


BMJ Open Effects of a physiotherapist-led approach based on a biopsychosocial model for spinal disorders: protocol for a systematic review

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ABSTRACT

Introduction Low back pain and neck pain are among the most common musculoskeletal disorders, and their related medical costs are rising every year. Many interventions are based on the biopsychosocial (BPS) model since the cause of pain is more multifaceted. Physiotherapists have increased opportunities to perform multidisciplinary interventions alone in clinical practice due to a lack of understanding of the model and its cost. Therefore, physiotherapist-led interventions using the BPS model are important and require an updated report summarising their effectiveness. Thus, the purpose of this study will be to summarise and synthesise the effects of physiotherapist-led interventions using the BPS model for spinal disorders.

Methods and analysis We will search the Web of Science, CENTRAL, MEDLINE, PsycINFO, CINAHL and PEDro electronic databases, using a date range from inception to September 2021. We will include only randomised controlled trials for patients diagnosed with spinal disorders who received physiotherapist-led interventions based on the BPS model. The search will be limited to English-language publications. Pain intensity and disability are the primary outcomes. Secondary outcomes are any psychological factors. We will examine the short-term, medium-term and long-term effects, and a subgroup analysis will be conducted, if possible, to investigate the role of additional physiotherapist training.

Ethics and dissemination This study is exempt from ethical approval because it involves publicly available documents. The findings will be submitted for publication in a relevant peer-reviewed journal.

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INTRODUCTION

Spinal disorders, such as low back and neck pain, are among the most common musculoskeletal disorders (MSDs), and their related medical costs are rising each year.^{1,2} Pain is an innate human response and often is cited as a complaint in patients with spinal disorders. Since ancient times, pain has been discussed according to the biomedical model in which tissue damage and structural abnormalities are the cause. Recently, pain is more complex.

Strengths and limitations of this study

- This systematic review focuses on the effectiveness of physiotherapist-led interventions based on the biopsychosocial model for spinal disorders, a topic of current interest and importance in healthcare.
- Two authors will conduct screening and article quality assessment alternately, and another author will perform the data extraction to minimise the possibility of personal bias.
- Outcomes will be examined separately for short-term, medium-term and long-term effects, and a subgroup analysis will be conducted, if possible, to investigate the role of additional physiotherapist training.
- Databases in languages other than English and grey literature will not be searched in this study.

According to the definition revised in 2020 by the International Association for the Study of Pain, pain is ‘An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.’³ Pain is a personal feeling that can be exacerbated by anxiety and incorrect knowledge and attitudes.⁴ For example, anxiety and distorted cognition have been shown to contribute to pain exacerbation and chronicity.⁵ In addition, another new type of pain called nociplastic pain that indicates the importance of cognition and emotions has also been identified.⁶ Those facts have led to the establishment of a biopsychosocial (BPS) model rather than a biomedical model for spinal disorders.⁷

Various interventions based on the BPS model have been attempted for spinal disorders. A typical example is cognitive-behavioural therapy (CBT).⁸ Another example is pain neuroscience education which the patient is educated about the

biological and physiological processes involved in the pain experience.⁹ It has been reported to improve pain, functional disability and psychological factors in patients with MSDs.^{9–11} Other interventions on the BPS model have been based on coping skills and motivational interviewing.^{12–13} However, the BPS model is still not well understood.¹⁴ One problem misunderstood with the BPS model is that it assumes that biological, psychological and social contributions are all equal.¹⁵ An accurate BPS approach requires that each individual occupies a different percentage of each domain and changes response depending on that individual. In some cases, the biological aspect may be the majority.

As healthcare professionals, physiotherapists can provide physical as well as psychological interventions and have increased opportunities to perform multidisciplinary interventions alone in clinical practice due to a lack of understanding of the model and its cost.^{16–17} However, physiotherapists do not have confidence in psychological issues.^{18–19} Therefore, systematically summarising the effects of interventions using the BPS model by physiotherapists for patients with spinal disorders and organising the current evidence are helpful for the current clinical setting.

Study rationale

Several systematic reviews have reported on the effects of physiotherapist-led interventions based on the BPS model. For example, one systematic review has summarised the effectiveness of CBT for non-specific low back pain.²⁰ However, this study was limited to CBT and did not include other interventions based on BPS models. In addition, another study has reported the effects of psychological intervention by physiotherapists on MSDs but includes only articles published up to 2016.²¹ This field should be added to the latest articles, as many studies have reported in recent years. Furthermore, reviews of this topic should include surgical conditions because interventions based on the BPS model may be effective in postoperative rehabilitation. Our review will include cases in which the physiotherapists did not receive any additional training in psychological interventions although the previous review excluded cases in those. Then, a subgroup analysis will be conducted to compare whether there is a difference between those who received additional training and those who did not. This may provide an opportunity to examine the value of additional psychological training for physiotherapists.

The purpose of this study is to synthesise the evidence on the effects of physiotherapist-led interventions based on the BPS model for spinal disorders.

Review objectives

1. To summarise the effects of physiotherapist-led interventions based on the BPS model for patients with spinal disorders.
2. To synthesise the evidence on physiotherapist-led interventions for spinal disorders based on the BPS model.

METHODS AND ANALYSIS

Protocol and registration

This systematic review was preregistered in the PROSPERO database and will proceed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-P) guidelines.²²

Inclusion criteria

Participants

Participants will include patients diagnosed with spinal disorders who received an intervention based on the BPS model by physiotherapists. We will include all types of spinal disorders and any symptom duration (acute, subacute and chronic). It will also place no restrictions on participants' gender, ethnicity or other demographic characteristics.

Interventions

Interventions based on the BPS model by physiotherapists will be defined as physiotherapists who mainly perform psychosocial and physical approach (eg, exercise, mobilisation). We plan to exclude cases with psychological intervention without physical intervention as well as cases with physical intervention without psychological interventions. We will consider all forms of delivery, including group instruction, individual briefings, presentations, books and leaflets.

Comparators

We will consider the control group as those for which physiotherapist-led BPS interventions were not done (eg, wait-list control, physiotherapy, other treatment methods, no treatment).

Outcomes

The primary outcomes will be pain intensity and self-reported disability. The secondary outcomes will be psychological factors such as fear of movement and catastrophic thinking. It will be divided into short-term effects (<3 months), medium-term effects (≥3–12 months) and long-term effects (≥12 months).

Studies

We will include only randomised controlled trials.

Publications

We will consider articles that are published in English. Also, we will deal with published articles and will exclude grey literature.

Search strategy

We will search the Web of Science, CENTRAL, MEDLINE, PsycINFO, CINAHL and PEDro electronic databases using a date range from inception to September 2021. A summary of search strategy is shown in [table 1](#). Search strategies of all databases are attached in online supplemental appendix 1. Moreover, we will manually search the relevant literature cited in the studies we discover.

Table 1 Summary of search terms

Category	Search terms
1	spinal diseases, cauda equina, spine, vertebrates, neck pain, back pain, hernia, radiculopathy, whiplash, whiplash injury, whiplash disorder, lumbar stenosis, failed back surgery syndrome, spinal fusion, lumbar surgery
2	cognitive behavioral therapy, cognitive behavioral therapy, pain management, patient education, patient education as topic, patient care management, Comprehensive Health Care, Pain Clinics, Social Support, Psychosocial Support Systems, Interviews as Topic, multidisciplinary biopsychosocial rehabilitation, cognitive functional therapy, pain neuroscience education, mindfulness, coping, biopsychosocial, motivational interviewing, interdisciplinary
3	randomized controlled trials, controlled clinical trial, randomized, placebo, drug therapy, randomly, trial, groups, human
4	#1 AND #2 AND #3

We will export the search results to EndNote, excluding duplicates.

Study selection and data selection process

The authors TM and YK will independently perform the screening and full-text inspection. They will not be blinded to publisher, author or publication year. Another author (HK) will moderate any disagreements. Following full-text screening, we will qualify the articles and create a flow diagram using the PRISMA checklist.

Assessment of methodological quality

We will assess the quality of the argument using the PEDro score, which was developed specifically to assess the methodological quality of physiotherapy trials,^{23 24} presenting the established scores. If no score is available, two independent reviewers (TM and YK) will assign a score. A third author (HK) will moderate any disagreements. We will summarise the risk of bias (RoB) for each outcome in each individual study and supply an RoB table. Moderate-quality to high-quality studies will be defined as those with a PEDro score of ≥ 6 .²³

If we decide to do a meta-analysis, we will identify the overall quality of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system,²⁵ which consists of five items which are RoB, inconsistency, indirectness, imprecision and publication bias. We will rate each criterion as high, moderate, low or very low, choosing the lowest quality as the overall quality of evidence. For evidence from randomised controlled trials, we will begin with a 'high' rating.

We will reduce the quality of evidence on specific outcomes by 1–2 levels depending on the performance of the comparative studies on these five factors. For RoB, we will reduce the quality of the evidence by 1 point if $>25\%$ and 2 points if $>50\%$ of the participants are from studies conducted using low-quality methods (ie, PEDro score <6). For inconsistency, we will reduce the quality of evidence by 1 point when the heterogeneity or variability in the results was large, as indicated by $I^2 >50\%$, and by 2 points for $I^2 >75\%$. Moreover, we will reduce 1 more point if differences among populations, interventions or outcomes are present.

For indirectness, we will assess whether the issues addressed in this systematic review differed from the available evidence on populations, interventions, comparisons and outcomes, deducting 1 point if indirectness exists in only 1 area and 2 points if it exists in >2 areas. For imprecision, we will deduct 1 point if the total number of participants is <400 . In addition, if no significant differences exist in outcomes, we will reduce the grade. For publication bias, we will create a funnel plot to compare at least 10 studies, reducing the evidence quality by 1 point if bias is suggested. Two authors (TM and YK) will independently assess GRADE scores in each meta-analysis, and any disagreements will be resolved by the third author (HK).

Data extraction

A single reviewer (TT) will extract the data and enter them into a Microsoft Excel spreadsheet. Participant data will include source and setting, age, gender and symptom duration. Intervention data will include description; duration and number of sessions and delivery type, such as individual or group. Data for comparisons will include type of intervention and duration or number of sessions. Outcomes data will include means and SD for pain, disability and psychological factors during short-term, medium-term and long-term follow-ups. We will define short term as <3 months, medium term as ≥ 3 –12 months and long term as ≥ 12 months.²⁶

Data synthesis and analysis

Depending on the data available, we decide to meta-analyse the results. If >2 or more papers have the same outcome, we will perform a meta-analysis. However, if $I^2 >75\%$, we will not perform a meta-analysis, because reliability cannot be ensured.²⁷

We will perform the meta-analysis using Review Manager V.5 (Nordic Cochrane Centre, Copenhagen, Denmark). We will calculate the standardised mean difference with 95% CIs using the random-effects model. We will assess the I^2 statistic for heterogeneity among trials, with interpretations as follows: 0%–40%=maybe insignificant, 30%–60%=moderate heterogeneity, 50%–90%=substantial heterogeneity and 75%–100%=considerable



heterogeneity.²⁸ We will perform a sensitivity analysis when considerable heterogeneity exists.

Subgroup analysis

A subgroup analysis will be conducted to see if there is a difference in intervention between physiotherapists who have received training in psychological intervention and those who did not.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of the research.

ETHICS AND DISSEMINATION

This study is exempt from ethical approval because it involves publicly available documents. The findings will be submitted for publication in a relevant peer-reviewed journal.

DISCUSSION

In this systematic review, we will examine the effects of BPS interventions by physiotherapists for patients with spinal disorders. Interventions based on this model are essential for the current clinical setting.²⁹ Several studies already have been conducted.^{30–32} However, it needs to have updated information as many studies have reported in recent years, and there have been no systematic reviews for spinal disorders. Therefore, this review can help summarise the evidence for BPS interventions for spinal disorders, as well as support the future development of physiotherapy.

This study has limitations: the articles can only be searched in English, are limited to published articles and the search engine is limited. However, these are valid to remove unreliable information. It should be a valuable systematic review, even if these are present. On the other hand, there are some strengths. Two independent authors will do primary screening and evaluation of the quality of the paper. Another author performs the data extraction. These will minimise the possibility of bias. In addition, this study will examine the effects for short-term, medium-term and long-term effects, respectively. We will also perform a subgroup analysis to examine how the effect of the intervention differs between physiotherapists who have received training in psychological strategies and those who have not. This will make it possible to examine the effects of physiotherapist-led interventions on the BPS model in various aspects.

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