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.

PROSPERO registration number CRD42021258071.

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. 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.

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.’ Pain is a personal feeling that can be exacerbated by anxiety and incorrect knowledge and attitudes.

For example, anxiety and distorted cognition have been shown to contribute to pain exacerbation and chronicity. In addition, another new type of pain called nociceplastic pain that indicates the importance of cognition and emotions has also been identified. Those facts have led to the establishment of a biopsychosocial (BPS) model rather than a biomedical model for spinal disorders.

Various interventions based on the BPS model have been attempted for spinal disorders. A typical example is cognitive-behavioural therapy (CBT). Another example is pain neuroscience education which the patient is educated about the...
biological and physiological processes involved in the pain experience.\textsuperscript{9} It has been reported to improve pain, functional disability and psychological factors in patients with MSDs.\textsuperscript{9–11} Other interventions on the BPS model have been based on coping skills and motivational interviewing.\textsuperscript{12,13} However, the BPS model is still not well understood.\textsuperscript{14} One problem misunderstood with the BPS model is that it assumes that biological, psychological and social contributions are all equal.\textsuperscript{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.\textsuperscript{16,17} However, physiotherapists do not have confidence in psychological issues.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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 psychological and intervention (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 (<5 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.
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, 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 if heterogeneity or variability in the results was large, as indicated by I² >50%, and by 2 points for I² >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 I² >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 I² statistic for heterogeneity among trials, with interpretations as follows: 0%–40%=may be insignificant, 30%–60%=moderate heterogeneity, 50%–90%=substantial heterogeneity and 75%–100%=considerable

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**Table 1** Summary of search terms

<table>
<thead>
<tr>
<th>Category</th>
<th>Search terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>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</td>
</tr>
<tr>
<td>2</td>
<td>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</td>
</tr>
<tr>
<td>3</td>
<td>randomized controlled trials, controlled clinical trial, randomized, placebo, drug therapy, randomly, trial, groups, human</td>
</tr>
<tr>
<td>4</td>
<td>#1 AND #2 AND #3</td>
</tr>
</tbody>
</table>
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 have already 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.

Acknowledgements The authors would like to thank Enago (www.enago.jp) for the English language review.

Contributors TM—protocol development and manuscript writing. YK and HK—protocol development. TT—paper revision. MS—protocol development and paper revision.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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APPENDIX 1. Search Strategy

MEDLINE

S1 (MH "Spinal Diseases+)
S2 Spinal Disorder
S3 (MH "Cauda Equina")
S4 (MH "Spine+")
S5 (MH "Neck Pain")
S6 neck NEAR3 pain
S7 (MH "Back Pain+")
S8 back NEAR3 pain
S9 Backache
S10 (MH "Hernia+")
S11 (MH "Radiculopathy")
S12 whiplash associated disorder
S13 lumbar stenosis or lumbar spinal stenosis
S14 (MH "Failed Back Surgery Syndrome") or Failed Back Surgery Syndrome
S15 spinal fusion
S16 lumbar surgery
S17 spine surgery
S18 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11
    OR S12 OR S13 OR S14 OR S15 OR S16 OR S17
S19 (MH "Pain Management")
S20 (MH "Patient Education as Topic+")
S21 (MH "Patient Care Management+")
S22 (MH "Comprehensive Health Care+")
S23 (MH "Pain Clinics")
S24 (MH "Social Support+")
S25 (MH "Psychosocial Support Systems")
S26 (MH "Interviews as Topic")
S27 multidisciplinary biopsychosocial rehabilitation
S28 cognitive functional therapy or cft
S29 pain neuroscience education
S30 mindfulness
S31 coping
S32 biopsychosocial
S33 motivational interviewing
S34 interdisciplinary
S35 S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34
S36 (MH "Randomized Controlled Trials as Topic+") or randomiz* controll* trial*
S37 (MH "Controlled Clinical Trials as Topic+") or controll* clinical trial
S38 "randomized"
S39 placebo*
S40 Drug Therapy
S41 "randomly"
S42 trial
S43 "groups"
S44 S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43
S45 (MH "Humans") OR "humans"
S46 (S43 AND S44)

CENTRL
#1 MeSH descriptor: [Spinal Diseases] explode all trees
#2 MeSH descriptor: [Cauda Equina] explode all trees
#3 MeSH descriptor: [Spine] explode all trees
#4 MeSH descriptor: [Vertebrates] explode all trees
#5 MeSH descriptor: [Neck Pain] explode all trees
#6 (neck NEAR3 pain):ti,ab,kw
#7 MeSH descriptor: [Back Pain] explode all trees
#8 back NEAR3 pain
#9 (Backache):ti,ab,k
#10 MeSH descriptor: [Hemia] explode all trees
#11 MeSH descriptor: [Radiculopathy] explode all trees
#12 MeSH descriptor: [Whiplash Injuries] explode all trees
#13 (whiplash disorder):ti,ab,kw
#14 (lumber stenosis):ti,ab,kw
#15 MeSH descriptor: [Failed Back Surgery Syndrome] explode all trees
#16 (Failed Back Surgery Syndrome):ti,ab,kw
#17 MeSH descriptor: [Spinal Fusion] explode all trees
#18 (spinal fusion):ti,ab,kw
#19 (lumbar surgery):ti,ab,kw
#20 (spine surgery):ti,ab,kw
#21 {OR #1-#20}
#22 MeSH descriptor: [Cognitive Behavioral Therapy] explode all trees
#23 (Cognitive Behavioral Therapy):ti,ab,kw
#24 MeSH descriptor: [Pain Management] explode all trees
#25 MeSH descriptor: [Patient Education as Topic] explode all trees
#26 MeSH descriptor: [Patient Care Management] explode all trees
#27 MeSH descriptor: [Comprehensive Health Care] explode all trees
#28 MeSH descriptor: [Pain Clinics] explode all trees
#29 MeSH descriptor: [Social Support] explode all trees
#30 MeSH descriptor: [Psychosocial Support Systems] explode all trees
#31 MeSH descriptor: [Interviews as Topic] explode all trees
#32 (multidisciplinary biopsychosocial rehabilitation):ti,ab,kw
#33 (cognitive functional therapy):ti,ab,kw
#34 (pain neuroscience education):ti,ab,kw
#35 (mindfulness):ti,ab,kw
#36 (coping):ti,ab,kw
#37 (biopsychosocial):ti,ab,kw
#38 (motivational interviewing):ti,ab,kw
#39 (interdisciplinary):ti,ab,kw
#40 {OR #22-#39}
#41 #21 AND #39

CINAHL (EBSCO host)

#1
- MW Spinal Diseases
- OR MW Cauda Equina
- OR MW Spine
- OR MW Vertebrates
- OR MW Neck Pain
- OR MW Back Pain
- OR MW Hernia
- OR MW Radiculopathy
- OR MW Whiplash Injuries
- OR MW Failed Back Surgery Syndrome
- OR MW Spinal Fusion
- OR TX Backache
- OR TX whiplash disorder
- OR TX lumber stenosis
- OR TX Failed Back Surgery Syndrome
- OR TX lumber surgery
- OR TX spine surgery

#2
MW cognitive behavioral therapy OR TX cognitive behavioral therapy OR MW pain management OR MW patient education OR MA patient education as topic OR MW patient care management OR MW Comprehensive Health Care OR MW Pain Clinics OR MW Social Support OR MW Psychosocial Support Systems OR MW Interviews as Topic OR TX multidisciplinary biopsychosocial rehabilitation OR TX cognitive functional therapy OR TX pain neuroscience education OR TX mindfulness OR TX coping OR TX biopsychosocial OR TX motivational interviewing OR TX interdisciplinary

#3
TX randomized controlled trials OR TX controlled clinical trial OR TX randomized OR TX placebo OR TX drug therapy OR TX randomly OR TX trial OR TX groups OR TX human

#4
#1 AND #2 AND #3

PsychoINFO (EBSCO host)

#1
MA spinal diseases OR MA cauda equina OR MA spine OR MA vertebrae OR MA neck pain OR MA back pain OR MA hernia OR MA radiculopathy OR MA whiplash OR MA whiplash injury OR TX whiplash disorder OR TX lumbar stenosis OR MA failed back surgery syndrome OR TX failed back surgery syndrome OR MA spinal fusion OR TX lumbar surgery

#2
MA cognitive behavioral therapy OR TX cognitive behavioral therapy OR MA pain management OR MA patient education OR MA patient education as topic OR MA patient care management OR MA Comprehensive Health Care OR MA Pain Clinics OR MA Social Support OR MA Psychosocial Support Systems OR MA Interviews as Topic OR TX multidisciplinary biopsychosocial rehabilitation OR TX cognitive functional therapy OR TX pain neuroscience education OR TX mindfulness OR TX coping OR TX biopsychosocial OR TX motivational interviewing OR TX interdisciplinary

#3
TX randomized controlled trials OR TX controlled clinical trial OR TX randomized OR TX placebo OR TX drug therapy OR TX randomly OR TX trial OR TX groups OR TX human

#4. #1 AND #2 AND #3

Web of Science
TS=(((Spin* Diseases or Cauda Equina or Vertebrates or Hernia or Radiculopathy or whiplash disorder or Failed Back Surgery Syndrome Spinal Fusion or Backache or lumber stenosis or (lumbar or spine) surgery) AND (cognitive behavioral therapy or pain management or patient education or patient education or patient care management or Comprehensive Health Care or Pain Clinics or Social Support or Psychosocial Support Systems or Interviews or multidisciplinary biopsychosocial rehabilitation or cognitive functional therapy or pain neuroscience education or mindfulness or coping or biopsychosocial or motivational interviewing or interdisciplinary)) AND (random* controlled trial or controll* clinical trial))

PEDro
Abstract & Title: any
Therapy: behaviour modification, education, fitness training
Problem: pain
Body Part: head or neck, thoracic spine, lumbar spine, sacro-iliac joint or pelvis
Method: clinical tria