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# **BMJ Open**

#### Strategies used to manage overlap of primary study data by exercise-related overviews. Protocol for a systematic methodological review.

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## SCHOLARONE<sup>™</sup> Manuscripts

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## Strategies used to manage overlap of primary study data by exercise-related overviews. 1 Protocol for a systematic methodological review. 2 Ruvistay Gutierrez-Arias<sup>1,2</sup>, Dawid Pieper<sup>3,4</sup>, Carole Lunny<sup>5</sup>, Rodrigo Torres-Castro<sup>6</sup>, Raúl 3 Aguilera-Eguía<sup>7</sup> and Pamela Seron<sup>8</sup> 4 5 **Affiliations:** 6 <sup>1</sup>Servicio de Medicina Física y Rehabilitación, Unidad de Kinesiología, Instituto Nacional 7 del Tórax, Santiago, Chile. 8 <sup>2</sup>Exercise and Rehabilitation Sciences Institute, School of Physical Therapy, Faculty of 9 Rehabilitation Sciences, Universidad Andres Bello, Santiago, 7591538, Chile. 10 <sup>3</sup>Faculty of Health Sciences Brandenburg, Brandenburg Medical School (Theodor Fontane), 11 Institute for Health Services and Health Systems Research, Rüdersdorf, Germany. 12 13 <sup>4</sup>Center for Health Services Research, Brandenburg Medical School (Theodor Fontane), Rüdersdorf, Germany. 14 <sup>5</sup>Knowledge Translation Program, Dalla Lana School of Public Health, University of 15 Toronto, Canada. 16 <sup>6</sup>Department of Physical Therapy, University of Chile, Santiago, Chile. 17 <sup>7</sup>Departamento de Salud Pública, Facultad de Medicina, Carrera de Kinesiología. 18 Universidad Católica de la Santísima Concepción. Concepción, Chile. 19

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36 All authors declare no competing interests.

#### 38 Data sharing

#### 39 Not applicable

Introduction: One of the most conflicting methodological issues when conducting an

overview is the overlap of primary studies included across systematic reviews (SRs). Overlap

in the pooled effect estimates across SRs may lead to overly precise effect estimates in the

overview. SRs that focus on exercise-related interventions are often included in overviews

aimed at grouping and determining the effectiveness of various interventions for the

**Objective:** The aim of this systematic methodological review is to describe the strategies used

by authors of overviews focusing on exercise-related interventions to manage the overlap of

## 

Abstract

primary studies.

management of specific health conditions.

Materials and methods: A comprehensive search strategy has been developed for different databases and their platforms. The databases to be consulted will be MEDLINE (Ovid), Embase (Ovid), The Cochrane Database of Systematic Reviews (Cochrane Library), and Epistemonikos. Two reviewers will independently screen the records identified through the search strategy and will extract the information from the included overviews. The frequency and the type of overlap management strategies of the primary studies included in the SRs will be considered as the main outcome. In addition, the recognition of the lack of use of any overlap management strategy and the congruence between planning and conducting the overview focusing on overlap management strategies will be assessed. A subgroup analysis will be carried out according to the journal impact factor, year of publication, and compliance with the PRIOR statement. 

**Discussion:** This methodological review will provide a complete and comprehensive summary of the frequency of use and types of strategies used for managing the overlap of primary studies across the SRs included in the overviews focusing on exercise-related interventions in different health conditions. Future studies should apply different overlap management strategies to understand their impact on results and conclusions. 

- Systematic review registration: INPLASY202250161.

**Keywords:** Overviews of systematic reviews; Umbrella review; Overlap; Review methods; 

Exercise; Rehabilitation. 

#### **Strengths and limitations**

- This study aims to describe the strategies used to manage the overlap of primary studies in exercise-related overviews.
- A sensitive search of MEDLINE (Ovid), Embase (Ovid), The Cochrane Database of Systematic Reviews (Cochrane Library), Epistemonikos databases, and registers of evidence synthesis study protocols will be conducted.
  - Secondarily, this study will assess the quality of overview reporting using the recently published Preferred Reporting Items for Overviews of Reviews (PRIOR) statement.
    - In addition, the aim is to analyze whether there is a relationship between the use of any overlap management strategy and the journal's impact factor, year of publication,
      - and compliance with the PRIOR statement.

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## Introduction The number of published primary studies covering a similar research question has grown exponentially (1), limiting the possibility of keeping up to date on a specific topic (2). It is in this context that systematic reviews (SRs) with and without meta-analyses (MAs) of interventions can offer a solution (3), as in addition to synthesizing the available evidence, they use reproducible methods to assess the risk of bias in the primary studies included (4). However, the number of published SRs and MAs has increased steadily in recent years despite the existence of repositories of SRs and MAs protocol registries (5–7) seeking to reduce duplication or redundancy of SR research (8,9). The growth in research evidence makes it difficult for clinicians to stay current and use interventions based on the best available evidence (10,11). Overviews, also known as umbrella reviews, can help clinicians make sense of duplicated SRs on the same topic. Overviews synthesize information and data from multiple similar SRs to guide health decision-making (12). Conducting overviews of health interventions is meant to map the available evidence (13). establishing the effects of different interventions on the same health condition or population (12), examining the effects of an intervention on different health conditions or populations (12), and determining the reasons for disagreement among SRs with or without MAs that answer the same research question (14).

Intuitively, one might think that conducting an overview presents the same steps as conducting an SR with MAs; however, overviews pose challenges stemming from the fact that the unit of analysis is the SR (15,16). When conducting an overview, one of the most

conflicting methodological issues is the overlap of primary studies included across SRs with or without MAs (17). When one or more primary studies are included in two or more SRs with or without MAs, the results and conclusions of the overviews may be biased. Overlapping data from the same primary studies may include overlapping in risk of bias and certainty of evidence assessments (e.g., Grading of Recommendations, Assessment, Development and Evaluations (GRADE)), or overlapping in the determination of the effect of a specific intervention and other MA outcomes such as heterogeneity (e.g.,  $I^2$ ) (18,19). Overlap in the pooled effect estimates across SRs may lead to overly precise effect estimates in the overview (20). Methodological studies from different medical fields reported that authors of overviews rarely assess the overlap of primary studies (16,17). However, these studies have not conducted an exhaustive search of overviews oriented to a specific health problem, specialty, or discipline (16,17), as they have only searched an electronic database (16) and included heterogeneous overviews concerning the research questions addressed (16,17). 

119 There are several ways to manage overlap (20). Some will depend heavily on the amount of 120 overlap and the existing evidence base. Thus, it can be challenging to determine the 121 methodological approach a priori. Changes to the protocol are likely to occur at this step and 122 should be clearly reported.

SRs that focus on exercise-related interventions are often included in overviews aimed at grouping and determining the effectiveness of various interventions to mange of specific health conditions. Assessing the application of overlap management strategies in overviews focused on exercise-related interventions could contribute to identifying specific or differentiating aspects. This could be because the concept of exercise is often misunderstood

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(21). In addition, the existence of multiple interventions related to exercise due to their
different modalities (e.g., continuous aerobic, intervallic aerobic, resistance exercise) and
dosage (e.g., frequency, intensity, time, and type) could result in a particular need to manage
the overlapping of primary studies data.

Considering the recently published Preferred Reporting Items for Overviews of Reviews (PRIOR) statement, which incorporates the need to report on the handling of overlapping primary studies, both in the data collection phase and in the presentation of results, in order to improve and standardise the reporting of overviews (22), this systematic methodological review aims to find out how often strategies for handling overlapping data from primary studies are used in systematic reviews considered by syntheses focusing on exercise-related interventions in different health conditions. Secondly, it aims to describe the overlap strategies used, the authors' acknowledgement of not using any overlap management strategies as a methodological weakness, and the congruence between the protocol and the final published summary in terms of overlap management. These findings are intended to be analysed according to the impact factor of the journal in which the overviews were published, the year of publication of the overview, and compliance with the PRIOR statement.

#### 144 Materials and methods

The protocol of this methodological review is reported following the Preferred Reporting
Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) (23) (see checklist
in Supporting Information). In addition, this protocol has been registered in the International
Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) under
number INPLASY202250161.

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150 Eligibility criteria

151 Studies will be eligible if they meet the following inclusion criteria for study design and 152 population. Given the purpose of this methodological review, the intervention and outcomes 153 will not determine the inclusion of studies, and the comparator or control intervention will 154 not be considered as it is not applicable.

155 <u>Study design</u>

We will include overviews that consider SRs with or without MAs, without distinction of the methodological design of the primary studies included. The definition of SR adopted by the authors of the overviews (24) will not be considered an eligibility criterion. Overviews that include primary studies not considered in the selected SRs will not be excluded.

160 For this review, an overview will be understood as any study (25) that:

161 1) synthesizes general information, methods, and outcome data from SRs, and

162 2) makes explicit the inclusion and exclusion criteria for SRs, and

163 3) includes an explicit search strategy for the studies, and

164 4) examines the effectiveness of health interventions.

165 Overviews that are conducted using a "rapid review" methodology (26) will be excluded, as 166 the time frame in which they are conducted to answer urgent questions will likely not 167 consider the overlap of the primary studies included in the SRs.

168 <u>Population</u>

169 Overviews include SRs that have considered primary studies that have studied any exercise-

170 based intervention, where exercise is understood as a subcategory of physical activity that is

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planned, structured, repetitive, and purposefully focused on improving or maintaining one or more components of physical fitness (21), will be included. These overviews may include only SRs related to exercise-based interventions, or other non-exercise interventions as well. Overviews that consider exercise training-based interventions that are applied both preventively and in the recovery phase, and that are delivered either as a stand-alone intervention, as part of a comprehensive rehabilitation program, or as an adjunct to other medical interventions in which exercise is the main component, will be included. Furthermore, the inclusion of overviews will not be limited to the context in which the exercise-based interventions were applied (e.g., primary care, specialized care) or whether they were delivered face-to-face, remotely, or mixed. Overviews that include SRs that consider physical activity as an intervention, understood as "any bodily movement produced by skeletal muscles that require energy expenditure" according to the World Health Organization (27), will be excluded. Therefore, to differentiate between exercise-based and physical activity-based interventions, it will be considered that the exercise, together with its structure and dosage (frequency, intensity, time, and type), must be prescribed or delivered by a professional related to physical training/rehabilitation. Intervention Our goal is to identify the strategies used to manage data from overlapping primary studies selected by SRs included in overviews. Strategies should be specified in the main text of the overviews and may be in the methods or results section, taking all possible methodological strategies that address overlap in the primary study data into consideration. Strategies

addressing overlap can address different objectives (20), such as quantifying the overlap

193	(17,28) (e.g., corrected covered area (CCA)), visually presenting overlap (29) (e.g., matrix,
194	Venn and Euler diagrams), and avoiding duplicate information by using one or more decision
195	algorithms (30) (e.g., quality of SRs, comprehensive SRs, up-to-datedness of SRs, statistical
196	methods).
197	<u>Outcomes</u>
198	The presence and the type of overlap management strategies of the primary studies included
199	in the SRs will be considered as the main outcome.
200	In addition, two aspects will be regarded as secondary outcomes:
201	1) Acknowledgement of the limitation in the conducting of the overview: we will assess
202	whether the overview's authors that did not include any strategy for managing
203	primary study overlap considered this limitation in their discussion or conclusion.
204	2) Congruence between planning and conducting the overview: we will review available
205	registry entries (e.g., PROSPERO) or published protocols in scientific journals (e.g.,
206	BMC Systematic Reviews Journal, BMJ Open) of all overviews included in this SR
207	to determine whether management of primary study overlap had been considered in
208	the planning phase of the overviews and to determine the congruence between the
209	methods proposed in the protocols and those ultimately used.
210	Search strategy
211	A search strategy translated to different databases and their platforms will be developed using
212	a controlled vocabulary (MeSH and Emtree) and text words. The search strategy will include
213	a search filter published in 2016 by Lunny et al. (31), which is validated to identify overviews
214	in MEDLINE-Ovid with 93% sensitivity (95% CI 87 to 96). The search strategy constructed

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- for this database and platform is shown in Table N°1, which will be used as a basis for
- adapting the search strategies of the other databases and search platforms.
  - Table 1. Search strategy for MEDLINE using the Ovid platform

1				
2	exp Exercise/			
2	exp Physical Fitness/			
3	exp Physical Exertion/			
4	exp Physical Therapy Modalities/			
5	exp Exercise Therapy/			
6	exp Rehabilitation/			
7	(rehabilitat\$ or fitness\$ or exercis\$ or physical\$ or train\$ or physiotherap\$ or kinesiotherap\$).ti,ab.			
8	aerobic\$.ti,ab.			
9	(muscle\$ adj3 resist\$).ti,ab.			
10	or/1-9			
11	((overview\$ or review or synthesis or summary or cochrane or analysis) and (reviews or meta-analyses or articles or umbrella)).ti. or umbrella review.ab. or (meta-review or metareview).ti,ab.			
12	(overview\$ or reviews).mp. and (systematic or cochrane).ti.			
13	(reviews adj2 meta).ab.			
14	(reviews adj2 (published or quality or included or summar\$)).ab.			
15	cochrane reviews.ab.			
16	(evidence and (reviews or meta-analyses)).ti.			
17	or/11-16			
18	and/10,17			

The databases to be consulted will be MEDLINE (Ovid), Embase (Ovid), The Cochrane Database of Systematic Reviews (Cochrane Library), and Epistemonikos. In addition, we will search protocol registries of SRs such as the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY) (https://inplasy.com/), PROSPERO (https://www.crd.york.ac.uk/PROSPERO/), and OSF Registries (https://osf.io/registries), and follow up protocols published in scientific journals (e.g., BMC Systematic Reviews Journal, BMJ Open). 

We will also review the references of the studies included in this review to identify overviews that may not have been identified by our electronic search strategy. 

We will include all languages in our search and will not be limited by the date of publication/indexing in databases. 

**Study selection** 

Two reviewers (RGA and RTC) will independently and blindly screen the records identified through the search strategy. In the first instance, the titles and abstracts will be evaluated for inclusion. Then the full texts of the records qualified as potentially eligible, and those that did not present sufficient information to be excluded, will be checked for compliance with all eligibility criteria. The Rayyan® application (32) will be used for this stage. Disagreements will be resolved by consensus, or ultimately by a third-party reviewer (RAE or PS). 

#### **Data extraction**

The extraction of information from the included overviews will also be carried out independently and blindly by two reviewers (RGA and RTC). For this, a standardized extraction form will be used which will contain data related to the basic information of the overviews:

Title. Journal name. Year of publication. Name of the authors. Objectives of SRs. 

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1		13
2		
3 4	248	• Number of SRs included
5 6	249	• Number of primary studies included
7 8	250	• Methodological aspects: databases consulted, date of search, type of synthesis of
9 10	251	results (narrative, MA, or both), and instruments for assessing the risk of
11 12		
13 14	252	bias/methodological quality of the SRs included.
15 16 17	253	Data will be extracted to respond to the findings of this methodological review:
17 18 19	254	• Type of overlap management strategy:
20 21	255	a. Quantifying overlap: e.g., CCA.
22 23 24	256	b. Visual presentation of the overlap: e.g., matrix, Venn or Euler diagrams.
24 25 26	257	c. Strategies to avoid duplicate information: e.g., Algorithms based on the quality of
27 28	258	SRs, comprehensive SRs, up-to-datedness of SRs, statistical methods such as
29 30	259	sensitivity analyses, or a combination of two or more criteria: e.g., Jadad algorithm
31 32 33	260	(33).
34 35	261	• Step in the conducting of the overview where the strategy has been deployed or used:
36 37	262	e.g., data extraction step, synthesis step.
38 39	263	• Level at which the strategies were applied: i.e., whether it was at the level of SR or
40 41		
42 43	264	reported outcomes (20).
44 45	265	In addition, the impact factor of the journal at the time of publication of the overviews will
46 47 48	266	be recorded. This will be extracted from the journals' official websites or from Web of
49 50	267	Science (https://www.webofscience.com/).
51 52		
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If more than one record or publication exists for an overview, the most recent version will be considered for analysis. Disagreements will be resolved by consensus, or ultimately by a third-party reviewer (RAE or PS). **Risk of bias and reporting quality assessment** This methodological review assesses one aspect that may affect the methodological quality or risk of bias of the overviews. The assessment of the overall risk of bias of the overviews is not an objective of this study. Two independent reviewers will assess the quality of the overviews' reporting by considering compliance with the PRIOR statement (22). Disagreements will be resolved by consensus, or ultimately by a third reviewer. **Strategy for data synthesis** The results of the study selection will be schematized through a PRISMA-type flow chart (34). In addition, the characteristics of the overviews included, as well as data related to the primary and secondary outcomes, will be presented in narrative form, and through tables and figures. Descriptive statistics will be used to quantify the number of overviews using overlap strategies, whether the strategies were used at the level of the SRs or the level of each reported outcome. In addition, these results will be organized by the type of strategy used. We will also assess whether the overlapping strategy successfully resolved overlap at the following steps: risk of bias assessment, the certainty of the evidence (e.g., GRADE), and the synthesis step. 

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#### 289 Analysis of subgroups

Differences in the percentage of overviews that include overlap management strategies, the type of strategies used, the recognition of the weakness of not using any strategy, and the congruence between the protocols and the methodology finally used among journals with and without IF will be assessed. In addition, this analysis will be repeated for impact factor journals, considering the median or quartiles of the impact factor of the journals at the time of publication of the overviews to form 2 or 4 groups respectively, depending on the number of overviews included in this methodological review. In addition, analysis will be carried out by subgroup according to the year of publication of the overviews and compliance with the items considered in the PRIOR statement. 

#### 299 Discussion

This methodological review will provide a comprehensive and exhaustive summary of the frequency of use of strategies for managing primary study overlap across SRs included in overviews focused on exercise-related interventions in different health conditions. It will also provide insight into the strategies used to quantify and visualize overlap, as well as those used to avoid duplicate data.

On the other hand, the findings of this review will tell us whether the authors of the overviews recognized the failure to include some strategy for handling overlap as a methodological weakness, taking into account that the greater the degree of overlap, the more falsely precise the estimates of the effects of the interventions (20). In addition, the congruence between the strategies used by the published overviews and their respective protocols will be revealed.

To our knowledge, the latter two aspects have not been addressed at the overview level by other studies before. Finally, all analyses will be performed by subgroup of overviews, considering the impact 

factor of the journal and the year of publication. Although the PRIOR statement was recently published (22), assessing compliance in the reporting of overviews, and its relation to the use of strategies for the management of overlapping primary studies, could expose the shortcomings and weaknesses that have been committed so far. 

#### Future research

To continue this line of research, different overlapping data management strategies should be applied to all, or a representative sample, of the overviews identified by this methodological review. This could empirically test the benefits and limitations of using any strategy. Ze,

#### Ethics and dissemination plans

This study will not involve human subjects and therefore does not require ethics committee approval. However, the conduct and reporting of the findings of this review will be conducted in a rigorous, systematic, and transparent manner, which relates to research ethics.

The findings of this review will be presented at scientific conferences and published as one or more studies in peer-review scientific journals related to rehabilitation, healthcare, or methodological aspects associated with evidence synthesis. 

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1 2			
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26 27	426		BMJ. 2021;372:n71.
28 29 30	427		
31 32 33	428	Auth	nor's contribution
34 35 36	429	RG-	A, DP, CL, and PS contributed to the conception and design of the study. RG-A
37 38	430	devel	loped the search strategies, which was reviewed by RT-C and RA-E. RG-A, DP, CL,
39 40 41	431	and I	PS designed the data analysis. RGA-A drafted the manuscript, and all authors read it
42 43	432	critic	ally.
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# Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

## Instructions to authors

 Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

44 45				Page
46 47			Reporting Item	Number
48 49 50 51	Title			
52 53 54	Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
55 56 57 58	Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	n/a
59 50		For pe	er review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2 3	Registration			
4 5		<u>#2</u>	If registered, provide the name of the registry (such as	4
6 7 8			PROSPERO) and registration number	
9 10 11 12 13 14	Authors			
	Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all	2
15 16			protocol authors; provide physical mailing address of	
17 18 19			corresponding author	
20 21	Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the	22
22 23 24			guarantor of the review	
24 25 26	Amendments			
27 28				
29 30 31 32		<u>#4</u>	If the protocol represents an amendment of a previously	n/a
			completed or published protocol, identify as such and list	
33 34 35			changes; otherwise, state plan for documenting important	
36 37			protocol amendments	
38 39	Support			
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42 43	Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	2
44 45 46 47	Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	2
47 48 49 50 51	Role of sponsor or	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s),	2
	funder		if any, in developing the protocol	
52 53 54 55	Introduction			
56 57 58	Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is	5-7
59 60		For pee	er review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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1 2			already known	
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 5 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 5 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 36 37 38 39 40 41 42 5 5 5 5 5 5 5 5 5 5 5 5 5	Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will	7
			address with reference to participants, interventions,	
			comparators, and outcomes (PICO)	
	Methods			
	Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design,	8-10
			setting, time frame) and report characteristics (such as years	
			considered, language, publication status) to be used as	
			criteria for eligibility for the review	
	Information	#9	Describe all intended information sources (such as electronic	11
	sources	<u></u>	databases, contact with study authors, trial registers or other	
	3001003			
			grey literature sources) with planned dates of coverage	
	Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one	10-13
			electronic database, including planned limits, such that it	
			could be repeated	
	Study records -	#11a	Describe the mechanism(s) that will be used to manage	12-15
	data management		records and data throughout the review	
43 44	0			
45 46	Study records -	<u>#11b</u>	State the process that will be used for selecting studies (such	12
47 48	selection process		as two independent reviewers) through each phase of the	
49 50			review (that is, screening, eligibility and inclusion in meta-	
51 52 53			analysis)	
54 55	Study records -	<u>#11c</u>	Describe planned method of extracting data from reports	12-14
56 57 58	data collection		(such as piloting forms, done independently, in duplicate), any	
59 60		For pee	r review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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1 2	process		processes for obtaining and confirming data from investigators	
3 4 5 6 7 8 9 10 11 12 13 14 15	Data items	<u>#12</u>	List and define all variables for which data will be sought	12-13
			(such as PICO items, funding sources), any pre-planned data	
			assumptions and simplifications	
	Outcomes and	<u>#13</u>	List and define all outcomes for which data will be sought,	10
	prioritization		including prioritization of main and additional outcomes, with	
	prioritization		rationale	
16 17 18			Tationale	
18         19         20         21         22         23         24         25         26         27         28         29         30         31         32         33         34         35	Risk of bias in	<u>#14</u>	Describe anticipated methods for assessing risk of bias of	14
	individual studies		individual studies, including whether this will be done at the	
			outcome or study level, or both; state how this information will	
			be used in data synthesis	
	Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively	n/a
			synthesised	
	Data synthesis	<u>#15b</u>	If data are appropriate for quantitative synthesis, describe	14
36 37			planned summary measures, methods of handling data and	
38 39 40 41 42 43 44 45 46 47 48			methods of combining data from studies, including any	
			planned exploration of consistency (such as I2, Kendall's τ)	
	Data synthesis	#15c	Describe any proposed additional analyses (such as	15
	5		sensitivity or subgroup analyses, meta-regression)	
49 50	Data synthesis	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type	14
51 52 53 54 55 56 57 58			of summary planned	
	Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as	n/a
			publication bias across studies, selective reporting within	
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n/a

1 2			studies)	
3 4	Confidence in	<u>#17</u>	Describe how the strength of the body of evidence will be	
5 6 7	cumulative		assessed (such as GRADE)	
, 8 9	evidence			
10 11 12	The PRISMA-P ela	boratior	n and explanation paper is distributed under the terms of the Creative	
13 14	Commons Attribution License CC-BY. This checklist was completed on 06. November 2022 using			
15 16	https://www.goodre	ports.o	rg/, a tool made by the <u>EQUATOR Network</u> in collaboration with	
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# **BMJ Open**

#### Strategies used to manage overlap of primary study data by exercise-related overviews. Protocol for a systematic methodological review.

Journal:	BMJ Open
Manuscript ID	bmjopen-2022-069906.R1
Article Type:	Protocol
Date Submitted by the Author:	16-Mar-2023
Complete List of Authors:	Gutiérrez-Arias, Ruvistay; Instituto Nacional del Torax, Servicio de Medicina Física y Rehabilitación, Unidad de Kinesiología, Instituto Nacional del Tórax, Santiago, Chile.; Universidad Andres Bello, Exercise and Rehabilitation Sciences Institute, School of Physical Therapy, Faculty of Rehabilitation Sciences, Universidad Andres Bello, Santiago, 7591538, Chile. Pieper, Dawid; Brandenburg Medical School Theodor Fontane, Department for Evidence Based Health Service Research Lunny, Carole; UBC, Knowledge Translation Program, Li Ka Shing Knowledge Institute Torres-Castro, Rodrigo; Universidad de Chile, Physiotherapy; Universidad de Chile, Department of Physical Therapy, University of Chile, Santiago, Chile. Aguilera-Eguía, Raúl ; Universidad Católica de la Santísima Concepción Facultad de Medicina, Salud Pública Seron, Pamela; Universidad de La Frontera, Departamento de Ciencias de la Rehabilitación & CIGES, Facultad de Medicina, Universidad de La Frontera, Temuco, Chile.
<b>Primary Subject Heading</b> :	Research methods
Secondary Subject Heading:	Sports and exercise medicine, Rehabilitation medicine, Medical publishing and peer review
Keywords:	REHABILITATION MEDICINE, STATISTICS & RESEARCH METHODS, SPORTS MEDICINE

## SCHOLARONE<sup>™</sup> Manuscripts

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2 3 4	1	Strategies used to manage overlap of primary study data by exercise-related overviews.
5 6	2	Protocol for a systematic methodological review.
7 8 9	3	Ruvistay Gutierrez-Arias <sup>1,2</sup> , Dawid Pieper <sup>3,4</sup> , Carole Lunny <sup>5</sup> , Rodrigo Torres-Castro <sup>6</sup> , Raúl
10 11 12	4	Aguilera-Eguía <sup>7</sup> and Pamela Seron <sup>8</sup>
13 14	5	
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# 31 Abstract

Introduction: One of the most conflicting methodological issues when conducting an overview is the overlap of primary studies across systematic reviews (SRs). Overlap in the pooled effect estimates across SRs may lead to overly precise effect estimates in the overview. SRs that focus on exercise-related interventions are often included in overviews aimed at grouping and determining the effectiveness of various interventions for managing specific health conditions. The aim of this systematic methodological review is to describe the strategies used by authors of overviews focusing on exercise-related interventions to manage the overlap of primary studies.

Methods and analysis: A comprehensive search strategy has been developed for different databases and their platforms. The databases to be consulted will be MEDLINE (Ovid), Embase (Ovid), The Cochrane Database of Systematic Reviews (Cochrane Library), and Epistemonikos. Two reviewers will independently screen the records identified through the search strategy and extract the information from the included overviews. The frequency and the type of overlap management strategies of the primary studies included in the SRs will be considered as the main outcome. In addition, the recognition of the lack of use of any overlap management strategy and the congruence between planning and conducting the overview focusing on overlap management strategies will be assessed. A subgroup analysis will be carried out according to the journal impact factor, year of publication, and compliance with the PRIOR statement.

#### *Ethics and dissemination*

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52 This study will not involve human subjects and therefore does not require ethics committee approval. However, the conduct and reporting of the findings of this review will be conducted 53 in a rigorous, systematic, and transparent manner, which relates to research ethics. 54 55 The findings of this review will be presented at scientific conferences and published as one or more studies in peer-review scientific journals related to rehabilitation or research 56 methods. 57 Keywords: Overviews of systematic reviews; Umbrella review; Overlap; Review methods; 58 Exercise; Rehabilitation. 59 60 **Strengths and limitations** 61 This methodological review will use a systematic approach to describe the strategies 62 used to manage the overlap of primary studies in exercise-related overviews. 63 This review will conduct a sensitive search of MEDLINE (Ovid), Embase (Ovid), 64 The Cochrane Database of Systematic Reviews (Cochrane Library), Epistemonikos 65 databases and registers of evidence synthesis study protocols to identify exercise-66 related overviews. 67 This review will be one of the first to assess the quality of synthesis reports using the 68 recently published Preferred Reporting Items for Overviews of Reviews (PRIOR) 69 70 statement. 71 A potential limitation of this review is that the overviews identified do not report in 72 detail the methodology used to deal with the overlap. 73

Introduction

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The number of published primary studies covering a similar research question has grown exponentially (1), limiting the possibility of keeping current on a specific topic (2). It is in this context that systematic reviews (SRs) with and without meta-analyses (MAs) of interventions can offer a solution (3), as in addition to synthesizing the available evidence, they use reproducible methods to assess the risk of bias in the primary studies included (4). However, the number of published SRs and MAs has increased steadily in recent years despite repositories of SRs and MAs protocol registries (5–7) seeking to reduce duplication or redundancy of SR research (8,9). The growth in research evidence makes it difficult for clinicians to stay current and use 

interventions based on the best available evidence (10,11). Overviews, also known as
umbrella reviews, can help clinicians make sense of duplicated SRs on the same topic.
Overviews synthesize information and data from similar SRs to guide health decisionmaking (12).

88 When conducting an overview, one of the most conflicting methodological issues is the 89 overlap of primary studies across SRs with or without MAs (13). When one or more primary 90 studies are included in two or more SRs with or without MAs, the results and conclusions of 91 the overviews may be biased. Overlapping data from the same primary studies may include 92 overlapping in risk of bias and certainty of evidence assessments (e.g., Grading of 93 Recommendations, Assessment, Development and Evaluations (GRADE)) or overlapping in 94 the determination of the effect of a specific intervention and other MA outcomes such as

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heterogeneity (e.g., I<sup>2</sup>) (14,15). Overlapping pooled effect estimates across SRs may lead to
overly precise effect estimates in the overview (16).

97 Methodological studies from different medical fields reported that authors of overviews 98 rarely assess the overlap of primary studies (13,17). However, these studies have not 99 conducted an exhaustive search of overviews oriented to a specific health problem, specialty, 100 or discipline (13,17), as they have only searched an electronic database (17) and included 101 heterogeneous overviews concerning the research questions addressed (13,17).

SRs that focus on exercise-related interventions are often included in overviews aimed at grouping and determining the effectiveness of various interventions to manage of specific health conditions. Assessing the application of overlap management strategies in overviews focused on exercise-related interventions could contribute to identifying specific or differentiating aspects. This could be because the concept of exercise needs to be understood (18). In addition, the existence of multiple interventions related to exercise due to their different modalities (e.g., continuous aerobic, intervallic aerobic, resistance exercise) and dosage (e.g., frequency, intensity, time, and type) could result in a particular need to manage the overlapping of primary studies data. 

111 Considering the recently published Preferred Reporting Items for Overviews of Reviews 112 (PRIOR) statement, which incorporates the need to report on the handling of overlapping 113 primary studies, both in the data collection phase and in the presentation of results, to improve 114 and standardize the reporting of overviews (19), this systematic methodological review aims 115 to find out how often strategies for handling overlapping data from primary studies are used 116 in systematic reviews considered by syntheses focusing on exercise-related interventions in 117 different health conditions. Secondly, it aims to describe the overlap strategies used, the

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authors' acknowledgment of not using any overlap management strategies as a methodological weakness, and the congruence between the protocol and the final published summary in terms of overlap management. These findings are intended to be analyzed according to the impact factor of the journal in which the overviews were published, the year of publication of the overview, and compliance with the PRIOR statement.

123 Materials and methods

The protocol of this methodological review is reported following the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) (20) (see checklist in Supporting Information). The start of this study with the preliminary design of the search strategies began in June 2022, and this methodological review is expected to be finalized in April 2023.

#### 129 Eligibility criteria

Studies will be eligible if they meet the following inclusion criteria for study design and population. Given the purpose of this methodological review, the intervention and outcomes will not determine the inclusion of studies, and the comparator or control intervention will not be considered as it is not applicable.

134 <u>Study design</u>

We will include overviews that consider SRs with or without MAs, without distinction of the methodological design of the primary studies included. The definition of SR adopted by the authors of the overviews (21) will not be considered an eligibility criterion. Overviews that include primary studies not considered in the selected SRs will not be excluded.

139 For this review, an overview will be understood as any study (22) that:

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140	1) synthesizes general information, methods, and outcome data from SRs, and
141	2) makes explicit the inclusion and exclusion criteria for SRs, and
142	3) includes an explicit search strategy for the studies, and
143	4) examines the effectiveness of health interventions.
144	Overviews that are conducted using a "rapid review" methodology (23) will be excluded, as
145	the time frame in which they are conducted to answer urgent questions will likely not
146	consider the overlap of the primary studies included in the SRs. In addition, overviews
147	published only as abstracts in conference proceedings will be excluded.
148	Population
149	Overviews include SRs that have considered primary studies that have studied any exercise-
150	based intervention, where exercise is understood as a subcategory of physical activity that is
151	planned, structured, repetitive, and purposefully focused on improving or maintaining one or
152	more components of physical fitness (18), will be included. These overviews may include
153	only SRs related to exercise-based interventions, or other non-exercise interventions as well.
154	Overviews that consider exercise training-based interventions that are applied both
155	preventively and in the recovery phase, and that are delivered either as a stand-alone
156	intervention, as part of a comprehensive rehabilitation program, or as an adjunct to other
157	medical interventions in which exercise is the main component, will be included.
158	Furthermore, the inclusion of overviews will not be limited to the context in which the
159	exercise-based interventions were applied (e.g., primary care, specialized care) or whether
160	they were delivered face-to-face, remotely, or mixed.
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Overviews that include SRs that consider physical activity as an intervention, understood as "any bodily movement produced by skeletal muscles that require energy expenditure" according to the World Health Organization (24), will be excluded. Therefore, to differentiate between exercise-based and physical activity-based interventions, it will be considered that the exercise, together with its structure and dosage (frequency, intensity, time, and type), must be prescribed or delivered by a professional related to physical training/rehabilitation.

*Intervention* 

Our goal is to identify the strategies used to manage data from overlapping primary studies selected by SRs included in overviews. Strategies should be specified in the main text of the overviews and may be in the methods or results section, taking all possible methodological strategies that address overlap in the primary study data into consideration. Strategies addressing overlap can address different objectives (16), such as quantifying the overlap (13,25) (e.g., corrected covered area (CCA)), visually presenting overlap (26) (e.g., matrix, Venn and Euler diagrams), and avoiding duplicate information by using one or more decision algorithms (27) (e.g., quality of SRs, comprehensive SRs, up-to-datedness of SRs, statistical methods). 

177 <u>Outcomes</u>

178 The presence and the type of overlap management strategies of the primary studies included179 in the SRs will be considered as the main outcome.

180 In addition, two aspects will be regarded as secondary outcomes:

- Acknowledgement of the limitation in the conducting of the overview: we will assess
   whether the overview's authors that did not include any strategy for managing
   primary study overlap considered this limitation in their discussion or conclusion.
  - Congruence between planning and conducting the overview: we will review available
    registry entries (e.g., PROSPERO) or published protocols in scientific journals (e.g.,
    BMC Systematic Reviews Journal, BMJ Open) of all overviews included in this SR
    to determine whether management of primary study overlap had been considered in
    the planning phase of the overviews and to determine the congruence between the
    methods proposed in the protocols and those ultimately used.

# 190 Search strategy

A search strategy translated to different databases and their platforms will be developed using a controlled vocabulary (MeSH and Emtree) and text words. The search strategy will include a search filter published in 2016 by Lunny et al. (28), which is validated to identify overviews in MEDLINE-Ovid with 93% sensitivity (95% CI 87 to 96). The search strategy constructed for this database and platform is shown in Table N°1, which will be used as a basis for adapting the search strategies of the other databases and search platforms.

197 Table 1. Search strategy for MEDLINE using the Ovid platform

N°	Search term
1	exp Exercise/
2	exp Physical Fitness/
3	exp Physical Exertion/
4	exp Physical Therapy Modalities/
5	exp Exercise Therapy/
6	exp Rehabilitation/
7	(rehabilitat\$ or fitness\$ or exercis\$ or physical\$ or train\$ or physiotherap\$ or kinesiotherap\$).ti,ab.
8	aerobic\$.ti,ab.

9 (muscle\$ adj3 resist\$).ti,ab.
10 or/1-9
((overview\$ or review or synthesis or summary or cochrane or analysis) and
11 (reviews or meta-analyses or articles or umbrella)).ti. or umbrella review.ab. or
(meta-review or metareview).ti,ab.
12 (overview\$ or reviews).mp. and (systematic or cochrane).ti.
13 (reviews adj2 meta).ab.
14 (reviews adj2 (published or quality or included or summar\$)).ab.
15 cochrane reviews.ab.
16 (evidence and (reviews or meta-analyses)).ti.
17 or/11-16
18 and/10,17
0
The databases to be consulted will be MEDLINE (Ovid), Embase (Ovid), The Cochrane
Database of Systematic Reviews (Cochrane Library), and Epistemonikos. In addition, we
will search protocol registries of SRs such as the International Platform of Registered
Systematic Review and Meta-analysis Protocols (INPLASY) (https://inplasy.com/),
PROSPERO (https://www.crd.york.ac.uk/PROSPERO/), and OSF Registries
(https://osf.io/registries), and follow up protocols published in scientific journals (e.g., BMC
Systematic Reviews Journal, BMJ Open). All search resources will be reviewed from
inception until June 2022.
We will also review the references of the studies included in this review to identify overviews
that may not have been identified by our electronic search strategy.
We will include all languages in our search and will not be limited by the date of
publication/indexing in databases.
Study selection
Two reviewers (RGA and RTC) will independently and blindly screen the records identified
through the search strategy. In the first instance, the titles and abstracts will be evaluated for

199	The databases to be consulted will be MEDLINE (Ovid), Embase (Ovid), The Cochrane
200	Database of Systematic Reviews (Cochrane Library), and Epistemonikos. In addition, we
201	will search protocol registries of SRs such as the International Platform of Registered
202	Systematic Review and Meta-analysis Protocols (INPLASY) (https://inplasy.com/),
203	PROSPERO (https://www.crd.york.ac.uk/PROSPERO/), and OSF Registries
204	(https://osf.io/registries), and follow up protocols published in scientific journals (e.g., BMC
205	Systematic Reviews Journal, BMJ Open). All search resources will be reviewed from
206	inception until June 2022.

inclusion. Then the full texts of the records qualified as potentially eligible, and those that did not present sufficient information to be excluded, will be checked for compliance with all eligibility criteria. A pilot test will be conducted with 50 studies to adjust the clarity of the eligibility criteria. The Rayyan® application (29) will be used for this stage. Disagreements will be resolved by consensus, or ultimately by a third-party reviewer (RAE or PS). **Data extraction** The extraction of information from the included overviews will also be carried out independently and blindly by two reviewers (RGA and RTC). For this, a standardized ain . extraction form will be used which will contain data related to the basic information of the overviews: Title. Journal name. Year of publication. Name of the authors. Objectives of SRs. Number of SRs included Number of primary studies included Methodological aspects: databases consulted, date of search, type of synthesis of results (narrative, MA, or both), and instruments for assessing the risk of bias/methodological quality of the SRs included. Data will be extracted to respond to the findings of this methodological review: 

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1		13
2 3 4	236	• Type of overlap management strategy:
5 6 7 8 9 10 11 12 13	237	a. Quantifying overlap: e.g., CCA.
	238	b. Visual presentation of the overlap: e.g., matrix, Venn or Euler diagrams.
	239	c. Strategies to avoid duplicate information: e.g., Algorithms based on the quality of
	240	SRs, comprehensive SRs, up-to-datedness of SRs, statistical methods such as
14 15 16	241	sensitivity analyses, or a combination of two or more criteria: e.g., Jadad algorithm
17 18	242	(30).
19 20	243	• Step in the conducting of the overview where the strategy has been deployed or used:
21 22 23	244	e.g., data extraction step, synthesis step.
23 24 25	245	• Level at which the strategies were applied: i.e., whether it was at the level of SR or
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40	246	reported outcomes (16).
	247	In addition, the impact factor of the journal at the time of publication of the overviews will
	248	be recorded. This will be extracted from the journals' official websites or from Web of
	249	Science (https://www.webofscience.com/).
	250	If more than one record or publication exists for an overview, the most recent version will be
	251	considered for analysis. The data extraction form will be tested with 10 studies to assess its
40 41 42	252	completeness, and adjusted if necessary. Disagreements will be resolved by consensus, or
43 44	253	ultimately by a third-party reviewer (RAE or PS).
45 46 47	254	Risk of bias and reporting quality assessment
48 49		
50 51	255	This methodological review assesses one aspect that may affect the methodological quality
52 53 54	256	or risk of bias of the overviews. The assessment of the overall risk of bias of the overviews
55 56	257	is not an objective of this study.
57 58		
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Two independent reviewers will assess the quality of the overviews' reporting by considering
compliance with the PRIOR statement (19). Disagreements will be resolved by consensus,
or ultimately by a third reviewer.

261 Strategy for data synthesis

The results of the study selection will be schematized through a PRISMA-type flow chart (31). In addition, the characteristics of the overviews included, as well as data related to the primary and secondary outcomes, will be presented in narrative form, and through tables and figures.

Descriptive statistics will be used to quantify the number of overviews using overlap
strategies, whether the strategies were used at the level of the SRs or the level of each reported
outcome. In addition, these results will be organized by the type of strategy used.

We will also assess whether the overlapping strategy successfully resolved overlap at the following steps: risk of bias assessment, the certainty of the evidence (e.g., GRADE), and the synthesis step. Resolution of the overlap will be considered to have been achieved when the authors manage to avoid double/multiple counting of information from the primary studies.

274 Analysis of subgroups

Differences in the percentage of overviews that include overlap management strategies, the type of strategies used, the recognition of the weakness of not using any strategy, and the congruence between the protocols and the methodology finally used among journals with and without IF will be assessed. In addition, this analysis will be repeated for impact factor journals, considering the median or quartiles of the impact factor of the journals at the time

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of publication of the overviews to form 2 or 4 groups respectively, depending on the number of overviews included in this methodological review.

In addition, analysis will be carried out by subgroup according to the year of publication of the overviews, compliance with the items considered in the PRIOR statement, and whether or not the overviews were published in the Cochrane Database of Systematic Reviews.

Patient and Public Involvement

Because this protocol is about conducting a methodological review, both patients and the public were not involved. This methodological review is intended to be of use to researchers of evidence synthesis studies.

## Discussion

This methodological review will provide a comprehensive and exhaustive summary of the frequency of use of strategies for managing primary study overlap across SRs included in overviews focused on exercise-related interventions in different health conditions. It will also provide insight into the strategies used to quantify and visualize overlap, as well as those used to avoid duplicate data.

On the other hand, the findings of this review will tell us whether the authors of the overviews recognized the failure to include some strategy for handling overlap as a methodological weakness, taking into account that the greater the degree of overlap, the more falsely precise the estimates of the effects of the interventions (16). In addition, the congruence between the strategies used by the published overviews and their respective protocols will be revealed. To our knowledge, the latter two aspects have not been addressed at the overview level by other studies before. 

Finally, all analyses will be performed by subgroup of overviews, considering the impact factor of the journal and the year of publication. Although the PRIOR statement was recently published (19), assessing compliance in the reporting of overviews, and its relation to the use of strategies for the management of overlapping primary studies, could expose the shortcomings and weaknesses that have been committed so far.

*Future research* 

To continue this line of research, different overlapping data management strategies should be applied to all, or a representative sample, of the overviews identified by this methodological review. This could empirically test the benefits and limitations of using any strategy.

### *Ethics and dissemination*

This study will not involve human subjects and therefore does not require ethics committee approval. However, the conduct and reporting of the findings of this review will be conducted in a rigorous, systematic, and transparent manner, which relates to research ethics.

The findings of this review will be presented at scientific conferences and published as one or more studies in peer-review scientific journals related to rehabilitation, healthcare, or methodological aspects associated with evidence synthesis.

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Health at the Autonomous University of Barcelona (UAB), Barcelona, Spain.

2								
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8 9	325	or not-for-profit sectors.						
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14 15	327	Competing interests						
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18	520	All authors declare no competing interests.						
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23	330	Data sharing						
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26 27	331	Not applicable						
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31								
32 33	333	Author's contribution						
34								
35	334	RG-A, DP, CL, and PS contributed to the conception and design of the study. RG-A						
36								
37 38	335	developed the search strategies, which was reviewed by RT-C and RA-E. RG-A, DP, CL,						
39								
40	336	and PS designed the data analysis. RGA-A drafted the manuscript, and all authors read it						
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# Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

# Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

			Page
		Reporting Item	Number
Title			
Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
Update	<u>#1b</u>	If the protocol is for an update of a previous systematic	n/a
		review, identify as such	
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1 2 3	Registration			
4 5		<u>#2</u>	If registered, provide the name of the registry (such as	4
6 7 8			PROSPERO) and registration number	
9 10 11 12 13 14	Authors			
	Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all	2
15 16			protocol authors; provide physical mailing address of	
17 18 19			corresponding author	
19 20 21 22 23 24	Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the	22
			guarantor of the review	
25 26	Amendments			
27 28				
29 30		<u>#4</u>	If the protocol represents an amendment of a previously	n/a
31 32 33 34 35 36 37			completed or published protocol, identify as such and list	
			changes; otherwise, state plan for documenting important	
			protocol amendments	
38 39	Support			
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42 43 44	Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	2
45 46 47	Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	2
48 49 50 51	Role of sponsor or	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s),	2
	funder		if any, in developing the protocol	
52 53 54 55	Introduction			
56 57 58	Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is	5-7
59 60		For pee	er review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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1 2			already known	
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 23 24 25 26 27 28 29 30 31 32 33 34 35	Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will	7
			address with reference to participants, interventions,	
			comparators, and outcomes (PICO)	
	Methods			
	Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design,	8-10
			setting, time frame) and report characteristics (such as years	
			considered, language, publication status) to be used as	
			criteria for eligibility for the review	
	Information	#9	Describe all intended information sources (such as electronic	11
	sources	<u></u>	databases, contact with study authors, trial registers or other	
	3001003			
			grey literature sources) with planned dates of coverage	
	Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one	10-13
			electronic database, including planned limits, such that it	
36 37			could be repeated	
38 39 40	Study records -	#11a	Describe the mechanism(s) that will be used to manage	12-15
40 41 42	data management		records and data throughout the review	
43 44	0			
45 46	Study records -	<u>#11b</u>	State the process that will be used for selecting studies (such	12
47 48	selection process		as two independent reviewers) through each phase of the	
49 50			review (that is, screening, eligibility and inclusion in meta-	
51 52 53			analysis)	
54 55	Study records -	<u>#11c</u>	Describe planned method of extracting data from reports	12-14
56 57 58	data collection		(such as piloting forms, done independently, in duplicate), any	
59 60		For pee	r review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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1 2 3 4 5 6 7 8 9 10 11 12 13	process		processes for obtaining and confirming data from investigators	
	Data items	<u>#12</u>	List and define all variables for which data will be sought	12-13
			(such as PICO items, funding sources), any pre-planned data	
			assumptions and simplifications	
	Outcomes and	<u>#13</u>	List and define all outcomes for which data will be sought,	10
	prioritization		including prioritization of main and additional outcomes, with	
14 15 16	prioritization		rationale	
16         17         18         19         20         21         22         23         24         25         26         27         28         29         30         31         32         33         34         35			Tationale	
	Risk of bias in	<u>#14</u>	Describe anticipated methods for assessing risk of bias of	14
	individual studies		individual studies, including whether this will be done at the	
			outcome or study level, or both; state how this information will	
			be used in data synthesis	
	Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively	n/a
			synthesised	
	Data synthesis	<u>#15b</u>	If data are appropriate for quantitative synthesis, describe	14
36 37			planned summary measures, methods of handling data and	
38 39 40 41			methods of combining data from studies, including any	
			planned exploration of consistency (such as I2, Kendall's τ)	
42 43 44	Data synthesis	#15c	Describe any proposed additional analyses (such as	15
45 46	5		sensitivity or subgroup analyses, meta-regression)	
47 48				
49 50	Data synthesis	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type	14
51 52 53 54 55 56 57 58			of summary planned	
	Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as	n/a
			publication bias across studies, selective reporting within	
59 60		For pee	r review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

n/a

1 2			studies)				
2 3 4 5 6 7	Confidence in	<u>#17</u>	Describe how the strength of the body of evidence will be				
	cumulative		assessed (such as GRADE)				
7 8 9 10	evidence						
10 11 12	The PRISMA-P ela	boratior	n and explanation paper is distributed under the terms of the Creative				
13 14	Commons Attribution License CC-BY. This checklist was completed on 06. November 2022 using						
15 16 17	https://www.goodre	eports.oi	rg/, a tool made by the EQUATOR Network in collaboration with				
18         19         20         21         22         23         24         25         26         27         28         29         30         31         32         33         34         35         36         37         38         39         40         41         42         43         44         45         46         47         48	Penelope.ai						
49 50 51 52 53 54 55 56 57 58 59		Eormo	ar roviou oply, http://hmiopop.hmi.com/cito/about/guidalines.yhtml				
60		For pee	er review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml				