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ORIGINAL ARTICLE

An algorithm provided as initial guidance for reporting registry records and published protocols in systematic reviews

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Abstract

Objective: We aim to synthesize the available guidance with existing practices by Cochrane reviewers to generate an algorithm as a starting point in assisting reviewers reporting of registry records and published protocols (TRRs/PPs) use in systematic reviews of interventions. Study Design: We used existing guidance from major review bodies, assessed the current reporting of TRRs/PPs use in a sample of Cochrane reviews, and engaged in critical analysis. Independent reviewers identified and extracted textual excerpts reporting the use of trial registry records and published protocols and codes following a systematic review framework. Based on these elements, and our initial research, we created an algorithm/graphical aid to visualize initial direction. Results: We included 166 Cochrane systematic reviews published between August 2015 and 2016 from 48 review groups. Review authors' terminology (e.g., ongoing, terminated) varied between and within reviews. Reporting practices were diverse and inconsistent. Conclusions: This is a timely investigation in an era where evidence synthesis informs health and health care decisions. Our proposed algorithm provides initial direction to systematize the reporting of TRR/PP use. We hope that the algorithm generates further discussion to enhance the transparency of TRR/PP reporting and methodological research into the complexities of using protocols in systematic reviews of interventions.

Keywords: Systematic reviews as topic; Clinical trials; Randomized controlled trial; Trial registry records; Protocols; Reporting guidance; Clinical trial protocol

1. Introduction

Evidence derived from systematic reviews of interventions plays a vital role in patient care and decision-making [1]. Studies utilizing a randomized design are often preferred, as these provide the most rigorous research design for assessment of the effects of interventions [2]. Health care and policy decision-making require high quality reviews, so it is important to be able to detect potential biases in the included studies. To increase trust in randomized control trials (RCTs), the scientific community have called for transparency in trial reporting and conduct and implemented a number of requirements to help this purpose [3]. Prospective trial registration is a cornerstone of transparency and reduction of bias; it is also a way to prevent duplication and waste in research, as well as informing patients and the public of clinical trials they may want to enroll in or follow [4].

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What is new?

Key findings

- Despite trial registry records (TRR) and published protocols (PP) role in evaluating and, possibly minimizing, publication and outcome reporting biases, systematic review bodies provide little guidance on the optimal methods for reporting their use. The present study suggests reporting of TRR/PP use of has terminology ambiguity and vagueness among review authors.

What this adds to what was known?

- Critical reflection of 166 Cochrane systematic reviews in the context of available guidance highlighted a need for clearer language in reporting TRR/PP use. We developed an algorithm/visual graphic that provides initial direction to think systematically about reporting TRR/PP use and improve language consistency, transparency, and help to link methods and data presented; it also would aid in improving reporting of assessment of bias (and therefore quality) in systematic reviews.

What is the implication and what should change now?

- We are making explicit the complexity of the interplay of trial status, publication status, and publication type in reporting use of TRRs/PPs. There is a need for work in this field; collaboration among systematic review bodies and trial registries would be important to move the field forward, as well as providing review authors with clear guidance in the area.

A trial protocol states the question and planned methods of a study. This record helps anyone evaluating published results to judge how far it fulfills its original objectives, if authors have followed pre-stated methods, or if amendments/modifications/trial closure were needed and why. Systematic review authors can use trial protocols for several purposes including: a) accounting for all evidence in the subject area (i.e., published and unpublished trials), b) reducing the potential for reporting biases (i.e., publication biases and selective outcome reporting), c) selective analysis biases (i.e., choosing the analysis to report), d) determining when updates are needed, and e) detecting and evaluating trials that have been terminated or discontinued. We have presented potential uses of trial registry records (TRRs) and published protocols (PPs) in Appendix A.

A protocol can take different forms; planned methods of a study are recorded in different document types and degrees of availability depending on the purpose of the protocol (see Appendix B). While there have been many advances in trial registration and publication, the reporting of TRRs/PPs in systematic reviews is variable [5–7]. In this study, we focus on TRRs and PPs. Trial registries constitute the main public source of basic TRR information [3]. Prominent among such registries is ClinicalTrials.gov, the main public source of basic TRR information. Other examples are the World Health Organization (WHO) trials portal (ICTRP) or subject-specific trial registers (e.g., Stroke Trials Registry) [8]. Second, we focus on protocols published in peer review journals; this has gained popularity in the recent years. TRRs and PPs exist independently or in addition to each other creating a reporting challenge for systematic reviewers.

This team previously conducted a systematic search of the written guidance related to TRRs/PPs provided by the major systematic review bodies [9]. Although there is encouragement to search for TRRs and increased awareness of the use of protocols in the detection of biases, there is no comprehensive direction on reporting of TRR/PP use in systematic reviews of interventions. Collectively, the main systematic review bodies have provided some methodological and conceptual guidance for certain areas of the review. This is a very complex and evolving topic, which needs to be aligned with methodological advances in systematic reviews to bring clarity for reviewers and reduce variability in reporting [5,7].

The objective of this study was to synthesize the available guidance with existing practices by Cochrane reviewers to generate an algorithm as a starting point in assisting reviewers the reporting of registry records and PP use in systematic reviews of interventions and to generate further methodological research where aspects of TRR/PP use still lack clarity. We acknowledge there have been concerns with trial registry data [10], addressing this issue was outside the scope of this study although we recognize it has downstream consequences on the quality of the work.

2. Methods

In our previous study, we compiled existing guidance on reporting of TRR/PP use in systematic reviews of interventions. In this study, we augmented this guidance by assessing the current reporting of TRR/PP use by extracting examples from Cochrane reviews published between August 2015 and August 2016. Our study was conducted following the initial study by Boden et al. [9] completion and submission (date November 2015). Using these examples, we combined existing guidance and filled gaps in that guidance to create an algorithm/visual graphic of proposed future practice.

Box 1 TRR/PP terminology

Clinical trial registry: it is an official and often public platform for registering a trial or study including human participants. To date, trial registration is not mandatory but strongly encouraged. Some journal policies such as manuscript acceptance upon proof of prospective trial registration have helped increase the number of registrations. For Cochrane authors, search of https://clinicaltrials.gov/ClincalTrias.gov Trials is plural and World Health Organization trials portal are mandatory Methodological Expectations for Cochrane Intervention Reviews (MECIR) standards.

Published protocol (PP): it is a trial protocol that is published in a (commercial) journal. Similar to the trial protocol, often includes a description of the objectives, design methodology, statistical considerations, and organization of the trial in addition to journal requests. Published protocols create the expectation of a future publication; they are static records, and no follow-up is provided or updated by the journal.

Trial protocol: it is the plan or set of steps to be followed when conducting a study. It often contains the study rationale, objective(s), and the methods that will be used to locate, select, collect, and analyze information from participants.

Trial registry record (TRR): it is the publication of an internationally agreed set of information about the design, conduct, a summary of results, and administration of clinical trials. These details are published on a publicly accessible website managed by a registry (WHO).

Thus, three main sources of information form the evidence used to guide development of an algorithm in this study:

2.1.
Available methodological guidance by review bodies on TRRs/PPs identified in the literature [9,11],
2.2.
Data extracted from a random sample of Cochrane systematic reviews of interventions. This provided examples of reporting practices we used to supplement existence guidance and in the development of our algorithm, and
2.3.
Our critical analysis and discussions to highlight potential challenges and areas of integration of all sources. The team has collective international expertise as Cochrane reviewers, and in areas of evidence synthesis, information science, and research methods.

2.1. Available methodological guidance by review bodies

We identified current guidance on the reporting of TRRs/PPs in a previous study [9,11]. Major organizations producing systematic review recommend reviewers should:

- (either for new or update reviews) search trial registries and electronic databases for TRRs/PPs [11–17];
- list all sources used [13,15]; the new PRISMA S recommends "To fully describe the study registries searched, list the name of each study registry searched, and include a citation or link to the study registry" [18];
- report the search terms used in addition to the bibliographic databases [13,15,17];
- match trials with publications found from the standard search noting a) trials with existing publication and b) trials for which no publication was found;
- compare outcomes reported in the "protocol" and the published report [14,17];
- request a copy of the study protocol from authors (Cochrane Handbook); and
- construct a table that provides information on trials found in the registry, their publication status and whether they are completed or currently active trials, and provide a count of the numbers of unique trials found along with their status at the time of the search [11].

2.2. Sample of Cochrane systematic reviews of interventions

We supplemented the methodological guidance with current practices extracted from Cochrane systematic reviews. We evaluated a sample of Cochrane systematic reviews of interventions (hereafter systematic reviews) to ascertain how review authors reported TRR/PP use in their reviews. An information specialist (CB) searched the Cochrane Library for 1-year period (August 2015 to August 2016) for systematic reviews. We used the terms "controlled trial*," "rct*," "clinical trial*," and "random*" combined with the Boolean operator "OR." A statistician (DT) selected a random sample with equal group size, stratified by Cochrane Editorial group for a representative sample. As this was an exploratory study, we only included systematic reviews of interventions. Inclusion was as follows: a) a published new or updated review, b) identified as a systematic review (i.e., not a title registration or protocol and network meta-analysis) of the effectiveness of an intervention, and c) had at least one included RCT. We excluded systematic review protocols; network meta-analyses; overviews of reviews; and systematic reviews of nonrandomized trials, diagnostic, prognostic, or methods reviews and withdrawn systematic reviews. A pair of authors independently screened (all levels) records for inclusion using Abstrackr software tool [19];

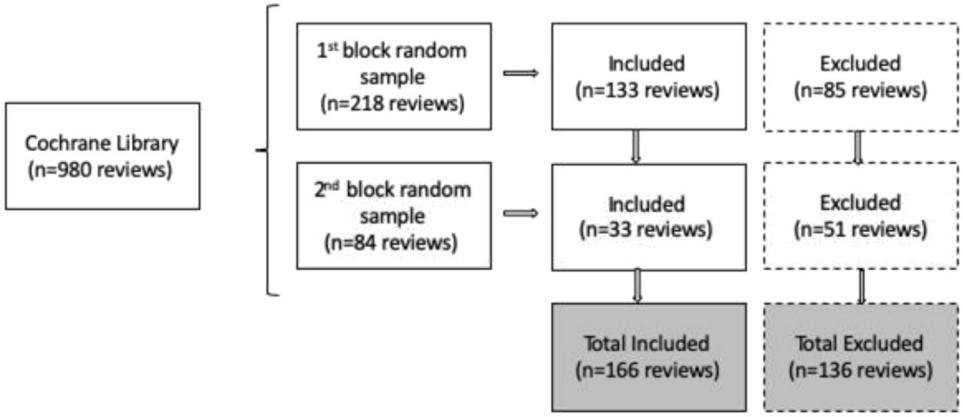

Fig. 1. Flow chart of block randomized screening with replacement.

we used a stratified (by Cochrane review group) sampling procedure through two rounds (with replacement) until we reached our goal of approximately 20% of the reviews found by the search. We made decisions following a priori criteria and consensus meeting with a third author available to resolve disagreements. Authors completed data extraction (JB, CB, and JFME) using piloted standardized Excel sheets created for this project. The Cochrane systematic review mandatory sections (i.e., abstract, methods, results) served as a guide for our data extraction. The team agreed on terms and phrases associated with TRRs/PPs, for example, ''protocol,'' ''trial registry,'' ''NCT,'' (to identify clinicaltrials.gov registry records) ''ongoing,'' or ''registry record'' to identify sentences or paragraphs reporting TRRs/PPs. Once we found these words, we confirmed they referred to TRRs/PPs and extracted the verbatim excerpt.

2.3. Development of algorithm/visual graphic

We engaged in critical reflections on the ways Cochrane authors reported TRR/PP use in the excerpts identified in 2.2 to highlight challenges and areas of commonality across sources. We combined the guidance, current practice, and our experience as reviewers to develop the algorithm/visual graphic. We used direct excerpts from the systematic reviews (when available) to illustrate findings and guide authors in reporting TRRs/PPs.

Box 1 presents a glossary of terms used in this article to clarify TRR/PP terminology [20].

3. Results

3.1. Sample of Cochrane reviews

The search yielded 980 citations; after several iterations, we included 166 reviews from 48 Cochrane Review Groups (Flow chart presented in Figure 1). Of these reviews, 48% were new reviews and 52% were review updates. Exclusions were due to review type (i.e., network meta-analysis, diagnostic review, and protocol), status (i.e., withdrawn review), or content (i.e., no RCTs included or empty reviews). We found information about TRRs/PPs in most sections of the reviews; however, for practical reasons, we focused on abstract, methods (i.e., planned), results, and discussion with associated references, tables, and figures.

Between reviews	Within reviews
[Search] *We searched for ongoing or completed unpublished trials in the clinical trial registries…''* [22] [Search] *We searched international trial registries via the World Health Organization trials portal (ICTRP) and* ClinicalTrials.gov *to identify unpublished and ongoing studies.''* [23] [Search] *we additionally searched the following clinical trial registries for ongoing or recently completed trials and for locating potential links to other related databases and resources on September 2012* [24]	Baker 2016 [25] [Result] *Three studies are ongoing (ISRCTN**339; NCT**361; and NCT**314).* [Conclusion] *Wider publication of study protocols would allow a clearer assessment of publication bias.* Dixit 2016 [26] [Method] *''We also contacted other researchers or nutritional and SCD experts working in this field to identify additional trials (including unpublished and ongoing trials)''* [Result] *''The trial included in the analysis had no protocol or like resource outlining previously defined outcomes, therefore, it was difficult to assess for reporting bias.''*

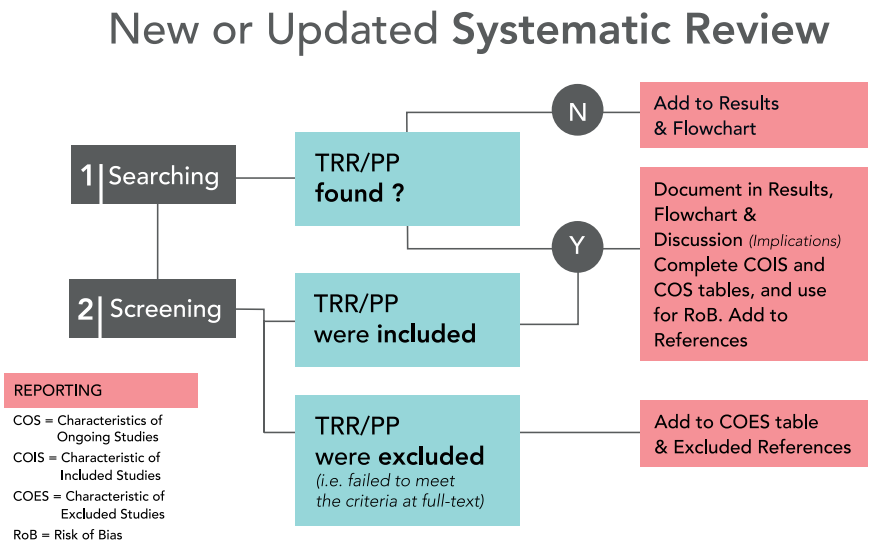

Fig. 2. Trial protocol reporting algorithm for search and screening phases for a systematic review.

As with Boden et al., [9] our data extraction indicated variations in terminology, phraseology and granularity, and authors did not consistently cite protocols, in the text and/or the references, making it challenging for readers to access the protocol themselves or track the progress of a protocol through the review. As studies are the unit of interest in a systematic review, when TRRs/PPs from one study are available, authors should collate them, and provide a citation as they would for any other document type [21].

Authors used a combination of publication types (published trial protocol and trial registry record), trial statuses (ongoing, completed, and terminated), and publication statuses (unpublished and published). Our results showed authors used terminology follows the current guidance, for example "*Searching trial registers* can *identify unpublished or ongoing trials.*" [12,14] Whereas in other instances, authors expanded it (e.g., ongoing, completed, or terminated). Not only were there variations across reviews but also within reviews.

The following textual excerpts illustrate inconsistency of terminology.

As an example of within review variations, authors' referred to a specific type/status of TRRs in the methods section (i.e., searching for ongoing trials) but use a broader term in the results/conclusion sections (i.e., there were no protocols). While this is technically correct, we argue the consistency and specificity in terminology within sections of the review will help with transparency.

The term *unpublished* in the context of a systematic review alludes to studies not published in a commercial journal (e.g., only disseminated as a poster presentation) but also to trial registry records and personal communications. As not all references to protocols were cited, it was hard to know if the information came from registries, conference abstracts, or personal communications with known experts. For example, *"In addition, we identified another 11 studies as ongoing or completed but with no data currently available."* [27] Some authors have started to differentiate between TRRs or PPs as the following example shows "*…there was no indication in any report of trial registration on whether a trial protocol had been published nor did we find any.*" [28]

In the Cochrane Handbook, different terminology seems to be appropriate within different sections of the review. We recommend following the transitions in TRR/PP phraseology used in the Handbook to provide greater clarity about trial status as reviewers' progress through the conduct of a review. The document type (TRRs and PPs) with publication status to justify (e.g., searching trial registry for unpublished studies) may be used in the Methods, and as more is known about the trial status when conducting the review, this more fine-grained phraseology should be used.

3.2. Algorithm/visual graphic

The aims of the algorithm/visual graphic are to encourage reviewers to report TRR and PP use, to improve the reporting of TRRs and PPs, and to generate further research by review methodologists (Figure 2). The algorithm/visual graphic is not a quality assessment instrument nor is it a validated tool but rather a visual representation of written guidance supplemented with current practices.

The algorithm in Figure 3 illustrates a reporting flowchart based on trial and publication status. We use direct excerpts from the systematic reviews (when available), but if excerpts were not available, we provide a suggestion marked as [example]. This section begins with selection (Searching and Screening) where publication type and status are more critical, and then addresses the reporting of TRRs/PPs by trial and publication status as the terminology and manner of reporting depends upon that status.

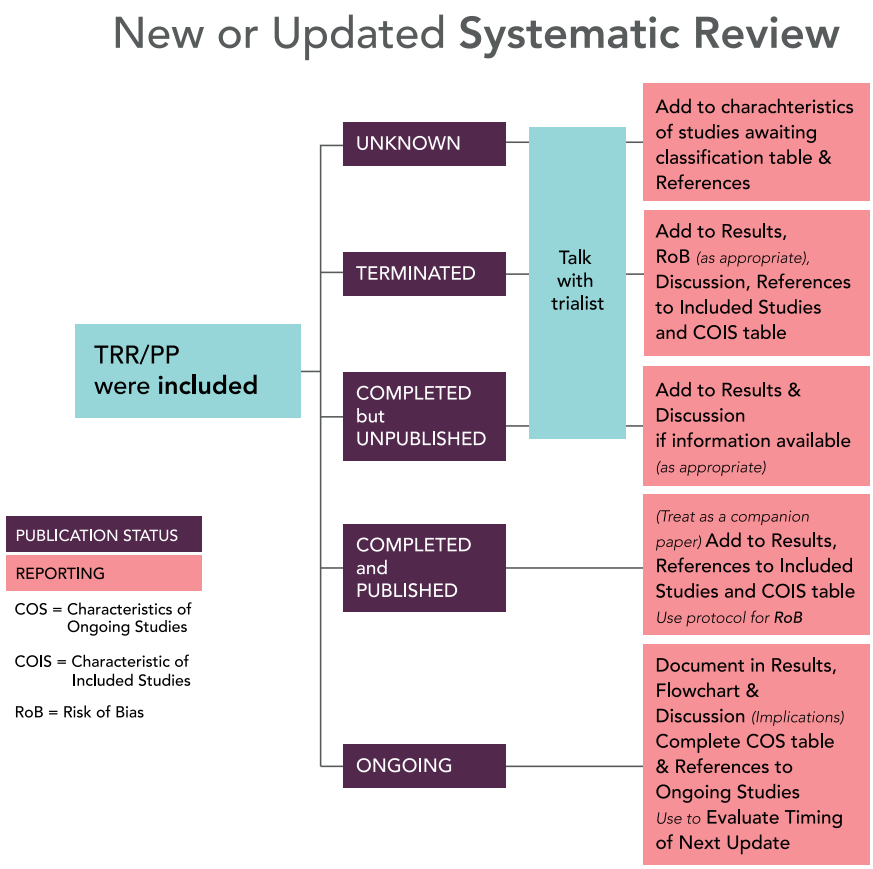

Fig. 3. Trial protocol reporting algorithm for included TRRs/PPs of different trial and publication statuses.

3.2.1. The search

As per the MECIR standards, [29] it is mandatory, in either new or updated systematic reviews, to search for TRRs/PPs [29]. Therefore, whether the search yields TRRs/PPs or not, this information should be reported at a minimum in the results section and PRISMA flowchart. For example,

> [Example] Results: we found 2 studies, and we found no trial registry records or published protocols that met our eligibility criteria.

3.2.2. Screen

Boden et al. [9] report a gap (i.e., no guidance) for the selection section of the review (i.e., inclusion/exclusion criteria). If the search identifies TRRs/PPs, the record or article should be screened for inclusion or exclusion. If excluded at full text, authors should complete the characteristic of excluded studies (CES) table and add the information to the excluded studies' references clearly indicating this was a TRR/PP. For example,

> [References-excluded] "Rohan 2004 Rohan KJ. Cognitive behavioral approaches to seasonal depression [NCT***]. *ClinicalTrials.gov [www.clinicaltrials.gov] 2004*" [23]

If the record is included at full text stage, we suggest identifying the status of the study (i.e., ongoing, terminated, completed and unpublished or completed and published, and unknown), using standardized terminology and proceeding as described in Sections 3.2.3. to 3.2.6. Figure 3 illustrates publication statuses and reporting initial direction for including TRRs/PPs.

3.2.3. Trial terminated

Reporting of the reason for trial termination is important for evidence-based decision-making [30]. We suggest checking the results database of the trial registry for accessing a summary of the results if available and identifying the reason for termination from the registry and/or consulting with trialist directly. The reason should be presented in the results, discussion, characteristics of included studies, risk of bias or characteristics of excluded studies, and references sections as appropriate. A few examples are provided below.

> [Results] we found no RCTs in the 2015 update meeting, the inclusion criteria for this review. The one

RCT identified in the 2014 review as ongoing, which includes children, **was terminated** (NCT***; characteristic of excluded table). The registry does not contain information on reasons for termination of the trial. We tried contacting the author, but after several unsuccessful attempts, the team decided to exclude the study [31].

[Results] Results of the Search: The previously identified ongoing study had been **terminated** without publication of results and was thus added to the CES table. We identified six new articles for inclusion in the review and identified that the ongoing study (NCT***) had been closed through poor accrual [32].

[Results] Risk of Bias: Incomplete outcome data (attrition bias) study was **prematurely terminated by the sponsor**…. Comments: high risk of attrition bias existed [33].

3.2.4. Ongoing trial

Boden et al. [9] indicates current guidance suggests identifying ongoing studies for inclusion and to help minimize bias and, then, describing relevant ongoing studies in the characteristics of ongoing studies (COS) table. In addition, previously identified ongoing trials should be reviewed for a change of status and/or data. In summary, an ongoing TRR/PP may follow a similar path to an included study. We suggest that reviewers document the presence of ongoing trials in the abstract, results, PRISMA flowchart, discussion, and implications for practice or research. In addition, we support current guidance that ongoing trials should be reported in the COS table and references. This information could be used as part of decision for next Cochrane update timing [34].

[Abstract] Conclusion: It is possible that the findings may change with the inclusion of large **ongoing** well-organized trials in future updates [35].

[Conclusion] Implications for research: The three **ongoing** GCIG trials will add data to answer the outstanding questions around the optimal IP drug, dose, combination, and number of courses of IP chemotherapy [36].

3.2.5. Completed and unpublished

Finding unpublished studies can help minimize bias [9]; however, it seems that there is incomplete guidance, particularly how use of TRRs/PPs to evaluate risk of bias. If found, completed and unpublished TRR should be described in the Methods, Results, and COIS tables. Only a fraction of completed and unpublished trials has data available in the registries. We suggest consulting the trialist to confirm that the available data are accurate and to provide any missing data. Trialists may be working in a draft manuscript or awaiting editorial approval; on the other hand, trialists may have no intention of publishing in a scientific journal, but they may be willing to share their results. Regardless, the status (e.g., draft manuscript submitted) and whatever information is available ***completed but unpublished*** studies should be added to the results and discussion, at a minimum, as appropriate.

[Results] Effects of the intervention 1.13.1 Clinically significant gamma-glutamyl transpeptidase levels. In this subgroup, we only found one relevant trial (n = 183) (NCT***). There was a clear difference between asenapine and placebo (RR 3.62....Analysis 1.13) [37].

[Discussion] Summary of main results: We were unable to find full publications for two included studies (NCT*** and NCT***) that were considered to be ‘‘negative trials’’ by their authors’’ [37].

3.2.6. Completed and published

These trial registrations/protocols should be included and processed as a companion study (i.e., associated with the published study results). As current guidance [9] suggests ‘‘trial registries can address reporting bias if they provide data on both ongoing and completed trials.’’ As included studies, completed trial records should be reported in the abstract, results, PRISMA flowchart, discussion, characteristic of included studies table, and references.

[Results] Included studies One study (Jerosch-Herold 2011) had an associated publication, which presented the trial protocol (Jerosch-Herold 2008) [38]

[References] Included studies - Kimani 2015 [39].

*Kimani J, Warren CE, Abuya T, Ndwiga C, Mayhew S, Vassall A, et al. Use of HIV counseling and testing and family planning services among postpartum women in Kenya: a multicentre, nonrandomized trial. BMC Women’s Health2015; 15:104.

Warren CE, Mayhew SH, Vassall A, Kimani JK, Church K, Obure CD, et al. **Study protocol** for the Integra initiative to assess the benefits and costs of integrating sexual and reproductive health and HIV services in Kenya and Swaziland. BMC Public Health 2012; 12:973 [40].

Evaluating risk of bias.

[Results] Risk of Bias. We found the protocol for one RCT (Itani 2010); all primary and secondary outcomes prespecified in the protocol were subsequently reported, and, accordingly, the trial was judged to be at low risk of bias for this domain. We searched, but did not find the protocols for the other included trials,

and so the remaining eight RCTs were judged to be at unclear risk of bias [41]

3.2.7. Unknown

There was no evidence available in the guidance documents nor did we find excerpts in the trials we sampled, but we recommend reporting it in awaiting classification section of the review until further information is available.

4. Discussion

A Cochrane systematic review of interventions is a detailed document for which clear and thoughtful methodology is established. Well-designed and properly executed systematic reviews of interventions provide the most reliable evidence to inform health care and policy decisions. We present an algorithm/visual graphic as initial attempt to encourage a more systematic and transparent reporting of TRR/PP use. Our algorithm/visual graphic is neither validated nor prescriptive but a starting point to start conversations in the area; it aims to prompt reviewers to consider what is it important to report and to generate discussion regarding current and future practices?

The algorithm/visual graphic presents a detailed series of steps for reporting of TRR/PP use in systematic reviews of interventions. As transparency is crucial and an important tenet of systematic reviews, we encourage use of the algorithm/visual graphic to begin to improve quality of reporting of TRR/PP in reviews. This may help clear linking of methods and results sections thereby improving the usability of the evidence and reflecting the quality of all included data.

As we noted previously [9], authors' use of terminology related to TRRs/PPs is confusing and inconsistent. We recommend using consistent language across reviews and citing protocols in the same manner as other document types. We hope this investigation and clarification of key concepts will help to move the field forward. The word ''ongoing'' has been used as a generic/broad term; however, we discourage the use of the word ''ongoing'' to describe every record found in the trial registries. First, TRR/PP indicates different types (trial registry record or published protocol). Second, they may have a different completion status (i.e., ongoing, terminated, and completed) or publication status (published and unpublished). Both completion status and publication status have implications for the systematic review.

Several authors report using the specialized Cochrane groups' trial registers; these registers are developed, maintained, and updated by information specialists. Registers are intended as a resource to Cochrane group members (teams/authors). Further, to our knowledge, the content of these databases varies across Cochrane groups and the only way we know what is included is to search them individually. The current reporting often presents a ready-made phrase for the Cochrane group that leaves the reader wondering about the inclusion of the trial registries and consequent findings reported in the review.

As review authors ourselves, we have experienced first-hand the lack of completeness of information contained in the registries [10]. We are aware that initial suggestions suggested here are to an extent dependent on the completeness of information in the registries. As far as we know, efforts are currently under way to improve and enforce trialists' reporting in registries, as well as making registries interface more user-friendly. We have also experienced the challenges of fnding more than one trial registration record (i.e. ClinicalsTrial.gov and European Union of Clinical Trials) or a trial registry record and a PP. We find our study timely in this regard, as there is an evident need to be transparent about sources and stages of protocols in the systematic reviews. Trial registration/publishing and protocol reporting appears to be evolving and into a more complex field. We would like to continue working in the area, for example, through a Delphi survey with stakeholders and conference workshops to validate and improve the algorithm but also to address deeper issues regarding what type of record and what information from these reviewers shall use. As the practice of protocol registration or publication continues to grow and evolve, our algorithm/visual graphic and conclusions will need to be revised.

We have assumed our readers are familiar with a Cochrane review process and understand the principles behind evidence synthesis. Typically, Cochrane reviews are held to high editorial and methodological standards. Our study may help to raise awareness and appeal to a broader systematic review author's audience—in particular those not yet associated with Cochrane practices.

We believe the inquisitive trained review author may have many questions regarding what to do in certain cases presented in the results, for example, how to assess the risk of bias of completed and unpublished trial, or how to handle results from a terminated trial. However important these issues are, they are complicated questions that require further analysis by methodologists.

4.1. Limitations of this study

The Cochrane Handbook update was launched at the time of writing this manuscript. We are unaware of any new developments planned for the reporting of TRR/PP use. We are aware, however, that new and exciting developments were initiated to ensure both trial registration and reporting of the results are available to the scientific community in a timely manner. New practices may have an impact on our algorithm/visual graphic, which may necessitate revisions and further development. Last, we are mindful that we have presented a small sample of extracts, representing practices, and views of review authors of some Cochrane Editorial Groups to illustrate a point.

These practices may not be common practice across the entire community of systematic reviewers in the Cochrane organization. Finally, methods in evidence synthesis are rapidly evolving; snapshots of practice such as this may need to be updated in the near future.

5. Conclusions

Our study expands on available guidance by describing in greater detail the reporting of registry records and PPs. We presented an algorithm/visual graphic; we hope will help bring transparency in the reporting of protocols in systematic reviews, bring clarification to current fuzziness in terminology and reporting, and ultimately lead to higher quality systematic reviews. Further methodological work is needed in the area; it is a timely investigation in an era where evidence synthesis informs health and health care decisions. We hope that the algorithm generates further discussion to enhance the recommendations we put forth here and research into the complexities of using protocols in systematic reviews of interventions.

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2020.09.025.

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