Revisiting systematic reviews from a methodological perspective

Revisitando las revisiones sistemáticas desde la perspectiva metodológica

Revisitando as revisões sistemáticas numa perspetiva metodológica

从方法论的视角对系统综述进行综述

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Abstract

The rapid expansion of systematic reviews in recent years has led to growth that has often lacked the required oversight. A large number of systematic reviews have been performed in practically all contexts and sub-contexts of knowledge. This has influenced the movement towards evidence-based practice and ease of access to a wide array of bibliographic sources. Nonetheless, this also makes it necessary to reposition systematic reviews from a methodological perspective. Alongside this, for various reasons, such as being alert to the often-incorrect use of terminology and procedural concepts, it will be necessary to redefine their aims and approach regarding strategy, propose an appropriate structure, bestow them with optimal breadth, depth and coverage, and evaluate the methodological quality of the primary documents on which they are based. In the present context, it is urged to structure such reviews from a mixed methods approach, which offers a continuum between the qualitative at one end and the quantitative at the other.

Keywords: Synthesis, mixed methods, aggregative and configurative reviews, methodological quality, PRISMA diagram.

Resumen

La veloz expansión de las revisiones sistemáticas en los últimos años ha dado lugar a un crecimiento que en muchas ocasiones ha adolectado del necesario control. Prácticamente en todos los ámbitos y subámbitos del conocimiento se han realizado multitud de revisiones sistemáticas, a lo cual ha influido el movimiento de la práctica basada en la evidencia y la facilidad de acceso a un amplio abanico de fuentes bibliográficas. Sin embargo, se hace necesario resituarlas desde una perspectiva metodológica, y por diversas razones, como estar alerta sobre un uso no siempre correcto de la terminología y los conceptos procedimentales, definir los objetivos y enfoque en cuanto a estrategia, plantear una estructura adecuada, dotar a las revisiones sistemáticas de una amplitud, profundidad y extensión idóneas, y evaluar la calidad metodológica de los documentos primarios, que en la actualidad recomendamos dimensionar desde un planteamiento mixed methods considerado como continuum, frente a la polarización anterior en las vertientes cualitativa y cuantitativa.

Palabras clave: Síntesis, mixed methods, revisiones agregativas y configurativas, calidad metodológica, diagrama PRISMA.

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Resumo

A rápida expansão das revisões sistemáticas nos últimos anos levou a um crescimento que, muitas vezes, não teve o controlo necessário. Foram efetuadas inúmeras revisões sistemáticas em praticamente todos os domínios e subdomínios do conhecimento, influenciadas pelo movimento da prática baseada na evidência e na facilidade de acesso a um vasto leque de fontes bibliográficas. No entanto, é necessário reposicioná-las numa perspetiva metodológica, e por diversas razões, tais como estar atento ao uso nem sempre correto da terminologia e dos conceitos processuais, definir os objetivos e a abordagem em termos de estratégia, propor uma estrutura adequada, dar às revisões sistemáticas uma amplitude, profundidade e extensão ideais, e avaliar a qualidade metodológica dos documentos primários, que, atualmente, recomendamos dimensionar a partir de uma abordagem de mixed methods considerada como um continuum, em oposição à polarização anterior nas vertentes qualitativa e quantitativa.

Palavras-chave: Síntese, mixed methods, revisões agregativas e configurativas, qualidade metodológica, diagrama PRISMA.

1. Systematic review: development and importance

Over the last decade and, particularly, recently due to the impact of the pandemic, growing interest has been shown in all scientific settings into the transparent collection of data, communication of outcomes and the sharing of data through shared networks. This is in accordance with the basic principles of open science (Vicente-Sáez & Martínez-Fuentes, 2018). This is closely related with the movement towards open access, which promotes free availability of research outcomes. Both open science and open access seek to improve the quality of research, the fullness of research data, the efficiency with which data is used, social impact and the application of academic research (Munafo et al., 2018; Tennant et al., 2016). In summary, they assist the realisation of the broad spectrum of synthesis studies.

The history of systematic reviews is relatively recent (Bohlin, 2012; Chalmers et al., 2002). Over the last twenty years diverse approaches have been developed, mainly focused on the inclusion of documents reporting primary qualitative and quantitative research, or the key role of theory for synthesising existing information (Pawson, 2006), or the understanding of research within...
its social and paradigmatic context (Greenhalgh et al., 2005).

In synthesis studies and, specifically, in systematic reviews, whilst tables and figures are largely responsible for the appealing presentation of quantitative research, experience charts and rhetorical figures perform the same task in qualitative research. As stated by Sandelowski (2007), whether you-as a reviewer-judge a set of research findings as vivid or lifeless, coherent or confusing, novel or pedestrian, or as ringing true or false, you are ultimately making, not just a communal judgement, but also a uniquely personal and aesthetic one (p. xix).

Given the explosion of knowledge and the ease of access to a wide array of information sources seen in the last decade, it is now possible to pinpoint information pertaining to a specific sub-context. The rapid growth of systematic revisions, according to Gough (2015), is due to a number of reasons: (1) The training required to perform such tasks has become broadly available; (2) The capacity to perform such tasks has increased; (3) Such tasks are conducted with maximum transparency; and (4) The methodology has been strengthened.

Debate around the use of qualitative-quantitative methodologies has lent great weight to the structuring and development of systematic reviews in the last quarter of the century. This has given rise to the systematic review, shaped by this approach to synthesis, being considered a qualitative approach by a large section of the scientific community. Further, in contrast to reviews of a quantitative nature, it is argued (Lockwood et al., 2020) that the typical characteristics inherent to systematic reviews dealing with qualitative data lead to them being questioned, adopted, rejected or transported, to a large extent, to analogous concepts and similar methods. In this sense, they are tailored to fit in with the particularities of research paradigms, especially those that are critical or interpretive in nature.

Systematic reviews are traditionally considered pieces of qualitative evidence. They have their roots in analysis of the complexity of human phenomena within natural or common frameworks and from a holistic perspective (Ailinger, 2003). The methodologies used by the primary documents on which they are based are often interviews and direct or indirect observation (Lockwood et al., 2020). However, it should also be made clear that they tend to take an out-of-date standpoint that it qualitative in nature.

The logic of systematic reviews is very simple. Transparent and rigorous approaches are used that require the prior selection of primary documents with the aim of integrating the outcomes reported by different studies in order to provide answers to a research question (research synthesis). Nonetheless, the development of this methodology has not gone hand in hand with a clear typology of systematic reviews, giving rise to an, often, convoluted terminology that has not helped to clarify and optimise this approach to synthesis (Gough, 2007). Further, this has enabled the emergence of excessive generalisations, unjustified simplifications and assumptions about differences that are only applicable to specific phrases. Further, highly polarised debate has raged about the usefulness and relevance of the different research paradigms used to provide context to the disperse primary documents being synthesised. Given this, knowledge about the nature and strong points pertaining to different types of review is necessary in order to be able to make appropriate decisions about the way in which systematic reviews should be conducted.

2.- Synthesis strategies used by systematic reviews

The different approaches to synthesis proposed by authors “cross-over” with traditional qualitative/quantitative approaches, which do not always lend themselves easily to intertwining (Sandelowski, Voils, Leeman, et al., 2011). From this, the mixed methods approach has emerged, with this approach being of particular interest to the present work.
The qualitative-quantitative “binary” has been useful to a certain extent, however, to another extent, it has been particularly conflictive. Indeed, Allwood (2011) considers it to represent a significant barrier to methodological advancement, a stance shared by the present research team.

Sandelowski et al. (2006) gave the name mixed research synthesis to any “type of systematic review aimed at the integration of results from both qualitative and quantitative studies in a shared domain of empirical research” (p. 29). To this, it must be added that mixed methods studies are also often used in the present day within systematic reviews as primary documents (Gough, 2015; Pluye, 2015; Pluye & Gough, 2014).

Of course, primary studies employing mixed methods are based on datasets from which data is made available from interviews, systematic observation, questionnaires, physiological measures, etc., via which information is directly obtained from participants recruited to the studies selected for systematic review. This contrasts with the data used in mixed research synthesis on which the findings reported by primary studies are based.

The focus of mixed research synthesis is concentrated in the integration of data or the findings they exhibit by the researchers responsible for gathering them. The outcomes of mixed methods synthesis is the integration of these findings by other researchers in order to “summarise” what is known about a specific phenomenon and orientate both practice and future research (Sandelowski et al., 2006).

The impetus with which mixed research synthesis emerged is the product of the convergence of evidence-based practice and the inception of qualitative research (Sandelowski et al., 2006). With regards to the former, different disciplines (medicine, education, social work, etc.) consider this type of practice to refer to the conscious, explicit and sensible use of information as the bedrock of practice (Trinder, 2000; Trinder & Reynolds, 2000). This has huge potential to increase the usefulness of research and the effectiveness of practice. With regards to the latter, the emergence of qualitative research over the last 40 years has given rise to an exponential increase in the number of publications and growing concern about their underuse. This, against the backdrop of a renovated interest in improving the usefulness of research through systematic reviews of these publications, has awoken interest in conducting qualitative research syntheses (Sandelowski, 2004). Hundreds of synthesis studies have been published in educational, psychological and sociological contexts, amongst others, and it is true that qualitative research is riding the wave of popularity (Morse, 1994).

Advances in qualitative and quantitative syntheses and the growing importance of mixed methods as the “third research paradigm” (Johnson & Onwuegbuzie, 2004) has contributed to an increased interest in mixed research synthesis. However, in order for mixed research synthesis to take a step forward, researchers must solve the problems generated by the methodological diversity found both within and between qualitative and quantitative studies. This is not an easy task. A great deal of discouragement (Sandelowski et al., 2006) originates from the complexity of the issue and, also, from the contradictions posed by this approach. This point is illustrated when striving to respond to the following question: What should be done when qualitative studies involving only a single participant (for example, a life story) are converged with another study involving only a single participant that is experimental in nature (N=1)? (Eisner, 1991; Owens & Ferron, 2012).

Qualitative researchers have urged for the development of synthesis methods tailored to qualitative research and have warned against dependence on quantitative research synthesis as a model for the synthesis of qualitative research (Barbour & Barbour, 2003; Jones, 2004). Nonetheless, debate rages on around a large number of related aspects (terminology, the recovery of all manuscripts from a determined context versus recovery just a
sample of manuscripts, the use of quality criteria to evaluate qualitative studies, the goals of qualitative synthesis, the interpretation of outcomes, etc.).

In the synthesis of quantitative studies, an essential issue is the methodological diversity found between observational and experimental studies, with the main contrast lying in the study of “real” and “artefactual” phenomena (Glasziou & Sanders, 2002). Another issue pertains to the internal heterogeneity found within each of these groups of studies. The large number of statistical techniques also used in the meta-analysis of data, which is largely identified with the synthesis of qualitative studies, also continue to generate debate.

Mixed research synthesis implies “mixing” together the differences inherent to the efforts made to integrate the outcomes produced by qualitative research with the efforts made to integrate the outcomes produced by quantitative research (Sandelowski et al., 2006).

Sandelowski et al. (2006) proposed three designs for mixed research synthesis: segregated design, integrated design and contingent design.

Segregated design maintains the conventional binary distinction between qualitative and quantitative research and is based on the following assumptions: (1) qualitative and quantitative studies are totally different and, therefore, should be dealt with separately; (2) qualitative and quantitative studies can be easily distinguished from each other; (3) differences between qualitative and quantitative studies call for separate analyses and syntheses of results; (4) the synthesis of qualitative conclusions requires “methods” (the present study uses the terminology “strategies”) developed specifically for the synthesis of qualitative conclusions; and (5) the synthesis of quantitative conclusions requires “methods” (the present study uses the terminology “strategies”) developed specifically for the synthesis of quantitative conclusions (Sandelowski et al. 2006).

This design is appropriate when respective qualitative and quantitative conclusions are seen to complement each other (for an example of this, see Maxwell 2004a, 2004b) and when synthesis is conceived as a means of configuration, for instance by revealing relationships between concepts, the temporal ordering of events, etc (for an example of this, see Greenhalgh et al. 2005 or Pound et al. 2005) and is not understood as a task of assimilation.

Integrated designs minimise the methodological differences existing between qualitative and quantitative studies to such an extent that it is considered that the conclusions reported by one study can be transformed to fit with those reported by another. This design is based on the following conclusions: (1) no difference that exists between qualitative and quantitative studies justifies separate analysis or synthesis; (2) studies designed to be qualitative or quantitative can not necessarily be distinguished from each other; (3) qualitative and quantitative studies from the same research ambit can have the same research objectives; and (4) the synthesis of qualitative and quantitative conclusions can be carried out using “methods” (the present research uses the terminology “strategies”) developed for qualitative and quantitative conclusions.

With integrated designs, studies from a determined context are grouped together for synthesis as opposed to being grouped based on the methods used (qualitative and quantitative). In other words, conclusions that respond to the same research question are grouped together as they could indicate one type of affirmation. Data can also be transformed, for instance via quantitizing and qualitizing (Anguera, 2022; Onwuegbuzie & Teddie, 2003; Sandelowski & Barroso, 2007; Sandelowski et al., 2009).

With contingent designs the results of a preliminary synthesis of conclusions within a first group of studies as a means to responding to research question are used to determine which group of studies are collected and

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analysed at the next step in order to respond to a second research question. The outcomes of this next analysis could, in turn, drive an examination of a third group of studies, which are subsequently gathered to respond to another research question. This cycle of systematic review continues until an exhaustive synthesis can be presented of the research addressing the aims proposed by the researchers.

Contingent designs may or not depend on the existence of dividing lines between qualitative and quantitative studies and between qualitative and quantitative research methods.

More recently, Pluye (2015) has worked, tirelessly, on conducting synthesis when qualitative, quantitative and mixed methods studies are found amongst the primary documents. This researcher described three main types of synthesis for systematic reviews: convergent qualitative designs (thematic synthesis, meta-narrative synthesis, realist synthesis and critical interpretive synthesis), convergent quantitative designs (content analysis and Boolean analysis) and sequential designs (exploratory or explanatory).

3.- Methodological standpoints of systematic reviews

The evidence-based practice movement, seen in diverse disciplines (Education, Psychology, Medicine, Sport, Nursing, etc.) has incorporated and strengthened the methodological standpoint of systematic reviews. This has led to the publication of a number of works on the integration of findings produced by methodologically diverse studies (Boaz et al., 2006; Harden & Thomas, 2005), raising interest in the outcomes of empirical research studies (Hawker et al. 2002), shining a spotlight on the methodological importance of primary studies (Gough et al., 2012; Pluye, 2015; Pluye & Gough, 2014) and, even, serving to make space for a methodological review of these studies (Alarcón-Espinoza et al., 2022; Anguera et al., 2023; Preciado et al., 2019, 2021; Sarmento et al., 2018; Tronchoni et al., 2022).

In fact, specifically, Gough et al. (2012) were the first to show interest in methodological aspects.

3.1.- Differential dimensions

The foundation of the present research ascribes to the assumption that systematic reviews follow a logic that can be applied to all research areas, meaning that as much heterogeneity can exist between systematic reviews as is found in the primary research they are based on. However, the fact that they are “systematic” suggests that they are carried out in adherence to methodological guidelines. Such is the potential variability between systematic reviews that Gough et al. (2012) proposed three encompassing differential dimensions: (1) objectives and approach with regards to methodology, (2) structure and components, and (3) breadth, depth and coverage. The present paper will refer to these later as a call for a correction of the terminology used regarding methodological issues (Figure 1).

0) Need for a correct use of methodological terms

Firstly, the present paper issues a serious warning about the deeply concerning confusion caused by the use of incorrect and generalised methodological terminology: strategy and methodology, method and technique, mixed methods and mutimethods, etc. This poor use of terms leads to a range of mistakes, such as considering something to be methodology that is, in fact, not, or attempting to compare methodological aspects that are not comparable (for example, thematic analysis, effect size calculation, creation of visual resources, …) (Gough et al., 2012; Sandelowski, Voils, Leeman, et al., 2011). On the one hand, the term “method” or “methodology” is often used to refer to an approach or strategy that is less structured and, on the other hand, the terms “method” and “technique” are often used indiscriminately, challenging the idea that different methods can
be contrasted within the same set of primary studies as a means to comparing their advantages and the outcomes of the synthesis of primary studies (Dixon-Woods et al., 2005; Lucas et al., 2007). Likewise, the non-specific use of terms/expressions such as *mixed methods* and *multimethods* has contributed to greater inaccuracy in a number of research works (Anguera et al., 2018).

Sometimes, transgressions from the norm are treated as methodological innovations, blurring the lines between reinvention and innovation (Taylor & Coffey, 2009; Travers, 2009) and between reinvention and methodological erosion (Greckhamer & Koro-Ljungberg, 2005). In this respect, it is important to be able to distinguish between that which is essential and that which is secondary.

Figure 1. Differential dimensions in Systematic Reviews

(1) Objectives and approach regarding strategy

Given that no agreed upon typology exists (Grant & Booth, 2009) and many authors use the term “methodology”, which we consider to be damaging or, at least, confusing, the strategy of conducting synthesis studies currently finds itself in a landscape in which the diversification of positions is encouraged. Further, given that the general aim is to examine whether theory is empirically supported, hypotheses can also be generated regarding causal relationships (Gough et al., 2012). Two main schools of thought exist, namely, that of aggregation and that of configuration. The choice between the two is not only due, at least not exclusively, to the preference of the researcher but, instead, to the inherent nature of the outcomes produced by the primary documents (Sandelowski, Voils, Leeman, et al., 2011).

An array of authors (Gough et al., 2012; Pawson et al., 2022; Sandelowski, Voils, Leeman, et al., 2011) have purported preferences for one strategy over the other and their reasons stand out as not always being coherent. In a systematic review, questions may be posed that pertain to the meaning of a phenomenon, accuracy of a specific tool, attributes of a specific activity, effect of an intervention, cost of an intervention, interpretation of results, etc. However, undoubtedly, pertinent decisions must be made that carry with them a number of important implications. For example, a search of primary documents that strives to achieve a

representative sample of primary documents from the outset (denominated “exhaustive search”), with the aim of avoiding bias, is not the same as progressive sampling, in which samples are gathered inductively based on emerging literature with the aim of providing more in-depth detail within the bounds of a theoretical framework.

Aggregative reviews gather empirical data in order to describe and examine pre-defined concepts. They use “aggregative” logic within pre-defined theoretical standpoints and are interested in the homogeneity of primary studies. The logic of aggregation is based on the identification of studies that mutually support each other and, therefore, instil the reviewer with greater confidence about the magnitude and variability of the phenomenon under investigation. In contrast, configurative reviews tend to be exploratory in nature. They adapt and iteratively select the way in which to proceed as research advances and are interested in the identification of patterns that contribute to study heterogeneity (Barnett-Page & Thomas, 2009). Thus, in this case, the aim is to identify enough cases to be able to explore commonalities and differences between studies.

Both aggregative and configurative reviews strive to avoid erroneous conclusions due to issues with primary documents. In the case of aggregative studies, there is a greater guarantee of methodological quality given that inclusion and exclusion criteria are explicitly outlined and it is possible to stipulate, for example, that only certain types of documents, with specific methodological characteristics are to be included. Nevertheless, configurative reviews are also characterised by less consensus when it comes to the practice of quality evaluation, with some authors rejecting the notion that study quality can be evaluated through an examination of the methodology applied. Instead, these authors prioritise other issues, such as the contribution of the study towards proving or generating theory (Harden & Gough, 2012).

Aggregative and configurative logics demand the application of different review strategies (Sandelowski, Voils, & Barroso, 2006; Sandelowski, Voils, Leeman, et al., 2011; Voils et al., 2008) and neither logic is superior to the other. In fact, systematic reviews tend to include components corresponding to both logics, although it is common for them to predominantly lean more towards one over the other. In the present day, multiplicity reigns over parsimony in research works presenting data synthesis.

In this context, the confusion that can be generated by differences between the epistemological orientation of the work of synthesis and that of the primary studies included in it must be avoided (Sandelowski, Voils, Leeman, et al., 2011; Suri & Clarke, 2009).

(2) Structure and components.

Systematic reviews vary in structure (Gough & Thomas, 2012), which can adopt different forms, with mapping being the most commonly adopted form. However, a diverse array of choices can be made, such as to synthesise only a sub-set of studies, or perform a number of synthesis corresponding to different zones of the same map.

The Gordian knot considered to be essential comes in the form of the mixed methods review, which shares a number of similarities with the basic approach taken by mixed methods primary studies. Qualitative and quantitative elements (data, results…) from different research studies are combined, making it possible to make different selections, for instance, in the development of iterative processes for certain aspects, aggregative reviews based on theoretical frameworks, etc.

A frequent approach taken by mixed method reviews is to conduct something known as a realist synthesis (Pawson, 2006). The structure of this consists, in the first instance, of specifying a theoretical basis and testing it empirically and, in the second instance, of examining the sub-components of the theory. The main difference of this from a “standard”
review is that the search for empirical evidence follows a process that is iterative in nature.

It is possible to conduct systematic reviews of data collated and presented by other systematic reviews (Smith et al., 2011). Reviews of reviews can be performed on previously obtained findings or by providing more in-depth detail on data made available by the initial review.

(3) Breadth, depth and coverage.

Primary documents and reviews are sometimes considered as isolated outputs, but they tend to represent a step or stage of a larger long-term study (Gough et al., 2009).

Some systematic reviews exist that adhere to the aggregative strategy and seek maximum homogeneity in the aim and methodology of primary documents. In the case of these aforementioned reviews, little breadth, or a narrow view is taken (Gough et al., 2012) and, whilst this is positive from some determined standpoints, it is also true that diverse “narrow” systematic reviews are needed when the aim is to inform appropriate decision making.

Nonetheless, when reviews seek to address complicated issues, a broader viewpoint is required, for example, when evaluating the impact of complex interventions. It appears obvious that such cases could produce multiple variations when it comes to issues related with frequency, duration extent, correct application of the intervention (Carroll et al., 2007), etc., which could all produce different effects within different participants and in the contexts in which they are deemed necessary. Such variability could have a differential impact on conceptual issues and on the way in which intervention effectiveness is understood. In this case, the review will need to branch out on the map in order to be able to hone in on more restricted aspects of the interpretation of the data synthesis conducted.

The breadth of a review, in conclusion, can be “calibrated” according to single reviews, a series of reviews, or reviews of reviews and, in any case, will always be wrapped up in a broader circle or commitment and response to the users of the research (Stewart & Oliver, 2012).

The necessary resources for a systematic review can be highly heterogeneous and will need to consider, not only, the breadth of the review, but, also, its depth. Mixed methods reviews require more resources given that the complexity is increased. When only a short time-frame is available and resources are scarce, a review denominated a “limited review” (Abrami et al., 2010) may, instead, be performed. In this case, certain aspects are reduced, for example, the breadth or scope of the research question, the number of sources examined, the depth of analysis, etc.

In conclusion, reviews can be performed with different levels of skill, efficiency and automated tools. In addition, the work required to carry out any given review is highly heterogeneous.

3.2.- Register of trials and protocols

In line with the philosophy of systematic reviews, an unusual amount of interest has focused on the preparation of protocols, due to the fact that it is considered that this will lead to an increase in the transparency and quality of research.

According to Plos Medicine Editors (2011), many reviews (especially medical reviews) started to demand that trials were registered beforehand as a condition to considering any subsequent report for publication. This policy was explicitly established in order to reduce what was considered to be the generalised bias towards publishing “positive” studies regarding a pre-determined desired or expected effectiveness and in order to guarantee that all clinical trials were made public prior to the inscription of participants.

Nonetheless, well-conducted systematic reviews (reviews of health interventions that use a pre-defined and detailed methodology to find and synthesise all relevant tests) are generally considered as higher calibre evidence than individual trials when it comes to decision making in determined ambits,
especially in the case of clinical practice and health policy. The superiority bestowed on these types of reviews derives from key aspects inherent to the process of conducting a systematic review. This type of study, when performed correctly, enables reviews to get closer to estimating the true effect of an intervention than any type of individual study is capable of doing. This is due to the fact that, firstly, these types of reviews gather and synthesise data from all pertinent studies and, secondly, because reviews evaluate each individual included study as a function of their risk of bias.

Nevertheless, there is increasing evidence of the existence of publication bias in systematic reviews (Kirkham et al., 2010), which may be due to the publication of incomplete studies (Tricco et al. 2009), the existence of discrepancies between systematic review protocols and the corresponding published report (Kirkham et al., 2010; Silagy et al., 2002), or a bias that favours the publication of "positive" outcomes (Silagy et al., 2002). Thus, in order for evidence from published studies to be interpreted within the context of their respective setting, especially when dealing with the clinical context, it is of vital importance that reviews are as rigorous and extensive as possible. The existence of a pre-established protocol should, therefore, be an automatic consideration of a review. This would make it possible to highlight any deviations provide information pertaining to review outcomes in accordance with the original study plan. Altogether, registering systematic review protocols would improve clarity regarding the realisation and notification of systematic reviews (Booth et al., 2011; Straus & Moher, 2010).

This record helps to minimise bias in the realisation and reporting of reviews, reduces the duplication of efforts between different groups and keeps systematic reviews up-to-date. Nonetheless, no general open register has previously existed in which all researchers around the world can register the existence and development of systematic reviews from their initiation to their completion.

Some of the generic advantages attributed to the registers discussed above are that they help researchers prepare the research process, choose the appropriate methods and specify, beforehand, the research questions and outcomes they seek to address (Moher et al., 2015). The use of protocols facilitates the task of conducting a review and reduces the unnecessary duplication of research seen between independent researchers (Krleza-Jeric et al., 2005). Further, they minimise the risk of bias and can help to avoid potential malpractice, such as the covering up of unfavourable outcomes, which can be a particular risk in the clinical setting.

At the present time, in which interest reigns that is focused on evidence, different organisations (Cochrane, Campbell, Joanna Briggs Institute, …) have come to the fore that are characterised by work in which high quality syntheses are performed. Although Cochrane reviews constitute only a small fraction (7%) of all published systematic reviews (Hoffmann et al., 2012), the reviews conducted by this organisation are considered to be the "gold standard". According to a recent study, in 2019 an average of 80 systematic reviews were published each day (Page et al., 2018).

A large proportion of authors publishing systematic reviews also produced protocols, with the aim of reducing overlap and the duplication of research and, as a consequence, the squandering of public funds (Moher, 2010; Stewart et al., 2012). Examples of this can be found in all ambits (Albrecht et al., 2021; Backman et al., 2018; Brown et al., 2022; Chicoine et al., 2021; Johnson et al., 2022; Johnstone et al., 2020; Leslie et al., 2016; Mazevska et al., 2022; Pearson et al., 2021; Rana et al., 2021; Vandyk et al, 2019; Wiafe et al., 2020).

Diverse repositories exist in which systematic reviews on any given topic can be searched for (JBI Evidence Synthesis, MEDLINE, DARE, PROSPERO, EPISTEMONIKOS, ACCESSSSS, Cochrane Database, CINAHL, PubMed).
In the specific case of PROSPERO (Prospective Register of Systematic Reviews) (Allers et al., 2018; Page et al., 2018), this register was opened in 2011 to enable researchers from diverse disciplines to register protocols pertaining to systematic reviews, with a particular focus on those related with healthcare. It is a free register, available to any individual throughout the world and generates a unique ID for each individual systematic review registered within it. This ID can (and should) appear in any publication in which the study is later mentioned. Researchers should use the register to bring attention to the existence of protocols detailing systematic reviews pertaining to health interventions that are being planned or currently underway and this should be done prior to selecting the studies to be included in the systematic review. The register requests a basic set of data in order to detail the key elements required to meaningfully register a systematic review. Key data elements include stating the research question, defining the patients and population, detailing the study intervention(s) and outcomes, outlining the inclusion and exclusion criteria used by studies within the systematic review, including a flow diagram of the search strategy, and detailing the methods used to evaluate the risk of bias and to analyse the studies included in the systematic review.

The main advantage of registering protocols is their ease of access and publication itself of such protocols could benefit from the improvements to methodological quality suggested by the reviewers themselves during the process.

The importance of these aforementioned protocols is of such an extent that some authors (Van der Braak et al., 2022) consider it to be a limitation that some publications do not include the protocol within the manuscript. In this sense, Allers et al. (2018) places this number to be around 12.5% of publications.

### 3.3 Evaluation of the methodological quality of primary documents

In recent years, interest has grown in conducting more in-depth analysis of the methodological quality of primary documents. Such interest has been expressed separately from both qualitative and quantitative standpoints.

1. From a qualitative perspective.

Data extraction: Data extraction in a meta-aggregation is a multi-step process that includes the identifying elements of papers, specifically, information regarding citations, context and year, alongside bibliometric information (number of authors, country of affiliation, journal ranking, impact factor…). At the next step, findings are extracted. Findings are understood in line with that proposed by Lockwood et al. (2020), that a finding is defined as a verbatim extract of the authors analytical interpretation, accompanied by either a participant voice, or fieldwork observations or other data (p. 56). Each finding should be accompanied by an illustration, which could be in the form of a voice recording or transcription, an observational record, or any other type of data used to support outcomes.

Data extraction requires the availability of documents of different levels of credibility. The credibility of documents is determined as follows: Unequivocal (when all documentation is available in its entirety), credible (some documentational elements are lacking and, although evidence is available, doubt remains), without documentational support (no explanatory data is available to justify findings).

Data synthesis: A meta-aggregative process requires 3 steps: (1) The extraction of all findings, each alongside their corresponding illustrations and level of credibility; (2) Category development, with at least 2 findings being outlined for each category; and (3) The realisation of one or more synthesis/es of at least 2 categories. Reviewers should describe: Data revealing consistent “findings” in the review. In this process, findings are identified (repeated reading of the text, selection of themes based on that detailed in the results section…), findings are grouped together to form categories (based on similarities between...
terms, concepts…), descriptions are made of the established categories (by a single reviewer, through consensus between various reviewers…), and the synthesis of findings and their descriptions is initiated and finalised.

Results: Should include details of the process of selecting studies for inclusion (PRISMA diagram: number of studies identified, number of studies screened, studies selected for recovery, motives for exclusion, number of studies evaluated and included/excluded, final number of studies included), the methodological quality of eligible studies (determined via the relevant ‘critical appraisal checklist’), detailed characteristics of included studies (descriptive and demographic data, geographical context, methodology applied, participants/sample, instruments used, type of data analysis…) and, of particular importance, a review of outcomes and of the synthesis process.

Discussion: Here it is important not to repeat information outlined in the results section. Discussion should be grounded within the context of existing scientific literature, demonstrating the strength of the evidence, limitations of the included primary documents (inconsistencies, errors…) and the extent to which results can be generalised.

Conclusions and recommendations: It is important to consider recommendations for practice (applicability) and for future research.

Conflicts of interest and acknowledgements.

Appendices: Details of the search strategy, data gathering, list of excluded studies, table of included articles, tables relative to the aspects deemed of interest to provide more detailed information…

Rating scales have been proposed as suitable tools for operationalising methodological quality. Of those available, the JBI Critical Appraisal Checklist for Qualitative Research (Aromataris & Munn, 2021) stands out. This checklist poses a series of questions, of which the following are selected to provide further detail:

(1) Is there congruity between the research methodology and the research question or objectives?
(2) Is there congruity between the research methodology and the methods used to collect data?
(3) Is there congruity between the research methodology and the representation and analysis of data?
(4) Is there a statement locating the researcher culturally or theoretically?
(5) Is the influence of the researcher on the research, and vice-versa, addressed?

Articles are rated in descending order according to the number of affirmative responses (4-5, 2-3, 0-1).

(2) From a quantitative perspective.

Traditionally, quantitative evidence has been obtained through studies conducted using methodologies that produced numerical data and in ambits that were inextricably and undoubtedly linked with healthcare. In this regard, primary documents typically examined therapies that were used to treat fevers, scurvy, paralysis, etc., and in which the incidence, prevalence or aetiology, etc., of illness was quantified (Brignardello-Petersen et al., 2015).

Such quantitative reviews examined the extent to which the intervention, when properly administered, led to the desired effect, with methodologies typically being experimental and quasi-experimental, given that the intervention is medium or high grade. It should be clarified, despite the fact that some authors also include observational studies here, this would only be possible in cases of low-grade interventions and when the usual context in which they would be applied could be guaranteed (Chacón-Moscoso et al., 2021).

This does not allow room for cohort studies or cross-sectional studies (inherent to the healthcare setting) to be considered.
Tufanaru et al. (2020) proposed a specific protocol for systematic reviews from a quantitative perspective. This protocol comprises the following sections:

1. Context and justification of the review, including that which is already known and prevailing uncertainties. The importance of the topic should be discussed, alongside the concerns of patients, professionals and serving politicians. The specificity of participant groups and related contexts should be mentioned, as should intervention characteristics and potential doubts regarding them, potential interventions with which those included in the review could be compared, ways of measuring outcomes and the relevance of existing primary studies. Likewise, previously conducted systematic reviews and meta-analyses should be examined and the need for a new review should be justified in light of its aims.

2. Selection criteria outlined in the primary documents (inclusion/exclusion). Such criteria must be explicit and unambiguous, based on scientific arguments and presented in a justified way. It is common to use the mnemonic anagram PICO (participants, intervention, comparator and outcome). It is important to distinguish between inclusion criteria based on study characteristics (participant profile, intervention modality [in addition to its frequency, intensity, timing, method of administration], type of measures, etc.) and those based on characteristics of the publication (date, language, databases in which they are included, impact factor, etc.).

3. Interventions outcomes and all performed comparisons (with placebo, other therapies, absence of treatment, etc.). Outcomes should be measurable and tailored to the objectives. Further, distinction should be made between outcomes that reflect a final endpoint (for example, number of years that a patient has lived with a disease) and alternative outcomes (for example, progression from one stage to another).

4. Search strategy used to identify relevant studies. Essentially, three potential routes are possible for identification: (a) include only those studies that fit the specific design type of interest; (b) include studies with greater coverage or reach than those of a more specific interest, in case articles of a more specific nature cannot be found; and (c) include all available empirical evidence, applying broadly inclusive criteria. With regards to the search, multiple options are available to choose from, for example, electronic databases (such as PubMed, WoS, PSYCINFO, EMBASE, etc.), journals included in Web of Science, contact with researchers, etc.

5. Procedure for study selection. A number of criteria can be established (title, abstract, full text review, etc.) and the approach to resolving discrepancies between reviews (consensus, third reviewer, etc.) is decided.

6. Critical evaluation of the process followed and the instruments used. The aim of the section is to perform a methodological evaluation of the primary documents and examine the extent to which the risk of bias has been excluded or minimised in the design, development and analysis. Bias can pertain to selection, performance, dropout, detection, reporting, etc.

7. Data gathering and instruments. It is highly important that the extraction of data is complete and meticulous. Information should be provided about publication of the study itself, participants, context, interventions, comparators, obtained measures,
design, statistical analysis and other relevant data (funding, conflicts of interest…).

(8) Procedure for resolving disagreement between authors of the systematic review when it comes to study selection, data gathering and the critical evaluation of the decisions taken. The involvement of a third reviewer is recommended.

Synthesis proposals. Two options essentially exist, namely, a statistical synthesis (meta-analysis) or a narrative synthesis. A meta-analysis, essentially, is the statistical synthesis of quantitative outcomes produced by two or more studies. When this type of synthesis is not possible, a narrative synthesis is performed. Meta-analyses should be reserved for the outcomes of studies that are considered to be similar from a clinical or methodological viewpoint (homogeneous studies) and, when this is not the case, justification is required. Clinical heterogeneity refers to differences pertaining to participants, interventions, comparators, contexts and outcomes. Methodological heterogeneity refers to design and risk of bias (Sutton et al., 2000).

4.- Mixed methods approach in systematic reviews

The strategies that can be followed when performing syntheses in systematic reviews, with particular reference to the approach put forward by Gough and Pluye (Gough, 2015; Pluye, 2015; Pluye & Hong, 2014), which includes the reporting of mixed methods in the primary documents, are undoubtedly at risk of being conceptualised as mixed methods.

In this sense, it is important to bear in mind that Sandelowski et al. (2006) warned that, “for ‘purists’ (Johnson & Onwuegbuzie, 2004, p. 14), who view qualitative and quantitative research as two wholly different species of inquiry, the chasm between qualitative and quantitative modes of inquiry is deep enough to make it difficult or even impossible to cross it without endangering the imperatives and integrity of one or both domains of inquiry” (p. 31).

Different “voices” on the issue must be heard, with debate widely expanding in recent years, demonstrating a high level of interest within the scientific community and in professionals from applied settings.

4.1.- Mixed methods as a continuum

The first authors to use the expression mixed methods (first, Parkhurst et al. [1972], followed by Newman & Benz [1998]), almost a quarter of a century ago, urged exploration of the joint qualitative-quantitative continuum in research. This was because they deemed the dichotomy that many other authors sought to demonstrate existed to be false and baseless, as it presented both options as contrasting paradigms and failed to accept that both qualitative and quantitative strategies are always found to be present in all studies. Their proposed approach focused on feedback between qualitative and quantitative analyses and can be considered as an accurate precursor of the current and complex state of the issue (Anguera, 2022). This early paradigm was to have an unquestionable impact on the realisation of systematic reviews.

In the relatively short, yet intense, history of mixed methods analysis, it has become clear that many forms exists of embedding monoanalysis studies within mixed methods studies. These types of studies are, of course, differentiated from studies that are truly mixed methods and it is, precisely, this integration that distinguishes mixed methods studies from monomethod studies that are considered independently. A broad array of possibilities is open to the researcher, with options increasing greatly when different types of analysis are applied (Anguera, 2022). This, however, generates more doubts when performing a systematic review.

At the centre of this swamp of possibility, qualitative and quantitative traditions in research stand out, alongside the war of paradigms, which various authors have rejected as being radical (Johnson &
Onwuegbuzie, 2004; Newman & Benz, 1998; Ridenour & Newman, 2008; Tashakkori & Teddlie, 2003, 2010), showing that clear preferences exist in the focus of both of these traditions. It is, also, clear that methodological divisions exist, despite the fact that rigid and exclusive “labelling” exists to signpost one approach over the other, with this prevailing until very recently in scientific literature regarding systematic reviews.

Faced with this polarisation, some authors defend the fact that purely quantitative methods do not exist as all involve qualitative elements at some stage of the process (Chang et al., 2009; Sandelowski, 2014). In a similar sense, Newman and Hitchcook (2011) argue that no “inherently quantitative, qualitative or mixed methods” research exists (p. 382). Essentially, the view taken by researchers of reality is shaped by their interactions with data, evaluative judgements and interpretations, and the way in which they quantify phenomena (Newman & Hitchcock, 2011). Indeed, rigid quasi-quant labelling could serve to undermine research quality (Ridenour & Newman, 2008). This issue is currently highly in the case of mixed methods studies (Fàbregues, Molina-Azorín, & Fetters, 2021; Fàbregues et al., 2019), as such rigid labelling is likely to have negative repercussions on synthesis studies.

In the context of these opposing standpoints regarding the conception of these methodologies as a continuum due to ideological-conceptual reasons, Onwuegbuzie and Tashakkori (2015) identified at least three overarching categories describing the beliefs underlying mixed methods studies: 1) Mixed methods as a multidimensional continuum (with the pure forms at either end); 2) mixed methods as a bridge between a dichotomy of assumptions and qualitative and quantitative standpoints; and 3) mixed methods as a guiding approach that includes mental models, assumptions and a series of methods that are not necessarily identified with any dichotomy of methodological proposals and, instead of achieving the desired integration, can lead to segregation.

Further, Onwuegbuzie (2012) proposed a “radical middle” in which value is added, arguing that researchers should not sit back in a comfortable qualitative or quantitative epistemological position, but, in contrast, promote a “consciously local, dynamic, interactive, situated, contingent, fluid and generative” space (p. 192). This led to the inception of the acronym MIXED (M: Methodological thinker; I: Integrative, integrated and integral researcher; X: Xenophile researcher; E: Empower; D: Development), which calls researchers to meet in the “radical middle” (p. 210). This MIXED space blends into crossover mixed analysis and reaffirms the existence of a continuum between qualitative and quantitative elements, as opposed to these aspects serving to contradict each other (Anguera, 2022).

In conclusion, this is the position taken by the present paper. Taking the continuum standpoint instead of seeing the qualitative and the quantitative as being in full on opposition brings hope that, in the coming years, consequences will be seen in the synthesis of primary documents.

4.2.- The fit of mixed methods in systematic reviews

The rapid development and expansion of mixed methods in the last quarter of a century has had an impact on systematic reviews. Hong et al. (2017) maintain that systematic reviews show a clear preference for quantitative evidence (especially from controlled clinical trials and the efficacy of clinical interventions), however, this is inadequate in other areas where qualitative evidence is needed. Equally, these authors argue that both types of evidence, qualitative and quantitative, can be used to complement each other in order to obtain better understanding of the impact of contextual factors, helping to focus on outcomes.

Systematic reviews are considered to represent the best source of evidence possible. This makes them useful for decision making (Hong & Pluye, 2019), with them reigning higher than other types of research in many evidential hierarchies. This is logical given that
decisions must be based on the entirety of the evidence and not only on a single study (Bunn et al., 2015).

Heyvaert et al. (2013) support the use of the typologies proposed for primary mixed methods studies, but, despite this, the same support is not seen at the synthesis level in relation to all of the diverse types of synthesis (systematic review, integrative review, research synthesis, realist synthesis, qualitative review, narrative review, meta-analysis). This being said, historically, syntheses are structured according to two overarching groups, namely, that corresponding to systematic reviews, from a qualitative perspective, and that corresponding to meta-analyses, from a quantitative perspective. Synthesis studies can be qualitative, quantitative or mixed methods and, in all cases, come from qualitative, quantitative or mixed methods primary studies. A mixed methods synthesis study is a systematic review that follows the principles of mixed methods. This implies that the findings have been extracted from qualitative, quantitative and mixed methods primary documents, in this way, combining their strengths. A mixed methods approach that combines elements of qualitative and quantitative research is used to integrate findings within a single systematic review.

Typologies relative to mixed methods primary studies exist (Collins & Cathain, 2009; Greene et al., 1989; Leech & Onwuegbuzie, 2009; Teddlie & Tashakkori, 2006), which have allowed a more flexible structure to be followed in mixed methods research, the development of conceptual-methodological frameworks, credibility and the production of illustrations, use of a shared language and facilitated instruction in this ambit (Heyvaert et al., 2013). Nonetheless, no parallelism exists with respect to typologies at the level of synthesis.

Heyvaert et al. (2013) proposed MMRS [Mixed Method Research Syntheses] as a way of conducting synthesis in which researchers combine qualitative, quantitative and mixed methods studies and take a mixed methods approach towards integrating data from all of the above in the spirit of maximum collaboration. These authors proposed the following dimensions: emphasis on the approach taken (QUAL dominant, QUAN dominant, shared status, dominant status, embedded design), temporal orientation (concurrent, sequential, parallel, simultaneous, complementary), purpose of the study (triangulation, exploratory, explanatory, initiation, expansion, complementary), theoretical framework (transformative, pragmatic).

The first two dimensions, together with the corresponding integration of data, comprise an important block with regards to the level of synthesis and in cases where integration enables differentiation between syntheses that consider all analysis and syntheses that only consider part of this aforementioned analysis, separately. For example, treatments in which high scores (quantitative data) are obtained in relation to specific values, but, in which, negative effects of this treatment are detected (qualitative data) in relation to specific aspects. Here, a mixed methods approach at the level of synthesis would enable discrepancies to be identified.

The present research team agrees with the stance of Heyvaert et al. (2013), that dimensions corresponding to the purpose of the study and the theoretical framework are less important at the synthesis level than they are at the level of the primary documents. This is because the former focuses on aspects that should not have any implications for the synthesis of data from different primary documents and, with regards to the latter, it is assumed that, practically at all times, empirical studies will form the basis of the work, as opposed to conceptual studies.

When conducting synthesis work, primary documents are selected following the application of inclusion and exclusion criteria and as a function of the PRISMA diagram (Moher et al., 2015). Consequently, the “load” of each individual one of these articles is taken
on with regards to the qualitative and quantitative elements held within these articles. Although Heyvaert et al. (2013) propose a classification framework for MMRS, the position taken by the present paper is more nuanced and flexible, leaving, at all times, space to enable the unfurling of the potential of mixed approaches. In the proposal outlined by Heyvaert et al. (2013), successive stages are proposed in order to systematically synthesise evidence produced through empirical research reported in primary documents. The stages are as follows: (1) Identification of the issue and formulation of questions, (2) development of a review protocol and literature search, (3) selection of an appropriate design and method, (4) data extraction and evaluation, (5) data analysis and interpretation, and (6) presentation and discussion of outcomes.

Along similar lines, Hong & Pluye (2019) proposed SMSR [Systematic Mixed Studies Review]. Likewise, this responds to the need to include qualitative, quantitative and mixed methods studies in systematic reviews (Heyvaert et al., 2016). According to these authors, a study is considered to be mixed methods when the following three conditions are met: (1) At least one qualitative method (QUAL) and one quantitative method (QUAN) are combined, (2) each method is applied rigorously, and (3) data collection and/or data analysis and/or outcomes are integrated (Johnson et al., 2007; Hong & Pluye, 2019).

Mays et al. (2005) acknowledges that a wide array of information sources is needed to inform decision making, with pressure constantly increasing to adopt a more systematic approach. Access to better quality syntheses is needed, with consensus still lacking around a single framework for the synthesis of different types of evidence. These same authors (Mays et al., 2005) highlight four basic narrative approaches (thematic analysis, narrative synthesis, realist synthesis and meta-narrative mapping), which convert all potential evidence into qualitative data, whilst others, such as meta-analysis and Bayesian analysis, are used in quantitative synthesis. Nonetheless, focus is still placed on the qualitative-quantitative dichotomy, from which we strive to get away from.

Continuing in this direction, a series of work conducted by the same research group (Pace et al., 2012; Pluye et al. 2011; Queiroga et al., 2015; Souto et al., 2014) stands out, with these authors continuing to work restlessly to fit mixed methods into systematic reviews, whilst also elaborating instruments to support the systematic review process.

5.- Epilogue: Proposed methodologies

The methodological basis of a systematic review is fundamentally important. Although this seems obvious, it is not always given the recognition it deserves and nor is it considered to an appropriate extent.

Turning attention back to the systematic review, we suggest a multiple methodology proposal:

(1) Methodological terminology must be adjusted with the aim of avoiding the confusion brought about by the increasingly generalised misuse of terms (method, design, technique, mixed methods, etc.);

(2) The nature of mixed methods is to be considered as a continuum instead of the current dichotomy found between the qualitative and the quantitative. It is recommended to examine the positioning of each, individual, primary study along this aforementioned continuum;

(3) It is essential to evaluate the methodological quality of primary documents.

6.- Conclusions

Systematic reviews have been the subject of exponential growth during recent years, with such growth being seen in all knowledge settings. We believe that this phenomenon is associated with growing concern for transparency regarding the dissemination of results and conclusions, but, also due to the increase in open access publications. Nonetheless, a number of speedbumps have emerged along the way, with many different
approaches being taken to their realisation. Further, they are characterised by a number of weaknesses that require methodological reinforcement, an aspect that, in our opinion, has been overly downplayed in the majority of systematic reviews. The present work strives to emphasise the methodological aspect of systematic reviews.

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