Author contacts for systematic reviews of RCTs: A systematic review protocol

Morris Gordon[1], Vassiliki Sinopoulou[1], Eshan Shah[1], Ewomazino Tonia Tony—jimmy[1]
[1]School of Medicine and Dentistry, UCLan, UK

INTRODUCTION

In clinical medicine, evidence-based medicine has been the cornerstone of decision making for more than three decades, underpinned by systematic reviews (SRs) to develop clinical guideline recommendations [1]. The most reliable SRs will primarily include only randomised controlled trials (RCTs) in their search and evidence synthesis process, as RCTs are the gold standard design for assessing the efficacy of a medical intervention [2]. This is derived from the reduced risk of bias inherent in the methods of an RCT.

There is substantial evidence that completeness and quality of methods information is still sporadically reported, even in high impact journals (*Gordon et al, in press*). There is also evidence that authors often release different forms of data over time meaning that SR authors may have questions that need clarifying or data that needs confirming [3]. Missing data, due to inadequate reporting of summary statistics or overall findings when results are unfavourable or null, is also a challenge and represents a significant source of bias. This can be observed in situations where the authors may hold the notion that certain results do not add value to their publication or limit impact, or there are pressures to deliver positive results due to commercial demands [4]. Incomplete data that don't make it into systematic reviews can result into healthcare decision makers making less-than-ideal choices for treatment protocols, resource allocation, and overall care, potentially resulting in poorer patient outcomes [5].

When conducting a systematic review, contacting the authors of eligible and included RCTs to clarify material or provide additional recorded data that may be missing is suggested [6, 7]. This can be beneficial for systematic reviews, as they are able to more clearly discern the risk of bias in each RCT and include RCTs that they would otherwise have had to discount. Their results would then be of a more representative sample and draw wider conclusions in their meta-analysis. Nonetheless, reviewers applying this guidance face challenges in identifying the authors or RCTs, frequently experience RCT authors failing to reply, and struggle with summarizing the process in their own systematic review [8]. Missing info about quality appraisal is also common.

We aim to investigate how often do systematic reviewers undertake contact with the authors of eligible and included papers for clarification on data and risk of bias concerns. We will explore the factors that influence whether SR authors contact make contact with the authors of the included studies or not, and the content and level of response to the communication. We also aim to explore variables including impact factor of journal and available funding.

METHODS

An ethical screening tool was submitted to the ethics office who confirmed that full approval was not required. The report of this study will follow the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guidelines

Literature Search

We performed a systematic electronic database search of all the RCTs published between 1 January 2024 and 19 February 2024 from the MEDLINE database on 19 February 2024. The search strategy was *"systematic review"[Title/Abstract] AND (RCT[Title/Abstract] OR randomised[Title/Abstract] OR trial[Title/Abstract])*.

All retrieved citations from this search were imported into Covidence and results de-duplicated.

Study Selection

In the first stage (title screening), two authors (ES and ETJ) will independently review all titles and abstracts, discarding those not meeting inclusion criteria. Disagreement will be resolved by discussion and consensus in the presence of a third and fourth author (VS, MG). In the second stage, all SR selected for full-text reviews will be downloaded and independently reviewed by two authors (ES and ETJ) to confirm whether papers met the inclusion criteria. Any differences will be resolved by the third and fourth authors (MG and VS).

Inclusion criteria for full-text SR manuscripts will be: 1) Full-text SR manuscripts of RCTs involving human participants; 2) Full-text SR manuscripts of RCT with interventions for the management of symptoms, involving any pharmacological or non-pharmacological intervention compared to any other intervention, placebo, no treatment or usual care. 3) Full-text SR manuscripts with outcome measures that directly impact patient health or risk to health. SRs that included any phase are eligible. There are no limitations on language or region.

Exclusion criteria will be: 1) manuscripts which reported outcome data of non-randomised or quasi-randomised trials; 2) manuscripts that reported on non-medical interventions

such as service evaluation, delivery, safety, and education trials; 3) manuscripts on in-vitro interventions; 4) manuscripts without outcome results (e.g. protocols, trial registrations);

Outcomes

- Whether contact with the included studies authors was initiated or not
- Factors that prevented reviewers from contacting authors
- Type of information requested when author contact was initiated
- Number of contacts initiated and number of responses received when contact was initiated
- Time given to primary authors to respond

Data Extraction

Key descriptive data from included SRs (full-text) will be collected, including year of publication, first author name, journal source, impact factor of SR publication journal, funding sources, and DOI using a predesigned extraction Excel sheet.

During full-text review, the above authors (ES and ETJ) will independently extract data on all outcomes and disagreements will be resolved by a third reviewer (MG, VS). Quotations of any comments made regarding author contact in the SR will be extracted.

Additionally, data on whom correspondence could be addressed to will be collected such as the name and email address of SR contact authors. Two Excel extractions spreadsheets will be used to store extracted data based on whether reference to contact with authors was initiated or not.

Missing information

SR contact authors will be contacted when information on their author contacts is not available. Contact authors of the SRs will be contacted via email at their listed correspondence email. Authors will be given two weeks to reply at which point a reminder will be sent. There will be an additional two weeks for the data set to be closed.

Data will be analysed and presented descriptively.

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