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Patient education materials for non-specific low back pain and sciatica: a protocol for a systematic review and meta-analysis

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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-centred 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 randomised 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 versus no intervention; (2) education alone versus another intervention; (3) education in addition to another intervention versus 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 homogeneous. 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.

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 randomised 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 3 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 (eg, healthcare costs) and indirect costs (eg, 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 US$100–US$200 billion in the USA 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 catastrophising, 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 catastrophising and beliefs/concern that non-specific LBP 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 favourable 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 standardised, evidence-informed educational materials may, therefore, be a time and cost-efficient way of (1) providing patient-centred 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 (eg, an information booklet, pamphlet, leaflet or video) for LBP in 2008 searching studies published up to 2006. They identified 10 studies that assessed education versus 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 programmes (eg, multisession and multicomponent education programmes or self-management interventions),[28 30 32–37] or a specific delivery method of education (eg, 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 multisession education programme 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 utilisation 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 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 online supplementary appendix A. 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 randomised 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 (eg, diagnosis, prognosis, self-management or other treatment advice) is provided to the patient by using a standardised 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 (eg, 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 multicomponent 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 with two main comparison groups (1) no other intervention and (2) 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 (ie, 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, this study will be included in the second comparison. Comparisons of non-conservative treatments (eg, 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 LBP including short-term 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 utilisation 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 and 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 and 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 standardised data extraction forms in Microsoft Excel (BF and GD). The extraction forms will include variables relating to study details (authors, year of publication, country of data collection), study characteristics (LBP type and duration, sample size, outcomes measures, study design, brief intervention group description, comparison group description). Intervention details will be extracted in accordance with the 12 variables outlined in the TIDieR checklist[46] (eg, 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 (SD). Point estimates of effect size and 95% CIs will be used to estimate the treatment effect. Review Manager V.5 will be used for the analysis.

After data extraction is complete, two authors will make independent judgements 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 and 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 versus no intervention.
2. Education alone versus another intervention.
3. Education in addition to another intervention versus 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 standardised 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 homogeneous. We anticipate there will be a small degree of clinical heterogeneity in the types of educational materials (eg, content or delivery of the intervention) and populations assessed (eg, duration of LBP) for which we consider to be acceptable given our overall study question. If I^2 >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 (eg, booklets, pamphlets) and soft copy (eg, 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 Grades of Recommendation, Assessment, Development and Evaluation (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 (ie, 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—(A) many included studies have a small sample size, (B) studies are or are likely to be industry sponsored, or (C) 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 and 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 an SD is not provided, it will be calculated or estimated using a relevant statistic provided in the study (eg, from confidence intervals, standard errors, p values).[49] If the SD 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 prioritising this question as part of an 'improving the management of LBP' 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 summarised and circulated in other formats as appropriate (eg, 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.

Contributors 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.

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Competing interests None declared.

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