A New Process Model for Study Identification in Systematic Review: Separating Studies From Reports

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Background

- Recent work illustrates that guidance handbooks propose the same process to study identification, irrespective of the studies sought for synthesis. This means that the same process is used to identify randomised studies as for any other design, e.g., qualitative studies.
- We propose that searches for randomised controlled trials (RCT) should have their own specific process of study identification since this might accelerate the process to help clarify plans for review and data synthesis earlier on than the current norm.

Objective

- **To describe and illustrate a new process model specific to the identification of RCT of clinical interventions.**

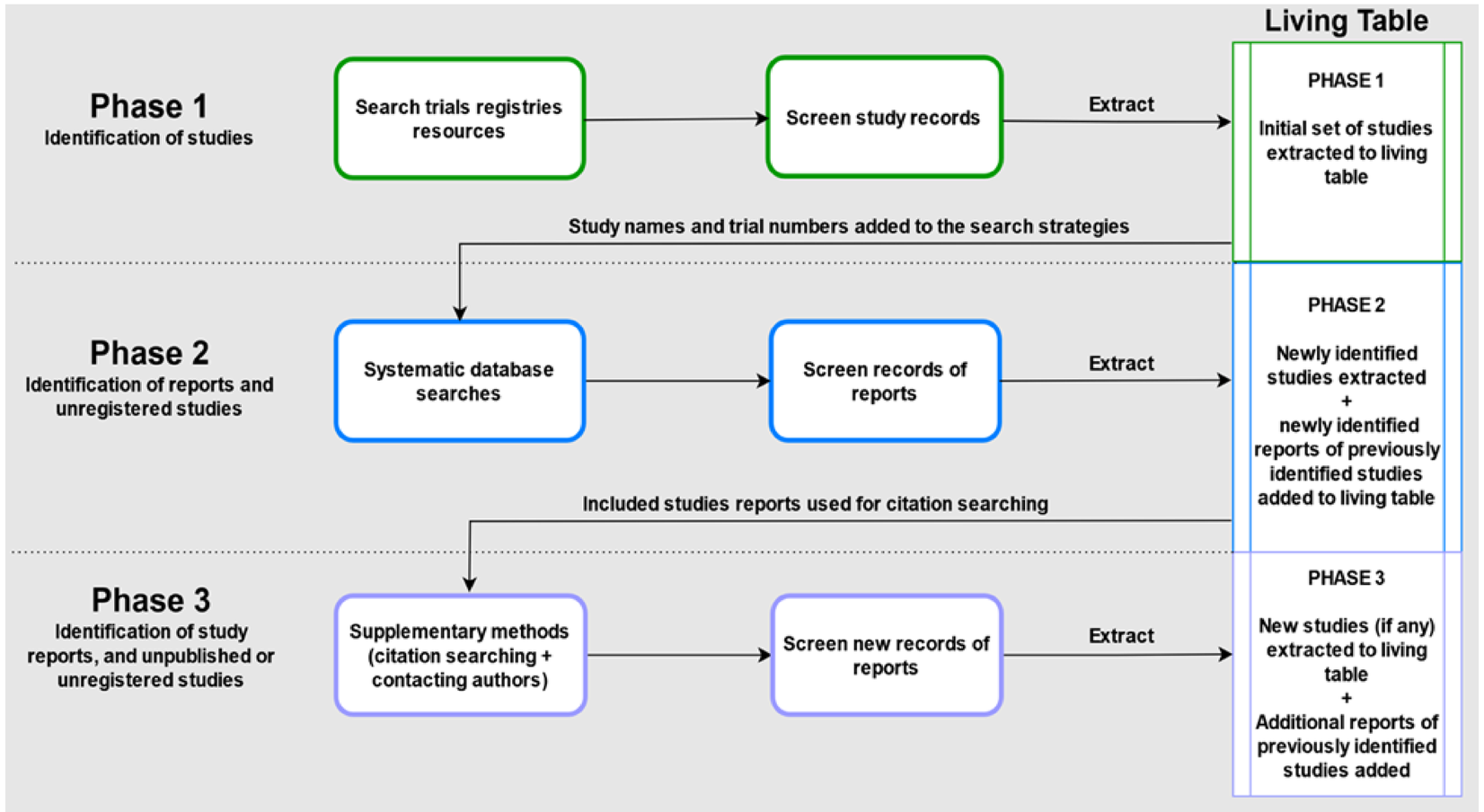
Methods

We separate the search for studies from study reports, anticipating a search in three phases compared to the usual one stage approach (see Figure 1). We also consider that the process is emergent, with the possibility that the process evolves as studies or reports are identified.

- **Phase 1**: trials registry resources are searched to identify studies. The searchers will need to decide either to focus on the interventions in scope OR by condition OR both. Study names, IDs, or registry numbers from eligible study reports are extracted and used as search terms in Phase 2. This helps ensure the comprehension of the searches.
- **Phase 2**: bibliographic databases relevant to the topic are searched. The aim in this phase is to identify study reports (possibly unregistered studies too). The PICOs structure can be used, supplemented by study specific data (e.g., trial name or number) from Phase 1. The logic would be ((review relevant PICOs) OR (study name OR study ID or study registry numbers)).
- **Phase 3**: identification of unpublished studies or additional study reports (and cross-checking the completeness of the search). Supplementary searches are indicated.

We include the possibility of secondary searches, as needed, on the basis that the review team will know more about a topic at the end of this process than the start. A protocol amendment may be required.

Figure 1: Our proposed process model for study identification of RCT in reviews of clinical effect



Results

In addition to reporting the searches following PRISMA guidance, we propose a Table which sets out the studies and associated reports identified as the process evolves.

We call this the 'Living Table' (see Table 1). Living, as it lives- and it 'grows' - during the review.

It is proposed that The Living Table be updated as each phase of the search process described above completes and as study selection evolves. The Living Table aims to clearly set out study specific detail, bringing clarity to wording in the review which might report 'one study (two reports) were identified'.

The Living Table offers a snapshot of the availability of studies and reports which can inform synthesis.

Table 1: Example of a Living Table

Study Name, ID, or acronyms	Primary report	Other reports
The Main Trial	Timothy et al., (2019). The Main Trial. Journal Name. 4 (8) 123-145	Timothy et al., (2018). Main Trial. Clinical Conference. Sydney, Australia [identified via handsearch] NCT01234567. Main Trial Protocol. clinicaltrials.gov/show/NCT01234567 (first received 31-Dec-2012).

Discussion

We propose that the process of study identification for RCT of clinical interventions should have its own process of study identification. We propose that this new model offers the following benefits over the current Conventional Approach*.

- **Simplification:** we separate searching trial registry records from database searching. This means studies are identified first and study selectors are not having to read registry records AND abstracts at the same time (easier on the brain).
- **Clarity on synthesis:** registers contain studies. After Phase 1 completes, it is possible to confirm the majority of eligible studies and start to map the possibility for synthesis - e.g. if sufficient studies/comparisons are available for statistical comparison.
- **Second searches:** reviewers know more at the end of a review than at the start. We allow second searches to process new knowledge.

Conclusions

A new process model of study identification for use by experienced authors undertaking systematic reviews of randomised studies evaluating the effect of medical interventions is presented.

This new model differs from the existing model of study identification for systematic reviews (The Conventional Approach*) as it separates the search for studies from the search for study reports and it seeks to link search methods to reports or data. The existing idea that study identification should be a single phase, undertaken at the start of a systematic review, is questioned with the proposal that the study identification process be undertaken in phases as review work happens in parallel and understanding of the topic develops.

This model also seeks to simplify the approach to study selection and facilitate the mapping of studies more efficiently. Accordingly, it is proposed that this process model will suit the needs of authors expecting to undertake large or complicated syntheses. **We think this model may be of particular use for Joint Clinical Assessment (JCA), the new 'style' of appraisal of clinical effectiveness planned for the European Union from 2025.**

See poster **#SA105 SLRs could benefit from a new approach to study identification: a case study** by Worsley *et al*., for a descriptive evaluation of using this model.

REFERENCES
* Cooper, C., Booth, A., Varley-Campbell, J. *et al.* Defining the process to literature searching in systematic reviews: a literature review of guidance and supporting studies. *BMC Med Res Methodol* **18**, 85 (2018). https://doi.org/10.1186/s12874-018-0545-3