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REVIEW ARTICLE

# A systematic review of meta-research studies finds substantial methodological heterogeneity in citation analyses to monitor evidence-based research

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## Abstract

**Objectives:** This systematic review aimed to identify the characteristics and application of citation analyses in evaluating the justification, design, and placement of the research results of clinical health studies in the context of earlier similar studies.

**Study Design and Setting:** We searched MEDLINE (Ovid), Embase (Ovid), and the Cochrane Methodology Register for meta-research studies. We included meta-research studies assessing whether researchers used earlier similar studies and/or systematic reviews

Systematic review registration number https://osf.io/8759p/.

Disclosure: D.P. and B.N. included the studies and extracted data. All authors contributed to the idea, validation of data, and risk of bias assessment and have read and approved the final manuscript.

Declaration of interests: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

Availability of data and materials: The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

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of such studies to inform the justification or design of a new study, whether researchers used systematic reviews to inform the interpretation of new results, and meta-research studies assessing whether redundant studies were published within a specific area. The results are presented as a narrative synthesis.

**Results:** A total of 27 studies were included. How authors of citation analyses define their outcomes appears rather arbitrary, as does how the reference of a landmark review or adherence to reporting guidelines was expected to contribute to the initiation, justification, design, or contextualization of relevant clinical trials.

**Conclusion:** Continued and improved efforts to promote evidence-based research are needed, including clearly defined and justified outcomes in meta-research studies to monitor the implementation of an evidence-based approach. 

*Keywords:* Systematic review; Citation analysis; Evidence-based research; EBR; Meta-research; Research redundancy

## 1. Introduction

Evidence-based research (EBR) has been defined as "*the use of prior research in a systematic and transparent way to inform a new study so that it is answering questions that matter in a valid, efficient, and accessible manner*" [1]. Besides considering an EBR approach when justifying and designing new studies, it is equally important to practice EBR when contextualizing new results with existing evidence [2].

The EBR approach, however, is still rather new [3] and far from wide implementation. The mean percentage of original studies using systematic reviews (SRs) as justification was estimated at 42% [4], study designs informed by SRs at 30% [5], and studies contextualizing their results with existing studies at 31% [6]. Implementing an EBR approach on a large scale may take time as it demands new knowledge and skills [1]. In addition, different implementation strategies should ideally be evaluated and implementation progress should be monitored via suitable outcomes. However, the best way to measure adherence to an EBR approach remains unclear.

A citation analysis has been identified as one way to monitor the use of an EBR approach [2,7] and has been defined as an examination of the frequency, patterns, and graphs of citations [8]. In the context of EBR, citation analysis can be used in different ways; for instance, to investigate the use of SRs to justify new trials as Engelking et al. have done in anaesthesiology [9] or to determine whether new clinical trial results were contextualized as Clarke and Hopewell have done [10].

Citation analysis seems to be used in a variety of ways and there is no consensus on how studies using this method should be conducted and reported. Hence, this SR was intended to empirically investigate the characteristics and applications of citation analyses that could be potentially be used to monitor the implementation of an EBR approach in health sciences and to provide guidance for its future use.

## 2. Methods

The protocol for this SR was registered in the Open Science Framework (https://osf.io/8759p/, also available as supplementary file) and followed rigorously during its execution except for adjustments in the risk of bias assessment; the risk of bias tool was reduced from 13 to 10 items and the assessment of reporting quality was omitted. Furthermore, minor adjustments regarding the extraction of relevant study characteristics were made. This review is reported as per the preferred reporting items for systematic review and meta-analysis guidelines [11].

### 2.1. Eligibility criteria

We included meta-research studies, or studies performing research on research, defined by Ioannidis as "… *the study of research itself: its methods, reporting, reproducibility, evaluation, and incentives.*" [12]. Thus, we included studies that assessed whether researchers used earlier, similar studies or SRs of earlier, similar studies to inform the justification and design of a new study; whether researchers used SRs to inform the interpretation of new results; or whether redundant studies were published within a specific medical field. Regarding redundancy, we relied on the definitions applied by the authors of the included studies.

### 2.2. Information sources and search strategy

This study is one of six planned evidence syntheses (five SRs and a scoping review) to assess the implementation of EBR in health sciences. Given the common aim across the evidence syntheses, an overall search strategy was designed to identify eligible meta-research studies.

The initial search was performed in June 2015 and included MEDLINE (PubMed, Ovid), Embase (Ovid), CINAHL (EBSCO), Web of Science (Science Citation Index Expanded), the Social Sciences Citation Index, the Arts & Humanities Citation Index, and the Cochrane Methodology Register (Methods Studies) (Appendix 1). In addition, the reference lists of the included studies were screened for relevant articles and the experts' literature, libraries, and abstracts from the Cochrane methodology reviews were screened. Publication year and language were not restricted but the search was limited to studies using human subjects.

Based on the results of the initial search, an updated and improved search strategy was developed and applied to MEDLINE and Embase via Ovid from January 2015 to June 2021 (Appendix 2). Again, the reference lists of the

**What is new?**

- This is the first study to investigate citation analysis in the context of evidence-based research.

**Key findings**

- Citation analyses are characterized by focusing on the citation of systematic reviews or meta-analyses and, to some extent, the citation of previous, similar trials or guideline adherence.

**What this adds to what was known?**

- How authors of meta-research citation analyses define their outcomes, that is, how the reference of a landmark review or adherence to reporting guidelines contributes to the justification, design, or contextualisation of relevant clinical trials, appears rather arbitrary.

**What is the implication and what should change now?**

- The overall lack of definition of relevant outcomes in meta-research studies conducting citation analyses is our most striking result.

new included studies were screened for relevant references and the experts' literature and abstracts from January 2015 to June 2021 of the Cochrane methodology reviews were screened.

### 2.3. Screening and study selection

The search results were uploaded to Rayyan (https://rayyan.qcri.org/welcome) for the initial screening.

The search results from the initial search (2015) were independently screened (title and abstract) by teams of two reviewers. A total of 20 screeners were paired and each pair included an experienced reviewer. To increase consistency among the reviewers, both reviewers initially screened 50 publications and discussed the results before the screening continued. Disagreements on study selection were resolved by consensus and discussion with a third reviewer, if necessary. The subsequent full-text screening was performed by four reviewers independently and in duplicate. Again, disagreements on study selection were resolved by consensus and discussion. This initial screening resulted in a gross list of studies relevant for all of the above-mentioned reviews and the scoping review.

For this specific SR, title and abstract screening and full-text screening were conducted independently by two authors (B.N. and D.P.) from the gross list using predetermined inclusion criteria. The reasons for not including studies were recorded and disagreements between the reviewers were resolved with discussion.

### 2.4. Data extraction

Before data extraction, a customized spreadsheet was developed, piloted, and refined to extract study characteristics and outcomes of interest. Two reviewers (D.P. and B.N.) independently extracted the data. Afterward, all remaining authors validated the extracted data and helped to resolve disagreements, if necessary.

The following study characteristics were extracted from each of the included studies: bibliographic information, study aim, study design, material (i.e., study types included), country (based on first author's affiliation), inclusion period, area of interest, results, and conclusion. The following details were then extracted to elucidate our aims: unit of analysis (what is analyzed); citations of interest or citation type; the number of units included; the rationale for the sample size; data extraction methods; the definition of using research articles in the context of justifications, design, or contextualization; and assessing whether redundant studies had been published within a specific area.

### 2.5. Risk of bias assessment

Because a thorough search did not identify any standard tool to evaluate the risk of bias of empirical meta-research studies, the Editorial Group of the Evidence-Based Research Network prepared a list of items considered important for evaluating the risk of bias in meta-research studies. The list was tested on a sample of included studies and, following a discussion, the list was adjusted to 10 items for which the risk of bias could be rated "low," "high," or "unclear" [5]. We added one or two prompts to each item defining a high risk of bias (Appendix 3). Two authors (B.N. and D.P.) determined the risk of bias of all of the included studies independently. Disagreements were solved through discussion. No study was excluded due to low quality.

### 2.6. Data synthesis and interpretation

First, we labelled the studies by their main focus, that is, the justification or design of a new study, whether researchers used SRs to contextualize new results, and studies assessing whether redundant studies were published within a specific area. Then, we identified different citation analysis methods and investigated patterns across the included studies. All results are presented descriptively and narratively.

## 3. Results

### 3.1. Study selection

After removing duplicates, 30,592 studies were identified with our search strategy and 27 studies were ultimately included in this SR [9,13–38] (Fig. 1).

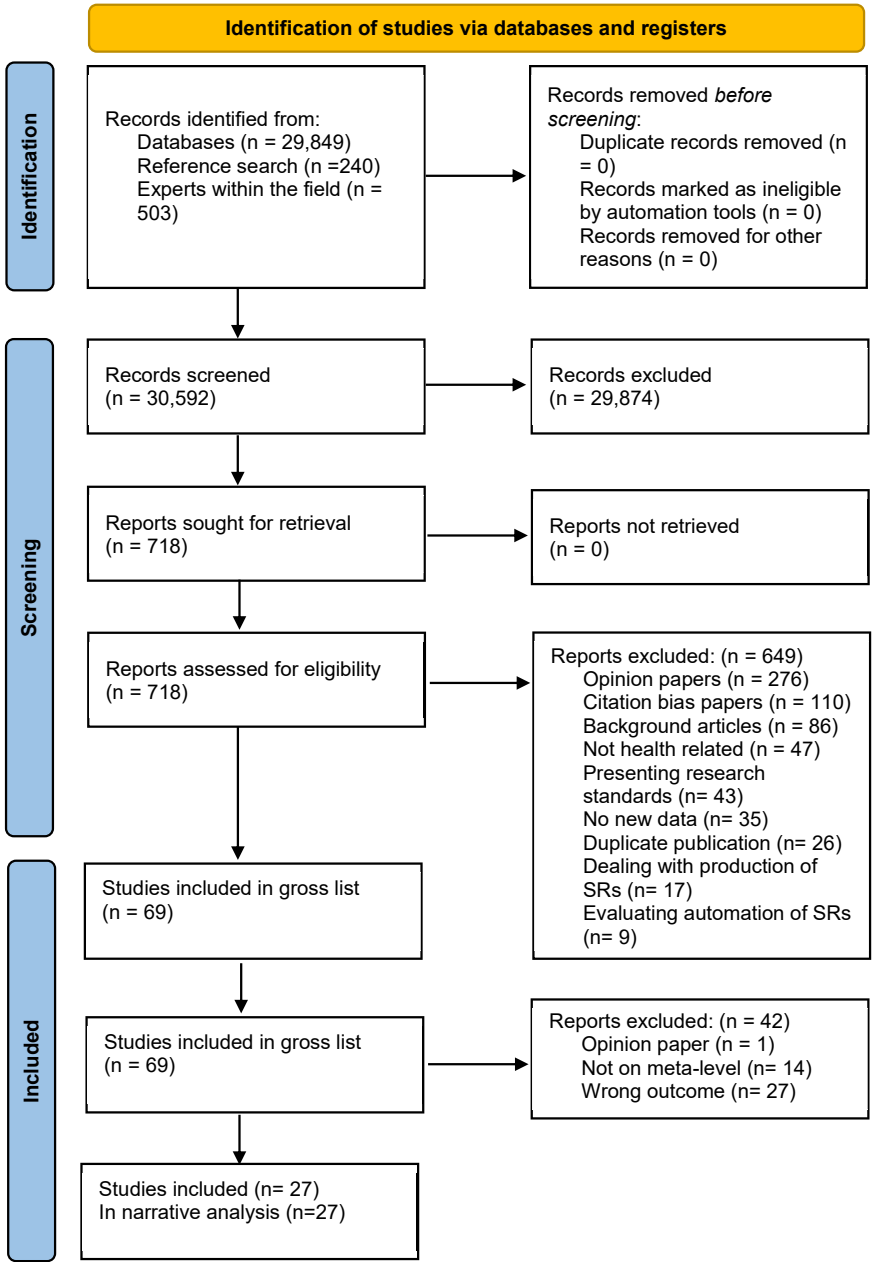


**Fig. 1.** Flowchart [11].

### 3.2. Study characteristics

The 27 included studies were published between 2011 and 2021. Nine studies originated from the United States [13,25,30,31,33,35–38], six from the United Kingdom [14,15,17,21,26,34], three from Switzerland [22,28,32], two from Germany [23,24] and Canada [18,20], respectively, and one study each from Spain [19], Croatia [9], New Zealand [16], the Republic of Korea [29], and Denmark [27].

All of the included studies conducted a literature review that applied a cross-sectional design, examining randomized controlled trial (RCT) protocols that were granted by the National Institute for Health and Care Research [15,26], protocols approved by a research ethics committee [27], RCTs published in a specific range of journals [9,19–21,23,25,32,35,37,38], or RCTs from specific databases [13,16,17,22,24,28–31,33,34]. One study additionally included a survey of authors of RCT protocols [14], one focused on medical specialties [18], and one on genes and phenotypes [36]. Eight studies stated a specific clinical focus, covering surgery [13,17,32], orthopedics [25], cardiology [14,33], dermatology [19], anesthesiology [9,22], genetics [29,36], obstetrics [31], urology [35], ophthalmology [37], dental specialty [34], general medicine [38],

**Table 1.** Study characteristics

| Study | Aim | Design | Material | Country | Inclusion period | Area of interest | Results | Conclusion |
|---|---|---|---|---|---|---|---|---|
| Andrade NS et al. 2013 [13] | To determine the effects of previous trials on the subsequent research agenda in the management of CNLBP | Cross-sectional | Published in PubMed and Web of Science | United States | 1993 to 2012 | Surgery | 39 trials included | No substantial changes in research agenda in the last 20 yr despite published RCTs |
| Ban JW et al. 2017 [14] | To assess whether authors of cardiovascular clinical prediction rules (CPRs) cited existing CPRs, why some authors did not cite existing CPRs and why they thought existing CPRs were insufficient | Cross-sectional | The International Register of Clinical Prediction Rules for Primary Care | United Kingdom | 1980 to 2009 Survey in November 2015 | Cardiovascular | 85 studies were included—48 (56.5%) cited at least one existing CPR 76 authors were contacted and 54 responded—46.3% were aware of existing CPRs | Cardiovascular CPRs are often developed without citing existing CPRs |
| Bhurke S et al. 2015 [15] | To investigate the use of SRs in the planning, design, and conduct of RCT | Cross-sectional | Proposals funded by the NIHR HTA Program | United Kingdom | Cohort 1: 2006-08 Cohort 2: 2013 | No specific speciality | Cohort 1: 47 trials included—42 used SR to inform design Cohort 2: 34 trials included—all referenced a SR to inform trial design | 49% of trials used one or more SR in design and planning |
| Bolland et al. (2018) [16] | To investigate waste attributable to RCTs and the citation of SRs in large RCTs and protocols. | Cross-sectional | RCTs, SRs, and quasi-randomized trials in four databases | New Zealand | None (search in December 2015) | No specific speciality | Three of 10 possible studies referred to a SR to justify. | Few large RCTs appeared to consider systematic reviews in their design. |
| Chapman et al. (2019) [17] | To quantify constituent components of waste in surgical RCTs and explore targets for improvement. | Cross-sectional | ClinicalTrials.gov was searched for RCTs registered and followed up by Serial systematic searches of PubMed and Scopus databases | United Kingdom | Registered between 2011 and 2012 | Surgery | Of 219 RCTs available for full-text review, 104 (47·4 per cent) did not cite a relevant SR. | This study identified a considerable burden of research waste in surgical RCTs. |
| Chow JT et al. 2017 [18] | To quantify and summarize what types of evidence are cited in the | Cross-sectional | Randomly chosen RCTs within six medical | Canada | January 2014 to July 2015 | Ophthalmology Otorhinolaryngology General surgery Psychiatry | *N* = 148 studies included; Ophthalmology = 25 studies Otorhinolaryngology = 20 studies | Justifications for RCTs vary widely within and between specialties and the justification |

(*Continued*)

**Table 1.** Continued

| Study | Aim | Design | Material | Country | Inclusion period | Area of interest | Results | Conclusion |
|---|---|---|---|---|---|---|---|---|
| | introduction section as the reason for the RCT to be performed | | specialties | | | Obstetrics-gynecology Internal medicine | General surgery = 25 studies Psychiatry = 25 studies Obstetrics-gynecology = 25 studies Internal medicine = 28 studies. Review articles were in total number of studies cited 2.96, 1.05, 1.40, 1.16, 0.68, and 1.11 times, respectively | for conducting RCTs are not standardized |
| Conde-Taboada A et al. 2014 [19] | To describe the use of SR in clinical trials and narrative reviews in dermatology | Cross-sectional | Four journals of dermatology; | Spain | 2010 and 2011 (narratives) | Dermatology | 113 articles included—of those SR existed for 72 RCTs and 24 cited an SR. 49 narrative reviews included | Authors appear to use Cochrane reviews even less than non-Cochrane reviews |
| De Meulemeester J. et al. 2018 [20] | To assess whether recent RCTs meet scientific criteria, hypothesis use, and SR use | Cross-sectional | RCTs published in NEJM and JAMA in 2015 | Canada | 2015 | No specific speciality | 208 included studies and 199 protocols—54% cited a relevant MA or SR in either the study or the protocol. | Up to 56% of published RCTs may not be scientifically and hence ethically justified |
| Engelking A et al. 2018 [9] | To analyse whether existing SRs were mentioned in RCTs published in journals as a rationale for conducting trial and for discussing results | Cross-sectional and meta-analysis | RCTs published in four journals of anesthesiology | Croatia | 2014 to2016 | Anaesthesia, Anaesthesia, and Analgesia, Anesthesiology | 622 RCTs included—126 (20%) mentioned verbatim or cited one or more SRs as justification for conducting a trial. | Less than a fifth of trials mention a previous SR as a justification for conducting the trial. |
| Goudie AC et al. 2010 [21] | To assess the extent to which authors currently make use of previous trial evidence in the design, analysis, and reporting of RCTs | Cross-sectional and meta-analysis | Published in JAMA and Archives of Internal Medicine | United Kingdom | 5 mo (January-May) 2007 | No specific speciality | 27 RCTs included—6 (22%) trials referred to a MA, 2 (7%) to a SR, and 1 (4%) referred to SR | Consulting previous research before embarking a new trial and basing it on the impact of an updated MA will make reporting and designing more efficient |
| Habre C et al. 2014 [22] | To examine whether the Picard review had had any | Cross-sectional | MEDLINE, Embase, and Cochrane | Switzerland | January 2002 —January 2013 | Anaesthesia, Anaesthesia and Analgesia, | 136 RCTs published at least 2 yr after the publication of the Picard review—72.8% | The impact of the Picard review on the design of subsequent |

(*Continued*)

**Table 1.** Continued

| Study | Aim | Design | Material | Country | Inclusion period | Area of interest | Results | Conclusion |
|---|---|---|---|---|---|---|---|---|
| | impact on subsequent research | | | | | Anaesthesiology, | cited the Picard review | research is low |
| Helfer B et al. 2015 [23] | To investigate whether MAs published in leading medical journals present an outline of available evidence by referring to previous MAs and SRs on the same topic. | Cross-sectional | NEJM, JAMA, BMJ, The Lancet, PLOS Medicine, Annals of internal medicine. PubMed was searched | Germany | Search completed in March 2013 | No specific speciality | 52 recent MAs and 242 previous MA and SRs. 48 studies could refer to previously published SRs and MAs. 45 of 48 referred to one or more previously published SR/MAs | MAs on pharmacological treatments do not consistently refer to findings of previous MAs. |
| Hoderlein X et al. 2017 [24] | To investigate the extent to which RCTs of clinical trials of physiotherapy interventions use high-quality clinical research to help justify the need for the trial in the introduction | Cross-sectional | Random selected sample from PeDRO (10% of all studies in year 2001 and 2015) | Germany | 2001 and 2015 | Physiotherapy | *N* = 70 in 2001 and 151 studies in 2015.14 studies (20%) and 76 studies (50%) did cite a SR in 2001 and 2015.<br>Overall, 91 of the 221 trial reports cited | Only 41% of reports of clinical trials of physiotherapy interventions cite a SR or other evidence in the introduction as part of the justification for the study. |
| Johnson et al. (2020) [25] | To evaluate the use of systematic reviews to justify RCTs | Cross-sectional | RCTs published in three high-ranking orthopedics journals and RCTs published in general orthopedics journals | United States | January 1, 2015 to November 30, 2018 | Orthopaedics | 128 RCTs included—Of the 128 RTCs, 91 (71.1%) cited an SR | Systematic reviews are frequently cited in orthopaedic trauma RCTs but are not commonly cited as justification for conducting a clinical trial. |
| Jones AP et al. 2013 [26] | To identify where existing research is used and to categorize ways in which SRs were used to inform the design of the trial | Cross-sectional | RCTs funded from NIHR HTA program | United Kingdom | 2006, 2007, and 2008 | No specific speciality | 48 applications were examined 20 referenced an SR regarding the design | SRs are frequently referenced in successful applications for funding |
| Paludan-Müller et al. (2019) | To study whether the ethical approval | Cross-sectional | Trial protocols approved by | Denmark | October 1, 2012 to March 31, | No specific specialty | 67 protocols included, Four cited an SR regarding the | A substantial minority of trials might lack a |

(*Continued*)

**Table 1.** Continued

| Study | Aim | Design | Material | Country | Inclusion period | Area of interest | Results | Conclusion |
|---|---|---|---|---|---|---|---|---|
| [27] | system ensures that trials justify their scientific rationale and use of comparators based on previous trials and take their results, whether positive or negative, into account | | one of the five regional research ethics committees in Denmark | | 2013 | | intervention, population, or indication | sufficient evidence base. |
| Pandis N et al. 2016 [28] | To assess the extent to which published protocols of RCTs adhere to SPIRIT | Cross-sectional | PubMed | Switzerland | December 2015 | No specific speciality | 101 protocols included<br>41 used SR to inform trial design | 41% of protocols involved citation of a SR or RCT to inform trial design |
| Park et al. (2017) [29] | To examine the nature of redundancies in genetic epidemiology research | Cross-sectional | MAs from PubMed | Republic of Korea | From inception to August 15, 2016 | Genetics | 94 published MAs included. Thirty one percent of the overlapping associations referenced a previous MA | Genetic association MAs were found to be redundant, erroneous, and lacking references |
| Robinson KA et al. 2011 [30] | To assess the extent to which reports of RCTs cite prior trials studying the same interventions | Cross-sectional and meta-analysis | Web of Science | United States | July 2004 | No specific speciality | 227 MAs comprising 1,523 RCTs included—3–58 prior citable RCTs (mean 9.7) of which an average of 1.9 were cited | Across health disciplines, less than 25% prior RCTs were cited |
| Rauh et al. (2020) [31] | To analyze published articles for citation of SRs for justification of conducting RCTs | Cross-sectional | PubMed | United States | January 1, 2014 –December 31, 2017 | Obstetrics and Gynecology | 458 included publications<br>279 (60.92%) cited an SR in the Introduction<br>34 (7.42%) cited an SR in the methods<br>207 (45.2%) cited an SR in the discussion | A large portion of the RCTs recently published in clinical obstetrics and gynecology journals are not citing SRs as justification for conducting their studies |
| Rosenthal R et al. 2017 [32] | To investigate the use of SRs to inform trial design and for overall evidence synthesis | Cross-sectional | RCTs in all issues of Annals of Surg., JAMA Surg., and British Journal of Surg in | Switzerland | 2010 | Surgical trials | 51 studies included—8 (16%) referred to a SR in the Introduction. | Two-thirds of the included RCT referenced an SR but none to inform trial design |

(*Continued*)

**Table 1.** Continued

| Study | Aim | Design | Material | Country | Inclusion period | Area of interest | Results | Conclusion |
|---|---|---|---|---|---|---|---|---|
| | | | 2010 | | | | | |
| Sawin et al. (2016) [33] | To examine citation within cohorts of trials across publication years | Cross-sectional | Meta-analyses, conducted within systematic reviews from ISI Web of Knowledge | United States | 2011 | Cardiovascular disease | 86 MAs were included with 580 trials. Reports of trials cited 25% of prior trials, capturing 31% of trial participants. | Selective undercitation of prior research continues; three-quarters of existing evidence is ignored. |
| Seehra et al. (2021) [34] | To assess the extent to which reports of dental RCTs cite prior SRs to explain the rationale or justification of the trial. | Cross-sectional | An electronic database search was undertaken to identify dental RCTs | United Kingdom | between January 1, 2014 and December 31, 2019 | Dental Specialty Journals | 682 RCTs were included of which 37.5% did not cite a SR in the introduction to justify the rationale | A relatively high proportion of dental RCTs (37.5%) did not cite a SR in the Introduction section. |
| Shepard et al. (2021) [35] | To appraise the use of SRs as justification in RCTs | Cross-sectional | RCTs published in the top four urology Journals based on Google Scholar h5 index. | United States | November 30, 2014 –November 30, 2019 | Urology | 276 RCTs included with a total of 403 SR citations: 15 SR citations (3.7%) in methods | RCTs published in four high impact urology journals inconsistently referenced an SR as justification. |
| Sigurdson et al. (2020) [36] | To determine when two articles are investigating the same association | Cross-sectional | Meta-analyses evaluating all types of genes and phenotypes. | United States | 2010 | Genetic epidemiology | 99 duplicate MA were included. Only 12 (32%) of the index MA were unambiguously unique. | Duplication is common in MA of genetic associations |
| Torgerson et al. (2020) [37] | To evaluate the use of systematic reviews to justify conducting a RCTs | Cross-sectional | RCTs published in the top five Google Scholar h-5 index journals | United States | December 5, 2018 | Ophthalmology and Optometry | 152 RCTs included of which none cited an SR regarding design Trials citing SR: 0 in methods | Less than one-quarter of phase III RCTs cited systematic reviews as justification for conducting the RCT. |
| Walters et al. (2020) [38] | To evaluate whether RCTs referenced SRs as the basis for conducting a trial. | Cross-sectional | RCTs published in three high impact factor | United States | January 1, 2016 –August 31, 2018 | General medicine | 637 RCTs included 728 SR citations 243 (38.1%) cited an SR for trial justification | Less than half of the analyzed clinical trials cited SRs as the basis for undertaking the trial. |

*Abbreviations*: RCT, randomized controlled trial; SR, systematic review; CPR, cardiovascular clinical prediction rules; CNLBP, chronic nonspecific low back pain; HTA, health technology assessment; NIHR, National Institute for Health and Care Research.

**Table 2.** Risk of bias (High; Low; Unclear)

| Study | 1. Clear and focused aim | 2. Match between aim and method(s) | 3. The best data source(s) chosen | 4. All important variables considered | 5. The same variables considered in all data sources | 6. Data collection transparent and data unambiguously identified | 7. Classification of the variables unaffected of prior knowledge about the results | 8. Appropriate analysis method | 9. Systematic error(s) or bias taken into consideration | 10. Conclusion supported by data |
|---|---|---|---|---|---|---|---|---|---|---|
| Andrade NS et al. 2013 [13] | Low | Low | Unclear | Low (argued) | Low | Low | High | Low | Low | Low |
| Ban JW et al. 2017 [14] | Low | Low | Low | Low | Low | Low | High | Low | Low | Low |
| Bhurke S et al. 2015 [15] | Low | Low | Low | Low | Low | Low | High | Low | Low | Low |
| Bolland et al. 2018 [16] | Low | Low | Unclear | Unclear | Low | Low | High | Low | High | Low |
| Chapman et al. 2019 [17] | Low | Low | Low | Low | Low | Low | High | Low | Low | Low |
| Chow JT et al. 2017 [18] | Low | Low | Unclear | Low | Low | Low | High | High | Low | Low |
| Conde-Taboada A et al. 2014 [19] | Low | Low | Low | Low | Low | Unclear | high | Low | Low | Low |
| De Meulemeester J. et al. 2018 [20] | Low | Low | Unclear | Low | Low | Low | High | Low | Low | Low |
| Engelking A et al. 2018 [9] | Low | Low | Unclear | Low | Low | Unclear | High | Low | Low | Low |
| Goudie AC et al. 2010 [21] | Low | Low | Unclear | Low | Low | Unclear | High | Low | Low | Low |
| Habre C et al. 2014 [22] | Low | Low | Low | Low | Low | Low | Low | Low | Low | Low |
| Helfer B et al. 2015 [23] | Low | Low | Unclear | Low | Low | Low | High | Low | Low | Low |
| Hoderlein X et al. 2017 [24] | Low | Low | Low | Low | Low | Low | High | Low | Low | Low |
| Johnson et al. 2020 [25] | Low | Low | Unclear | Low | Low | Low | Low | Low | Low | Low |
| Jones AP et al. 2013 [26] | Low | Low | Unclear | Low | Low | Low | High | Low | Low | Low |
| Paludan-Müller et al. (2019) [27] | Low | Low | Low | Low | Low | Low | High | Low | Low | Low |
| Pandis N et al. 2016 [28] | Low | Low | Low | Low | Low | Low | High | Low | Low | Low |
| Park et al. 2017 [29] | Low | Low | Unclear | Low | Low | Low | High | Low | High | Low |
| Robinson KA et al. 2011 [30] | Low | Low | Unclear | High | Low | Unclear | High | Low | Low | Low |
| Rauh et al. 2020 [31] | Low | Low | Unclear | Unclear | Low | Low | High | Low | High | Low |
| Rosenthal R et al. 2017 [32] | Low | Low | Unclear | Unclear | Low | Low | High | Low | High | Low |
| Sawin et al. 2016 [33] | Low | Low | Unclear | High | Low | Low | High | Low | High | Low |

(*Continued*)

**Table 2.** Continued

| Study | 1. Clear and focused aim | 2. Match between aim and method(s) | 3. The best data source(s) chosen | 4. All important variables considered | 5. The same variables considered in all data sources | 6. Data collection transparent and data unambiguously identified | 7. Classification of the variables unaffected of prior knowledge about the results | 8. Appropriate analysis method | 9. Systematic error(s) or bias taken into consideration | 10. Conclusion supported by data |
|---|---|---|---|---|---|---|---|---|---|---|
| Seehra et al. 2021 [34] | Low | Low | Unclear | Low | Low | Low | High | Low | Low | Low |
| Shepard et al. 2021 [35] | Low | Low | Low | Low | Low | Low | High | Low | Low | Low |
| Sigurdson et al. 2020 [36] | Low | Low | Unclear | Low | Low | High | Unclear | Low | Low | Low |
| Torgerson et al. 2020 [37] | Low | Low | Unclear | Low | Low | Low | High | Low | Low | Low |
| Walters et al. 2020 [38] | Low | Low | Unclear | Low | Low | Low | High | Low | High | Low |

physiotherapy [24], or focusing across medical specialties [18]. The remaining nine studies [15,16,20,21,23,26–28,30] did not focus on a specific specialty.

The number of publications analyzed in the included studies varied considerably, ranging from 27 [22] to 637 [35]. Further details of the study characteristics are presented in Table 1.

### 3.3. Risk of bias assessment

All of the included studies presented a clear and focused aim and a good match between aim and methods; they considered the same variables from all sources and their conclusions were supported by data (Table 2). However, two-thirds (18/27) of the studies provided no or insufficient justification or explanation for selecting their sources and were given an unclear risk of bias rating and 89% (24/27) of the studies had no publicly available protocol registered before the study, resulting in a high risk of bias rating.

### 3.4. Narrative synthesis

Regarding citation analysis methods for monitoring the implementation of EBR, the majority ($n$ = 19) of the included studies examined whether SRs were cited in published trial reports [9,15–21,23–26,29,31,32,34,35,37,38], whereas the remaining studies examined whether earlier published trials influenced subsequent research questions [13], earlier published trials were cited in subsequent trials [14,30,33], a specific review was cited in subsequent research [22], ethically approved protocols justify their rationale based on previous trials [27], or published protocols adhered to a specific guideline (SPIRIT) [28]. One study investigated whether published meta-analyses were unique or redundant and one study added a survey to their literature review to examine why some authors did not cite an existing SR [14].

### 3.5. Justifying new research

Most of the included studies ($n$ = 19) focused on the justification of new research (Table 3). Overall, the rationale was either to determine the effect of previous research on subsequent research or to understand why researchers initiate new trials when similar trials exist. The approach to citation analyses in the included studies was highly heterogeneous. Simple approaches involved investigating whether a reference to another study was made to provide a rationale and justify new research. In this context, most authors referred to SRs or meta-analyses to support their claims, while others also allowed primary studies as justification. In most cases, one reference was considered sufficient to justify new research. More elaborate approaches requested more than one reference as justification. For example, one study called for several criteria to be met: a clearly stated hypothesis, references to ‘‘equipoise’’ or ‘‘lack of consensus,’’ an indication of uncertainty, and a review supporting these claims [20]. Only two studies considered whether a citation related to a relevant SR as judged by the authors [20] or a specific SR, respectively [22].

### 3.6. Designing new studies

Ten studies addressed both the ‘‘justification of new research’’ and the ‘‘informed design of new studies,’’ while four studies focused only on the ‘‘informed design of new studies.’’ Two studies, Jones et al. (2013) and Bhurke et al. (2015), looked for citations to inform trial design [15,26], which can be regarded as another simple approach. Furthermore, one of the studies [15] replicated Jones et al.’s

**Table 3.** Results

| Study | Unit of analysis (what is analysed) | Citations of interest/citation type (e.g., RCTs, SRs); definition (if reported) | Number of units included | Definition of using research articles in the context of Justifications, Design, and Placing in context |
|---|---|---|---|---|
| Andrade NS et al. 2013 [13] | RCT publications | The number of times RCTs from 2010 to 2011 cited four specific indication (index) RCTs. The number of indication trials published after the first four indication trials. Citation frequency as indication of the impact of the four indication trials | 39 RCTs | To determine the effect of previous research on the subsequent research agenda (i.e., **justification**) |
| Ban JW et al. 2017 [14] | Primary studies publications | The citation of existing CPR (in the field) | 85 CPRs | **Justification** (to understand why authors proceed to develop a new CPR when previous CPR exist) |
| Bhurke Set al. 2015 [15] | RCT publications | SRs (Cochrane review); other reviews if SR was mentioned in the title and methods | 47 (cohort I)<br>34 (cohort II) | **Design** justification of design elements |
| Bolland et al. 2018 [16] | (Large) RCTs | SRs of RCTs (relevant to primary endpoint of the trial) | 25 RCTs (18 published, seven ongoing or planned) | **Justification** |
| Chapman et al. 2019 [17] | RCT publications | SRs | 221 RCTs | **Justification, design** (justification of design elements) |
| Chow JT et al. 2017 [18] | RCT publications | Any information relating to the justification for conducting RCTs | 148 RCTs | **Justification**<br>The use of previous evidence as the reason for conducting an RCT |
| Conde-Taboada A et al. 2014 [19] | RCT publications and narrative reviews | SRs | 72 RCTs and 24 narrative reviews (for which a SR was available) | Not specifically stated but the risk of redundant studies is mentioned—**justification** |
| De Meulemeester J et al. 2018 [20] | RCT publications | SRs | 208 RCTs (and 199 corresponding protocols) | **Justification and design**<br>Three scientific criteria justifying an RCT. Protocol design |
| Engelking A et al. 2018 [9] | RCT publications | SRs/relevant SRs | 622 RCTs | **Justification, design, and context**<br>Whether a SR was mentioned to justify (introduction and methods) or when discussing |
| Goudie AC et al. 2010 [21] | RCT publications | SR with meta-analysis | 27 RCTs | **Justification, design, and context**<br>Consulting previous research before embarking a new trial and basing it on the impact of an updated MA will make reporting and designing more efficient |
| Habre C et al. 2014 [22] | RCT publications | SRs with meta-analysis (i.e., the Picard review) | 136 RCTs | **Design**<br>Whether the Picard review had influenced the design of subsequent trials |
| Helfer B et al. 2015 [23] | SR/MA publications | SR/MA | 48 MAs | **Justification and context**<br>Whether MAs present an outline of available evidence |
| Hoderlein X et al. 2017 [24] | RCT publications | SRs (should be part of a clinical guideline) | 121 (70 trials published in 2001 and 151 trials published in 2015) | **Justification and context**<br>To use high-quality clinical research to justify the need for the trial |
| Johnson et al. 2020 [25] | RCT publications | SRs | 128 RCTs | **Justification** |

(*Continued*)

**Table 3.** Continued

| Study | Unit of analysis (what is analysed) | Citations of interest/citation type (e.g., RCTs, SRs); definition (if reported) | Number of units included | Definition of using research articles in the context of Justifications, Design, and Placing in context |
|---|---|---|---|---|
| Jones AP et al. 2013 [26] | RCT funding applications | SRs (85 SR referenced in 37 applications; SR cited and specific information how it was used in the study design and planning) | 48 trials | **Design** (justification of design elements) |
| Paludan-Müller et al. (2019) [27] | RCT protocols submitted to ethics committees | SRs and RCTs | 67 protocols | **Justification and design** |
| Pandis N et al. 2016 [28] | RCT protocol publications | RCTs | 101 protocols | **Design**<br>The extent to which published protocols of RCTs adhere to SPIRIT |
| Park et al. 2017 [29] | Meta-analyses publications | Meta-analyses | 94 Meta-analyses | **Context** |
| Rauh et al. (2020) [31] | RCT publications | SRs | 458 RCTs | **Design, justification, and context** |
| Robinson KA et al. 2011 [30] | RCT publications | RCTs, SRs (only in a small subset of 30 RCTs; citation of RCTs that were published more than 1 yr before the citing RCT.) | 1,523 RCTs (in 257 SRs) | Not stated |
| Rosenthal R et al. 2017 [32] | RCT publications | RCTs (Citation of a SR on the same topic as the RCT) | 51 RCTs | **Design, justification, and context**<br>The use of SRs to inform trial design and for overall evidence synthesis (of results) |
| Sawin et al. 2016 [33] | Meta-analyses | Meta-analyses, conducted within systematic reviews | 86 meta-analyses | Not stated citation of previous trials in the same cohort. A trial was determined to be citable if it was published at least 1 yr before the citing trial. |
| Seehra et al. 2021 [34] | RCT publications | SRs (citation of prior SRs in RCTs) | 682 RCTs | **Justification**<br>Citation of a SR used to justify the rationale of the trial and relevant to the primary trial<br>Outcome (yes or no) |
| Shepard et al. 2021 [35] | RCT publications | SRs (citation SRs in RCTs) | 276 RCTs | **Justification and design**<br>Whether the RCT used these citations to justify the trial |
| Sigurdson et al. 2020 [36] | Meta-analyses publications | MA (citation of previous MAs in MAs) | 99 meta-analyses | Not stated<br>MAs citing previous MAs |
| Torgerson et al. 2020 [37] | RCT publications | SRs (citation SRs in RCTs) | 152 RCTs | **Justification and design**<br>RCTs that cited a systematic review as justification for conducting the RCT (verbatim or inferred) |
| Walters et al. 2020 [38] | RCT publications | SRs (citation SRs in RCTs) | 637 RCTs | **Justification, design, and context**<br>Whether SRs were cited as justification for conducting the RCT in the introduction, methods, and discussion/ conclusion |

*Abbreviations*: RCT, randomized controlled trial; SR, systematic review; MA, meta-analysis.

[26] study to identify changes over time. Habre et al. (2014) took a more sophisticated approach, focusing on the citation of a specific review. However, this study operated on a clinical single-case scenario, comparing trials published before or after the landmark review. Finally, one study followed the SPIRIT guideline in which one item calls for the citation of prior research and justification based on gaps in the underlying evidence [28].

### 3.7. Putting research into context

None of the studies focused exclusively on contextualizing research. Five studies focused on justification, design, and context [9,21,31,32,38] and applied the same methodology to all three categories, while two studies used the same methods to elucidate justification and contextualization [23,24].

## 4. Discussion

This is the first study to investigate citation analysis in the context of EBR. This review has shown that citation analyses are characterized by focusing on the citation of SRs or meta-analyses and, to some extent, the citation of previous trials or guideline adherence. However, how authors of meta-research define their outcomes, that is, how the reference of a landmark review or adherence to reporting guidelines contribute to the justification, design, or contextualization of clinical trials appears rather arbitrary. Thus, our most striking result appears to be the overall lack of definition of relevant outcomes in meta-research studies conducting citation analyses.

The use of citation analysis in meta-research is rather new in health sciences. The oldest study in our review was published in 2010, while the number of citation analyses is rising steadily. Citation analysis, originally rooted in bibliometrics, has been used in other contexts for decades [39]. However, citation analyses are not necessarily strongly related to EBR but rather are considered a relevant proxy by which EBR may be monitored. This also explains why no similar studies were identified to compare and contextualize our results. As citation analyses are applied across disciplines, the sharing of knowledge and experiences is highly desirable to further develop citation analysis as a way to monitor EBR.

In our sample, we observed substantial heterogeneity in methodological approaches. While we acknowledge that some methodological differences might be explained by the different focuses of the analyzed studies, the main differences observed are general in nature. First, the citations of interest in the included studies were mostly SRs or meta-analyses. This is likely due to the general guidance that RCTs should be informed by SRs [40]. However, in areas with little research activity (i.e., no SRs and only a few primary studies), the citations of interest can also be primary studies, as was true in some of our included studies. We also observed huge heterogeneity in sampling strategies, whose rationales were rarely given. Sample size also differed considerably across studies and was rarely explained. A lack of reporting guidance for methodological studies is known; however, reporting guidelines are currently being created [41]. Positively, data extraction methods often resembled the recommended SR methodology (e.g., data extraction by two independent reviewers) and may have contributed to reducing systematic biases and errors.

The methodological approaches applied in the included studies also varied widely in their complexity. Some studies simply assessed whether an SR was cited as a justification, resulting in yes or no answers (e.g., Engelking et al. [9]). The advantage of this approach is that it is widely applicable and thus a potentially feasible way to monitor the use of EBR. However, some questions need to be considered. First, the term ‘‘SR’’ is ill-defined in the scientific community [42]. Second, none to several published SRs could be cited and how authors should proceed in the latter case is unclear. Balancing the recentness and the methodological quality or risk of bias of SRs will pose a familiar challenge [43]. Citation cherry-picking might be an issue, particularly when SRs with discordant findings exist [44]. Third, simply looking for whether a citation is provided might be too simple. One might argue that this provides insufficient information for the reader to judge whether an RCT was justified. More sophisticated approaches might be needed to address this question. In one of our included studies, Helfer et al. [23] differentiated between citations that were cited, described, or discussed. This approach permits up-to-datedness and quality to be taken into account, improving on the simple approach. However, defining clear-cut guidance for differentiating between these categories (citing, describing, and discussing) might prove challenging.

### 4.1. Strengths and limitations

We applied a standard SR methodology for our study and specified the methods before starting the review (https://osf.io/8759p/). We included an international team of experts on the topic (EVBRES consortium) and conducted a comprehensive literature search. However, we must also acknowledge several limitations. First, despite relying on an extensive search strategy, we were likely unable to identify all citation analyses due to the broad concept (EBR) and vague terminology (citation analysis) we used. We also acknowledge that although we used a broad definition of citation analysis (examination of the frequency, patterns, and graphs of citations), while our included studies only reflect a narrow type of citation analysis (whether SRs or primary studies were cited to justify and/or design new research and/or to contextualize the results). Preparing the search strategy showed the complexity of searching for meta-research related to EBR, including the lack of unique search terms for both EBR and meta-research. Thus, our search strategy had a high sensitivity to capture the relevant studies

and, hence, a high degree of noise. Moreover, although the included meta-research studies were overall rated with a low risk of bias, this might not reflect the true variance among these studies but rather be a consequence of the checklist created to assess the risk of bias for this set of SRs. Despite being thoroughly discussed and continuously adjusted, the checklist still includes some challenges. However, a checklist or guidance appropriate for this study was not available and our checklist was continuously customized and adapted to fit our specific purpose. However, we fully acknowledge the need for a validated and reliable tool for evaluating the risk of bias in meta-research studies.

Finally, the analysis is limited to the application of citation analyses in biomedical and health sciences and should be expanded in future studies to cover more disciplines.

## 5. Conclusion

This review provides a starting point to further develop rigorous methods for citation analyses to make them useful for monitoring the implementation of EBR. We have highlighted some crucial points to seek consensus on and consider in future studies. Continued and improved efforts to promote EBR are needed, including a deliberate and systematic use of previous evidence when new clinical studies are justified, designed, or contextualized, to decrease potential research redundancy.

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## Appendix B

## Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2022.06.021.

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