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Physical activity referral scheme components: a study protocol for systematic review and meta-regression

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ABSTRACT

Introduction In its attempt to establish effective physical activity promotion methods, research on physical activity referral schemes (PARS) is attracting significant attention. Sometimes known as physical activity on prescription schemes, PARS involve a well-defined procedure whereby a primary healthcare professional introduces a participant to the topic of physical activity and employs prescription or referral forms to connect the participant to physical activity opportunities, such as local fitness offers. The planned systematic review will focus on these referral routes and scheme components and how they are integrated into various PARS models worldwide. We seek to identify the evidence-based core components that play the most important roles in the effectiveness of PARS.

Methods and analysis The development and reporting of the protocol follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols guidelines. We plan to conduct a systematic main literature search on PubMed, Scopus, Web of Science, CINAHL, HTA, SpringerLink and other databases. We will include studies that report outcomes on physical activity, PARS uptake and adherence rates or descriptive information about PARS models. We intend for all review stages, citation screening, data extraction and risk of bias assessment to be conducted by at least two independent reviewers. As a broad spectrum of study designs, including randomised and non-randomised studies of interventions and mixed methods, will be eligible, we will use three separate tools to assess the risk of bias in individual studies. The data will be primarily synthesised narratively, following Intervention Component Analysis. If the data allow, we will perform a random-effects meta-analysis and meta-regression to investigate the impact of specific PARS components on effect sizes.

Ethics and dissemination This systematic review does not require formal ethics approval. The results will be submitted to a peer-reviewed journal and international conferences to reach the scientific community.

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Strengths and limitations of this study

- The planned systematic review will look into the structural design of physical activity referral schemes (PARS) and their components by painting a comparative picture across countries.
- The qualitative synthesis and meta-regression may further our understanding of core components that promote the effectiveness of PARS.
- The variability in study design, between-study variability in terms of interventions and outcomes, comparability and complexity may prevent quantitative synthesis.

INTRODUCTION

The health-promoting value of physical activity and significant contributions of a lack of physical activity to the current epidemic of chronic non-communicable diseases (NCDs)[1] are well accepted in the scientific community. Insufficient physical activity is a global trend, with approximately a quarter (27.5%) of the adult population not meeting the recommended physical activity levels[2] required to experience health benefits. This alarming prevalence, especially among persons with NCDs,[3] demands efficient strategies to counteract these two interrelated public health challenges. Against this backdrop, primary healthcare interventions, such as counselling and exercise referrals, have been endorsed as practical approaches to promote physical activity[4] and tackle NCDs.[5] These models began emerging in the 1990s as exercise referral schemes in the UK[6] and physical activity prescription schemes in the Nordic countries,[7] and they subsequently proliferated rapidly worldwide. They have been referred to as physical activity referral schemes (PARS),[8] exercise by prescription schemes,[9] exercise on prescription,[10] green prescription[11] or exercise is medicine,[12] with these terms often used interchangeably.[8] This inconsistency, which Dugdill *et al*[13] describe as the dilemma of terminology, may be attributed to the similar and improper use of physical activity and exercise as synonyms. In our review, we will adopt the term PARS because it comprises the spectrum of general

health-enhancing physical activity and specifically targeted exercise interventions.

The chain of PARS typically starts with the care-seeker visiting a primary care unit, although secondary care referrals are also widespread in the UK.[9] The healthcare professional, usually a general practitioner, then issues a prescription[14 15] or referral form, which represents a formal procedure linking the participant to physical activity resources, such as local sport clubs or walking routes. PARS are complex, multifaceted interventions made up of multiple components.[13] Thus, various components may be incorporated as a required minimum into the PARS design. For instance, the definition provided by the National Institute for Health and Care Excellence (NICE) includes an additional tailor-made physical activity intervention, progress monitoring and referral-taker follow-up.[16]

In the last three decades, a mounting body of evidence has been published on PARS. Systematic reviews highlight the promising results of integrating PARS as part of standard healthcare.[17 18] The pooled effect sizes from randomised controlled trials (RCTs) indicate that a greater number of PARS participants perform 90–150 min of moderate-to-intensity physical activity per week than people who receive only standard healthcare (without PARS).[19 20] However, the effect of PARS appears small.[19 21] Seventeen inactive persons must participate for one to become moderately active.[21] Although studies have provided inconclusive evidence,[17 20] researchers advocate PARS as an intervention method worth considering.[20] However, the health benefits of increasing one's level of physical activity engagement from none to some[22] remain inadequately addressed in the existing evidence base.[16] Moreover, NICE has suggested that in addition to physical activity, a sense of belonging, social relations and reducing health inequalities may be important aspects of PARS evaluation.[16]

The concerns above highlight the need for a broader perspective on effectiveness. The research findings to date may have been affected by insufficient attention to context interpretation,[23] uptake and adherence rates,[24] potentially inefficient use of resources,[21] lack of behavioural change strategies and tailored individualised approaches[25] or diversity in measured outcomes.[20] Authors have also pointed out differences in the design and characteristics of PARS models within and between countries that have adopted them.[7 8] For instance, referral reason and follow-up period may influence adherence rates and physical activity levels.[8] However, the contribution of other characteristics, such as interventional components, to PARS effectiveness remains unclear. It has been suggested that identifying key interventional elements is essential to establishing the effect of the intervention[6 26] and relevant to its subsequent success.[27] In their research brief, Blase and Fixen[26] use the term core component, which suits the purpose of this systematic review and, thus, will be used consistently. This term is not unheard of in PARS research; the Swedish model, which has proven effective,[18] is explicitly described as consisting of five core components—namely, patient-centred individualised counselling, evidence-based physical activity recommendation, written prescription, follow-up and a community-based network that nurtures a supportive environment for the participant.[28] However, there have been limited attempts to investigate various PARS models at an international level,[8 29] especially in terms of interventional components and the associated referral systems. Consequently, there is little guidance for new efforts to design PARS for countries where this model of physical activity promotion is still in its infancy. A thorough investigation of these features may be worthwhile, providing programme developers with empirically derived content and helping to direct future research initiatives regarding previously unaddressed aspects.

Objectives

The planned systematic review aims to collate and compare existing international models of PARS. Specifically, it will address the following two questions:

1. What are the components that make up different PARS?
2. Which are the core components that, if integrated, promote the scheme's effectiveness in terms of physical activity level and PARS uptake and adherence?

METHODS

The development of this protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Protocols guidelines[30] (see online supplemental file 1) and the Cochrane Handbook for Systematic Reviews of Interventions.[31]

Patient and public involvement

We will not involve patients or the public in the development of this protocol. Because we will base the systematic review on published literature, participant and public involvement in the research and dissemination of findings is not applicable.

Eligibility criteria

Studies published in English or German will be considered for inclusion. The following study selection criteria will be applied.

Population

According to PARS-specific eligibility criteria, persons aged 16 years or over and qualified for inclusion in PARS will be eligible.

Intervention

Of interest are PARS interventions with the primary objective of increasing physical activity. We define PARS as a primary healthcare professional-initiated and systemised pathway that includes a formally issued (1) physical activity prescription or (2) referral to third-party exercise services, located within or outside the healthcare

system, for further physical activity support or exercise opportunities. Additionally, PARS may include other activities or interventions that contribute to the goal of increasing physical activity. The International Classification of Health Interventions defines prescription for physical activity (IHI code; VEB.TI.ZZ) as 'Instruction, direction or authoritative recommendation to obtain or pursue a specified health intervention, targeting patterns of behaviour in relation to physical activity'.[22] A physical activity prescription may not require collaboration with other exercise or allied health professionals or services, as in the case of referral.

Comparison

There will be no restriction by comparator group. PARS can be compared with brief advice, counselling, pedometers, other alternative interventions, usual care, wait-list control or no comparator.

Outcome of interest

Studies must report physical activity outcomes, uptake rates or adherence rates related to the PARS intervention.

Setting

The intervention should be initiated in a primary or secondary healthcare setting.

Study design

A broad spectrum of study designs will be eligible, including RCTs, uncontrolled trials, pragmatic trials, non-randomised studies of interventions (quasi-randomised, cohort, controlled before-and-after studies, prospective longitudinal studies), mixed methods, process evaluations, qualitative studies, policy documents and official governmental, departmental or clinical study reports.

The following exclusion criteria will be applied: (1) literature reviews, cross-sectional studies, commentaries, dissertations, conference abstracts, opinion articles, working papers and book chapters; (2) studies focusing on the patient's or health professional's perspective on PARS or the role of scheme actors; (3) interventions consisting of advice or counselling that do not include a written format, such as prescription or referral; (4) studies focusing on training content, rehabilitation programmes and therapeutic exercise prescriptions and (5) park and social prescriptions with/without a physical activity element.

Information sources

We will run a literature search of the following bibliographic databases: PubMed, Scopus, Web of Science, Health Technology Assessment, CINAHL, ScienceDirect, SpringerLink and Wiley Online Library. Electronic journal collections such as, SAGE Journals and Taylor & Francis, will also be explored. Additional information sources, such as CORE, Google Scholar and OpenGrey, will complement the search. We will carry out forward and backward snowballing to track other potentially relevant citations from the included articles using a systematic approach and documentation form. Previous systematic reviews on the topic will be checked to ensure that no eligible articles are missed. Any additional articles of which the review authors are aware but the search might overlook will also be considered. When necessary, we will contact the original authors for supporting information.

Search strategy

A university librarian was included in the development of the search strategy. The search will be conducted in two stages.[12] The first stage will involve combining key terminology in the literature and previous systematic reviews, such as exercise referral scheme, exercise referral, exercise prescription or physical activity on prescription scheme. The second stage will entail running additional searches combining terms related to physical activity promotion and primary healthcare using truncation, controlled vocabulary and spelling variations, utilising wildcards. Various combinations of search terms have been tested for sensitivity and specificity based on studies already known to the reviewers. A search built on interchangeable PARS designations was found to be optimal. As the PARS approach dates back to the 1990s,[12] we will apply search filters from those years. We will set search alerts for database-specific search queries to keep the search continually up to date as new publications become available. Table 1 provides the search string for PubMed, which will be translated to the search parameters of other databases.

Study records

Data management

We will import all identified citations into the reference management software Citavi V.6 (Swiss Academic Software), which we will use for all the screening stages.

Selection process

After deduplication, the identification of relevant references will proceed in two phases. First, the first reviewer will screen at the title and abstract levels to rule out ineligible hits based on a piloted screening tool. We will use the concept of crowdsourcing to distribute the second independent reviewer's task within the review team. Thus, two other reviewers will administer the second independent screening of the titles and abstracts. Second, the first reviewer will obtain the qualified articles in full text, and two independent reviewers will thoroughly assess the content against the eligibility criteria. The screening process will be documented using standardised formats, including reasons for exclusion. The study selection process and results will be recorded in the PRISMA flow diagram (online supplemental file 2). Duplicate reports of a research study will be included and linked as a single study result.[28 31] All research reports concerning a specific PARS model will be carefully checked to determine whether they were derived from the same study and will be linked accordingly. Any uncertainties will be discussed

Table 1 The search syntax for PubMed

Stage 1	
#1	exercise referral scheme*[Title/Abstract]
#2	"exercise referral"[Title/Abstract]
#3	"exercise prescription schemes"[All Fields]
#4	"exercise on prescription"[Title/Abstract]
#5	"physical activity prescription"[Title/Abstract]
#6	physical activity referral scheme*[Title/Abstract]
#7	"green prescription"[Title/Abstract]
#8	physical activity prescription scheme[All Fields]
#9	"physical activity referral"[Title/Abstract]
#10	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
Stage 2	
#1	Motor Activity[MeSH Terms]
#2	physical activit*[Title/Abstract]
#3	Exercise[MeSH Terms]
#4	Exercise Therapy[Mesh Terms]
#5	exercise[Title/Abstract]
#6	#1 OR #2 OR #3 OR #4 OR #5
#7	counseling[MeSH Terms]
#8	(referral and consultation[MeSH Terms])
#9	directive counselling[MeSH Terms]
#10	prescriptions[MeSH Terms]
#11	prescription[Title/Abstract]
#12	(referral[Title/Abstract]) OR "prescribed physical
#13	activity"[Title/Abstract]
#14	#7 OR #8 OR #9 OR #10 OR #11 OR #12
#15	primary health care[MeSH Terms]
#16	health promotion[MeSH Terms]
#17	physicians, primary care[MeSH Terms]
#18	general practi*[Title/Abstract]
#19	primary care intervention*
#19	#14 OR #15 or #16 OR #17 OR #18
	#6 AND #13 AND #19

Search filters applied for humans and articles published as of 1 January 1990.

Table 2 Descriptive characteristics of the included studies

Publication characteristics	Author, year
	Design
	Country
	Risk of bias
Population characteristics	Sample size
	No randomised
	Age
	Gender
	Underlying conditions or risk factors
PARS characteristics	Theoretical underpinning
	Year introduced and implemented
	Scheme eligibility criteria
	PARS components and content
	Dosage
	PARS length
	Mode of delivery
	Actors involved in delivery
	Comparator details
	Setting
Comparator characteristics	Control group description
Outcomes and measurement details	Physical activity
	Uptake rate
	Adherence rate
Other details	Follow-up duration
	Key findings

PARS, physical activity referral schemes.

by two reviewers, and, if necessary, a third reviewer will adjudicate disagreements until full consensus is reached.

Data collection and data items

Articles that qualify for the data extraction stage will be grouped according to geographical location and the PARS model. Using a study as a unit of interest, two or more reports of the same study will be collated before data extraction is initiated, and only one of the results will be considered for the analysis.[31] We will use a standardised data extraction form, which will be piloted a priori via calibration exercises to increase the reviewers' familiarity with the extraction process and ensure consistency. Hanson *et al*'s checklist[32] will be used as an additional data collection checklist to identify gaps in reporting, and we will probe its applicability for systematic reviews. We will gather data on the following study characteristics: design features and methods (eg, duration, follow-up, data collection, statistical analysis, source of funding, all the required information to support risk of bias assessment), population (eg, sample size, participant characteristics, eligibility criteria), geographical location, setting, intervention (eg, components, dosage, duration, comparator), outcomes (eg, time point, measurement instruments, metric, method of data aggregation), results (eg, participants included in the analysis, drop-outs, effect size), number of prescriptions/referrals issued and key findings. Descriptive characteristics of the included studies will be presented in tabular format (table 2).

At the scheme level, all text or sentences describing particularities of PARS will be collected (components, content, methods, mode of delivery, setting, actor involved, qualifications, required training, communication routes). Discussion sections will be thoroughly checked for endorsements of any components that may play an important role in the success of PARS. All the information collected on PARS will first be collected as text parts. Additionally, information on the following scheme characteristics will be important: year introduced, year implemented, scheme length, target group, target behaviour and theoretical constructs, which will be extracted on a

country-by-country basis. One reviewer will extract data, and another reviewer will check the extracted information for accuracy. Interrater agreement will be calculated by independently extracting and coding a subset of 15% of the final included articles. A third reviewer will be invited to join the discussion as an adjudicator in case of uncertainties or disagreements. One reviewer will contact the authors of primary studies to supply missing information or to clarify questions via one email and a maximum of one follow-up attempt 1 week later.

Outcomes and prioritisation

The main outcome of this systematic review relates to the study's first objective of determining the most common components integrated into PARS models. A component can be a discrete and active piece of PARS and can be implemented separately from other parts of the intervention,[33] for instance, prescription or physical activity counselling. Alternatively, a component may represent a central principle of the scheme, a theoretical or methodological underpinning, for instance, a patient-centred approach.

The secondary outcome will be physical activity level measured either objectively or subjectively. Other secondary outcomes will be uptake and adherence rate. Uptake refers to attendance at the first PARS activity after receiving a referral or prescription and is expressed as the proportion of persons who took up the offered PARS.[24] Adherence describes the extent to which the prescribed activities or enrolled programmes are completed—in other words, the level of participation in PARS.[19] Both uptake and adherence rates can be estimated via self-report or determined objectively, for instance, via attendance records.

Risk of bias

We will use a combination of separate Cochrane Collaboration tools to assess risk of bias at the study level. Non-randomised interventions of effectiveness, such as quasi-randomised trials, controlled before-and-after studies, interrupted time series studies and cohort studies, will be assessed using Risk of Bias in Non-randomised Studies-of Interventions (ROBINS-I).[34] This tool is concerned with the seven following domains of bias in non-randomised interventions: confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes and selective reporting of results.[34] For randomised interventions, we will use the Cochrane risk-of-bias (RoB 2) tool to assess bias in six domains: selection, performance, detection, attrition, reporting and any other bias.[35] We will use the Mixed Methods Appraisal Tool (MMAT) to assess the methodological quality of mixed methods.[36] The MMAT checklist consists of five categories, each pertaining to a study design (qualitative, quantitative RCTs, quantitative non-randomised, quantitative descriptive and mixed methods) and including five questions and three response options: yes, no and cannot tell.[36] After piloting and becoming familiar with the assessment checklist, two assessors will independently rate the included studies. Disagreements will be discussed between the two primary assessors, and, if necessary, a third assessor will be requested to aid in making the final decision. Tabular formats and the web application RoB VISualisation (robvis) will be used to present the risk of bias results in the final report.[37] The authors do not plan to exclude studies exposed to a high risk of bias. Instead, the results will be integrated into the subgroup analysis.

Quality of evidence

We will use Grading of Recommendations Assessment, Development and Evaluations to assess the quality of evidence if quantitative summary is achieved.[38] The confidence in the effect estimates for physical activity, uptake rates and adherence rates will be classified as either high, moderate, low or very low.[38]

Data synthesis

The primary data synthesis is planned to have a narrative nature. The collected information on PARS models will be analysed using principles of the Intervention Component Analysis (ICA),[39] adapted to the context of this review. ICA is based on two main principles: intervention description through inductive content analysis[40] and the integration of informal evidence derived from discussion sections.[39] This enables and facilitates the identification of components of a complex intervention and its implementation procedures.[39] The first stage of ICA involves two processes that happen in parallel—namely, narrative effectiveness synthesis and the identification of intervention characteristics.[39] Qualitative analysis methods will be used to single out similar or distinctive characteristics and components of PARS models.[40] Additionally, the second level of the PARS checklist[32] will be used to support the coding and classification of PARS characteristics. The identified components and processes will be modelled logically and sketched out in cross-functional flowcharts (figure 1) using the software Lucidchart (https://www.lucidchart.com/pages/). The first stage will result in a list of components found in different PARS models.

In the second stage, these components will be weighed using effectiveness data to propose core components that may be crucial to the success of PARS[39] If the data allow, we will supplement the qualitative synthesis with a meta-analysis.[31] Given that previous reviews reported high heterogeneity[8 20] and that a fixed-effects model may not be suitable for analysing complex interventions,[41] we will employ a random-effects model. In the case of heterogeneity and of more than 10 studies being available for each component,[31] we intend to conduct a random-effects meta-regression to test whether the presence of the identified PARS components as categorical variables impacts the effect estimates. If a study compares a PARS model with modified versions of this model, the mean effect sizes for both interventions will be compared with identify any additional core component.[42] If more than

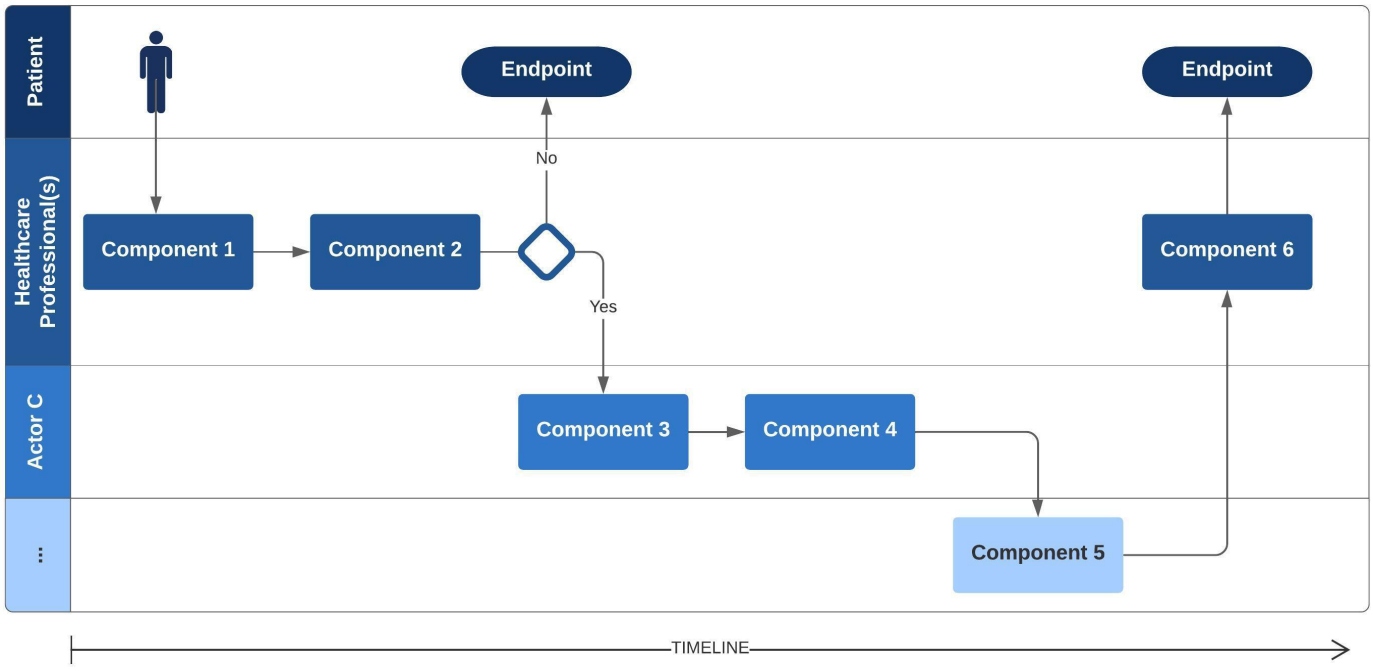

Figure 1 Example of a cross-functional flow chart. Note: the figure is a simple example of how we intend to present the synthesised information for each referral scheme. Each swimlane represents an important actor (partaker), group of persons, institution or similar entity with the responsibility of delivering, in part or in whole, one or more scheme components. Given our focus on PARS that start in a primary healthcare setting, we have appointed professional(s) a priori among the scheme actors. PARS, physical activity referral schemes.

one physical activity variable is reported in a study, we will take the total level of physical activity,[43] if available, or we will calculate an average effect size.[42] However, if there are certain physical activity-related outcomes that appear in most studies and would make an interesting investigation, such as the intensity of physical activity, they will be extracted and considered for the quantitative analysis. The standardised mean differences between the PARS group and the control group and relative risks with 95% CIs[20] will be used to calculate the study effects for continuous and dichotomous variables, respectively. If, however, only means and standard errors are available, we will convert them to SD. Medians will be taken as means, and SD will be calculated by dividing the IQR by 1.35.[43] Heterogeneity will be assessed using the I^2 statistic and explored using subgroup analysis[44] based on geographical location, PARS classification, scheme length, risk of bias, study design, follow-up and population characteristics. To translate the results for clinical practice and decision-makers, we will calculate the number needed to treat for a PARS participant to become active.[45] Publication bias will be explored via Egger's graphical and regression test.[46] All analyses will be performed using R package V.4.0.3,[47] including extension packages meta, metasens[48] and metafor.[49]

DISCUSSION

This systematic review will seek to compare PARS models internationally, explore their components and how they interconnect via referral processes and identify a set of core components that may promote the effectiveness of PARS expressed in terms of physical activity, uptake and adherence. However, the number of studies, substandard reporting, inconsistency in the definition of components and level of comparability between PARS may impact successful achievement of the desired review outcomes. The complexity of these multicomponent interventions and the multidirectional interaction including the individuals, context and intervention itself[41] may sophisticate the comparison of various models. This complexity may hamper the application of statistical methods to explore how certain components relate to intervention effects.[39] The results from this review may assist intervention developers in designing and refining effective PARS.

ETHICS AND DISSEMINATION

This systematic review does not require formal ethics approval because it will be based on published studies. The results will be submitted to a peer-reviewed journal and international conferences to reach the scientific community. The findings will also be disseminated to interested national stakeholders involved in the development of PARS.

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Contributors EM designed and drafted the protocol. WG and KP both played prominent advisory roles. All the authors supported the review conceptualisation. The entire review team (IN, AW, SK, WG, KA-O, PG and KP) contributed to the

iterative process of methodological decision making, revised the protocol, approved the final version of the manuscript and agreed with the order of presentation of the authors.

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

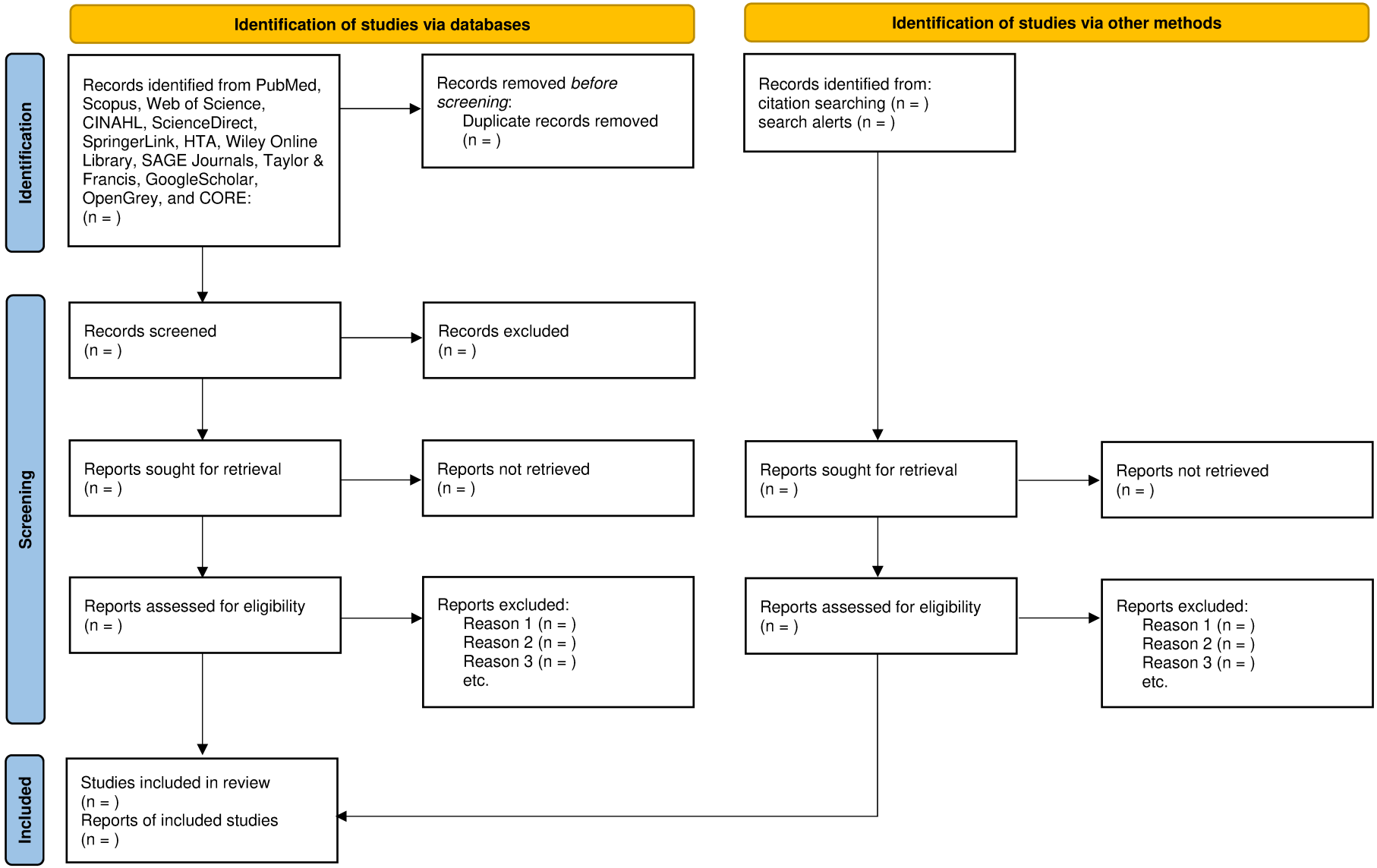
Section and topic	Item No	Checklist item	Reported on page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	13-14
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	-
Support:			
Sources	5a	Indicate sources of financial or other support for the review	13
Sponsor	5b	Provide name for the review funder and/or sponsor	13
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	13
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5-6
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6-7
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7
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	7-8

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	9
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9-10
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	9-10
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	11-12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	12
	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 (such as I^2, Kendall's τ)	12-13
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	13
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	12
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	13
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	13

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Supplementary File 2. PRISMA 2020 flow diagram



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/