-10)	The Fundac ~ao de Amparo a Pesquisa do Estado de S~ao Paulo - FAPESP, Brazil funding approval number: 2012/13910-2 and the Conselho Nacional de Desenvolvimento Cientıfico e Tecnologico – CNPq (funding approval number: 473929/2012-0
Dias, 2021(136)	175 participants with chronic low back pain from Brazil	Interferential current therapy, 140	Placebo interferential current therapy, 35	NRS (0-10)	None

Espejo-Antunez, 2021(137)	49 participants with chronic low back pain from Spain	Interferential current therapy, 25	Sham interferential current therapy, 24	NRS (0-10)	None
Franco, 2017(138)	148 participants with chronic low back pain from Brazil	Interferential current therapy + pilates, 74	Sham interferential current therapy + pilates, 74	NRS (0-10)	São Paulo Research Foundation (FAPESP - 2013/17303-6)
Fuentes, 2014(139)	59 participants with chronic low back pain from Canada	Interferential current therapy, 30	Sham interferential current therapy, 29	NRS (0-10)	The Physiotherapy Foundation of Canada (PFC) through the Ortho Canada Research Award and the Department of Physical Therapy, University of Alberta, through the Thesis Research Operating Grant Program. Mr Fuentes is supported by the University of Alberta through the Dissertation Fellowship Award.
Kibar, 2020(140)	63 participants with chronic low back pain from Turkey	Interferential current therapy, 33	Sham interferential current therapy + sham TENS, 29	VAS (0-100)	None
Laser and light					
Abdelbasset, 2020(141)	36 participants with chronic low back pain from Saudi Arabia	High intensity laser therapy, 18	Sham laser therapy, 18	VAS (0-10)	The deanship of Scientific Research at Princess Nourah Bint Abdulrahman University through the Fast-track Research Funding Program
Alayat, 2014(142)	52 participants with chronic low back pain from Saudi Arabia	High intensity laser therapy + exercise, 28	Sham laser therapy + exercise, 24	VAS (0-10)	None
Ay, 2010(143)	80 participants with acute and chronic low back pain from Turkey	Low intensity laser therapy + heat pack, 40	Placebo laser therapy + heat pack, 40	VAS (0-10)	None
Basford, 1999(144)	63 participants with mixed duration low back pain from the US	Nd:YAG laser therapy, 32	Detuned Nd:YAG laser therapy, 31	VAS (0-100)	Supported by LaserBiotherapy, Inc., Dallas, TX
Cho, 2020(145)	37 participants with chronic low back pain from South Korea	Portable low intensity laser therapy, 19	Placebo low intensity laser therapy, 18	VAS (0-10)	Ministry of Health & Welfare, Republic of Korea (grant number: HI16C2319)

Djavid, 2007(146)	40 participants with chronic low back pain from Iran	Laser therapy, 20	Detuned laser therapy, 20	VAS (0-10)	None
Glazov, 2009(147)	100 participants with chronic low back pain from Australia	Laser acupuncture, 50	Detuned laser acupuncture, 50	VAS (0-10)	Australian Medical Acupuncture College
Glazov, 2014(148)	144 participants with chronic low back pain from Australia	Laser acupuncture, 96	Detuned laser acupuncture, 48	VAS (0-10)	Commonwealth Government of Australia; PHCRED bursary awarded in 2008
Guimarães, 2021(149)	148 participants with chronic low back pain from Brazil	Photobiomodulation therapy, 74	Detuned photobiomodulation therapy, 74	NRS (0-10)	Sao Paulo Research Foundation (FAPESP), postdoctoral scholarship of Shaiane Silva Tomazoni Grant #2016/10265-0. This study was financed in part by the Coordenac¸ao de Aperfeic¸oamento de Pessoal de N´ıvel Superior—Brasil (CAPES)—Finance Code 001, PhD, scholarship of Layana de Souza Guimaraes.
Hsieh, 2014(150)	70 participants with chronic low back pain from Taiwan	Light therapy, 35	Detuned light therapy, 35	VAS (0-100)	Shin Kong Wu Ho-Su Memorial Hospital (SKH-8302-99-DR-41) and the National Science Council, Taiwan (NSC 99–2628-B-002-061-MY3)
Kholoosy, 2022(151)	40 participants with chronic low back pain from Iran	Low level light therapy, 20	Placebo light therapy, 20	VAS (0-10)	PTE (Eshragh engineering group) company
Kim, 2022(152)	35 participants with chronic low back pain from South Korea	Laser acupuncture, 30	Detuned laser acupuncture, 15	VAS (0-10)	The Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HF21C0044)
Klein, 1990(153)	20 participants with chronic low back pain from the US	Low energy laser therapy, 10	Detuned laser therapy, 10	VAS (0-7.5)	Santa Barbara Cottage Hospital and Sansum Medical Research Foundation

Leichtfried, 2014(154)	85 participants with chronic low back pain from Austria	Bright light therapy + usual treatment, 43	Sham light therapy + usual treatment, 42	BPI (0-10)	The lighting network "K-Licht," Aldrans, Austria
Lin, 2012(155)	57 participants with chronic low back pain from Taiwan	Laser acupuncture + soft cupping, 28	Detuned laser acupuncture + soft cupping, 29	VAS (0-10)	Department of Health, Taipei City Government (099XDAA00076). United Integrated Services Co., Ltd for instruments support.
Lin, 2017(156)	40 participants with chronic low back pain from Taiwan	Laser acupuncture + cupping, 20	Detuned laser acupuncture + cupping, 20	VAS (0-10)	Not reported
Nardin, 2022(157)	40 participants with chronic low back pain from Brazil	Photobiomodulation therapy, 20	Detuned photobiomodulation therapy, 20	VAS (0-10)	None
Panah, 2021(158)	45 participants with acute low back pain from Iran	Low level laser therapy, 30	Detuned laser therapy, 15	VAS (0-10)	Not reported
Ruth, 2010(159)	102 participants with chronic low back pain from Germany	Laser acupuncture, 51	Detuned laser acupuncture, 51	VAS (0-11)	None
Shin, 2015(160)	56 participants with chronic low back pain from South Korea	Laser acupuncture, 28	Detuned laser acupuncture, 28	VAS (0-100)	Korea Institute of Oriental Medicine (Grants nos. K15121 and K15020) and the Technology Innovation Program (Grant no. 10028438, D12081) funded by the Ministry of Trade, Industry & Energy (MI, Korea)
Tomazoni, 2021(161)	18 participants with chronic low back pain from Brazil	Photobiomodulation therapy, 9	Detuned photobiomodulation, 9	NRS (0-10)	Ernesto Cesar Pinto Leal-Junior receives research support from Multi Radiance Medical (Solon - OH, USA), a laser device manufacturer. Shaiane S. Tomazoni has a personal relationship with Ernesto Cesar Pinto Leal-Junior.
Massage					
Arguisuelas, 2017(162)	54 participants with chronic low back pain from Spain	Myofascial release, 27	Sham myofascial release involving gently placing the hands over the back without	VAS (0-100)	None

			sliding, just enough to maintain contact for the desired time, 27		
Borges, 2014(163)	30 participants with chronic low back pain from Brazil	Massage by acupressure, 15	Detuned laser therapy, 15	NRS (0-10)	Not reported
Farasyn, 2006(164)	40 participants with acute low back pain from Belgium	Roptrotherapy, 20	LPG endermologie, 20	VAS (0-100)	None
Mazreati, 2021(165)	60 participants with chronic low back pain from Iran	Craniosacral therapy, 30	Placebo craniosacral therapy involving light touch, 30	McGill Pain Questionnaire	Kashan University of medical sciences supported this study grant no. 96226
Preyde, 2000(115)	51 participants with mixed duration low back pain from Canada	Soft-tissue manipulation, 25	Detuned laser therapy, 26	McGill Pain Questionnaire	The College of Massage Therapists of Ontario
Siglan, 2023(166)	46 participants with chronic low back pain from Turkey	Myofascial release, 23	Sham myofascial release involving light touch without exerting pressure, lift or traction, 23	NRS (0-10)	None
Mobilisation					
Buran Çirak, 2021(167)	30 participants with chronic low back pain from Turkey	Sustained natural apophyseal glides, 15	Sham sustained natural apophyseal glides involving similar positioning without intervention to the spine, 15	VAS (0-10)	None
Degenhardt, 2017(168)	26 participants with chronic low back pain from the US	Muscle energy technique, 13	Detuned ultrasound, 13	NRS (0-10)	American Osteopathic Association grant, #06-04-550
Dougherty, 2014(169)	136 participants with chronic low back pain from the US, Canada and Europe	Mobilisation, 69	Detuned ultrasound, 67	VAS (0-100)	None
Eardley, 2013(170)	45 participants with chronic low back pain from the UK	Professional kinesiology practice, 24	Sham kinesiology involving a polite conversation, 21	VAS (0-100)	Rufford Maruice Laing Foundation

Geisser, 2005(112)	100 participants with chronic low back pain from the US	Muscle energy technique + non-specific exercise 24 Muscle energy technique + specific exercise, 25	Sham muscle energy technique + non-specific exercise 24 Sham muscle energy technique + specific exercise, 25	VAS (0-10)	The National Center for Medical Rehabilitation Research, National Institute of Child and Human Development, and the National Institutes of Health grant (R03-HD35893)
González, 2021(171)	54 participants with acute low back pain from Spain	Neural mobilisation, 28	Sham neural mobilisation, 26	VAS (0-10)	None
Goodsell, 2000(172)	26 participants with mixed duration low back pain from Australia	Posteroanterior mobilisation, 12	Sham mobilisation involving lying prone, 14	VAS (0-100)	None
Hall, 2006(173)	24 participants with mixed duration low back pain from Australia	Mulligan bent leg raise technique, 12	Placebo Mulligan bent leg raise involving soft tissue manipulation of the foot, 12	VAS (0-10)	None
Hidalgo, 2015(174)	32 participants with chronic low back pain from Belgium	Sustained natural apophyseal glides, 16	Sham sustained natural apophyseal glides, 16	VAS (0-100)	None
Hussein, 2021(175)	64 participants with chronic low back pain from Egypt	Sustained natural apophyseal glides, 32	Sham sustained natural apophyseal glides involving light touch and without force, 32	VAS (0-10)	Not reported
Kogure, 2015(176)	186 participants with chronic low back pain from the US	AKA-H method, 93	Sham AKA-H method without sacroiliac joint movement, 93	VAS (0-100)	None
Konstantinou, 2007(177)	26 participants with chronic low back pain from the UK (cross-over trial)	Mobilisations with movement, 26	Sham mobilisations involving static lying, 26	VAS (0-10)	State Scholarships Foundation (IKY), Republic of Greece, and the Chartered Society of Physiotherapy Charitable Trust Fund
Krekoukias, 2021(178)	50 participants with chronic low back pain from Greece	Mobilisation, 25	Sham mobilisation, 25	NRS (0-10)	None

Martí-Salvador, 2018(179)	66 participants with chronic low back pain from Spain	Mobilisation, 33	Sham diaphragm intervention, 33	VAS (0-100)	CEU Cardenal Herrera University (grant no. INDI 16/35) and the Instituto de Salud Carlos III, Spain (grant no. PI12/02710)
Schäfer, 2005(180)	24 participants with acute low back pain from Germany	Mulligan bent leg raise technique, 12	Foot massage, 12	VAS (0-10)	None
Thomas, 2020(181)	108 participants with chronic low back pain from the US	Mobilisation, 54	Sham cold laser therapy, 54	NRS (0-10)	National Center for Complementary and Integrative Health of the NIH under award number R01AT006978
Wreje, 1992(182)	46 participants with acute low back pain from Sweden	Muscle energy mobilisation, 23	Gluteus Medius transverse friction, 23	VAS (0-10)	None
Yakut, 2022(183)	36 participants with chronic low back pain from Turkey	Sustained natural apophyseal glides, 19	Sham sustained natural apophyseal glides, 17	VAS (0-10)	None
Muscle relaxants					
Arbus, 1990(184)	49 participants with mixed duration low back pain from France	Oral tetrazepam, 25	Oral placebo, 24	NRS (1-5)	None
Baratta, 1982(185)	120 participants with acute low back pain from the US	Oral cyclobenzaprine, 60	Oral placebo, 60	VAS (0-10)	None
Berry, 1988(186)	112 participants with acute low back pain from the UK	Oral tizanidine, 59	Oral placebo, 53	VAS (0-100)	Sandoz Ltd, Basel
Chandanwale, 2011(187)	240 participants with acute low back pain from India	Oral eperisone hydrochloride, 120	Oral placebo, 120	VAS (0-100)	Eisai Pharmaceuticals India Pvt. Ltd
Dapas, 1985(188)	200 participants with acute low back pain from the US	Oral baclofen, 100	Oral placebo, 100	NRS (1-5)	CIBA-GEIGY Corp
Hoiriis, 2004(189)	106 participants with acute low back pain from the US	Oral cyclobenzaprine, carisoprodol and methocarbamol, 53	Oral placebo, 53	VAS (0-10)	Research Center of Life University

Ketenci, 2005(190)	97 participants with acute low back pain from Turkey	Oral thiocolchicoside, 38 Oral tizanidine, 32	Oral placebo, 27	VAS (0-10)	None
Ketenci, 2022(191)	292 participants with mixed duration low back pain from Turkey	Topical thiocolchicoside, 147	Topical placebo, 145	VAS (0-10)	Sponsor (not specified)
Marcel, 1990(192)	98 participants with acute low back pain from France	Oral thiocolchicoside, 49	Oral placebo, 49	VAS (0-100)	Not reported
Samsamshariat, 2021(193)	64 participants with acute low back pain from Iran	Oral methocarbamol, 32	Oral placebo, 32	VAS (0-10)	None
Schliessbach, 2017(194)	49 participants with chronic low back pain from Switzerland (cross-over trial)	Oral clobazam, 49	Oral active placebo, 49	NRS (0-10)	The Swiss National Science Foundation SNF in the context of the Special Program for University Medicine SPUM 33CM30_140339
Tüzun, 2003(195)	149 participants with acute low back pain from Turkey	IM thiocolchicoside injection, 77	IM placebo injection, 72	VAS (0-100)	None
Uberall, 2012	245 participants with chronic low back pain from Germany	Oral flupirtine, 123	Oral placebo, 122	NRS (0-10)	TEVA, Germany
Muscle relaxants + NSAIDs					
Berry, 1988(196)	105 participants with acute low back pain from the UK	Oral Tizanidine + ibuprofen, 51	Oral placebo, 54	VAS (0-100)	Sandoz Ltd, Basel
Brizzi, 2004(197)	18 participants with chronic low back pain from Italy	Hydroelectrophoresis prometazine + Sodium diclofenac + mesilate pridinole, 9	Hydroelectrophoresis placebo, 9	VAS (0-100)	None
NSAIDs					
Allegrini, 2009(198)	179 participants with mixed duration low back pain from Italy	Piroxicam patch, 60 Piroxicam cream, 60	Placebo patch, 59	VAS (0-100)	Sponsor (not specified) provided the treatment

Babej-Dölle, 1994(199)	172 participants with acute low back pain from Germany	IM diclofenac injection, 86	IM placebo injection, 86	VAS (0-100)	Hoechst AG, Frankfurl/Main, Germany
Birbara, 2003(200)	319 participants with chronic low back pain from the US	Oral etoricoxib, 210	Oral placebo, 109	VAS (0-100)	Merck & Co Inc, West Point, PA
Coats, 2004(201)	291 participants with chronic low back pain from the US	Oral valdecoxib, 148	Oral placebo, 148	VAS (0-100)	None
Dreiser, 2001(202)	532 participants with acute low back pain from France	Oral meloxican, 352	Oral placebo, 180	VAS (0-100)	Not reported
Dreiser, 2003(203)	372 participants with acute low back pain from France	Oral ibuprofen, 122 Oral diclofenac, 124	Oral placebo, 126	VAS (0-100)	Novartis Consumer Health SA, Nyon, Switzerland
Gastaldi, 2019(126)	36 participants with acute low back pain from France	IV ketoprofen injection, 19	IV placebo injection, 17	VAS (0-100)	The Direction de la Recherche Clinique et de l'innovation of CHU Grenoble Alpes
Gurrell, 2018(30)	148 participants with chronic low back pain from the US	Oral naproxen, 74	Oral placebo, 74	NRS (0-10)	Pfizer
Hancock, 2007(204)	120 participants with acute low back pain from Australia	Oral diclofenac + spinal manipulation, 60	Oral placebo + spinal manipulation, 60	NRS (0-10)	The Australia's National Health and Medical Research Council. The active diclofenac was donated by Alphapharm.
Herrmann, 2009(205)	164 participants with acute low back pain from Denmark	Oral lornoxicam, 53 Oral diclofenac, 55	Oral placebo, 56	VAS (0-100)	Nycomed Pharma Austria supplied study treatment and co-sponsored the study with Merckle GmbH, Ulm, Germany
Katz, 2003(206)	690 participants with chronic low back pain from the US	Oral rofecoxib, 462	Oral placebo, 228	VAS (0-100)	Corporate/Industry funds (not specified)
Katz, 2011(37)	129 participants with chronic low back pain from the US	Oral naproxen + IV placebo injection, 88	Oral placebo + IV placebo injection, 41	NRS (0-10)	Corporate/Industry funds (not specified)

Kivitz, 2013(38)	525 participants with chronic low back pain from the US	Oral naproxen, 295	Oral placebo, 230	NRS (0-10)	Pfizer
Pallay, 2004(207)	325 participants with chronic low back pain from the US	Placebo etoricoxib, 215	Oral placebo, 110	VAS (0-100)	Merck & Co., Inc.,West Point, PA, USA. K O'Brien, L Mucciola, CS Skalky, RA Petruschke, NR Bohidar, GP Geba are employees of Merck & Co., Inc. RM Pallay, W Seger, JL Adler, RE Ettlinger, EA Quaidoo, R Lipetz are clinical investigators whose investigational sites received funding for the conduct of the study from Merck & Co., Inc.
Serinken, 2016(208)	140 participants with acute low back pain from Turkey	Ketoprofen gel + IV dexketoprofen injection, 70	Placebo ketoprofen gel + IV dexketoprofen injection, 70	VAS (0-100)	None
Szpalski, 1994(209)	73 participants with acute low back pain from Belgium	IM tenoxicam injection and oral tenoxicam, 37	IM placebo injection and oral placebo, 36	VAS (0-10)	Not reported
Taguchi, 2023(210)	538 participants with chronic low back pain from Japan	Diclofenac patch, 271	Placebo patch, 267	VAS (0-100)	Hisamitsu Pharmaceutical Co., Inc., Tokyo, Japan
Von Heymann, 2013(211)	62 participants with acute low back pain from Germany	Oral diclofenac + sham spinal manipulation, 37	Oral placebo + sham spinal manipulation, 25	VAS (0-100)	Deutsche Gesellschaft für Manuelle Medizin (DGMM) - Aerzteseminar für Manuelle Wirbelsaeulenund Extremitaetentherapie (MWE)
Weber, 1993(212)	214 participants with acute low back pain from Norway	Oral piroxicam, 120	Oral placebo, 94	VAS (0-100)	Pfizer
Nucleoside					
Bannwarth, 2005(213)	161 participants with acute low back pain from France	Oral adenosine tri-phosphate, 81	Oral placebo, 80	VAS (0-100)	Laboratoires Mayoly-Spindler, France
Opioids					

Buynak, 2010(214)	965 participants with chronic low back pain from the US	Oral tapentadol, 318 Oral oxycodone, 328	Oral placebo, 319	NRS (0-10)	R Buynak received funding for study support from Johnson & Johns LLC
Christoph, 2017(215)	641 participants with chronic low back pain from 11 European countries	Oral tapentadol, 126 Oral cebranopadol, 389	Oral placebo, 126	NRS (0-10)	Gruenenthal GmbH
Chu, 2012(216)	131 participants with chronic low back pain from the US	Oral morphine, 61	Oral placebo, 70	VAS (0-100)	Dr. Chu's work was supported by a career development award from the National Institutes of Health
Gordon, 2010(217)	78 participants with chronic low back pain from Canada	Transdermal buprenorphine, 39	Transdermal placebo, 39	VAS (0-100)	Purdue Pharma
Hale, 2007(218)	142 participants with chronic low back pain from the US	Oral oxymorphone hydrochloride, 70	Oral placebo, 72	VAS (0-100)	Endo Pharmaceuticals, Inc
Hale, 2010(219)	268 participants with chronic low back pain from the US	Oral hydromorphone, 134	Oral placebo, 134	NRS (0-10)	Neuromed and Covidien Pharmaceuticals
Hale, 2015(220)	294 participants with chronic low back pain from the US	Oral hydrocodone, 148	Oral placebo, 146	NRS (0-10)	Teva Branded Pharmaceutical Products R & D, Inc.
Katz, 2007(221)	205 participants with chronic low back pain from the US	Oral oxymorphone, 105	Oral placebo, 100	VAS (0-100)	Endo Pharmaceuticals Inc. Dr. Katz serves as a consultant for Endo Pharmaceuticals Inc., and H. Ahdieh, T. Ma, R.G. van der Hoop, and R. Kerwin are employees
Katz, 2015(222)	389 participants with chronic low back pain from the US	Oral oxycodone, 193	Oral placebo, 196	NRS (0-10)	Collegium Pharmaceuticals
Lin, 2016(223)	21 participants with chronic low back pain from the US	Oral morphine, 11	Oral placebo, 10	BPI	National Institute on Drug Abuse

Markman, 2020(39)	1019 participants with chronic low back pain from the US	Oral tramadol + subcutaneous placebo injection, 610	Oral placebo + subcutaneous placebo injection, 409	NRS (0-10)	Pfizer Inc. (manufacturer of tanezumab) and Eli Lilly and Company
Rauck, 2014(224)	302 participants with chronic low back pain from the US	Oral hydrocodone, 151	Oral placebo, 151	NRS (0-10)	Zogenix, Inc
Rauck, 2015(225)	281 participants with chronic low back pain from the US	Oral oxycodone + naltrexone, 147	Oral placebo, 134	NRS (0-10)	Pfizer
Rauck, 2016(226)	461 participants with chronic low back pain from the US	Buccal buprenorphine, 229	Buccal placebo, 232	NRS (0-10)	Endo Pharmaceuticals Inc., Malvern, PA. RL Rauck has received research funding from Endo Pharmaceuticals and BioDelivery Sciences International Inc., and is a consultant for Endo Pharmaceuticals. Q Xiang is an employee and shareholder of Endo Pharmaceuticals, receiving salary, bonus and stocks. E Tazanis is a former employee and stock holder of Endo Pharmaceuticals. A Finn is an employee and shareholder of BioDelivery Sciences International.
Schnitzer, 2000(227)	254 participants with chronic low back pain from the US	Oral tramadol, 127	Oral placebo, 127	VAS (0-10)	Ortho-McNeil Pharmaceutical, Raritan, NJ
Serinken, 2016(228)	200 participants with acute low back pain from Turkey	IV morphine injection, 100	IV placebo injection, 100	VAS (0-100)	None
Steiner, 2011(229)	541 participants with chronic low back pain from the US	Transdermal buprenorphine, 257	Transdermal placebo, 284	NRS (0-10)	Purdue Pharma L.P., Stamford, CT. All authors affiliated with Purdue Pharma L.P. are full-time employees.
Uberall, 2012(230)	238 participants with chronic low back pain from Germany	Oral tramadol, 118	Oral placebo, 120	NRS 0-10	TEVA, Germany

Webster, 2006(231)	719 participants with chronic low back pain from the US	Oral oxycodone, 206 Oral oxytrex, 412	Oral placebo, 101	NRS (0-10)	None
Wen, 2015(232)	588 participants with chronic low back pain from the US	Oral hydrocodone, 296	Oral placebo, 292	NRS (0-10)	Purdue Pharma L.P. W Wen, S Lynch, E He, S Ripa, and HA Caporoso are full-time employees of Purdue Pharma, L.P. S Sitar was an investigator for this study.
Opioids + paracetamol					
Lee, 2013(233)	245 participants with chronic low back pain from Korea	Oral tramadol + acetaminophen, 125	Oral placebo, 120	VAS (0-100)	Janssen Korea, Ltd
Peloso, 2004(234)	338 participants with chronic low back pain from the US	Oral tramadol + acetaminophen, 167	Oral placebo, 171	VAS (0-100)	Ortho-McNeil Pharmaceutical, Raritan, New Jersey, USA
Ruoff, 2003(235)	322 participants with chronic low back pain from the US	Oral tramadol + acetaminophen, 162	Oral placebo, 160	VAS (0-100)	None
Schiphorst Preuper, 2014(236)	50 participants with chronic low back pain from the Netherlands	Oral tramadol + acetaminophen, 25	Oral placebo, 25	VAS (0-10)	Gruenenthal BV and Stichting Beatrixoord, The Netherlands
Orthopedic device					
Park, 2022(237)	30 participants with mixed duration low back pain from South Korea	Orthopedic device (LSM-01), 15	Sham orthopedic device (lacked fixation between roller pin and motor hindering rotation), 15	VAS (0-100)	None
Osteopathic					
Gibson, 1985(88)	75 participants with mixed duration low back from the UK	Osteopathic manipulation, 41	Detuned short wave diathermy, 34	VAS (0-100)	Arthritis and Rheumatism Council
Licciardone, 2003(238)	71 participants with chronic low back pain from the US	Osteopathic manipulation, 48	Sham osteopathic manipulation involving range of motion and light touch simulated osteopathic techniques, 23	VAS (0-10)	The American Osteopathic Association grant 99-11-487

Licciardone, 2013(239)	455 participants with chronic low back pain from the US	Osteopathic manipulation, 230	Sham osteopathic manipulation involving range of motion and light touch simulated osteopathic techniques, 225	VAS (0-100)	National Institute of Health
Nguyen, 2021(240)	400 participants with chronic low back pain from France	Osteopathic manipulation, 200	Sham osteopathic manipulation involving light touch, 200	NRS (0-100)	The French Ministry of Health (PHRC 2011, project P110142) and sponsored by the Département de la Recherche Clinique et du Développement de l'Assistance Publique-Hôpitaux de Paris
Panagopoulos, 2015(241)	64 participants with acute low back pain from Australia	Osteopathic visceral manipulation, 32	Sham osteopathic manipulation, 32	NRS (0-10)	None
Tozzi, 2012(242)	140 participants with acute low back pain from Italy	Osteopathic fascial manipulation, 109	Sham osteopathic manipulation involving light touch, 31	McGill Pain Questionnaire	None
Ozone injection					
Sucuoğlu, 2021(243)	46 participants with acute low back pain from Turkey	IM ozone injection, 23	IM placebo injection, 23	VAS (0-10)	None
Paracetamol					
Serinken, 2016(228)	200 participants with acute low back pain from Turkey	IV paracetamol injection, 100	IV placebo injection, 100	VAS (0-100)	None
Williams, 2014(244)	1646 participants with acute low back pain from Australia	Oral paracetamol, 1099	Oral placebo, 547	NRS (0-10)	The National Health and Medical Research Council of Australia and GlaxoSmithKline Australia.
Probiotic					
Jensen, 2019(245)	94 participants with chronic low back pain from Denmark	Oral probiotic dicofor, 46	Oral placebo, 48	VAS (0-10)	The Danish Rheumatism Association, Peter and Helga Korningsfond. and Gigtforeningen (Grant No. R139-A3924).
Pyrazolone derivatives					

Babej-Dölle, 1994(199)	174 participants with acute low back pain from Germany	IM dipyrone injection, 88	IM placebo injection, 86	VAS (0-100)	Hoechst AG, Frankfurl/Main, Germany
Radiotherapy					
Hackenberg, 2001(246)	31 participants with chronic low back pain from Germany	Radiotherapy, 18	Placebo (low dose) radiotherapy, 13	NRS (0-10)	Not reported
Reflexology					
Quinn, 2008(247)	15 participants with chronic low back pain from the UK	Reflexology, 7	Sham reflexology involving simple foot massage, 8	VAS (0-10)	None
Spinal manipulative therapy					
Balthazard, 2012(248)	42 participants with chronic low back pain from Switzerland	Spinal manipulative therapy, 22	Detuned ultrasound, 20	VAS (0-100)	Swiss National Science Foundation
Bialosky, 2014(249)	55 participants with mixed duration low back pain from the US	Spinal manipulative therapy, 28	Sham spinal manipulative therapy involving no motion of the pelvis, 27	NRS (0-100)	The University of Florida Research Opportunity Fund, the Rehabilitation Research Career Development Program (5K12HD055929-02). MER and SZG received support from the National Center for Complementary and Alternative Medicine (5R01AT006334).
Bond, 2020(250)	29 participants with chronic low back pain from the US	Spinal manipulative therapy, 14	Sham spinal manipulative therapy involving no motion of the pelvis, 15	NRS (0-100)	National Chiropractic Mutual Insurance Company Foundation
Didehdar, 2020(251)	25 participants with chronic low back pain from Iran	Spinal manipulative therapy, 10	Sham spinal manipulative therapy involving similar positioning but without manipulation, 15	NRS (0-10)	Not reported
Fagundes Loss, 2020(252)	24 participants with chronic low back pain from Brazil	High-velocity low amplitude lumbar manipulation, 12	Sham manipulative therapy involving similar positioning but without manipulation, 12	NRS (0-10)	None

Fisher, 2020(253)	101 participants with mixed duration low back pain from the US	Spinal thoracic manipulation, 52	Sham manipulative therapy involving similar positioning but without manipulation, 49	NRS (0-10)	None
Ghroubi, 2007(254)	64 participants with chronic low back pain from Tunisia	Spinal manipulative therapy, 32	Sham manipulation, 32	VAS (0-100)	None
Hancock, 2007(204)	120 participants with acute low back pain from Australia	Spinal manipulative therapy + real or placebo diclofenac, 60	Detuned ultrasound + real or placebo diclofenac, 60	NRS (0-10)	The Australia's National Health and Medical Research Council.
Hoiriis, 2004(189)	103 participants with acute low back pain from the US	Spinal manipulative therapy, 50	Sham manipulative therapy involving the same positioning and light pressure, 53	VAS (0-10)	The Research Center of Life University
Sanders, 1990(255)	12 participants with acute low back pain from the US	Spinal manipulative therapy, 6	Sham manipulative therapy involving light touch, 6	VAS (0-4)	The Foundation for Chiropractic Education and Research
Senna, 2011(256)	65 participants with chronic low back pain from Egypt	Spinal manipulative therapy, 25	Sham manipulative therapy, 40	VAS (0-100)	None
Thomas, 2020(181)	108 participants with chronic low back pain from the US	Spinal manipulative therapy, 54	Detuned cold laser, 54	NRS (0-10)	National Center for Complementary and Integrative Health of the NIH under award number R01AT006978
Triano, 1995(257)	86 participants with chronic low back pain from the US	Spinal manipulative therapy, 47	Sham manipulation involving low force manipulation, 39	VAS (0-100)	The Lincoln College Education and Research Fund, The Foundation for Chiropractic Education and Research, and the Foundation for the Advancement of Chriopractic Education
Vieira-Pellenz, 2014(258)	40 participants with mixed duration low back pain from Spain	Spinal manipulative therapy, 20	Sham manipulative therapy involving similar positioning but without manipulation, 20	VAS (0-100)	Not reported
von Heymann, 2013(211)	63 participants with acute low back pain from Germany	Spinal manipulative therapy + placebo diclofenac, 38	Sham manipulative therapy + placebo diclofenac, 25	VAS (0-100)	Deutsche Gesellschaft für Manuelle Medizin (DGMM) - Aerzteseminar für Manuelle Wirbelsaeulenund Extremitaetentherapie (MWE)

Waagen, 1986(259)	19 participants with chronic low back pain from the US	Spinal manipulative therapy, 9	Sham manipulative therapy involving low force spinal manipulation, 10	VAS (0-10)	Palmer College of Chiropractic Presidential Research Grant to the Senior Author
Taping					
Abbasi, 2020(260)	30 participants with chronic low back pain from Iran	Kinesio taping, 15	Placebo kinesio taping involving no tension, 15	VAS (0-10)	The School of Rehabilitation at Tehran University of Medical Sciences
Al-Shareef, 2016(261)	40 participants with chronic low back pain from Saudi Arabia	Kinesio taping, 20	Sham kinesio taping, 20	VAS (0-10)	Research Center of the Female Scientific and Medical Colleges Deanship of Scientific Research, King Saud University
Araujo, 2018(262)	148 participants with chronic low back pain from Brazil	Kinesio taping, 74	Sham kinesio taping, 74	NRS (0-10)	Sao Paulo Research Foundation (FAPESP)
Castro-Sanchez, 2012(263)	60 participants with chronic low back pain from Spain	Kinesio taping, 30	Sham kinesio taping, 30	VAS (0-10)	None
Chen, 2012(264)	43 participants with mixed duration low back pain from Australia	Kinesio taping, 21	Sham kinesio taping, 22	VAS (0-100)	Medical Kinetics, Australia and the Australian Centre for Research into Sports Injury and its Prevention
de Brito Macedo, 2019(265)	54 participants with chronic low back pain from Brazil	Kinesio taping, 27	Sham kinesio taping involving no tension, 27	NRS (0-10)	Coordenac¸ão de Aperfeic¸oamento de Pessoal de Nível Superior (CAPES)
Jassi, 2021(266)	80 participants with chronic low back pain from Brazil	Shar-shaped kinesio taping, 40	Sham kinesio taping involving no tension, 40	NRS (0-10)	None
Keles, 2017(267)	60 participants with chronic low back pain from Turkey	Kinesio taping, 30	Sham kinesio taping, 30	NRS (0-10)	Not reported
Koroglu, 2017(268)	40 participants with chronic low back pain from Turkey	Kinesio taping, 20	Sham kinesio taping, 20	VAS (0-10)	Not reported

Luz Junior, 2015(269)	40 participants with chronic low back pain from Brazil	Kinesio taping, 20	Sham kinesio taping, 20	NRS (0-10)	Not reported
Macedo, 2021(270)	30 participants with chronic low back pain from Brazil	Kinesio taping, 15	Sham kinesio taping involving no tension, 15	NRS (0-10)	Not reported
Mengi, 2020(271)	96 participants with chronic low back pain from Turkey	Kinesio taping, 65	Sham kinesio taping involving no tension, 31	VAS (0-10)	None
Parreira, 2014(272)	148 participants with chronic low back pain from Brazil	Kinesio taping, 74	Sham kinesio taping, 74	NRS (0-10)	Fundac ̧a ̃o de Amparo a Pesquisa do Estado de Sa ̃o Paulo (FAPESP) and National Council for Scientific and Technological Development (CNPq) Brazil
Peñalver-Barrios, 2021(273)	62 participants with chronic low back pain from Spain	Kinesio taping, 31	Sham kinesio taping involving no tension, 31	NRS (0-10)	Convocatoria de Consolidacio´n de Indicadores CEU-UCH 2020-2021/INDI20/27
Pires, 2020(274)	42 participants with chronic low back pain from Brazil	Kinesio taping, 21	Sham kinesio taping, 21	NRS (0-10)	None
Uzunkulaoglu, 2018(275)	60 participants with chronic low back pain from Turkey	Kinesio taping, 30	Sham kinesio taping, 30	VAS (0-10)	None
TENS					
Aguilar Ferrándiz, 2016(276)	39 participants with chronic low back pain from Belgium	TENS, 19	Sham TENS, 20	VAS (0-100)	Nervomatrix Ltd
Amirdelfan, 2021(277)	36 participants with chronic low back pain from the US	High frequency impulse therapy, 17	Sham high frequency impulse therapy, 19	NRS (0-10)	Thimble Bioelectronics Inc. dba Enso
Bertalanffy, 2005(278)	63 participants with acute low back pain from Austria	TENS, 30	Sham TENS, 33	VAS (0-100)	The Vienna Red Cross

Cheing, 1999(279)	30 participants with chronic low back pain from Canada	TENS, 15	Detuned TENS, 15	VAS (0-100)	Fonds de la Recherche en SantC du Quebec
Dias, 2021(136)	105 participants with chronic low back pain from Brazil	TENS, 70	Sham TENS, 35	NRS (0-10)	Not reported
Ezema, 2022(280)	70 participants with chronic low back pain from Nigeria	TENS, 35	Detuned TENS, 35	NRS (0-10)	None
Glaser, 2001(281)	80 participants with mixed duration low back pain from the US	Electrical muscle stimulation + exercise, 40	Sham electrical muscle stimulation + exercise, 40	Low back pain outcome instrument	RS Medical Corporation, Vancouver, CA
Hazime, 2017(282)	46 participants with chronic low back pain from Brazil	Peripheral electrical stimulation, 23	Sham peripheral electrical stimulation, 23	NRS (0-10)	None
Herman, 1994(283)	58 participants with acute low back pain from Canada	TENS + exercise, 29	Detuned TENS + exercise, 29	VAS (0-100)	National Health and Welfare Canada (grant #6606-4077-60)
Kibar, 2020(140)	68 participants with chronic low back pain from Turkey	TENS, 34	Placebo TENS + placebo interferential current therapy, 34	VAS (0-100)	None
Starkweather, 2015(284)	30 participants with chronic low back pain from the US	Calmare1 neurocutaneous electrical pain intervention, 15	Sham Calmare1, 15	NRS (0-10)	National Institute of Nursing Research, National Institutes of Health
Thompson, 2008(285)	60 participants with chronic low back pain from the US	Transcutaneous spinal electroanalgesia therapy, 30	Detuned transcutaneous spinal electroanalgesia therapy, 30	VAS (0-10)	Not reported
Topuz, 2004(96)	45 participants with chronic low back pain from Turkey	TENS, 30	Detuned TENS, 15	VAS (0-10)	None
Yaksi, 2021(286)	74 participants with chronic low back pain from Turkey	TENS, 50	Detuned TENS, 24	VAS (0-10)	Scientific Research Projects Coordination Unit of Istanbul University (Project number: 28997)
Topical Rubefacient					

Gaubitz, 2016(287)	805 participants with acute low back pain from Germany	Topical nicoboxil ointment, 201 Topical nonivamide ointment, 198 Topical nicoboxil + nonivamide ointment, 202	Topical placebo ointment, 204	NRS (0-10)	Boehringer Ingelheim
Ginsberg, 1987(288)	40 participants with acute low back pain from Belgium	Topical rado-salil ointment, 20	Topical placebo ointment, 20	VAS (0-10)	Not reported
Traction					
Beurskens, 1995(289)	151 participants with chronic low back pain from the Netherlands	Traction, 77	Sham traction involving <20% total body weight, 74	VAS (0-100)	The Fund of Investigative Medicine from the National Insurance Council and the Ministry of Education and Science, Netherlands
Schimmel, 2009(290)	60 participants with chronic low back pain from the Netherlands	Traction + standard graded activity program, 31	Sham traction involving <10% total body weight + standard graded activity program, 29	VAS (0-100)	Not reported
Sherry, 2001(291)	44 participants with chronic low back pain from Australia	Vertebral axial decompression therapy, 22	TENS, 22	VAS (0-10)	Dr Russell Smart is contracted to and a shareholder in VAX-D Australasia Pty. Ltd., a private company that delivers VAX-D service in Australia
Transcranial stimulation					
Adhia, 2023a(292)	30 participants with chronic low back pain from New Zealand	Transcranial infraslow pink-noise stimulation, 15	Sham transcranial infraslow pink-noise stimulation, 15	NRS (0-10)	The New Zealand Health Research Council (20/618), Healthcare Otago Charitable Trust, Brain Health Research Centre, and a gift from John Ward
Adhia, 2023b(293)	60 participants with chronic low back pain from New Zealand	Electroencephalography-based infraslow-neurofeedback, 45	Placebo electroencephalography-based infraslow-neurofeedback, 15	BPI	The Otago Medical School Trust (Dean's Bequest) Funding and Brain Health Research Centre (through a Philanthropist)

Corti, 2022(294)	30 participants with chronic low back pain from Australia	Transcranial electrical stimulation, 15	Sham transcranial direct current stimulation, 15	VAS (0-10)	None
Gabis, 2009(295)	33 participants with chronic low back pain from Israel	Transcranial electrical stimulation, 17	Placebo transcranial electrical stimulation, 16	VAS (0-10)	Not reported
Hazime, 2017(282)	46 participants with chronic low back pain from Brazil	Transcranial direct current stimulation, 23	Sham transcranial direct current stimulation, 23	NRS (0-10)	None
Jiang, 2019(296)	51 participants with chronic low back pain from Hong Kong	Dry electrode based transcranial direct current stimulation, 26	Sham dry electrode based Sham transcranial direct current stimulation, 25	NRS (0-10)	National Natural Science Foundation of China (81572193), Hong Kong RGC GRF (17656116) and China Postdoctoral Science Foundation (2018M643264)
Mariano, 2019(297)	21 participants with chronic low back pain from the US	Transcranial direct current stimulation, 10	Sham transcranial direct current stimulation, 11	Defense and Veterans Pain Rating Scale (0-10)	The Butler Hospital, the National Institute of Mental Health R25 MH101076 (TYM), a 2015 NARSAD Young Investigator Grant (TYM), the Brown Institute for Brain Science, and the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Rehabilitation Research and Development Service and the Center of Excellence for Neurorestoration and Neurotechnology at the Providence VA Medical Center
TRPV1 agonist					
Frerick, 2003(298)	319 participants with chronic low back pain from Austria	Topical capsaicin plaster, 159	Topical placebo plaster, 160	Arhus pain scale (0-30)	None
Keitel, 2001(299)	154 participants with chronic low back pain from Germany	Topical capsaicin plaster, 77	Topical placebo plaster, 77	Arhus pain scale (0-30)	None
Ultrasound					

Durmus, 2010(300)	42 participants with chronic low back pain from Turkey	Ultrasound + exercise + heat pack, 21	Sham ultrasound + exercise + heat pack, 21	VAS (0-100)	Not reported
Ebadi, 2012(301)	50 participants with chronic low back pain from Iran	Ultrasound + exercise, 25	Placebo ultrasound + exercise, 25	VAS (0-100)	Research Deputy, Tehran University of Medical Sciences

VAS, Visual Analogue Scale; NRS, Numeric Rating Scale; VRS, Verbal Rating Scale; CPGS, Chronic Pain Grade Scale; IV, Intra-venous; IM, Intra-muscular; DDS, Descriptor Differential Scale; BPI, Brief Pain Inventory

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Appendix 3.11. Characteristics of pain duration of included acute low back pain studies

Treatment (*N* trials; participants)	Low back pain duration		
	Acute (< 2 weeks) *N* trials (participants)	**Acute/subacute (2-6 weeks) *N* trials (participants)**	**Subacute (6-12 weeks) *N* trials (participants)**
>1 study analyses			
	Subgroup 1: acute (< 2 weeks)	Subgroup 2: subacute (2-12 weeks)	
Acupuncture (4; 226)	-	-	4 (226)
Behavioural/education (3; 376)	-	1 (202)	2 (174)
Exercise (2; 412)	-	1 (299)	1 (113)
Glucocorticoid injections (2; 111)	1 (77)	-	1 (34)
Heat (2; 255)	-	-	2 (255)
Laser and light (3; 85)	-	-	3 (85)
Mobilization (3; 117)	-	-	3 (117)
Muscle Relaxants (10; 999)	6 (538)	2 (140)	2 (321)
NSAIDs (13; 1763)	10 (1446)	1 (117)	2 (200)
Osteopathic (2; 202)	-	1 (62)	1 (140)
Paracetamol (3; 1843)	1 (200)	2 (1643)	-
SMT (4; 383)	2 (69)	2 (314)	-
TENS (2; 121)	1 (63)	-	1 (58)
Topical Rubefacient (4; 845)	1 (40)	3 (805)	-
1 study only (acute)			
Immunoglobulin (1; 41)	1 (41)	-	-
Opioids (1; 200)	1 (200)	-	-
1 study only (subacute)			
Cannabinoid (1; 100)	-	-	1 (100)
Extracorporeal shockwave (1; 53)	-	-	1 (53)
Massage (1; 40)	-	-	1 (40)
Muscle Relaxant + NSAID (1; 105)	-	-	1 (105)
Nucleoside (1; 161)	-	-	1 (161)
Ozone injection (1; 41)	-	1 (41)	-
Pyrazolone derivative (1; 168)	-	-	1 (168)
Uricosuric agent (1; 15)	-	-	1 (15)

Appendix 3.12. Risk of bias assessments

Author, Year	Eligibility criteria	Random allocation	Concealed allocation	Groups similar at baseline	Participant blinding	Therapist blinding	Assessor blinding	< 15% dropout	Intention-to-treat analysis	Between-group difference reported	Point estimates and variability reported	Total score (/10)	*Overall judgement (low/high)
Abbasi, 2020	y	y	y	y	y	n	n	y	n	y	y	7	**Low**
Abdelbasset, 2020	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Adhia, 2022	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Adhia, 2023	y	y	y	y	y	n	y	n	y	y	y	8	**High**
Aguilar Ferrándiz, 2016	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Al-Shareef, 2016	y	y	y	y	n	n	y	y	n	y	y	7	**Low**
Alayat, 2014	y	y	n	y	y	n	n	n	n	y	y	5	**High**
Albert, 2013	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Allegrini, 2009	y	y	n	n	n	n	n	n	n	y	y	3	**High**
Almeida Silva, 2021	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Almeida, 2022	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Almhdawi, 2020	y	y	n	y	n	n	y	y	n	y	y	6	**High**
Alzayed, 2020	y	y	n	y	y	n	y	n	n	y	y	6	**High**

Amaral, 2023	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Amirdelfan, 2021	y	y	y	y	y	y	y	y	n	y	y	9	**Low**
Araujo, 2018	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Arbus, 1990	n	y	n	n	y	y	y	y	y	y	y	8	**High**
Arguisuelas, 2017	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Ashar, 2022	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Atkinson, 1998	y	y	n	n	y	y	y	n	y	y	y	7	**High**
Atkinson, 1999	y	y	y	n	y	y	y	n	y	y	y	8	**High**
Atkinson, 2016	y	y	n	y	y	y	y	n	y	y	n	7	**High**
Ay, 2010	n	y	n	y	y	n	y	y	n	y	y	7	**High**
Babej-Dölle, 1994	n	y	y	y	y	n	y	y	n	y	y	8	**Low**
Balthazard, 2012	y	y	y	y	n	n	n	y	n	y	y	6	**High**
Bannwarth, 2005	y	y	n	y	y	y	y	y	y	y	y	9	**High**
Baratta, 1982	n	y	y	n	y	y	y	y	n	y	y	8	**Low**
Basford, 1999	y	y	n	y	y	y	y	y	n	y	y	8	**High**
Bebee, 2021	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Bergquist-Ullman, 1977	y	y	n	n	n	n	n	n	y	y	y	4	**High**
Berry, 1988a	y	y	n	y	y	n	n	y	n	y	y	6	**High**
Berry, 1988b	y	y	n	y	y	y	y	y	n	y	y	8	**High**
Bertalanffy, 2005	y	y	y	y	y	n	y	y	n	y	y	8	**Low**

Beurskens, 1995	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Bialosky, 2014	y	y	y	y	n	n	n	y	n	y	y	6	**High**
Birbara, 2003	y	y	n	y	y	y	y	n	y	y	y	8	**High**
Bond, 2020	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Borges, 2014	y	y	n	y	n	n	n	y	n	y	y	5	**High**
Bråten, 2019	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Brinkhaus, 2006	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Brizzi, 2004	y	y	y	y	y	y	y	y	n	y	y	9	**Low**
Buran Çirak, 2021	y	y	y	y	n	n	y	y	n	y	y	7	**Low**
Buynak, 2010	y	y	y	y	y	y	y	n	y	y	y	9	**High**
Carlsson, 2001	y	y	y	y	n	n	y	y	n	y	y	7	**Low**
Castro-Mendez, 2013	y	y	y	y	n	n	n	y	n	y	y	6	**High**
Castro-Sanchez, 2012	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Çelik, 2020	n	y	n	y	n	n	y	y	n	y	y	6	**High**
Chandanwale, 2011	y	y	y	y	y	y	y	y	n	y	y	9	**Low**
Cheing, 1999	n	y	n	y	n	n	n	y	n	y	y	5	**High**
Chen, 2012	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Chenard, 1991	y	y	y	y	y	n	n	y	y	y	n	7	**Low**
Chiu, 2011	y	y	n	y	y	n	y	y	n	y	y	7	**High**
Cho, 2013	y	y	y	y	y	n	y	y	n	y	y	8	**Low**

Cho, 2020	y	y	n	y	y	y	y	y	n	y	y	8	**High**
Christoph, 2017	y	y	y	y	y	y	y	n	n	y	y	8	**High**
Chrubasik, 1999	y	y	n	y	y	y	y	y	y	y	y	9	**High**
Chrubasik, 2000	y	y	n	n	y	y	y	y	y	y	y	8	**High**
Chu, 2012	y	y	n	y	y	n	y	n	n	y	y	6	**High**
Coats, 2004	y	y	n	y	y	y	y	y	y	y	y	9	**High**
Corrêa, 2016	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Corti, 2022	n	y	n	y	y	n	n	n	n	y	y	5	**High**
Costa, 2009	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Dakin, 2021	y	y	y	y	y	y	y	n	y	y	y	9	**High**
Dapas, 1985	n	y	n	y	y	y	y	y	n	y	n	7	**High**
de Brito Macedo, 2019	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
de Melo Salemi, 2021	n	y	y	y	y	n	y	y	n	y	y	8	**Low**
Degenhardt, 2017	y	y	n	y	n	n	n	y	n	y	y	5	**High**
Del-Canto-Fernández, 2022	y	y	n	n	y	n	y	y	n	y	y	6	**High**
Dias, 2021	n	y	n	y	n	n	y	n	n	y	y	5	**High**
Dickens, 2000	y	y	y	n	y	y	y	y	y	y	y	9	**Low**
Didehdar, 2020	y	y	n	y	y	n	y	y	y	y	y	8	**High**
Djavid, 2007	y	y	y	y	n	n	n	y	y	y	y	7	**Low**
Dougherty, 2014	y	y	n	y	y	n	y	y	y	y	y	8	**High**

Dreiser, 2001	n	y	n	y	y	y	y	y	y	y	y	9	**High**
Dreiser, 2003	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Duplan, 1983	y	y	y	y	y	n	y	y	y	y	n	8	**Low**
Durmus, 2010	n	y	n	y	y	n	y	n	n	y	y	6	**High**
Dzik, 2018	n	y	n	n	y	n	y	y	n	y	y	6	**High**
Eardley, 2013	y	y	y	y	n	n	n	n	n	y	y	5	**High**
Ebadi, 2012	y	y	y	y	y	n	y	n	y	y	y	8	**High**
Elshiwi, 2019	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Espejo-Antunez, 2021	n	y	n	y	n	n	y	y	y	y	y	7	**High**
Ezema, 2022	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Faas, 1993	y	y	y	y	n	n	n	y	y	y	y	7	**Low**
Fagundes Loss, 2020	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Farasyn, 2006	n	y	n	y	n	n	n	y	n	y	y	5	**High**
Fisher, 2020	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Franco, 2017	n	y	y	y	n	n	y	y	y	y	y	8	**Low**
Frerick, 2003	n	y	y	y	y	y	y	y	y	y	n	9	**Low**
Friedman, 2006	y	y	y	n	y	y	y	y	n	y	y	8	**Low**
Fuentes, 2014	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Gabis, 2009	y	y	n	y	n	n	n	y	n	y	y	5	**High**
Gale, 2006	y	y	n	n	y	n	y	y	n	y	y	6	**High**

Garcia, 2018	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Garcia, 2021	y	y	y	y	n	n	n	y	y	y	n	6	**High**
Gastaldi, 2019	y	y	n	y	y	y	y	y	y	y	y	9	**High**
Gaubitz, 2016	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Geisser, 2005	y	y	n	n	n	n	n	n	n	y	y	3	**High**
Ghroubi, 2007	n	y	n	y	n	n	n	y	n	n	y	4	**High**
Gibson, 1985	y	y	n	y	n	n	y	n	n	n	y	4	**High**
Ginsberg, 1987	n	y	n	n	y	y	y	y	n	y	y	7	**High**
Ginsberg, 1987	n	y	n	n	y	n	y	y	n	y	y	6	**High**
Glaser, 2001	y	y	n	n	y	n	y	n	n	y	y	5	**High**
Glazov, 2009	y	y	y	y	y	y	y	y	n	y	y	9	**Low**
Glazov, 2014	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Goforth, 2014	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Goldby, 2006	y	y	n	n	n	n	y	n	n	y	y	4	**High**
González, 2021	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Goodkin, 1990	y	y	n	y	y	y	y	y	n	y	y	8	**High**
Goodsell, 2000	y	y	n	y	n	n	y	n	n	y	y	5	**High**
Gordon, 2010	y	y	y	n	y	y	y	n	n	y	y	7	**High**
Gould, 2020	y	y	y	y	y	y	y	n	y	y	y	9	**High**
Guimarães, 2021	y	y	y	y	y	y	y	y	y	y	y	10	**Low**

Gurrell, 2018	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Gyulai, 2015	y	y	n	n	y	n	y	n	y	y	y	6	**High**
Haake, 2007	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Hackenberg, 2001	y	y	y	y	y	n	n	y	y	y	n	7	**Low**
Hale, 2007	y	y	n	y	y	y	y	n	n	y	y	7	**High**
Hale, 2010	y	y	y	y	y	y	y	n	y	y	y	9	**High**
Hale, 2015	y	y	y	y	y	y	y	n	n	y	y	8	**High**
Hall, 2006	y	y	y	n	n	n	y	y	n	y	y	6	**High**
Hancock, 2007	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Hansen, 1993	y	y	n	y	n	n	y	n	n	y	n	4	**High**
Harden, 2007	y	y	n	y	y	n	y	y	n	y	n	6	**High**
Hasegawa, 2014	y	y	n	y	y	n	y	y	y	y	y	8	**High**
Hashmi, 2012	y	y	y	n	y	y	y	n	n	y	y	7	**High**
Hazime, 2017	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Herman, 1994	y	y	n	y	n	n	y	y	n	y	y	6	**High**
Herrmann, 2009	y	y	y	y	y	y	y	y	y	y	n	9	**Low**
Hidalgo, 2015	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Hoiriis, 2004	y	y	n	y	y	n	y	n	y	y	y	7	**High**
Hsieh, 2014	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Huang, 2019	y	y	y	y	y	n	y	y	y	y	y	9	**Low**

Hussein, 2021	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Imamura, 2016	y	y	y	y	n	n	n	y	y	y	y	7	**Low**
Inoue, 2006	y	y	n	y	y	n	y	y	n	y	y	7	**High**
Itoh, 2006	y	y	n	y	y	n	y	n	n	y	y	6	**High**
Jassi, 2021	y	y	y	y	n	n	n	n	n	y	y	5	**High**
Jensen, 2019	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Jiang, 2019	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Kapitza, 2010	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Karasel, 2021	y	y	n	y	n	n	n	y	n	y	y	5	**High**
Katz, 2003	y	y	y	y	y	y	y	n	n	y	y	8	**High**
Katz, 2005	y	y	n	n	y	y	y	n	n	y	n	5	**High**
Katz, 2007	y	y	y	y	y	y	y	n	n	y	y	8	**High**
Katz, 2011	y	y	n	y	y	n	y	n	y	y	y	7	**High**
Katz, 2015	y	y	y	y	y	y	y	n	y	y	y	9	**High**
Keitel, 2001	n	y	n	y	y	y	n	y	y	y	y	8	**High**
Keles, 2017	n	y	y	y	n	n	y	y	n	y	y	7	**Low**
Kennedy, 2008	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Kent, 2015	y	y	n	y	n	n	n	n	y	y	y	5	**High**
Kerr, 2003	y	y	n	y	n	n	y	n	n	y	y	5	**High**
Ketenci, 2005	y	y	y	n	y	n	y	y	y	y	y	8	**Low**

Ketenci, 2022	y	y	y	y	y	y	y	y	n	y	y	9	**Low**
Kholoosy, 2022	n	y	n	y	n	n	n	n	n	n	y	3	**High**
KİBar, 2020	y	y	n	y	n	n	y	y	n	y	y	6	**High**
Kim, 2021	y	y	n	y	n	n	y	n	y	y	y	6	**High**
Kim, 2022	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Kivitz, 2013	y	y	n	y	y	n	y	n	y	y	y	7	**High**
Klein, 1990	y	y	n	y	y	y	y	n	n	y	y	7	**High**
Kogure, 2015	y	y	n	y	n	n	n	y	n	y	y	5	**High**
Koivisto, 2014	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Konno, 2016	y	y	n	y	y	y	y	y	n	y	y	8	**High**
Konstantinou, 2007	y	y	n	n	n	n	y	y	n	y	y	5	**High**
Koppenhaver, 2021	y	y	y	y	n	n	n	y	y	y	y	7	**Low**
Koroglu, 2017	y	y	n	y	n	n	n	y	n	y	y	5	**High**
Kovacs, 1997	y	y	n	y	y	n	y	y	y	y	y	8	**High**
Krafft, 2017	y	y	n	y	y	n	n	y	n	y	y	6	**High**
Krekoukias, 2021	n	y	n	y	n	n	n	n	n	y	y	4	**High**
Ku, 2018	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Kurniawati, 2020	y	y	n	n	y	n	y	y	n	y	y	6	**High**
Lange, 2021	y	y	y	y	y	n	y	n	y	y	y	8	**High**
Lee, 2006	n	y	n	y	y	y	y	y	n	y	y	8	**High**

Lee, 2013	y	y	y	y	y	y	y	n	y	y	n	8	**High**
Leibing, 2002	y	y	n	y	n	n	y	n	n	y	y	5	**High**
Leichtfried, 2014	y	y	y	y	n	n	n	n	n	y	y	5	**High**
Leite, 2018	n	y	y	y	n	n	y	n	n	y	y	6	**High**
Li, 2021	y	y	n	y	y	n	y	n	n	y	y	6	**High**
Licciardone, 2003	y	y	y	y	n	n	n	y	n	y	y	6	**High**
Licciardone, 2013	n	y	n	y	n	n	y	y	y	y	y	7	**High**
Lin, 2012	y	y	n	y	n	n	n	n	n	y	y	4	**High**
Lin, 2016	y	y	n	n	y	n	y	n	n	y	y	5	**High**
Lin, 2017	y	y	y	y	y	y	n	n	y	y	y	8	**High**
Lisi, 2019	y	y	n	y	y	n	y	n	y	y	n	6	**High**
Luz Junior, 2015	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Macedo, 2021	n	y	y	y	n	n	n	n	n	y	y	5	**High**
Makary, 2015	n	y	n	n	n	n	n	n	n	y	y	3	**High**
Marcel, 1990	y	y	y	y	y	n	n	y	y	y	y	8	**Low**
Mariano, 2019	y	y	y	n	y	y	y	y	y	y	y	9	**Low**
Markman, 2020	y	y	y	y	y	y	y	n	y	y	y	9	**High**
Martí-Salvador, 2018	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Martín-Corrales, 2020	y	y	y	y	y	n	n	y	y	y	y	8	**Low**
Masse-Alarie, 2017	n	y	y	y	n	n	y	y	n	y	y	7	**Low**

Mathieson, 2017	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Mauro, 2000	y	y	n	n	y	y	y	y	n	y	y	7	**High**
Mazreati, 2021	y	y	n	y	n	n	n	y	y	y	y	6	**High**
Mendelson, 1983	n	y	n	y	n	n	y	n	n	y	y	5	**High**
Mendonca, 2022	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Mengi, 2020 A	y	y	n	y	y	n	y	y	y	y	y	8	**High**
Molsberger, 2002	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Moon, 2017	y	y	y	y	y	n	y	n	n	y	y	7	**High**
Moura, 2019	y	y	y	y	n	n	y	n	n	y	y	6	**High**
Muehlbacher, 2006	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Nadler, 2003	y	y	n	y	n	n	n	y	n	y	y	5	**High**
Nadler, 2003	y	y	n	y	n	n	n	y	n	y	y	5	**High**
Nardin, 2022	n	y	y	y	n	n	y	y	y	y	y	8	**Low**
Naylor, 2020	y	y	n	n	y	y	y	n	n	y	y	6	**High**
Nguyen, 2021	y	y	y	y	y	n	y	n	n	y	y	7	**High**
Nicholas, 1992	y	y	y	y	n	n	n	y	n	y	y	6	**High**
Oliveira, 2022	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Pach, 2011	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Pallay, 2004	y	y	y	y	y	y	y	n	y	y	y	9	**High**
Panagopoulos, 2015	y	y	y	y	y	n	y	y	y	y	y	9	**Low**

Panah, 2021	y	y	y	n	y	n	n	y	n	y	y	6	**High**
Park, 2022	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Parreira, 2014	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Peloso, 2004	n	y	n	y	y	y	y	n	n	y	y	7	**High**
Peñalver-Barrios, 2021	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Pengel, 2007	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Pires, 2020	n	y	y	y	n	n	y	y	y	y	y	8	**Low**
Prakash, 2023	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Preyde, 2000	y	y	n	y	n	n	y	y	n	y	y	6	**High**
Qin, 2022	n	y	n	y	y	y	n	y	y	y	y	8	**High**
Quinn, 2008	y	y	y	y	n	n	n	n	n	n	y	4	**High**
Rajfur, 2022	n	y	n	y	n	n	n	y	n	y	y	5	**High**
Rajfur, 2022	n	y	n	y	y	n	y	y	y	y	y	8	**High**
Rauck, 2014	y	y	n	y	y	n	y	n	y	y	y	7	**High**
Rauck, 2015	n	y	n	y	y	y	y	n	y	y	y	8	**High**
Rauck, 2016	y	y	n	y	y	n	y	n	y	y	y	7	**High**
Ricci, 2022	y	y	n	n	y	y	n	n	n	y	y	5	**High**
Ruoff, 2003	y	y	y	y	y	y	y	y	n	y	y	9	**Low**
Ruth, 2010	y	y	y	y	y	y	y	y	n	y	y	9	**Low**
Ryan, 2014	y	y	y	y	y	n	y	n	n	n	y	6	**High**

Samsamshariat, 2021	y	y	n	n	y	y	y	y	y	y	y	8	**High**
Sanders, 1990	n	y	n	y	n	n	n	n	n	n	y	3	**High**
Sandoughi, 2015	y	y	y	n	y	y	y	n	n	y	y	7	**High**
Sanga, 2016	y	y	y	y	y	y	y	n	y	y	y	9	**High**
Sator-Katzenschlager, 2004	y	y	n	n	y	y	y	y	y	y	y	8	**High**
Schäfer, 2005	y	y	y	n	n	n	y	y	n	y	y	6	**High**
Schimmel, 2009	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Schiphorst Preuper, 2014	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Schliessbach, 2017	y	y	n	n	y	y	y	n	n	y	y	6	**High**
Schnebel, 1988	y	y	n	y	y	y	y	n	n	y	n	6	**High**
Schnitzer, 2000	n	y	n	n	y	y	y	n	y	y	y	7	**High**
Schnitzer, 2016	y	y	y	y	y	y	y	y	n	y	y	9	**Low**
Schrader, 1999	y	y	y	y	y	y	y	n	n	y	y	8	**High**
Senna, 2011	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Seo, 2017	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Serinken, 2016a	y	y	y	n	y	y	y	y	y	y	y	9	**Low**
Serinken, 2016b	y	y	y	n	y	y	y	y	y	y	y	9	**Low**
Shakoor, 2008	y	y	n	y	n	n	n	n	n	y	y	4	**High**
Shea, 2022	y	y	y	y	y	y	y	n	n	y	y	8	**High**
Sherry, 2001	y	y	n	y	n	n	n	y	n	y	y	5	**High**

Shin, 2015	y	y	y	y	y	n	y	y	n	y	y	8	**Low**
Shirzad-Siboni, 2022	y	y	n	y	y	n	y	y	n	y	y	7	**High**
Siems, 2010	n	y	n	n	y	y	y	n	n	y	y	6	**High**
Siglan, 2023	n	y	y	y	y	n	y	y	n	y	y	8	**Low**
Skljarevski, 2009	n	y	y	y	y	y	y	n	y	y	y	9	**High**
Skljarevski, 2010	n	y	n	y	y	n	y	n	y	y	y	7	**High**
Snook, 1998	y	y	n	y	n	n	n	n	y	y	n	4	**High**
Spratt, 1993	n	y	n	y	n	n	n	n	n	y	n	3	**High**
Starkweather, 2015	y	y	y	y	n	n	n	y	n	y	y	6	**High**
Steiner, 2011	n	y	n	y	y	n	y	n	n	y	y	6	**High**
Stuckey, 1986	y	y	n	y	n	n	n	n	n	y	y	4	**High**
Sucuoğlu, 2021	y	y	n	y	y	n	y	n	y	y	y	7	**High**
Szpalski, 1994	n	y	n	y	y	n	y	y	n	y	y	7	**High**
Taguchi, 2023	y	y	n	y	y	y	y	y	y	y	y	9	**High**
Taheri, 2021	n	y	n	y	n	n	n	n	n	y	y	4	**High**
Thomas, 2020	y	y	n	y	n	n	y	y	y	y	y	7	**High**
Thompson, 2008	y	y	y	n	n	n	n	y	n	y	y	5	**High**
Tomazoni, 2021	y	y	y	y	y	y	y	y	y	y	y	10	**Low**
Topuz, 2004	y	y	y	y	n	n	n	y	n	y	y	6	**High**
Torres, 2023	y	y	y	y	y	n	y	y	y	y	y	9	**Low**

Tozzi, 2012	n	y	n	y	y	n	y	n	n	y	y	6	**High**
Traeger, 2019	y	y	y	y	n	n	y	y	y	y	y	8	**Low**
Triano, 1995	y	y	y	y	n	n	y	n	n	y	y	6	**High**
Tu, 2019	n	y	n	n	y	n	y	n	n	y	y	5	**High**
Tüzun, 2003	y	y	n	y	y	n	y	y	y	y	y	8	**High**
Uberall, 2012	y	y	n	y	y	n	y	y	y	y	y	8	**High**
Urquhart, 2018	y	y	y	y	y	y	y	n	y	y	y	9	**High**
Ushinohama, 2016	y	y	y	n	n	n	y	y	y	y	y	7	**Low**
Uzunkulaoglu, 2018	y	y	y	n	y	n	y	y	y	y	y	8	**Low**
Vieira-Pellenz, 2014	y	y	n	y	y	n	y	y	y	y	y	8	**High**
von Heymann, 2013	y	y	y	y	n	n	y	n	y	y	y	7	**High**
Waagen, 1986	y	y	n	y	n	n	y	n	n	y	y	5	**High**
Wachi, 2022	y	y	n	n	y	n	n	y	n	y	y	5	**High**
Walewicz, 2019	y	y	n	y	y	n	n	y	y	y	y	7	**High**
Weber, 1993	y	y	n	n	y	n	y	y	n	n	n	4	**High**
Webster, 2006	y	y	n	y	y	n	y	n	y	y	y	7	**High**
Weiner, 2003	y	y	n	y	n	n	y	y	y	y	y	7	**High**
Wen, 2015	n	y	n	y	y	n	y	n	y	y	y	7	**High**
Wilkens, 2010	y	y	y	y	y	n	y	y	y	y	y	9	**Low**
Williams, 2014	y	y	y	y	y	y	y	y	y	y	y	10	**Low**

Wreje, 1992	y	y	n	n	n	n	y	n	n	y	y	4	**High**
Xu, 2021	y	y	n	y	n	n	y	y	y	y	y	7	**High**
Yaksi, 2021	y	y	n	y	n	n	n	y	n	y	y	5	**High**
Yakut, 2022	y	y	n	y	n	n	n	y	y	y	y	6	**High**
Yeh, 2013	y	y	n	y	y	n	y	y	n	y	y	7	**High**
Yeh, 2014	y	y	n	y	y	n	y	y	y	y	y	8	**High**
Yeh, 2015	y	y	n	n	y	n	y	n	y	y	y	6	**High**
Zhan, 2022	y	y	y	y	y	y	y	y	y	y	y	10	**Low**

*Studies with a PEDro score of ≤6/10 or one critical items marked as no/unclear, were classified as high risk of bias. Studies with a PEDro score of ≥7 and no critical items marked no/unclear were classified as low risk of bias.

Appendix 3.13. GRADE Evidence Profile

	Certainty assessment					Summary of findings			
Intervention	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**No of trials (No of participants)**	**Mean difference (95% CI), 0-100**	**Heterogeneity I^2**	**Overall certainty of evidence**
Acute low back pain									
Non-pharmacological intervention									
Acupuncture	Downgraded[1]	Not downgraded	Not downgraded	Downgraded[4]	Not downgraded	4 (226)	-10.5 (-13.9 to -7.1)	0%	Low
Behaviour/education	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	3 (376)	-4.4 (-10.3 to 1.4)	55%	Very low
Exercise	Not downgraded	Downgraded[2]	Not downgraded	Not downgraded	Not downgraded	2 (412)	-4.1 (-12.0 to 3.7)	76%	Moderate
Extracorporeal shockwave	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (53)	14.6 (2.0 to 27.2)	NA	Very low
Heat	Downgraded[1]	Not downgraded	Not downgraded	Downgraded[4]	Downgraded[7]	2 (255)	-17.6 (-23.7 to -11.4)	48%	Very low
Laser and light	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	2 (85)	-4.7 (-19.2 to 9.7)	73%	Very low
Massage	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (40)	-22.0 (-34.4 to -9.6)	NA	Very low
Mobilisation	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	3 (117)	2.9 (-9.3 to 15.0)	60%	Very low
Osteopathic	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	2 (202)	-7.7 (-20.6 to 5.2)	81%	Very low
Spinal manipulative therapy	Not downgraded	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	4 (383)	-12.4 (-23.2 to -1.6)	86%	Low
TENS	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	2 (121)	-14.9 (-42.2 to 12.4)	93%	Very low
Pharmacological intervention									
Cannabinoid	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (100)	4.0 (-6.0 to 14.0)	NA	Low

Colchicine	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (15)	15.0 (-10.6 to 40.6)	NA	Very low
Glucocorticoid injections	Not downgraded	Not downgraded	Not downgraded	Downgraded[4]	Not downgraded	2 (111)	0.4 (-11.8 to 12.6)	0%	Moderate
Immunoglobulin	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (41)	-34.4 (-56.4 to -12.5)	NA	Very low
Muscle relaxants	Downgraded[1]	Downgraded[2]	Not downgraded	Not downgraded	Not downgraded	9 (999)	-13.4 (-18.7 to -8.0)	73%	Low
Muscle relaxants + NSAIDs	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Downgraded[7]	1 (105)	-6.0 (-18.8 to 6.8)	NA	Very low
NSAIDs	Downgraded[1]	Not downgraded	Not downgraded	Not downgraded	Not downgraded	10 (1763)	-3.8 (-5.8 to -1.8)	1%	Moderate
Nucleoside	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Downgraded[7]	1 (161)	-4.0 (-11.5 to 3.5)	NA	Very low
Opioids	Not downgraded	Downgraded[6]	Downgraded[3]	Downgraded[4]	Not downgraded	1 (200)	-24.5 (-30.0 to -19.1)	NA	Very low
Ozone injections	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (41)	-13.0 (-20.0 to -6.0)	NA	Very low
Paracetamol	Not downgraded	Downgraded[2]	Not downgraded	Not downgraded	Not downgraded	2 (1843)	-2.5 (-8.2 to 3.3)	88%	Moderate
Pyrazolone derivatives	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Downgraded[7]	1 (168)	-12.3 (-18.5 to -6.1)	NA	Very low
Topical rubefacient	Not downgraded	Downgraded[2]	Not downgraded	Not downgraded	Downgraded[7]	2 (845)	-14.5 (-22.7 to -6.2)	90%	Low
Chronic low back pain									
Non-pharmacological intervention									
Acupressure	Downgraded[1]	Not downgraded	Not downgraded	Downgraded[4]	Not downgraded	4 (168)	-19.9 (-25.4 to -14.4)	0%	Low
Acupuncture	Not downgraded	Downgraded[2]	Not downgraded	Not downgraded	Downgraded[5]	19 (2006)	-11.7 (-18.0 to -5.4)	91%	Low
Behavioural/education	Downgraded[1]	Downgraded[2]	Not downgraded	Not downgraded	Not downgraded	7 (550)	-8.2 (-14.3 to -2.1)	65%	Low
Biofeedback	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	5 (178)	-1.1 (-10.5 to 8.4)	54%	Very low

Diathermy	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	4 (284)	0.4 (-2.1 to 2.9)	74%	Very low
Dry cupping	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	2 (127)	-8.7 (-37.7 to 20.3)	93%	Low
Electroacupuncture	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	5 (255)	-8.6 (-28.1 to 10.9)	95%	Very low
Electromagnetic	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	7 (257)	-8.1 (-19.6 to 3.4)	96%	Very low
Exercise	Downgraded[1]	Not downgraded	Not downgraded	Not downgraded	Not downgraded	7 (676)	-7.9 (-13.6 to -2.2)	45%	Moderate
Extracorporeal shockwave	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	5 (179)	-9.8 (-21.1 to 1.5)	86%	Very low
Foot orthotics	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (51)	-34.7 (-44.3 to -25.1)	NA	Very low
Infrared	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Downgraded[7]	2 (92)	-19.6 (-32.2 to -7.1)	62%	Very low
Interferential	Downgraded[1]	Downgraded[2]	Not downgraded	Not downgraded	Downgraded[5]	7 (691)	-15.7 (-22.9 to -8.6)	83%	Very low
Laser and light	Downgraded[1]	Downgraded[2]	Not downgraded	Not downgraded	Not downgraded	18 (1182)	-7.2 (-11.8 to -2.7)	79%	Low
Massage	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	4 (182)	-22.4 (-33.2 to -11.6)	91%	Very low
Mobilisation	Downgraded[1]	Downgraded[2]	Not downgraded	Not downgraded	Not downgraded	13 (869)	-14.6 (-24.3 to -4.9)	95%	Low
Osteopathic	Downgraded[1]	Downgraded[2]	Not downgraded	Not downgraded	Not downgraded	3 (790)	-2.2 (-9.2 to 4.8)	71%	Low
Radiotherapy	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (32)	-1.3 (-16.6 to 14.0)	NA	Low
Reflexology	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (15)	-8.0 (-19.2 to 3.2)	NA	Very low
Spinal manipulative therapy	Downgraded[1]	Not downgraded	Not downgraded	Not downgraded	Not downgraded	9 (445)	-6.4 (-10.3 to -2.5)	43%	Moderate
Taping	Not downgraded	Downgraded[2]	Not downgraded	Not downgraded	Not downgraded	15 (967)	-6.3 (-12.1 to -0.4)	87%	Moderate
TENS	Downgraded[1]	Downgraded[2]	Not downgraded	Not downgraded	Not downgraded	11 (581)	-16.5 (-22.5 to -10.5)	79%	Low

Traction	Not downgraded	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	3 (250)	-13.6 (-42.0 to 14.8)	95%	Low
Transcranial stimulation	Downgraded[1]	Not downgraded	Not downgraded	Downgraded[4]	Not downgraded	7 (260)	-9.3 (-14.2 to -4.5)	0%	Low
Ultrasound	Downgraded[1]	Downgraded[2]	Not downgraded	Downgraded[4]	Not downgraded	2 (92)	-12.0(-27.5 to 3.6)	87%	Very low
Pharmacological interventions									
Allosteric modulator of the g-aminobutyric acid type A (GABAA) receptor	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Downgraded[7]	1 (148)	1.6 (-3.7 to 6.9)	NA	Very low
Anaesthetics	Not downgraded	Not downgraded	Not downgraded	Downgraded[4]	Not downgraded	2 (281)	-7.8 (-16.4 to 0.7)	23%	Moderate
Antibiotic/antimicrobials	Not downgraded	Not downgraded	Not downgraded	Downgraded[4]	Not downgraded	3 (351)	-7.0 (-14.6 to 0.6)	46%	Moderate
Antibody injection	Downgraded[1]	Not downgraded	Not downgraded	Not downgraded	Downgraded[7]	5 (3401)	-4.8 (-6.6 to -3.0)	0%	Low
Anticonvulsants	Downgraded[1]	Downgraded[2]	Downgraded[3]	Downgraded[4]	Not downgraded	2 (204)	-10.4 (-18.8 to -2.0)	66%	Very low
Antidepressants	Downgraded[1]	Not downgraded	Not downgraded	Not downgraded	Not downgraded	10 (1695)	-4.9 (-6.8 to -2.9)	0%	Moderate
Antidepressants + paracetamol	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (63)	5.7 (-4.3 to 15.7)	NA	Very low
Bee Venom	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (54)	-9.3 (-18.7 to 0.1)	NA	Low
Bisphosphonates	Not downgraded	Not downgraded	Not downgraded	Downgraded[4]	Downgraded[7]	2 (61)	-11.4 (-22.9 to 0.2)	0%	Low
Bushen Huoxue formula	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (66)	-11.6 (-16.3 to -6.9)	NA	Low
Complementary medicines	Downgraded[1]	Downgraded[2]	Not downgraded	Not downgraded	Downgraded[5]	11 (1145)	-10 (-17.7 to -2.3)	90%	Very low
Endogenous steroids	Downgraded[1]	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (83)	-5.5 (-13.3 to 2.3)	NA	Very low
Hypnotic medicines	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Downgraded[7]	1 (52)	-19.9 (-31.5 to -8.3)	NA	Very low

Muscle relaxants	Downgraded[1]	Not downgraded	Not downgraded	Downgraded[4]	Not downgraded	2 (268)	-6.3 (-10.4 to -2.2)	0%	Low
Muscle relaxants + NSAIDs	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (18)	-10.0 (-56.0 to 36.0)	NA	Low
NSAIDs	Downgraded[1]	Not downgraded	Not downgraded	Not downgraded	Downgraded[5]	8 (2612)	-4.9 (-6.6 to -3.1)	0%	Low
Opioids	Downgraded[1]	Downgraded[2]	Not downgraded	Not downgraded	Downgraded[5]	19 (7269)	-7.9 (-9.8 to -6.0)	59%	Very low
Opioids + analgesics	Downgraded[1]	Not downgraded	Not downgraded	Not downgraded	Downgraded[7]	4 (821)	-7.5 (-12.5 to -2.5)	46%	Low
Probiotic	Not downgraded	Downgraded[6]	Not downgraded	Downgraded[4]	Not downgraded	1 (88)	1.0 (-8.0 to 10.0)	NA	Low
TRPV1 agonists	Downgraded[1]	Not downgraded	Not downgraded	Not downgraded	Not downgraded	2 (433)	-8.2 (-13.0 to -3.5)	0%	Moderate

[1]Downgraded one level: > 25% of participants were from trials at high risk of bias

[2]Downgraded one level: heterogeneity (I^2) was >50%

[3]Downgraded one level: > 50% of trials included participants with spine-related leg pain

[4]Downgraded one level: < 400 participants in the analysis

[5]Downgraded one level: evidence of funnel plot asymmetry

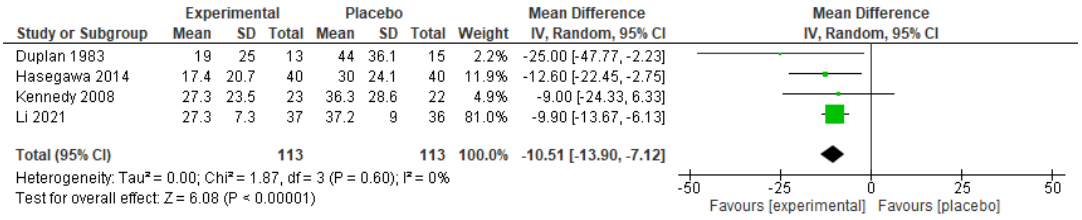
[6]Downgraded one level: single trial comparison

[7]Downgraded one level: >50% of participants were from industry funded trials with potential conflicts of interest

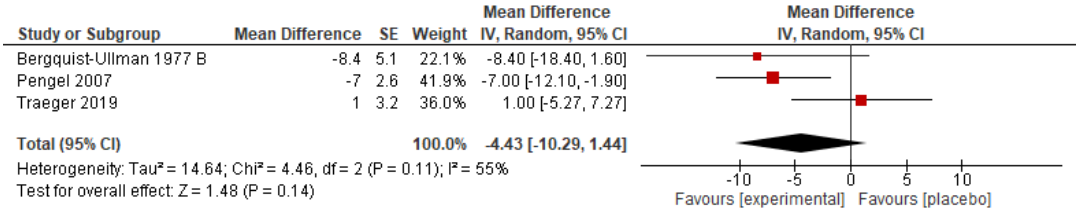
Appendix 3.14. Forest plots of meta-analyses for acute and chronic low back pain

Acute low back pain

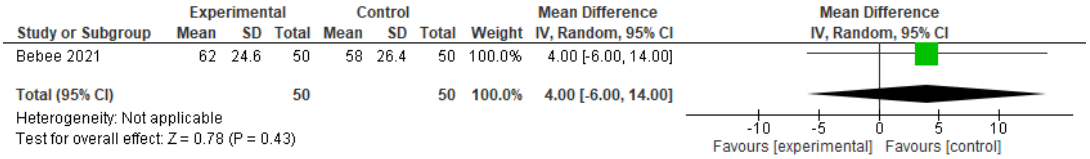
Acupuncture



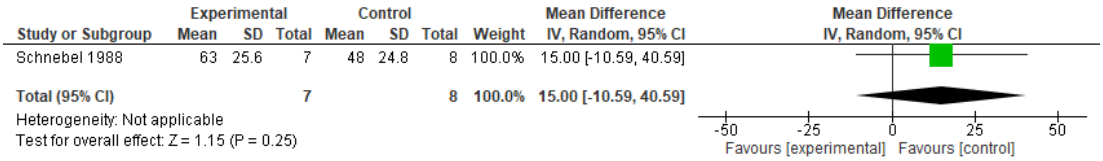
Behaviour/education



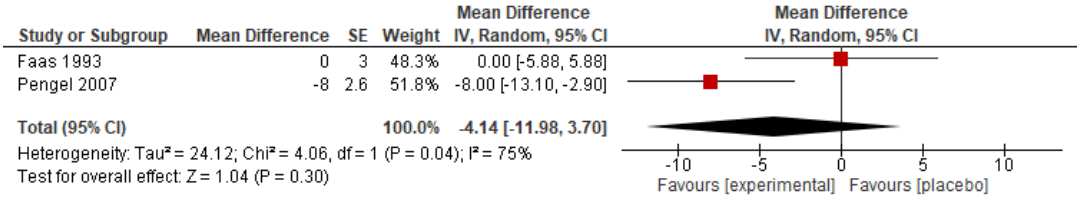
Cannabinoid



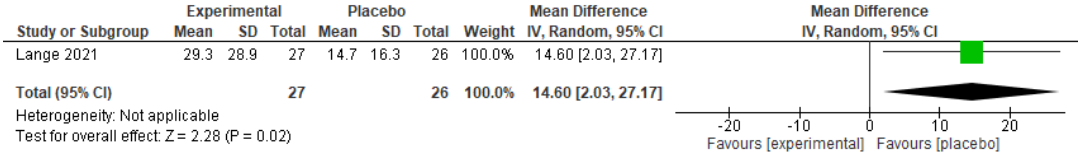
Colchicine



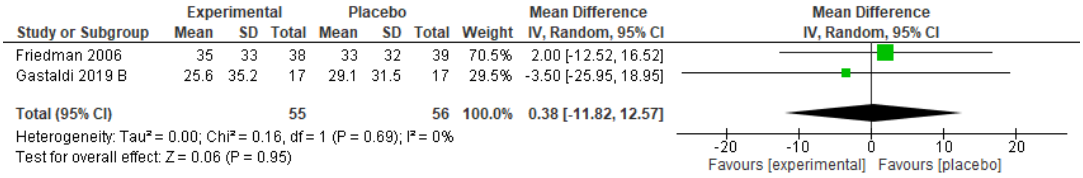
Exercise



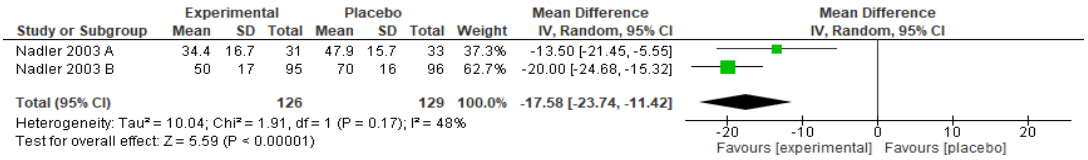
Extracorporeal shockwave



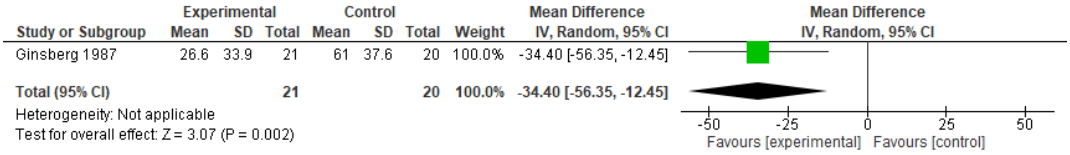
Glucocorticoid injections



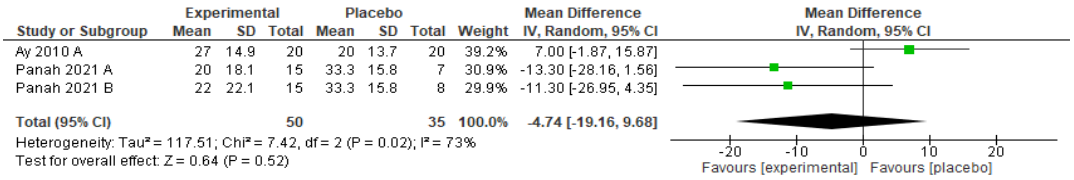
Heat



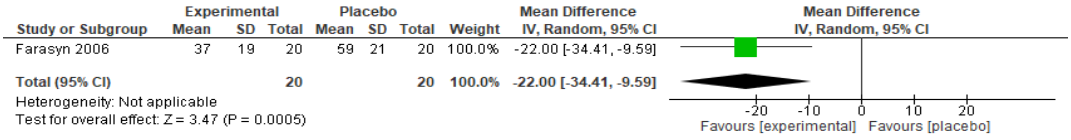
Immunoglobulin



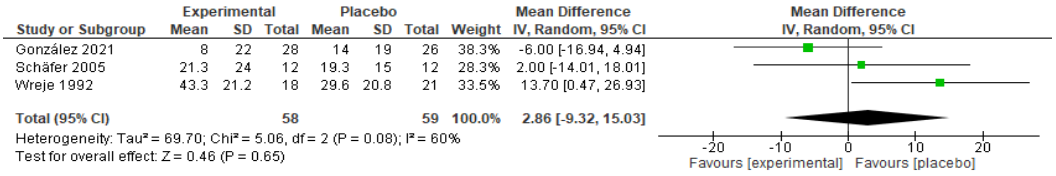
Laser and light



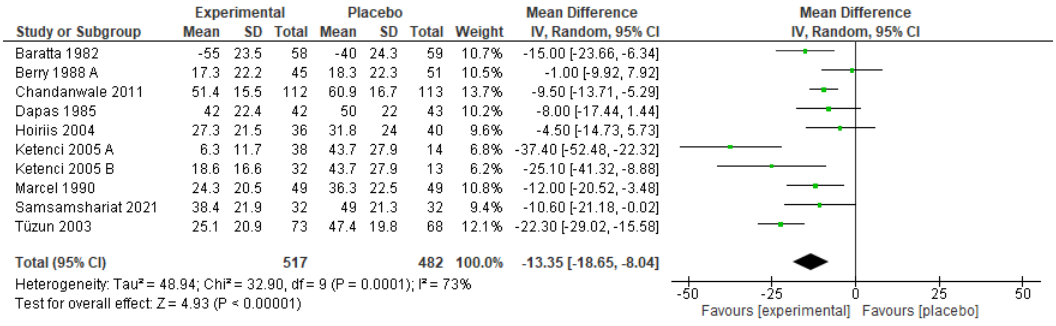
Massage



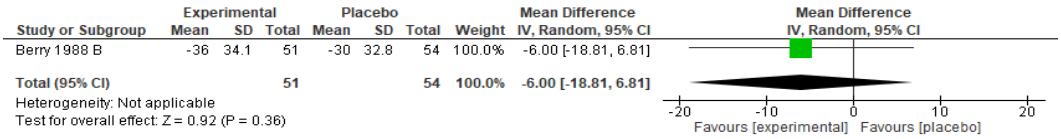
Mobilisation



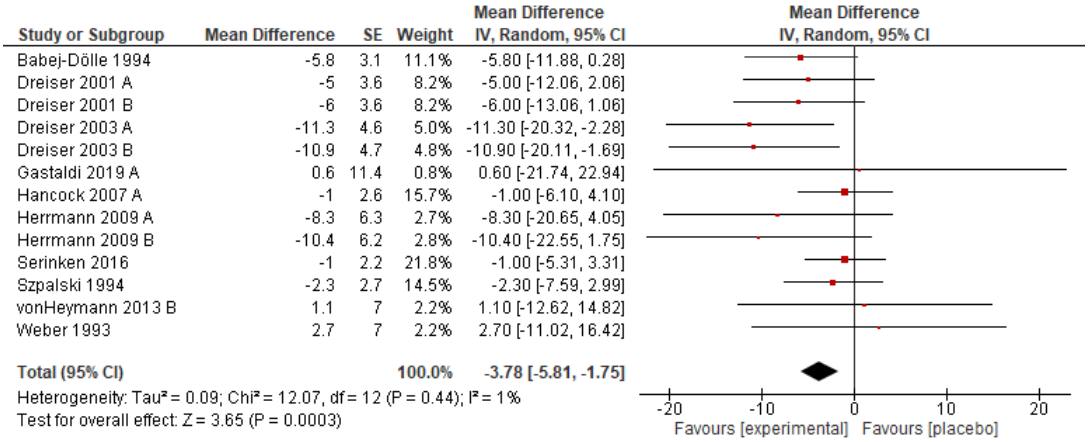
Muscle relaxants



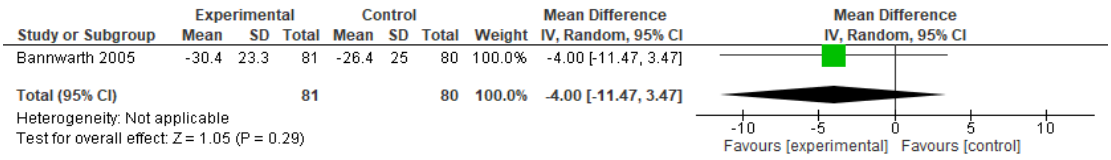
Muscle relaxants + NSAIDs



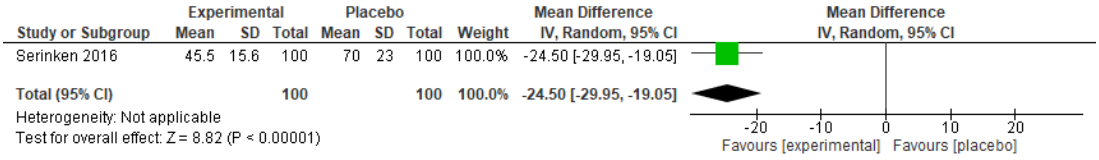
NSAIDs



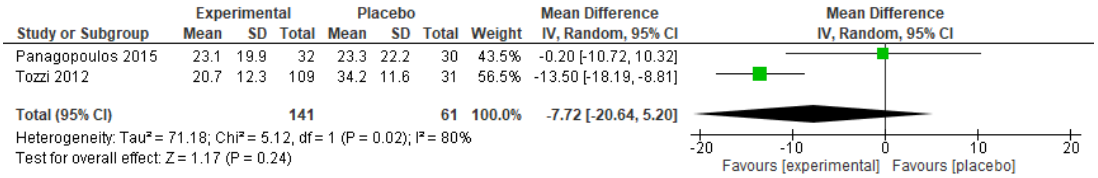
Nucleoside



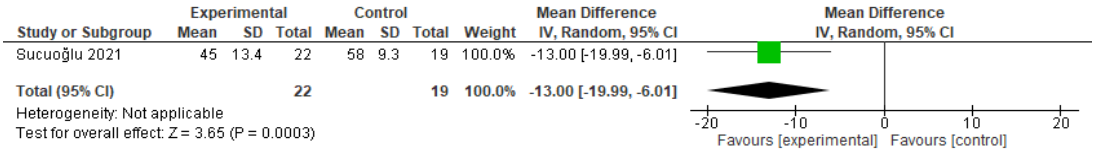
Opioids



Osteopathic



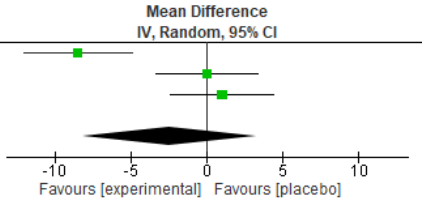
Ozone injections



Paracetamol

Study or Subgroup	Experimental Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Serinken 2016	-16	15.3	100	-7.5	10.2	100	33.0%	-8.50 [-12.10, -4.90]
Williams 2014 A	17	23	550	17	23	274	33.6%	0.00 [-3.33, 3.33]
Williams 2014 B	18	24	546	17	23	273	33.5%	1.00 [-2.39, 4.39]
Total (95% CI)			**1196**			**647**	**100.0%**	**-2.47 [-8.23, 3.30]**

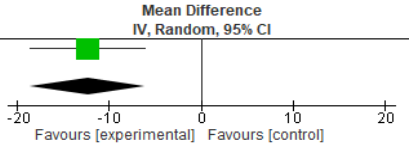
Heterogeneity: Tau² = 22.85; Chi² = 16.83, df = 2 (P = 0.0002); I² = 88%
Test for overall effect: Z = 0.84 (P = 0.40)



Pyrazolone derivatives

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Babej-Dölle 1994	57.9	22.1	86	70.2	18.9	82	100.0%	-12.30 [-18.51, -6.09]
Total (95% CI)			**86**			**82**	**100.0%**	**-12.30 [-18.51, -6.09]**

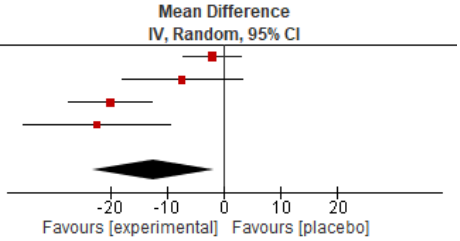
Heterogeneity: Not applicable
Test for overall effect: Z = 3.88 (P = 0.0001)



Spinal manipulative therapy

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Hancock 2007 A	-2	2.6	28.5%	-2.00 [-7.10, 3.10]
Hoiriis 2004	-7.4	5.4	23.5%	-7.40 [-17.98, 3.18]
Sanders 1990	-20	3.7	26.8%	-20.00 [-27.25, -12.75]
vonHeymann 2013 A	-22.3	6.6	21.2%	-22.30 [-35.24, -9.36]
Total (95% CI)			**100.0%**	**-12.39 [-23.15, -1.63]**

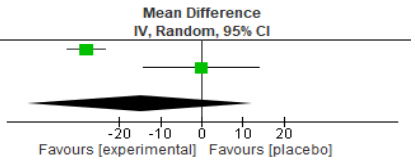
Heterogeneity: Tau² = 98.89; Chi² = 20.23, df = 3 (P = 0.0002); I² = 85%
Test for overall effect: Z = 2.26 (P = 0.02)



TENS

Study or Subgroup	Experimental Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Bertalanffy 2005	49	8	30	77	11	33	52.9%	-28.00 [-32.72, -23.28]
Herman 1994	35.8	27.7	29	35.9	27	29	47.1%	-0.10 [-14.18, 13.98]
Total (95% CI)			**59**			**62**	**100.0%**	**-14.87 [-42.16, 12.42]**

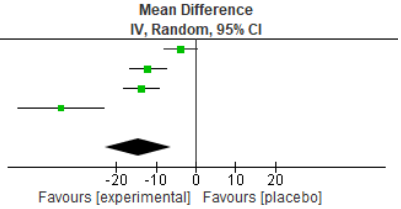
Heterogeneity: Tau² = 360.51; Chi² = 13.56, df = 1 (P = 0.0002); I² = 93%
Test for overall effect: Z = 1.07 (P = 0.29)



Topical rubefacient

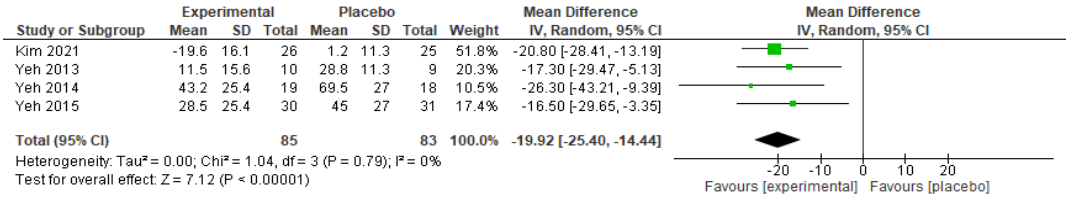
Study or Subgroup	Experimental Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Gaubitz 2016 A	-14.3	15.5	201	-10.5	15.1	68	27.1%	-3.80 [-7.98, 0.38]
Gaubitz 2016 B	-22.5	19.8	198	-10.5	15.1	68	26.7%	-12.00 [-16.53, -7.47]
Gaubitz 2016 C	-24.1	19.6	202	-10.5	15.1	68	26.8%	-13.60 [-18.09, -9.11]
Ginsberg, Famaey 1987	-37.9	19.6	20	-4	15.1	20	19.4%	-33.90 [-44.74, -23.06]
Total (95% CI)			**621**			**224**	**100.0%**	**-14.46 [-22.74, -6.17]**

Heterogeneity: Tau² = 61.47; Chi² = 29.97, df = 3 (P < 0.00001); I² = 90%
Test for overall effect: Z = 3.42 (P = 0.0006)

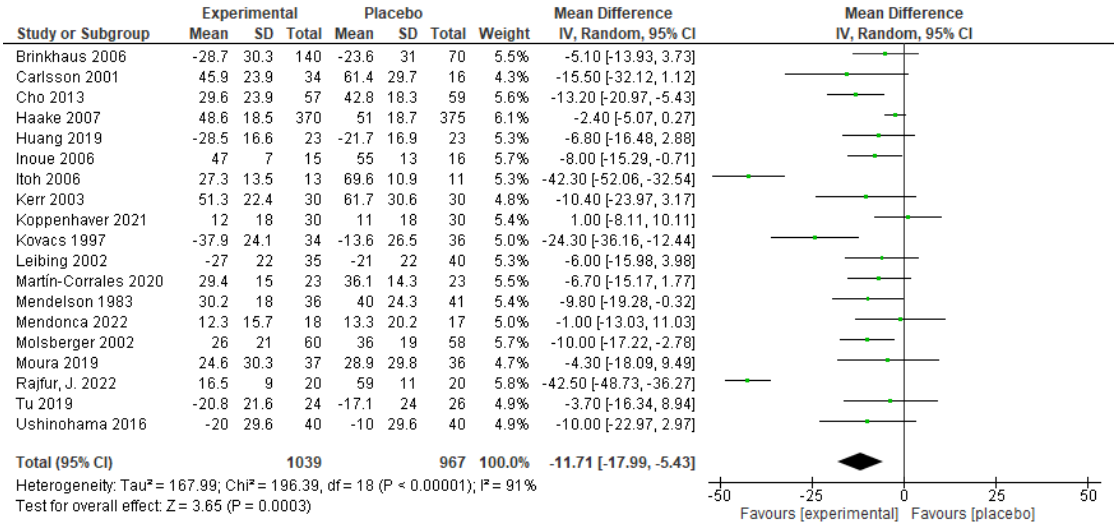


Chronic low back pain

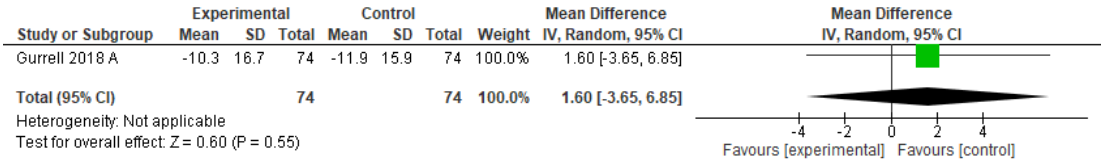
Acupressure



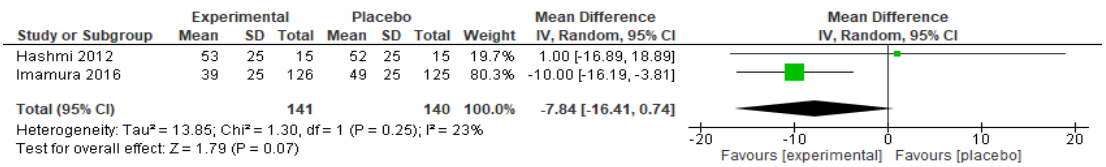
Acupuncture



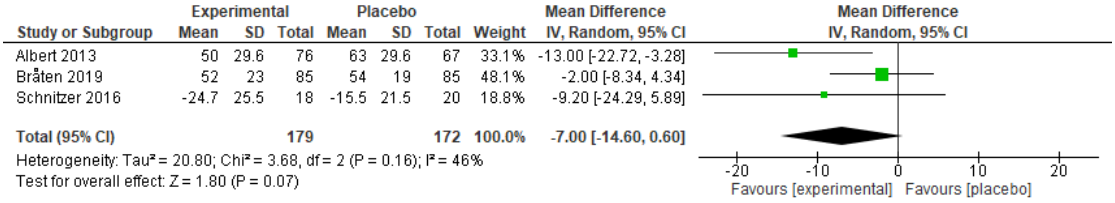
Allosteric modulator of the g-aminobutyric acid type A (GABAA) receptor



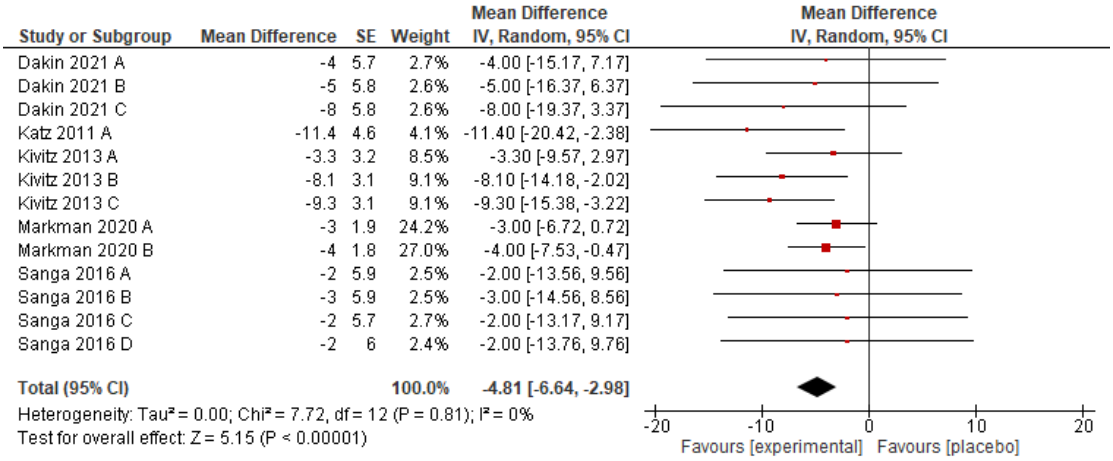
Anaesthetics



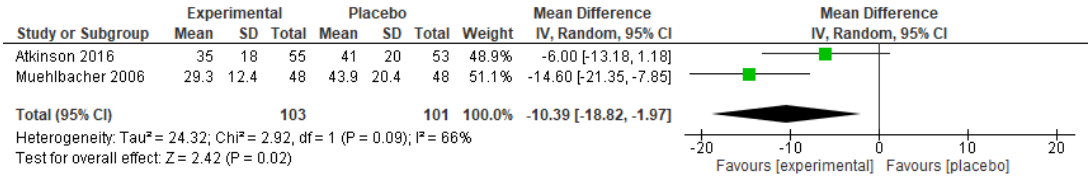
Antibiotic/antimicrobials



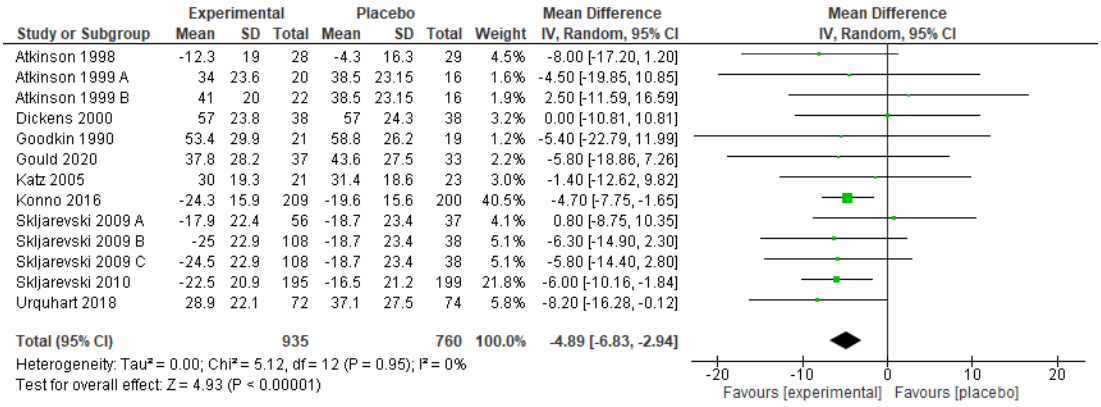
Antibody injections



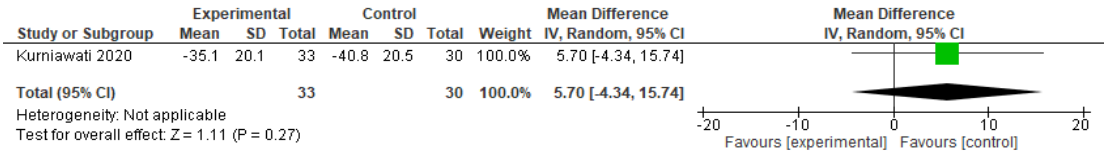
Anticonvulsants



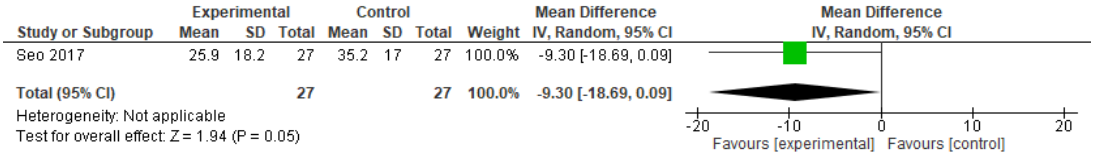
Antidepressants



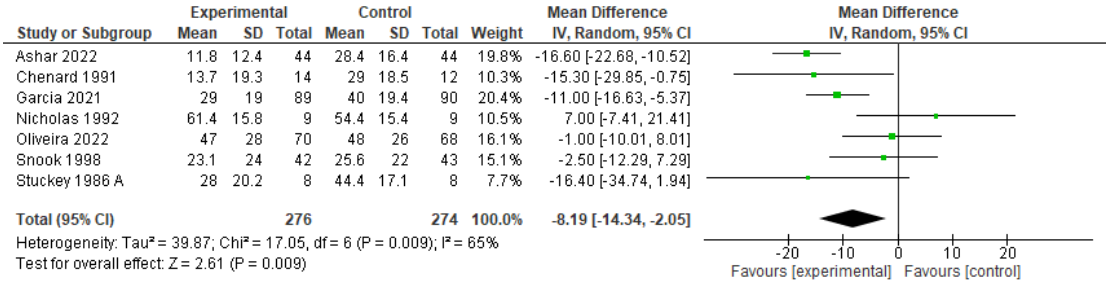
Antidepressants + paracetamol



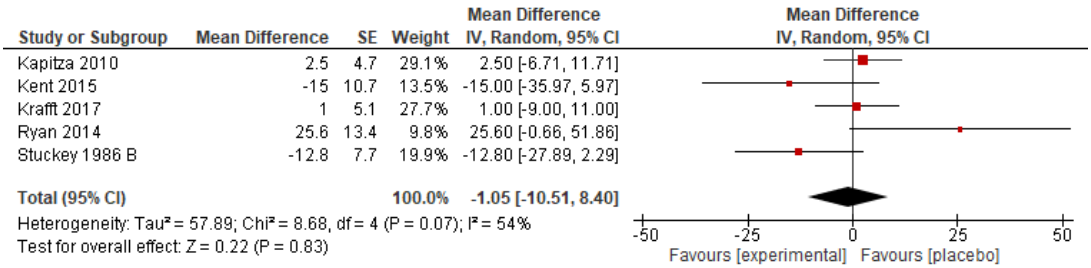
Bee Venom



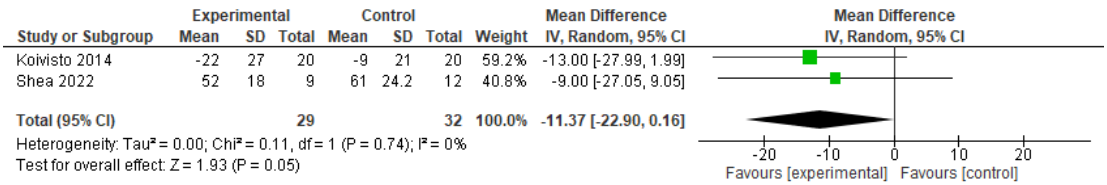
Behavioural/education



Biofeedback



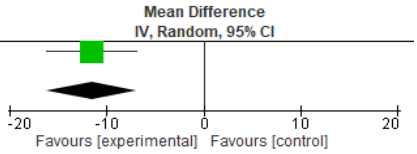
Bisphosphonates



Bushen Huoxue Formula

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Zhan 2022	35.5	10.1	34	47.1	9.4	32	100.0%	-11.60 [-16.30, -6.90]
Total (95% CI)			**34**			**32**	**100.0%**	**-11.60 [-16.30, -6.90]**

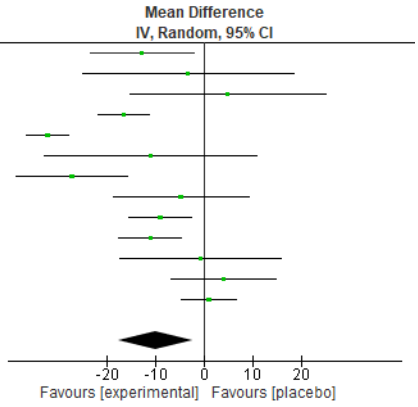
Heterogeneity: Not applicable
Test for overall effect: Z = 4.83 (P < 0.00001)



Complementary medicines

Study or Subgroup	Experimental Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Chiu 2011	38.6	22.3	32	51.5	19.4	26	8.1%	-12.90 [-23.64, -2.16]
Chrubasik 1999 A	39.8	61.5	66	43.2	46.7	33	5.4%	-3.40 [-25.17, 18.37]
Chrubasik 1999 B	48.1	51.6	65	43.2	46.7	33	5.8%	4.90 [-15.38, 25.18]
Chrubasik 2000 A	39.8	18.6	70	56.4	9.2	35	9.2%	-16.60 [-21.92, -11.28]
Chrubasik 2000 B	24.1	13.6	70	56.4	9.2	35	9.3%	-32.30 [-36.71, -27.89]
Dzik 2018	37.4	24.3	14	48.5	28.8	10	5.4%	-11.10 [-33.02, 10.82]
Mauro 2000	9.5	16.5	30	36.8	27.4	30	7.9%	-27.30 [-38.75, -15.85]
Pach 2011	37	35.9	50	41.8	33.1	43	7.3%	-4.80 [-18.83, 9.23]
Prakash 2023	59	11	26	68	12	23	9.0%	-9.00 [-15.48, -2.52]
Qin 2022	12.4	8.6	54	23.5	22.7	54	9.0%	-11.10 [-17.57, -4.63]
Sandoughi 2015	30.3	31.4	26	31.1	30.8	27	6.6%	-0.80 [-17.55, 15.95]
Schrader 1999	64	17	20	60	19	23	8.1%	4.00 [-6.76, 14.76]
Wilkens 2010	25	22.8	125	24	22.8	125	9.1%	1.00 [-4.65, 6.65]
Total (95% CI)			**648**			**497**	**100.0%**	**-10.01 [-17.73, -2.30]**

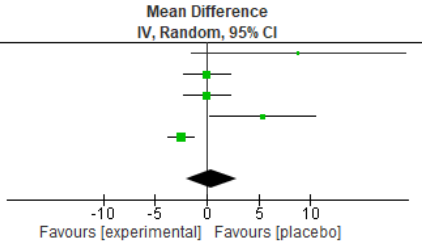
Heterogeneity: Tau² = 161.85; Chi² = 121.15, df = 12 (P < 0.00001); I² = 90%
Test for overall effect: Z = 2.54 (P = 0.01)



Diathermy

Study or Subgroup	Experimental Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Amaral 2023	23.9	15.7	18	15.1	16	18	4.9%	8.80 [-1.56, 19.16]
Karasel 2021 A	30	2.5	30	30	4	15	25.8%	0.00 [-2.21, 2.21]
Karasel 2021 B	30	2.5	30	30	4	15	25.8%	0.00 [-2.21, 2.21]
Ku 2018	-8	9.8	28	-13.4	9.8	28	13.6%	5.40 [0.27, 10.53]
Shakoor 2008	9	2.5	50	11.5	4	52	29.9%	-2.50 [-3.79, -1.21]
Total (95% CI)			**156**			**128**	**100.0%**	**0.42 [-2.07, 2.91]**

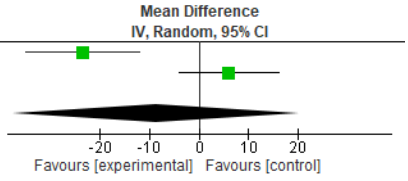
Heterogeneity: Tau² = 4.96; Chi² = 16.09, df = 4 (P = 0.003); I² = 75%
Test for overall effect: Z = 0.33 (P = 0.74)



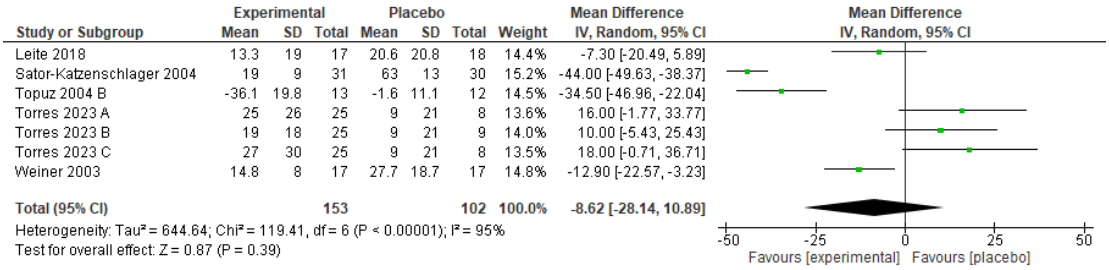
Dry cupping

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
de Melo Salemi 2021	23.9	17.9	19	47.5	17.8	18	49.6%	-23.60 [-35.11, -12.09]
Silva 2021	33	29	45	27	19	45	50.4%	6.00 [-4.13, 16.13]
Total (95% CI)			**64**			**63**	**100.0%**	**-8.67 [-37.68, 20.34]**

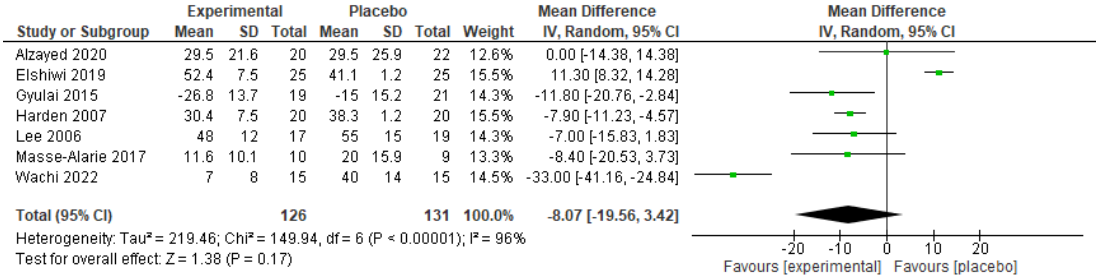
Heterogeneity: Tau² = 407.49; Chi² = 14.32, df = 1 (P = 0.0002); I² = 93%
Test for overall effect: Z = 0.59 (P = 0.56)



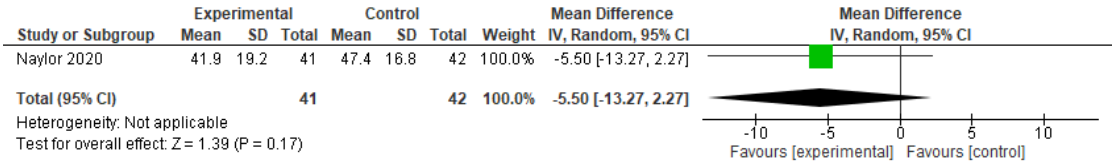
Electroacupuncture



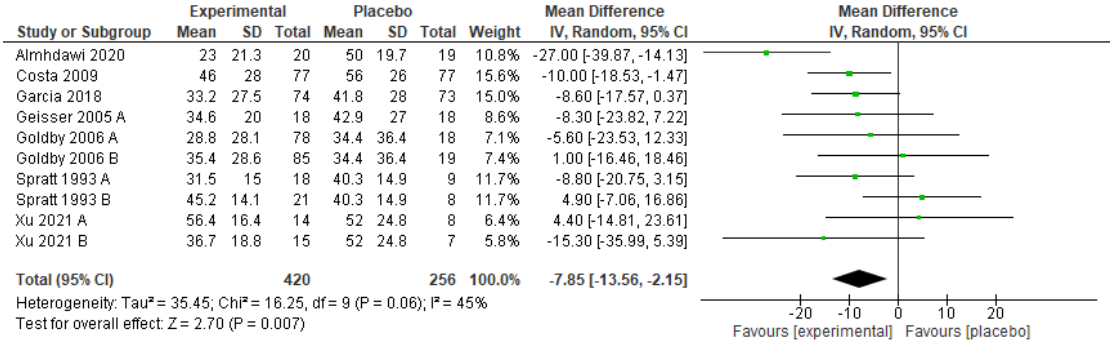
Electromagnetic



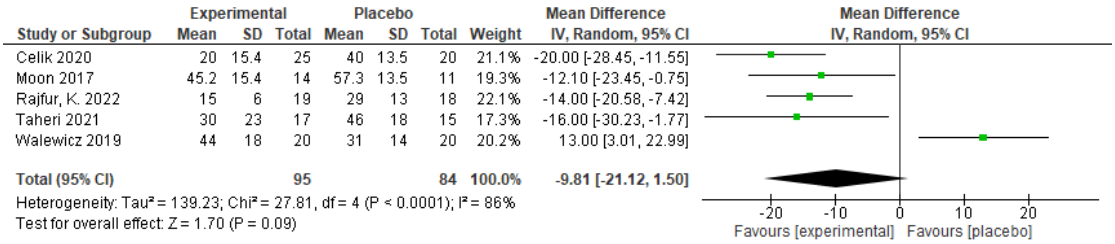
Endogenous steroids



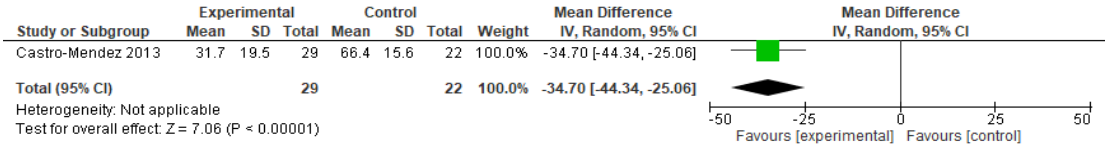
Exercise



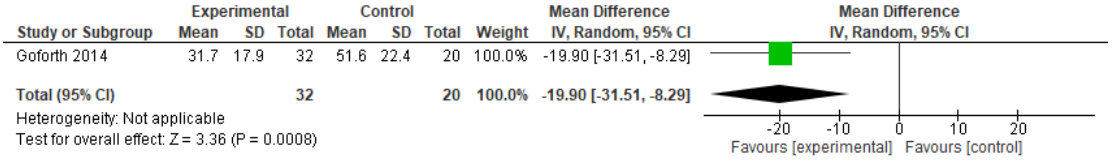
Extracorporeal shockwave



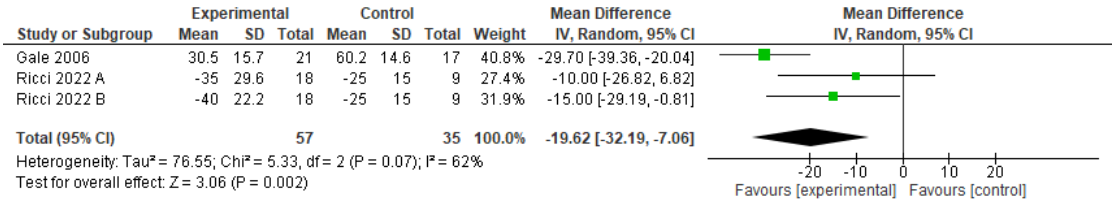
Foot orthotics



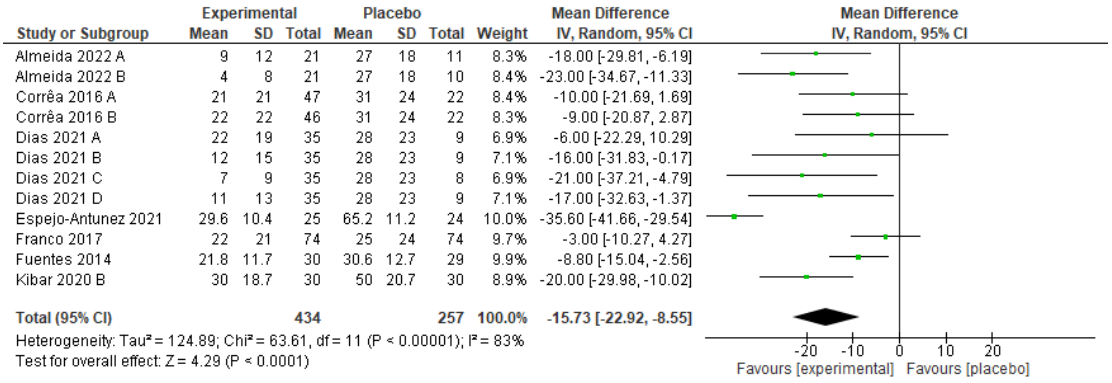
Hypnotic medicines



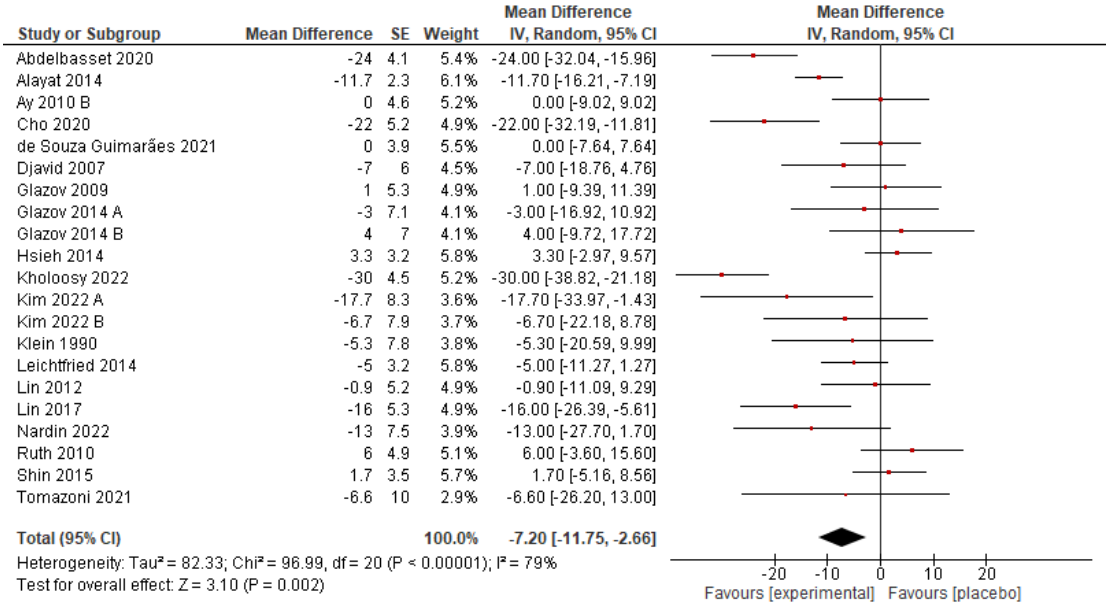
Infrared



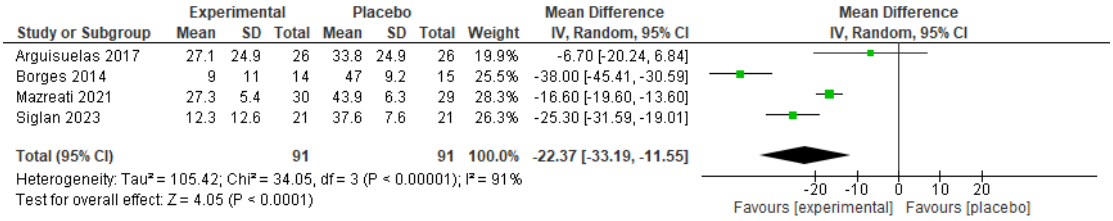
Interferential



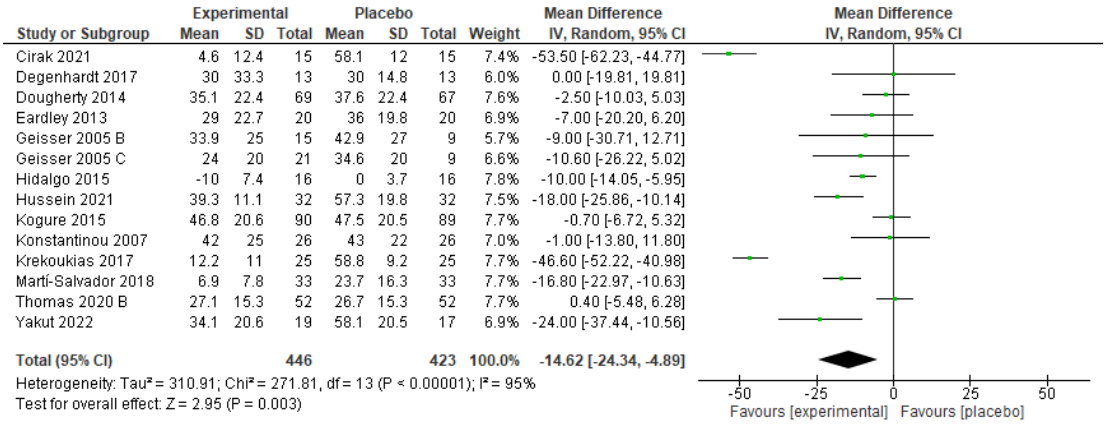
Laser and light



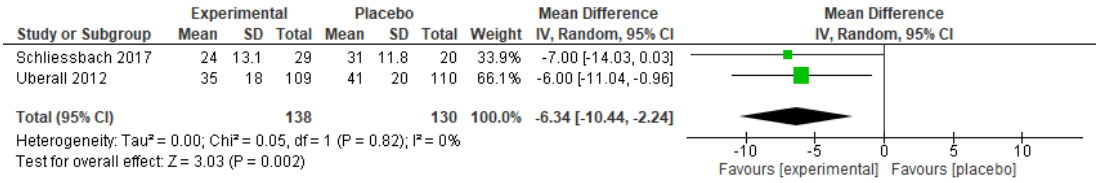
Massage



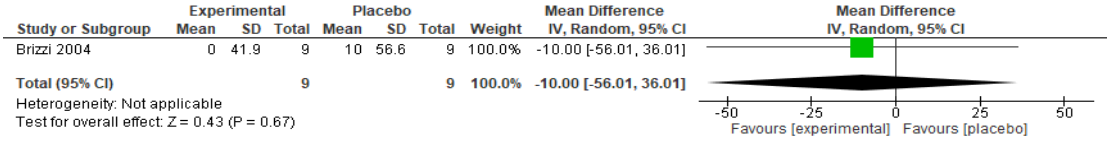
Mobilisation



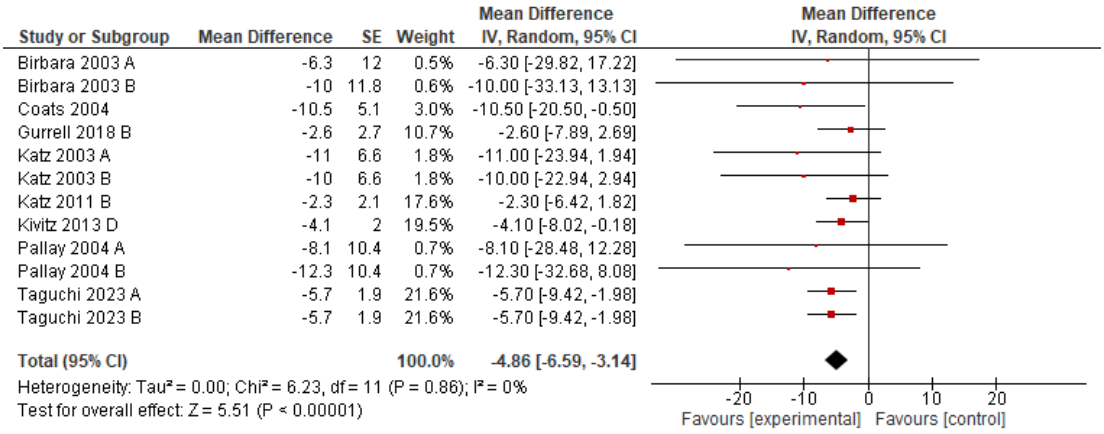
Muscle relaxants



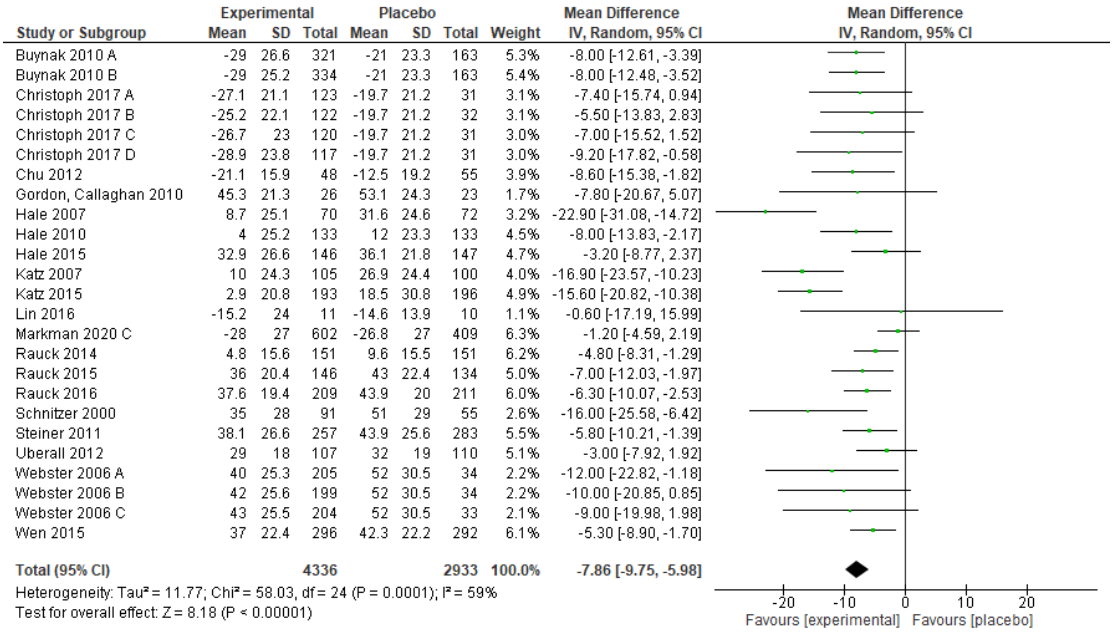
Muscle relaxants + NSAIDs



NSAIDs



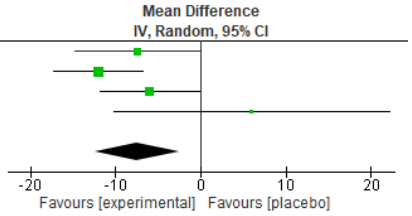
Opioids



Opioids + analgesics

Study or Subgroup	Experimental Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Lee 2013	-23	24.3	83	-15.5	24.4	87	25.4%	-7.50 [-14.82, -0.18]
Peloso 2004	-20	24	162	-8	24	159	34.7%	-12.00 [-17.25, -6.75]
Ruoff 2003	-22	26	141	-16	24	140	31.8%	-6.00 [-11.85, -0.15]
SchiphorstPreuper 2014	51	28.1	24	45	29.6	25	8.1%	6.00 [-10.16, 22.16]
Total (95% CI)			**410**			**411**	**100.0%**	**-7.50 [-12.45, -2.54]**

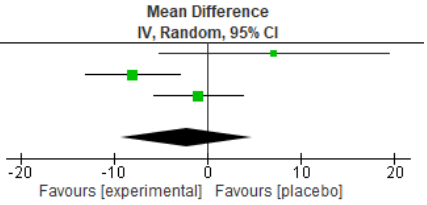
Heterogeneity: Tau² = 11.24; Chi² = 5.56, df = 3 (P = 0.14); I² = 46%
Test for overall effect: Z = 2.96 (P = 0.003)



Osteopathic

Study or Subgroup	Experimental Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Licciardone 2003	30.8	22.1	32	23.7	21.4	19	19.7%	7.10 [-5.20, 19.40]
Licciardone 2013	-20	25.2	175	-12	22.2	170	39.8%	-8.00 [-13.01, -2.99]
Nguyen 2021	-8.1	24.3	197	-7.1	24.3	197	40.5%	-1.00 [-5.80, 3.80]
Total (95% CI)			**404**			**386**	**100.0%**	**-2.19 [-9.20, 4.82]**

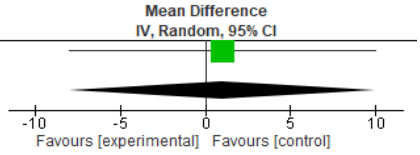
Heterogeneity: Tau² = 25.63; Chi² = 7.00, df = 2 (P = 0.03); I² = 71%
Test for overall effect: Z = 0.61 (P = 0.54)



Probiotic

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Jensen 2019	52	21.9	43	51	20.9	45	100.0%	1.00 [-7.95, 9.95]
Total (95% CI)			**43**			**45**	**100.0%**	**1.00 [-7.95, 9.95]**

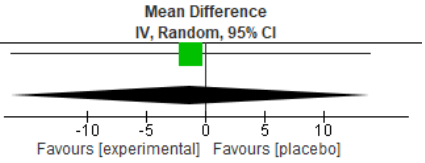
Heterogeneity: Not applicable
Test for overall effect: Z = 0.22 (P = 0.83)



Radiotherapy

Study or Subgroup	Experimental Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Hackenberg 2001	8.1	24	18	9.4	20	14	100.0%	-1.30 [-16.55, 13.95]
Total (95% CI)			**18**			**14**	**100.0%**	**-1.30 [-16.55, 13.95]**

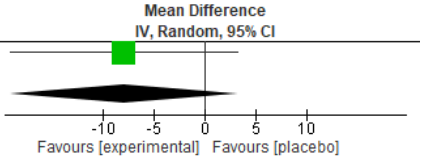
Heterogeneity: Not applicable
Test for overall effect: Z = 0.17 (P = 0.87)



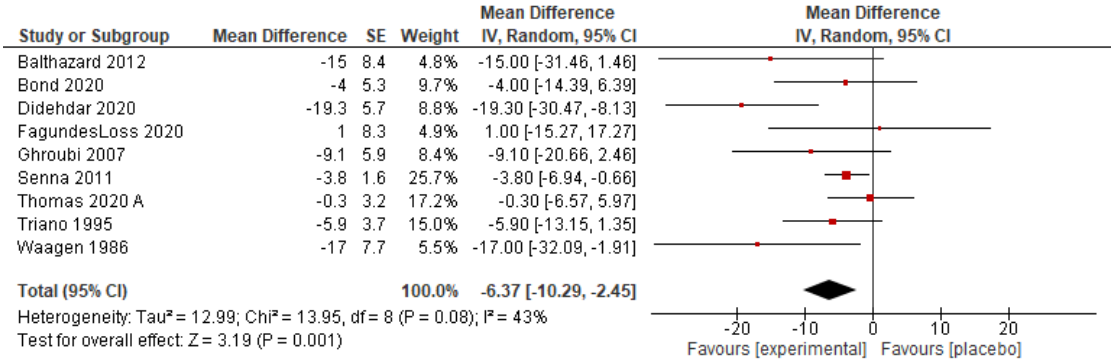
Reflexology

Study or Subgroup	Experimental Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Quinn 2008	31	3.7	7	39	15.6	8	100.0%	-8.00 [-19.15, 3.15]
Total (95% CI)			**7**			**8**	**100.0%**	**-8.00 [-19.15, 3.15]**

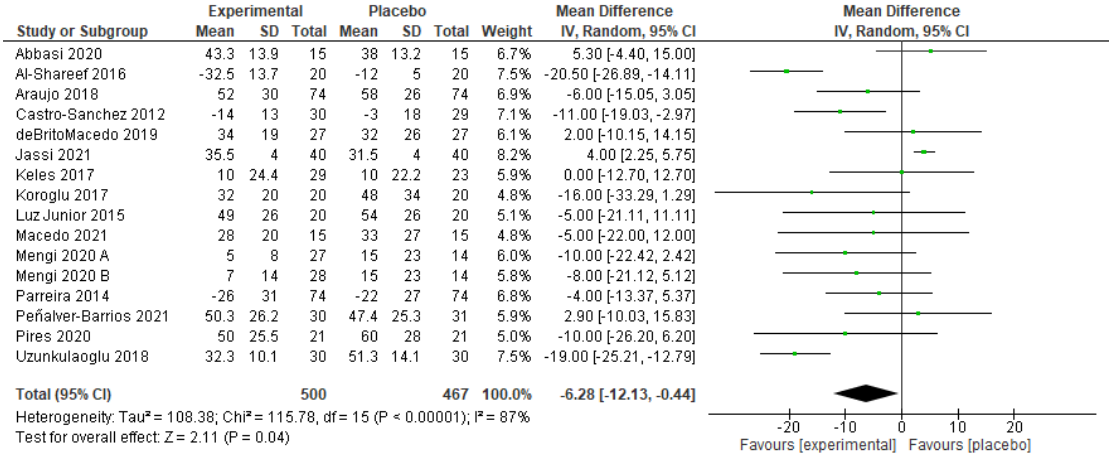
Heterogeneity: Not applicable
Test for overall effect: Z = 1.41 (P = 0.16)



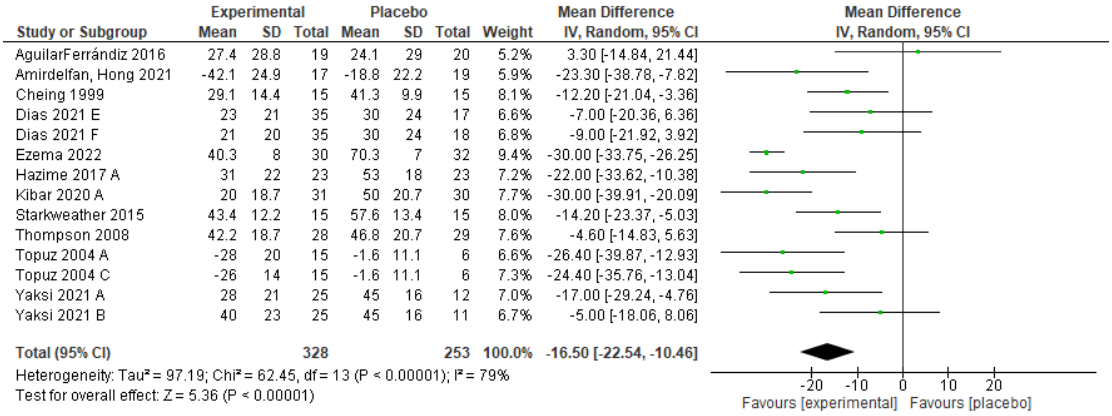
Spinal manipulative therapy



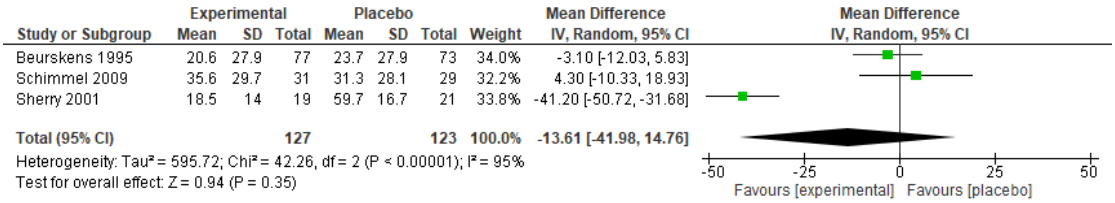
Taping



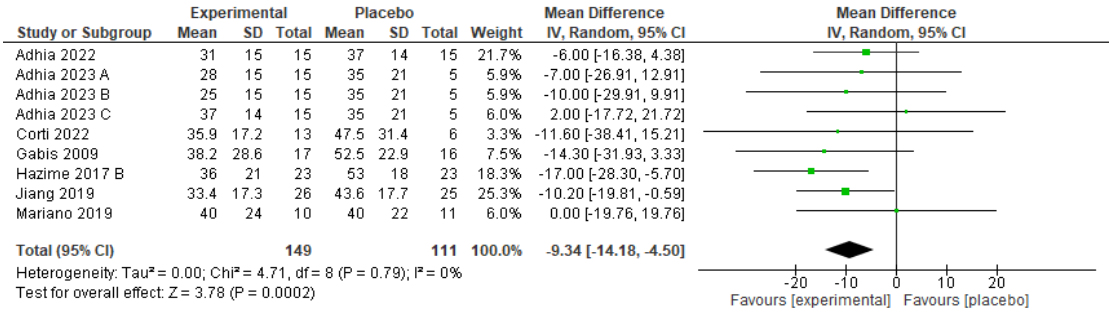
TENS



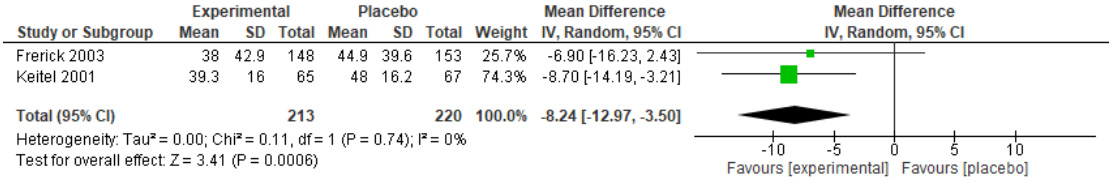
Traction



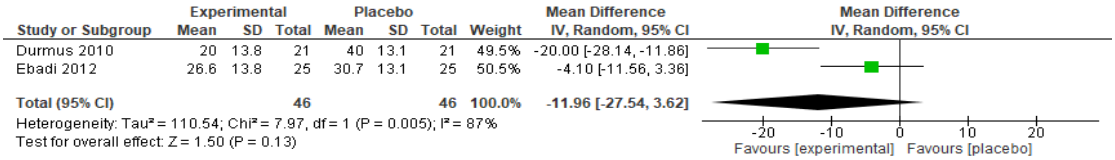
Transcranial stimulation



TRPV1 agonists



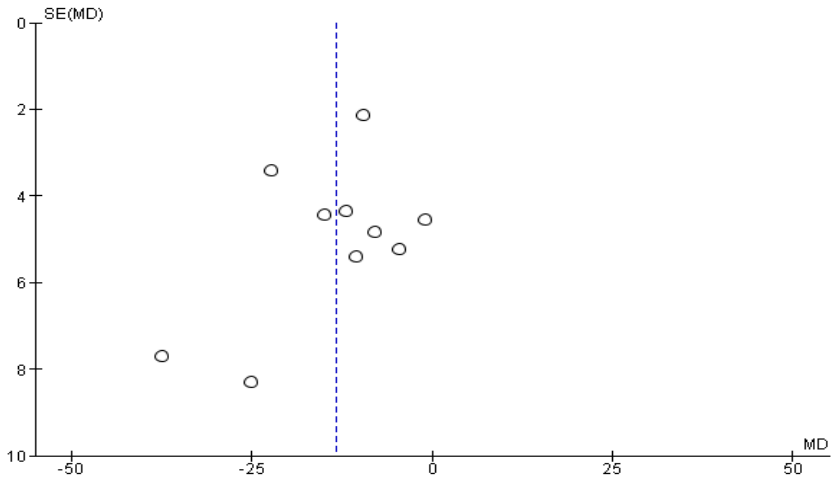
Ultrasound



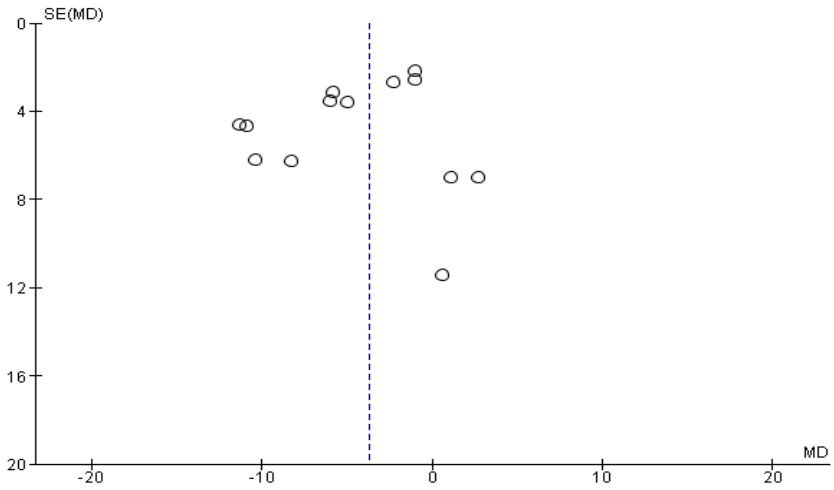
Appendix 3.15. Funnel plots of meta-analyses for interventions with ten or more trials included for acute and chronic low back pain.

Acute low back pain

Muscle relaxants

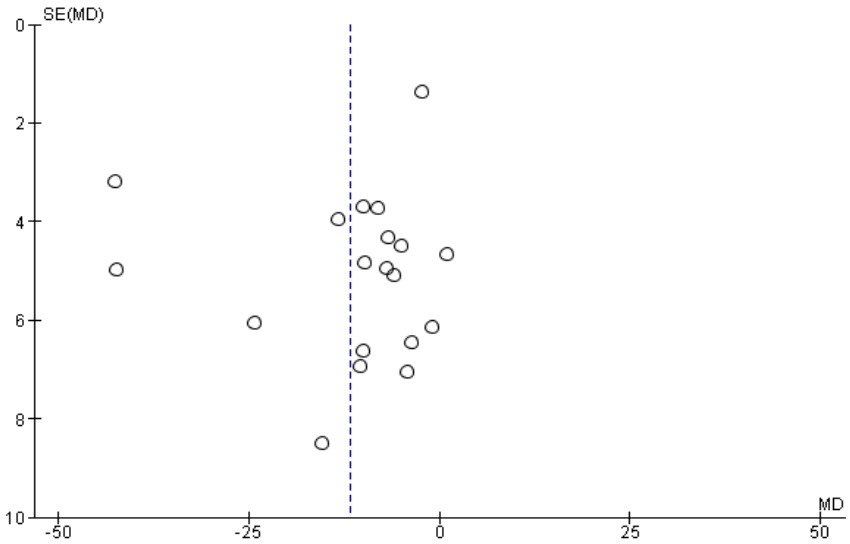


NSAIDs

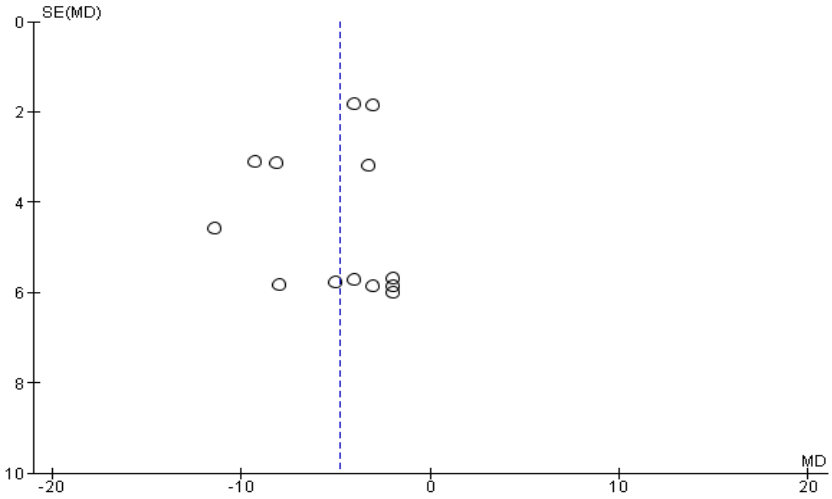


Chronic low back pain

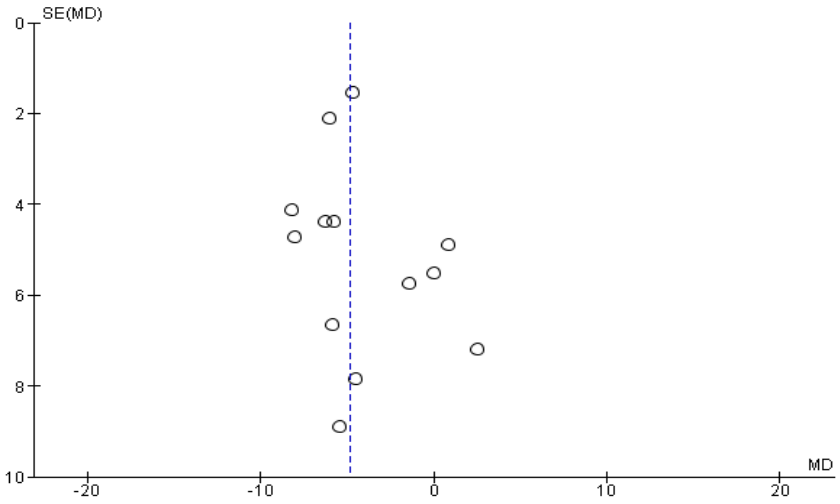
Acupuncture



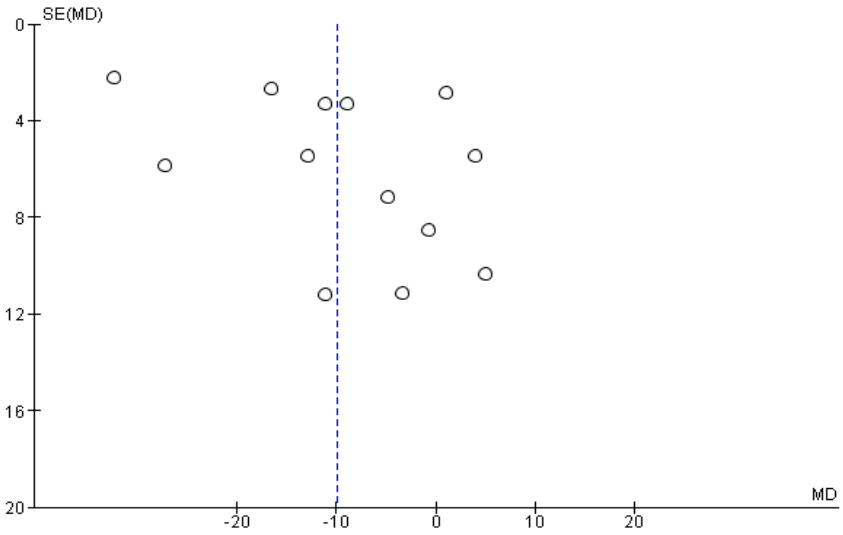
Antibody injections



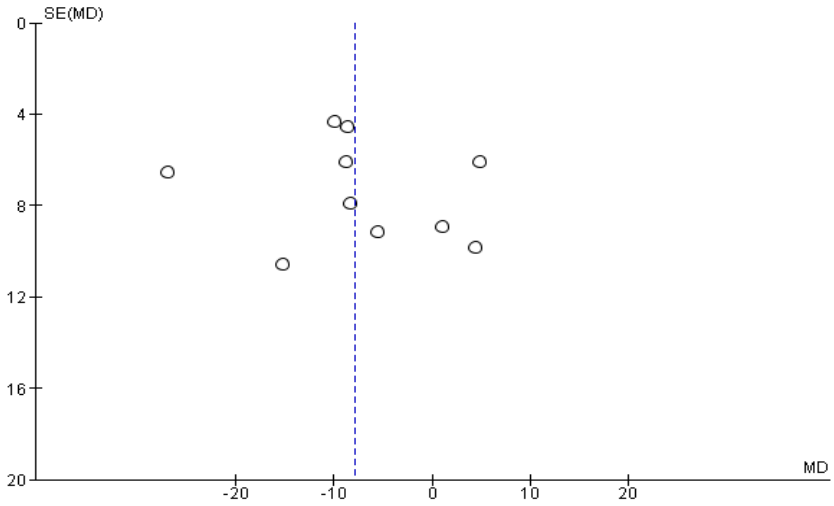
Antidepressants



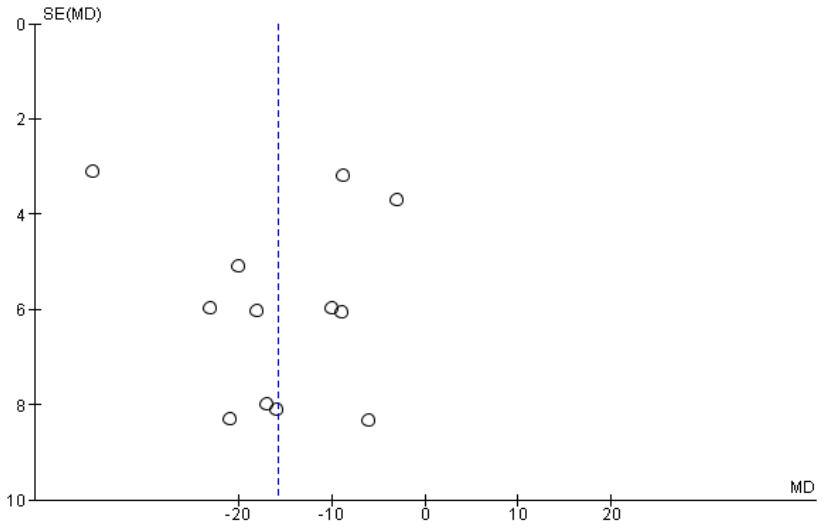
Complementary medicines



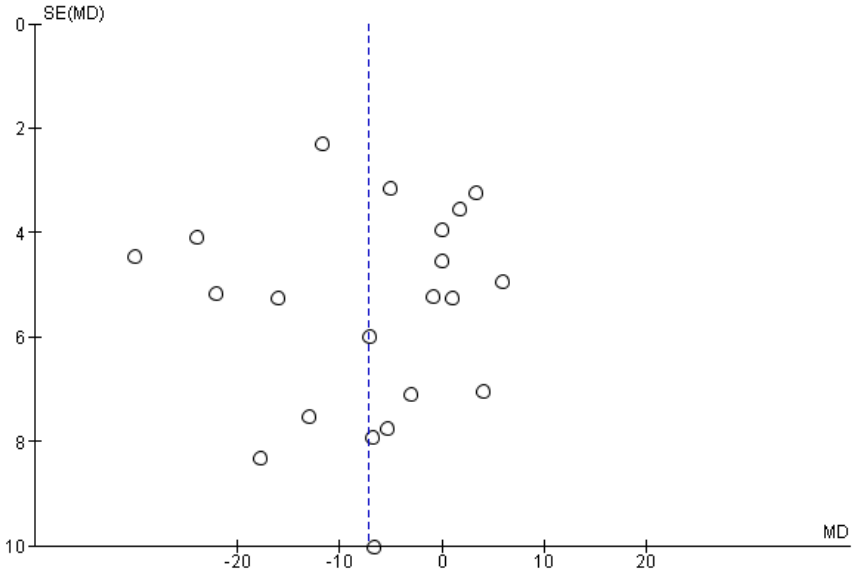
Exercise



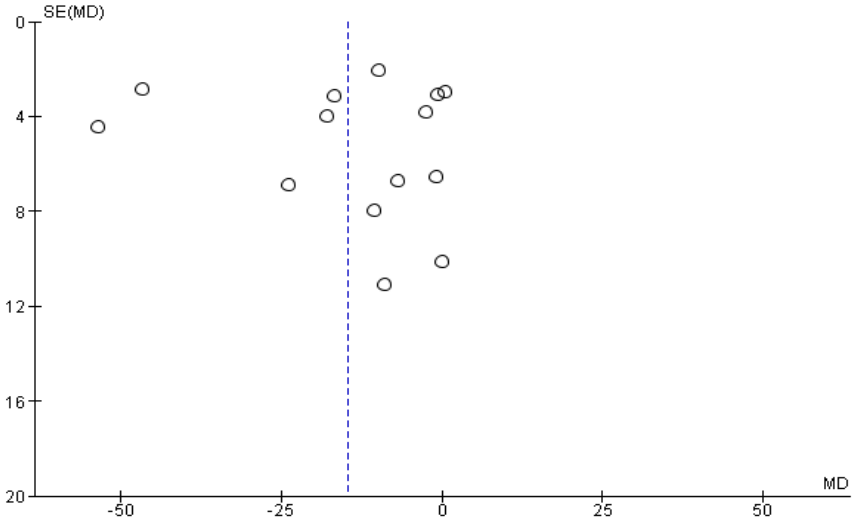
Interferential



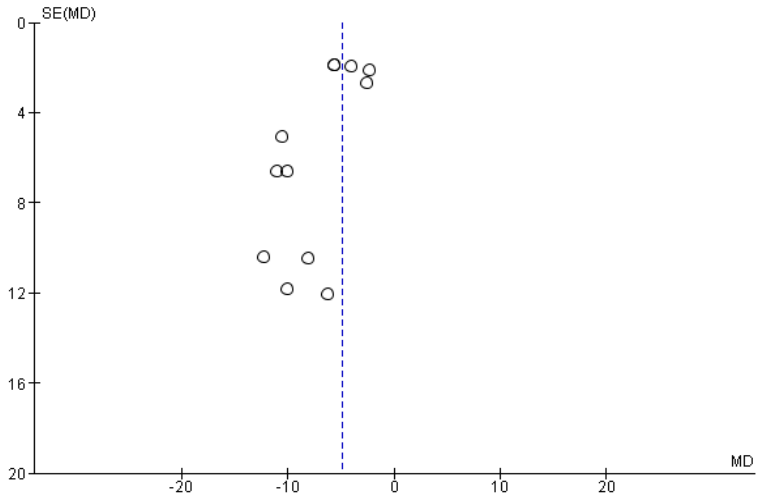
Laser and light



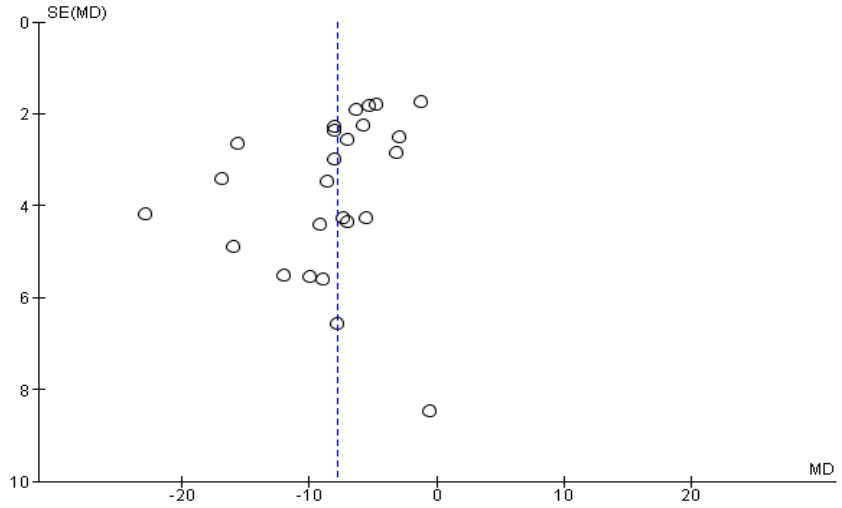
Mobilisation



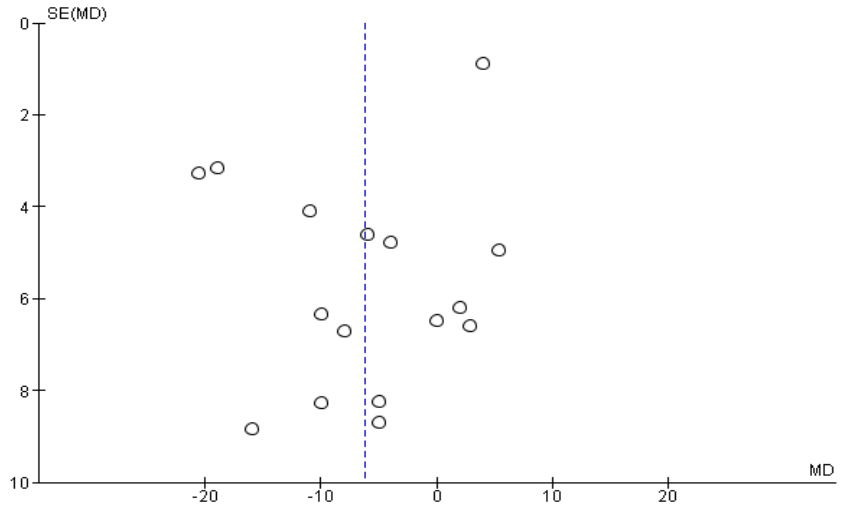
NSAIDs



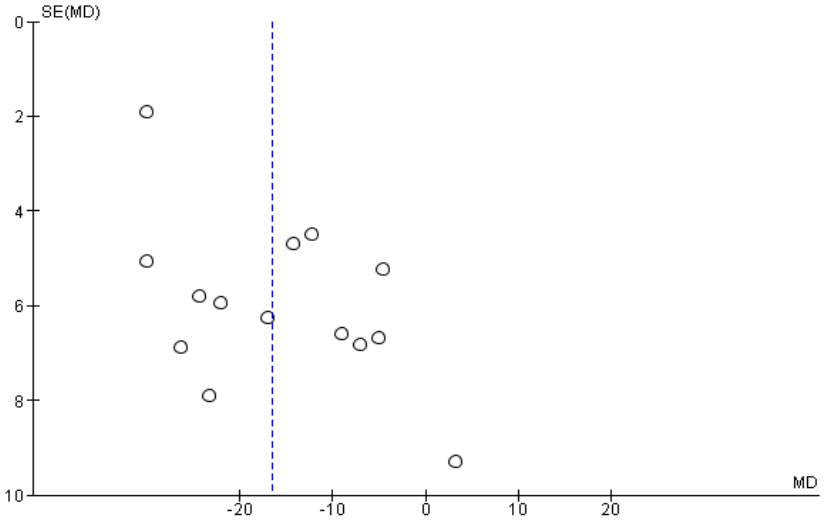
Opioids



Taping



TENS



Appendix 3.16. Post treatment effects on pain intensity (0-100) for studies with mixed duration low back pain

Intervention	Study, Year (Reference)	Intervention			Placebo		
		Mean	SD	N (Analysed)	Mean	SD	N (Analysed)
Acupuncture	Del-Canto-Fernández, 2022(8)	45.0	15.1	10	47.0	17.7	10
Acupuncture	Makary, 2015(21)	26.4	13.4	28	33.1	17.0	19
Anticonvulsants	Mathieson, 2017(42)	2.0*	-6 to 10*	100	-	-	93
Complementary medicines	Shirzad-Siboni, 2022(85)	1.1	3.7	30	9.7	15.6	30
Diathermy	Gibson, 1985(88)	28.0	24.0	32	27.0	20.0	33
Electromagnetic	Lisi, 2019(104)	20.0	14.9	13	20.3	25.9	12
Exercise	Hansen,1993(114) (Exercise)	29.8	26.4	60	33.3	26.0	61
Exercise	Hansen, 1993(114) (Pragmatic physiotherapy)	29.8	18.4	59	33.3	26.0	61
Exercise	Preyde, 2000(115)	32.0	16.0	22	32.0	16.0	26
Infrared	Siems, 2010(133)	73.1	25.0	32	82.4	25.0	11
Laser and light	Basford, 1999(144)	17.1	15.8	27	32.8	28.5	29

Massage	Preyde, 2000(115)	20.0	14.0	25	32.0	16.0	26
Muscle relaxants	Arbus, 1990(184)	43.3	32.8	22	59.5	27.0	21
Muscle relaxants	Ketenci, 2022(191)	38	21	139	39	23	137
Mobilisation	Goodsell, 2000(172)	24.0	21.0	12	36.0	23.0	14
Mobilisation	Hall, 2006(173)	20.0	20.6	12	20.0	20.5	12
NSAIDs	Allegrini, 2009(198) (Piroxicam patch)	38.3	26.6	60	47.6	26.6	59
NSAIDs	Allegrini, 2009(198) (Piroxicam cream)	42.2	21.7	60	47.6	26.6	59
Orthopedic device	Park, 2022(237)	32.1	13.4	15	46.1	15.9	14
Osteopathic	Gibson, 1985(88)	21.0	22.5	39	27.0	20.0	33
Spinal manipulative therapy	Fisher, 2020(253)	-15.2	16.2	52	-14.5	20.7	49
Spinal manipulative therapy	Vieira-Pellenz, 2014(258)	20.0	22.5	20	29.1	26.4	20
Spinal manipulative therapy	Bialosky, 2014(249)	-11.2	18.2	27	-14.0	18.2	27
Taping	Chen, 2012(264)	-20.4	19.9	21	-12.9	20.5	22
TENS	Glaser, 2001(281)	39.2	10.8	32	35.4	12.5	23

*Between group difference and corresponding 95% confidence interval

Negative values indicate change scores with larger negative scores indicating greater reductions in pain.

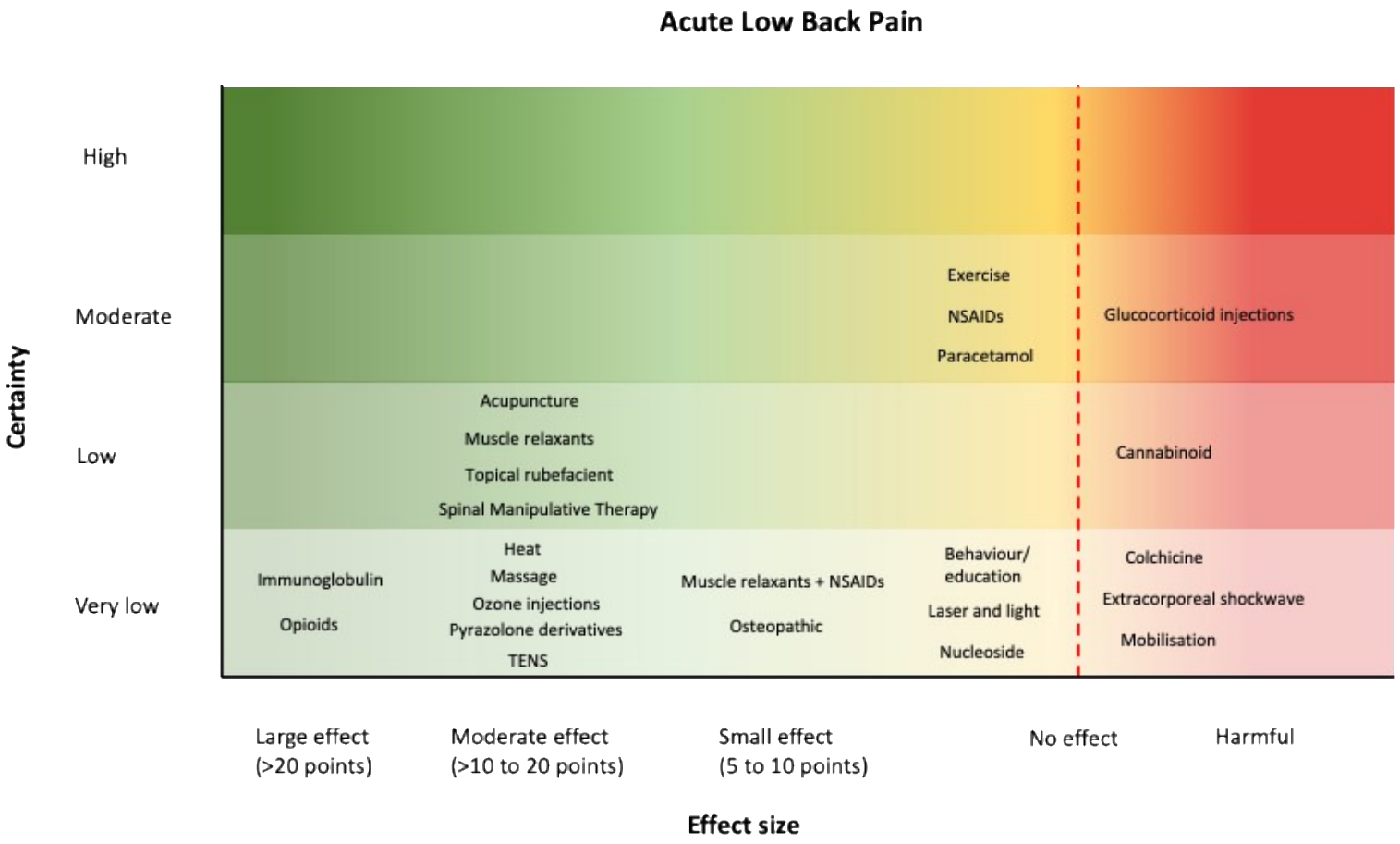
Appendix 3.17. Sensitivity analyses exploring the effect of risk of bias

Intervention	Original estimate Mean difference (95% CI)	Sensitivity estimate (high ROB studies removed) Mean difference (95% CI)	Statistically different (non-overlapping confidence intervals)? (Y/N)
Acute low back pain			
Non-pharmacological interventions			
Acupuncture	-10.5 (-13.9 to -7.1)	-14.7 [-29.7, 0.3]	N
Behaviour/education	-4.4 (-10.3 to 1.4)	-3.2 [-11.1, 4.6]	N
Exercise	-4.1 (-12.0 to 3.7)	No high risk of bias studies	-
Extracorporeal shockwave	14.6 (2.0 to 27.2)	All studies (n=1) high risk of bias	-
Heat	-17.6 (-23.7 to -11.4)	All studies (n=2) high risk of bias	-
Laser and light	-4.7 (-19.2 to 9.7)	All studies (n=3) high risk of bias	-
Massage	-22.0 (-34.4 to -9.6)	All studies (n=1) high risk of bias	-
Mobilisation	2.9 (-9.3 to 15.0)	-6.0 [-16.9, 4.9]	N
Osteopathic	-7.7 (-20.6 to 5.2)	-0.2 [-10.7, 10.3]	N
Spinal manipulative therapy	-12.4 (-23.2 to -1.6)	-2.0 [-7.1, 3.1]	N
TENS	-14.9 (-42.2 to 12.4)	-28.0 [-32.7, -23.3]	N
Pharmacological intervention			
Cannabinoid	4.0 (-6.0 to 14.0)	No high risk of bias studies	-
Colchicine	15.0 (-10.6 to 40.6)	All studies (n=1) high risk of bias	-
Glucocorticoid injections	0.4 (-11.8 to 12.6)	2.0 [-12.5, 16.5]	N
Immunoglobulin	-34.4 (-56.4 to -12.5)	All studies (n=1) high risk of bias	-
Muscle relaxants	-13.4 (-18.7 to -8.0)	-17.39 [-25.34, -9.44]	N
Muscle relaxants + NSAIDs	-6.0 (-18.8 to 6.8)	All studies (n=1) high risk of bias	-
NSAIDs	-3.8 (-5.8 to -1.8)	-5.19 [-8.69, -1.69]	N
Nucleoside	-4.0 (-11.5 to 3.5)	All studies (n=1) high risk of bias	-
Opioids	-24.5 (-30.0 to -19.1)	No high risk of bias studies	-
Ozone injections	-13.0 (-20.0 to -6.0)	All studies (n=1) high risk of bias	-
Paracetamol	-2.5 (-8.2 to 3.3)	No high risk of bias studies	-
Pyrazolone derivatives	-12.3 (-18.5 to -6.1)	No high risk of bias studies	-
Topical rubefacient	-14.5 (-22.7 to -6.2)	-9.8 [-15.8, -3.7]	N
Chronic low back pain			
Non-pharmacological intervention			

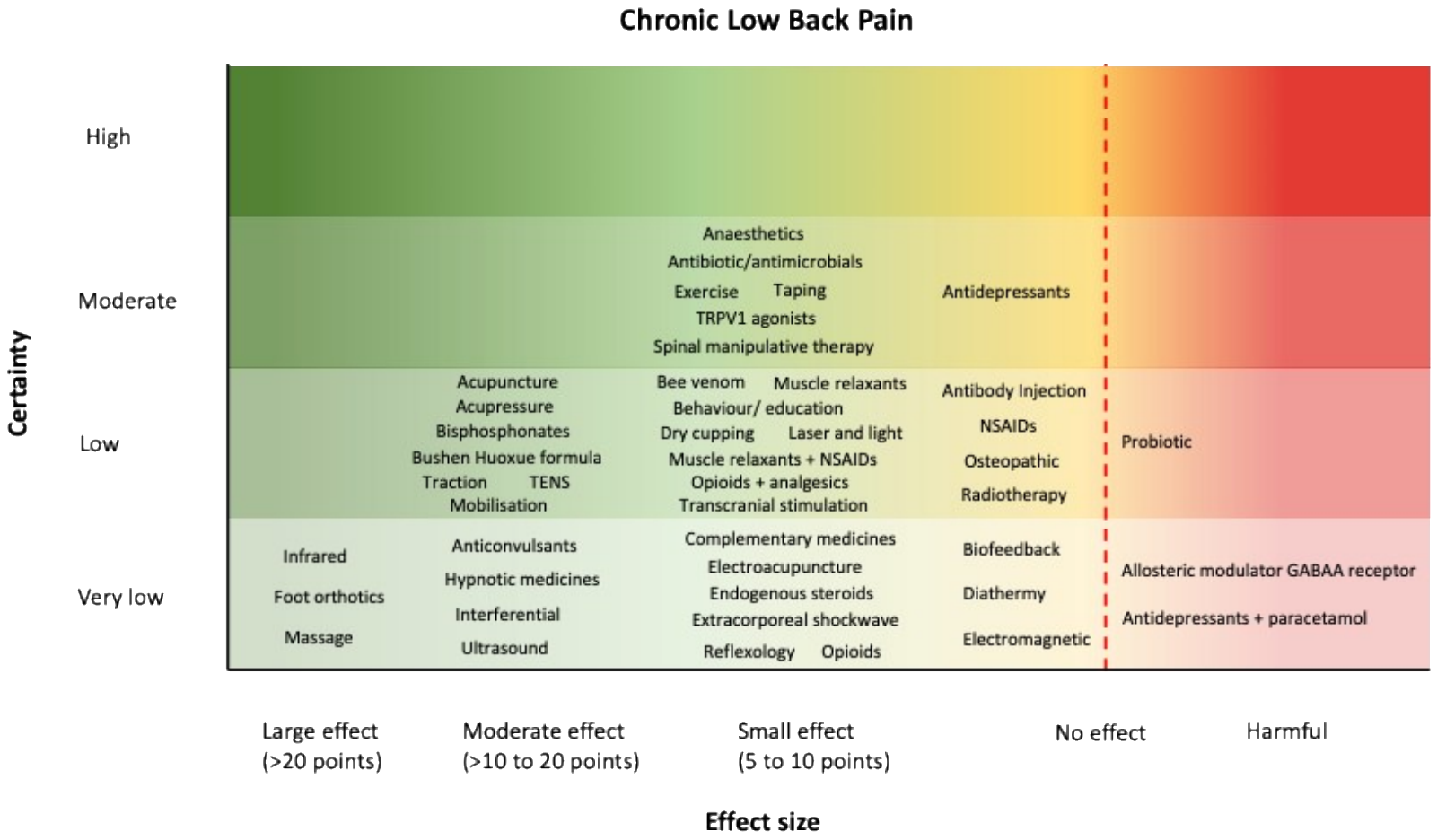
Acupressure	-19.9 (-25.4 to -14.4)	All studies (n=4) high risk of bias	-
Acupuncture	-11.7 (-18.0 to -5.4)	-6.0 [-9.2, -2.8]	N
Behavioural/education	-8.2 (-14.3 to -2.1)	-10.8 [-21.7, 0.1]	N
Biofeedback	-1.1 (-10.5 to 8.4)	2.5 [-6.7, 11.7]	N
Diathermy	0.4 (-2.1 to 2.9)	6.1 [1.5, 10.7]	N
Dry cupping	-8.7 (-37.7 to 20.3)	No high risk of bias studies	-
Electroacupuncture	-8.6 (-28.1 to 10.9)	14.1 [4.2, 24.0]	N
Electromagnetic	-8.1 (-19.6 to 3.4)	2.4 [-16.9, 21.6]	N
Exercise	-7.9 (-13.6 to -2.2)	-9.3 [-15.5, -3.2]	N
Extracorporeal shockwave	-9.8 (-21.1 to 1.5)	All studies (n=5) high risk of bias	-
Foot orthotics	-34.7 (-44.3 to -25.1)	All studies (n=1) high risk of bias	-
Infrared	-19.6 (-32.2 to -7.1)	All studies (n=3) high risk of bias	-
Interferential	-15.7 (-22.9 to -8.6)	-10.9 [-16.5, -5.3]	N
Laser and light	-7.2 (-11.8 to -2.7)	-4.2 [-9.8, 1.4]	N
Massage	-22.4 (-33.2 to -11.6)	-17.0 [-35.1, 1.1]	N
Mobilisation	-14.6 (-24.3 to -4.9)	-24.3 [-40.5, -8.0]	N
Osteopathic	-2.2 (-9.2 to 4.8)	All studies (n=3) high risk of bias	-
Radiotherapy	-1.3 (-16.6 to 14.0)	No high risk of bias studies	-
Reflexology	-8.0 (-19.2 to 3.2)	All studies (n=1) high risk of bias	-
Spinal manipulative therapy	-6.4 (-10.3 to -2.5)	-3.7 [-6.6, -0.7]	N
Taping	-6.3 (-12.1 to -0.4)	-6.7 [-12.6, -0.7]	N
TENS	-16.5 (-22.5 to -10.5)	-20.1 [-32.1, -8.1]	N
Traction	-13.6 (-42.0 to 14.8)	-1.1 [-8.7, 6.5]	N
Transcranial stimulation	-9.3 (-14.2 to -4.5)	-9.8 [-15.6, -4.1]	N
Ultrasound	-12.0 (-27.5 to 3.6)	All studies (n=2) high risk of bias	-
Pharmacological interventions			
Allosteric modulator of the g-aminobutyric acid type A (GABAA) receptor	1.6 (-3.7 to 6.9)	No high risk of bias studies	-
Anaesthetics	-7.8 (-16.4 to 0.7)	-10.0 [-16.2, -3.8]	N
Antibiotic/antimicrobials	-7.0 (-14.6 to 0.6)	No high risk of bias studies	-
Antibody injection	-4.8 (-6.6 to -3.0)	All studies (n=13) high risk of bias	-
Anticonvulsants	-10.4 (-18.8 to -2.0)	-14.6 [-21.4, -7.9]	N
Antidepressants	-4.9 (-6.8 to -2.9)	0.0 [-10.8, 10.8]	N
Antidepressants + paracetamol	5.7 (-4.3 to 15.7)	All studies (n=1) high risk of bias	-
Bee Venom	-9.3 (-18.7 to 0.1)	No high risk of bias studies	-
Bisphosphonates	-11.4 (-22.9 to 0.2)	-13.0 [-28.0, 2.0]	N
Bushen Huoxue formula	-11.6 (-16.3 to -6.9)	No high risk of bias studies	-
Complementary medicines	-10 (-17.7 to -2.3)	-4.0 [-11.3, 3.3]	N

Endogenous steroids	-5.5 (-13.3 to 2.3)	All studies (n=1) high risk of bias	-
Hypnotic medicines	-19.9 (-31.5 to -8.3)	No high risk of bias studies	-
Muscle relaxants	-6.3 (-10.4 to -2.2)	All studies (n=2) high risk of bias	-
Muscle relaxants + NSAIDs	-10.0 (-56.0 to 36.0)	No high risk of bias studies	-
NSAIDs	-4.9 (-6.6 to -3.1)	-2.6 [-7.9, 2.7]	N
Opioids	-7.9 (-9.8 to -6.0)	All studies (n=25) high risk of bias	-
Opioids + analgesics	-7.5 (-12.5 to -2.5)	-2.5 [-13.2, 8.3]	N
Probiotic	1.0 (-8.0 to 10.0)	No high risk of bias studies	-
TRPV1 agonists	-8.2 (-13.0 to -3.5)	-6.9 [-16.2, 2.4]	N

Appendix 3.18. Analgesic efficacy of treatments for acute low back pain stratified by both the magnitude and certainty of the evidence



Appendix 3.19. Analgesic efficacy of treatments for chronic low back pain stratified by both the magnitude and certainty of the evidence



Appendix 3.20. PRISMA checklist.

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	P88
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	P89-91
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	P93-94
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	P93-94
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	P94-97
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	P97
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix 3.4
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	P98
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	P98, appendix 3.5
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	P98
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Appendix 3.5
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	P99

Section and Topic	Item #	Checklist item	Location where item is reported
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	P100-101
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	P100-101
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	P100-101
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	P100-101
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	P100-101
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	P100-101
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	P100-101
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	P100-101
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	P99-100
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	P101-102
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	P102
Study characteristics	17	Cite each included study and present its characteristics.	P103
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	P103
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Appendix 3.14
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Appendix 3.13

Section and Topic	Item #	Checklist item	Location where item is reported
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Appendix 3.14
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Appendix 3.13
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Appendix 3.17
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Appendix 3.13
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Appendix 3.13
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	P115
	23b	Discuss any limitations of the evidence included in the review.	P116-117
	23c	Discuss any limitations of the review processes used.	P116-117
	23d	Discuss implications of the results for practice, policy, and future research.	P117-119
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	P94
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	P94
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Appendix 3.2
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	P120
Competing interests	26	Declare any competing interests of review authors.	P120
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	P121

Appendix 4.1. Protocol for Chapter 4

This protocol was registered on Open Science Framework. Bradley Furlong, Andrea Pike, Holly Etchegary, Kris Aubrey-Bassler, Simon Davidson, Amanda Hall (2024). Does your patient education material for low back pain meet patients' information and education needs? A protocol for the development of a new checklist. https://osf.io/vctdb

We made minor changes to the original protocol uploaded on June 9th, 2023 and describe them in detail in Appendix 4.1A. We have also updated the methodology for this study to reflect these changes and outline the updated methodology below *(the original protocol is available in Appendix 4.1B).*

Methods for updated protocol

We were unable to identify a standardized method for developing checklists. As a result, we will develop our checklist in a series of steps related to those in Boetang et al. [1], a paper outlining best practices for developing scales. Specifically, we will (i) describe our domains of interest, (ii) generate items for the checklist, (iii) assess the face validity of our items, and (iv) pre-test our items.

Domains description

As described in Appendix 4.1A, we will use the Ormandy [2] review as the basis with which to conceptualize and develop a working definition of patient information needs (PINs) and patient education needs (PENs).

Item generation

To generate items, best practices suggest using both deductive and inductive methods where possible [1]. Deductive methods involve identifying relevant items from existing assessment tools to contribute to an initial pool of items and inductive approaches involve the generation of new items from the responses of individuals gained from qualitative data [3].

Patient information needs (PINs)

Our initial review of the literature did not identify any existing tools for the assessment of PINs for low back pain (LBP), requiring us to rely solely on an inductive approach for item generation. Fortunately, Lim et al. [4] recently published a systematic

review of qualitative data regarding PINs, which will serve as the basis for our inductive analysis. We have already engaged with patient experts to gain feedback on the 11 PIN themes identified by Lim et al. [4] regarding their understanding and agreement with each theme and to determine if any themes were missing from this list. We had planned to generate items based on these themes, but realized two problems in how they were coded. Firstly, various themes had overlapping concepts, particularly between those describing "general" PINs (e.g., "General information content related to LBP") and other more specific PINs. Second, certain themes were based on patient expectations rather than PINs including the "Perceived needs for imaging" theme, which described patients' incorrect beliefs about the purposes of diagnostic imaging for LBP (as described in Appendix 4.1A). Fortunately, in their paper, Lim et al. [4] provide a comprehensive list of the qualitative data they used to code their themes, which included a combination of direct quotations from patients with LBP and authors' interpretations of study findings. We will extract all of this data and re-code it into more distinct themes, ensuring they are all relevant to PINs. Under each new theme, we will further re-arrange the data into more distinct concepts that we will use to generate items for the checklist.

Patient education needs (PENs)

To identify items related to PENs, we will use a deductive approach as numerous questionnaires for the assessment of patients' knowledge, beliefs, and attitudes about LBP have been used and reported in the literature. A recent systematic review investigating peoples' beliefs and attitudes about LBP [5] will form the basis of our questionnaire identification, supplemented by an updated search in PubMed and Google Scholar for key

words related to attitudes, beliefs, expectations, about LBP. We will include any study using a tool to assess these constructs, then investigate their response data to determine which items were answered incorrectly by some proportion of the population. We will consider the items where people lacked knowledge to represent potential PENs and used them as a basis from which to conduct our deductive analysis. We will extract these items from each tool to contribute to the initial pool of possible items to be used in our checklist. To reduce redundancy, we will rearrange similar items into common themes relating to PENs, from which we will generate more specific items for our checklist. We will engage with clinical and academic LBP experts to determine if any items appear to be missing from our list or if any tools to assess these constructs were missed in our literature search.

Question and response option development

Once items are generated, reviewed, and consensus reached, we will draft the checklist with response options for each item. Patients with LBP vary substantially according to their context, background, pain severity, and conceptualizations of pain, among many other factors [6]. For this reason, we will not design response options around specific criteria for information to address each need since different patients will require different information to satisfy their goals. We will therefore phrase each item as a question that asks the rater if the material they are assessing contains any information relating to the corresponding PINs or PENs. Thus, the checklist will not be intended to measure the accuracy or completeness of information related to each need, nor will it be intended to measure how likely the information is to satisfy the reader's needs. Rather, it

will be intended to tell us if any information relating to each need is present. We will therefore design the checklist with simple "Yes" or "No" response options with example descriptions of what types of information may warrant each answer option. An answer of "Yes" will indicate that the material contains information related to the corresponding need and an answer of "No" will indicate that the material does not contain any information related to the corresponding need. For items with an answer of "Yes," the rater will be asked to extract, ad verbatim, any information from the material that is relevant to the corresponding need. The primary output of the PIC-LBP will therefore not be an overall quantitative score, rather it will be the qualitative data extracted directly from the materials, which raters can use to provide a qualitative synthesis of the specific types of information used to address each need. From these syntheses, experts can begin to make more complex judgements about the accuracy and completeness of such information and how it can be modified or improved to satisfy patients' needs.

Face validity

Face validity is the degree to which end users of a tool judge the items to be relevant to the domain of interest [7]. The primary goal of this activity will be to review the checklist to determine if the items accurately represent the PINs and PENs we identify from the literature and confirm during the process of item generation. To do this, we will hold two sessions with content experts for each section of the tool. The first section (part A) will comprise items based on PINs only, the second section (part B) will comprise items based on both PINs and PENs, and the third section (part C) will comprise items based on PENs only. We will consider content experts to be patients for parts A and B

and clinical and academic LBP experts for parts B and C. Each session will follow the same general procedure, where we will email content experts a brief summary of the tool with the items relevant to their expertise, then hold a virtual meeting separately for each group. In these meetings, the lead investigator will deliver a short summary of the checklist and how it was developed before each item is reviewed, one-by-one, to determine if they accurately reflect the PINs or PENs identified from the literature and confirmed during item generation. Content experts will be asked to provide feedback for each item on the checklist and to review those items against PINs or PENs to make sure the checklist adequately covers all identified needs.

Pre-testing

Pre-testing the tool aims to minimize misunderstanding of the questions and subsequent measurement error by highlighting and eliminating poorly worded or double barrelled questions [1]. This process should result in a revision of phrasing to be maximally understood by all future users of the tool. Pre-testing should be completed by end users of the tool, which in this case are people who intend to evaluate or develop patient education materials (PEMs) for LBP such as clinicians or researchers. Pre-testing will be conducted by a clinician and academic researcher (SD) experienced with LBP on a minimum of two PEMs for LBP. We will ask the pre-tester for feedback on the wording of the items and response options, overall formatting of the checklist, qualitative data extraction processes, and their general experience with using the tool in terms of its feasibility for use in practice.

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2. Ormandy P. Defining information need in health–assimilating complex theories derived from information science. Health expectations. 2011;14: 92–104.

3. Hinkin TR. A Review of Scale Development Practices in the Study of Organizations. Journal of Management. 1995;21: 967–988. doi:10.1177/014920639502100509

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Appendix 4.1A. Modifications to Original Protocol

We originally uploaded the protocol for this study on June 9th, 2023. We have since made modifications to the domain and target users of our checklist and outline the reasons for these changes below.

Domain: we modified our domain for the following two reasons:

- First, we had initially intended to develop a tool that could be used to assess if patient education materials (PEMs) had sufficient information to satisfy patients' information needs (PINs) for low back pain (LBP). However, after reviewing the literature we could not find any previously developed conceptual frameworks that describe satisfying the PINs of patients with LBP, and frameworks for patient satisfaction and PINs more generally are broad and not well conceptualized. For example, Marchionini and White [8] describe information seeking in six steps where the information seeker (1) recognizes a need for more information, (2) decides to take action to fulfill this need, (3) formulates the problem, (4) expresses the need, (5) examines the results, and (6) uses the information. Often, steps 3-5 involve an iterative process where the seeker reformulates the problem and/or re-expresses the need until they understand, and are satisfied by, the information they find. However, it is unclear from the framework how exactly the information seeker becomes 'satisfied' by this information, and this is perhaps unsurprising as there is also little consistency amongst conceptualizations of patient satisfaction. For example, a recent review on measurement tools used to assess patient satisfaction in oral healthcare settings found 14 different tools covering widely

varying dimensions (e.g., access, communication, quality, beliefs, clinical atmosphere, waiting time, affordability, location, among many others) with little consistency between tools in terms of the dimensions covered and terminology used [9]. More work is required in the areas of patient satisfaction and satisfying PINs so we decided to omit this construct from our domain.

- Second, we noticed that certain themes identified by Lim et al. 2019 [4] (i.e., the systematic review we had originally planned to use to inform what PINs to include on our checklist) were based on patients' expectations or misconceptions about LBP rather than PINs. For example, the "Perceived needs for imaging" theme primarily described patients' expectations and misconceptions about diagnostic imaging for LBP with supporting quotations describing how patients believe they "need imaging to know the cause of symptoms" or how "imaging was expected to show 'visible structural damage' responsible for LBP." Though some themes represented expectations or unhelpful beliefs rather than PINs, we considered these to be similarly important knowledge gaps that should be addressed. Therefore, we plan to conduct an additional literature search to find studies investigating the knowledge, beliefs, and/or attitudes of patients with LBP and the general public to determine if there were any additional expectations or unhelpful beliefs (i.e., knowledge gaps) that people should improve their knowledge about. Using a paper by Ormandy [2], we defined these additional knowledge gaps separately from PINs and will from here on refer to them as patient education needs (PENs).

Ultimately, rather than developing a tool that could measure if a PEM contains information to satisfy PINs, we instead sought to develop a checklist that could be used to determine if PEMs contain any information relevant to the PINs and PENs of patients with LBP. We have defined PINs as a subjective realization that one lacks knowledge to achieve a goal [2] and PENs as an objective, rather than subjective, measure of knowledge deficit [10]. In other words, PINs refer to what patients perceive they have inadequate knowledge about, and PENs refer to what LBP experts (e.g., clinicians, researchers) have identified that patients have inadequate knowledge about.

Target users of the checklist: we piloted the checklist with a group of patient partners as we had planned in the original protocol. Patients understood and agreed with most of the items. They valued the purpose of the checklist and agreed it could have beneficial implications for patients with LBP in practice. They did, however, comment that patients may not want to use the PIC-LBP themselves in practice. Rather, they suggested it would instead be a more useful resource for researchers or clinicians interested in finding the best available PEMs that they could then provide to patients with LBP in their practice. For this reason, the intended users of the checklist will be clinicians or researchers interested in evaluating or developing PEMs for LBP, rather than patients with LBP.

Appendix 4.1B. Original Protocol

Introduction

Low back pain (LBP) is a global problem that has become progressively more common and burdensome over the past three decades [1,2]. Two recent systematic reviews identified that (i) patients with LBP have health information needs for which they seek education, but have difficulty accessing information to address these needs [3] and (ii) only about 20% of patients with LBP receive education from their family practitioner [4], a missed opportunity to provide helpful information to facilitate recovery. Patient education materials for LBP (PEMs) are one method to help transfer accurate knowledge about LBP diagnosis, prognosis, and treatment. Our recent systematic review found PEMs to be more effective than usual care for patients with acute and chronic LBP across various clinical (e.g., pain, disability), process (e.g., knowledge, pain self-efficacy), and health system (e.g., imaging, days off work) outcomes [5]. However, few of the included PEMs were co-developed with patients and none were assessed to determine if they meet the health information needs of patients with LBP. Since there is currently no tool developed to assess this information, we have partnered with a group of patients with LBP to co-develop a new checklist that can be used to determine if existing PEMs include sufficient information to meet their needs. We plan to call this tool the Patient Information Needs Checklist for Low Back Pain (PIC-LBP).

Methods

We will follow the procedure proposed by Boateng et al. [6], who outline best practices for developing scales. We plan to develop the PIC-LBP and conduct multiple rounds of face validity checks; however, we do not plan to gather a sample size large enough to conduct exploratory factor analyses and reliability and validity testing. Consequently, we will follow only parts of the first four steps described in Boateng et al. [6], including (i) identification of domain and item generation, (ii) content validity, (iii) pre-testing of questions, and (iv) sampling and survey administration. Future validation studies with a larger sample size of PEMs will be required to fully validate the PIC-LBP.

Step 1: Identification of the Domain(s) and Item Generation

Domain identification

The intended use of the PIC-LBP is to assess if PEMs contain information to address the known health information needs of patients with LBP. Health information needs can be defined as a patient's desire for additional information that they believe could help them better manage their condition [3,7]. We intend to design the tool so that it can be used by patients, clinicians, or researchers interested in determining which PEMs contain the most relevant information for patients with LBP. We expect it will aid clinicians and researchers make more informed decisions about which PEMs should be used in practice, and that it will be a useful resource for developing new PEMs as it will clearly outline the known information requirements of patients with LBP. Since we are unaware of previously developed conceptual frameworks describing the resolution of health information needs of patients with LBP, we will use four related theoretical frameworks to inform the synthesis of this new domain:

1) **Patient information needs:** generally, patient information needs are defined as a realization that one lacks knowledge to achieve a goal, and the type or strength of information need can be influenced by an individual's context, situation, and time [8]. Coulter et al. [9] developed a framework of 12 patient information needs, described in terms of the information's use. For example, they state that patients need information to (i) understand what is wrong, (ii) gain a realistic idea of prognosis, or (iii) assist in self-care. We will use this framework to inform our domain and the items to include on the PIC-LBP.
2) **Knowledge:** first, one realizes there is a "gap" in their knowledge that hinders their ability to achieve a goal, thereby creating a desire for more information [8]. To satisfy their information need, it is necessary to find information they can use to improve their knowledge (i.e., fill their perceived knowledge gap). Different goals can result in different information needs, which may require improvements in different knowledge types, or "constructs." To achieve their goals, some patients might require general information about "what" something is, while others may want to know "why" that information is important or "how" to perform certain actions. To ensure the PIC-LBP covers these theoretical aspects of knowledge, we will refer to the "knowledge" domain in the second version of the theoretical domains framework (TDFv2) by Cane et al. [10] (originally developed in 2005 by Michie et al. [11]), a widely used framework for understanding health behaviour and choices. For example, when generating items, we will consider

what knowledge constructs are relevant. If we identify an information need that concerns self-management strategies for LBP, we might generate an item about "what" self-management options are available and another for "why" they are thought to be useful (i.e., relevant to the "knowledge, including knowledge of condition/scientific rationale" construct in TDFv2) or "how" to carry out each strategy (i.e., relevant to the "procedural knowledge" construct in TDFv2). See table 1 for the proposed format of the PIC-LBP, which includes a visualization of how we will map items to knowledge constructs under each information need.

3) **Information seeking:** recognizing a gap in knowledge is often motivation to seek additional information to fill this gap [8]. This can be outlined using Marchionini and White's [12] conceptual framework describing information seeking in six steps. The information seeker (1) recognizes a need for more information, (2) decides to take action to fulfill this need, (3) formulates the problem, (4) expresses the need, (5) examines the results, and (6) uses the information. Often, steps 3-5 involve an iterative process where the seeker reformulates the problem and/or re-expresses the need depending on what information they find. The framework states that the information seeker stops seeking additional information once they understand, and are satisfied by, the information they find. It should be noted that recognizing a gap in knowledge does not necessarily lead to a decision to seek information and some researchers distinguish information 'wants' (i.e., information that an individual desires) from information 'demands' (i.e., information that individual expresses their desire to attain) [13–15]. However, we

have omitted this distinction because readers of PEMs have already made the decision to seek such information.

4) **Satisfying information needs:** to our knowledge, no conceptual framework has been developed to describe satisfying the health information needs of patients with LBP, nor are there any widely accepted frameworks for patient satisfaction more generally. For example, a recent review on measurement tools used to assess patient satisfaction in oral healthcare settings found 14 different tools covering widely varying dimensions (e.g., access, communication, quality, beliefs, clinical atmosphere, waiting time, affordability, location, among many others) with little consistency between tools in terms of the dimensions covered and terminology used [16]. Similarly, LBP is complex as it is influenced by biophysical, psychological, and social factors [1]; therefore, information needs, and what is required to satisfy them, will vary from person to person. For these reasons, extrapolating from the information needs and information seeking frameworks, we have broadly defined the resolution of an information need as the point where the information seeker subjectively feels they have acquired sufficient knowledge to achieve their goal(s) (i.e., they are 'satisfied' with the information they have acquired). This perception of satisfaction is one component of the resolution of patients' health information needs, and we will continue to inform and revise this definition based on feedback from patient partners.

We have combined aspects of these frameworks to develop a new conceptual framework representing the origin, course, and resolution of health information needs (Figure 1). It describes (1) the origin of information needs and the process of information seeking, (2) the acquiring of information, which can be used to improve knowledge, and (3) the resolution of the information need as the point where the individual feels satisfied by the knowledge they have gained. This framework provides a theoretical understanding of how information needs are resolved, with a focus on acquiring information to improve knowledge that might help achieve one's goals. Patients with LBP have many different goals, which might require different types of information to improve different types of knowledge (e.g., knowledge about "what" something is vs. "how" to do something vs. "why" something is important vs. "where" something is). We will use this framework to inform the development of the PIC-LBP, its items, and corresponding anchor descriptions, so that it reflects these information and knowledge requirements. We intend to work closely with patients at all stages (i.e., from protocol development, to refining the domain, items, and scoring method, to pre-testing) so that the tool closely reflects what patients think would improve knowledge and ultimately satisfy their health information needs. However, the subject of this tool is PEMs, not patients, so it is not intended to directly assess the knowledge or satisfaction of the information seeker. Rather, we hypothesize that higher scores on this tool (i.e., corresponding to greater coverage of information relevant to known information needs), will positively correlate with validated, patient-reported measures of knowledge and satisfaction. In addition, our framework omits other factors that might contribute to satisfying information needs more generally, such as the understandability, actionability, reliability, quality, and readability

of the information itself. However, there are already numerous tools to measure these factors such as the Patient Education Materials Assessment Tool (PEMAT) [17], DISCERN [18], and the Flesh-Kincaid Grade Ease (FKGE) and/or Flesch-Kincaid Grade-Level (FKGL) algorithms. Formal assessment of PEMs should include use of these tools in addition to the PIC-LBP to determine the best available PEMs to use in practice. Our research group plans to perform such an assessment with all of these tools, including the finalized PIC-LBP, in a future study.

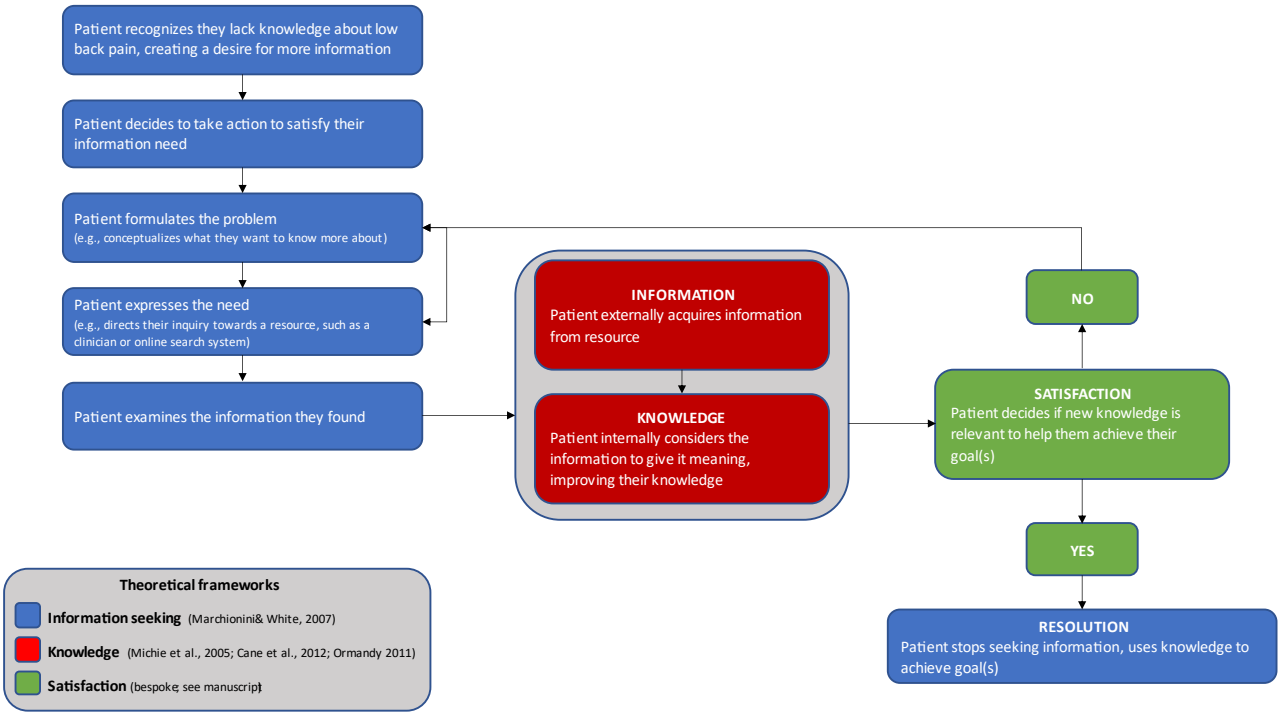

Figure 1. A new conceptual framework describing the resolution of health information needs for LBP

Item generation

We will use our domain and a range of deductive and inductive methods [21] to inform the initial items of the PIC-LBP. First, we will use Lim et al.'s [3] recent systematic review, which provides a comprehensive synthesis of the perceived health information needs of patients with LBP. Second, we conducted two relevant studies since the publication of Lim et al. [3]: (i) a cross-sectional population-based survey in Newfoundland and Labrador, Canada, to examine the nature of patient beliefs and expectations regarding LBP [19], and (ii) a qualitative study involving interviews with patients and general practitioners across Newfoundland and Labrador to gather information from both populations about their experiences with LBP and LBP care (unpublished data). We will use these quantitative and qualitative data to identify additional health information needs not included in Lim et al. [3]. Once we develop an initial list of items, we plan to supplement this existing content with feedback from patient partners to determine if any additional content is required.

Based on our conceptual framework, we intend to first develop a comprehensive list of the health information needs of patients with LBP. Then, from this list, we plan to create individual items corresponding to the information requirements for each knowledge construct deemed relevant to each information need. Each item will have a binary response option (i.e., "Agree/Disagree") where a score of 1 will correspond to "Agree" and a score of 0 will correspond to "Disagree." All items will have the same weight (i.e., each item can only have scores of 1 or 0), and the overall score will be calculated by dividing the total points over the total possible points, multiplied by 100% to convert the score to a percentage ranging from 0% to 100%. Higher percentage scores

will indicate that a greater amount of relevant information to resolve the health information needs of patients with LBP is provided.

Step 2: Content Validity

We will conduct multiple rounds of face and content validity checks by engaging with patient partners and academic experts familiar with LBP and scale development to obtain feedback on the items, anchor descriptions, and scoring methods, and their relevance to our domain. We will hold engagement sessions with patients from the Patient Partnership Council (i.e., a nine-member council of patient partners living across Canada, some of whom are currently living with chronic LBP), formed as part of the Canadian Institutes of Health Research Strategy for Patient Oriented Research [20]. At all stages of PIC-LBP development, we intend to follow best practices for patient engagement by offering flexibility and choice in the activities patients can engage in, as well as the levels with which they can choose to participate in these activities (i.e., inform, consult, involve, or collaborate) [21,22]. We will also offer flexibility regarding the mode and frequency of communication, in that we will use patients' preferred communication methods (e.g., e-mail, video conferencing software, pre-recorded presentations that can be accessed anytime, etc.) and meet as many times as they wish to continue to work together. Our patient engagement lead (HE) has already given advance notice about the details of this project to all patient partners, who have committed to working with the team to create and refine the PIC-LBP.

First, we plan to use the literature to synthesize the known health information needs for LBP into a preliminary item set. This item set will contain broader categories of

health information needs, similar to how they are outlined in Lim et al. [3], such as "Perceived needs for imaging" or "Information about prognosis." Patient partners will be asked to provide feedback on these items regarding (i) wording and format, (ii) their understanding and agreement with each listed item, (iii) if items should be added or removed, and (iv) any additional feedback they wish to provide so that the categories of items resemble our domain and patients' lived experiences with information needs for LBP. We will also engage with academic content experts to discuss item redundancy, wording, and overall structure, so that the items are based on up-to-date, evidence-based information about LBP. We will follow an iterative process where we will reconvene as many times as necessary until both patients and academic experts are satisfied with the initial item set.

Once finalized, we will use this preliminary item set to create the first draft of the PIC-LBP, which we expect will include a much larger set of more specific items (i.e., we will create multiple items under each broader information need category). We will follow recommendations by De Vet et al. [23] for the wording, formatting, and structure of items and anchor descriptions. We will then reconvene, as many times as necessary, with the patient partnership council and academic experts for additional feedback on the items, anchor descriptions, scoring methods, and interpretation of scores. In particular, we will ask patient partners if the items cover the aspects of knowledge they feel are relevant to their experiences with information needs for LBP (e.g., do the items cover all the information they think they would want to know, and do they think this information

might satisfy each information need?). We will also ask content experts to review the items and anchor descriptions for information accuracy based on up-to-date evidence.

Step 3: Pre-Testing Questions

We will conduct two pre-testing phases with expert judges to ensure the items contain accurate information about LBP, are meaningful to patients and represent the domain of interest, as well as to minimize misinterpretation and measurement error [6]. First, we will send the first draft of the PIC-LBP and user guide (i.e., a guide that describes each item and how they are to be rated), as well as one PEM, to patient partners at least one week ahead of a planned engagement session. We will provide patients the option of using the PIC-LBP to assess the PEM in advance of the session, or during the session, whatever they prefer. During the session, we plan to conduct a cognitive interview-style session [24], where we will ask patients to verbalize their thought process as they rate items on the PIC-LBP. The purpose of this session will be to determine if the items are meaningful to patients and are understood as intended, and we will clarify or modify items as needed to better fit the purpose of the tool [6]. After modifying the tool based on feedback during this phase, we will ask at least two study investigators to fully and independently assess at least one PEM with the PIC-LBP to provide additional feedback. We will update the PIC-LBP once more, then share this version with the patient partnership council and research team with the opportunity to provide any remaining feedback before finalizing the tool.

Step 4: Survey Administration and Sample Size

Survey Administration

We plan to develop the PIC-LBP in Microsoft Word (see Table 1 for the planned format of the PIC-LBP). Once completed, we will make two versions of the tool, both of which will be freely available for use for any interested stakeholders. The first option will be a downloadable PDF document (i.e., paper and pen/pencil interviewing (PAPI)), and the second option will be a downloadable Microsoft Excel document with an accompanying auto-scoring function (i.e., computer assisted personal interviewing (CAPI)) [6]. Stakeholders may choose whichever option works best for them.

Table 1. Proposed format of the PIC-LBP

Item #	Item description	Knowledge construct	Response options	Rating (0 or 1 to be input by user)
Health information need #1				
1	The material provided general information about or some reference to health information need #1	A	Disagree=0, Agree=1	
2	The material provided information about why this information is important (scientific rationale behind this information)	A	Disagree=0, Agree=1	
3	The material described how to carry out its recommendations	B	Disagree=0, Agree=1	
4	The material described what resources might be necessary to carry out its recommendation(s)	C	Disagree=0, Agree=1	
Health information need #*n*				
4	The material provided general information about or some reference to health information need #*n*	A	Disagree=0, Agree=1	
5	The material provided information about why this information is important (scientific rationale behind this information)	A	Disagree=0, Agree=1	
6	The material described how to carry out its recommendations	B	Disagree=0, Agree=1	
7	The material described what resources might be necessary to carry out its recommendation(s)	C	Disagree=0, Agree=1	
SCORING Total Points: _____ Total Possible Points (do not include n/a responses): _____ Overall score (%): _____ (Total Points / Total Possible Points) × 100				

This table outlines the proposed format of the PIC-LBP. It demonstrates how we plan to organize the tool first by broad categories of health information needs, then by the knowledge construct items relevant to each health information need. The number, "*n*", of health information needs included on the PIC-LBP will be decided during the literature review and face validity checks with the patient partnership council. We expect there will be at least 11 broader categories of health information needs (as this is the number of 'themes' identified in Lim et al. [3]) in addition to other health information needs deemed relevant by our expert panels. All item responses will have equal weightings with a rating of 0 or 1. We will not include the "Knowledge construct" column in the finalized tool, but we include it here to help visualize how we plan to map knowledge constructs to items. Knowledge constructs are (A) knowledge (including knowledge of condition/scientific rationale), (B) procedural knowledge, and (C) knowledge of task environment. Descriptive statistics will be used to ascertain how each of the individual knowledge constructs were addressed in PEMs. Details are subject to change based on our content validity checks with the expert panel.

Sample size

As described above, this is not a full validation study. Therefore, we do not plan to gather a sample size of PEMs large enough to conduct exploratory factor analyses or reliability and validity testing. However, we will still outline how we plan to identify relevant and credible PEMs that we will use during the pre-testing phases.

We define PEMs as interventions where any information about non-specific LBP or sciatica (e.g., diagnosis, prognosis, self-management or other treatment advice) is provided within a standardized evidence-based supplement (e.g., structured pamphlets, booklets, links to online resources, audio files, videos, or workbooks) intended for use by patients with LBP. We will conduct a literature search to identify PEMs that meet the inclusion criteria described in Table 2.

Table 2. Inclusion and exclusion criteria for PEMs

Inclusion criteria	**Exclusion criteria**
PEMs must be tested in a published study or recommended by clinical LBP guidelines or other credible sources (e.g., Choosing Wisely Canada)	PEMs obtained from alternative sources, such as basic internet searches
Developed from year 2000 onward	Developed before the year 2000 (as clinical guidelines for LBP were more

	inconsistent before this and certain treatment recommendations have since changed)
Written in English	Written in non-English languages
User-friendly in family practice setting (e.g., short pamphlets or scannable codes to direct patients towards a mobile app, etc.)	Not user-friendly in a family practice setting (e.g., textbooks)
Freely accessible to the public	Not freely accessible to the public (e.g., require academic subscriptions, sign-up fees, etc.)
Included PEM must be the most up to date version	If there are more than one version of the same PEM, we will exclude all other versions that are not the most up to date version.

We first intend to gather copies of PEMs used in trials included in two recently published systematic reviews on the effectiveness of PEMs [5] and individual patient education [25] for LBP. We will contact study authors to request materials where necessary. Second, we intend to gather copies of PEMs recommended for use by clinical guidelines for LBP [26] and other credible sources (e.g., Choosing Wisely Canada, CORE Back Tool, etc.). After obtaining PEMs from these sources, we will screen each PEM with our inclusion criteria to obtain the most relevant PEMs for content assessment and develop a PRISMA-style flow chart (example provided in Figure 2) to detail how and why each of the PEMs were included or excluded. Since the focus of this study is checking face validity rather than conducting factor analyses and reliability testing, we will only include a subset of eligible PEMs to be used during the pre-testing phases. Once we have a finalized list of appropriate PEMs, we will discuss with the research team which PEMs would be best suited for the purposes of our face validity checks.

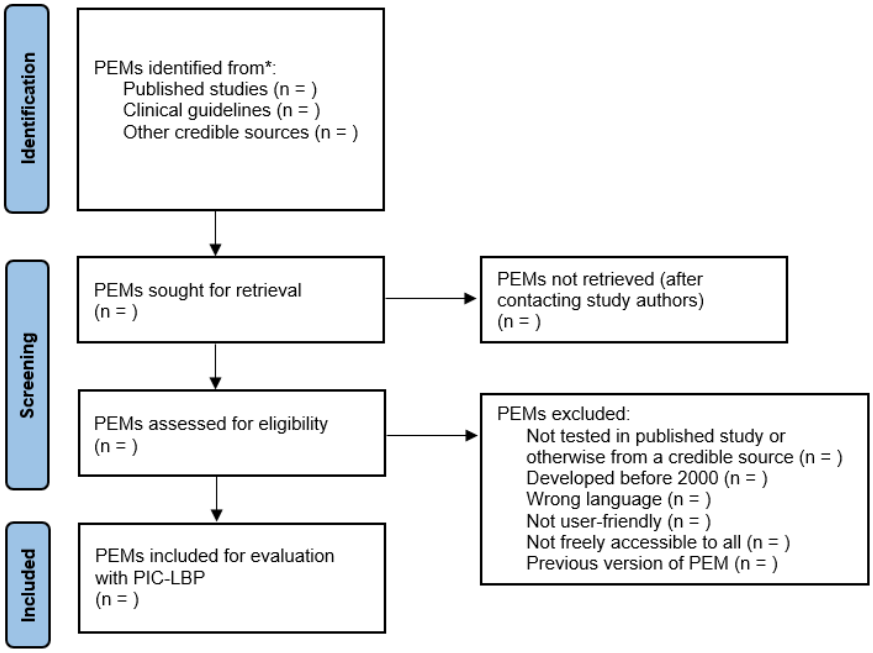

Figure 2. PRISMA-style flow of the identification of PEMs and assessment of eligibility (PEMs = patient education materials for LBP, PIC-LBP = patient information needs checklist for low back pain)

Future research (item reduction, factor analyses, reliability and validity testing)

As discussed above, the focus of this study is to develop the PIC-LBP and assess its face validity. Future studies, with a larger sample size of PEMs, will be required to properly conduct item reduction strategies, factor analysis, and reliability and validity testing.

Ethics

Ethical approval is not required for this study.

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Appendix 4.2. Search strategy for identifying studies using questionnaires to investigate peoples' knowledge, attitudes, beliefs, and expectations about low back pain

We searched PubMed and Google Scholar from January 1st, 2014 to February 8th, 2024 for English-language studies using questionnaires to investigate peoples' knowledge, attitudes, beliefs, or expectations about low back pain using the following search strings:

Database	Search string
PubMed	(low back pain[Title] OR lumbar pain[Title]) AND (attitude*[Title] OR belief*[Title] OR believ*[Title] OR expectation*[Title] OR knowledge[Title])
Google Scholar	(intitle:low back pain OR intitle:lumbar pain) AND (intitle:attitude OR intitle:attitudes OR intitle:belief OR intitle:beliefs OR intitle:believe OR intitle:expectation OR intitle:expectations OR intitle:knowledge)

Appendix 4.3. Patient information and education needs codes that were omitted before item generation, with reasons

Code	Description	Supporting information obtained from Lim et al. 2019* and existing questionnaires to assess low back pain beliefs, attitudes, and knowledge	Reason(s) for omission
Omitted codes relating to patient information needs			
Information about support services for LBP	Patients want information about availability of medical and allied health services, and non-medical support from social networks and support groups	**<u>*Supporting information from Lim et al. 2019:</u>** • Need information regarding social network/support groups available 'You don't have friends when you get to where you can't go and you can't do anything… they forget about you…' (K) • Patients wanted to know 'where to get a doctor' and 'what is available'…'I don't even know where to look…', 'Information is just not there; it's not available…', 'I have asked people … where to get a doctor… they don't know' (K) • Patients wanted information from employer regarding absence management policy and procedures (eg, extent of time off allowed for LBP) as they were particularly worried about the effect of company bonus schemes on their decision to take time off. Some would even choose/consider using annual leave instead of sick leave for their LBP (K) • Further 'professional follow-up' was desired to provide certainty about treatment of LBP '… many… felt too much on their own after the intervention, where they were instructed to continue exercising while…' (K) **<u>Supporting questionnaire items:</u>** N/A	It would not be feasible to include information about available support services tailored to the local context of all readers of the patient education material
Tailored information	Patients want personalized treatment specific to their own	**<u>*Supporting information from Lim et al. 2019:</u>**	It would not be feasible to include information about LBP management

regarding LBP management	circumstances, taking into account their other health conditions, age, and specific lifestyle needs. They do not want generic exercise prescription –they want individually tailored and specific exercise advice	• Advice and exercise prescribed need to be feasible with lifestyle 'I cannot pull my knees to my chest at work, can I? I sit for 8 hours to take calls…' (G) • Need tailored advice regarding range of management options available for LBP, including non-interventional and interventional therapies (G) • Need 'person-specific'' general management, considering their beliefs on 'what to do during acute LBP' and measures to prevent/manage recurrpence as they were more likely to reject advice if it conflicted with their lived experience, life goals, and strongly held beliefs 'My doctor put me on amitriptyline, but every time I said the pain was worse, he'd just increase the dose 'til I was just like a zombie, but still had the pain. So, I refused to take any more amitriptyline…' (G) • Treatment plan should consider individual circumstances and characteristics (eg, age, injury and lifestyle) and recommendations on exercise program should be individualised, rather than standard exercise print-outs 'Whenever they were doing… anything into my back, they were never hitting the spots ever… I think it's whatever they do isn't right for me'. (G) • Important to consider personal circumstances in managing chronic LBP, especially for older patients (G) • Patients wanted to know options available for LBP management that is tailored to patients' need (eg, lifestyle changes, maintaining physical activity) (G) • Need tailored/individualised advice regarding range of 'self-management' options and 'specific' exercise and suitable lifestyle adaptation. Patients want supervised exercise programmes, tailored to them. '… left on your own and try and work out what's available and what's appropriate… like they just said well do the exercises… you know…' '… I find… the best thing that I can do is just walk…' (G)	that is tailored to all readers of the patient education material

		• Need for individualised advice to integrate exercises into daily life (G) • Management of LBP needed to be 'specific', rather than 'general principles' that patient already known (eg, 'specific' information and 'rational' to understand the role of exercises in LBP, to avoid unnecessary 'refrain' from physical activities) (G) **Supporting questionnaire items:** N/A	
Omitted codes relating to the mode of delivery of the information			
Need for high quality information	With regard to the quality of information provided by various healthcare practitioners, participants valued valid, trustworthy and consistent information. They disliked receiving conflicting and discordant advice from different health professionals.	***Supporting information from Lim et al. 2019:** • Patients wanted reliable information, eg, from specialists as they believed GP is not skilled in pain management and 'not up to date' with LBP management. • Need for updated, evidence-based, valid and trustworthy information as alternative Information received from other professionals, eg, physiotherapists, osteopaths, chiropractors, 'was often conflicting'. • Patients wanted consistent information, not to be confused by conflicting advices or discordant expert opinion: We believe you have a trace of spondylolisthesis.and when I went to see the consultant, he said "no, your spine is fine.; I was very upset.well who you believe? Do you believe an orthopaedic surgeon, or do you believe a radiologist.; Is somebody else going to say that is something else entirely different later on? **Supporting questionnaire items:** N/A	It is outside the scope of the checklist to assess the quality of information content within patient education materials. There are also other tools available, such as the DISCERN tool, which are intended to assess the quality of information
Need for health information to be delivered in a suitable tone and understandable language	Patients wanted health information to be delivered in a suitable tone and understandable language. Patients	***Supporting information from Lim et al. 2019:** • Need open and clear communication with focus on personal circumstances to provide more emotional support for patients with LBP. • Clinicians need to show better communication and understanding towards patients and avoid using medical	It is outside the scope of the checklist to assess the tone or understandability of the information content within patient

	perceived a need for information to be communicated in an open and clear way, with emotional support, and using simple language without medical jargon and with acceptable tone.	terminology to 'de-medicalise' the whole medical consultation process: They treat you as if you don't understand what they're talking about.I'd like to be spoken to on my own level.; They fail to recognise the reality of feelings of the sufferer **Supporting questionnaire items:** N/A	education materials. There are also other tools such as the PEMAT to assess the understandability of information of patient education materials
Where to find credible information	Patients want to know where to obtain credible information about LBP	***Supporting information from Lim et al. 2019:** • Patients desired information from credible and trusted sources, personal or professionals: If it was recommended by somebody I had confidence in...if it's somebody who's either had it done or it's recommended by a GP • Need to know where to get help • Alternative sources of information leading to conflicting advice: When no information obtained from GP, patients access alternative sources of information from other healthcare professionals such as physiotherapists, osteopaths and chiropractors, and other sources such as family and friends., which could be conflicting **Supporting questionnaire items:** N/A	It is outside the scope of the checklist to assess the credibility of the information content within patient education materials. There are also already other tools, such as the DISCERN tool, that one could use to gauge the credibility or trustworthiness of information
Omitted codes relating to patient education needs			
The role of work in making pain worse or harming your back	The literature using these questionnaires shows that people think they might injure or damage their back if they work or that work is the cause of their low back pain. It also shows that people	***Supporting information from Lim et al. 2019:** N/A **Supporting questionnaire items:** • My pain was caused by my work or by an accident at work (FABQwork) • My work aggravated my pain (FABQwork) • My work is too heavy for me (FABQwork) • My work makes or would make my pain worse (FABQwork) • My work might harm my back (FABQwork)	Work is a broad concept and the various patients who will read patient education materials could partake in many different forms of 'work.' We therefore do not see how addressing the

	avoid work for fear of making their pain or other symptoms worse.	• I should not do my normal work with my present pain (FABQwork) • I do not think that I will be back to my normal work within 3 months (FABQwork) • One recovers faster from back pain if one continues at work, or return as soon as possible. (Morton 2019 standalone items)	safety of all the different types of work would be feasible in a patient education material
Other	-	***Supporting information from Lim et al. 2019:** N/A **Supporting questionnaire items:** • People aren't taking my medical condition seriously enough (TSK-G) • It is hard to understand what back pain is like if you have never had it yourself (BACK-PAQ) • These are symptoms of low back pain. Mark TWO correct alternatives: a) a cough, sluggishness and loss of energy b) tiredness and pain throughout the body c) pain in the lumbar region that worsens when carrying weight d) difficulty in picking up objects from the floor e) I don't know. (LKQ)	These miscellaneous items were outside the scope of this checklist

Abbreviations: FABQwork = Fear Avoidance Beliefs Questionnaire (Work subscale); BACK-PAQ = Back Pain Attitudes Questionnaire; LKQ = Low Back Pain Knowledge Questionnaire; TSK-G = The Tampa Scale for Kinesiophobia (a version of the TSK that can be administered to the general population)

*The quotes from Lim et al. 2019 were obtained from their appendix material. They categorized these quotes into eleven themes. We kept track of where these quotes originated by labeling them with the letter corresponding to the original themes outlined in Lim et al. 2019: (A) General information content related to LBP, (B) Diagnosis, cause/aetiology for LBP, (C) Perceived needs for imaging, (D) Prognosis, including future disability and effect on work capacity, (E) Information regarding precipitation of flares, (F) General information regarding LBP management, (G) The need for tailored information regarding LBP management, (H) Information regarding pain management, (I) Information regarding management of flares and preventive measures, (J) Self-management strategies, (K) Information regarding support services for LBP.

Appendix 4.4. Content analysis for patient information needs and patient education needs about low back pain

PIN/ PEN ?	Item #	Item	Codes	Supporting information obtained from Lim et al. 2019* and existing questionnaires to assess low back pain beliefs, attitudes, and knowledge
Prognosis, causes and aetiology[¥]				
PIN + PEN	#1	Does the material contain any information about prognosis for low back pain?	*Low back pain prognosis.* Interview data shows that patients want information about the prognosis of LBP, in particular its favourable prognosis and benign nature. Questionnaire data shows that patients lack knowledge about low back pain prognosis (e.g., agreeing with the items 'Once you have had back trouble there is always a weakness' and 'There is a high chance that an episode of back pain will not resolve')	**<u>*Supporting information from Lim et al. 2019:</u>** • Understandable explanation regarding nature of LBP. 'It's not an illness, it's just something you get…' (A) • Nature of acute LBP (A) • Nature of LBP, desire clear explanation (A) • Understand the fluctuating and intermittent nature and characteristics of LBP (A) • Important to know and gain understanding of prognosis of LBP. '… explained that it may get worse if I continue with my bad habits but if I watch how I sit I will be fine… that was a relief' (D) • Prognosis of LBP is important '… felt powerless in the face of their LBP and feared that it would be chronic…' (D) • Need education regarding prognosis of LBP (D) • Need information to further understand the natural history of LBP '… it wasn't getting better… and I knew that I needed to sort of have something further checked out…' (D) • Patients need information about their ability to work with LBP due to concern about their ability to retain work and to reduce uncertainty about future working capacity. '… they're getting fed up at work you know, when flare-up happens' (D) • Participants wanted to be reassured on LBP's favourable prognosis that they 'will not end up disabled', with clear information that cancer or other serious diseases could be ruled out with reasonably high certainty (D) • Need to know the nature of LBP. Patients were 'unsure what the future held as they did not really know whether to expect that their pain would get better or worse,' '… but sometimes I think to myself, I could end up in a wheelchair'… that's how worried I am sometimes' (D)

				• Nature of LBP, largely relating to its unknown cause, unpredictable and fluctuating course. '…well, does that mean one day I won't be able to walk? and I get really scared if anything ever happens…' (A) • Patients wanted information regarding nature of LBP, to de-myth concerns regarding development of future disability. 'I will end up in a wheelchair and go nowhere in my life and that pain will always restrict me in daily regular life' (D) • Patients wanted to learn about the nature of the pain and to be reinforced of its benign nature of recurrence to deconstruct fear. 'The physios are much more laid back about a prolapsed disc than I thought they would… like it was… a common cold…', 'I thought whenever my back went into spasm, I had hurt it again… but I haven't actually kind of re-hurt the injury… nobody had ever mentioned…' (D) • Need education regarding benign nature of LBP as most patients fear of 'something serious' (D) • Importance of reassurances on the benign nature in the absence of red flags, to help alleviate fears (D) • Participants worried about the possibility of permanent damage to the spine and required reassurance of its benign nature. '…it actually really, really frightened me… you start to worry about paralysis or whatever' (D) **<u>Supporting questionnaire items:</u>** • If I had long-term low back pain, the rest of my life would become endangered (TSK-G); My accident has put my body at risk for the rest of my life (TSK-SV) • Back trouble will eventually stop you from working (BBQ) • Back trouble means periods of pain for the rest of one's life (BBQ) • Back trouble makes everything in life worse (BBQ) • Back trouble may mean you end up in a wheelchair (BBQ) • Back trouble means long periods of time off work (BBQ) • Once you have had back trouble there is always a weakness (BBQ) • Later in life back trouble gets progressively worse (BBQ) • Most back pain settles quickly, and you can get on with normal activities such as going to work (activity, rest, and use of painkillers items from Gross 2006, used in Hall 2021 public beliefs)

				• Most back pain settles quickly, at least enough to get on with normal activities (BACK-PAQ, reverse scored) • Once you have had back pain there is always a weakness (BACK-PAQ) • There is a high chance that an episode of back pain will not resolve (BACK-PAQ) • Having back pain makes it difficult to enjoy life (BACK-PAQ) • Statement about whether individual believed pain would last forever. (Morton 2019 standalone items) • Back pain is usually disabling. (Morton 2019 standalone items) • Back pain recovers best by itself. (Morton 2019 standalone items) • If you ignore back pain, you may cause damage to your back (BACK-PAQ) • In regards to acute low back pain, mark TWO correct alternatives: a) **The great majority of patients recover in three weeks**. b) After recovery and improvement of the pain, the patient is cured and there is no risk of further crises. c) Instructions on how to protect the spine are only important during the crisis. d) The orientations for spine protection and energy conservation should be routine in patients with a history of low back pain because relapses are frequent. e) I don't know. (LKQ)
PIN + PEN	#2	Does the material contain any information about low back pain flare-ups and/or recurrence?	*Flare-ups and/or recurrence of low back pain.* Interview data shows that patients want information about the unpredictability of low back pain in terms of future flare-ups and recurrence. Questionnaire data shows that patients lacked knowledge about the possibility of future low back pain flares.	**<u>*Supporting information from Lim et al. 2019:</u>** • Patients wanted explanation on natural history of LBP, specifically related to the unpredictability of acute flare (D) • Focus should be on symptom fluctuation, unpredictability and recurrence of LBP (E) **<u>Supporting questionnaire items:</u>** • In regards to acute low back pain, mark TWO correct alternatives: a) The great majority of patients recover in three weeks. b) **After recovery and improvement of the pain, the patient is cured and there is no risk of further crises**. c) Instructions on how to protect the spine are only important during the crisis. d) The orientations for spine protection and energy conservation should be routine in patients with a history of low back pain because relapses are frequent. e) I don't know. (LKQ)
PIN + PEN	#3	Does the material contain any information	*Causes or aetiology of low back pain.* Interview data shows that patients are interested in	**<u>*Supporting information from Lim et al. 2019:</u>** • 'Broad spectrum of explanation on aetiology of LBP, including aging, environmental precipitants, overuse, psycho-social factors, childbirth (B)

		about low back pain causes or aetiology?	causes/aetiological factors related to low back pain. Questionnaire data shows that patients have misconceptions about what might cause an episode of LBP.	• Patients wanted explanation on aetiology of LBP rather than 'aged-related changes' or being told 'unfit'. The surgeon who 'stood in front of four nurses one day and said 'there's nothing wrong with you, you're really very unfit'. I felt stupid' (B) • Need for education regarding precipitants of LBP (E) • Need for education regarding causes and precipitants of LBP (B) **Supporting questionnaire items:** • These can cause low back pain. Mark TWO correct alternatives: a) cold and aging b) postural problems, arthrosis and a herniated disc c) tumors, infections and fractures d) diabetes e) I don't know. (LKQ)
PEN	#4	Does the material contain any information about the influence of psychological factors on low back pain?	*The relationship between psychological factors and low back pain.* The literature using these questionnaires shows that people are unaware of the influence psychosocial factors can have on low back pain symptoms, such as that thoughts, feelings, or stress can influence pain intensity or low back pain recovery	***Supporting information from Lim et al. 2019:** N/A **Supporting questionnaire items:** • Thoughts and feelings can influence the intensity of back pain (BACK-PAQ, reverse scored) • Stress in your life (financial, work, relationship) can make back pain worse (BACK-PAQ, reverse scored) • Worrying about your back can delay recovery from back pain (BACK-PAQ, reverse scored) • Focussing on things other than your back helps you to recover from back pain (BACK-PAQ, reverse scored) • Expecting your back pain to get better helps you to recover from back pain (BACK-PAQ, reverse scored)
Prevention[¥]				
PIN	#5	Does the material contain any information about the prevention of low back pain?	*Preventative approaches to low back pain.* Patients want to know information about preventative approaches for low back pain	***Supporting information from Lim et al. 2019:** • Patients wanted to learn preventative approaches for LBP 'I did not know how can I reduce my pain or get rid of it. Right now, I know something about healthy preventive behaviour, but, before – nothing' '… I did not do the strength exercise; of course, I did not know what that was…' (F) • Need to know techniques to help prevent LBP (I) • Need to know 'what to do during acute LBP' and 'person-specific' measures to prevent/manage recurrence (I) • Need education regarding self-awareness and knowledge in **preventing onset**/worsening of symptoms in managing LBP flare (I) • Need for advice regarding ways to prevent re-injury (I)

				• Need advice regarding preventative measures in LBP, in particular application of this knowledge in difficult circumstances (eg, in time constraints or labour shortages, ie, 'real-life situations' rather than academic and theoretical advice) (I) • Patients desired for strategies to prevent exacerbation of LBP, to reduce anxiety from the unpredictability nature of LBP (I) **Supporting questionnaire items:** N/A
Functional anatomy[¥]				
PEN	#6	Does the material contain any information about the functional anatomy of the spine?	*The functional anatomy of the spine.* The literature using these questionnaires shows that people are uncertain about the functional anatomy of the spine (e.g., general anatomy and/or information about the strength, vulnerability, or flexibility of the spine and associated structures)	***Supporting information from Lim et al. 2019:** N/A **Supporting questionnaire items:** • Your back is one of the strongest parts of your body (BACK-PAQ, reverse scored) • Your back is well designed for the way you use it in daily life (BACK-PAQ, reverse scored) • It is important to have strong muscles to support your back (BACK-PAQ) • It is easy to injure your back (BACK-PAQ) • You could injure your back if you are not careful (BACK-PAQ) • You can injure your back and only become aware of the injury sometime later (BACK-PAQ) • It is worse to have pain in your back than your arms or legs (BACK-PAQ) • In regards to the general anatomy of the spinal column, mark ONE incorrect alternative: a) It has the cervical, thoracic and lumbar vertebrae and the sacrum. b) Between each vertebra, there is an intervertebral disc that acts as a "shock absorber". c) The vertebrae form a canal through which the spinal cord passes. d) The back and abdominal muscles have no function in supporting the spinal column. e) I don't know (LKQ)
Diagnosis[¥]				
PIN + PEN	#7	Does the material contain any information about low back pain diagnosis?	*Diagnosis of low back pain.* Interview data overwhelmingly shows that patients want an "exact" diagnosis of LBP and the cause of their symptoms – particularly a biomechanical or	***Supporting information from Lim et al. 2019:** • Need explanation of pain, cause of pain and why the pain developed. 'desperate to know what was causing the pain' (B) • Participants wanted definitive 'diagnosis' and explanation of nature of pain '… I can't adopt to a different way of lifestyle other than what I've been… to manage the pain and… I just want to know what the pain is' (B)

			physical explanation. Questionnaire data shows that patients lack knowledge about the varying low back pain diagnoses (e.g., acute vs. chronic low back pain).	• Biomechanical and 'anatomical' explanation of their back problems. '… he must explain the wrong movements and positions...' '… I wanted to know what are the lumbar, coccygeal vertebrae made of and what is spondylosis' (B) • 'Definitive diagnosis' and explanation regarding cause of chronic LBP 'When I first got sick, I had every type of symptoms… but nothing coming back with the tests, and I was like 'I'm not making this up', 'I would like to find out what's wrong…' (B) • Need for a 'physical cause' for LBP… 'I have pain so there must be a physical cause'…'Patients were upset that their pain could not be substantiated …' (B) • 'Exact' diagnosis and causes of LBP with a desire to explain the pain. (B) • Need for a diagnosis and search for cause of LBP (B) • Participants wanted a 'diagnosis', cause and explanation of pain. 'The doctors haven't explained to me why the pain is cold all around my back in a ring... just to take painkillers' 'They… just say its age-related wear and tear, and that you have to accept it… it makes me feel quite angry' (B) • Patients were keen for a diagnosis and explanation of the cause of pain to know 'why it hurts'. Patients perceived it to be very important to receive an understandable explanation of the LBP, or, if possible 'getting a diagnosis' (B) • Patients wanted a 'diagnosis' and explanation of the pain which was perceived to provide a huge relief (B) • Patients have strong belief in organic pathology and demand biomechanical explanations. (B) • Need explanation of the cause of LBP '…was frustrated because none of the clinicians… would give (him) straight answers as to what caused his LBP' (B) • Important for patients to know the cause of LBP (B) • Precise diagnosis was important to patients '…cause I was never properly diagnosed…', '… it's other people's attitude to you having back pain… there's a tendency for people to assume 'oh what a waster!' (B) • Patients' desire for a diagnosis - 'I did feel once the diagnosis had been made I thought right I can, I'll handle this' (B)

				• Need a 'diagnosis' and explanation of LBP '… people say to you, 'well, what's the problem?' and … 'I really don't know'. It makes you feel so stupid'." (B) • 44% of public expect a diagnosis when they consult their GP (B) • Need for a diagnosis. 'What worries me is that… every time I said, why am I getting the pain? They can't answer that question… because they're not prepared to give you a diagnosis', 'It's partly why I think the NHS is groaning at the edges, people expect to have [a] proper diagnosis made, proper treatments given …' (B) • Patients need to know the causes of symptoms and wanted a diagnosis (B) • Need 'thorough diagnosis', and expect careful histories, detailed examinations and diagnostic investigations to reach a diagnosis (B) • Need for acceptable explanatory model of pain, including physical 'diagnosis' and psychological explanations. Physical explanation is important, in addition to psychological explanations. ' … it might be mind over matter, it might be sort of a lot in my head…' (B) • Patients would like to understand pain (ie, pain severity) and its functional implication (A) • Need for a 'diagnosis' with thorough evaluation, including physical examination, diagnostic tests (B) • Participants wanted individualised explanations of the causes of their pain rather than generic diagnoses. 'We've all got pain and got different reasons for causing it…', 'What helped me a lot… was trying to understand what's going on…' (B) • Patients want facts and basic information regarding LBP (A) • General education regarding LBP. More than half of participants voiced lack of knowledge about their backs (A) • Participants were keen to have information and explanations about their LBP (A) • More detailed explanations on the disease (A) • 'I had just no frame of reference to figure out like what it was… with a back. I don't know… I'm just completely in the dark' (A) • Patients desire for justification of LBP (ie, a 'diagnosis' for an attributable cause of LBP). Patients felt cautious about disclosing the fact that they had LBP due to fear of being labelled a 'fraud', or 'as disabled' which could

				prevent them from working. Patients want to 'justify their symptoms', and hence seek investigations to receive a diagnosis (B) • Need 'diagnosis' to maintain credibility of LBP, as this makes it easier for others to believe them (B) • 'Exact' diagnosis and causes of LBP with a desire to explain the pain. (B) • Need for a 'physical cause' for LBP… 'I have pain so there must be a physical cause'…'Patients were upset that their pain could not be substantiated …' (B) • Patients have strong belief in organic pathology and demand biomechanical explanations. (B) • Precise diagnosis was important to patients '…cause I was never properly diagnosed…', '… it's other people's attitude to you having back pain… there's a tendency for people to assume 'oh what a waster!' (B) • Need a 'diagnosis' and explanation of LBP '… people say to you, 'well, what's the problem?' and … 'I really don't know'. It makes you feel so stupid'." (B) • Need 'thorough diagnosis', and expect careful histories, detailed examinations and diagnostic investigations to reach a diagnosis (B) **<u>Supporting questionnaire items:</u>** • What is low back pain? Mark ONE correct alternative: a) pain located between the lowest ribs and the pelvis b) pain between the lowest ribs and the pelvis that radiates down the leg to the foot c) pain in any region of the back, from the neck to the hip d) pain in the abdomen, lower part of the pelvis or kidneys e) I don't know (LKQ) • What is acute low back pain? Mark ONE correct alternative: a) pain in the lumbar region that usually improves in three weeks, with or without treatment b) untreatable pain in the lumbar region c) pain in the lumbar region requiring surgery d) pain in the lumbar region lasting more than 3 months e) I don't know. (LKQ) • What is chronic low back pain? Mark ONE correct alternative: a) pain in the lumbar region that usually improves in three weeks, with or without treatment b) untreatable pain in the lumbar region c) pain in the lumbar region requiring surgery d) pain in the lumbar region lasting more than 3 months e) I don't know (LKQ)

				• What is sciatica pain? Mark ONE correct alternative: a) pain located between the lowest ribs and the pelvis b) pain between the lowest ribs and the pelvis that radiates to the leg down to the foot c) pain in any region of the back, from the neck to the hip d) pain in the abdomen, lower part of the pelvis or kidneys e) I don't know. (LKQ)
PEN	#8	Does the material contain any information about the types of tests, investigations, and/or exams required or not required to diagnose low back pain?	*The role of tests, investigations, and/or exams in diagnosing low back pain.* Both the questionnaire and interview data show that patients still commonly perceive imaging for low back pain as a routine part of low back pain management. There are various misconceptions about imaging, such as that imaging is required to get 'the best medical care for low back pain,' that imaging is required to obtain an accurate diagnosis and that it will find the 'visible structural damage' responsible for the pain, among others. Questionnaire data also shows that patients lack knowledge in alternative diagnostic methods such as a patient history and physical examination to diagnose low back pain.	***Supporting information from Lim et al. 2019:** • Need for imaging as part of management of LBP (C) • Need 'thorough work ups' with additional imaging test to allow precise ascertainment of physical cause of LBP (C) • 74% of public expect GP to send them for an X-ray (imaging) to aid diagnosis (C) • Participants believed 'accurate diagnosis could only be achieved through detailed examination (assessment though physical touch)' and/or imaging (X-rays and MRI scans)' (C) • Need imaging to know the cause of symptoms (C) • Need tests or imaging to confirm legitimacy of LBP 'I kind of cried with relief when I saw what was wrong… but you don't want this unexplained pain.' (C) • Need imaging tests to provide reassurance and confirmation of diagnosis '… X-ray might show the cause in my spine' … '…XR was to establish whether, … was just a pulled muscle of whether it was called herniated disc…' (C) • Imaging was expected to show 'visible structural damage' responsible for LBP or as reassurance (C) **Supporting questionnaire items:** • X-rays or scans are necessary to get the best medical care for low back pain (Jenkins 2016 BBQ study imaging questions) • Everyone with low back pain should have spine imaging (e.g X-ray, CT, MRI) (Jenkins 2016 BBQ study imaging questions) • X-ray and newer imaging tests can always identify the cause of pain. (Morton 2019 standalone items) • Modern X-rays will usually identify the cause of pain. (Morton 2019 standalone items) • Everyone with back pain should have a spine X-ray. (Morton 2019 standalone items)

				• Medical scans of the low back will identify the cause of back pain (LBP-MSBQ) • People with higher levels of low back pain will have worse findings on medical scans (LBP-MSBQ) • When back pain improves, a repeat medical scan would show improvement (LBP-MSBQ) • If your pain gets worse, it will be reflected by a deterioration on your medical scan (LBP-MSBQ) • Medical scans are necessary to get the best medical care for low back pain (LBP-MSBQ) • What is needed for the diagnosis of low back pain? Mark TWO correct alternatives: a) Magnetic resonance imaging (MRI) and computerized tomography (CT scan) are always needed. b) An x-ray is not always needed. c) The diagnosis is often possible through the medical history and physical exam of the patient without the need of supplementary exams. d) laboratory tests such as glycemia, cholesterol and urine are always needed. e) I don't know. (LKQ)
PIN	#9	Does the material contain any information about leg pain/symptoms?	*Leg pain.* Patients want to know more information about leg pain or 'sciatica'	**<u>*Supporting information from Lim et al. 2019:</u>** • Patients required information about the nature of sciatica '… I think they were guarded about giving any particular time-scales' (D) **<u>Supporting questionnaire items:</u>** N/A
PEN	#10	Does the material contain any information about the relationship between exact diagnosis and treatment?	*The relationship between exact diagnosis (i.e., determining the specific pathoanatomical cause of low back pain) and using said diagnosis to inform treatment recommendations*. Both the questionnaire and interview data show that people believe pinpointing the exact physical cause of one's low back pain is required as an essential first step to inform treatment recommendations	**<u>*Supporting information from Lim et al. 2019:</u>** • 'Proper' diagnosis required as an essential first step (B) • '… they basically haven't got a clue what's causing my problem and unless they find out… they can't make it better…' illustrates the need for a 'diagnostic label' (B) • Need for diagnosis, which was considered by patients as the starting point for deciding on a treatment regimen and to identify cause and obtain full clinical explanation of their leg pain to help them cope '…through over-stretching, initially, when I was pulling the branches down …' (B) **<u>Supporting questionnaire items:</u>** • To effectively treat back pain you need to know exactly what is wrong (BACK-PAQ)

Treatment[¥]

The following supporting data are about treatment but were more general in nature and did not fit under any specific treatment item below:

Supporting information from Lim et al. 2019:

- Need information regarding other treatment options, rather than just medication to treat symptom (F)
- The role of pain management is extremely important for patients as the pain interferes with their daily activities (H)
- **Need to know 'what to do during acute LBP'** and 'person-specific' measures to prevent/manage recurrence (I)
- '… the most frustrating thing for anyone with back pain is the fact that you are told there is no treatment…' '… they really can't do anything…' (F)

Supporting questionnaire items:

- There is no real treatment for back trouble (BBQ)
- Once you have a back problem, there is not a lot you can do about it (BACK-PAQ)

It is important to see a health professional when you have back pain (BACK-PAQ)

PIN + PEN	#11	Does the material contain any information about pharmacological treatment for low back pain?	*Pharmacological treatment options for low back pain.* Interview data shows that patients with low back pain want information on available pharmacological treatment options and their role in managing low back pain. They are also interested in information about the efficacy and safety profiles/side effects of these medications. Questionnaire data shows that patients lacked knowledge about appropriate pharmacological treatment options for low back pain	**<u>*Supporting information from Lim et al. 2019:</u>** • Patients wanted to know the role of simple analgesia in LBP, in relation to the safety profile, side effects, effectiveness and impact on work. 'I'm not a great lover of painkillers… you start on one painkiller and then you have to go higher and higher and higher…' '… so, I had to stop taking the medication so I could go to work' (H) • Patients wanted to know treatment approaches for LBP, including role and efficacy of simple analgesia in symptom control '… so, I went to the doctor, he prescribed anti-inflammatories for… a long time, didn't work…' (F) • Patients desired to learn the role of simple analgesia on management of LBP as some patients consider simple analgesia to be ineffective (H) • Need explanation of role and efficacy of simple analgesia in symptom control (H) • **Need information on 'pain-centred' management** (eg, **medication,** rest, massage, etc) and the role of exercise/activity rehabilitation 'I took different drugs. I don't know which medications I have not yet taken…' 'Natural healers fix arms, legs and backs' (F) **<u>Supporting questionnaire items:</u>** • Simple painkillers are usually enough to control most back pain (activity, rest, and use of painkillers items from Gross 2006, used in Hall 2021 public beliefs)

				• In regards to drug treatment for low back pain, mark ONE incorrect alternative: a) Anti-inflammatory medicines and analgesics may be used during acute crises. b) Corticosteroids may be necessary during an acute crisis. c) Antidepressants and anticonvulsants may be used for chronic low back pain. d) Topical medications such as gel, plasters or ointments are always indicated. e) I don't know. (LKQ) • What can be used to treat chronic low back pain? Mark TWO correct alternatives: a) **the long-term use of anti-inflammatory medicines** b) instructions on spine protection and exercises c) abdominal supportive belt when performing heavy-duty activities d) Physical means such as short waves, ultra-sound, and Bier's oven which are more important than oriented physical exercises. e) I don't know (LKQ)
PIN + PEN	#12	Does the material contain any information about provider-based non-pharmacological treatment for low back pain?	*Provider-based non-pharmacological treatment options for low back pain.* Interview data shows that patients with low back pain want information on available provider-based, non-pharmacological treatment options (we have defined this as treatments which are administered by a registered health professional such as supervised exercise, spinal manipulation, massage, and cognitive behavioural therapy). They were also interested in the effectiveness and role of these treatments in managing their low back pain. Questionnaire data shows that patients lacked knowledge about appropriate provider-based non-pharmacological treatment options for low back pain.	**<u>*Supporting information from Lim et al. 2019:</u>** • Need advice to continue independent living despite the pain, including psychological strategies (F) • Patients wanted to learn management options for LBP, including referral for physiotherapy or osteopathy (F) • Patients wanted comprehensive open discussion regarding treatment options, including use of complementary therapy. Many felt they were unable to pursue complementary therapy due to lack of information (F) • Patients wanted to learn how to cope in despair and carry on with life when proposed treatments offered no relief on LBP. 'There were times when I felt like giving up… you've got to try and help yourself as much as you can…' (F) • Need advice regarding strategies on lifestyle changes, **to cope with pain**, to increase participation in life and the type of activities restriction (F) • Patients desired for information on coping strategies for chronic LBP (eg, acceptance of 'loss of self' and to 'learn to live with it') (F) • Need advice on benefit and role of physiotherapy and specific advice on what activities can be done while having pain (F) • Need pain management, including advice on non-pharmacological modalities (H) • **Explore non-pharmacological pain management methods for LBP** (eg, heat and cold application, relaxation, **massage**) (F) • **Need information on 'pain-centred' management** (eg, medication, rest, **massage,** etc) and the role of exercise/activity rehabilitation 'I took different

				drugs. I don't know which medications I have not yet taken…' 'Natural healers fix arms, legs and backs' (F) • Need information on other support services available within GP practice (eg, osteopathy and physiotherapy) (K) **<u>Supporting questionnaire items:</u>** • What can be used to treat chronic low back pain? Mark TWO correct alternatives: a) the long-term use of anti-inflammatory medicines b) instructions on spine protection and exercises c) abdominal supportive belt when performing heavy-duty activities d) **Physical means such as short waves, ultra-sound, and Bier's oven which are more important than oriented physical exercises**. e) I don't know (LKQ)
PIN + PEN	#13	Does the material contain any information about general exercise or sports for low back pain?	*General exercise or sports as a treatment option for low back pain.* Interview data shows that patients with low back pain want information on general exercise or sports treatment options (we have defined this as more structured general exercise classes or organized sports including options like land aerobics, water aerobics, stretching and/or strengthening classes, yoga, tai chi, Pilates, or spin classes). Questionnaire data shows that patients lacked knowledge about general exercise or sport.	**<u>*Supporting information from Lim et al. 2019:</u>** • Need practical advice on range of physical activities LBP patients are capable of performing (F) • They wanted advice and exercise prescription for LBP management. '…must explain the plan *in steps* within a timeframe and the benefits of every exercise…' (F) • Patients need detailed explanation on the objectives and choice of exercises included in the program in management of chronic LBP (F) • Need information on 'pain-centred' management (eg, medication, rest, massage, etc) and **the role of exercise/activity rehabilitation** 'I took different drugs. I don't know which medications I have not yet taken…' 'Natural healers fix arms, legs and backs' (F) **<u>Supporting questionnaire items:</u>** • In regards to physical activity and low back pain, mark ONE incorrect alternative: a) Walking three times a week for an hour can improve chronic low back pain. **b) Intensive exercises are indicated for acute low back pain. c) Aquatic activities may be beneficial to the patient with chronic low back pain.** d) The most highly recommended exercises are strengthening of the abdomen and the back muscles, stretching and physical conditioning. e) I don't know. (LKQ)
PIN + PEN	#14	Does the material contain any information	*Self-management options for low back pain.* Interview data shows that patients with low	**<u>*Supporting information from Lim et al. 2019:</u>** • Need specific advice on 'safe' everyday activities and ways to protect the back (F)

		about self-management strategies for low back pain?	back pain want information on available self-management treatment options like heat, cold, lifestyle changes, specific exercises to strengthen or protect the back, and staying active. Questionnaire data shows that patients lacked knowledge about appropriate self-management treatment options for low back pain.	• Need advice on how to return to normal activities (F) • Need advice regarding strategies **on lifestyle changes**, to cope with pain, to **increase participation in life and the type of activities restriction** (F) • Explore non-pharmacological pain management methods for LBP (**eg, heat and cold application, relaxation,** massage) (F) • Patients wanted to be reinforced on the importance of remaining active during acute episode and be equipped with information on correct postures, specific back muscle strengthening to help 'protect the spine'. • 'Self-management' strategies for LBP (eg, special exercises for LBP) (I) • Patients keen to learn what sort of exercises can be done to relieve fear of uncertainty over risks involved in LBP self-management 'What can they do to help ease the pain? I don't really know'. 'I don't know what I'm doing… I'm not pushing myself, I don't know, it's still it's a bit scary…' (I) • Need self-help information to deal with LBP. Patients were prepared to make behavioural changes which might help alleviate symptoms. 'If I know what exercises to try to do to strengthen 'my back', I can may be try to alter how I do the things…' (F) • Need for 'self-management' advice in managing LBP to return to normal activities (J) • Want to know what kind of activity he/she preferably could or should do and 'should avoid' (J) • Need information addressing self-management strategies 'I like doing them [stretches and exercises] and I know I have to…' (J) • Patients wanted to know about 'self-management' (ie, what they could do about the pain and future treatment plan) 'I'm crying out for somebody to take an interest in me for I'm a fighter and I want to improve my health' (J) • Patients wanted to be responsible for their back care and desire for explanation and to learn their role in the treatment process. 'It is my back, it's my responsibility to always look after it…' (F) • Participants wanted to gain self-control on the unpredictable nature of LBP, especially with flare-ups 'I'd lost confidence in my back because it can go at any time…' (E) **<u>Supporting questionnaire items:</u>** • What can be used to treat chronic low back pain? Mark TWO correct alternatives: a) the long-term use of anti-inflammatory medicines **b)**

				instructions on spine protection and exercises c) abdominal supportive belt when performing heavy-duty activities d) Physical means such as short waves, ultra-sound, and Bier's oven which are more important than oriented physical exercises. e) I don't know (LKQ) • In regards to physical activity and low back pain, mark ONE incorrect alternative: **a) Walking three times a week for an hour can improve chronic low back pain**. b) Intensive exercises are indicated for acute low back pain. c) Aquatic activities may be beneficial to the patient with chronic low back pain. d) **The most highly recommended exercises are strengthening of the abdomen and the back muscles, stretching and physical conditioning**. e) I don't know. (LKQ)
PEN	#15	Does the material contain any information about the role of surgery as a treatment option for low back pain?	*The role of surgery as a treatment for low back pain.* The literature using these questionnaires shows that people are uncertain about the role of surgery as a treatment for low back pain (e.g., when surgery is a viable option for low back pain)	**<u>*Supporting information from Lim et al. 2019:</u>** N/A **<u>Supporting questionnaire items:</u>** • In regards to surgical treatment for low back pain, mark TWO correct alternatives: a) It is indicated in few cases. b) It may be important in cases with nerve root compression and spinal column instability that do not improve with clinical treatment. c) Surgery guarantees the cure of low back pain. d) It is the best treatment for any type of low back pain e) I don't know. (LKQ) • If you have a slipped disc, you must have surgery. (Morton 2019 standalone items)
PIN + PEN	#16	Does the material contain any information about the management of low back pain flare-ups and/or recurrence?	*Managing flare-ups and/or recurrence of low back pain.* Interview and questionnaire data shows that patients want information about or are uncertain about how to cope with or manage a flare up of low back pain.	**<u>*Supporting information from Lim et al. 2019:</u>** • Need information on how to cope and deal with acute flare of LBP (I) • Need education regarding self-awareness and knowledge in preventing onset/**worsening of symptoms in managing LBP flare (I)** **<u>Supporting questionnaire items:</u>** • In regards to acute low back pain, mark TWO correct alternatives: a) The great majority of patients recover in three weeks. b) After recovery and improvement of the pain, the patient is cured and there is no risk of further crises. c) Instructions on how to protect the spine are only important during the crisis. d) **The orientations for spine protection and energy conservation should be routine in patients with a history of low back pain because relapses are frequent**. e) I don't know. (LKQ)

PEN	#17	Does the material contain any information promoting staying active or not resting?	*The role of staying active compared to bed rest.* The literature using these questionnaires shows that people still disagree or are uncertain that you should stay active with low back pain and/or agree or are uncertain that you should rest in bed with low back pain.	**<u>*Supporting information from Lim et al. 2019:</u>** N/A **<u>Supporting questionnaire items:</u>** • Bed rest is the mainstay of therapy. (Morton 2019 standalone items) • Low back pain should have rest and tranquillity until recovery. (Morton 2019 standalone items) • If you have back pain you should try to stay active (BACK-PAQ, reverse scored) • If you have back pain, you should try to stay active (activity, rest, and use of painkillers items from Gross 2006, used in Hall 2021 public beliefs) • If you have back pain, you should rest until it gets better (activity, rest, and use of painkillers items from Gross 2006, used in Hall 2021 public beliefs) • If I had back pain, I would try to stay physically active (TSK-G, reverse scored) • Back trouble must be rested (BBQ) • If your back hurts, you should avoid bed rest and keep as physically active as possible. (Morton 2019 standalone items) • In regards to the treatment for acute low back pain. Mark TWO correct alternatives: a) One week of absolute bed rest is indicated. b) Definitive sick leave from work is indicated. c) Low back pain may improve even without treatment. d) The least possible rest is indicated. e) I don't know. (LKQ)
Activities of daily living[¥]				
PEN	#18	Does the material contain any information about functional tasks in relation to low back pain?	*The relationship between functional tasks and low back pain.* The literature using these questionnaires shows that people are uncertain about the relationship between functional tasks such as lifting, carrying, and bending and low back pain symptoms.	**<u>*Supporting information from Lim et al. 2019:</u>** N/A **<u>Supporting questionnaire items:</u>** • Lifting without bending the knees is not safe for your back (BACK-PAQ) • Belief that backpack weight does not affect the back. (Morton 2019 standalone items) • Most back pain is caused by injuries or heavy lifting. (Morton 2019 standalone items) • Bending your back is good for it (BACK-PAQ, reverse scored) • To protect the spine, mark TWO correct alternatives: a) The best way to sleep is on your stomach. b) Sit down to put on your socks and shoes. **c) Pick up objects from the floor without bending your knees** d) Wash the dishes with your stomach leaning against the sink. e) I don't know (LKQ)

				• Again, in relation to spinal protection, mark ONE incorrect alternative: a) You should get out of bed carefully, turning sideways with the help of our hands. b) Avoid carrying too much weight on one side of the body (divide the load between both arms). c) Avoid twisting of the spine. d) Wear high heels all day. e) I don't know. (LKQ)
PEN	#19	Does the material contain any information about postures in relation to low back pain?	*The relationship between postures and low back pain.* The literature using these questionnaires shows that people are uncertain about the relationship between postures such as sitting, standing, and positioning and low back pain symptoms or health	**<u>*Supporting information from Lim et al. 2019:</u>** N/A **<u>Supporting questionnaire items:</u>** • Sitting is bad for your back (BACK-PAQ) • The longer you remain seated, the healthier your back. (Morton 2019 standalone items) • Good posture is important to protect your back (BACK-PAQ) • To protect the spine, mark TWO correct alternatives: **a) The best way to sleep is on your stomach. b) Sit down to put on your socks and shoes.** c) Pick up objects from the floor without bending your knees **d) Wash the dishes with your stomach leaning against the sink.** e) I don't know (LKQ)
Pain neuroscience education[¥]				
PEN	#20	Does the material contain any information about the relationship between pain and injury?	*The relationship between pain and injury.* The literature using these questionnaires shows that people have misconceptions about the relationship between pain and injury, for example that hurt equals harm (i.e., that pain in the back means there is something seriously or dangerously wrong with the back or that the back is injured or damaged).	**<u>*Supporting information from Lim et al. 2019:</u>** N/A **<u>Supporting questionnaire items:</u>** • Back pain means that there is something dangerously wrong with your body (TSK-G); My body is telling me I have something dangerously wrong (TSK-SV) • Back pain means the body is injured (TSK-G) • There would perhaps be less back pain if there weren't something wrong with the back (TSK-G); I would not have this much pain if there were not something potentially dangerous going in my body (TSK-SV) • Even though something would cause me a lot of back pain, I don't immediately think it is dangerous (TSK-G, reverse scored) • If back pain increases through physical activity, that doesn't mean that it is dangerous (TSK-G, reverse scored) • Back pain means that you have injured your back (BACK-PAQ) • A twinge in your back can be the first sign of a serious injury (BACK-PAQ)

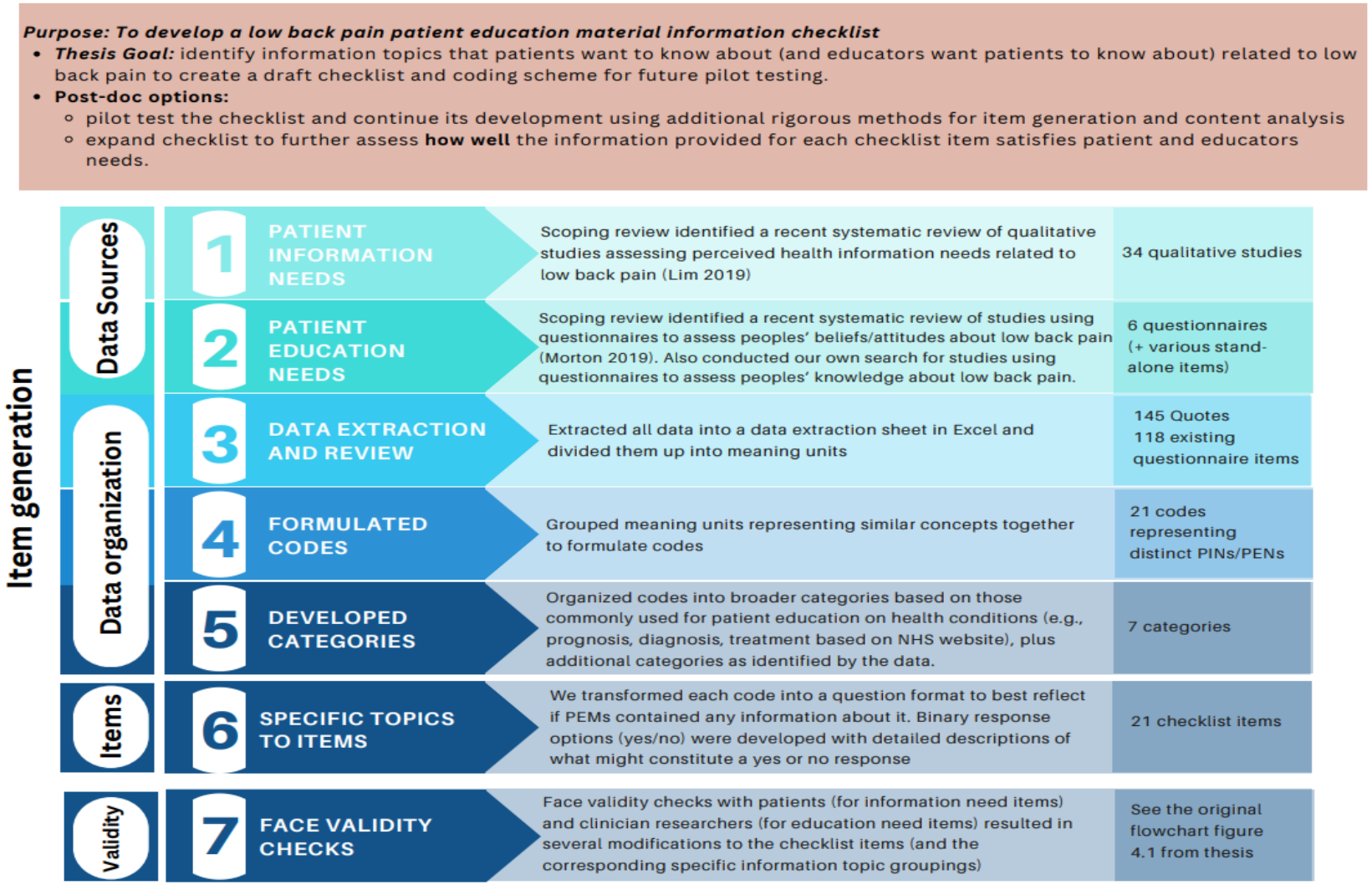
				• When you have back pain, you can do things which increase your pain without harming the back (BACK-PAQ, reverse scored)
PEN	#21	Does the material contain any information about the safety of physical activity and/or exercise and/or sport?	*The role of movement or physical activity in making pain worse or harming your back / the relationship between movement and low back pain symptoms.* The literature using these questionnaires shows that patients think they might injure or damage their back if they perform certain movements or activities and that patients avoid movement for fear of making their pain or other symptoms worse. Interview data supports these findings, with direct quotations from patients highlighting their fear-avoidance beliefs.	**<u>*Supporting information from Lim et al. 2019:</u>** • Education required to deconstruct fear of specific movements that thought to aggravate LBP 'It's just like a common cold' in deconstructing fear of specific movements. 'If you bent in a certain way, and your disc slipped and you are incapacitated…', 'I used to be just so frightened, and I'd think… the more I aggravated it, the worse it was gonna be… so I would avoid doing things…' (E) • Need advice on exercise for LBP, as many participants thought exercise was counterintuitive and feared it would further damage their LBP. 'It was turned upside down for me. I was told that worst thing to do is to sit down or lie down…' (F) • '… expected passive treatments like medication, relaxation, rest, massage… ' '… active treatment is considered 'illogical' and 'counterproductive'…' '… preferred passive treatments including medication and rest… did not understand why they should increase activity in the presence of pain…' (F) • 'I really have to be very, very careful about everything I do' 'I can't go out and do what I want to do…' '… you never know when it will get you and debilitate you to the point where you can't function' (I) • They valued reassurance about safety of movement in setting of LBP (F) **<u>Supporting questionnaire items:</u>** • I'm afraid sometimes that I might injure my back if I exercise (TSK-G) • I should not have to exercise if I would have back pain (TSK-G) • For a person with back complaints it is not advisable to be physically active (TSK-G); It is really not safe for a person with a condition like mine to be physically active (TSK-SV) • Back pain means a person should stop exercising to prevent injury (TSK-G); Pain let us me know when to stop exercising so that I do not injure myself (TSK-SV) • The safest way to prevent back pain from worsening, is being careful not to make any unnecessary movements (TSK-G) • I am afraid that I might injury myself accidentally (TSK-G); I am afraid that I might injure myself accidentally (TSK-SV)

				• I can't do all the things normal people do, because I think I can easily get back complaints (TSK-G) • Physical activity makes my pain worse (FABQphys/mFABQ) • Physical activity might harm my back (FABQphys/mFABQ) • I should not do physical activities which (might) make my pain worse (FABQphys/mFABQ) • I cannot do physical activities which (might) make my pain worse (FABQphys/mFABQ) • If an activity or movement causes back pain, you should avoid it in the future (BACK-PAQ) • If your back hurts, you should take it easy until the pain goes away (BACK-PAQ) • If you have back pain you should avoid exercise (BACK-PAQ) • When you have back pain the risks of vigorous exercise outweigh the benefits (BACK-PAQ) • If you overuse your back, it will wear out (BACK-PAQ) • Physical activity and sport is bad for your back. (Morton 2019 standalone items) • The more you exercise and practice sport, the healthier your back. (Morton 2019 standalone items) • If I had low back pain and I were to try to overcome it, my pain would increase (TSK-G); If I were to try to overcome it, my pain would increase (TSK-SV) • Back pain decreases when a person stays physically active (TSK-G, reverse scored); My pain would probably be relieved if I were to exercise (TSK-SV) • If you compete in any sport, you must follow your trainer's instructions in order to avoid hurting your back (Morton 2019 standalone items)

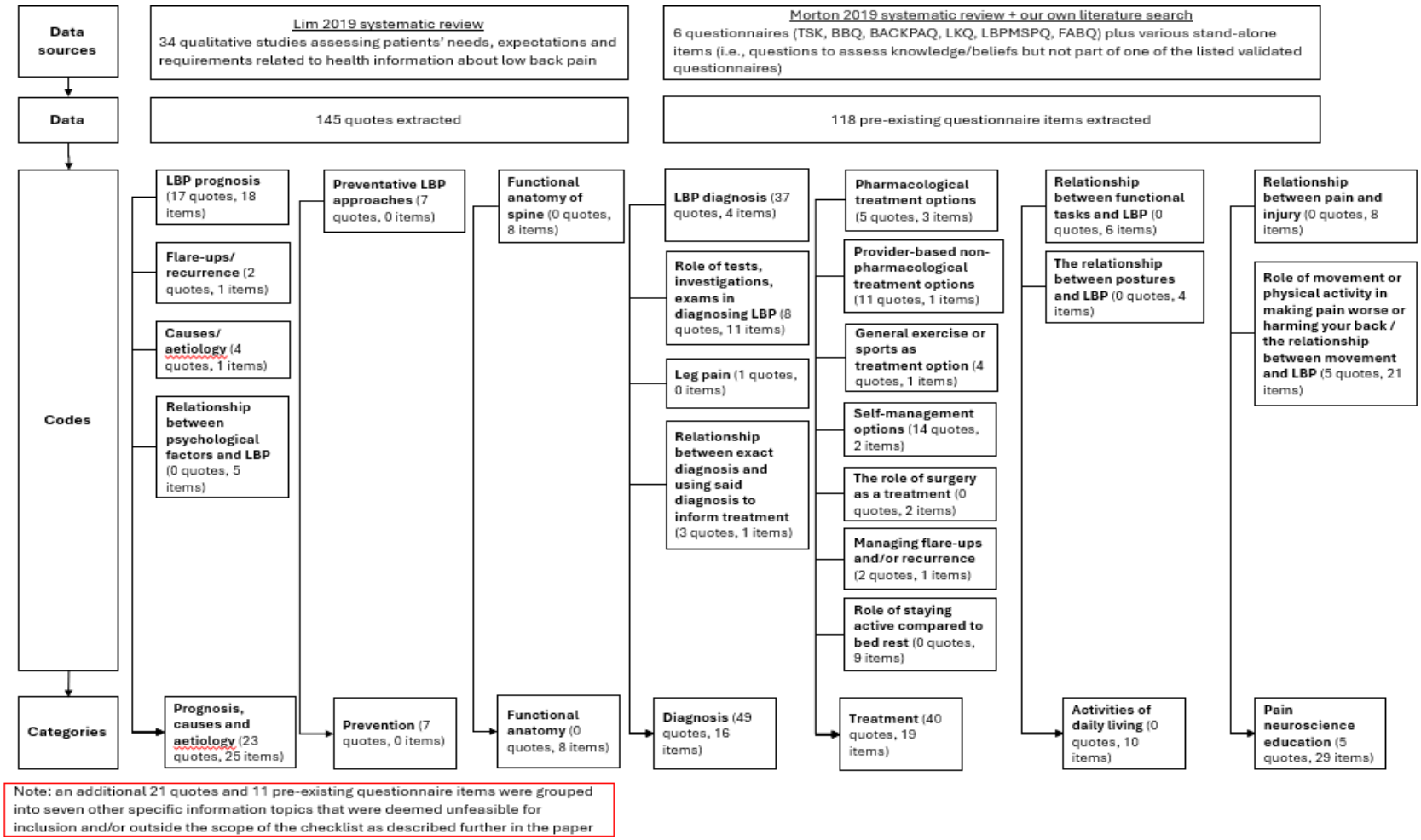
Abbreviations: PIN = patient information need; PEN = patient education need; mFABQ = Modified Fear-Avoidance Beliefs Questionnaire (comprising 4 of 5 original physical subscale items and no work subscale items); FABQ German = Fear-Avoidance Beliefs Questionnaire German; BBQ = Back Beliefs Questionnaire; BACK-PAQ = Back Pain Attitudes Questionnaire; LBP-MSBQ = Low Back Pain Medical Scans Beliefs Questionnaire; LKQ = Low Back Pain Knowledge Questionnaire; TSK-G = The Tampa Scale for Kinesiophobia (a version of the TSK that can be administered to the general population); TSK-SV = Tampa Scale for Kinesiophobia Short Version (comprising 8 of 17 original TSK items).
If a supporting quote or questionnaire item was relevant to two or more codes, we duplicated the quote under each code and bolded only the text that was relevant to the corresponding code.

*The quotes from Lim et al. 2019 were obtained from their appendix material. They categorized these quotes into eleven themes. We kept track of where these quotes originated by labeling them with the letter corresponding to the original themes outlined in Lim et al. 2019: (A) General information content related to LBP, (B) Diagnosis, cause/aetiology for LBP, (C) Perceived needs for imaging, (D) Prognosis, including future disability and effect on work capacity, (E) Information regarding precipitation of flares, (F) General information regarding LBP management, (G) The need for tailored information regarding LBP management, (H) Information regarding pain management, (I) Information regarding management of flares and preventive measures, (J) Self-management strategies, (K) Information regarding support services for LBP. ¥All headings in grey bars represent categories. All codes relate to the corresponding category they are placed under.

Appendix 4.5. Flow chart depicting the steps of our content analysis.



Appendix 4.6. Flow diagram depicting how we grouped quotes and existing questionnaire items at each stage of our content analysis.



Appendix 4.7. Full version of the Patient Information and Education Needs Checklist for Low Back Pain (PINE-LBP)

Prognosis, causes and aetiology				
#1	Does the material contain any information about prognosis for low back pain?	Yes = Y, No = N		
Including, but not limited to, any information related to: • Low back pain's generally favorable prognosis or benign nature (e.g., it generally gets better in a few weeks for most people and there is little cause for concern) • How low back pain should not impact a person's ability to carry out their daily or work activities despite the pain • The unpredictable recovery period (e.g., though most peoples' low back pain will get better within a few weeks, some people might take a shorter or longer amount of time to fully recover from their low back pain and this is not a cause for concern) *Summary of supporting information from Lim et al. 2019 and questionnaire response data: Interview data shows that patients want information about the natural history or prognosis of low back pain, in particular its favourable prognosis and benign nature. Questionnaire data shows that patients lack knowledge about low back pain prognosis (e.g., agreeing with or uncertain about the items 'Once you have had back trouble there is always a weakness' and 'There is a high chance that an episode of back pain will not resolve')				
#2	Does the material contain any information about low back pain flare-ups and/or recurrence?	Yes = Y, No = N		
Including, but not limited to, any information related to: • How low back pain can come back again or 'flare up' in the future even after you have recovered from low back pain in the past • How low back pain flare-ups are a normal part of low back pain that do not indicate any sort of permanent or lingering damage to the back • Psychological, social, or lifestyle factors that can precipitate low back pain flare-ups *Note: any information about *managing* flare-ups and/or recurrence should be included in item #16 and not in this item.				

*Summary of supporting information from Lim et al. 2019 and questionnaire response data: Interview data shows that patients want information about the unpredictability of low back pain in terms of future flare-ups and recurrence. Questionnaire data shows that patients lacked knowledge about the possibility of future low back pain flares.				
#3	Does the material contain any information about low back pain causes or aetiology?	Yes = Y, No = N		
Including, but not limited to, any information related to: • Any actions or other aetiological factors that could cause an episode of low back pain *Summary of supporting information from Lim et al. 2019 and questionnaire response data: Interview data shows that patients are interested in causes/aetiological factors related to low back pain. Questionnaire data shows that patients have misconceptions about what might cause an episode of LBP				
#4	Does the material contain any information about the influence of psychological factors on low back pain?	Yes = Y, No = N		
Including, but not limited to, any information related to: • How psychological factors (e.g., thoughts or feelings of stress or worry) can influence the intensity of low back pain symptoms or low back pain recovery *Summary of supporting information from back beliefs questionnaires: The literature using these questionnaires shows that people are unaware of the influence psychosocial factors can have on low back pain symptoms, such as that thoughts, feelings, or stress can influence pain intensity or low back pain recovery				
Prevention				
#5	Does the material contain any information about the prevention of low back pain?	Yes = Y, No = N		
Including, but not limited to, any information related to: • Preventing a first low back pain episode or future low back pain flare-ups				

*Summary of supporting information from Lim et al. 2019: Patients want information about preventative approaches or techniques for low back pain				
Functional anatomy				
#6	Does the material contain any information about the functional anatomy of the spine?	Yes = Y, No = N		
Including, but not limited to, any information related to: • The anatomical or structural aspects of the spine, such as how the spine is made up of the cervical, thoracic, and lumbar vertebrae • The anatomical or structural aspects of the associated muscles, ligaments, and/or tendons, such as how these associated muscles can help to support the spine • The strength, vulnerability, or flexibility of the spine and/or associated structures *Summary of supporting information from back beliefs questionnaires: The literature using these questionnaires shows that people are uncertain about the functional anatomy of the spine (e.g., general anatomy and/or information about the strength, vulnerability, or flexibility of the spine and associated structures)				
Diagnosis				
#7	Does the material contain any information about low back pain diagnosis?	Yes = Y, No = N		
Including, but not limited to, any information related to: • The types of low back pain (e.g., non-specific vs. specific low back pain) • How low back pain is diagnosed in the presence or absence of red flags (i.e., signs or symptoms that suggest a more serious form of low back pain) • How the exact cause of pain cannot be identified for most people with non-specific low back pain • How the spine and other associated body parts may cause pain (e.g., non-specific low back pain can be caused by strains or sprains of the muscles, ligaments, or tendons around the spine) *Summary of supporting information from Lim et al. 2019 and questionnaire response data: Interview data overwhelmingly shows that patients want an "exact" diagnosis of low back pain and the causes of their symptoms – particularly a biomechanical or physical explanation. Questionnaire data shows that patients lack knowledge about the varying low back pain diagnoses (e.g., acute vs. chronic low back pain)				

#8	Does the material contain any information about the types of tests, investigations, and/or exams required or not required to diagnose low back pain?	Yes = Y, No = N		
Including, but not limited to, any information related to: • How doctors are trained to identify serious signs and symptoms during a routine physical exam and patient history, so they can reliably rule out these signs and symptoms of more serious low back pain without imaging • How imaging is only helpful for people with 'red flags' (e.g., diagnostic imaging is only useful for people with the more serious signs and symptoms, or 'red flags,' of low back pain, such as a fracture in the spine, because these signs and symptoms are what diagnostic imaging was designed to detect • How, in the absence of the more serious signs and symptoms suggesting more serious (i.e., 'specific') low back pain, diagnostic imaging is unable to identify any physical causes for non-specific low back pain, hence the name 'non-specific'. • How structural changes or differences or abnormalities in the spine (e.g., herniated/protruding discs) other than the select few 'red flags' do not necessarily cause low back pain and/or are not necessarily a cause for concern (e.g., studies show that spinal abnormalities such as herniated or protruding discs are common in patients with no low back pain symptoms, so they are not necessarily the cause of your low back pain) *Summary of supporting information from Lim et al. 2019 and questionnaire response data: Both the interview and questionnaire response data show that patients still commonly perceive imaging for low back pain as a routine part of low back pain management. There are various misconceptions about imaging, such as that imaging is required to get 'the best medical care for low back pain,' that imaging is required to obtain an accurate diagnosis and that it will find the 'visible structural damage' responsible for the pain, among others. Questionnaire data also shows that patients lack knowledge in alternative diagnostic methods such as a patient history and physical examinations to diagnose low back pain.			
#9	Does the material contain any information about leg pain/symptoms?	Yes = Y, No = N		
Including, but not limited to, any information related to: • The nature of leg pain, sciatica, radiculopathy, or lumbar radicular syndromes • Leg pain or other leg symptoms such as loss of sensation, numbness, or weakness *Summary of supporting information from Lim et al. 2019: Patients want information about the nature of sciatica				
#10	Does the material contain any information about the relationship between exact diagnosis and treatment?	Yes = Y, No = N		

Including, but not limited to, any information related to: • How an exact diagnosis (i.e., identification of the exact physical cause of low back pain) is not necessary to inform future treatment recommendations. For example, the material could describe how non-specific low back pain is a useful diagnosis, even if the exact source of pain cannot be identified, because this means there is likely nothing seriously wrong with the back. It could emphasize that this means non-specific low back pain is a useful and informative diagnosis that can be used to inform treatment recommendations because the doctor knows that there is nothing serious wrong with the back. *Summary of supporting information from Lim et al. 2019 and questionnaire response data: Both the interview and questionnaire response data show that people believe pinpointing the exact physical cause of one's low back pain is required as an essential first step to inform treatment recommendations				
Treatment				
#11	Does the material contain any information about pharmacological treatment for low back pain?	Yes = Y, No = N		
Including, but not limited to, any information related to: • Pharmacological treatment options for low back pain such as non-steroidal anti-inflammatory drugs (NSAIDs), anti-depressants, muscle relaxants, weak opioids • How these treatments are thought to be helpful for low back pain (i.e., mechanism of action) • The benefits and/or harms or side effects of these treatments • The impact of these treatments on work capacity • How to taper or reduce pain control medications once no longer needed *Summary of supporting information from Lim et al. 2019 and questionnaire response data: Interview data shows that patients with low back pain want information on available pharmacological treatment options and their role in managing low back pain. They are also interested in information about the efficacy and safety profiles/side effects of these medications. Questionnaire data shows that patients lacked knowledge about appropriate pharmacological treatment options for low back pain				
#12	Does the material contain any information about provider-based non-pharmacological treatment for low back pain?	Yes = Y, No = N		
Including, but not limited to, any information related to: • Provider-based non-pharmacological treatment options for low back pain such as supervised exercise, spinal manipulation, massage, cognitive behavioural therapy that are administered by a registered health professional • How these treatments are thought to be helpful for low back pain (i.e., mechanism of action)				

<table>
<tr><td colspan="5">• The benefits and/or harms of these treatments

<u>*Summary of supporting information from Lim et al. 2019 and questionnaire response data:</u> Interview data shows that patients with low back pain want information on available provider-based, non-pharmacological treatment options (we have defined this as treatments which are administered by a registered health professional such as supervised exercise, spinal manipulation, massage, and cognitive behavioural therapy). They were also interested in the effectiveness and role of these treatments in managing their low back pain. Questionnaire data shows that patients lacked knowledge about appropriate provider-based non-pharmacological treatment options for low back pain.</td></tr>
<tr><td>#13</td><td>Does the material contain any information about general exercise or sports for low back pain?</td><td>Yes = Y,
No = N</td><td></td><td></td></tr>
<tr><td colspan="5"><u>Including, but not limited to, any information related to:</u>
• General exercise classes or organized sports including land aerobics, water aerobics, stretching and/or strengthening classes, yoga, tai chi, Pilates, or spin classes
• How to perform these strategies
• How these treatments are thought to be helpful for low back pain (i.e., mechanism of action)
• The benefits and/or harms of these treatments

<u>*Summary of supporting information from Lim et al. 2019 and questionnaire response data:</u> Interview data shows that patients with low back pain want information on general exercise or sports treatment options (we have defined this as more structured general exercise classes or organized sports including land aerobics, water aerobics, stretching and/or strengthening classes, yoga, tai chi, Pilates, or spin classes that are not provided by a registered health professional and that do not fall under the self-management strategies category, which include stretches and exercises prescribed specifically to manage low back pain symptoms). Questionnaire data shows that patients lacked knowledge about general exercise or sports treatment options for low back pain</td></tr>
<tr><td>#14</td><td>Does the material contain any information about self-management strategies for low back pain?</td><td>Yes = Y,
No = N</td><td></td><td></td></tr>
<tr><td colspan="5"><u>Including, but not limited to, any information related to:</u>
• Self-management strategies for low back pain that patients can do on their own without a healthcare provider, excluding general exercise classes and sports, such as heat and cold applications, specific exercises/pain-relieving exercises for low back pain (e.g., exercises prescribed specifically to alleviate low back pain symptoms), stretches prescribed specifically for low back pain (e.g., knees to chest, pelvic tilts, cat-cow), or using correct postures.
• How to perform these strategies
• How these treatments are thought to be helpful for low back pain (i.e., mechanism of action)
• The benefits and/or harms of these treatments
• Information about lifestyle changes (e.g., eating heathier, reduce alcohol and smoking consumption, sleeping better)</td></tr>
</table>

*Summary of supporting information from Lim et al. 2019 and questionnaire response data: Interview data shows that patients with low back pain want information on available self-management treatment options (i.e., management strategies that patients can do on their own without a registered health professional or activities that would fall under the general exercise or sports category outlined above) like heat, cold, lifestyle changes, specific exercises to strengthen or protect the back, and staying active. Questionnaire data shows that patients lacked knowledge about appropriate self-management treatment options for low back pain.				
#15	Does the material contain any information about the role of surgery as a treatment option for low back pain?	Yes = Y, No = N		
Including, but not limited to, any information related to: • The role of surgery as a treatment option for low back pain, such as for what low back pain diagnoses surgery is recommended and not recommended *Summary of supporting information from back beliefs questionnaires: The questionnaire response data shows that people are uncertain about the role of surgery as a treatment for low back pain (e.g., when surgery is a viable option for low back pain)				
#16	Does the material contain any information about the management of low back pain flare-ups and/or recurrence?	Yes = Y, No = N		
Including, but not limited to, any information related to: • How to cope with or manage an acute flare. Note: recommendations for the management of low back pain flares may be similar to the management strategies recommended for one's first low back pain episode (i.e., the pharmacological, provider-based non-pharmacological, general exercise classes or sports, and self-management strategies outlined in items #11-14). Though the management strategies are the same, for this item there should be some specific reference to these management strategies in terms of them also being beneficial for managing future low back pain flares. *Summary of supporting information from Lim et al. 2019 and questionnaire response data: Both the interview and questionnaire response data shows that patients want information about or are uncertain about how to cope with or manage a flare up of low back pain.				
#17	Does the material contain any information to promote staying active and/or not resting?	Yes = Y, No = N		

<table>
<tr><td colspan="5">Including, but not limited to, any information related to:
• How you should stay active when you have low back pain
• Why you should stay active when you have low back pain (e.g., staying active can strengthen your back)
• Why you should avoid bed rest when you have low back pain (e.g., the longer one rests in bed can make it harder to get back to normal activities, can cause low back pain to get worse and last longer, or lead to other health problems)

Key definitions:
• “Staying active” in this context refers to continuing on with one’s normal daily or work activities. By normal daily activities we are referring to activities of daily living (ADLs) or instrumental activities of daily living (IADLs) (Katz 1983, Journal of the American Geriatrics Society 31(12), 721-727). ADLs include basic tasks such as dressing, feeding, grooming, and bathing oneself. IADLs include more complex activities such as transportation, shopping, and housecleaning.

*Summary of supporting information from questionnaire response data: The questionnaire response data shows that people still disagree or are uncertain that you should stay active with low back pain and/or agree or are uncertain that you should rest in bed with low back pain.</td></tr>
<tr><td colspan="5">Activities of daily living</td></tr>
<tr><td>#18</td><td>Does the material contain any information about functional tasks in relation to low back pain?</td><td>Yes = Y,
No = N</td><td></td><td></td></tr>
<tr><td colspan="5">Including, but not limited to, any information related to:
• Functional tasks such as lifting, carrying, and bending
• The relationship between functional tasks and low back pain symptoms

*Summary of supporting information from questionnaire response data: The literature using these questionnaires shows that people are uncertain about the relationship between functional tasks such as lifting, carrying, and bending and low back pain symptoms</td></tr>
<tr><td>#19</td><td>Does the material contain any information about postures in relation to low back pain?</td><td>Yes = Y,
No = N</td><td></td><td></td></tr>
<tr><td colspan="5">Including, but not limited to, any information related to:
• Postures such as sitting, standing, and positioning
• The relationship between postures and low back pain symptoms</td></tr>
</table>

*Summary of supporting information from questionnaire response data: The literature using these questionnaires shows that people are uncertain about the relationship between functional tasks such as lifting, carrying, and bending and low back pain symptoms				
Pain neuroscience education				
#20	Does the material contain any information about the relationship between pain and injury?	Yes = Y, No = N		
Including, but not limited to, any information related to: • How the presence of pain (hurt) does not necessarily indicate a presence of serious injury (harm) • The role of pain as a 'warning signal' and that pain does not mean there is damage to the body (e.g., pain just means that something in your body might not be quite right and is your body's way of letting you know this, or that pain is there to tell the body that it might be a good idea to avoid something that could be dangerous, but does not necessarily mean it is dangerous) *Summary of supporting information from back beliefs questionnaires: The questionnaire response data shows that people have misconceptions about the relationship between pain and injury, for example that hurt equals harm (i.e., that pain in the back means there is something seriously or dangerously wrong with the back or that the back is injured or damaged).				
#21	Does the material contain any information about the safety of physical activity and/or exercise and/or sport?	Yes = Y, No = N		
Including, but not limited to, any information related to: • How movement (i.e., physical activity, exercise, or sport) is safe for the back and/or thought to help improve low back pain symptoms • How movement (i.e., physical activity, exercise, or sport) should not cause damage to the back Key definitions: • Physical activity, defined as "any bodily movement produced by skeletal muscles that results in energy expenditure" (Caspersen et al. 1985. *Public health reports, 100*(2), 126) • Exercise, defined as "a series of specific movements with the aim of training or developing the body by a routine practice or as physical training to promote good physical health" (Abenhaim et al. 2000. *Spine, 25* (4S), 1S-33S) • Sport, defined as "a subset of exercise that can be undertaken individually or as a part of a team. Participants adhere to a common set of rules or expectations, and a defined goal exists" (Khan et al. 2012. *The Lancet, 380* (9836), 59-64) *Summary of supporting information from Lim et al. 2019 and questionnaire response data: The questionnaire response data shows that patients think				

they might injure or damage their back if they perform certain movements or activities and that patients avoid movement for fear of making their pain or other symptoms worse. Interview data supports these findings, with direct quotations from patients highlighting their fear-avoidance beliefs.

Appendix 5.1. Protocol for Chapter 5

This protocol was registered on Open Science Framework. Bradley Furlong, Holly Etchegary, Kris Aubrey-Bassler, Mona Frey, Simon Davidson, Giovanni Ferreira, Amanda Hall (2024). A protocol for assessing patient education materials about low back pain for their understandability, actionability, quality, readability, accuracy, and relevance of content to patients' needs. DOI 10.17605/OSF.IO/62GKT

Introduction

Clinical practice guidelines for low back pain (LBP) nearly universally recommend education as a first-line treatment option [1,2], but patients still have difficulty accessing clear and consistent information about LBP in practice [3,4]. We recently conducted a systematic review that found patient education materials for LBP (PEMs) were more effective than usual care for improving various clinical (e.g., pain, disability), process (e.g., knowledge, pain self-efficacy), and health system (e.g., imaging, days off work) outcomes for patients with acute and chronic LBP [5]. Therefore, PEMs are a potentially effective, as well as quick and low-cost option, to support the transfer of accurate knowledge about LBP diagnosis, prognosis, and treatment in practice. However, details regarding how these PEMs were developed or evaluated were not reported in most studies, so it is unclear if their content is accurate or relevant to patients' needs, nor if it is written or presented in a way that patients can understand. To determine what are the best available PEMs that should be provided to patients in practice and if they can be improved, we will assess PEMs used in the literature in terms of their content (i.e., do they contain accurate information about LBP that is relevant to patients' needs) and readiness for use in practice (i.e., is the information understandable, actionable, readable, and of high-quality) using evidence-based and validated tools.

Methods

Data sources

PEMs can be defined as an intervention where any information about non-specific LBP or sciatica (e.g., diagnosis, prognosis, causes, self-management or other treatment advice) is provided using an evidence-based supplement (e.g., structured pamphlets, booklets, links to online resources, audio files, videos, apps, or workbooks) intended for use by patients with LBP. There are many documents that could meet this definition and we have narrowed our inclusion to only those PEMs found in published synthesized literature including those that (i) are recommended in clinical practice guidelines and (ii) have been evaluated for effectiveness on clinical, process or health system outcomes. In addition, as an overall aim of this work is to reduce unnecessary LBP imaging, we will supplement this search with a hand search of PEMs pertaining to LBP imaging produced by Choosing Wisely, as it is an internationally recognized body for producing recommendations to reduce unnecessary tests and treatments [6].

To find clinical practice guidelines for LBP we will refer to the two most recent overviews of clinical practice guidelines for LBP by Oliveira et al. [1] and Zaina et al. [2]. To find PEMs that have been evaluated for effectiveness on clinical, process, or health system outcomes, we will search the literature to find systematic reviews investigating PEMs and conduct a hand search of the studies included in these reviews. To find relevant systematic reviews, we will replicate the search strategy from Furlong et al. [5] to search MEDLINE, EMBASE, CINAHL, PsycINFO, and SPORTDiscus from inception to present. We will screen records retrieved from this search using Covidence systematic review software [7].

Inclusion criteria

The overall goal of this study is to find PEMs that can be provided to patients in primary care. It is likely that PEMs recommended for use by clinical practice guidelines and Choosing Wisely are feasible for use in practice, but systematic reviews of educational interventions for LBP vary greatly and the provision of PEMs is often not the primary focus of these reviews [8]. Therefore, we will include systematic reviews that focus primarily on the provision of PEMs and, more specifically, PEMs that can be provided feasibly in a primary care setting. We will also include systematic reviews investigating individual patient education (i.e., education provided during an individual health appointment) as this often involves the provision of PEMs that are feasible for use in primary care (e.g., [9–11]). We will exclude systematic reviews where the PEMs are (i) provided in a group-based setting (e.g., back schools) as we believe this does not adequately reflect education provided in a primary care-based health appointment; (ii) are provided as part of multidisciplinary interventions, as PEMs are often not the primary focus of these studies; (iii) provided over multiple sessions, as it is often not feasible to provide multi-session interventions in primary care settings; and (iv) are based on specific types of education, such as pain neuroscience education, because patients with LBP have various health information needs outside of these specific types of education [4]. Finally, though self-management interventions are inconsistently and broadly defined [12], we will include systematic reviews of self-management strategies for LBP so long as they meet the above criteria.

After obtaining PEMs from these sources, we will screen them according to our inclusion criteria outlined in Table 1 to identify those that are most feasible for use in

primary care. We will develop a PRISMA-style flow chart (Figure 1) to detail how and why PEMs were included or excluded during screening. We will contact study authors and guideline producers to request PEMs where necessary.

Table 1. Inclusion and exclusion criteria for PEMs

Inclusion criteria	**Exclusion criteria**
Developed from year 2000 onward	Developed before the year 2000
Written in English	Written in non-English languages
User-friendly in family practice setting (e.g., booklets/pamphlets or scannable codes to direct patients towards a mobile application)	Not user-friendly in a family practice setting (e.g., textbooks)
Freely accessible to the public	Not freely accessible to the public (e.g., require academic subscriptions, sign-up fees, etc.)
Most up to date version of the PEM	If there is more than one version of the same PEM, we will exclude all other versions that are not the most up to date version
PEMs that are not specific to one educational topic about LBP	PEMs specific to one educational topic about LBP, such as PEMs focused solely on pain neuroscience education
Non-interactive materials (i.e., where all the information from the material can be accessed by all users)	Interactive materials (i.e., question and response-based materials that generate information tailored to an individual's responses)

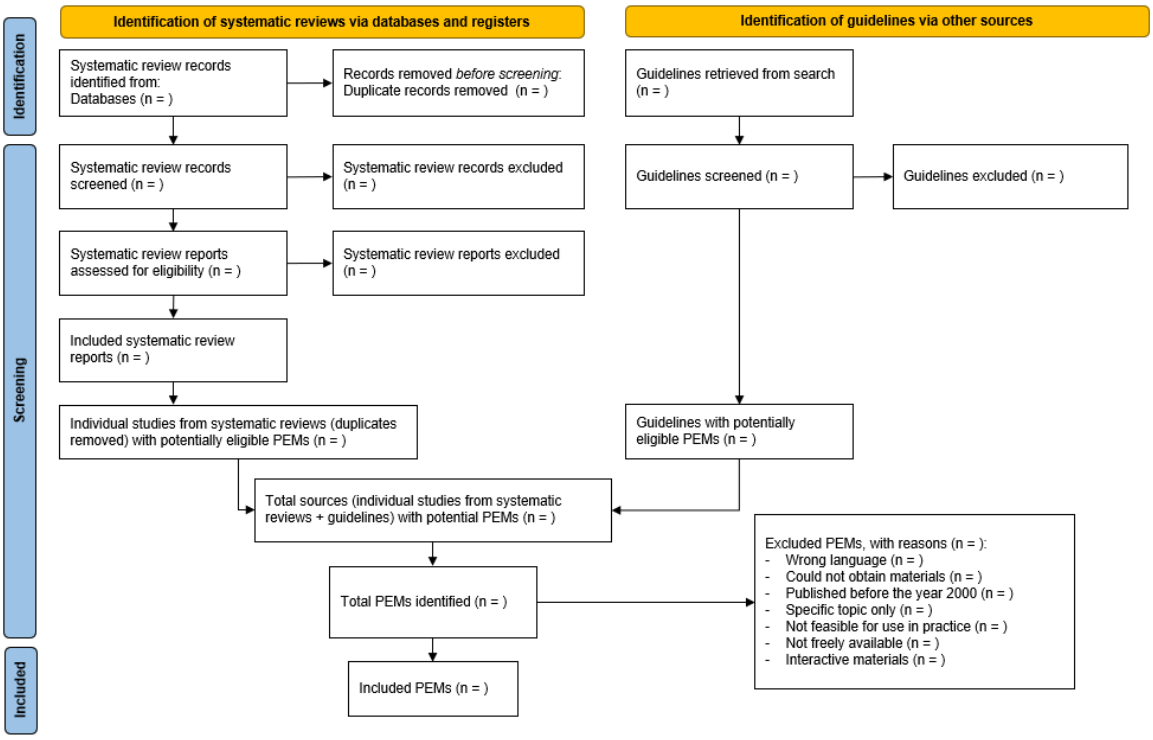


Figure 1. PRISMA-style flow chart of the identification of PEMs and assessment of eligibility

Outcomes

We will assess all included PEMs with the Patient Information and Education needs checklist for Low Back Pain (PIE-LBP) to determine the relevance of their content to patient information needs and patient education needs about LBP (currently under development by our research team [13]), the Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P) and Audiovisual Materials (PEMAT-A/V) [14] to determine their understandability and actionability, the DISCERN tool [15] to determine their quality, and the Flesh Reading Ease (FRE) and Flesch-Kincaid Grade-Level (FKGL) algorithms to determine their readability. We will assess information accuracy using methods outlined in Ferreira et al. [16].

Understandability and Actionability

The PEMAT is an instrument developed in 2014 that can be used to assess if PEMs are understandable (i.e., can patients process and describe the information) and actionable (i.e., can patients carry out some action based on the information) for people of different backgrounds or health literacy levels [14]. English [14] and Japanese [17] versions are available, and both are reliable and valid [14,17,18]. It has been used extensively across the literature including in studies assessing PEMs for laryngectomy [19], breast cancer risk assessment [20], hypertension [21], and Zenker's Diverticulum [22] with moderate or higher inter-rater reliability. There are two versions of the PEMAT, one intended for use on printable (PEMAT-P) materials, and the other for audiovisual (PEMAT-A/V) materials [14]. The number of items vary between each tool, but the understandability scales generally involve questions about content, word choice and style, use of numbers, organization, layout and design, and use of visual aids, while the actionability scales generally include items about whether the PEMs described what actions the user can take and how to carry out those actions. The PEMAT produces a score for understandability and another for actionability, which are to be interpreted separately. Response options for items are binary (i.e., 1 for “Agree” and 0 for “Disagree”), and the overall scores are calculated as the total points accumulated divided by the total possible points, multiplied by 100% to achieve a score between 0% and 100%. PEMs scoring above 70% on the understandability or actionability scales are determined to be understandable or actionable, respectively [14].

Information Quality

The DISCERN tool, developed in 1999 [15], is a reliable and valid tool used to assess the quality of text-based information regarding treatment choices [15,23,24]. It is intended for use by anyone (i.e., information consumers or providers), who is interested in evaluating the quality of written health information. It consists of 16 items, each scored on a 5-point Likert-type scale ranging from 1 to 5 (1 = "No", 3 = "Partially", 5 = "Yes"), where higher scores reflect greater quality of health information. The items are subdivided into three sections. Section 1 (items 1 to 8) includes questions about the PEM's aims, evidence sources, and sources of potential bias, and is intended to assess the reliability or trustworthiness of the information. Section 2 (items 9 to 15) includes questions about treatment choices (e.g., what treatment options are available, how do they work, and what are their benefits and risks) and is intended to assess the quality of the information. Section 3 (item 16) consists of a single item, which asks the user for their overall interpretation of information quality based on their responses to items 1 to 15. The DISCERN Handbook [25] provides little information on how to interpret its scores, so we will use the following interpretation commonly used in previous studies [26–30]: very poor (< 27 points), poor (27 to 38 points), fair (39 to 50 points), good (51 to 62 points), and excellent (> 62 points) quality.

Readability

The Flesh Reading Ease (FRE) and Flesch-Kincaid Grade-Level (FKGL) are two algorithms for measuring readability. They both use the same variables (i.e., total words, syllables, and sentences) but apply different weightings to them. The FRE is scored on a

0-100 scale, where higher scores represent easier reading, and the FKGL provides a score that corresponds to the grade school levels in the United States, where a lower grade level represents easier reading. Readability scores will be based on plain text only, excluding any non-related text (e.g., acknowledgements, references, developer and publisher information, links) and non-textual elements (e.g., images, figures, videos). The American Medical Association recommends that health education materials should be written at a sixth grade level or lower [31], which corresponds to a score of 80 or greater on the FRE and 6 or lower on the FKGL.

Relevance of content to patients' needs

The PIE-LBP is currently under development by our research team [13] and will comprise a comprehensive list of patients' information and education needs about LBP identified from the literature. Patient information needs are defined as one's subjective realization that they lack knowledge to achieve a goal [32] and patient education needs are defined as an objective measure of knowledge deficit [33]. In other words, the checklist can be used to determine if PEMs contain information relevant to what patients have said they want to know more about (i.e., information needs) and what clinicians and researchers have identified that patients should know more about (i.e., education needs). Each item on the checklist will correspond to a distinct information and/or education need with binary response options of "Yes" and "No." A response of "Yes" indicates that the material contains information related to the corresponding need and an answer of "No" indicates that the material does not contain any information related to the corresponding need. In this study, for all items with an answer of "Yes," the rater will also be asked to

extract, ad verbatim, any information from the material that is relevant to the corresponding need. We will use the checklist to identify and gather information used in PEMs that are relevant to patients' information and education needs and provide a qualitative synthesis of this information.

Information accuracy

We will assess the accuracy of information about LBP treatments using the method developed by Ferreira et al. [16]. We define information accuracy as the number and proportion of accurate and clear recommendations for treatments provided in PEMs that are in concordance with clinical practice guideline recommendations. Using guidelines by the National Institute for Health and Care Excellence [34] and American College of Physicians [35], we will code what treatments for LBP (i) are endorsed by at least one guideline, (ii) are dismissed by at least one guideline, and (iii) have conflicting recommendations between the two guidelines. To define what treatments described in PEMs are in concordance with guideline recommendations, we will use the following codes:

- Appropriate endorsement: the PEM recommends to use a treatment that is endorsed by at least one guideline.
- Appropriate dismissal: the PEM recommends to avoid a treatment that is dismissed by at least one guideline.
- Inappropriate endorsement: the PEM recommends to use a treatment that is dismissed by at least one guideline.

- Inappropriate dismissal: the PEM recommends to avoid a treatment that is endorsed by at least one guideline.
- Endorsed: the PEM recommends to use a treatment that was not mentioned in either guideline.
- Dismissed: the PEM recommends to avoid a treatment that was not mentioned in either guideline.

Accurate recommendations for treatments will be coded as those that have been appropriately endorsed, appropriately dismissed, or dismissed by the PEM, and inaccurate recommendations for treatments will be coded as those that have been inappropriately endorsed, inappropriately dismissed, or endorsed by the PEM. Unclear recommendations for treatments will be coded as recommendations that vaguely describe a treatment. For example, a recommendation to use "spinal injections" would be considered unclear since neither the injection site (e.g., epidural vs. facet joint) nor the medication being injected (e.g., corticosteroids) is specified.

Assessment procedure and data synthesis

We will extract information on the characteristics of each PEM including its developer, country, purpose, LBP type, format, and length, where applicable. Included PEMs will be rated using each of the assessment tools described above by one of four authors (BF, MF, SD, GF). Raters will meet regularly to discuss and resolve any questions that are encountered during the rating process, involving a senior author (AH) if necessary to come to consensus. All data relevant to the PIE-LBP, PEMAT, DISCERN,

and information accuracy assessments will be entered into Microsoft Excel [36]. Data for the FRE and FKGL assessments will be entered into Microsoft Word [37].

Data synthesis

Statistics for the PIE-LBP, PEMAT, DISCERN tool, and information accuracy assessments will be calculated using Microsoft Excel [36]. FRE and FKGL scores will be calculated using the readability statistics in Microsoft Word [37]. Individual assessment tool scores will be provided for each included PEM (Table 2). PEMAT, DISCERN, and FRE/FKGL scores will be interpreted using their predefined cut-off scores described above. Information accuracy data will be presented as the number and proportion of clear accurate recommendations to (i) use a treatment and (ii) to avoid a treatment. Using the PIE-LBP, we will also conduct a synthesis of the qualitative data extracted from PEMs to describe what types of information related to patients' information and education needs were used. We would like to rank the PEMs to determine what are the best PEMs to provide in practice but we are currently unaware of a method to rank PEMs based on the scores of multiple assessment tools. Should we identify a method for this before finalizing the study we will include these recommendations in our final manuscript.

Table 2. Patient education material characteristics and assessment tool scores

PEM characteristics	PEM #1	PEM #2	PEM #*n*
Developers			
Country			
Purpose			
Low back pain type			

Format			
Length (pages)			
Assessment tools (score range)	**PEM #1**	**PEM #2**	**PEM #*n***
PIE-LBP[a] (0-100%)			
PEMAT-P Understandability[b] (0-100%)			
PEMAT-P Actionability[b] (0-100%)			
PEMAT-A/V Understandability[b] (0-100%)			
PEMAT-A/V Actionability[b] (0-100%)			
DISCERN[c] (15-75)			
FRE[d] (0-100)			
FKGL[e] (0-18)			
Clear accurate recommendations to use a treatment[f] (0-100%)			
Clear accurate recommendations to avoid a treatment[f] (0-100%)			

Abbreviations: PEM = patient education material; PIE-LBP = Patient Information and Education need checklist for Low Back Pain; PEMAT-P = Patient Education Materials Assessment Tool for Printable Materials; PEMAT-A/V = Patient Education Materials Assessment Tool for Audiovisual Materials; FRE = Flesh Reading Ease ; FKGL = Flesch-Kincaid Grade-Level

[a]The PIE-LBP score describes the proportion of information and education needs that the PEM contained potentially relevant information about. Note that it does not express the accuracy or sufficiency of this information to satisfy patients' needs

[b]PEMAT scores of 70% or greater on the understandability and/or actionability subscales indicate an understandable and/or actionable PEM, respectively

[c]DISCERN scores will be interpreted as follows: very poor (< 27 points), poor (27 to 38 points), fair (39 to 50 points), good (51 to 62 points), and excellent (> 62 points) quality health information

[d]FRE scores of 80 or greater are considered sufficiently readable (i.e., at a sixth-grade level or lower)

[e]FKGL scores of 6 or lower are considered sufficiently readable (i.e., at a sixth-grade level or lower)

[f]Information accuracy will be presented as the number and proportion of clear accurate recommendations to (i) use a treatment and (ii) to avoid a treatment.

Ethics

Ethical approval is not required for this study.

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Appendix 5.2. Inclusion and exclusion criteria for patient education materials for low back pain

Inclusion criteria	**Exclusion criteria**
Developed from year 2000 onward	Developed before the year 2000
Written in English	Written in non-English languages
User-friendly in family practice setting (e.g., booklets/pamphlets or scannable codes to direct patients towards a mobile application)	Not user-friendly in a family practice setting (e.g., textbooks)
Freely accessible to the public	Not freely accessible to the public (e.g., require academic subscriptions, sign-up fees, etc.)
Most up to date version of the PEM	If there is more than one version of the same PEM, we will exclude all other versions that are not the most up to date version
PEMs that are not specific to one educational topic about LBP	PEMs specific to one educational topic about LBP, such as PEMs focused solely on pain neuroscience education
Non-interactive materials (i.e., where all the information from the material can be accessed by all users)	Interactive materials (i.e., question and response-based materials that generate information tailored to an individual's responses)

Appendix 5.3. Codebooks for assessment tools

Patient Education Material Assessment Tool (PEMAT) codebook

General rules:

If a material has two distinct printable and audiovisual components, we will assess the printable component with the PEMAT-P and the audiovisual component with the PEMAT-A/V. For example, the MyBackPain website has a page dedicated to video content only with no printable components (https://mybackpain.org.au/library). We would therefore consider this page to be the audiovisual component of this material, as described in the user guide, and assess it with the PEMAT-A/V. The website also has separate pages comprising text-based information only with no audiovisual components (e.g., https://mybackpain.org.au/treatments/low-back-pain-treatments). We would therefore consider these pages to be the printable component of this material, as described in the user guide, and assess them with the PEMAT-P.

Item-specific rules:

Item #4: Medical terms are used only to familiarize audience with the terms. When used, medical terms are defined

We will require a definition of all medical terms related to low back pain, including terms like X-ray, MRI, and CT. For example, in the Choosing Wisely New Zealand booklet, they state "Your health professional might recommend an X-ray, MRI or CT scan if the test is likely to help find out what is causing your pain and how best to treat it." Though they infer that these are 'tests' that 'might help find out what is causing your pain,' they

do not explain what these tests are, so this booklet would receive a "disagree" rating for this item. For an agree rating, the booklet would have had to state, for example, "Your health professional might recommend a X-ray, MRI or CT, *which are scans that can take an image of the bones or other structures around your spine* to identify what is causing your pain."

Item #15: The material uses visual aids whenever they could make content more easily understood (e.g., illustration of healthy portion size)

In the validity study of the PEMAT by Vishnevetsky et al. (2018), multiple raters found this item to be confusing, especially the *"whenever they could"* component of the item, which they felt was too subjective a criteria. Raters also commented on how it is unclear from the user guide if they should rate the item "Agree" or "Disagree" if no visual aids were included because they would not be helpful. We experienced the same confusion while rating this item. For these reasons, we will AGREE with this item if the material uses *at least one* visual aid *that makes the content more easily understood* and DISAGREE with this item if either (i) the material uses NO visual aids or (ii) it uses visual aid(s), but none of the visual aid(s) make the content more easily understood.

<u>Examples of visual aids that could make the content more easily understood are:</u>

i. an illustration of exercises for low back pain to accompany a description of these exercises in the text
ii. a diagram of the bones, joints, ligaments, and/or nerves in the spine to accompany a description of these structures in the text

iii. a picture of a person riding a bicycle to accompany a description of staying active with low back pain in the text

Examples of visual aids that would NOT make the content more easily understood are:

i. an image of a person riding a bike or a person folding laundry where the text only describes how to control one's pain with pain medicines

ii. an image of a person bending over and holding their back

We would consider each of these two examples to be "generic pictures" (as described in the user guide for item 16) that are unlikely to help improve the understanding of the text

Item 20: The material clearly identifies at least one action the user can take (P and A/V)

We provide additional examples below of what we would consider to be statements with clearly identifiable actions that are more specific to the context of the materials we are rating:

Additional examples with clearly identifiable actions the user can take:

- *"Talk to your doctor if you have back pain with any of the following symptoms..."* The clearly identifiable action is to "talk to your doctor"
- *"You should see your doctor right away if..."* The clearly identifiable action is to "You should see your doctor right away"

- *"using heat and simple medications (eg, ibuprofen such as Nurofen or a diclofenac such as Voltaren) for pain relief can be helpful."* The clearly identifiable actions are to use heat or any of the listed medications

Additional examples *without* clearly identifiable actions the user can take:

- *"Staying active can be helpful."* Similar to the "physical activity" example in the user guide, we would not consider this to be a clearly identifiable action because "staying active" is a broad term that can refer to many different forms of activity. If the material instead stated "staying active, such as by going for a walk three times a week and keeping up with your normal daily activities, can be helpful," we would consider going for a walk and keeping up with your normal daily activities to be clearly identifiable actions the user can take.
- *"Resting in bed for long periods is generally discouraged."* In this example they are recommending the avoidance of an action. We will not consider statements like this in our ratings.
- *"Most people can safely return to work even if the pain has not yet gone away."* Though the material is referring to 'returning to work,' it is unclear whether this is an 'action the user can take' because they are making a more general statement and it is unclear if the user would fall into the category of "most people." If the material instead stated *"you can return to work even if the pain has not yet gone away"* the clearly identifiable action for the user to take would be to return to work.

- Though materials with prescription pads (also known as decision support tools or personalized care plans that are meant to be completed by the physician and patient together) would likely include clearly identifiable actions for the patient once they are filled in, we will not make any assumptions like this for the rating of this item. That is, we will only consider what information is available in the original version of the patient education material. For example, the "Best practice care for people with acute low back pain" booklet by the ACI Musculoskeletal Network, includes 3 pages (pages 6-8) of a personalized care plan that is to be filled in together by the patient and a clinician. We would not consider any of the information in this incomplete personalized care plan to contain any clearly identifiable actions.

References:

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DISCERN tool codebook

General rules:

- When rating items from Section 2 on the DISCERN instrument (i.e., items #9-15 about treatment options) we will use the list of treatments in the table provided

below. In order to be considered in the rating of these items, the material must explicitly refer to one of the listed treatments. We will not make assumptions or inferences using information contained in the material. For example, if the material recommends to "avoid bed rest," we will not infer that this is equivalent to a recommendation to 'stay active.' The material must explicitly recommend 'staying active' as a treatment option to be considered. Conversely, where the material describes the risks of 'bed rest,' we will not infer that these are equivalent to the risks of 'not staying active.'

    - In scenarios like this where a treatment could be inferred given the material's description, but it does not explicitly describe one of the treatments listed below, the rater will make note of the material and the inferred treatment for the review team (BF, MF, AH) to discuss and come to consensus on how to approach scenario for the DISCERN ratings.

- For rating the section 2 DISCERN items (i.e., items #9-15), we consider treatments to be only those options that are recommended for patients to use in the education material. We will not consider information on "not recommended treatments" (i.e., treatments that the material recommends to avoid and treatments that the material identifies as having uncertain effectiveness) for this assessment. For example, the So Your Back Hurts booklet includes a section titled "Treatments That Don't Work" where they list bed rest and traction as treatments that don't work and are not recommended. In addition, it includes a section titled "Treatments That We Aren't Sure About" that lists many treatments that 'have insufficient research to determine if they are helpful for low back pain.' We would

therefore not consider any information about the treatments listed in either of these sections in our DISCERN ratings for this material. We will, however, keep note of which booklets include information on not recommended treatments.

- Any potential treatments that are listed in a patient education material, but are not included in the list of treatments below, will be noted and discussed by two authors (BF, MF) to determine the eligibility of the treatment for inclusion in our codebook list. A third author will be involved to come to consensus if necessary (AH).
- Videos will be excluded from the DISCERN ratings since this tool is validated to assess text-based information.
- If the material recommends "exercise" as a treatment but does not specify any type of exercise, we will still include "exercise" as a treatment to be considered in the DISCERN ratings. If specific types of exercises are recommended, but it is clear that these are recommended as part of the same overarching discussion of "exercise" (e.g., in the Choosing Wisely Canada booklet where they explicitly refer to lifting light weights, yoga, walking, using a treadmill and water aerobics as exercises), they will be considered to fall under the category of "exercise" and therefore only one treatment (i.e., exercise) will be considered in the DISCERN ratings. However, if exercises such as yoga, Pilates, walking, etc., are mentioned as treatments *in addition to* or *separate* from the discussion of "exercise" then they will be considered as separate treatments to consider in the DISCERN ratings. We will also consider 'staying active' to fall under the exercise category if

it is clear that it is being recommended as part of the same overarching discussion of "exercise."

- If the material recommends an overarching/broad category of treatments (e.g., 'pain medications,' which includes multiple types of treatment with different mechanisms of action and varying effectiveness) without mentioning at least one specific type of said treatment (e.g., paracetamol, opioids) we will do the following:
    - In a material where this broad treatment category is the only treatment mentioned, we will automatically rate the item with a "1," regardless of what information is provided in the material about this broad treatment category.
    - In a material where more than just the broad treatment category is mentioned, we will consider the broad treatment to have an unclear or incomplete description, regardless of what information is provided in the material. For example, if we have a material that recommends staying active and exercise and we are rating item #9 "Does it describe how each treatment works." Let's say the material provides sufficient information on how staying active and exercise works – enough for the rater to give the overall item a rating of "5." If the same material also included discussion of 'pain medications' but did not specify what types of pain medications they are referring to, we would rate the overall score for this item with a lower score, perhaps with a score of 3 or 4, since we would now consider

the material to include a sufficient description of how only some (i.e., 2 of 3) of the mentioned treatments work.

Question-specific rules:

- **Question #1:** "Are the aims clear?" we will go by the following statement provided in the 'Rating this question' pop-out on the website: "Examine the opening paragraphs or home page for a description of the content, scope and target audience of the publication. Although the publication's title or URL/address may be descriptive, the aims should be clearly outlined in the text at the beginning if the publication is to get a good rating." In other words, we will not consider titles/headings/subheadings/subtitles for the rating of this question. If the material does not have any statement of aims provided in its text (i.e., information about an aim provided outside of titles/headings/subheadings/subtitles) it would be rated with a score of '1.' See also the example for a rating of '1' in the DISCERN handbook.
- **Question #2:** if question #1 is rated with a '1', automatically rate this question with a '1' as well.
    - When question #1 is NOT rated with a '1', we will rate this question based only on information that is provided in the material that is relevant to the stated aim. If the material contains additional information that is not relevant to the stated aim, this information will not be considered. As an example, let's say we have a material with an aim of describing why bed

rest is not good for LBP. If this material provides information about why bed rest is not recommended for LBP and additional information about other LBP treatments and diagnostic tests, we would still only consider whether the information about bed rest is sufficient to achieve this aim. We would not consider any information about LBP treatments and diagnostic tests while rating this question for this material because it is not relevant to the stated aim.

- **Question #3:** since clinical practice guideline recommendations for treatments may differ for acute and chronic LBP, if the material does not specify whether its treatment recommendations are for either acute or chronic LBP (or both), the material cannot receive a rating of '5' for this item (i.e., it can only receive, at maximum, a partial rating of '4').
- **Question #5:** If a date of the publication is given but no sources (or no dates for sources), this item will receive a rating of 3 since the handbook states it should receive a partial rating in this scenario.
- **Question #7:** if we are unable to find one or more of the referenced or linked sources of support and information (e.g., broken link to website) from a material, the material *cannot* receive a rating of '5' for this question (i.e., it can only receive a maximum rating of '4')
- **Question #8:** in the handbook for this question they discuss 'uncertainty' around the lack of evidence of *treatments* (i.e., if evidence is contradictory or uncertain as

to who is likely to benefit), therefore we will only consider discussion of the uncertainty around *treatments listed in our codebook* for this question.

- **Question #12:** we will consider statements such as "back pain gets better on its own" or "people usually recover in a few weeks, even without medical intervention" to be relevant for this item since they are clearly referring to what happens to back pain if no treatment were used. We will not consider statements around 'avoiding activity' or 'resting in bed' to indicate no treatment.
- **Question #15:** if the material provides information on "When to contact my healthcare provider" (e.g., in the presence of listed red flags), but no other information that might contribute to shared decision making, we will give this question a partial rating of '2'
    - We would not generally accept additional information from references or external links provided by the material. However, a unique case is in the Choose Physio for Acute Low Back Pain material where they state *"Your physiotherapist might use a short questionnaire to help determine whether you should expect your recovery to be fast or slow. Some tools such as the STarT Back Tool and MyBack are available online for you to fill out yourself. You can use this information to help decide on a management plan that is right for you. The results of these questionnaires are good things to discuss with your physiotherapist."* In cases like this we will give this question a rating of '3' because, although the material links tools which are outside of the material itself, discussion of these tools and how

they might benefit shared decision making is provided within the content of the material itself. Alternatively,

- If the material had simply linked these tools as 'additional resources,' without elaborating within the text how these tools might aid discussion with a healthcare provider, we would rate this question with a '1'
- If the tools were provided directly within the material itself, then this question would receive a rating of '5'

List of treatments that will be considered in the DISCERN ratings
CONSERVATIVE TREATMENTS*
Pharmacological treatments: • Anticonvulsants: including gabapentinoids, barbiturates, hydantoins, iminostilbene, ozazolidinedione, Succinimide, Aliphatic carboxylic acids, Miscellaneous. • Antidepressants: including selective noradrenaline reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs) selective serotonin reuptake inhibitors (SSRIs), noradrenaline-dopamine reuptake inhibitors (NDRIs), serotonin antagonist and reuptake inhibitors (SARIs), tetracyclic antidepressants, monoamine oxidase inhibitors (MAOIs), reversible inhibitors of monoamine oxidase A (RIMAs), melatonergic antidepressants • Bee venom injection • Glucocorticoids • Monoclonal antibody injections (administered subcutaneously or intravenously) • Muscle relaxants: including antispastic, non-benzodiazepine antispasmodic, benzodiazepines, and miscellaneous muscle relaxants • Non-steroidal anti-inflammatory drugs (NSAIDs): including selective cyclooxygenase-2 inhibitors or non-selective NSAIDs • Opioids • Opioids + analgesics

- Topical rubefacient
- Paracetamol/acetaminophen
- Bisphosphonates
- Complementary medicines
- TRPV1 agonists
- Anaesthetics
- Antibiotics/antimicrobials

Non-pharmacological treatments:

- Acupressure: application of mechanical pressure to specified acupuncture points
- Acupuncture: insertion of fine needles into the skin at specified points
- Behavioural/Education: information about the condition and/or beliefs surrounding a person's condition plus or minus support for changing behaviours
- Biofeedback: real-time feedback to the person relevant to their back
- Diathermy: high frequency electrical current that produces heat in the muscles
- Electroacupuncture: application of electrical current to needles inserted in the skin
- Electromagnetic: application of electromagnetic energy to the back
- Exercise: specific body movements with the aim of increasing fitness, strength, mobility or motor control
- Extracorporeal Shockwave: high frequency, high energy pulsed sound waves delivered to the back tissues
- Heat: application of warmth to the back
- Interferential: application of electrical currents at two different frequencies that interfere with each other
- Laser and light: application of focused light or laser beams to the back
- Massage: manual rubbing or kneading of the back muscles and tissues
- Mobilisation: non-physiological movement of back joints using manual pressure
- Osteopathic: manual therapy according to osteopathic models, usually involving mobilisation, manipulation and/or massage
- Spinal Manipulative Therapy (SMT): high force, low amplitude thrusts to spinal joints delivered by manual pressure
- Taping: adhesive fabric applied to the back
- Transcutaneous Electrical Nerve Stimulation (TENS): application of electrical current to the skin over the back that causes gentle muscle contractions
- Traction: application of external force to stretch the back structures longitudinally
- Transcranial Stimulation: application of magnetic or electrical field to the head to stimulate nerve activity
- Ultrasound: application of low energy sound waves to the back

- Dry cupping
- Foot orthotics
- Infrared
- Orthopedic device
- Yoga
- Tai Chi
- Pilates
- Cold
- Walking
- Water aerobics
- Lifting weights
- Staying active – this can also include recommendations of 'getting back to activities,' 'continuing on with normal activities,' or recommendations to 'be active,' 'get moving,' 'movement'

NON-CONSERVATIVE TREATMENTS*

- Interdisciplinary rehabilitation
- Prolotherapy
- Intradiscal steroid injection
- Fusion surgery
- Facet joint steroid injection
- Artificial disc replacement
- Botulinum toxin injection
- Local injections
- Epidural steroid injection
- Medial branch block (therapeutic)
- Sacroiliac joint steroid injection
- Radiofrequency denervation
- Intradiscal electrothermal therapy
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
- Coblation nucleoplasty
- Spinal cord stimulation
- Intrathecal therapy
- Open discectomy or microdiscectomy
- Laminectomy with or without fusion
- Chemonucleolysis
- Interspinous spacer device

*We obtained a list of conservative treatments from a systematic review being conducted by our research group on the analgesic effects of conservative treatments for low back pain compared with placebo (unpublished data). We obtained the list of non-conservative (i.e., surgical) treatments from Chou et al. (2009). Since our systematic review of conservative treatments included only randomized placebo-controlled trials, we also included a list of additional low

back pain treatments that are not usually compared with placebo controls in effectiveness trials such as yoga, tai chi, and Pilates.

References:

1. Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine. 2009;34: 1066–1077.

Information accuracy codebook

- We will categorize treatment recommendations by acute and chronic low back pain and code each patient education material as being intended for either acute or chronic low back pain to better align with clinical practice guideline recommendations. If the material does not explicitly state whether it was intended for acute or chronic low back pain, we will read the material to determine if there are any indications to suggest the information was intended primarily for acute or chronic low back pain. For example, the Doc Mike Evans video does not explicitly state whether it is intended for acute or chronic low back pain, but it provides specific treatment suggestions for chronic low back pain and not for acute. It also states *"it may be helpful to stop seeing your recurrent back pain as discrete events and more as a chronic vulnerability that you need to create what I call a back resilience plan."* We therefore categorized this material as being for

chronic low back pain, and assessed the concordance of its treatment recommendations with those for chronic low back pain provided in clinical practice guidelines.

    - Of note, the My Back Pain website is the only material that provided separate recommendations for both acute and chronic low back pain for most treatments, so we conducted two separate information accuracy analyses on this material (i.e., one on its treatment recommendations for acute low back pain and another on its treatment recommendations for chronic low back pain). Where there was insufficient evidence to provide separate treatment recommendations for acute and chronic low back pain, they provided an overall recommendation for low back pain of unspecified duration. However, since the available evidence was based on mixed populations of acute and chronic low back pain, we included these recommendations in both the acute and chronic information accuracy analyses. For example, the website recommends McKenzie therapy as a treatment for low back pain of unspecified duration so we considered this to be a recommendation for McKenzie therapy for both acute and chronic LBP.

- If a material mentions a treatment but does not explicitly recommend for or against its use (e.g., it states that there is not enough evidence to recommend for or against a treatment) we will not consider the treatment in our information accuracy assessment. For example, if a material states “there is insufficient evidence to recommend for or against the use of mobilisation” we would consider

mobilisation to have no accompanying recommendation and it would therefore be excluded from the information accuracy analysis.

- For treatments with conflicting recommendations between guidelines (e.g., acupuncture), we will consider any endorsement of these treatments to be inappropriate. We will consider dismissals of these treatments to be appropriate since there is no consensus on whether these are effective treatments that should be recommended for low back pain.
- If a guideline recommended for or against a treatment, but did not specify for what duration (e.g., acute or chronic), we considered that recommendation to apply to both acute and chronic LBP. For example, the NICE guideline recommends against ultrasound for the management of low back pain, but does not specify for what duration. We therefore considered this to be a recommendation against ultrasound for both acute and chronic low back pain.
- Examples of treatment recommendations we considered to be unclear:
    - We considered an endorsement or dismissal of "over-the-counter medications" to be an unclear endorsement or dismissal of paracetamol and NSAIDs, since these are the two typically recommended over-the-counter medications for low back pain.
    - The clinical practice guidelines provided separate recommendations for three classes of antidepressants (i.e., selective serotonin reuptake inhibitors, SSRIs; serotonin-norepinephrine reuptake inhibitors, SNRIs; tricyclics). We therefore considered any endorsement or dismissal of

"antidepressants" to be an unclear endorsement or dismissal of SSRIs, SNRIs, and tricyclics.

- One material made reference to "hands-on treatment" in the context of physiotherapy without explicitly stating what treatments it was referring to. We considered this to be an unclear reference to both spinal manipulative therapy and massage as these are two treatments that are often referred to as 'hands-on treatments' in practice.
- We considered an endorsement or dismissal of 'electrical stimulation' to be an unclear endorsement or dismissal of both PENS and TENS
- We considered an endorsement or dismissal of 'relaxation' to be an unclear endorsement or dismissal of progressive relaxation
- We considered an endorsement or dismissal of "pain medicines" to be an unclear endorsement or dismissal of the following pain medicines: NSAIDs, opioids, paracetamol, systemic steroids, and muscle relaxants.

Appendix 5.4. The number and proportion of patient education materials answering 'Agree' to Patient Education Material Assessment Tool (PEMAT) items

Item	*n* (%) of materials answering 'Agree' *
PEMAT-P[¥] (*n* = 18 materials)	
Understandability	
1. The material makes its purpose completely evident.	3 (16.7)
2. The material does not include information or content that distracts from its purpose.	2 (11.1)
3. The material uses common, everyday language.	18 (100)
4. Medical terms are used only to familiarize audience with the terms. When used, medical terms are defined.	2 (11.1)
5. The material uses the active voice.	17 (94.4)
6. Numbers appearing in the material are clear and easy to understand.	16 (94.1)
7. The material does not expect the user to perform calculations.	18 (100)
8. The material breaks or "chunks" information into short sections.	7 (38.9)
9. The material's sections have informative headers.	17 (94.4)
10. The material presents information in a logical sequence.	15 (83.3)
11. The material provides a summary.	6 (33.3)
12. The material uses visual cues (e.g., arrows, boxes, bullets, bold, larger font, highlighting) to draw attention to key points.	17 (94.4)
15. The material uses visual aids whenever they could make content more easily understood (e.g., illustration of healthy portion size).	11 (61.1)
16. The material's visual aids reinforce rather than distract from the content.	4 (33.3)
17. The material's visual aids have clear titles or captions.	0 (0)
18. The material uses illustrations and photographs that are clear and uncluttered.	9 (75.0)
19. The material uses simple tables with short and clear row and column headings.	2 (100)
Actionability	
20. The material clearly identifies at least one action the user can take.	13 (72.2)
21. The material addresses the user directly when describing actions.	10 (55.6)
22. The material breaks down any action into manageable, explicit steps.	1 (5.6)
23. The material provides a tangible tool (e.g., menu planners, checklists) whenever it could help the user take action.	2 (11.1)
24. The material provides simple instructions or examples of how to perform calculations.	n/a[µ]
25. The material explains how to use the charts, graphs, tables, or diagrams to take actions.	0 (0)
26. The material uses visual aids whenever they could make it easier to act on the instructions.	0 (0)
PEMAT-A/V[¥] (*n* = 3 materials)	

Understandability	
1. The material makes its purpose completely evident.	1 (33.3)
3. The material uses common, everyday language.	3 (100)
4. Medical terms are used only to familiarize audience with the terms. When used, medical terms are defined.	1 (33.3)
5. The material uses the active voice.	3 (100)
8. The material breaks or "chunks" information into short sections.	0 (0)
9. The material's sections have informative headers.	2 (66.7)
10. The material presents information in a logical sequence.	3 (100)
11. The material provides a summary.	2 (66.7)
12. The material uses visual cues (e.g., arrows, boxes, bullets, bold, larger font, highlighting) to draw attention to key points.	3 (100)
13. Text on the screen is easy to read.	2 (66.7)
14. The material allows the user to hear the words clearly (e.g., not too fast, not garbled).	2 (66.7)
18. The material uses illustrations and photographs that are clear and uncluttered.	1 (33.3)
19. The material uses simple tables with short and clear row and column headings.	n/a[µ]
Actionability	
20. The material clearly identifies at least one action the user can take.	2 (66.7)
21. The material addresses the user directly when describing actions.	0 (0)
22. The material breaks down any action into manageable, explicit steps.	0 (0)
25. The material explains how to use the charts, graphs, tables, or diagrams to take actions.	n/a[µ]
*****Due to some items having a 'not applicable' response option, the denominators for certain items varied [¥]Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P), Patient Education Materials Assessment Tool for Audiovisual Materials (PEMAT-A/V) [µ]This item was rated as not applicable for all materials	

Appendix 5.5. The average rating of DISCERN questions across patient education materials

DISCERN question	Rating Mean ± SD
1. Are the aims clear?	1.9 ± 1.3
2. Does it achieve its aims?*	3.9 ± 0.6
3. Is it relevant?	3.9 ± 1.0
4. Is it clear what sources of information were used to compile the publication (other than the author or producer)?	1.6 ± 0.9
5. Is it clear when the information used or reported in the publication was produced?	2.4 ± 1.1
6. Is it balanced and unbiased?	3.0 ± 1.5
7. Does it provide details of additional sources of support and information?	2.4 ± 1.5
8. Does it refer to areas of uncertainty?	1.8 ± 1.6
9. Does it describe how each treatment works?	1.7 ± 1.3
10. Does it describe the benefits of each treatment?	2.3 ± 1.6
11. Does it describe the risks of each treatment?	2.0 ± 1.5
12. Does it describe what would happen if no treatment is used?	1.7 ± 1.5
13. Does it describe how the treatment choices affect overall quality of life?	1.4 ± 0.8
14. Is it clear that there may be more than one possible treatment choice?	3.2 ± 1.0
15. Does it provide support for shared decision-making?	3.2 ± 1.4
16. Based on the answers to all of the above questions, rate the overall quality of the publication as a source of information about treatment choices	2.7 ± 0.8
*This question was only rated if the material stated its aims (i.e., received an answer of 2 or higher on the 1 to 5 scale). Since some materials did not state their aims, the denominator (i.e., the total number of materials the question was rated for) for this question is therefore smaller (n=8) than for all other questions (n=18)	

Appendix 5.6. Qualitative synthesis of information provided in patient education materials that related to patients' information and education needs

PROGNOSIS, CAUSES, AND AETIOLOGY (4 items)

Summary: Most PEMs commented on the generally favourable prognosis of LBP (e.g., symptoms usually improve over a few weeks or do not cause long-term problems) but only about one-third provided any additional information about prognosis. Less than half of included PEMs provided information about LBP flare-ups and/or recurrence, most of which simply stated that they are common or likely. About one-third of included PEMs provided information about causes or aetiology, but this information varied. Some listed various causes or risk factors while others stated that the causes of LBP are not well understood, and some PEMs disagreed on whether lifting is or is not a risk factor for LBP. About half of included PEMs suggested that psychological factors like anxiety and stress can hinder recovery and/or increase pain, but few commented on how addressing these psychological aspects may improve recovery and/or reduce pain.

Item #1: Does the material contain any information about prognosis for low back pain? (n=18/19 PEMs)

Most PEMs provided some basic information about the generally positive prognosis of LBP (e.g., symptoms improve in a few weeks and/or it doesn't usually cause long-term

problems and/or it often gets better on its own without medical intervention). Six materials mentioned caveats to the generally positive prognosis pointing out that it is possible for symptoms to last longer than a few weeks and/or that pain may interfere with the ability to carry out daily activities and/or work. Three materials specifically provided information on prognosis of chronic LBP. Two stated that chronic LBP also has a generally favourable prognosis but may take longer to recover from. One presented a more negative outlook, stating that the longer one has pain the less likely it is to go away.

Item #2: Does the material contain any information about low back pain flare-ups and/or recurrence? (n=9/19 PEMs)

All nine PEMs provided information about how LBP can come back again in the future, often stating that flare-ups are common and/or likely. Four stated that flare-ups are not a cause for concern or an indication that your LBP is serious or getting worse, and one stated that inactivity may contribute to flare-ups.

Item #3: Does the material contain any information about low back pain causes or aetiology? (n=8/19 PEMs)

Four PEMs stated that factors like lifting, bending, physical inactivity, poor posture, smoking and alcohol consumption, anxiety, depression, and/or job dissatisfaction, among others, can cause or increase the risk of LBP, while three stated that similar factors can increase the risk of chronic or long-term LBP. Conversely, two PEMs stated that causes are not well understood and one stated that it is a myth that LBP is caused by wear and tear, lifting, or heavy physical activity.

Item #4: Does the material contain any information about the influence of psychological factors on low back pain? (n=14/19 PEMs)

Eleven PEMs stated that psychological factors such as anxiety, stress, anger, and negative thinking, can hinder recovery and/or increase pain; but only five stated that addressing these psychological aspects or staying positive can improve recovery and/or reduce pain. One stated that psychological factors can influence recovery, but did not indicate the direction of this relationship (e.g., if they hinder or improve recovery). Finally, two PEMs stated that chronic pain may cause emotional distress and/or depression.

PREVENTION (1 item)

Summary: About one-third of included PEMs provided information about prevention, most of which suggested strategies like staying active and exercise can prevent LBP. Few commented on preventative approaches that are not evidence supported, such as lumbar supports and shoe insoles.

Item #5: Does the material contain any information about the prevention of low back pain? (n=8/19 PEMs)

Seven PEMs recommended strategies to prevent LBP (e.g., staying active, exercising, adopting a positive attitude, and/or losing excess weight), two of which stated specifically that these strategies are evidence-supported. Two PEMs provided information on preventative approaches that they specifically stated are not evidence-supported (e.g.,

lifting less weight, lifting with special techniques, lumbar supports, shoe insoles, ergonomic chairs or mattresses, and/or long-term spinal manipulative therapy or mobilization).

FUNCTIONAL ANATOMY (1 item)

Summary: About one-third of included PEMs provided information about the functional anatomy of the spine. Of these, most commented on the general anatomy of the back as opposed to its strength or flexibility.

Item #6: Does the material contain any information about the functional anatomy of the spine? (n=6/19 items)

Five PEMs provided information about the general anatomy of the back (e.g., information about the vertebrae, discs, joints, ligaments, spinal cord, and/or muscles; how these structures support and/or protect one another). In addition to general anatomical information, four PEMs commented on the robust strength of the spine and one provided information about the flexibility of the spine.

DIAGNOSIS (4 items)

Summary: Nearly all PEMs provided information about LBP diagnosis but the information varied. About half defined LBP in general terms (e.g., ‘pain below the ribs

and above the bottom') or defined acute and/or chronic LBP and about half were more specific in describing, for example, how we cannot identify the cause of pain or that the cause is not serious. Less than half of included PEMs were explicit in describing how knowing the exact cause of pain is not necessary or is unlikely to change the treatment plan. All 19 PEMs recommended against routine imaging for non-specific LBP, but only about half described why (e.g., imaging usually cannot identify the source of pain, imaging has risks such as exposure to radiation). Only eight PEMs commented on different diagnostic techniques such as patient histories and physical examinations that can be conducted by healthcare professionals.

Leg pain specifically: Most PEMs provided information about leg pain or other symptoms, most of which simply listed various leg symptoms as red flags to see a provider or get further tests for. Few PEMs provided information about specific leg pain diagnoses and those that did used various terminology (e.g., lumbar radiculopathy, sciatica, pinched nerve, nerve compression) to refer to what was apparently the same condition. Conversely, one PEM stated that having "sciatica" does not necessarily mean you have a pinched nerve, which conflicts with how the term was used in other PEMs. Few PEMs commented on the prognosis or treatment of leg pain conditions.

Item #7: Does the material contain any information about low back pain diagnosis? (n=18/19 PEMs)

Roughly half of the PEMs defined LBP in general terms (e.g. “pain in your back region below your lowest ribs and above your bottom”) or provided information delineating acute and chronic LBP. Thirteen PEMs, however, provided more specific diagnostic information regarding non-specific LBP. Eleven suggested that non-specific LBP may originate from the anatomical structures of the back (e.g., muscles, joints, ligaments) and ten indicated that a specific cause cannot be identified, is not important, and/or is not caused by anything serious. Finally, thirteen PEMs provided information about red flags (e.g., weakness in the legs or incontinence), which are typically indicative of a more serious form of LBP.

Item #8: Does the material contain any information about the types of tests, investigations, and/or exams required or not required to diagnose low back pain? (n=19/19 PEMs)

All 19 PEMS stated that imaging is generally not needed or helpful for most people and/or is only needed under specific or rare circumstances. Some provided more specific information about imaging, indicating that imaging usually cannot identify the source of pain (n=11), is only recommended in the presence of red flags and/or for pre-surgical workups (n=11); or that structural changes found on scans may be unrelated to the pain or are normal changes with age (n=10). Twelve PEMs commented on the risks of imaging including exposure to radiation (n = 10), possibility of further unnecessary tests or treatments (n = 7), possibility of creating unnecessary worry (n = 6), and that imaging is costly (n = 5) and time consuming (n = 2). Six PEMs commented on the influence of imaging on recovery or symptoms, stating that imaging does not help people get better

faster (n = 5) and/or that imaging is associated with worse patient outcomes (n = 4). Finally, eight PEMs provided information relating to how healthcare providers can rule out red flags without imaging by conducting patient histories and physical examinations.

Item #9: Does the material contain any information about leg pain/symptoms? (n=17/19 PEMs)

Eleven PEMs indicated that patients should visit a provider or may require further tests for leg symptoms such as numbness, weakness, pins and needles, and severe unsteadiness on feet, as these may indicate the presence of a more serious condition. Additionally, five PEMS provided information about specific leg pain diagnosis. They stated that leg pain can be the result of irritated or inflamed nerves, but various terminology was used for this diagnosis (e.g., lumbar radiculopathy, sciatica, a pinched nerve, nerve compression). Conversely, three PEMs described leg pain associated with non-specific or "simple" LBP. Two stated that non-specific LBP can also involve leg pain. One stated that sciatica simply refers to having pain in the leg and that this does not necessarily mean you have a pinched nerve, which conflicts with how the term "sciatica" was used in other PEMs. Three PEMs provided information on the prognosis of leg pain. One stated that leg pain associated with non-specific LBP usually gets better as the back pain gets better, one stated that lumbar radiculopathy generally fully recovers without invasive treatments, and one stated that sciatica usually gets better on its own. One PEM stated that the risk of developing chronic LBP increases if you have leg pain. Finally, five PEMs commented on treatment options for leg pain, four of which suggested surgery is a possibility and one

stated that simple pain medications may not be enough for severe LBP with radiating leg pain.

Item #10: Does the material contain any information about the relationship between exact diagnosis and treatment? (n=10/19 PEMs)

Five PEMs stated that knowing the exact cause of pain does not change the treatment plan and/or is not needed to treat LBP, four stated that imaging findings usually do not change the course of treatment, and two stated that you do not need to aim treatment directly at the source of pain.

TREATMENT (n=7 items)

Summary: All PEMs provided information about treatments for LBP. They all made recommendations to stay active and/or to avoid bed rest and most provided information on pharmacological treatments and self-management strategies. While most PEMs listed various LBP treatments and explained at least one benefit of these treatments (e.g., reduces pain, improves recovery), very few commented on their safety and only one described their potential mechanisms of action. Less than half of included PEMs provided information about surgery as a treatment option for LBP, most of which stated that surgery is not needed or only needed in rare cases. Very few PEMs commented on how to manage flare-ups and/or recurrence.

Item #11: Does the material contain any information about pharmacological treatment for low back pain? (n=17/19 PEMs)

Fifteen PEMs recommended using at least one over-the-counter medication (e.g., paracetamol, NSAIDs) and six recommended using muscle relaxants. All of these commented on the benefits of medications (e.g., they may help a patient mobilize by reducing pain) and seven mentioned their favourable safety profile, but only one described their potential mechanism of action. Four, however, stated that pain medications are generally only helpful in the short-term, two indicated that patients should not rely solely on pain medication to treat LBP, one stated that pain medications are not usually necessary for treating LBP, and one stated that sometimes simple pain medications may not be enough. Seven PEMs also discussed stronger pain medications (e.g., opioids) indicating that these medications are either rarely or never recommended.

Item #12: Does the material contain any information about provider-based non-pharmacological treatment for low back pain? (n=13/19 PEMs)

Eleven PEMs recommended one or more specific provider-based treatments (most commonly acupuncture, massage, and manipulation) while the other simply listed health providers that can provide non-pharmacological treatment. Four PEMs provided information about ineffective or unproven treatments that are not recommended including traction and electrical stimulation. Eight of the PEMs that addressed non-pharmacological treatments reported them to be beneficial, with five specifying that these benefits are primarily short-term. Two PEMs commented on the safety of these treatments and one provided information on their potential mechanisms of action.

Item #13: Does the material contain any information about general exercise or sports for low back pain? (n=7/19 PEMs)

Seven of 19 PEMs provided information about general exercise or sports for LBP. All seven recommended one or more general exercises (e.g., yoga, Pilates, and water aerobics or aqua therapy) and one recommended continuing sports activity, but at a lower intensity. Additionally, two PEMs made general statements recommending to perform general exercises that strengthen the core and trunk muscles. Only three PEMs commented on the benefits of exercise or sports and only one provided information about their safety or potential mechanisms of action.

Item #14: Does the material contain any information about self-management strategies for low back pain? (n=17/19 PEMs)

Seventeen of 19 PEMs provided information about self-management strategies for LBP, recommending one or more self-management strategies (e.g., applying heat or cold, walking, running, cycling, lifestyle changes). In addition to specific self-management strategies, six PEMs provided general recommendations to pace or modify activities as needed (e.g., start slow and/or only do activities within your physical limits). Eleven PEMs mentioned at least one benefit of the recommended self-management strategies, but only one commented on their safety and potential mechanisms of action.

Item #15: Does the material contain any information about the role of surgery as a treatment option for low back pain? (n=8/19 PEMs)

Eight of 19 PEMs provided information about surgery for LBP. Four made general statements that surgery is only needed in rare cases, three stated that people who get surgery for non-specific LBP do not recover any faster than those who do not get surgery, and two stated that surgery is not needed for non-specific LBP.

Item #16: Does the material contain any information about the management of low back pain flare-ups and/or recurrence? (n=4/19 PEMs)

Only four of 19 PEMs provided information about the management of LBP flare-ups and/or recurrence. Three suggested using the same management strategies that were used for previous bouts of LBP. Two, however, recommended specific strategies (e.g., remain active, return to work and normal activities, limit activity for a few days, avoid bed rest, manage stress, and/or get good quality sleep).

Item #17: Does the material contain any information to promote staying active and/or not resting? (n=19/19 PEMs)

All 19 PEMs made statements promoting staying active and/or not resting. Twelve PEMs stated that staying active can reduce pain and/or improve recovery, and eleven PEMs stated that bed rest or avoiding activity can increase pain and/or hinder recovery. Six PEMs provided information on why bed rest is not helpful (e.g., muscles and/or bones become weak, muscles and spine become stiff, loss of physical fitness) and five provided information on why staying active is helpful (e.g., strengthens the muscles and/or bones, keeps you mobile and flexible, releases natural chemicals that reduce pain).

ACTIVITIES OF DAILY LIVING (n=2 items)

Summary: One-third of included PEMs provided information about functional tasks and postures. The information about functional tasks was conflicting. Some PEMs commented on the safety of lifting and/or bending while others reported that lifting can increase the risk of LBP and some described specific techniques that should be used when lifting while one stated that lifting with specific techniques does not prevent LBP. As for postures, the PEMs mainly recommended to change positions regularly and to use proper body postures, while some recommended specific sitting and standing techniques.

Item #18: Does the material contain any information about functional tasks in relation to low back pain? (n=7/19 PEMs)

All seven provided information about lifting and/or bending. About half (n = 4) provided general statements about the safety of lifting and/or bending, while others reported that lifting heavy loads or repeated lifting can increase risk of LBP (n = 2) or that bending forwards may induce pain (n = 1). Finally, two PEMs suggested specific lifting and bending techniques (e.g., avoid lifting heavy or awkward loads, bend the knees and keep the back as straight as possible, kneel or squat instead of bending at the waist).

Item #19: Does the material contain any information about postures in relation to low back pain? (n=7/19 PEMs)

Seven of 19 PEMs provided information about postures in relation to LBP. Six PEMs made general statements about postures. Five recommended to change positions regularly and three recommended to avoid slouching and/or to use proper body postures, one of which specifically stated that proper postures can help reduce pain and get you back to normal activities. Two PEMs made general statements indicating that sitting or sitting in a specific way is not a risk factor for LBP. Two other PEMs provided specific sitting tips (e.g., use lumbar supports or adjustable back rests) and one of these also provided specific standing tips (e.g., tilt your pelvis to flatten the curve in your spine).

PAIN NEUROSCIENCE EDUCATION (n=2 items)

Summary: About two-thirds of included PEMs provided information about the relationship between pain and injury, all of which made statements indicating that pain does not mean there is any damage to the back. Few elaborated on pain neuroscience education in more detail, such as by describing how pain is a warning signal that helps prevent damage. About two-thirds of included PEMs suggested that movement is helpful for the back, but few made explicit statements about the safety of movement.

Item #20: Does the material contain any information about the relationship between pain and injury? (n=13/19 PEMs)

Thirteen of 19 PEMs provided information about the relationship between pain and injury. All 13 PEMs made statements indicating that pain does not mean there is any

damage to the back. Two provided more specific information suggesting that pain is a warning signal to help prevent damage.

Item #21: Does the material contain any information about the safety of physical activity and/or exercise and/or sport? (n=13/19 PEMs)

Thirteen of 19 PEMs provided information about the safety of movement (i.e., physical activity and/or exercise and/or sport). Eleven PEMs stated that various types of movement (e.g., exercise, staying active) can help LBP recovery and/or reduce pain, but only six PEMs made more explicit statements related to safety. Of these, four made statements related to how movement will not, or is unlikely to, cause any damage to the back and three specifically stated that movement is safe.

Appendix 5.7. Frequency (%) of patient education materials endorsing or dismissing treatments mentioned in guidelines for acute low back pain (n = 15)

Treatment	Appropriate endorsement	Inappropriate endorsement	Appropriate dismissal	Inappropriate dismissal	Unclear recommendation	Omissions[1]
Treatments endorsed by at least one guideline						
Advice to stay active	14 (93.3)	-	-	-	-	1 (6.7)
Cognitive behavioural therapy	-	-	-	-	-	15 (100)
Education	3 (20.0)	-	-	-	-	12 (80.0)
Exercise	10 (66.7)	-	-	1 (6.7)	-	4 (26.7)
Heat	9 (60.0)	-	-	-	-	6 (40.0)
Massage	1 (6.7)	-	-	1 (6.7)	1 (6.7)	12 (80.0)
Mobilisation	-	-	-	-	-	15 (100)
Muscle relaxants	3 (20.0)	-	-	-	1 (6.7)	11 (73.3)
Non-steroidal anti-inflammatory	9 (60.0)	-	-	-	1 (6.7)	5 (33.3)
Spinal manipulative therapy	3 (20.0)	-	-	-	1 (6.7)	11 (73.3)
Weak opioids[2]	2 (13.3)	-	-	-	1 (6.7)	12 (80.0)
Treatments dismissed by at least one guideline						
Anticonvulsants	-	-	-	-	-	15 (100)
Antidepressants (serotonin-norepinephrine reuptake inhibitors)	-	-	1 (6.7)	-	-	14 (93.3)
Antidepressants (selective serotonin reuptake inhibitors)	-	-	1 (6.7)	-	-	14 (93.3)
Antidepressants (tricyclics)	-	-	1 (6.7)	-	-	14 (93.3)
Belts	-	-	1 (6.7)	-	-	14 (93.3)
Corsets	-	-	1 (6.7)	-	-	14 (93.3)
Epidural steroid injections	-	-	1 (6.7)	-	-	14 (93.3)
Facet joint steroid injections	-	-	1 (6.7)	-	-	14 (93.3)

Foot orthotics	-	-	1 (6.7)	-	-	14 (93.3)
Interferential therapy	-	-	-	-	-	15 (100)
Paracetamol	-	5 (33.3)	2 (13.3)	-	1 (6.7)	7 (46.7)
Percutaneous electrical nerve stimulation	-	-	-	-	1 (6.7)	14 (93.3)
Rocker sole shoes	-	-	-	-	-	15 (100)
Strong opioids	-	-	3 (20.0)	-	1 (6.7)	11 (73.3)
Surgery (disc replacement)	-	-	1 (6.7)	-	-	14 (93.3)
Surgery (fusion)	-	-	1 (6.7)	-	-	14 (93.3)
Systemic steroids	-	-	2 (13.3)	-	1 (6.7)	12 (80.0)
Transcutaneous electrical nerve stimulation	-	-	1 (6.7)	-	1 (6.7)	13 (86.7)
Traction	-	-	2 (13.3)	-	-	13 (86.7)
Ultrasound	-	1 (6.7)	2 (13.3)	-	-	12 (80.0)
Conflicting recommendations						
Acupuncture	-	1 (6.7)	-	-	-	14 (93.3)

Some values may not add up to 100% due to rounding
[1]Number of patient education materials that did not mention the corresponding treatment
[2]Weak opioids were recommended only if there were contraindications to other medications or if other medications were ineffective

Appendix 5.8. Frequency (%) of patient education materials endorsing or dismissing treatments mentioned in guidelines for chronic low back pain (n = 5)

Treatment	Appropriate endorsement	Inappropriate endorsement	Appropriate dismissal	Inappropriate dismissal	Unclear recommendation	Omissions[1]
Treatments endorsed by at least one guideline						
Advice to stay active	4 (80.0)	-	-	-	-	1 (20.0)
Behavioural (operant) therapy	-	-	-	-	-	5 (100)
Cognitive behavioural therapy	3 (60.0)	-	-	-	-	2 (40.0)
Education	2 (40.0)	-	-	-	-	3 (60.0)
Electromyography biofeedback	-	-	-	-	-	5 (100)
Exercise	5 (100)	-	-	-	-	-
Low level laser therapy	-	-	-	1 (20.0)	-	4 (80.0)
Massage	2 (40.0)	-	-	-	1 (20.0)	2 (40.0)
Mindfulness	1 (20.0)	-	-	-	-	4 (80.0)
Mobilisation	-	-	-	-	-	5 (100)
Motor control exercise	1 (20.0)	-	-	-	-	4 (80.0)
Multidisciplinary treatment	3 (60.0)	-	-	-	-	2 (40.0)
Non-steroidal anti-inflammatory	2 (40.0)	-	-	-	1 (20.0)	2 (40.0)
Progressive relaxation	1 (20.0)	-	-	-	1 (20.0)	3 (60.0)
Radiofrequency denervation	-	-	-	1 (20.0)	-	4 (80.0)
Spinal manipulative therapy	2 (40.0)	-	-	1 (20.0)	1 (20.0)	1 (20.0)
Tai Chi	-	-	-	-	-	5 (100)
Yoga	3 (60.0)	-	-	-	-	2 (40.0)
Treatments dismissed by at least one guideline						
Anticonvulsants	-	-	-	-	-	5 (100)
Antidepressants (selective serotonin reuptake inhibitors)	-	-	2 (40.0)	-	1 (20.0)	2 (40.0)
Antidepressants (tricyclics)	-	1 (20.0)	1 (20.0)	-	1 (20.0)	2 (40.0)

Belts	-	-	1 (20.0)	-	-	4 (80.0)
Corsets	-	-	1 (20.0)	-	-	4 (80.0)
Epidural steroid injection	-	1 (20.0)	1 (20.0)	-	-	3 (60.0)
Facet joint steroid injection	-	1 (20.0)	1 (20.0)	-	-	3 (60.0)
Foot orthotics	-	-	1 (20.0)	-	-	4 (80.0)
Interferential therapy	-	-	-	-	-	5 (100)
Paracetamol	-	2 (40.0)	2 (40.0)	-	1 (20.0)	-
Percutaneous electrical nerve stimulation	-	-	-	-	-	5 (100)
Rocker sole shoes	-	-	-	-	-	5 (100)
Surgery (disc replacement)	-	-	1 (20.0)	-	-	4 (80.0)
Surgery (fusion)	-	-	2 (40.0)	-	-	3 (60.0)
Transcutaneous electrical nerve stimulation	-	-	3 (60.0)	-	-	2 (40.0)
Traction	-	-	3 (60.0)	-	-	2 (40.0)
Ultrasound	-	-	2 (40.0)	-	-	3 (60.0)
Conflicting recommendations						
Acupuncture	-	3 (60.0)	-	-	-	2 (40.0)
Opioids	-	1 (20.0)	-	-	-	4 (80.0)
Antidepressants (serotonin-norepinephrine reuptake inhibitors)	-	-	1 (20.0)	-	1 (20.0)	3 (60.0)
Some values may not add up to 100% due to rounding [1]Number of PEMs that *did not* mention the corresponding treatment at all						

Appendix 5.9. Accuracy and comprehensiveness of patient education material recommendations

Material	Total # of recs	AE	IE	AD	ID	END	DIS	UNC END	UNC DIS	Clear accurate recs to use a treatment		Clear accurate recs to avoid a treatment		Total clear accurate recs (Information accuracy)		Recs from guidelines correctly covered by PEMs (Comprehensiveness)	
										#	%	#	%	#	%	#	%
Acute low back pain																	
Low Back Pain (PainHealth)	10	5	0	1	0	3	1	0	0	5	62.5	2	100	7	70	6	19.4
Managing LBP	7	3	0	1	0	1	2	0	0	3	75.0	3	100	6	85.7	4	12.9
Best practice care	5	3	0	1	0	0	1	0	0	3	100	2	100	5	100	4	12.9
Treating/Imaging LBP (US)	4	2	0	0	0	1	1	0	0	2	66.7	1	100	3	75	2	6.5
Patient Handout	10	1	0	0	0	2	1	0	6	1	33.3	1	14.3	2	20	1	3.2
Truth about LBP	12	4	1	1	0	6	0	0	0	4	36.4	1	100	5	41.7	5	16.1
Understanding LBP	9	2	0	0	0	6	1	0	0	2	25.0	1	100	3	33.3	2	6.5
Physio for Acute LBP	8	5	0	0	0	0	1	2	0	5	71.4	1	100	6	75	5	16.1
Free for People with LBP	2	2	0	0	0	0	0	0	0	2	100	0	0	2	100	2	6.5
So Your Back Hurts (Acute)	17	7	1	3	1	1	2	0	2	7	77.8	5	62.5	12	70.6	10	32.3
Should Know (Acute)	5	3	1	0	0	0	1	0	0	3	75.0	1	100	4	80	3	9.7
Back Book	12	6	2	0	0	3	1	0	0	6	54.5	1	100	7	58.3	6	19.4
Managing/Imaging LBP (NZ)	6	1	1	0	0	3	1	0	0	1	20	1	100	2	33.3	1	3.2
Treating/Imaging LBP (CA)	8	5	1	0	0	1	1	0	0	5	71.4	1	100	6	75	5	16.1
My Back Pain (Acute)	41	5	0	15	1	8	12	0	0	5	38.5	27	96.4	32	78.0	20	64.5
Chronic low back pain																	
So Your Back Hurts (Chronic)	22	6	5	3	1	4	2	1	0	6	37.5	5	83.3	11	50	9	25.7
Should Know (Chronic)	9	4	1	0	0	2	2	0	0	4	57.1	2	100	6	66. 7	4	11.4

Physio for Persistent LBP	13	3	0	5	0	0	0	2	3	3	60.0	5	62.5	8	61.5	8	22.9
LBP (DocMikeEvans)	14	6	1	0	0	5	0	2	0	6	42. 9	0	0	6	42.9	6	17.1
My Back Pain (Chronic)	49	10	2	14	2	9	12	0	0	10	47.6	26	92.9	36	73.5	24	68.6

Recs, recommendations; AE, appropriate endorsement; AD, appropriate dismissal; IE, inappropriate endorsement; ID, inappropriate dismissal; END, endorsed; DIS, dismissed; UNC END, unclear endorsement; UNC DIS, unclear dismissal

Appendix 5.10. PRISMA Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Pg. 154
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Pg. 156
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pg. 159-160
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Pg. 160
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Pg. 161-162
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Pg. 160-162
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Pg. 160-162, appendix 4.2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Pg. 160-162
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Pg. 163-168
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Pg. 163-168
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Pg. 163-168

Section and Topic	Item #	Checklist item	Location where item is reported
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	n/a
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Pg. 163-169
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	n/a
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Pg. 169
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Pg. 169
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Pg. 169
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	n/a
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	n/a
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	n/a
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	n/a
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Pg. 169-170
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	n/a
Study characteristics	17	Cite each included study and present its characteristics.	Pg. 169-173
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	n/a

Section and Topic	Item #	Checklist item	Location where item is reported
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Pg. 174-182
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	n/a
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Pg. 174-182
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	n/a
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	n/a
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	n/a
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	n/a
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pg. 182-183
	23b	Discuss any limitations of the evidence included in the review.	Pg. 183-184
	23c	Discuss any limitations of the review processes used.	Pg. 183-184
	23d	Discuss implications of the results for practice, policy, and future research.	Pg. 185-187
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Pg. 160
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Pg. 160
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	n/a
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Pg. 189
Competing interests	26	Declare any competing interests of review authors.	Pg. 189

Section and Topic	Item #	Checklist item	Location where item is reported
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Appendices & tables contain all data