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Postsurgical rehabilitation for adults with low back pain with or without radiculopathy who were treated surgically: protocol for a mixed studies systematic review

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ABSTRACT

Introduction Surgical rates for low back pain (LBP) have been increasing in Europe, North America and Asia. Many patients treated surgically will require postsurgical rehabilitation. Little is known about the effectiveness of postsurgical rehabilitation interventions on health outcomes or about patients' experiences with these interventions.

Objectives To conduct a mixed studies systematic review of quantitative and qualitative studies regarding: (1) the effectiveness and safety of postsurgical rehabilitation interventions for adults with LBP treated surgically and (2) the experiences of patients, healthcare providers, caregivers or others involved with the rehabilitation.

Methods and analysis We will search MEDLINE, Embase, PsycINFO, CINAHL, the Index to Chiropractic Literature, the Cochrane Controlled Register of Trials and the Rehabilitation & Sports Medicine Source for peer-reviewed empirical studies published from inception in any language. Studies using quantitative, qualitative and mixed methodologies will be included. We will also search reference lists of all eligible articles. Data extraction will include type of presurgical pathology, indication for surgery, surgical procedure, how the intervention was delivered and by whom, context and setting. We will conduct a quality assessment of each study and consider study quality in our evidence synthesis. We will use a sequential approach at the review level to synthesise and integrate data. First, we will synthesise the quantitative and qualitative studies independently, conducting a meta-analysis of the quantitative studies if appropriate and thematic synthesis of the qualitative studies. Then, we will integrate the quantitative and qualitative evidence by juxtaposing the findings in a matrix.

Ethics and dissemination Ethical approval is not required for this knowledge synthesis. Findings will be disseminated through knowledge translation activities including: (1) presentations at national and international conferences and scientific meetings; (2) presentations to local and international stakeholders; (3) publications in peer-reviewed journals and (4) posts on organisational websites.

Strengths and limitations of this study

- This is the first systematic review of the quantitative and qualitative literature to examine the effectiveness and safety of postsurgical rehabilitation interventions in adults with low back pain with or without radiculopathy who were treated surgically.
- This review will consider studies with a broad range of rehabilitation interventions as described by WHO, and outcomes as described by the International Classification of Functioning, Disability and Health framework.
- This systematic review protocol follows the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines.
- This review has no language limitation in articles.
- This review is limited to published, peer-reviewed articles, and potential publication bias will not be assessed.

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INTRODUCTION

Rationale

Low back pain (LBP) is burdensome to patients, their families, healthcare systems and society.[1] LBP is the leading cause of years lived with disability globally, and may be associated with falls, occupational injuries or motor vehicle collisions.[2–7] It is a common condition, with a lifetime prevalence estimated at approximately 38.9% globally.[8] LBP may present with radiculopathy, whereby the patient experiences pain, weakness or numbness in the leg due to irritation of spinal nerve roots (eg, from foraminal stenosis or disc herniation).[9 10] LBP is also associated with high healthcare costs and frequent healthcare use.[5–7] Although most episodes

resolve, approximately 20% of adults with LBP experience chronic symptoms, functional limitations or difficulties participating in their communities or returning to work.[11 12]

A proportion of patients suffering from LBP undergo surgery, particularly those with persistent radicular symptoms. In the UK (population of about 63 million), approximately 10 000 lumbar disc excisions were performed in hospitals of the National Health Service from 2011 to 2012.[13 14] In the USA (population of about 287 million), approximately 280 000 lumbar discectomies were performed in 2002.[15] Surgical rates for these conditions have also increased over time. In England, the number of surgical procedures for degenerative lumbar spine disease nearly doubled between 1999 and 2013 (ie, from 25 to 49 per 100 000).[16] Similar trends have been reported in other regions, including in Asia and the USA.[17–22] The surgical rates for lumbar disc herniations have also increased over time. For instance, the number of lumbar disc surgeries increased twofold in South Korea from 2003 to 2008.[23]

Postsurgical rehabilitation refers to interventions provided following surgery, and is often recommended to patients who undergo lumbar spinal surgery. It is aimed at helping individuals, who are experiencing or likely to experience disability, achieve and maintain optimal functioning within their environments.[24] Rehabilitation programs can target improvements in individual functioning (eg, exercises, non-pharmacological or pharmacological therapies) or the individual's environment (eg, assistive devices, adaptations to the workplace). However, little is known about the effectiveness of postsurgical rehabilitation in managing patients' symptoms, function and return to activity. Few systematic reviews have synthesised the evidence in this area to better inform shared decision making related to postsurgical rehabilitation for LBP. A previous systematic review[25] examining the effectiveness of rehabilitation following lumbar disc surgery suggested that exercise programs starting 4–6 weeks postsurgery led to a faster decrease in pain and disability compared with no treatment. Better results were seen with high-intensity vs low-intensity exercise.[25] However, the authors noted that the overall quality of the evidence was low, and high-quality randomised trials were needed.[25] In another systematic review[26] that examined the effectiveness of rehabilitation following first-time lumbar disc surgery, authors reported strong evidence for considering intensive exercise programs 4–6 weeks following surgery. In two high-quality randomised controlled trials (RCTs),[27 28] intensive exercise programs were more effective in improving functional status and led to faster return to work during short-term follow-up (6 months) compared with mild exercise programs. However, there was no difference between intensive exercise programs and mild exercise programs with regard to improvement at the 12-month follow-up. Finally, evidence from a systematic review[29] examining the effectiveness of rehabilitation for lumbar stenosis indicated that active rehabilitation following decompression surgery was more effective than usual care in improving both short-term and long-term functional status.[29]

Healthcare providers implementing evidence-based postsurgical rehabilitation should also consider its effects on patient-important outcomes, such as return to work or meaningful activities. These outcomes should be informed by the International Classification of Functioning, Disability and Health (ICF) framework,[30] and by the experiences of those involved in rehabilitation such as patients, healthcare providers and caregivers. Additionally, little is known about individuals' experiences and perceptions about spine surgery and postsurgical rehabilitation.[31–33] Primary studies of patient experience provide a number of overlapping themes. Abbott *et al* explored patient experiences postlumbar fusion within the context of the ICF framework.[30] Patients' experiences were most frequently linked to psychological, sensory, neuromusculoskeletal and movement attributes, which correspond to the 'body function and structures' and 'activity' domains of the ICF framework.[30] Archer *et al* identified several factors based on patient interviews that could optimise recovery.[31] These include an ability to adjust expectations, acceptance of functional outcomes, setting realistic and achievable goals, provision of familial and friend support, being positive and realistic, working hard at rehabilitation and communicating with caregivers.[31] Rushton *et al* used focus group methodology to explore perceptions, preferences and feelings of the rehabilitation programme in patients who underwent lumbar discectomy and physiotherapy.[32] They found variation in patients' preferences for leaflet only, individual one-on-one or group physiotherapist led interventions, suggesting that a stepped care approach accounting for patient preferences may be of value when planning postsurgical spine rehabilitation programs.[32] Therefore, understanding patients' experiences and preferences with postsurgical care, as well as healthcare providers and other caregivers, may help explain the outcomes of postsurgical rehabilitation interventions and improve programme compliance and recovery rates.[34]

The previous systematic reviews have limitations and require updating. For example, the literature searches for the systematic reviews published in 2014 and 2003 ended in 2013 and 2000, respectively.[25 26 29] Some systematic reviews included randomised trials only, and thus may not have captured evidence from observational and qualitative studies potentially useful for informing programs and policy.[25 29] We are not aware of any systematic reviews of qualitative studies exploring experiences with postsurgical spine rehabilitation among individuals involved in rehabilitation. Qualitative evidence can help to illuminate the mechanisms through which interventions work.[35] Finally, the previous reviews focused on clinical rehabilitation. Our review will investigate rehabilitation from a clinical and community-based perspective, explore patients' and others' experiences and perspectives with such interventions, and then integrate these results into a unique practical matrix. To our best knowledge, there

are no systematic reviews examining the effectiveness of a wide range of postsurgical rehabilitation interventions (including community-based rehabilitation) in adults treated surgically for LBP. Furthermore, there are no reviews that combine the findings from different types of studies to produce a more comprehensive synthesis of the evidence on 'what works' for this population.

Objectives

Our overall objective is to systematically search, assess and synthesise quantitative and qualitative studies regarding the effectiveness and experiences of postsurgical rehabilitation interventions for improving pain, health, functioning and disability among adults with LBP treated surgically. Our review questions are:

1. What is the effectiveness and safety of postsurgical rehabilitation interventions for improving pain, function, disability and health outcomes in adults with LBP with or without radiculopathy who were treated with surgery?
2. What are patients', providers' and caregivers' experiences, views and opinions of postsurgical rehabilitation interventions delivered in any healthcare setting for adults with LBP with or without radiculopathy who were treated with surgery?
3. What can be hypothesised from the integration of the quantitative and qualitative evidence about the effectiveness and safety of postsurgical rehabilitation interventions in adults with LBP with or without radiculopathy who were treated with surgery?

We are targeting healthcare professionals and policy makers involved in delivering and planning postsurgical rehabilitation interventions. We aim to provide them with knowledge regarding effective and positively experienced interventions for adults treated surgically for LBP.

METHODS

We developed this systematic review protocol using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols[36] (online supplementary file 1). [37] We will report our systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[38]

Eligibility criteria

Population

We targeted studies including adults (aged 18 years and older) who underwent surgery for LBP with or without radiculopathy. We defined LBP as pain and discomfort below the costal margin and above the inferior gluteal folds, with or without referred leg pain.[39] Radiculopathy refers to inflammation, injury/dysfunction or compression of the spinal nerve roots that can present as pain, weakness or altered sensation in a myotomal or dermatomal distribution. Lumbar radiculopathy may be attributed to spinal stenosis (narrowing of the spinal or foraminal canals) or lumbar disc herniation (localised displacement of disc material beyond the normal margins of the intervertebral disc space).[10 40]

Intervention

The quantitative component of this review included studies that investigated the effectiveness of postsurgical spine rehabilitation interventions or programs of care initiated within the first 3 months after surgery. The WHO defines rehabilitation as a set of interventions that assist individuals who experience, or are likely to experience, disability to achieve and maintain optimal functioning when interacting with their environments.[24]

Postsurgical rehabilitation interventions include rehabilitation medicine/therapy, which aims to: (1) improve function through the diagnosis and treatment of health conditions, reducing impairments, preventing or treating complications and (2) restore and compensate loss of functioning, and prevent or slow deterioration in functioning in every area of a person's life.[24] Rehabilitation interventions may also include assistive technology, which refers to any item, piece of equipment, or product used to increase, maintain or improve functional capabilities.[24] Postsurgical rehabilitation interventions can be provided by different healthcare providers including, but not limited to, general practitioners, orthopaedic surgeons, physiotherapists, chiropractors and occupational therapists. Examples of postsurgical rehabilitation interventions include, but are not limited to (table 1):

1. Patient education and self-management.
2. Compensatory strategies, training and exercises (eg, stretching, strengthening, range of motion; supervised or unsupervised; aerobic or anaerobic exercises).
3. Manual therapies (eg, manipulation, mobilisation, traction, soft tissue therapy).
4. Passive physical modalities (eg, ultrasound, interferential current therapy, transcutaneous electrical nerve stimulation).
5. Acupuncture (eg, needle acupuncture, electroacupuncture, acupressure).
6. Pharmacological interventions used in the rehabilitation period (ie, not intended to alleviate procedural/surgery-related pain) (eg, non-steroidal anti-inflammatory drugs, acetaminophen, muscle relaxants, routes of administration include topical, oral or injected).
7. Social support and advice.
8. Psychological interventions (eg, cognitive behavioural therapy).
9. Modifications to the environment.[41 42]
10. Provision of resources.
11. Adaptation of workplace.
12. Assistive technologies (eg, crutches, orthoses, braces or wheelchairs for people with mobility impairments).

Comparators

The quantitative component of this review considered comparisons including other interventions, placebo or sham interventions, wait list and no intervention.

Table 1 Examples of selected interventions for rehabilitation

Intervention	Definition	Examples
Patient education and self-management	Teaching patients skills that they can use to manage their health condition	► Learning disease-specific information ► Learning general managing skills (eg, problem solving, finding and using community resources, working with healthcare team) ► Learning strategies to increase confidence (ie, self-efficacy) in ability to engage in behaviours that are needed to manage their condition on a daily basis ► Adequate peer role models and support networks that facilitate the initiation and maintenance of desired behavioural changes
Exercise	A subcategory of physical activity that is planned, structured, repetitive and purposeful; can be supervised (eg, by a healthcare professional) or unsupervised	► Stretching ► Strengthening ► Range of motion exercises ► Aerobic (eg, swimming, cycling, walking, running) ► Anaerobic (eg, jumping, sprinting, weight lifting)
Manual therapies	Manipulation: techniques incorporating a high-velocity low-amplitude impulse or thrust applied at or near the end of a joint's passive range of motion Mobilisation: techniques incorporating a low-velocity and small or large amplitude oscillatory movement, within a joint's passive range of motion Traction: manual or mechanically assisted application of an intermittent or continuous distractive force Soft tissue therapy: a mechanical form of therapy where soft-tissue structures are pressed and kneaded, using physical contact with the hand or mechanical device	► Lumbar manipulation, mobilisation or traction ► Massage ► Muscle energy technique ► Strain counterstrain
Passive physical modalities	A form of cold, heat or light application affecting the body at the skin level or ultrasonic or electromagnetic radiation affecting structures beneath the skin surface: Passive assistive devices: device to encourage immobilisation in anatomic positions or actively inhibit or prevent movement	► Heat application: heat pack, hydrotherapy ► Cryotherapy: cold pack, vapocoolant spray ► Low-level laser ► Electrical muscle stimulation ► Pulsed electromagnetic therapy
Acupuncture	Any body needling, moxibustion, electric acupuncture, laser acupuncture, microsystem acupuncture and acupressure	► Traditional needling ► Dry needling ► Burning of specific herbs ► Electroacupuncture ► Photoacupuncture
Pharmacological interventions	A substance used in treating disease or relieving pain	► Acetaminophen ► Nonsteroidal anti-inflammatory drugs ► Muscle relaxants ► Antidepressants
Psychological interventions	Activities used to modify behaviour, emotional state or feelings	► Cognitive behavioural therapy ► Counselling ► Social network and environment-based therapies ► Psychoeducational interventions ► Mindfulness meditation
Assistive technologies	Any item, piece of equipment or product system, used to increase, maintain or improve the functional capabilities of people with disabilities	► Walking aids ► Orthoses ► Braces ► Wheelchairs

Outcomes

The quantitative component of this review considered studies that included outcomes related to pain, functioning, disability and health as described by the ICF framework, as well as adverse events (table 2).[43] These will include:

1. Body function and structure (to describe a person's impairment).
   a. Examples of constructs include: pain (eg, intensity, frequency, duration), range of motion, psychological and experiential outcomes (eg, depression, anxiety).

Table 2 Definitions from the International Classification of Functioning, Disability and Health

Term	Definition
Body functions	Physiological functions of body systems (including psychological functions)
Body structures	Anatomical parts of the body such as organs, limbs and their components
Impairments	Problems in body function or structure such as a significant deviation or loss
Activity	Execution of a task or action by an individual
Participation	Involvement in a life situation
Activity limitations	Difficulties an individual may have in executing activities
Participation restrictions	Problems an individual may experience in involvement in life situations
Environmental factors	External contextual factors that make up the physical, social and attitudinal environment in which people live and conduct their lives
Personal factors	Internal contextual factors that influence how disability is experienced by the individual

   b. Examples of tools to measure constructs: Numeric Rating Scale or Visual Analogue Scale to measure pain intensity[44–46]; goniometer to measure range of motion; Centre for Epidemiologic Studies Depression Scale[47] or Beck Depression Inventory to measure depressive symptoms.[48 49]
2. Activity and participation (to describe a person's functional status, health-related quality of life).
   a. Examples include disability, communication, mobility, interpersonal interactions, preferences, self-care, learning, applying knowledge, return to work/activities/school.
   b. Examples of tools to measure constructs: Roland-Morris Low Back Pain and Disability Questionnaire[39] or Oswestry Disability Index to measure disability[50]; 36-item Short Form Survey (SF-36)[51] or EuroQol-5D (EQ-5D)[52] for quality of life.
3. Additional surgeries.
   a. Examples include revision surgeries, surgeries for complications.
4. Adverse events.
   We define adverse events as any unfavourable sign, symptom or disease temporarily associated with the treatment, whether or not caused by the treatment.[53] We will also consider indirect harms, where the use of an intervention delays a diagnosis or treatment, and such delay holds a potential harm.[54]

Phenomena of interest

The qualitative component of this review considered studies that explore the experiences, views and opinions (eg, perceived benefits and challenges) regarding postsurgical rehabilitation interventions related to surgery for LBP with or without radiculopathy among patients, healthcare providers, caregivers and others involved with postsurgical rehabilitation.

Study design

We will conduct a mixed studies review.[55] This design integrates quantitative, qualitative and mixed methods studies, providing a rich, detailed understanding of complex health interventions and programs.[56] We included studies published in peer-reviewed journals and representing a range of methodologies: randomised controlled studies (minimum 30 participants per arm at baseline), cohort studies and case–control studies (minimum 100 participants per group at baseline), qualitative and mixed method studies. A sample size of 30 in randomised controlled studies is conventionally considered the minimum needed for non-normal distributions to approximate the normal distribution.[57] The assumption that data are normally distributed is required to ascertain a difference in sample means between treatment arms. In cohort and case–control studies, a sample of 100 is conventionally considered the minimum needed to obtain well-balanced groups at baseline and control bias (especially confounding by indication). Qualitative studies included phenomenology, grounded theory, ethnography, action research and descriptive qualitative studies, or any qualitative methodologies that explore patients', providers' or others' experiences with postsurgical rehabilitation related to surgery for LBP with or without radiculopathy. Mixed methods studies were only considered if data from the quantitative or qualitative components could be clearly extracted.

Context and setting

We considered postsurgical rehabilitation interventions/programs of care delivered in any healthcare organisation within a metropolitan or non-metropolitan (regional, rural and remote) area and in any healthcare setting (eg, acute care, hospital, primary healthcare, rehabilitation clinics), or in the community. Community-based rehabilitation is implemented through the combined efforts of people with disabilities, their families and communities, relevant government and non-government health, education, vocational, social and other services (eg, workplace interventions, advocacy programme).[58]

Exclusion criteria

We excluded: (1) studies of patients with LBP with or without radiculopathy attributed to major structural or systemic pathology (eg, fracture, infection, tumour, osteoporosis, inflammatory arthritides and cauda equina syndrome); (2) studies of patients with failed back surgery syndrome defined as surgical end-stage after one or several surgical interventions to relieve LBP with or without radiculopathy without positive effect[59]; (3) studies assessing pharmacological interventions for procedural pain control alone immediately postsurgery; (4) studies assessing postsurgical rehabilitation interventions solely conducted at the societal level, such as barrier removal

initiatives (eg, fitting a ramp to a public building); (5) study designs including pilot studies assessing feasibility, protocol studies, cross-sectional studies, case reports, case series, systematic reviews and other review papers, clinical practice guidelines, biomechanical studies, laboratory studies, cadaveric or animal studies and conceptual papers and (6) publication types including letters, editorials, commentaries, unpublished manuscripts, dissertations, government reports, books and book chapters, conference proceedings, meeting abstracts, lectures and addresses, consensus development statements and guideline statements.

Information sources

We developed the search strategy in consultation with an experienced health sciences librarian. The search was reviewed by a second experienced health sciences librarian using the Peer Review of Electronic Search Strategies Checklist.[60 61] We conducted an electronic search of the following databases from database inception: MEDLINE (Ovid), Embase (Ovid), PsycINFO (Ovid), CINAHL (Cumulative Index to Nursing and Allied Health Literature, EBSCO*host*), the Index to Chiropractic Literature (Chiropractic Library Collaboration), the Cochrane Controlled Register of Trials (Ovid) and the Rehabilitation & Sports Medicine Source (EBSCO*host*). We will also search the reference lists of all eligible articles for additional relevant studies. We included studies in any language and will use professional medical translation services where required.

Search strategy

The searches included a combination of subject headings specific to databases (eg, MeSH in MEDLINE) and free text words to capture the key concepts of postsurgical rehabilitation and LBP with or without radiculopathy (online supplementary file 2).

Patient and public involvement

Patients were not involved with the design of our study. However, our research questions and outcomes stemmed from our collective clinical experiences and encounters with patients with LBP who received surgery. We also included qualitative studies with an aim of capturing patients' and caregivers' experiences and preferences regarding postsurgical interventions. Public consultation will be conducted during the guidelines development phase of this project.

STUDY RECORDS

Data management

Electronic search results were downloaded into Endnote X9 reference manager software (Clarivate Analytics, Philadelphia, Pennsylvania, USA). We removed duplicates and the remaining references were uploaded to the Evidence for Policy and Practice Information (EPPI) and Coordinating Centre Reviewer software for the data extraction stages (EPPI-Reviewer V.4, UCL Institute of Education, University of London, UK). EPPI-Reviewer software stores references, manages and monitors the data extraction process and provides an audit trail for the review.[62]

Selection process

First, paired reviewers independently screened titles and abstracts for assessment against the inclusion and exclusion criteria. Second, the reviewers independently assessed the full text of each selected article to confirm its inclusion in the study. Disagreements related to the inclusion of any article were discussed and resolved, involving a third reviewer if necessary. We conducted training exercises prior to initiating the screening process to ensure high inter-rater reliability. Review members have been meeting weekly to discuss the progress of the screening process and any unanticipated problems.

Data items and data extraction process

Paired reviewers will independently extract the data from all eligible studies. The data extracted will include details about: (1) populations: sociodemographic information (eg, age, sex, gender, education, occupation, culture), health status (eg, comorbidities, previous surgeries), geographical region, type of presurgical pathology (eg, herniated nucleus pulposus, spondylolisthesis and spinal stenosis), indication for surgery (eg, acute/subacute/chronic LBP with or without radiculopathy), surgical procedure (eg, microdiscectomy, decompressive laminectomy/laminotomy/foraminotomy, spinal fusion); (2) study methods; (3) interventions: type (eg, resistance exercise, manual therapy, modalities), setting (eg, hospital, community), temporality (time of initiation after surgery), type of healthcare provider(s) delivering intervention, duration (eg, 4 weeks, 3 months), dosage (eg, 3 times per week); (4) comparators; (5) phenomena of interest or outcomes of significance to the review objective linked to corresponding ICF categories (body functions and structures, activity and participation, and environmental and personal factors) by established linking rules,[63–65] additional surgeries and adverse events; (6) key findings stratified according to patient characteristics, presurgical pathology, type of surgical intervention and specific type of postsurgical rehabilitation therapies or programs of care, where possible and (7) methodological quality of studies. If multiple outcome measures are used to assess one construct, we will stratify our analyses by outcome measures and describe how the results vary. We will report the unit of analysis of adverse events as reported by the study authors (eg, proportion of participants that experienced adverse events or number of adverse events experienced). Paired reviewers will pretest the data extraction form and revise as needed. EPPI-reviewer software will be used to manage the data extraction process.

Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer.

Authors of papers will be contacted to request missing or additional data, where required.

Quality assessment

We will assess the quality of studies using the Scottish Intercollegiate Guidelines Network (SIGN) criteria for RCTs, cohort studies and case–control studies[66]; the Joanna Briggs Institute (JBI) critical appraisal checklist for qualitative studies[67] and the Mixed Methods Appraisal Tool (MMAT) for mixed methods studies.[68] The SIGN checklists allow reviewers to assess internal validity by considering the impact of selection bias, information bias and confounding on study results. The JBI checklist allows reviewers to assess the possibility of bias in qualitative studies' design, conduct and analysis. The MMAT allows reviewers to assess the interdependent qualitative and quantitative components of the study and criteria to consider, such as justification for mixing evidence, and appropriate ways of integrating the data. We will categorise the validity or credibility of each study as either acceptable or unacceptable. Authors of papers will be contacted to request missing or additional data for clarification where required. Paired reviewers will independently assess the selected studies for quality. Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer.

DATA

Data synthesis

We will use a sequential approach at the review level to synthesise and integrate the data.[35] This will involve separate quantitative and qualitative synthesis followed by integration of the resultant quantitative and qualitative evidence. We will interpret the findings in consideration of study quality.

Quantitative synthesis

Clinical, methodological and statistical (using the I^2 statistic)[69] heterogeneity among studies will be assessed. Clinical heterogeneity may result from differences in populations, interventions, comparators or outcomes across studies. Methodological and statistical heterogeneity may result from differences in risk of bias and differences in outcomes across studies beyond what could be expected by chance alone. Methodological heterogeneity across studies will be assessed based on the overall judgement from SIGN as low or moderate (acceptable) vs high (unacceptable) risk of bias. Statistical heterogeneity will be assessed using the I^2 statistic, whereby I^2 of <25%–50% will be considered low to moderate (homogeneous) and ≥50% considered high (heterogeneous).[69] Where possible, data will be pooled with statistical meta-analysis using EPPI-Reviewer software. Where statistical pooling is not possible (ie, if there is clinical, methodological and statistical heterogeneity), the findings will be presented qualitatively according to the principles of best evidence synthesis.[70] We will use data provided in the studies to measure the association between tested interventions and outcomes by computing the relative risk and its 95% CI where this information is available. Similarly, we will compute the difference in mean change between groups and 95% CI to quantify the effectiveness of interventions. The computation of the 95% CI for the difference in mean change is based on the assumption that the preintervention and postintervention outcomes are highly correlated (r=0.8).[71 72] We will interpret the evidence on the effectiveness of postsurgical rehabilitation interventions by determining whether an intervention was superior, equal or inferior to a comparison intervention.

Qualitative synthesis

We will use thematic synthesis to synthesise the qualitative research findings.[73 74] First, verbatim study findings will be entered into a database (EPPI-Reviewer). Pairs of trained reviewers will then independently code each line of text and develop descriptive themes according to its meaning and content, and subsequently generate analytical themes to answer our review questions. Reviewers will finalise the descriptive and analytical themes through discussion.

Integration of quantitative and qualitative evidence

We will juxtapose findings using a matrix to compare and contrast the findings across the syntheses in the review. The use of a matrix will allow us to explore heterogeneity in the findings of the quantitative studies and may indicate why some interventions may be effective and safe, and some may not.[35] For example, we may list themes from the qualitative synthesis along one side of the matrix, and then plot the interventions evaluated in the quantitative synthesis against the themes as either a match (when the intervention matched a theme) or a mismatch (when the intervention was the opposite of a theme). We will identify gaps in knowledge if a particular theme for an intervention does not match with any of the interventions evaluated in the quantitative studies.

DISSEMINATION

We will collaborate with our national and international consultants and knowledge users, who include decision makers and managers, healthcare and other service providers, patients and their caregivers. In addition to this mixed studies review, we will provide clinical scenarios and demonstrate how healthcare providers and others can apply this evidence in an effort to improve patient health, function and disability outcomes after LBP surgery. Knowledge translation activities will include ongoing consultation and feedback between knowledge users and the research team during preparation of our project deliverables; presentations in national and international conferences and scientific meetings; presentations to local and international stakeholders; publications in peer-reviewed journals; posts and lay language summaries on organisations' websites (open access).

DISCUSSION

Findings from this mixed studies review will advance our knowledge on the effectiveness and safety of a wide range of postsurgical rehabilitation interventions for LBP, as well as improve our understanding of patients' and other key individuals' experiences and perceptions of rehabilitation interventions. This work will provide the evidentiary basis to develop user-friendly care pathways outlining evidence-based postsurgical rehabilitation, which can be adapted for specific settings (eg, hospitals, rehabilitation clinics and workplaces) and geographical regions prior to implementation. Specifically, postsurgical rehabilitation interventions that are identified as effective, safe and positively experienced could be considered by patients, their families and caregivers, healthcare providers and other stakeholders (eg, workplaces) during shared decision making. In contrast, interventions that are identified as ineffective (eg, leading to outcomes no better than comparison interventions) or even harmful, and negatively experienced, should not be considered when planning the postsurgical rehabilitation programme of care. Moreover, we will map findings to the ICF framework to allow healthcare providers and stakeholders to use standardised language in the assessment and management of individuals during their postsurgical rehabilitation programme. This may further facilitate improvements in postsurgical functioning, disability and health outcomes in this patient population.

Our review has potential limitations. We included only published, peer-reviewed studies; therefore, publication bias is possible. Our literature search strategies may have missed potentially relevant studies. However, we tried to mitigate this by having a second experienced health sciences librarian peer review the searches, and searching reference lists of eligible studies. Finally, we excluded RCTs with fewer than 30 participants per treatment arm. This may have omitted potentially relevant studies; however, this minimum sample size is recommended to apply central limit theorem for non-normal distributions to approximate normal distributions.[57]

Findings from our review will guide future research by identifying both the methodological limitations of previous studies, and the knowledge gaps in the current scientific literature. Future studies can be designed to minimise these methodological limitations and address key knowledge gaps to further advance our understanding of the role of postsurgical rehabilitation for patients with LBP. This novel interpretation of quantitative and qualitative evidence according to the ICF framework serves as a model for how outcomes related to pain, functioning, disability and health can be prioritised in future research.[6]

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