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

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

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ABSTRACT

Introduction

Chronic non-specific low back pain (CNLBP) is amongst the most common musculoskeletal system conditions reported worldwide, however few studies are available from low- and middle-income countries (LMICs). Self-management is a comprehensive interdisciplinary pain program which offers a combination of medical management, psychological, cognitive behavioural therapy, psychological acceptance commitment therapy, graded exercise, lifestyle management and pain education to help patients better self-manage their pain and improve overall daily function. A 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 self-management programs 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. The 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 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 synthesize results and heterogeneity will be assessed using the I^2 test statistic and Chi square test.

Ethics and dissemination

Ethics clearance was obtained for the broader PhD study on the development of self-management for programme for adult people with CNLBP in Limpopo Province, South Africa. The results manuscript for this protocol will be published in peer reviewed journal and also presented in conferences, symposia and congresses.

Review registration number

This systematic review PROSPERO registration number the review protocol is submitted awaiting for the registration number (PROSPERO acknowledgement of receipt ID 399572).

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KEYWORDS

Chronic non-specific low back pain; low-income countries; middle-income countries; self-management program

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STRENGTH AND LIMITATIONS OF THIS STUDY

- This is a protocol to conduct a systematic review of the effectiveness of physiotherapy self-management interventions in LMICs. This summary of evidence can be used to develop a self-management programme within the LMICs.
- The language restriction will not be applied in the selection of studies. This will reduce the risk of bias and enhance the study findings.
- Compliance to the PRISMA-P 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 a 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 World Health Organization (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. ² It was also projected that the number of people with LBP will increase in the future and even quicker in low- and middle-income countries (LMICs). ^{1, 2} Chronic non-specific low back pain is a musculoskeletal condition that is not attributable to a recognisable, or known specific pathology (e.g., 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 review the CNLBP is defined as LBP which persisted for at least more than three months excluding known specific pathology, and include both 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 \$1,045. On the other hand, middle-income countries are those with a GNI per capita, of more than \$1,045 but less than \$12,736. ⁴

The WHO has proposed non-drug, non-surgical approaches as the first line of treatment for LBP including education on pain management, and manual therapies. This type of rehabilitation is an important element in addressing the global burden of musculoskeletal conditions, including LBP. ¹ 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 (aspect 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 World Health Organization to publish its International Classification of Functioning, Disability and Health (WHO ICF). ⁸ In addition, biopsychosocial approach has been broadly used in research patterning the rehabilitation and disability which includes chronic pain and functional disorder. ^{9, 10}

However, implementing self-management is challenging, particularly in LMICs. ⁵ The self-management, therefore, includes both biomedical and biopsychological elements, where the biomedical elements tend to be the current standard of care approach, i.e., electrotherapy, myofascial release, and mobilisation. ¹¹ Literature on the biopsychosocial approach as management of chronic musculoskeletal conditions, exists, however, research in this approach on CNLBP in LMICs is lacking. ⁵

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¹²⁻¹⁵ 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, 13} 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.

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 (for example improvement after stroke) and lower the cost when the patients are actively participating in self-management programme. ^{16, 17} Despite the importance of self-management interventions, there is a dearth of studies done on this topic, particularly on the effectiveness of self-management interventions for CLBP in LMICs. ¹⁸ The systematic review on effectiveness of 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 SMP for people with CNLBP in LMICs.

AIM

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

Objectives

- To determine the effectiveness of 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 self-management interventions for adults with CNLBP living in LMICs?
- To determine if there are differences in effectiveness, depending on the participant characteristics such as age and gender?

METHODS

Protocol design, reporting and registration

The systematic review will be guided by the PRISMA 2020 guidelines for systematic reviews, which comprises of eligibility criteria (participants, interventions, comparators, outcomes, and context), search strategy, study selection, assessment of methodological quality, and data extraction, synthesis and assessing certainty in the findings. ¹⁹ (Refer to the **supplementary documents, Appendix I.**) This

systematic review is registered with the international database of 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.²⁰ The registration number is number the review protocol is submitted awaiting for the registration number (PROSPERO acknowledgement of receipt ID 399572).

Eligibility criteria

Type of studies

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

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

Expert opinions and published systematic reviews will be 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 World Bank will be included.

Study participants

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

Types of Interventions

Self-management strategies for the management of CNLBP which follows a biopsychosocial approach will be considered (for example pain neuroscience education (PNE), cognitive behaviour therapy (CBT), acceptance and commitment therapy (ACT), and various forms of exercise training).²¹⁻²³ The intervention can be a prescribed education programme, physiotherapy-led intervention and multidisciplinary intervention that targets an individual or a group of individuals. The non-physiotherapy treatment regime (outside the scope of physiotherapy profession interventions) either used as the intervention or control will be excluded.

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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).

Type of Outcomes

Primary outcome pain

Pain (visual analogue scale or numerical pain rating scale)

Secondary outcome

Disability (Oswestry or modified Oswestry, Roland Morris, and Quebec disability), self efficiency and health related quality of life (HRQL).

Definitions of concepts

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

- **Chronic non-specific low back pain** is defined as LBP which persisted for at least more than three months excluding known specific pathology, and include both RLBP and PLBP.

- **Self-management** is tasks performed by the patient aiming at managing their symptoms, and interference in activities, mood, and relationships due to pain. ²⁴ A self-management programme (SMP) comprises problem-solving, decision making, resource utilisation, action planning, self-tailoring, self-monitoring, and creating partnerships.

- **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. ²⁵ This process can include patient-orientated therapy, exercise training, family support, counselling, modification of the environment, and self-management strategies.

- **Standard treatment guidelines** (STG) are systematically developed statements to help practitioners or prescribers to decide about treatments to be used for specific clinical conditions. ²⁶ This includes the 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 deliver treatment for conditions that incorporates biological, psychological, and social factors. This approach views health and illness as the product of

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biological characteristics (genes); behavioural factors (lifestyle, stress, health beliefs); and social conditions (cultural influences, family relationships, social support).²⁷

Search strategy

The information sources will be searched from different databases in 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 searches conducted on the 21 February 2023 from the period of inception to date. Physical hand searching for all included sources reference list will also be conducted. The search will not be limited by language. The absence of an inception date of searches is chosen to be appropriate in this systematic review based on the systematic review that reported the limited studies done on self-management for adults with CNLBP in LMICs.¹⁴

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.²⁸ 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, EBSCO, 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**).

Table 1: Results of Pilot Search Strategy

| Search date | Query | Database | Records retrieved |
|----------------------------------|--|-----------------------------|-------------------|
| 21/02/2023 | "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 Afghanistan 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 |
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Study selection

Following the database search, articles with relevant titles will be exported to an Endnote 20 library and duplicates will be removed. A screening tool that comprises of inclusion and exclusion criteria will be created using Rayyan, a web based systematic review software that will be piloted before the screening.²⁹ The screening will be done in two stages by two independent reviewers. Firstly, we will screen for Abstracts. Disagreements at this stage will be resolved through discussions until a consensus is reached. Secondly, we will screen the full texts of the articles that have made it past the Abstract screening stage. Disagreements at this stage will be resolved by inviting a third reviewer. The studies that do not meet the inclusion criteria will be excluded and the reason for exclusion will be stated. The process of study selection will be presented in the PRISMA flow diagram attached in **Figure 2.**¹⁹

To determine the inter-rater level of agreement between the two reviewers, the 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 risk of bias independently for all the included studies. If there is disagreement a third reviewer will be consulted. The RoB 2.0 tool covers five domain (1) randomisation sequence, (2) allocation concealment, (3) blinding, (4) completeness of outcome and (5) selective outcome reporting and it also classifies the studies into low, high or unclear risk of bias.³⁰ The non-randomised trial (NRCT) will be assessed by the use of ROBINS-I tool, given that it is particularly useful for systematic reviews that include NRCT studies of intervention.³¹ This tool is guided through seven chronologically arranged bias domain at pre-intervention, intervention and post intervention, and the interpretation of domain-level. Overall bias risk judgement in ROBIN-I are classified in low, moderate, serious or critical risk of bias.³¹ The two independent reviewers will assess and score the selected studies and disagreement 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.

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Data extraction

A data extraction form will be developed and piloted before implementation. The data extracted will include specific details about the participants (i.e., age, sex), intervention (i.e., self-management, biopsychosocial), context, outcomes (pain, disability, self-efficiency, HRQL), study design methods, year publication, country of publication and key findings relevant to the review question. Data extraction will be conducted by two reviewers, independently 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 reviews to identify systematic reviews that we can synthesise to identify generic and specific effects of physiotherapy SMP across and within health problems (CNLBP). The primary and secondary outcome will be priorities long-term effects of physiotherapy SMP on pain, disability, and self-efficiency and HRQL outcomes. Outcomes where no long-term (≥ 12 month) follow-up 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 efficiency there are multiple SMP outcomes, we will make a list of all available outcomes reported. If we find an additional common outcome, deemed meaningful to improve an individual function or physical activities, which we have not focused on, we can return to the review and extract this information.

We will group all of the reviews that include pain, disability, self efficiency and HRQL outcome 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 SMP (i.e. pain neuroscience education, cognitive behavior therapy 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, which 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 reviews that are 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-efficiency, HRQL and the most common physical outcome), we will perform a subgroup analysis comparing: (1) reviews that include RCTs with high intensity SMP, (2) those with low intensity SMP, (3) those with a mixture of high and low intensity SMP RCTs. In addition, if we find reviews that directly compare high and low intensity SMP within the review, we shall group these and if possible pool the results, comparing high to low intensity 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 to additional analyses for an example control group type or follow-up period.

Data synthesis

The risk of bias assessment may be incorporated into synthesis by performing sensitive analysis. A descriptive analysis will be conducted for all the included studies and will be presented in the 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 amongst the intervention types, components, and outcomes, which will potentially limit pooled analysis. The standardized mean difference (SMD) effect size will be used for pain and disability outcomes in order to make them comparable across studies and the bias. Meta-analysis will be applied using the intention-to-treat principle, where appropriate for instance if a group of studies has sufficient comparable intervention and outcome and performed in the same setting. In case of categorical data, risk ratio (RR) will be considered for effect size.³² 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.³³

We will use 95% of confidence interval to present the deviation from the point of estimate for both individual and grouped studies estimate. The heterogeneity between the studies will be assessed by using the I² statistic and the Chi-square test (p<0.1 will be considered significant).³⁴ 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 analysis that contain more than 10 studies.³⁵ All analyses will be done using Stata version 17 statistical software.

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Confidence in cumulative evidence

The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach will be used to determine the quality of evidence for making recommendations on the effectiveness of self-management interventions for adults with CNLBP.³⁶ This process will be done by the two reviewers and in the case of disagreement, the third reviewer will be substantively involved.

Patient and public involvement

There is no patient involved. Only the physiotherapists working in a middle-income country, was consulted in the development of this proposal.

Ethics and dissemination

Ethical approval and consent in this review are not applicable. Consent for publication in this review is not applicable. This systematic review was, nevertheless, approved as part of an PhD umbrella study aiming on the development of self-management for programme for adult people with CNLBP in Limpopo province South Africa (Ethics reference no: 514/2021 Refer to the **supplementary documents, Appendix II.**). The article is to be uploaded to academic, and public science, repositories. Papers will be targeted for conferences, symposia and congresses. Practice-based findings will be offered to public or private clinical practitioners as 'science for society'. Presentations of the results will also be given at the different hospitals where a follow-up study, within the umbrella study, will be done.

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 LMICs. Identifying the effective self-management interventions for chronic low back pain is of importance, considering the burden related to chronic low back pain, globally, and including LMICs.

This systematic review will assist to update the knowledge on the effectiveness of self-management interventions since we aim at exploring the setting of LMICs where the adult people 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

implementation of better treatment regimens for the current and future of 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.

CONTRIBUTORSHIP STATEMENT

SM, MM, AM and NN conceptualised the proposal. SM wrote the first version of the proposal. MM and AM assisted with the refinement of the proposal methods and KK with the search strategy. KM and NN critically revised the manuscript. All authors approved the final version.

COMPETING INTERESTS

The authors declare no conflict of interest or any personal, financial, professional, or intellectual bias.

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DATA SHARING STATEMENT

This systematic review proposal does not yield data with clinical implications, apart from the studies which will be included in the review itself. Further information based on reasonable requests will be made available

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The authors would like to thank the physiotherapists, Limpopo Province, South Africa, for their assistance with the strengthening of the search strategy.

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FIGURES

Figure 1 Classification of low back pain

Figure 2 PRISMA Flow diagram

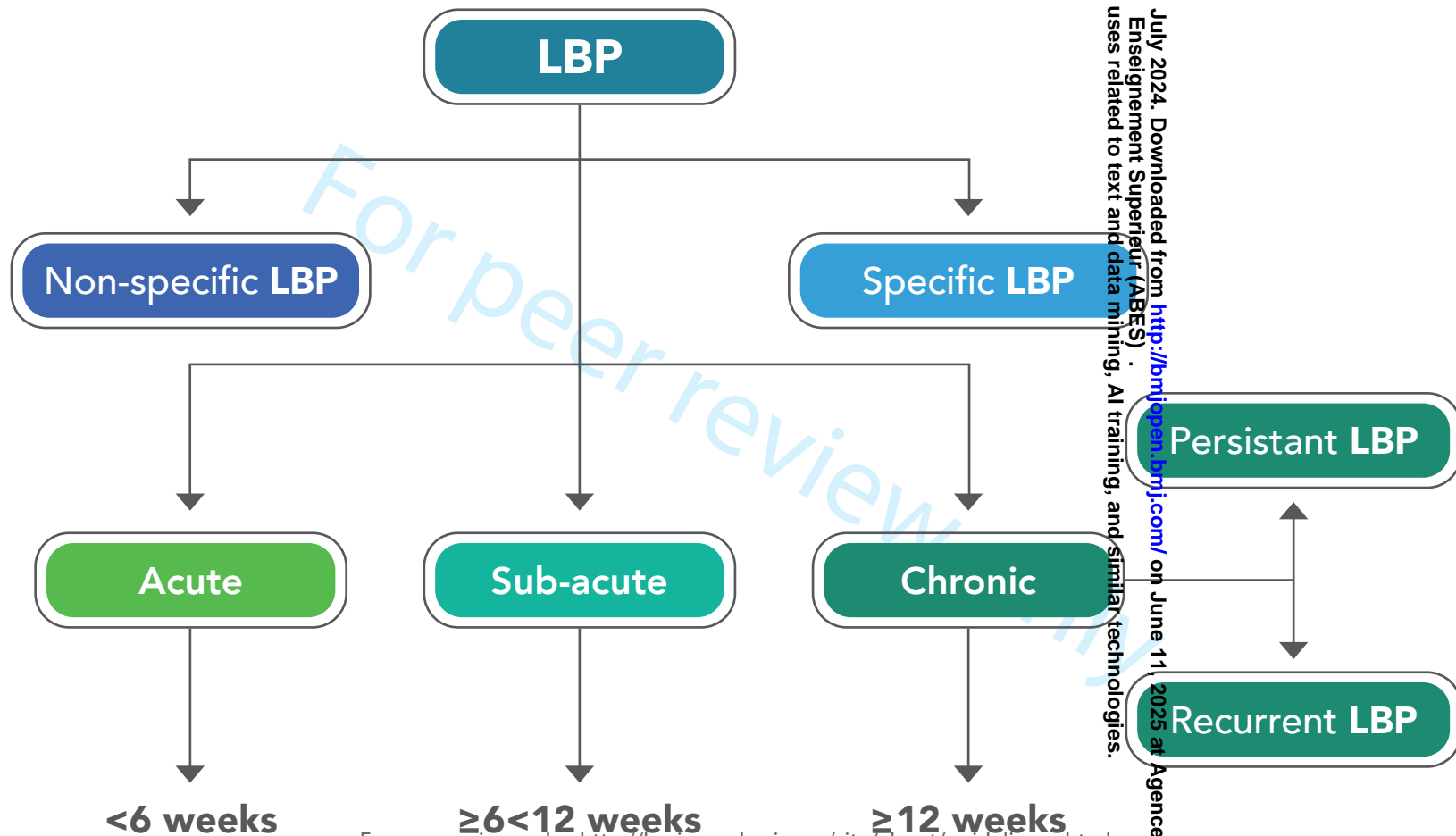
SUPPLIMENT DOCUMENTS

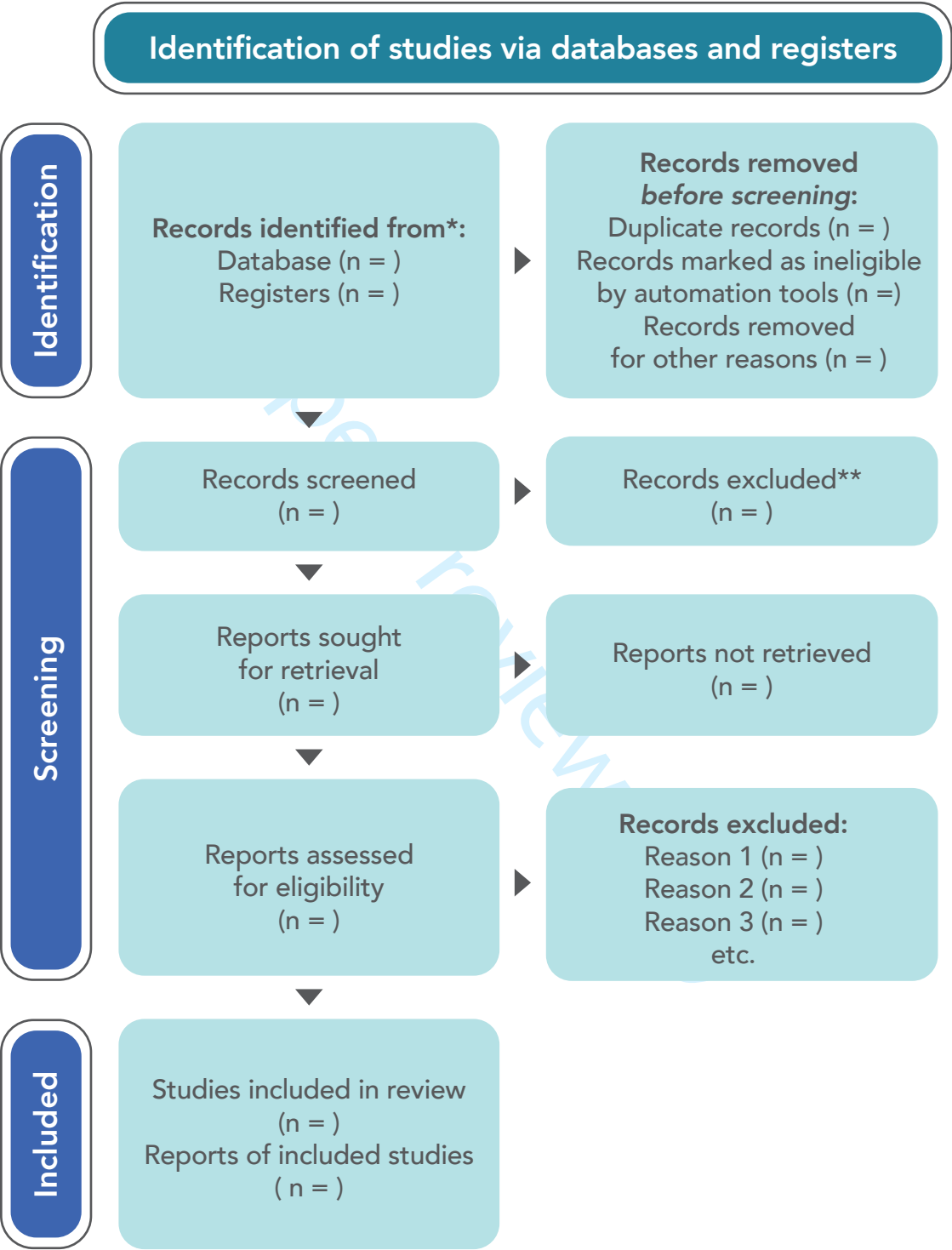
Appendix I: PRISMA P Checklists

Appendix II: Ethical clearance certificate

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PRISMA 2020 Checklist

| Section and Topic | Item # | Checklist item | Location where item is reported |
|-------------------------------|--------|---|--|
| TITLE | | | |
| Title | 1 | Identify the report as a literature review. | Page 1 |
| ABSTRACT | | | |
| Abstract | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings. See the PRISMA 2020 for Abstracts checklist for the complete list. | Page 2 |
| INTRODUCTION | | | |
| Rationale | 3 | Describe the rationale for the review in the context of existing knowledge, i.e., what is already known about your topic. | Page 5 to 6 |
| Objectives | 4 | Provide an explicit statement of the objective(s) or question(s) the review addresses with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | Page 6 |
| METHODS | | | |
| Eligibility criteria | 5 | Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses with study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | Page 7 to 8 |
| Information sources | 6 | Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted. | Page 9 |
| Search strategy | 7 | Present the full search strategies for all databases, registers and websites, including any filters and limits used. | Page 10 |
| Selection process | 8 | State the process for selecting studies (i.e., screening, eligibility). Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process. | Page 11 |
| Study risk of bias assessment | 11 | Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process. | Page 11 This process is not yet implemented as we are still at protocol phase |
| RESULTS | | | |
| Study selection | 16a | Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram. | Page 11 This process is not yet implemented as we are still at protocol phase |
| | 16b | Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded. | Page 11 This process is not yet implemented as we are still at protocol phase |
| Study characteristics | 17 | Cite each included study and present its characteristics (e.g., study size, PICOS, follow-up period). | Page 11 This process is not yet implemented as |

PRISMA 2020 Checklist

| Section and Topic | Item # | Checklist item | Location where item is reported |
|---|--------|--|--|
| | | | we are still at protocol phase |
| Risk of bias in studies | 18 | Present assessments of risk of bias for each included study. | Page 11 This process is not yet implemented as we are still at protocol phase |
| Results of individual studies | 19 | For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots. | Page 13 This process is not yet implemented as we are still at protocol phase |
| DISCUSSION | | | |
| Discussion | 23a | Provide a general interpretation of the results in the context of other evidence. | Page 14 This process is not yet implemented as we are still at protocol phase |
| | 23b | Discuss any limitations of the evidence included in the review. | Page 14 This process is not yet implemented as we are still at protocol phase |
| | 23c | Discuss any limitations of the review processes used. | Page 14 This process is not yet implemented as we are still at protocol phase |
| | 23d | Discuss implications of the results for practice, policy, and future research. | Page 14 This process is not yet implemented as we are still at protocol phase |
| OTHER INFORMATION | | | |
| Registration and protocol | 24a | Provide registration information for the review, including register name and registration number, or state that the review was not registered. | Page 7 |
| | 24b | Indicate where the review protocol can be accessed, or state that a protocol was not prepared. | Page 7 |
| | 24c | Describe and explain any amendments to information provided at registration or in the protocol. | N/A |
| Support | 25 | Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review. | Page 15 |
| Competing interests | 26 | Declare any competing interests of review authors. | Page 15 |
| Availability of data, code, and other materials | 27 | Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review. | Page 12 to 13 |

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BMJ Open

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

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| Manuscript ID | bmjopen-2023-073916.R1 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 12-Jan-2024 |
| Complete List of Authors: | Motha, Sergeant; University of Pretoria Faculty of Health Sciences, Department of Physiotherapy Naidoo, Niri; University of Cape Town, Division of Physiotherapy Department of Health and Rehabilitation Sciences Moyo-Chilufya, Maureen; University of Pretoria Faculty of Health Sciences, School of Health Systems and Public Health Musekiwa, Alfred; University of Pretoria Faculty of Health Sciences, School of Health Systems Kgarosi, Kabelo; University of Pretoria Faculty of Health Sciences, School of Health Systems and Public Health Mostert, Karien; University of Pretoria, Physiotherapy |
| Primary Subject Heading: | Rehabilitation medicine |
| Secondary Subject Heading: | Rehabilitation medicine, Public health, Sports and exercise medicine, Patient-centred medicine, Medical education and training |
| Keywords: | SPORTS MEDICINE, PUBLIC HEALTH, Primary Health Care, PAIN MANAGEMENT, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY |
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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

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Keywords: Chronic non-specific low back pain; low and middle-income countries; self-management programme

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ABSTRACT

Introduction

Chronic non-specific low back pain (CNLBP) is amongst 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 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 self-management programs 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. The 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 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 synthesize results and heterogeneity will be assessed using the I^2 test statistic and Chi-square test.

Ethics and dissemination

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

Review registration number

This systematic review PROSPERO registration number is CRD42023399572.

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KEYWORDS

Chronic non-specific low back pain; low-income countries; middle-income countries; self-management programme

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STRENGTH AND LIMITATIONS OF THIS STUDY

- This is a protocol to conduct a systematic review of the effectiveness of physiotherapy self-management interventions in LMICs. This summary of evidence can be used to develop a self-management programme within the LMICs.
- The language restriction will not be applied in the selection of studies. This will reduce the risk of bias and enhance the study findings.
- Compliance to the PRISMA-P 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 a 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 World Health Organization (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. [1] It was also projected that the number of people with LBP will increase in the future and even quicker in low- and middle-income countries (LMICs). [1 ,2] CNLBP is a musculoskeletal condition that is not attributable to a recognisable, or known specific pathology (e.g., 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 review, the CNLBP is defined as LBP which persisted for at least more than three months excluding known specific pathology 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 \$1,045. On the other hand, middle-income countries are those with a GNI per capita, of more than \$1,045 but less than \$12,736. [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 (aspect 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 World Health Organization to publish its International Classification of Functioning, Disability and Health (WHO ICF). [8] In addition a biopsychosocial approach has been broadly used in research patterning the rehabilitation and disability which includes chronic pain and functional disorder. [9 ,10]

However, implementing self-management is challenging, particularly in LMICs. [5] The self-management programme should include both biomedical and psychosocial elements, where the biomedical elements tend to be the current standard of care approach, i.e., electrotherapy, myofascial

release, and mobilisation. [11 ,12] Literature on the biopsychosocial approach as management of chronic musculoskeletal conditions, exists, however, research in this approach on CNLBP in LMICs is lacking. [5 ,13-16] In 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 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 (for example improvement after stroke) and lower the cost when the patients are actively participating in self-management programme. [17 ,18] Despite the importance of self-management interventions, there is a dearth of studies done on this topic, particularly on the effectiveness of self-management interventions for CLBP in LMICs. [19] The systematic review on effectiveness of 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 SMP for people with CNLBP in LMICs.

AIM

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

Objectives

- To determine the effectiveness of 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 self-management interventions for adults with CNLBP living in LMICs?
- To determine if there are differences in effectiveness, depending on the participant characteristics such as age and gender?

METHODS

Protocol design, reporting, and registration

The systematic review will be guided by the PRISMA 2020 guidelines for systematic reviews, which comprises of eligibility criteria (participants, interventions, comparators, outcomes, and context), search strategy, study selection, assessment of methodological quality, and data extraction, synthesis and assessing certainty in the findings. [20] (Refer to the **supplementary documents, Appendix I.**) This systematic review is registered with the international database of 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 current date that has information on the effectiveness of self-management interventions for CLBP among adults in LMICs will be included in this study such as experimental study designs, randomised controlled trials (RCT with concealed allocation), pseudo randomised control trial (RCT without concealed allocation), non-randomised controlled trials, and quasi-experimental studies (experimental study without randomization) will be included in this study.

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

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Types of Interventions

Self-management strategies for the management of CNLBP which follow a biopsychosocial approach will be considered for example pain neuroscience education (PNE), and 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 and multidisciplinary intervention that targets an individual or a group of individuals. 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).

Type of Outcomes

Primary outcome

Self-efficacy (self-efficacy scale), function (patient specific functional scale (PSFS)) 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 biopsychosocial approach, rehabilitation, and standard treatment guidelines (examples of interventions include home exercise programmes).

- **Chronic non-specific low back pain** is defined as LBP which persisted for at least more than three months excluding known specific pathology and includes both RLBP and PLBP.
- **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. [26] A self-management programme (SMP) comprise of 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. [27] This process can include patient-orientated therapy, exercise training, family support, counselling, modification of the environment, and self-management strategies.

• **Standard treatment guidelines** (STG) are systematically developed statements to help practitioners or prescribers to decide about treatments to be used for specific clinical conditions. [28] This includes the 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 deliver 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). [29]

Search strategy

The information sources will be searched from different databases in 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 the 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 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 of searches is chosen to be appropriate in this systematic review based on the systematic review that reported the limited studies done on 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. [30] 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

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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. Thirdly, 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**).

Table 1: Results of Pilot Search Strategy

| Search date | Query | Database | Records retrieved |
|-------------|---|--------------------------|-------------------|
| 21/02/2023 | "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 Afghanistan 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" | Academic Search Complete | 169 |

| | | | |
|---|---|--|--|
| | OR “West Bank” and “Gaza Strip” OR Yemen OR Zambia OR Zimbabwe) AND (rct or randomized control trial or randomized controlled trial | | |
| Not limited to date and language The language translation firstly 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. | | | |

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. [31] 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 ten articles will be screened, and agreement assessed before proceeding with all of the articles. We will begin with 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 of inclusion or exclusion on the conflicted articles amongst the two reviewers. The studies that do not meet the inclusion criteria will be excluded and the reason for 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, the 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 risk of bias 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 low, high or unclear risk of bias. [32] The non-randomised trial (NRCT) will be assessed by the use of ROBINS-I tool, given that it is particularly useful for systematic reviews that include NRCT studies of intervention. [33] This tool is guided through seven chronologically arranged bias domain at pre-intervention, intervention and post intervention, and the interpretation of domain-level. Overall bias risk judgement in ROBINS-I is classified in low, moderate, serious, or critical risk of bias. [33] The two independent reviewers will assess and score the selected studies and disagreement 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 (i.e., age, sex), intervention (i.e., self-management, biopsychosocial), context, outcomes (self-efficacy, HRQL, function, pain and disability), study design methods, year of publication, country of publication and key findings relevant to the review question. Data extraction will be conducted by two reviewers, independently 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 synthesize 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 SMP on self-efficacy, HRQL, function, pain and disability 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 self-efficacy, HRQL, function, pain and disability and there are multiple SMP outcomes, we will make a list of all available outcomes reported. If we find an additional common outcome, deemed meaningful to improve an individuals 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 self-efficacy, HRQL, function, pain and disability 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 SMP (i.e., pain neuroscience education,

digital health intervention 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, which 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 reviews that are selected and extract effect sizes, confidence intervals (CIs) and heterogeneity measures. For effect sizes based on continuous outcome measures, the combined intervention/control group means, standard deviation (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 (self-efficacy, HRQL, function, pain, disability and the most common physical outcome), we will perform a subgroup analysis comparing: (1) articles that include RCTs with high intensity SMP, (2) those with low intensity SMP, (3) those with a mixture of high and low intensity SMP RCTs. In addition, if we find articles that directly compare high and low intensity SMP within the review, we shall group these and if possible, pool the results, comparing high to low intensity 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 to additional analyses for an example control group type or follow-up period.

Data synthesis

The risk of bias 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 the 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 amongst the intervention types, components, and outcomes, which will potentially limit pooled analysis. The standardized mean difference (SMD) effect size will be used for self-efficacy, HRQL, PSFS, pain and disability outcomes to make them comparable across studies and the bias. 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 case of categorical data, the risk ratio (RR) will be considered for effect size. [34] The SMD will be categorised

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as small, medium, and large based on the thresholds 0, 2, 0, 5, and 0, 8 respectively as per Cohen's suggestion. [35]

We will use 95% confidence interval to present the deviation from the point of estimate for both individual and grouped studies estimates. The heterogeneity between the studies will be assessed by using the I^2 statistic and the Chi-square test ($p < 0.1$ will be considered significant). [36] 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 analysis that contains more than 10 studies. [37] All analyses will be done using Stata version 17 statistical software.

Confidence in cumulative evidence

The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach will be used to determine the quality of evidence for making recommendations on the effectiveness of self-management interventions for adults with CNLBP. [38] 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 and 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 self-management programme for adult people with CNLBP in Limpopo province South Africa (Ethics reference no: 514/2021 Refer to the **supplementary documents, Appendix II.**). 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 effective self-management

interventions for chronic low back pain is of importance, considering the burden related to chronic low back pain, globally, and including LMICs.

This systematic review will assist to update the knowledge on the effectiveness of 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 implementation of better treatment regimens for the current and future of 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.

CONTRIBUTORSHIP STATEMENT

SM, MM, AM and NN conceptualised the proposal. SM wrote the first version of the proposal. MM and AM assisted with the refinement of the proposal methods and KK with the search strategy. KM and NN critically revised the manuscript. All authors approved the final version.

COMPETING INTERESTS

The authors declare no conflict of interest or any personal, financial, professional, or intellectual bias.

FUNDING

A grant was obtained from the Ernest and Ethel Eriksen Trust (ITRUST 11110/05). The funders will not play any role in the review process. The authors will be solely responsible for all statements and reviews to be made.

DATA SHARING STATEMENT

This systematic review proposal does not yield data with clinical implications, apart from the studies which will be included in the review itself. Further information based on reasonable requests will be made available.

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WORD COUNT

4 101

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FIGURES

Figure 1 Classification of low back pain

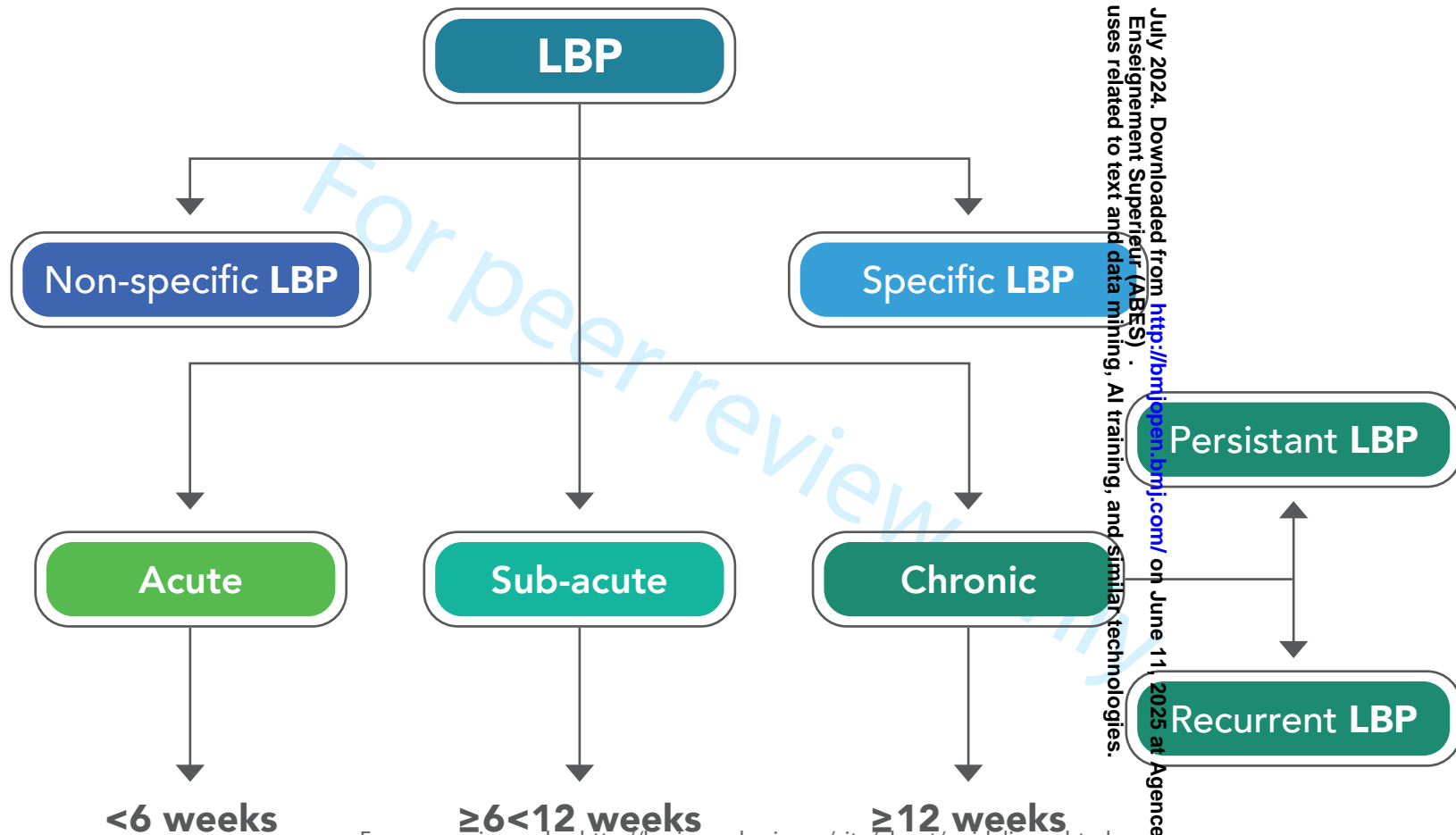
Figure 2 PRISMA Flow diagram

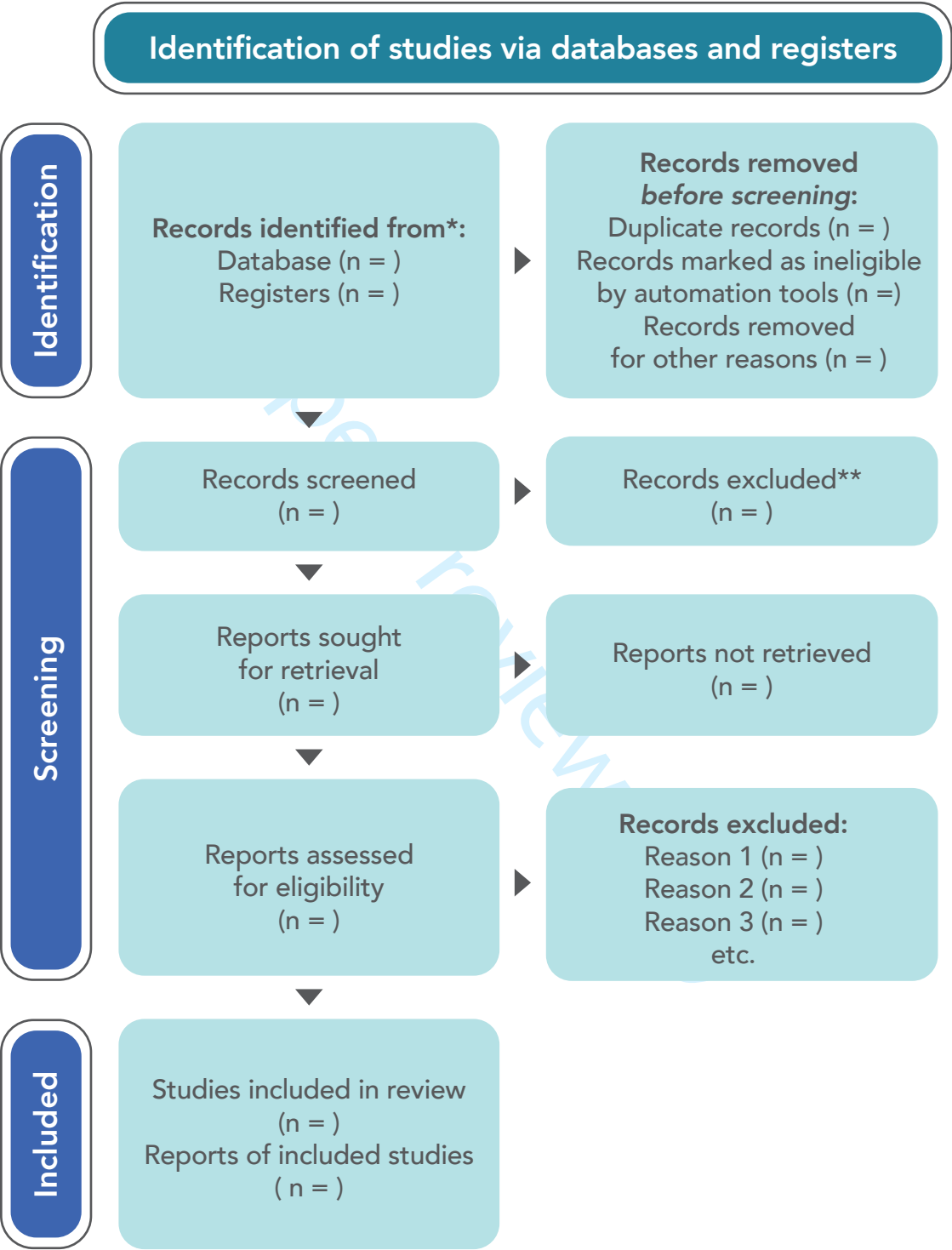
SUPPLIMENT DOCUMENTS

Appendix I: PRISMA P Checklists

Appendix II: Ethical clearance certificate

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PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 1 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P 1, Line 4 |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | <input type="checkbox"/> | <input checked="" type="checkbox"/> | N/A |
| Registration | 2 | If registered, provide the name of the registry (e.g., PROSPERO) and registration number of the protocol abstract | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P 1, Line 1-12 |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | N/A, new protocol |
| Support | | | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P 1, Line 21 - 22 & P 14, Line 15 - 17 |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P7, Line 11 - 13 |
| Risk of bias in individual studies | 14 | Describe anticipated methods for assessing risk of bias of individual studies, including when this will be done at the outcome or study level, or both; state how this information will be used in data synthesis | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P10, Line 18 - 23 & P11, Line 1 - 6 |
| DATA | | | | | |
| Synthesis | 15a | Describe criteria under which study data will be quantitatively synthesized | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P13, Line 1 - 7 |
| | 15c | Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P12, Line 10 - 17 |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P13, Line 3 - 7 |
| Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (e.g., GRADE) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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"

BMJ Open

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

| | |
|---------------------------------|--|
| Journal: | <i>BMJ Open</i> |
| Manuscript ID | bmjopen-2023-073916.R2 |
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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

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ABSTRACT

Introduction

Chronic non-specific low back pain (CNLBP) is amongst 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-GUIDE 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 self-management programs 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. The 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 synthesize results and heterogeneity will be assessed using the I^2 test statistic and Chi-square 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 manuscript for this protocol will be published in peer reviewed journal and also presented in conferences, symposia, and congresses.

Review registration number

This systematic review PROSPERO registration number is CRD42023399572.

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KEYWORDS

Chronic non-specific low back pain; low-income countries; middle-income countries; physiotherapy-
GUIDED self-management programme

For peer review only

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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 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 in the selection of studies. This will reduce the risk of bias and enhance the study findings.
- Compliance to the PRISMA-P 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 a 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 World Health Organization (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. [1] It was also projected that the number of people with LBP will increase in the future and even quicker in low- and middle-income countries (LMICs). [1, 2] CNLBP is a musculoskeletal condition that is not attributable to a recognisable, or known specific pathology (e.g., 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 review, the CNLBP is defined as LBP which persisted for at least more than three months excluding known specific pathology 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 \$1,045. On the other hand, middle-income countries are those with a GNI per capita, of more than \$1,045 but less than \$12,736. [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 (aspect 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 World Health Organization to publish its International Classification of Functioning, Disability and Health (WHO ICF). [8] In addition a biopsychosocial approach has been broadly used in research patterning the rehabilitation and disability which includes chronic pain and functional disorder. [9, 10]

However, implementing of physiotherapy-GUIDED self-management is challenging, particularly in LMICs. [5] The physiotherapy-GUIDED self-management programme should include both biomedical and psychosocial elements, where the biomedical elements tend to be the current standard of care approach, i.e., electrotherapy, myofascial release, and mobilisation. [11, 12] Literature on the biopsychosocial approach as management of chronic musculoskeletal conditions, exists, however, research in this approach on CNLBP in LMICs is lacking. [5, 13-16] In 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 (for example improvement after stroke) and lower the cost when the patients are actively participating in self-management programme. [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 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 the participant characteristics such as age and gender?

METHODS

Protocol design, reporting, and registration

The systematic review will be guided by the PRISMA 2020 guidelines for systematic reviews, which comprises of eligibility criteria (participants, interventions, comparators, outcomes, and context), search strategy, study selection, assessment of methodological quality, and data extraction, synthesis and assessing certainty in the findings. [20] (Refer to the **supplementary documents, Appendix 1.**) This systematic review is registered with the international database of 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 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 (RCT with concealed allocation), pseudo randomised control trial (RCT without concealed allocation), non-randomised controlled trials, and quasi-experimental studies (experimental study without randomization) will be included in this study.

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

Types of Interventions

Physiotherapy-GUIDED Self-management strategies for the management of CNLBP which follow a biopsychosocial approach will be considered for example pain neuroscience education (PNE), and 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 and multidisciplinary intervention that targets an individual or a group of individuals. The biopsychosocial approach in physiotherapy-GUIDED self-management entails a therapist utilising 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 other hand, 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).

Type of Outcomes

Primary outcome

Self-efficacy (self-efficacy scale), patient specific functional scale (PSFS) 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 biopsychosocial approach, rehabilitation, and standard treatment guidelines (examples of interventions include home exercise programmes).

- **Chronic non-specific low back pain** is defined as LBP which persisted for at least more than three months excluding known specific pathology and includes both RLBP and PLBP.
- **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. [26] A physiotherapy-GUIDED self-management programme (SMP) comprise of 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. [27] This process can include patient-orientated therapy, exercise training, family support, counselling, modification of the environment, and self-management strategies.
- **Standard treatment guidelines** (STG) are systematically developed statements to help practitioners or prescribers to decide about treatments to be used for specific clinical conditions. [28] This includes the 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 deliver 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). [29]

Search strategy

The information sources will be searched from different databases in 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 the 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 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 of searches is chosen to be

appropriate in this systematic review based on the systematic review that reported 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. [30] 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. Thirdly, 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**).

Table 1: Results of Pilot Search Strategy

| Search date | Query | Database | Records retrieved |
|-------------|---|--------------------------|-------------------|
| 21/02/2023 | "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 Afghanistan 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 | Academic Search Complete | 169 |

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| 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 | | |
| Not limited to date and language The language translation firstly 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. | | |

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. [31] 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 ten articles will be screened, and agreement assessed before proceeding with all of the articles. We will begin with 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 of inclusion or exclusion on the conflicted articles amongst the two reviewers. The studies that do not meet the inclusion criteria will be excluded and the reason for exclusion will be stated. The process of study selection will be presented in the PRISMA flow diagram attached in **Figure 2**. [20]

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To determine the inter-rater level of agreement between the two reviewers, the 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 risk of bias 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 low, high or unclear risk of bias. [32] The non-randomised trial (NRCT) will be assessed by the use of ROBINS-I tool, given that it is particularly useful for systematic reviews that include NRCT studies of intervention. [33] This tool is guided through seven chronologically arranged bias domain at pre-intervention, intervention and post intervention, and the interpretation of domain-level. Overall bias risk judgement in ROBINS-I is classified in low, moderate, serious, or critical risk of bias. [33] The two independent reviewers will assess and score the selected studies and disagreement 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 (i.e., age, sex), intervention (i.e., 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 by two reviewers, independently 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 synthesize 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, and 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 make a list of all available outcomes reported. If we find an additional common outcome, deemed meaningful to improve an individuals 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 (i.e., pain neuroscience education, digital health intervention 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, which 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 reviews that are selected and extract effect sizes, confidence intervals (CIs) and heterogeneity measures. For effect sizes based on continuous outcome measures, the combined intervention/control group means, standard deviation (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 and low intensity physiotherapy-GUIDED SMP RCTs. In addition, if we find articles that directly compare high and low intensity physiotherapy-GUIDED SMP within the review, we shall group these and if possible, pool the results, comparing high 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 to additional analyses for an example control group type or follow-up period.

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Data synthesis

The risk of bias 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 the 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 amongst the intervention types, components, and outcomes, which will potentially limit pooled analysis. The standardized mean difference (SMD) effect size will be used for pain and disability outcomes to make them comparable across studies and the bias. 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 case of categorical data, the risk ratio (RR) will be considered for effect size. [34] 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. [35]

We will use 95% confidence interval to present the deviation from the point of estimate for both individual and grouped studies estimates. The heterogeneity between the studies will be assessed by using the I^2 statistic and the Chi-square test ($p < 0.1$ will be considered significant). [36] 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 analysis that contains more than 10 studies. [37] All analyses will be done using Stata version 17 statistical software.

Confidence in cumulative evidence

The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) 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. [38] 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 and public involvement. Only physiotherapists working in a middle-income country, were consulted in the development of this proposal.

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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 self-management programme for adult people with CNLBP in Limpopo province South Africa (Ethics reference no: 514/2021 Refer to the **supplementary documents, 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 LMICs. Identifying the effective of physiotherapy-GUIDED self-management interventions for chronic low back pain is of importance, considering the burden related to chronic low back pain, globally, and including LMICs.

This systematic review will assist to update 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 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.

CONTRIBUTORSHIP STATEMENT

SM, MM, AM and NN conceptualised the proposal. SM wrote the first version of the proposal. MM and AM assisted with the refinement of the proposal methods and KK with the search strategy. KM and NN critically revised the manuscript. All authors approved the final version.

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COMPETING INTERESTS

The authors declare no conflict of interest or any personal, financial, professional, or intellectual bias.

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DATA SHARING STATEMENT

This systematic review proposal does not yield data with clinical implications, apart from the studies which will be included in the review itself. Further information based on reasonable requests will be made available.

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WORD COUNT

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FIGURES

Figure 1 Classification of low back pain

Figure 2 PRISMA Flow diagram

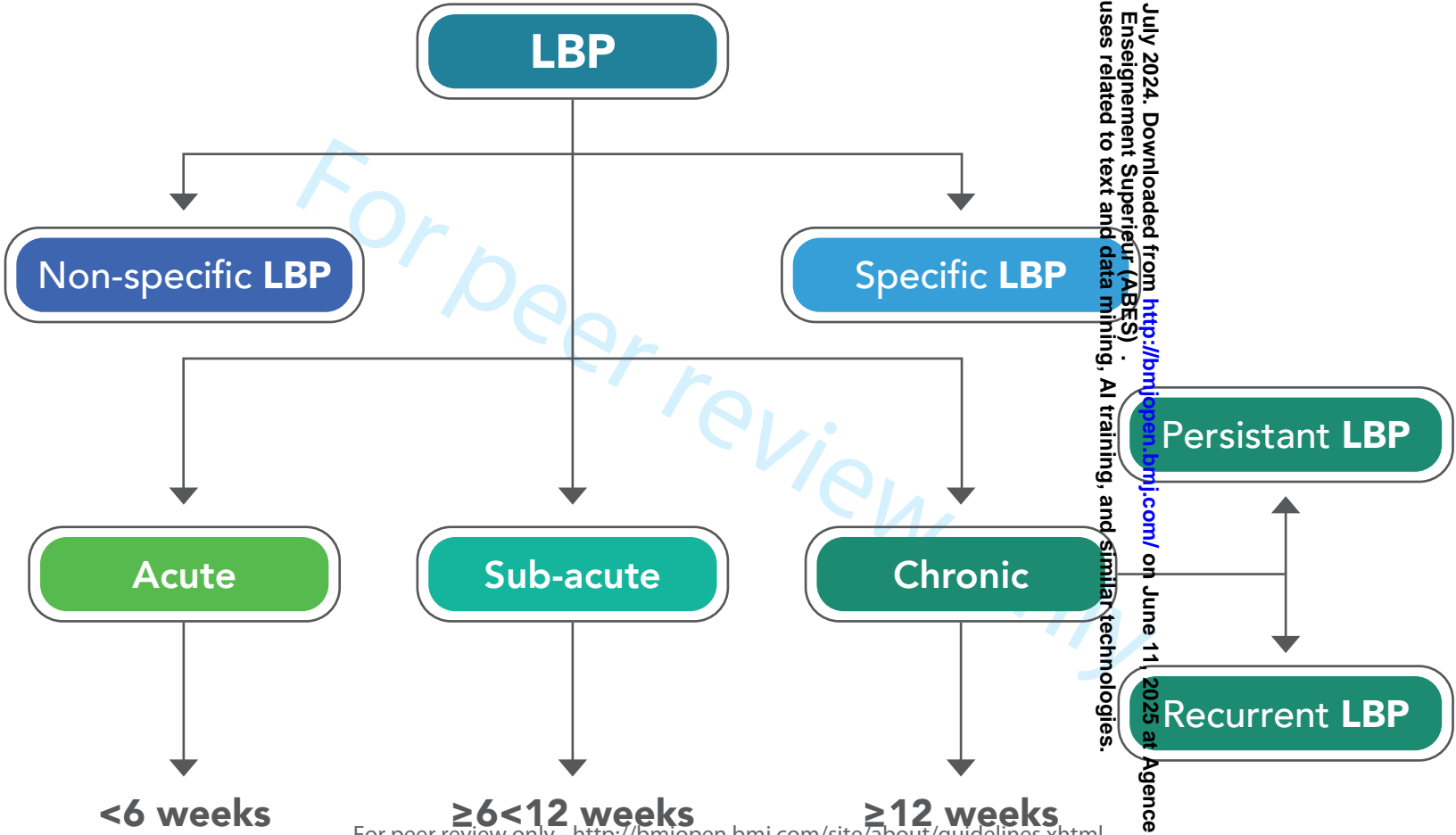
SUPPLIMENT DOCUMENTS

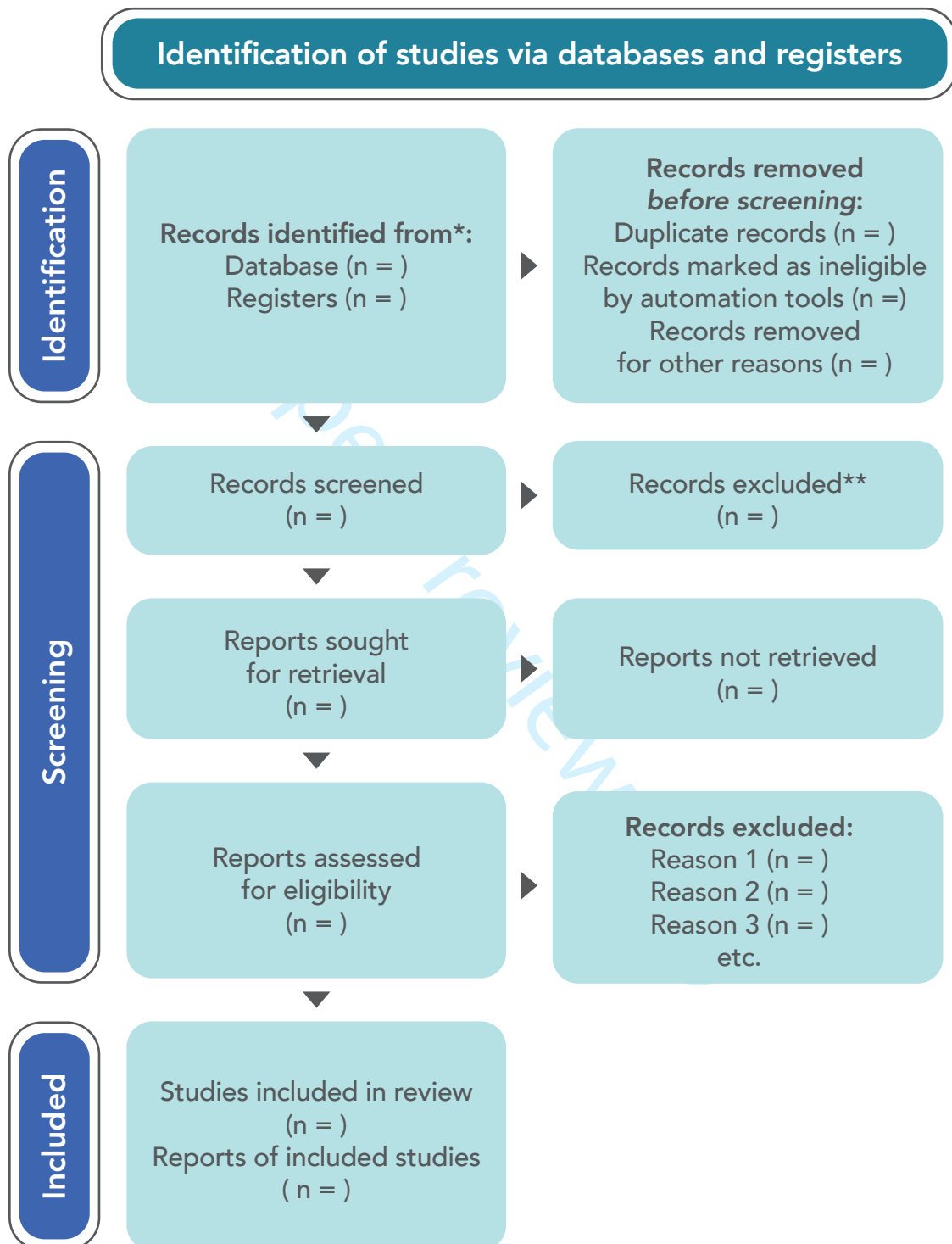
Appendix 1: PRISMA P Checklists

Appendix 2: Ethical clearance certificate

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PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 1 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P 1, Line 4 |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | <input type="checkbox"/> | <input checked="" type="checkbox"/> | N/A |
| Registration | 2 | If registered, provide the name of the registry (e.g., PROSPERO) and registration number | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P 2, Line 20 |
| Abstract | | | | | |
| Authors | | | | | |
| Contact | 3a | Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P 1, Line 1-12 |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | N/A, new protocol |
| Support | | | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P 1, Line 21 - 22 & P 14, Line 15 - 17 |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P7, Line 11 - 13 |
| Risk of bias in individual studies | 14 | Describe anticipated methods for assessing risk of bias of individual studies, including when this will be done at the outcome or study level, or both; state how this information will be used in data synthesis | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P10, Line 18 - 23 & P11, Line 1 - 6 |
| DATA | | | | | |
| Synthesis | 15a | Describe criteria under which study data will be quantitatively synthesized | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P13, Line 1 - 7 |
| | 15c | Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P12, Line 10 - 17 |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P13, Line 3 - 7 |
| Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (e.g., GRADE) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 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”



Faculty of Health Sciences

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).