



BMJ Open Characteristics of RCTs focusing on health promotion in community samples: a scoping review protocol based on the d-CoSPICO framework

M. Angeles López-González,¹ Francisco Rodríguez-Cifuentes ¹,
Fernando Rubio-Garay,² Paloma Amor-Hernández,² Luis Angel Saúl ²

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¹Department of Psychology, Universidad Rey Juan Carlos, Alcorcón, Spain

²Faculty of Psychology, Universidad Nacional de Educación a Distancia, Madrid, Spain

Correspondence to
Dr Luis Angel Saúl;
lasaul@psi.uned.es

ABSTRACT

Introduction Developing the capabilities of individuals, groups and communities to enhance their health has received a great deal of attention in the literature. One essential source of results is evidence-based intervention programmes, which often involve a number of different variables. This paper describes a methodology for carrying out a scoping review that maps available evidence on randomised controlled trials focusing on health promotion intervention programmes.

Methods and analysis The scoping review protocol follows the general Preferred Reporting Items for Systematic Reviews and Meta-Analyses and Joanna Briggs Institute guidelines. It also incorporates some modifications to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Review flowchart and complements its methodological framework. This new format, called documents, Concept, Studies, Participants, Interventions, Comparator, and Outcomes (d-CoSPICO), guides the review sequence, which is represented in a flowchart. The search will focus on different sources of information using formal (searches in thematic –PubPsych, ERIC, MedLine, PsychINFO– and multidisciplinary databases –Academic Search Ultimate, Core Collection Web of Science, Scopus and ProQuest–, repositories and other websites), informal (contact with researchers), and retrospective (previous reviews on this topic) strategies to identify relevant publications until 2021, including grey literature. Coding, identification, selection, and data extraction will be carried out following the generation of a database in which each retrieved record's content (abstract and/or full text) can be analysed. The review is expected to be completed in 2023.

Ethics and dissemination Ethical approval is not required for this review. The d-CoSPICO framework and the results will be disseminated through (a) peer-reviewed publications; (b) presentations at scientific dissemination events and (c) training activities for applying this protocol.

INTRODUCTION

Health promotion is a comprehensive social and political process that seeks to improve health by strengthening the skills and capacities of individuals and modifying social, environmental and economic conditions.¹

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The research question and the inclusion and exclusion criteria were based on the documents, Concept, Studies, Participants, Interventions, Comparator, and Outcomes approach.
- ⇒ The search for records combined different information sources: formal, informal, and retrospective.
- ⇒ Primary screening of the registers and data extraction will be performed independently by three to minimise the probability of personal biases.
- ⇒ In this research, only databases managed in North American and European countries will be included. This limitation may cause geographical and cultural biases.
- ⇒ Randomised controlled trials may not provide information that could be better discovered with observational and quasi-experimental studies.

Individual health skills and capacities and the capability of groups and communities to collaborate have often been developed through the design, development and implementation of a wide variety of intervention programmes. A 'standard' intervention programme must be based on evidence and consists of organised and differentiated practices that can guide and explain what should be administered, to whom and the time, place, and mode of application.² In the specific field of health promotion, a wide variety of intervention programmes have been developed involving a multiplicity of factors and variables. Consequently, the analysis of this type of programme is no simple task and constitutes a real challenge for several reasons.

First, health promotion is a broad-ranging term that encompasses a varied set of actions and activities aimed at fostering the maintenance and improvement of health at the individual or population level, including governments' social and health policies, health education and the promotion of

healthy cities. In this field, health equity is viewed as a fundamental element and refers to the idea that all people should have the same opportunities to enjoy a healthy life.³

Second, it is necessary to consider the historiographic evolution of intervention programmes on health promotion, from classic actions focusing on potential risk behaviours to emerging interventions aimed at achieving sustainable health within the context of Planetary Health,⁴ a perspective which understands that human health is an issue that also involves the care of nature. In this sense, it is also necessary to consider the intense debate currently taking place between advocates and detractors of experimental versus observational methodologies in health promotion studies.^{5,6} Randomised controlled trials (RCTs) have long been considered the gold standard in the biomedical field and their feasibility and relevance in health promotion are beyond doubt. Nevertheless, it has also been argued that interventions in this field are generally complex, encompassing programmes involving public policies, environmental actions and community services, among others,⁷ and therefore, evidence of effectiveness should be evaluated by combining both experimental and observational methodologies.⁸ However, as evaluation mechanisms, adequately designed RCTs that seek to answer specific research questions are far superior to other approaches that have recently become popular.⁶

The third challenge derives from the variety of different knowledge fields that engage in the study of health promotion. In this sense, health promotion research is characterised by its multidisciplinary nature and is influenced by many areas, from Education and Epidemiology to Politics, Social Sciences, and Anthropology.⁶

The fourth challenge is linked to the great diversity of psychological and sociodemographic variables considered to be consequences or promoters of changes in health behaviours. It is generally accepted that certain factors can improve motivation and, in turn, prompt changes in behaviour. Based on the analysis of multiple socio-cognitive and emotional factors, different models and theories have been developed and are currently under debate in health psychology. Various cognitive-social models have been proposed to explain behaviour changes,⁹ ranging from continuum models (eg, the theory of planned behaviour and the health action process approach, among others) to phase or stage models (eg, the transtheoretical model of health behaviour change).

The fifth challenge is linked to the heterogeneity of the intervention strategies, which range from behavioural approaches to current movements to create healthy cities and municipalities.

Finally, one last challenge concerns the differences that people present in matters related to their health. The current state of health of people can interact with previously mentioned aspects. Thus, a health promotion intervention for a group of people could be detrimental to others (eg, Tengland¹⁰ exposes the possible differences in health consequences of the habit of drinking red

wine between alcoholic populations and very moderated consumers).

The aforementioned aspects serve to highlight the need for a scoping review to help clarify concepts and definitions, summarise the results of existing studies, identify critical factors and detect gaps in the literature.^{11,12} Although there are previous reviews, they all refer to specific health promotion contexts or interventions.^{13,14} Thus, for example, an umbrella review of interventions on health risk behaviours in students conducted by Hutchesson *et al*¹³ revealed a moderate volume of experimental research on university students' mental health. Another review aimed at providing an overview of artificial intelligence technologies in elderly healthcare by Ma *et al*¹⁴ showed the great potential of artificial intelligence technologies in elderly healthcare. However, we are not aware of reviews that have provided a global and general overview of the psychological and sociodemographic variables related to health promotion. To enable and facilitate the replication of scoping reviews, some specific protocols have been developed and adapted to this kind of literature synthesis, including Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Review (PRISMA-ScR)—an extension of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement¹⁵ and the Manual for Evidence Synthesis published by the Joanna Briggs Institute (JBI).¹⁶ However, we consider that some guidelines included in the manuals for synthesising the cited research results could be clarified to benefit the replicability of this type of study.¹⁷

The protocol outlined in this paper aims to describe a methodology for conducting a scoping review of RCTs focusing on psychological and sociodemographic variables in health promotion. To avoid an excessively large volume of data that would greatly complicate its analysis, we have circumscribed the object of study to health promotion studies in community samples, excluding people with pathologies. To this end, the classic PICO format for constructing the research question and the literature search has been modified into a strategy called documents, Concept, Studies, Participants, Interventions, Comparator, and Outcomes (d-CoSPICO). Our specific aims are: (a) to explore the scope and temporal evolution of health promotion RCTs and their characteristics; (b) to map the psychological and sociodemographic variables examined in health promotion RCTs; (c) to identify the action strategies that allow us to delimit different areas of intervention and (d) to identify the main gaps in the existing evidence base and the most pressing issues for future research.

METHODS AND ANALYSIS

Design

This scoping review protocol includes a series of control mechanisms designed to reduce the biases that may occur a priori, as suggested by the PRISMA

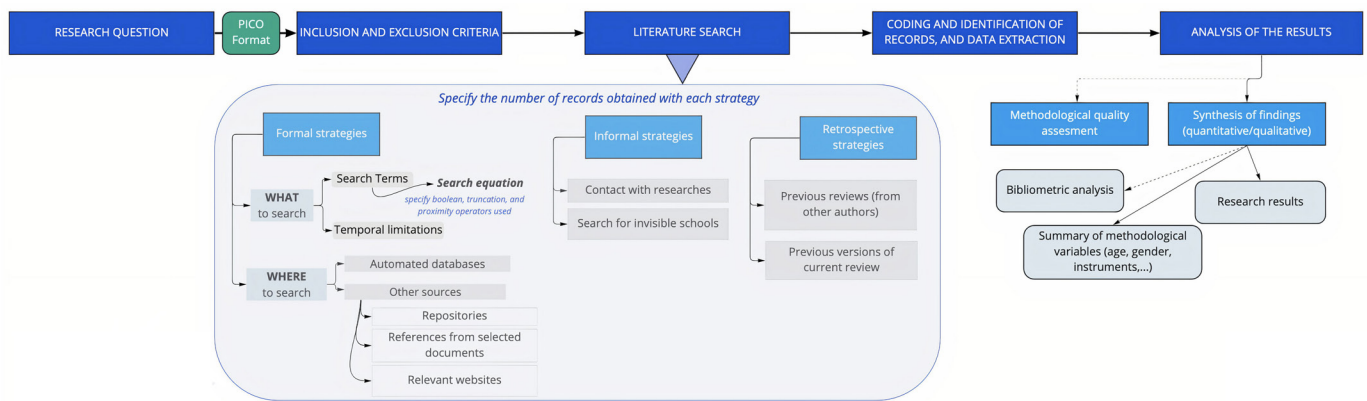


Figure 1 The general sequence of the review process. PICO, Participants, Interventions, Comparator, and Outcomes.

statement,^{18 19} the JBI Manual for Evidence Synthesis¹⁶ and the Cochrane Manual for Systematic Reviews of Interventions.²⁰ The review process is therefore organised following the stages described in figure 1. The standard PICO's process may be adapted to the specific review. This review process is already underway, and the review of all records is expected to be accomplished by the end of 2023.

The research question, which should always guide the review, can be operationalised by means of a method that usually follows the PICO structure.²¹ This structure provides the dimensions necessary for formulating the question and clearly defining the inclusion and exclusion criteria, but should be adapted to the review's objectives.²² The next process involves translating the concepts being researched into a series of terms or keywords that are linked using different operators (Boolean, truncation or proximity). These operators articulate the relationship between the terms in order to configure what is known as the 'search equation'. Once we have defined 'what to look for', we must decide 'where to look for it', a process that requires an in-depth exploration of possible strategies to be adopted. Generally, in all reviews, the search equation is executed in bibliographic databases, which can handle a logical language that allows even complex searches to be processed. Even though a correct review requires running searches in enough databases to cover many documents, it is vital to complement this formal strategy (replicable systematised searches) with informal ones also. This approach allows the researcher to locate valuable information with low circulation or difficult access (literature fugitive).²³ Moreover, other retrospective strategies are required to access documents retrieved in previous reviews and/or in earlier versions of the same research.

Inclusion and exclusion criteria

From an operational point of view, the research question in this review will be formulated using an adaptation of the PICO strategy. In this case, we will use the d-CoSPICO approach.

Documents

The following documents will be included: research articles, doctoral theses, books, and book chapters. Master's or bachelor theses, journalistic articles, short communications, case reports, technical notes, obituaries, editorials and similar literature will be excluded.

Concept

The concept is critical in a scoping review and guides the study's procedure, scope, and breadth.²⁴ In this review, the phenomenon of interest will be health promotion programmes addressing psychological and sociodemographic variables, considering the different points of view from which interventions can be approached. Psychological and sociodemographic variables encompass a wide range of factors related to an individual's psychological state and social environment and can have positive or negative consequences for health and behaviour. Psychological attributes and characteristics can be positive, such as joy, affection, vitality, etc, or harmful, such as anxiety, perceived stress, hostility, depression, hopelessness, etc. In addition, there are other factors of a structural nature or the social environment of people, such as social support, working conditions, etc. In this sense, within the large group of psychological variables, different subcategories can be distinguished: intrapersonal variables, interpersonal variables, social variables and community variables. The delimitation of the inclusion and exclusion criteria in this central section will follow a sequential methodology: (a) step 1: publications focusing on health promotion; (b) step 2: inclusion/exclusion of papers, depending on whether or not they analyse psychological and sociodemographic variables; excluded works will be organised according to discipline; (c) step 3: classification of intervention programmes according to the focus of analysis in terms of specific health issues (nutrition, physical exercise, etc), orientation towards specific groups or health settings.

The inclusion and exclusion criteria will be specified in the flow chart, as shown in figure 2.

Studies

Only quantitative empirical studies will be deemed eligible. Case studies, reviews, and theoretical papers,

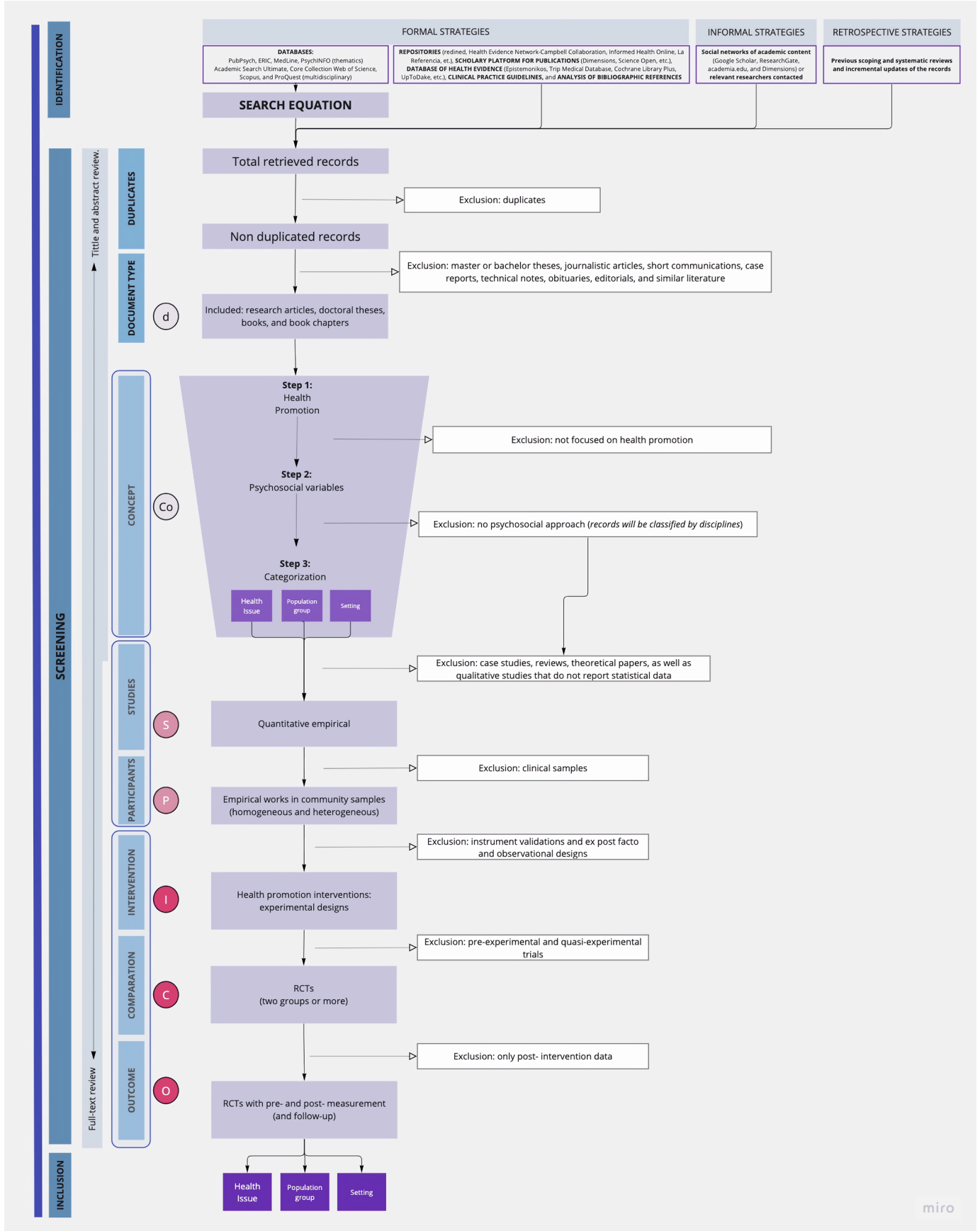


Figure 2 Flow chart of the methodological process. RCT, randomised controlled trial.

as well as qualitative studies that do not report statistical data will be excluded.

Participants

Studies with people belonging to both homogeneous and heterogeneous community samples (general or non-clinical) will be included with no limitations regarding sample size, age, sex or any other sociodemographic characteristic. Intervention programmes involving people with diagnosed health problems will be excluded. This criterion is justified by the intention to assure the external validity of the review.

Interventions

Empirical studies that evaluate the efficacy of a health promotion treatment will be included.

Comparisons

Experimental RCTs will be included, with both two-group (experimental and control) and multi-group/control group (active or passive) formats being accepted. Quasi-experimental studies (that do not randomise subjects to experimental conditions), experimental trials without a control group and case studies will be excluded.

Outcomes

Included works must necessarily include pretest and post-test measures, inform about the use of validated evaluation instruments, and provide evidence of reliability. In this sense, eligible studies will be those using assessment instruments that present high methodological quality as determined independently by the reviewers of the research team based on the COSensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) guideline for patient-reported outcome measures (PROMs).²⁵ The COSMIN initiative (www.cosmin.nl) includes a taxonomy of measurement properties relevant to health-related PROMs, classified into three broad domains: reliability (internal consistency, reliability and measurement error); validity (content validity, criterion validity and construct validity) and responsiveness, which contains the measurement property responsiveness.

Search strategy

The search string must be adapted to the structure and character limit established by the search engines of each database (see online supplemental table). The search will impose no language or time limitations. This search equation was developed by the authors through initial exploratory searches in collaboration with librarian at the Universidad Nacional de Educación a Distancia.

Information sources

Formal strategies

The documents will be obtained by searching different sources of information. First, eight automated databases containing thematic (PsycINFO, PubPsych, ERIC and Medline) and multidisciplinary content (Scopus, Academic Search Ultimate, Core Collection of the Web of Science, and ProQuest Research Library) will be searched.

Since most of these information sources are principally English-language ones, it is best to include other databases also, such as PubPsych. This European open access database retrieves records from databases in Germany (PsychData, PsycIndex and PsychOpen), the Netherlands (Narcis), Norway (Norart), France (PASCAL) and Spain (ISOC). Moreover, the guidelines established for evidence-based reviews²⁶ also recommend that doctoral theses (grey literature) be included to avoid publication bias (tendency to publish research with statistically significant results). In this regard, ProQuest includes ProQuest Dissertations and Theses, one of the leading collections of dissertations and doctoral theses worldwide, especially from the USA and Canada.

Second, we will complement this search by directly consulting documents located in different sources: specialised repositories (Redined, Health Evidence Network, Campbell Collaboration, Informed Health Online, LA Referencia, etc.), scholarly platforms for publications (Dimensions, ScienceOpen, etc), health evidence databases (Epistemonikos, Trip Medical Database, Cochrane Library Plus, UpToDate, etc.) and clinical practice guidelines. Following recommendations from previous studies,^{27 28 29 30} we will also analyse bibliographic references to identify relevant publications.

Our research includes documents published until 2022. These strategies could be replicated in the future, incrementally updating records, always using the same search equation.

Informal strategies

Relevant researchers in the field will be contacted by email or through academic social networking sites (Google Academic, ResearchGate, Academia.edu, Dimensions, Publons, etc.) to locate unpublished or those published studies in institutional repositories.

Retrospective strategies

The documentary search employing formal and informal search strategies will be complemented by analysing documents from previous scoping and systematic reviews.

Coding and identification of records, and data extraction

The records obtained from each database will be exported to a bibliographic reference manager (EndNote 20). A single file will then be generated in which all the records will be included, and any items found to be duplicated due to the use of multiple databases will be eliminated. Next, a personalised database will be created for processing each record. A series of bibliometric data will be included: year of publication, author(s), title, name of the journal, DOI, aims, abstract, and number of pages. Moreover, a series of enriched fields will be added in accordance with the d-CoSPICO format: (a) documents; (b) Concept; (c) Study; (d) Participants; (e) Interventions; (f) Comparisons and (g) Outcomes. This database will record both valid and non-relevant studies based on a qualitative analysis resulting from categorising the abstracts and

full texts of the retrieved papers. Finally, a third block of fields will be created once the relevant papers have been identified: (a) basic qualitative content analysis: through a process of open coding, broad categories would be created using a deductive approach to fit our data into a framework established in the literature, as suggested by Elo and Kyngäs³¹; (b) methodology: participants (sex, age, geographical origin, socioeconomic status, marital status and other potentially relevant sociodemographic variables), sampling and instruments; (c) substantive variables: the psychological and sociodemographic variables addressed and the theoretical model used; and (d) recording of the interventions: information will be obtained on the content of the RCTs and their format (individual vs group), type (digital vs face-to-face), intervention setting and session structure (session duration, number of sessions per week, total number of sessions, interval between sessions, length of the intervention and record of pre-post and follow-up measures, in both the experimental and the treatment groups). From this database, and through a deductive process, the psychological and sociodemographic variables present in the RCTs will be identified, as well as the action strategies carried out and the areas of intervention. Once this categorisation is done, the scientific evidence can be quantified and visually represented, as well as the evolution of RCTs in recent decades. For the categorisation and analysis process, we will use specific software for data analysis and bibliometric network construction such as Tableau, Voyant or VOSviewer.

During coding and data extraction, each reference will be blindly analysed by seven independent reviewers (MALG, FRG, PAM, FRC, MPGB, BMM, and ACPC) to eliminate duplicates and non-relevant records. Periodic internal seminars will be organised to discuss inconsistencies, doubts and disagreements, both in the selection and coding of studies and in data extraction, with issues being resolved by consensus and consultation with the other members of the team.^{18 19 32}

Finally, we would like to clarify two final important issues linked to the screening and data extraction process. The first refers to the traditional approach that considers the screening process to be independent of the eligibility process,^{18 19} rather than seeing them as two parts of the same process, which is the current tendency,³² although the idea of starting the screening process by first reviewing the title and abstract, and subsequently the full text, is maintained. In practice, this approach is not realistic, since the process tends to be more dynamic and parallel, and while the information provided in the titles and abstracts of the documents is often sufficient, researchers sometimes must consult the full text at the beginning of the process. The second issue is connected to the accessibility of the papers. Often, only retrievable texts are selected, which generates a bias in the total number of documents since, depending on the agreements established between database management platforms and research entities, some journals may be under temporary

embargo, rendering the full texts of the papers published in them inaccessible. Currently, different resources such as (inter)library loans, personal contact with authors and academic social networks can be used to access almost all records. For this reason, document accessibility cannot be a criterion for selecting records.

The result of the record coding process will be presented in the results section in the form of a flow chart outlining each of the phases (d-CoSPICO) and the number of records included and excluded.

Patients and public involvement

None.

ETHICS AND DISSEMINATION

Since the fundamental purpose of the scoping review will be to provide a retrospective review of publicly available sources of evidence, no ethical approval is required for the synthesis and analysis of the information.

The strategy developed by the research team ensures complete dissemination of the research results. First, this paper enables the dissemination of the protocol model developed, which involves minor modifications to the framework that are designed to clarify the organisation and categorisation of the information retrieved in review research. This dissemination will be complemented by the organisation of a workshop focusing on the importance of following a framework during the planning and carrying out of a review, adjusting certain aspects to the characteristics of the research being conducted. In this paper, we present the d-CoSPICO framework as a potentially helpful tool for guiding scoping reviews of controlled interventions. The authors will use this framework in both the courses they teach and the theses they direct.

Second, the scoping review will be published in a peer-reviewed journal. The results will also serve to inform subsequent systematic reviews in specific areas of health promotion by the same or other research groups, based on the results obtained. Moreover, the team members will attend and participate in conferences, seminars and other scientific events to share the retrieved information with interested researchers, practitioners, private entities and public health organisations.

DISCUSSION

The scoping review will provide an overview of the state of the art regarding RCTs focusing on health promotion intervention programmes. Our aim is to gauge their scope, determine how they have evolved over recent years and explore the psychological and sociodemographic variables examined in this type of intervention programme.

Additionally, the study will also serve to highlight existing gaps and needs in the field of health promotion, thereby helping to guide future research.

Finally, we believe that this protocol is characterised by its clarity and transparency. Both are key issues in any review process whose ultimate aim is to synthesise scientific evidence, thereby reducing arbitrariness in decision-making.^{18,24} In this sense, the different versions, and extensions of the PRISMA statement recommend portraying the search process carried out in the form of a flow chart outlining the preset inclusion and exclusion criteria. However, in many cases, this diagram does not precisely match the procedure followed to identify and select studies. The review protocol presented here therefore makes some modifications to the general instructions provided by the PRISMA-ScR extension, adopting a different structure (d-CoSPICO) which aims to achieve an exact match between this format, the flowchart and the future review process. As well as rendering the process clearer and more ‘transparent’, we believe this will also help other ‘researchers replicate’ the process.

A limitation that should be mentioned refers to the databases included in this review. Access to databases managed in North American and European countries may cause geographical and cultural biases due to possible omissions of documents located in other databases. Another limitation refers to the inner limitations of RCTs to provide information when it is compared with observational and quasi-experimental studies.

Contributors MAL-G: conceptualisation, methodology, writing – draft preparation, writing – graphics design, supervision. FR-C: conceptualisation, methodology, writing – draft preparation, writing – graphics design. FR-G: conceptualisation, methodology, writing – draft preparation, writing – graphics design. PA-H: conceptualisation – support, methodology, writing – reviewing and editing. LAS: writing – reviewing and editing, supervision, project administration, funding acquisition.

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ORCID iDs

Francisco Rodríguez-Cifuentes <http://orcid.org/0000-0001-9633-9137>
Luis Angel Saúl <http://orcid.org/0000-0002-6351-8283>

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