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Effectiveness of a physiotherapy self-management programme for adult patients with chronic non-specific low back pain in low- and middle-income countries: protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Chronic non-specific low back pain (CNLBP) is among the most common musculoskeletal system conditions reported worldwide; however, few studies are available from low- and middle-income countries (LMICs). Self-management is a set of tasks performed by the patient aiming at managing their symptoms and interference in activities, mood and relationships due to pain. A physiotherapy-guided self-management programme (SMP) following a biopsychosocial approach has been reported as effective and affordable in the management of CNLBP in high-income countries. The objective of this systematic review is to determine the overall effectiveness of SMPs for adults with CNLBP in LMICs.

Methods and analysis In this systematic review, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Protocol (PRISMA-P) guidelines will be followed. A three-step search strategy will be used to search the electronic databases (PubMed, MEDLINE, SPORTDiscus, Scopus and CINAHL, Academic Search Complete and PEDro) for randomised controlled trials assessing the effectiveness of physiotherapy-guided self-management for CNLBP among adult participants in LMICs. The processes of screening search results for eligible studies, extracting data from included studies and appraising will be done independently by at least two review authors. Random effects meta-analysis will be used to synthesise results and heterogeneity will be assessed using the I^2 test statistic and χ^2 test.

Ethics and dissemination Ethics clearance was obtained for the broader PhD study on the development of a physiotherapy-guided SMP for adult people with CNLBP in Limpopo Province, South Africa. The results of the manuscript for this protocol will be published in peer-reviewed journals and also presented at conferences, symposia, and congresses.

PROSPERO registration number CRD42023399572.

STRENGTH AND LIMITATIONS OF THIS STUDY

⇒ This is a protocol to conduct a systematic review of the effectiveness of physiotherapy-guided self-management interventions in low- and middle-income countries (LMICs). This summary of evidence can be used to develop a physiotherapy-guided self-management programme within the LMICs.
⇒ The language restriction will not be applied to the selection of studies. This will reduce the risk of bias and enhance the study findings.
⇒ Compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Protocol checklist and the Cochrane handbook guide will be used for methodological rigour.
⇒ The operationalisation of the search strategy will be developed by an experienced librarian and tailored to six large databases.
⇒ The possibility of limited studies and the low quality of some studies may affect the outcome or evidence of this systematic review.

INTRODUCTION

Chronic non-specific low back pain (CNLBP) is one category of low back pain (LBP). According to the WHO, CNLBP or LBP is the most common musculoskeletal condition globally with a high prevalence and leading cause of disability, especially in low- and middle-income countries (LMICs).[1] It was also projected that the number of people with LBP will increase in the future and even quicker in LMICs.[1 2] CNLBP is a musculoskeletal condition that is not attributable to a recognisable or known specific pathology (eg, infection, tumour, fracture, structural deformity, inflammation disorder, radicular syndrome or equine syndrome) and persists for more than 12 weeks.[3] According to the classification of low back pain (LBP) attached in figure 1, recurrent low back pain (RLBP) and persistent low back pain (PLBP) form part of CNLBP. In the current systematic

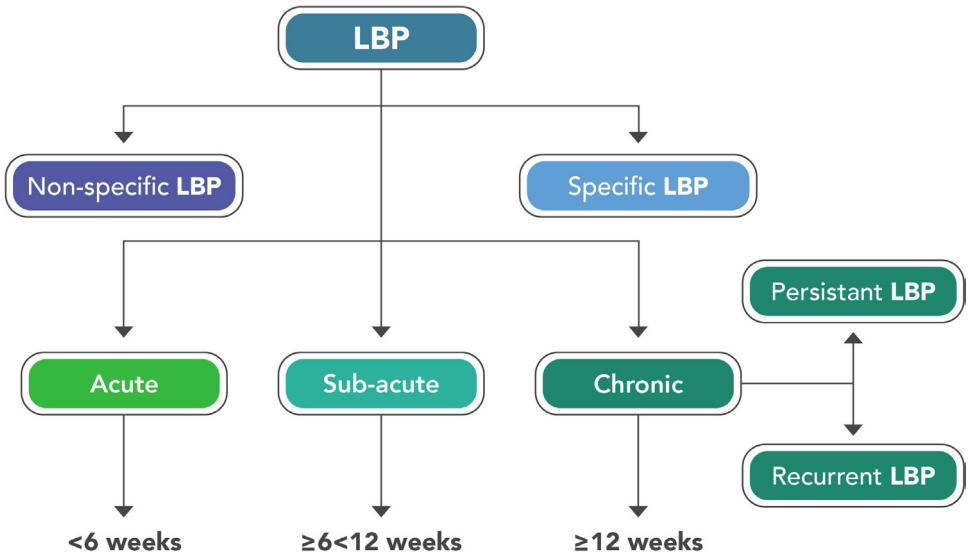

Figure 1 Classification of low back pain (LBP).

review, the CNLBP is defined as LBP that persisted for at least more than 3 months excluding known specific pathologies and including RLBP and PLBP. According to World Bank Atlas methods, low-income countries are defined as those countries with a gross national income (GNI) per capita, calculated using the World Bank Atlas method, of $1,135. On the contrary, middle-income countries are those with a GNI per capita, of more than $4,446 but less than $13,845.[4]

Rehabilitation, in its essence, is a set of interventions needed when a person is experiencing limitations in everyday physical, mental and social functioning due to ageing or a health condition, including chronic diseases or disorders, injuries or trauma.[1 2] The WHO has proposed non-drug, non-surgical approaches as the first line of treatment for LBP, including education on pain management, manual therapies and exercise rehabilitation. This type of rehabilitation is an important element in addressing the global burden of musculoskeletal conditions, including LBP.[2] A recent clinical guideline recommended the biopsychosocial approach or self-management as the best management for CNLBP.[5] The biopsychosocial approach consists of three components, namely, biological (associated with the relationship of disease and body health), psychological (aspects of mental and emotional wellness that also relate to behaviour) and social (interpersonal factors such as social interactions and community activities).[6 7] This approach was also used by the WHO to publish its International Classification of Functioning, Disability and Health (WHO ICF).[8] In addition, a biopsychosocial approach has been broadly used in research on rehabilitation and disability, which includes chronic pain and functional disorder.[9 10]

However, the implementation of physiotherapy-guided self-management is challenging, particularly in LMICs.[5] The physiotherapy-guided self-management programme (SMP) should include both biomedical and psychosocial elements, where the biomedical elements tend to be the current standard of care approach, that is, electrotherapy, myofascial release and mobilisation.[11 12] Literature on the biopsychosocial approach as management of chronic musculoskeletal conditions exists; however, research on this approach in CNLBP in LMICs is lacking.[5 13–16] The current literature, including reviews done in LMICs for the management of CLBP or LBP and the implementation of the available treatment guidelines, is limited.[5 14] A preliminary literature search was done in the Cochrane Database of Systematic Reviews and the JBI Database of Systematic Reviews and Implementation Reports, and no systematic reviews were found on this topic.

A physiotherapy-guided self-management approach has been reported as the best intervention for chronic disease including chronic low back pain, and it also improves clinical disease parameters (eg, improvement after stroke) and lowers the cost when the patients are actively participating in an SMP.[17 18] Despite the importance of physiotherapy-guided self-management interventions, there is a dearth of studies done on this topic, particularly on the effectiveness of physiotherapy-guided self-management interventions for CLBP in LMICs.[19] The systematic review on the effectiveness of physiotherapy-guided self-management may therefore benefit the patients with CNLBP in LMICs by improving their condition and reducing the costs of hospital visits. The findings of the current systematic review will be used to guide the development of a physiotherapy-guided SMP for people with CNLBP in LMICs.

Aim

The aim of this systematic review is to investigate the effectiveness of existing physiotherapy-guided self-management interventions on pain and disability outcomes for adults (>18 years) with CNLBP living in LMICs.

Objectives

- To determine the effectiveness of physiotherapy-guided self-management interventions on outcomes (pain, disability, self-efficacy, and quality of life) for adults with CNLBP living in LMICs?
- To determine if there are differences in effectiveness, depending on the components of physiotherapy-guided self-management interventions for adults with CNLBP living in LMICs?
- To determine if there are differences in effectiveness depending on participant characteristics such as age and gender?

METHODS

Protocol design, reporting and registration

The systematic review will be guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines for systematic reviews, which comprises eligibility criteria (participants, interventions, comparators, outcomes and context), search strategy, study selection, assessment of methodological quality, data extraction, synthesis and assessing certainty in the findings.[20] (Refer to the supplementary documents, online supplemental appendix 1) This systematic review is registered with the international database of a prospectively registered systematic review with a health-related outcome (PROSPERO) for the benefit of peer review, reducing duplication effort and increasing the transparency of research.[21] The registration number for this review protocol on PROSPERO is CRD42023399572.

Eligibility criteria

Type of studies

Any study published from the onset to the current date that has information on the effectiveness of physiotherapy-guided self-management interventions for CLBP among adults in LMICs will be included in this study such as experimental study designs, randomised controlled trials ((RCTs) with concealed allocation), pseudo randomised control trials (RCT without concealed allocation), non-RCTs and quasi-experimental studies (experimental study without randomisation).

Studies will be included without language restrictions. Descriptive and correlational quantitative research, qualitative studies and clinical guidelines will be excluded from this study.

Expert opinions and published systematic reviews will only be used for bibliographic checks to ensure that any eligible studies are not omitted.

Study setting

Only studies that are conducted in LMICs as defined by the World Bank will be included.

Study participants

All studies that include adults who are 18 years of age and older with CNLBP will be included in this study.

Types of interventions

Physiotherapy-guided self-management strategies for the management of CNLBP that follow a biopsychosocial approach will be considered, for example, pain neuroscience education (PNE), digital health intervention (DHI), behaviour change theory (brief motivational interviewing), physiotherapy training (including physiotherapists who will administer the SMP to patients) and various forms of exercise training.[22–25] The intervention can be a prescribed education programme, physiotherapy-led intervention or a multidisciplinary intervention that targets an individual or a group of individuals. The biopsychosocial approach in physiotherapy-guided self-management entails a therapist using a combination of biological, psychological and social factors in treatment. The biological aspect may involve exercises, activities or self-treatment methods such as heat therapy. On the contrary, the psychosocial component focuses on educating and empowering patients to enhance self-efficacy, self-control and self-responsibility. This may also involve exposure to feared activities, encouraging social participation and other related interventions. The non-physiotherapy treatment regime (outside the scope of physiotherapy profession interventions) either used as the intervention or control will be excluded.

Types of control

The intervention should be compared with the standard of care (no treatment or intervention or no change in usual activities of care).

Types of outcomes

Primary outcome

Self-efficacy (self-efficacy scale), Patient-Specific Functional Scale and Health-Related Quality of Life (HRQL).

Secondary outcome

Pain (Visual Analogue Scale or Numerical Pain Rating Scale) and disability (Oswestry or modified Oswestry, Roland Morris, and Quebec disability).

Definitions of concepts

Physiotherapy-prescribed SMPs as an intervention in CNLBP can be described in different terms which include a biopsychosocial approach, rehabilitation and standard treatment guidelines ((STGs) examples of interventions include home exercise programmes).

- Chronic non-specific low back pain is defined as LBP that persists for at least more than 3 months excluding known specific pathology and includes both RLBP and PLBP.
- Self-management is a set of tasks performed by the patient aimed at managing their symptoms, and interference in activities, mood and relationships due to pain.[25] A physiotherapy-guided SMP comprises both biomedical and psychosocial elements, where the biomedical elements tend to be the current standard of care approach.

- Rehabilitation is the process across the continuum of care in the lifespan of a person with a disability that aims to maximise function and participation in key aspects of life within the individual environment.[26] This process can include patient-orientated therapy, exercise training, family support, counselling, modification of the environment and self-management strategies.
- STGs are systematically developed statements to help practitioners or prescribers decide about treatments to be used for specific clinical conditions.[27] This includes information on clinical features, diagnostic criteria, non-drug and drug treatments (first, second and third line), as well as referral criteria.
- The biopsychosocial approach is an approach to delivering treatment for conditions that incorporates biological, psychological and social factors. This approach views health and illness as the product of biological characteristics (genes), behavioural factors (lifestyle, stress, health beliefs) and social conditions (cultural influences, family relationships, social support).[28]

Search strategy

The information sources will be searched from different databases at two levels: (1) electronic database searching and (2) physical searching from the reference lists and citations of the included sources. The electronic databases will include PubMed, MEDLINE, SPORTDiscus, Scopus and CINAHL, Academic Search Complete and PEDro. A pilot search was conducted on 21 February 2023 from the period of inception to date and this will be refined to establish the final search strategies for the respective databases. Physical hand-searching for all included sources and reference lists for all included studies will also be conducted. The search will not be limited by language and where necessary services of a translator will be utilised. The absence of an inception date for searches is chosen to be appropriate in this systematic review based on the limited studies done on physiotherapy-guided self-management for adults with CNLBP in LMICs.[15]

The search strategies will be drafted with the assistance of the co-author (KK), an experienced information specialist. During the process of drafting, other information specialists will conduct a peer review using the Peer Review of Electronic Search Strategies (PRESS) checklist.[29] The recommendations from the other information specialists and systematic review experts will be taken into consideration during the refining or amending of the final search strategies.

A three-step search strategy will be used to search the databases. The initial search of Academic Search Complete, MEDLINE PubMed, EBSCOhost, Scopus and CINAHL will be conducted, followed by an analysis of the text words in the title and abstract of the retrieved papers and of the index terms used to describe the articles. A second search using all identified keywords and index terms will then be undertaken across all included databases. Third, the reference lists of all identified reports and articles will be searched for additional relevant studies. If more information is required from the selected studies, the authors of primary studies or reviews will be contacted. A pilot search was conducted in Academic Search Complete to identify the possibility of conducting the proposed systematic review (refer to table 1).

Study selection

Following the database search, articles with relevant titles will be exported to an Endnote 20 library and duplicates will be removed. Screening will be conducted using Rayyan, a web-based systematic review software.[30] The screening will be conducted by two independent reviewers. Initially, a calibration exercise will be employed to ensure that the inclusion and exclusion criteria are clear for all screeners. The first 10 articles will be screened and agreement assessed before proceeding with all of the articles. We will begin with the title and abstract screening. Disagreements at this stage will be resolved through discussions by the two reviewers until a consensus is reached. We will then proceed with full article screening for the included articles. Disagreements at this stage will be resolved by inviting a third reviewer to make a final decision on inclusion or exclusion of the conflicting articles among the two reviewers. The studies that do not meet the inclusion criteria will be excluded, and the reason for the exclusion will be stated. The process of study selection will be presented in the PRISMA flow diagram attached in figure 2.[20]

To determine the inter-rater level of agreement between the two reviewers, Cohen's kappa statistic will be calculated. The kappa statistic will be interpreted as follows: <0.1 will represent no agreement and 0.10–0.20 will represent none to the slight agreement, 0.21–0.40 will represent fair agreement, 0.41–0.60 will represent moderate agreement, 0.61–0.80 will represent substantial agreement and 0.81–1.00 will represent almost perfect agreement.

Assessment of methodological quality

A Cochrane Collaboration revised tool of Risk of Bias (RoB 2.0) will be used by two reviewers to assess the RoB independently for all the included studies. If there is disagreement, a third reviewer will be consulted. The RoB 2.0 tool covers five domains: (1) randomisation sequence, (2) allocation concealment, (3) blinding, (4) completeness of outcome and (5) selective outcome reporting, and it also classifies the studies into the low, high or unclear RoB.[31] The non-randomised controlled trial (NRCT) will be assessed using the ROBINS-I tool, given that it is particularly useful for systematic reviews that include NRCT studies of intervention.[32] This tool is guided through seven chronologically arranged bias domains at pre-intervention, intervention and post-intervention, and the interpretation of domain level. Overall bias risk judgement in ROBIN-I is classified as low, moderate, serious or

Table 1 Results of pilot search strategy

Search date	Query	Database	Records retrieved
21 February 2023	'Self-management treatment program*' OR 'Self-management program*' OR 'Self management treatment program*' OR '"Self management program*' OR therapy OR therapeutics OR self- manag* OR 'self manag*' OR self-car* OR 'self car*') AND ('chronic nonspecific low back pain' OR 'Chronic non-specific low back pain' OR 'Chronic Low back pain' OR 'non-specific low back pain') AND ('low- and middle-income countr*' OR 'low and middle income countr*' OR 'low-middle income countr*' OR 'low middle income countr*' OR 'Low income countr*' OR 'Middle income countr*' OR Afghanista OR Albania OR Algeria OR Angola OR Antigua OR Argentina OR Armenia OR Azerbaijan OR Bangladesh OR Belarus OR Benin OR Bhutan OR Bolivia OR Bosnia and Herzegovina OR Botswana OR Brazil OR Burkina Faso OR Burundi OR Cabo Verde OR Cambodia OR Cameroon OR Central African Republic OR Chad OR China OR Colombia OR Comoros OR Democratic Republic of Congo OR Congo OR Costa Rica OR Côte d'Ivoire OR Cuba OR Djibouti OR Dominica OR 'Dominican Republic' OR Ecuador OR Egypt OR 'El Salvador' OR 'Equatorial Guinea' OR Eritrea OR Eswatini OR Ethiopia OR Fiji OR Gabon OR Gambia OR Georgia OR Ghana OR Grenada OR Guatemala OR Guinea OR 'Guinea-Bissau' OR Guyana OR Haiti OR Honduras OR India OR Indonesia OR Iran OR Iraq OR Jamaica OR Jordan OR Kazakhstan OR Kenya OR Kiribati OR Democratic People's Republic of Korea OR Kosovo OR Kyrgyzstan OR Lao People's Democratic Republic OR Lebanon OR Liberia OR Libya OR Madagascar OR Malawi OR Malaysia OR Maldives OR Mali OR 'Marshall Islands' OR Mauritania OR Mauritius OR Mexico OR Micronesia OR Moldova OR Montenegro OR Montserrat OR Morocco OR Mozambique OR Myanmar OR Namibia OR Nauru OR Nepal OR Nicaragua OR Niger OR Nigeria OR Niue OR 'North Macedonia' OR Pakistan OR Palau OR Panama OR 'Papua New Guinea' OR Paraguay OR Peru OR Philippines OR Rwanda OR 'Saint Helena' OR Samoa OR 'São Tomé' and Príncipe OR Senegal OR Serbia OR 'Sierra Leone' OR 'Solomon Islands' OR Somalia OR 'South Africa' OR 'South Sudan' OR 'Sri Lanka' OR 'Saint Lucia' OR 'Saint Vincent and the Grenadines' OR Sudan OR Suriname OR 'Syrian Arab Republic' OR Tajikistan OR Tanzania OR Thailand OR Timor-Leste OR Togo OR Tokelau OR Tonga OR Tunisia OR Turkey OR Turkmenistan OR Tuvalu OR Uganda OR Ukraine OR Uzbekistan OR Vanuatu OR Venezuela OR Vietnam OR 'Wallis and Futuna' OR 'West Bank' and 'Gaza Strip' OR Yemen OR Zambia OR Zimbabwe) AND (rct or randomized control trial or randomized controlled trial)	Academic Search Complete	169
Not limited to date and language The language translation first will translate titles using Google translate, then proceed to abstracts and full-text article if they are available. If necessary, specific sections may be translated by human translators. The final output should be in English.			

critical RoB.[32] The two independent reviewers will assess and score the selected studies, and disagreements will be resolved by the third reviewer. The narrative summary of the risk bias for each outcome across individual studies will be reported in tabular form.

Data extraction

A data extraction form will be developed and piloted before implementation. The data extracted will include specific details about the participants (ie, age, sex), intervention (ie, self-management, biopsychosocial), context, outcomes (pain, disability, self-efficiency, HRQL), study design methods, year of publication, country of publication and key findings relevant to the review question. Data extraction will be conducted independently by two reviewers, and for any disagreements, a third reviewer will act as the moderator in the discussion.

Processes of data extraction

We will focus on the common outcomes examined within the included studies to identify RCTs that we can synthesise to identify generic and specific effects of physiotherapy SMP across and within health problems (CNLBP). The primary and secondary outcomes will be priorities for the long-term effects of physiotherapy-guided SMP on pain, disability, self-efficacy and HRQL outcomes. Where no long-term follow-up outcomes data are available, we shall present the longest follow-up point available or the time point where the meta-analytic synthesis was performed. If there are separate analyses for several measurements of the same outcome, then we will choose the analysis with the largest number of RCTs included. If they are equal, then we will select the analysis of the measurement with the best outcome properties. If, in addition to or instead of pain, disability, HRQL and self-efficacy there are multiple physiotherapy-guided SMP outcomes, we will

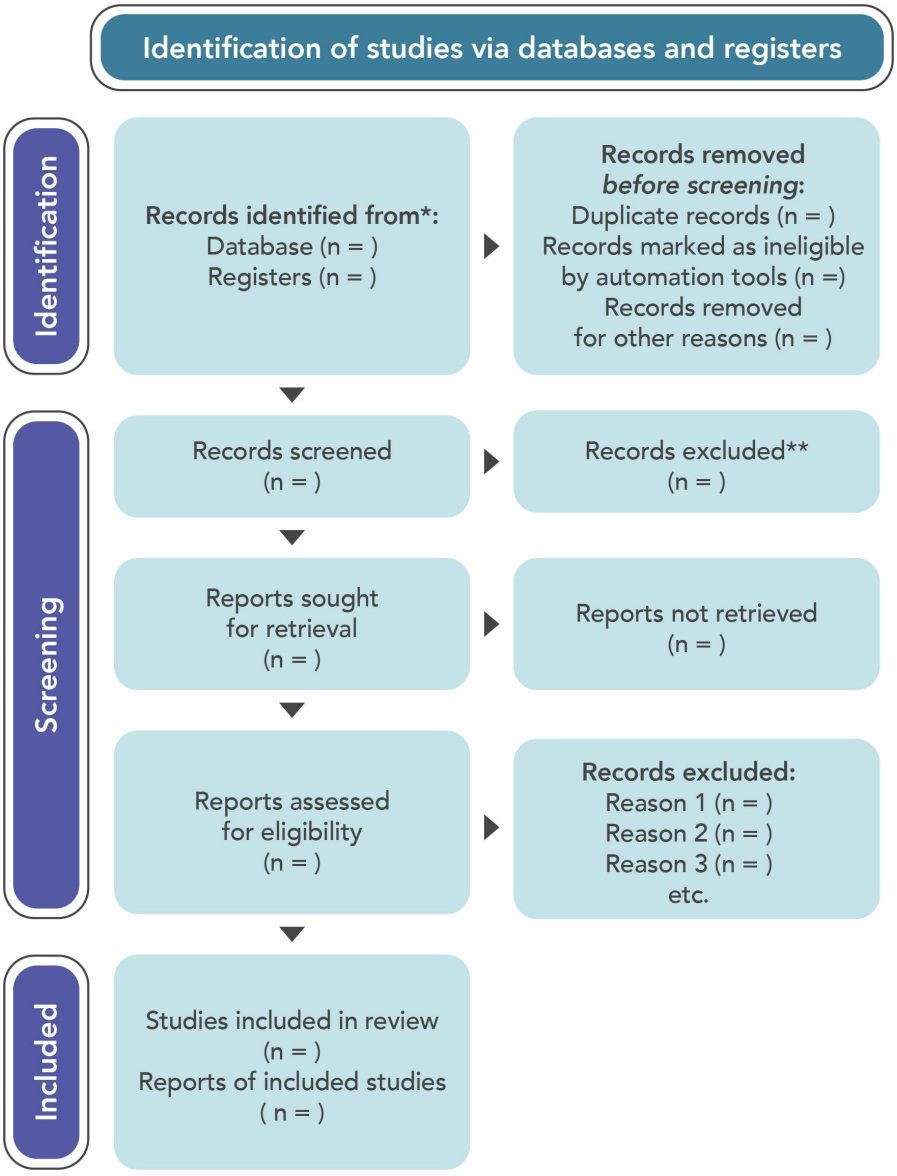

Figure 2 Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Protocol flow diagram.

make a list of all available outcomes reported. If we find an additional common outcome, deemed meaningful to improve an individual's function or physical activities, which we have not focused on, we will return to the review and extract this information.

We will group all the reviews that include pain, disability, self-efficacy and HRQL outcomes together. From these, we shall identify those that have performed a meta-analysis of the data. These reviews shall be grouped by type or method of physiotherapy-guided SMP (ie, PNE, DHI and rehabilitation). At this stage, we shall check if any of the included systematic reviews, within a health problem category (CNLBP), share primary RCTs. If we identify two or more reviews that are eligible for inclusion but share the same primary RCTs, we will use the following criteria hierarchy to choose one review for inclusion. We shall return to the full text of the reviews that were selected and extract effect sizes, CIs and heterogeneity measures. For effect sizes based on continuous outcome measures, the combined intervention/control group means, SD and the total number of participants per group shall be extracted. For binary outcomes, we shall extract from the combined intervention/control group the number of participants who have achieved the desired outcome plus the total number of participants. The selected reviews will be examined to identify those with moderate clinical, design and statistical homogeneity.

Subgroup analysis

For each of our key outcomes (pain, disability, self-efficacy, HRQL and the most common physical outcome), we will perform a subgroup analysis comparing: (1) articles that include RCTs with high-intensity physiotherapy-guided SMP, (2) those with low-intensity physiotherapy-guided SMP, (3) those with a mixture of high-intensity and low-intensity physiotherapy-guided SMP RCTs. In addition, if we find articles that directly compare high-intensity and low-intensity physiotherapy-guided SMP within the review,

we shall group these and if possible, pool the results, comparing high-intensity to low-intensity physiotherapy-guided SMP groups rather than intervention to control groups. We do not plan to perform any further subgroup analyses; however, if the data are suitable, we are flexible with additional analyses for example, control group type or follow-up period.

Data synthesis

The RoB assessment may be incorporated into synthesis by performing sensitivity analysis. A descriptive analysis will be conducted for all the included studies and will be presented in tabular form based on the categories, such as year of publication, countries of origin, outcomes, and research methods if appropriate.

Based on our knowledge of the self-management literature, we anticipate heterogeneity among the intervention types, components and outcomes, which will potentially limit pooled analysis. The standardised mean difference (SMD) of the numerical scores for self-effficacy, HRQL, pain and disability outcomes will be used to compare across studies. Meta-analysis will be applied using the intention-to-treat principle, where appropriate for instance if a group of studies has sufficient comparable interventions and outcomes and performed in similar settings. In the case of categorical data, the risk ratio (RR) will be considered for effect size.[33] The SMD will be categorised as small, medium and large based on the thresholds 0. 2, 0. 5 and 0. 8, respectively, as per Cohen's suggestion.[34]

We will use a 95% CI to present the deviation from the point of estimate for both individual and grouped study estimates. The heterogeneity between the studies will be assessed by using the I^2 statistic and the χ^2 test ($p<0.1$ will be considered significant).[35] The random effects model of meta-analysis will be used to take account of the potential heterogeneity. We will evaluate the possibility of publication bias by use of funnel plots and by conducting Egger's test for analyses that contain more than 10 studies.[36] All analyses will be done using Stata V.17 statistical software.

Confidence in cumulative evidence

The Grading of Recommendations, Assessment, Development, and Evaluation approach will be used to determine the quality of evidence for making recommendations on the effectiveness of physiotherapy-guided self-management interventions for adults with CNLBP.[37] This process will be done by the two reviewers and in the case of disagreement, the third reviewer will be involved.

Patient and public involvement

There is no patient or public involvement. Only physiotherapists working in a middle-income country were consulted in the development of this proposal.

ETHICS AND DISSEMINATION

Ethical approval and consent for this systematic review protocol are not applicable. This systematic review protocol was, nevertheless, approved as part of a PhD umbrella study aimed at a physiotherapy-guided SMP for adult people with CNLBP in Limpopo Province, South Africa (Ethics reference no: 514/2021 refer to the supplementary documents, online supplemental appendix 2). The published article is to be uploaded to academic, and public science, repositories and presented at conferences, symposia and congresses.

DISCUSSION

Despite the fact that self-management for chronic low back pain has been broadly reported as an effective approach, there are knowledge gaps and a lack of standardised approaches to the self-management of affected adult people in LMCs. Identifying the effectiveness of physiotherapy-guided self-management interventions for chronic low back pain important, considering the burden related to chronic low back pain, globally and including LMICs.

This systematic review will assist in updating the knowledge on the effectiveness of physiotherapy-guided self-management interventions since we aim to explore the setting of LMICs where adults receive healthcare services. Our results will be underwritten through the rigorous methodology provided by the Cochrane handbook, and the results will be reported as stipulated by the PRISMA statement. This systematic review will therefore provide the relevant knowledge that will guide, influence or facilitate the implementation of better treatment regimens for the current and future of physiotherapy-guided self-management interventions for people with chronic low back pain in LMICs. Notwithstanding the benefits, the evidence of this systematic review may be limited by the quality of the individual studies and by the limited number of studies available or even may not provide a complete picture, given that the systematic review is but one methodology in a slate of research possibilities.

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Contributors SGM, MM-C, AM and NN conceptualised the protocol. SGM wrote the first version of the protocol and acting as guarantor. MM-C and AM assisted with the refinement of the protocol methods and KK with the search strategy. KM and NN critically revised the manuscript. All authors approved the final version.

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Disclaimer All the statements and reviews to be made will be solely the responsibility of the author.

Competing interests None declared.

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

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`PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	P 1, Line 4
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☒	☐	P 2, Line 20
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	P 1, Line 1-12
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	P 14, Line 11 - 13
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☒	N/A, new protocol
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	P 1, Line 21 - 22 & P 14, Line 15 - 17
Sponsor	5b	Provide name for the review funder and/or sponsor	☒	☐	P 1, Line 21-22
Role of	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☒	☐	P 14, Line 15 - 17

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
sponsor/funder					
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	P 4, Line 19 - 29
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	P 5, Line 18 - 26
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	P 6, Line 1 - 10 & P7, 1 - 13
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	P 8, Line 11 - 20
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	P 8, Line 21 - 29 & P 9, Table 1
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	P10, Line 1 - 3
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	P 10, Line 1 - 13
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	P11, Line 12 - 25
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	P11, Line 6 - 11

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	P7, Line 11 - 13
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	P10, Line 18 - 23 & P11, Line 1 - 6
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☒	☐	P11, Line 13 - 24
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☒	☐	P13, Line 1 - 7
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☒	☐	P12, Line 10 - 17
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	P12, Line 13 - 17
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☒	☐	P13, Line 3 - 7
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	P13, Line 8 - 11

Checklist for the ''Effectiveness of physiotherapy self-management programme for adult patients with chronic non-specific low back pain in low- and middle-income countries: Protocol for a systematic review and meta-analysis''

UNIVERSITEIT VAN PRETORIA
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Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 18 March 2022 and Expires 18 March 2027.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through June 30, 2025 and Expires 07/28/2026.

Faculty of Health Sciences **Research Ethics Committee**

9 November 2023

Approval Certificate
Annual Renewal

Dear Mr SG Motha,

Ethics Reference No.: 514/2021 – Line 3
Title: Development of a self-management programme for patients with chronic non-specific low back pain in Limpopo Province, South Africa

The **Annual Renewal** as supported by documents received between 2023-10-24 and 2023-11-08 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2023-11-08 as resolved by its quorate meeting.

Please note the following about your ethics approval:

- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2024-11-09.
- The Research Ethics Committee (REC) must monitor your research continuously. To this end, you must submit as may be applicable for your kind of research:
  a) annual reports;
  b) reports requested *ad hoc* by the REC;
  c) all visitation and audit reports by a regulatory body (e.g. the HPCSA, FDA, SAHPRA) within 10 days of receiving one;
  d) all routine monitoring reports compiled by the Clinical Research Associate or Site Manager within 10 days of receiving one.
- The REC may select your research study for an audit or a site visitation by the REC.
- The REC may require that you make amendments and take corrective actions.
- The REC may suspend or withdraw approval.
- Please remember to use your protocol number (514/2021) on any documents or correspondence with the Research Ethics Committee regarding your research.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

On behalf of the FHS REC, Dr R Sommers
MBChB, MMed (Int), MPharmMed, PhD
Deputy Chairperson *of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health).

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