SWAR 15: Strategies for obtaining study conduct information from trial investigators to assist with the assessment of risk of bias using the Cochrane Risk of Bias 2 tool

Objective of this SWAR
To compare two strategies for requesting study conduct information from trial investigators to assist with the assessment of risk of bias using the Risk of Bias 2 (RoB 2) tool.

Study area: Data collection, Study author contact
Sample type: Study authors
Estimated funding level needed: Unfunded

Background
Reports of trials and other studies often lack adequate detail about how the study was done (e.g. method of randomization and allocation concealment), do not present full data sets, or present data in a way that does not allow them to be included in a meta-analysis. Therefore, further information is often needed for systematic reviewers to assess studies comprehensively for risk of bias, meta-analyse study results and draw useful conclusions. One method to obtain the information required is to contact corresponding authors of the primary studies and a systematic review has found that it is common for review authors to contact primary study investigators, with one of the main reasons for this being poor reporting of information to assist their assessment of risk of bias.[1] However, response rates to these data requests are low,[2] and it can take more than a year for the study authors to provide the necessary data.[3] Reasons for not providing data may include concerns about the time and resources it would take to prepare and share data, uncertainties about data security and lack of access to the data after study completion.[4] Previous work has found that the likelihood of sharing data may be associated with study-specific characteristics such as funding type, study size and risk of bias, and treatment effect.[3] The method of requesting information may also influence success rate.[5] To our knowledge, no previous study has explored the optimal approach for requesting study conduct information to assist with the completion of Risk of Bias assessments using the RoB 2 tool.[6]

In this SWAR, a short cover email would be sent to the corresponding authors of eligible studies, with the following attachments: 1) a headed PDF letter (outlining the project and who is in the team, clarifying correct contact details for the trial, explaining why we are undertaking detailed risk-of-bias assessments, inviting comments on the draft protocol and requesting study conduct information), 2) the draft IPD meta-analysis protocol (including data to be collected, statistical approaches to be used and timeline), and 3) an attachment asking the investigators to fill in the desired study conduct information (which will be the randomly assigned form as noted below). One attempt would be made to follow up on individuals who do not respond.

The intention was to include this SWAR in a major update of a large Cochrane Review of the effects interventions to prevent obesity in children, but a lack of resources means that the SWAR will not be done.

Interventions and comparators
Intervention 1: Attach a completed RoB 2 assessment for the trial (as a Microsoft Word document) with missing details highlighted and ask the trialist to fill in the gaps and/or correct any misinterpretations.
Intervention 2: Attach an empty form containing a standard set of questions pertaining to issues addressed in the RoB 2 tool and ask the trialist to complete this. (This would be used to inform the RoB 2 assessments for the review.)

Index Type: Data collection, Risk of bias assessment

Method for allocating to intervention or comparator
Randomisation. A numerically ordered list of study authors to approach would be passed to an independent statistician who would assign them according to a randomized sequence Blocked randomisation with size 6, stratified by year of publication of the trial report (before 2015 vs 2015 or later) would be used. The authors would then be contacted in the order originally listed to ensure

that the two groups are treated as similarly as possibly in respects other than the intervention comparison.

Outcome measures
Primary: 1. Completeness of final RoB 2 assessment, measured as the proportion of bias domains for which a full assessment can be made without uncertainties around trial details; 2. Number of overall judgements altered because of feedback from triallists
Secondary: 1. Response from the trial authors (no response, some response but without RoB 2 information supplied, response with some RoB 2 information supplied; response with complete RoB 2 information supplied); 2. Time from request to return of the (a) initial relevant information and (b) complete requested information); 3. Time it takes reviewers to prepare emails; 4. Number of domain-level judgements altered as a result of feedback from trialists; 5. Number of signalling question responses altered as a result of feedback from trialists; 6. Number of signalling questions for which information received by correspondence conflicts with information presented in previously identified reports of the study (with presence of conflict agreed across the central systematic review team).

Analysis plans
For primary outcome 1 and secondary outcome 1: ordinal regression (proportional odds model) would be used to compare the two groups (with estimation of difference in mean level and accompanying t-test as a sensitivity analysis).

For secondary outcome 2: proportional hazards regression would be used to compare the two groups, with censoring at end of follow.

For primary outcome 2 and secondary outcomes 3-5: estimation of difference in mean value and accompanying t-test would be used to compare the two groups.

We do not anticipate any missing data for the primary outcomes 1 and 2 or secondary outcomes 1, 2, 4 or 5. Missing data for secondary outcome 3 is possible and we would impute missing data based on best recollections and compare this with a complete case analysis.

Possible problems in implementing this SWAR
It may be difficult to find up to date contact details for corresponding authors of studies published some time ago.

References
1. Meursinge Reynders R, Ladu L, Di Girolamo N. Contacting of authors modified crucial outcomes of systematic reviews but was poorly reported, not systematic, and produced conflicting results. Journal of Clinical Epidemiology 2019;115:64-76.

2. Kelley GA, Kelley KS. Retrieval of individual participant data for exercise meta-analyses may not be worth the time and effort. BioMed Research International 2016;5059041.

3. Veroniki AA, Ashoor HM, Le SP, et al. Retrieval of individual patient data depended on study characteristics: a randomized controlled trial. Journal of Clinical Epidemiology 2019;113:176-88.

4. Cooper H, Patall EA. The relative benefits of meta-analysis conducted with individual participant data versus aggregated data. Psychological Methods 2009;14(2):165.

5. Danko KJ, Dahabreh IJ, Ivers NM, et al. Contacting authors by telephone increased response proportions compared with emailing: results of a randomized study. Journal of Clinical Epidemiology 2019;115:150-9.

6. Sterne JAC, Savović J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019;366:l4898.

Publications or presentations of this SWAR design

Examples of the implementation of this SWAR

People to show as the source of this idea: Julian Higgins, Jelena Savovic, Eve Tomlinson, Francesca Spiga
Contact email address: eve.tomlinson@bristol.ac.uk
Date of idea: 29/SEP/2021
Revisions made by:
Date of revisions: