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Evidence gaps in conservative non-pharmacological interventions and guideline implementation for high-burden non-communicable diseases: protocol for an overview of reviews

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ABSTRACT

Non-communicable diseases (NCDs) represent a high burden for the society and affected individuals. Conservative non-pharmacological interventions play a first-line role in the treatment and management of most NCDs. Systematic reviews (SRs) provide the highest level of evidence and significantly influence clinical decision-making. The primary aim of this study is to provide an overview of the evidence on the effectiveness of recommended conservative non-pharmacological interventions for highly burdensome NCDs. The secondary aim is to provide an overview of the evidence for guideline implementation. A literature search was performed in Medline (PubMed), EMBASE and Cochrane CENTRAL. Six reviewers will, in duplicate, independently screen and select studies following eligibility criteria. The population will include individuals with NCDs from disease categories chosen based on WHO burden of disease data and the importance of conservative rehabilitation for their management. Eligible interventions will encompass conservative non-pharmacological approaches recommended by clinical practice guidelines (ie, physical, psychological and education/advice). Eligible comparator will include no or minimal intervention and other competitive interventions. Outcomes will comprise proposed core outcomes for the respective diseases, including patient-reported (eg, pain) and performance-based (eg, physical functioning) outcomes. SRs published in the last 5 years as peer-reviewed journal article in the English language will be eligible. The overview will be reported in accordance with the Preferred Reporting Items for Overviews of reviews.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Worldwide, there is a high burden of non-communicable diseases (NCDs), and the prevalence is expected to increase further.

⇒ Conservative non-pharmacological interventions delivered by various rehabilitation professionals are considered a cornerstone in the management of most NCDs.

⇒ Numerous systematic reviews with varying degrees of scope, rigour and up-to-dateness are available, limiting current understanding of treatment effectiveness, evidence gaps and needed implementation efforts.

WHAT THIS STUDY ADDS

⇒ This overview of reviews will provide a comprehensive summary of the available systematic review literature on the effectiveness and barriers/facilitators for implementing the top-ranked conservative non-pharmacological interventions for the highest burdensome NCDs.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings of this overview will guide and improve future research decision-making by informing about evidence gaps in multiple disease categories.

⇒ The overview will provide a comprehensive and accessible document for clinicians, enabling better evidence-based clinical decisions.

INTRODUCTION

With the increasing prevalence of non-communicable diseases and an ageing population, the number of people suffering from high-burden (ie, highly prevalent, highly disabling) diseases is expected to increase.[1–3] Global Burden of Disease estimates show that in 2019, 2.41 billion people worldwide suffered from non-communicable diseases, which contributed to 310 million years of disability, an increase of 63% between 1990 and 2019.[3] In addition, global demand for health services and associated costs are likely

to climb. Similar trends have been observed in the USA (from US$1.4 trillion in 2000 to US$4.3 trillion in 2021),[4] Australia (US$50.6 billion in 2012[5] to US$94.4 billion in 2021[6]) and Germany (€218.4 billion in 2000[7] to €440.6 billion in 2020[8]).

Conservative non-pharmacological treatments (eg, exercise, respiratory training and education) are typically offered by allied health professions, such as physiotherapy, exercise physiology and psychology, to manage non-communicable chronic diseases. Many international guidelines now recommend conservative non-pharmacological interventions as the first-line treatment or therapy for non-communicable diseases.[9–13] The delivery of conservative non-pharmacological treatments can improve symptoms and enable patients to manage them independently, reducing costs overall.[14–17] Systematic reviews and meta-analyses provide higher-quality clinical practice guidelines, representing the highest level of evidence for clinical practice.[18 19]

As new primary research is published, existing systematic reviews and associated meta-analyses lose currency over time. One analysis[20] published in 2007 proved that approximately 25% of systematic reviews that met predefined minimum quality standards were no longer up to date after 2 years, and approximately 50% were outdated after 5 years. Similarly, an analysis[21] of Spanish clinical practice guidelines noted that one in five recommendations were outdated after 3 years. A consensus publication in the *BMJ*[22] guided decision-making when a given systematic review may no longer be current. For example, the authors suggest that a new systematic review may no longer be current if there are new relevant (systematic review) methods, new primary research or updated information on existing included studies (eg, retractions).[22] In informing clinical practice and guidelines, it is relevant to assess the presence and recency of systematic reviews for key diseases as well as their treatments. Furthermore, recent findings suggest that 96% of published reviews in psychology report positive statistically significant results[23] as opposed to only 5% in Cochrane Reviews, including high-quality evidence.[24] These findings highlight the need to systematically identify high-quality reviews to make trustworthy clinical recommendations. We aim to conduct an overview of systematic reviews for high-burden non-communicable diseases that are amenable to management via non-pharmacological conservative interventions.

In doing so, the prioritisation of diseases to assess may be driven by assessing the burden of disease data.[25] In prioritising which treatments should be included in this assessment, existing evidence-based clinical practice guidelines inform which interventions are currently recommended for routine care. In addition, understanding the barriers and facilitators to guideline implementation is critical to providing high-quality care to those who need it most. However, to our knowledge, work has yet to be done to identify existing research gaps and update research priorities.

The objectives of this overview of reviews are to provide an overview (presence and currency of systematic reviews) in two areas: (1) intervention effectiveness in high burden and relevant to conservative rehabilitative professions diseases and (2) barriers and facilitators to guideline implementation in clinical practice.

METHODS

This overview of reviews is conducted and reported following the PRIOR reporting guideline for overviews of reviews[26] (online supplemental data 1). The review was prospectively registered (Open Science Framework: https://osf.io/s94qf).

Patient and public involvement

Patients and/or the public were not involved in the design and conduct of this research.

Search strategy

The full search strategy can be found in the appendix (online supplemental data 2,3). The following databases (limits) were searched from the last 5 years to the current date: MEDLINE via PubMed (last 5 years), EMBASE via Ovid (Exclude MEDLINE; last 5 years) and CENTRAL (no time limit). Searches were performed in March 2023. We chose to target only these three databases as the major medical databases, as higher-quality systematic reviews are more likely to be published in journals listed in these databases. As we were not searching for primary randomised controlled trials, where broad search terms are required to ensure all relevant literature is captured, search terms were chosen that focused specifically on the disease and intervention of interest. Citation tracking was not performed as systematic reviews are readily identifiable in databases, and citation tracking has been shown[27] to have minimal additional benefits in identifying systematic reviews.

If no relevant studies were identified from the last 5 years, an additional hand search was performed, and the most recent review was included. Two independent assessors (RD, TSaueressig, TB, JZ, AJ and RSchäfer) screened the studies using Covidence. Disagreements were resolved through collaborative discussion within the review team and involved a three-stage process: first, reviewers and extractors engaged in discussions; second, in cases of uncertainty, there was consultation with an adjudicator (RD or TSchleimer); and finally, if no resolution could be achieved at the previous stages, the matter was referred to a designated team member.

Before each phase (title/abstract and full-text screening), a pilot was conducted. Each reviewer independently screened the same randomly chosen 100 titles/abstracts (RD, TSaueressig, TB, JZ, AJ and RSchäfer) and 20 full texts (RD, TSzikszay, TB, JZ, AJ and RShala). Article data (eg, author, publication year, title and abstract) and inclusion/exclusion criteria were copied into a Microsoft Excel (V.16.0) spreadsheet template. After collating the results, all reviewers discussed themes of disagreement

and refinement of the screening process. This procedure was repeated if no consensus was reached.

Eligibility criteria

Inclusion criteria followed the Participants, Interventions, Comparators, Outcomes and Study design framework.[28]

Systematic reviews of treatment efficacy (primary research question)

Participants: In line with data from the Global Burden of Disease Study 2019,[1 3] the following high-burden diseases were chosen to be included: back pain, osteoarthritis, rheumatoid arthritis, cerebral palsy, Alzheimer/dementia, stroke, chronic obstructive pulmonary disease (COPD), ischaemic heart disease (IHD) and lung cancer (see online supplemental data 4) for detail on the process of population selection). The target population(s) were included if separate analysis was performed per disease category. Reviews that encompassed studies/reports with participants who had undergone surgery before or after rehabilitation were excluded.

Interventions: The approach from Rauch *et al*[29] was adopted to identify relevant interventions; clinical practice guidelines from the UK, USA and Germany reporting on non-pharmacological interventions were evaluated (see online supplemental data 5) for a list of guidelines used) and if relevant guidelines were not available, expert team members were asked to provide suggestions on current conservative non-pharmacological interventions (see online supplemental data 6) for details on the interventions considered). In total, 12 experts, comprising team members and international experts, ranked the suggested interventions based on the importance of evidence mapping with the question: 'Select (tick) the interventions according to your view of the importance/urgency to do evidence mapping and identify knowledge gaps'. The top three interventions for each disease category were selected. If more than three interventions received equal votes in the survey, a panel of three experts (DLB, TSzikszay and RD) met to discuss and select the top interventions. Table 1 lists the resulting interventions, of which one had to be included in the review.

Comparators: Reviews were included if the intervention was compared with minimal or no intervention (eg, 'usual care', placebo/sham, true (no intervention) control) or with other interventions. The rationale for including other interventions as comparators was that most interventions show efficacy compared with, for example, no intervention, and it is, therefore, more informative for clinical practice if data on the comparative effects of different interventions are also presented. Reviews were excluded if a combination of non-pharmacological conservative interventions with pharmacological or non-conservative interventions (eg, exercise plus surgery) was examined. Similarly, the comparison of different aspects within the same intervention domain, such as exercise against another form of exercise, was also excluded.

Outcomes: The inclusion criteria for reviews were based on the assessment of specific core outcomes for various disease categories, including the consideration of conservative non-pharmacological interventions. This approach was adopted to ensure a comprehensive evaluation of the effectiveness and relevance of different treatment modalities in managing specific disease categories.

For back pain, osteoarthritis or rheumatoid arthritis, reviews were included if they evaluated pain, disability and/or quality of life.[30–32] For cerebral palsy, Alzheimer's disease or dementia, the assessments of physical functioning and/or quality of life were considered.[33 34] For stroke, COPD, IHD or lung cancer, reviews that evaluated exercise capacity and/or quality of life were included.[35–38]

Study design: Systematic reviews of randomised controlled trials (RCTs) in English were included. We defined a systematic review as a study that addresses a specific research question by identifying primary research evidence that meets defined eligibility criteria identified by a search of academic research databases. Further, peer-reviewed full-text journal publications from the last 5 years (ie, with reference to publication date) were eligible. The rationale for this was that reviews should be recent, as per findings[20] on the loss of currency of reviews. The most recent Cochrane review on the topic will be included, irrespective of the time frame. Suppose there are more than five reviews of the last 5 years. In that case, the reviews available will be prioritised according to (a) how specific the included population was to the target population, (b) the relevance of the intervention evaluated to the target intervention, (c) in what setting the intervention was performed (d), number of databases searched, (e) number of RCTs included and (f) whether the study was published in a journal from a potentially predatory publisher (see online supplemental data 7). The levels of priority (=Prio) were assigned an ordinal value of 1 for 'high', 0 for 'moderate' and −1 for 'low' and were summed for each review based on the aforementioned criteria. The five highest priority reviews will be included.

Our operationalisation of the inclusion criteria as part of the screening process is presented in online supplemental data 8.

Systematic reviews of implementation (secondary research question)

For systematic reviews of implementation (focusing on barriers/facilitators and trials of guideline implementation), the same criteria were used for participants as for the primary research question on systematic reviews of treatment efficacy. There were no restrictions on the criteria for interventions, comparators or outcomes. The systematic review had to be focused on either barriers/facilitators to implementing evidence in clinical practice or trials for implementing evidence in clinical practice. Systematic reviews, which included RCT or cluster trials and non-randomised study designs such as interrupted time series and controlled before/after studies and/or

Table 1 Diseases, interventions and outcomes considered

Disease	Education	Cognitive behavioural therapy	Exercise	Cognitive behavioural therapy+exercise	Physical activity/ promotion	Behavioural change technique	Postural training	Occupational therapy	Telehealth	Early mobilisation	Intensive mobilisation	Breathing technique	Outcome	Quality of life	Pain intensity	Physical functioning	Exercise capacity
Back pain (acute)																	
Back pain (subacute/ chronic)																	
Osteoarthritis																	
Rheumatoid arthritis																	
Cerebral palsy																	
Alzheimer/ dementia																	
Stroke																	
Chronic obstructive pulmonary disease																	
Ischaemic heart disease																	
Lung cancer																	

Physical functioning refers to the ability to perform physical tasks and/or activities related to daily living.[44] This includes aspects such as strength, flexibility, balance and coordination, as well as walking, climbing stairs and others. In this review, we defined it as being measured by a questionnaire. Exercise capacity is a specific component of overall physical functioning that focuses on the maximum amount of physical exertion one can sustain.[45] This review defined it as performance-based tests rather than patient-reported outcomes.

qualitative or mixed-methods studies, were included as long as these addressed the research question.

Data extraction

Two independent reviewers will extract the data of included reviews, including publication demographics (eg, authors, publication year), population (name of diagnosis/condition), stage of the condition (acute, subacute, chronic), intervention, comparators in a meta-analysis, outcomes included in our review (number of reports included, number of patients, effect size estimate, Grading of Recommendations Assessment, Development and Evaluation assessment if performed). The data will be compiled and organised in a spreadsheet using Microsoft Excel (V.16.0). If conflicts arise, the two reviewers will discuss them, and the adjudicator will be consulted if a conflict cannot be resolved. When only figures are presented (rather than numerical data within the text), data will be extracted using the web app WebPlotDigitizer (https://automeris.io/WebPlotDigitizer/). If not possible, data will be manually extracted using ImageJ (https://imagej.nih.gov/ij/) to measure the length (in pixels) of the axes to calibrate and then the length in pixels of the data points of interest.[39] Where information was unavailable within a paper, authors will be contacted at least three times over 4 weeks to request the data.

Data extraction will be piloted on five reports chosen at random before extraction. All reviewers will conduct the pilot extraction independently. The results will be discussed with all coauthors to refine the extraction template. This step will be repeated unless a consensus is reached.

Identification of study overlap

To quantitatively assess the degree of overlap between included systematic reviews, the corrected covered area (CCA) will be calculated.[40] The CCA considers the degree of similarity between different systematic reviews and provides a measure of the extent to which they have studied, populations, interventions, comparators and/or outcomes in common. In addition, a qualitative assessment will be conducted to describe the percentage of overlap in the findings.

Quality of included systematic reviews

Two reviewers will independently assess the methodological quality of the included systematic reviews using (A MeaSurement Tool to Assess systematic Reviews; https://amstar.ca/Amstar-2.php) according to an internal protocol (see online supplemental data 9). In case of conflicts, the two reviewers will discuss and contact an adjudicator if conflicts persist.

Quality of primary studies included in the systematic review

The method (eg, Cochrane Risk of Bias version 1 or 2,[41] PEDRO scale)[42] used in the systematic review to assess the risk of bias in the primary studies will be recorded. Furthermore, the summary estimates of the risk of bias of the included studies (ie, percentage rated as low risk of bias) will be recorded.

Synthesis methods

The data synthesis will be performed narratively and via summary information (eg, the number of reviews on a particular research question). A reanalysis of underlying primary studies will not be performed.

Reporting bias

Whether authors attempted to assess reporting bias will be recorded. If it is present, we will record whether this was via statistical (eg, Egger's test) or visual (eg, assessment of funnel plot asymmetry) means only or whether authors attempted to identify potentially unpublished studies (eg, via assessment of clinical trial registries).

Certainty assessment

Whether a certainty assessment is present in a systematic review will be assessed. If it is present, the certainty assessment made by the authors will be recorded.

DISCUSSION

Our study protocol outlines the need for up-to-date evidence in the management of high-burden diseases. The emphasis on non-pharmacological conservative treatments aligns with current healthcare trends and international guidelines, which focus on patient-centred, cost-effective approaches. We aim to produce evidence maps on the existence and recency of systematic reviews of non-pharmacological conservative treatments for high-burden diseases, which, together with identifying facilitators and barriers to treatment uptake, will inform the design of future health strategies and research initiatives. Pending a more conclusive understanding of the evidence, our work supports urging public health authorities (eg, WHO, Centers for Disease Control and Prevention, National Institute for Health and Care Excellence and Robert Koch Institute) to adopt refined programmes based on the latest high-quality evidence.

Strengths

Recognising the diminishing relevance of systematic reviews over time, our study addresses this challenge by providing a contemporary overview of the evidence landscape. We aim for a focused examination of relevant evidence, emphasising high-quality sources, particularly systematic reviews, including those published by the Cochrane Collaboration. We enhance the reliability and generalisability of the findings by mapping the current state of systematic reviews of RCTs. This emphasis on RCTs highlights their methodological rigour and unique strengths in minimising bias and providing reliable evidence for informed decision-making.[43] Furthermore, the integration of evidence-based clinical practice guidelines into our disease selection process will provide a robust basis for recommendations. In addition, our careful disease selection process, informed by the latest burden of disease data and guided by specialists in the

field, ensures the relevance of our findings. The use of expert panels is a distinct advantage, facilitating nuanced selections.

Limitations

While expert panels are adept at identifying nuances in the available evidence, they introduce a potential for subjectivity in the delineation of disease and treatment categories. Similarly, we recognise the impact of national perspectives on our findings, which may underscore the different disease and treatment landscapes in global contexts. This, together with our prioritisation strategy based on review quality, may result in a limited number of reviews being considered. Furthermore, the heterogeneity of disease definitions, diagnoses, interventions and comparison groups presents a major challenge to evidence synthesis. Hence, the methods we have outlined for the qualitative presentation and synthesis of evidence should provide the reader with a comprehensive framework for interpreting the results.

In perspective, recognising the inherent limitations of heterogeneity of evidence, our work will provide a contemporary and focused overview of reviews, emphasising high-quality sources and expert input.

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