SWAR 20: Evaluating the integrity of trials included in a systematic review assessing different numerical formats for communicating risk

Objective of this SWAR
To assess the effect of performing integrity assessments in a systematic review using the Cochrane Pregnancy and Childbirth Trustworthiness Screening Tool (CPC-TST) on
- the inclusion and exclusion of studies within the review
- the effect estimates and 95% confidence intervals (CI) for the meta-analyses
- the overall certainty of evidence
- the overall review conclusions

To document the process of implementing research integrity checks (using the CPC-TST), including ease of use, limitations, impact on the systematic review process and areas for development.

Study area: Study Identification, Statistical Analysis
Sample type: Editors, Reviewers
Estimated funding level needed: Unfunded

Background
Scientific integrity is a fundamental part of medical research but research misconduct is a substantial and a growing problem. Research misconduct refers to unethical practices that include fabrication, falsification, misrepresentation of data, plagiarism, causing unnecessary risk or harm, and improper data handling.[1] Misconduct had previously been considered to have little effect because science was assumed to be self-correcting, but there is increasing evidence that its prevalence is greatly underestimated. For example, research published in 2019 showed that article retraction in the field of obstetrics and gynaecology was increasing, and that the most common reasons for retraction were plagiarism and data falsification.[2] Journals are also retracting increasing numbers of articles due to recent efforts to better assess data trustworthiness and detect research misconduct.[3]

These issues have been highlighted by critical appraisal of randomised trials assessing the outcomes of COVID-19 patients treated with ivermectin. Initial systematic reviews suggested that ivermectin resulted in a large reduction in mortality,[4] but critical appraisal of the included trials observed methodological flaws and found data irregularities.[5] The initial reviews greatly impacted perception of ivermectin's efficacy and the drug has been used widely for the treatment of COVID-19,[6] leading to serious adverse effects on patient care.[7]

Research misconduct is unfortunately not limited to such high-profile cases and as much as 20% of the published biomedical literature is thought to be affected by research misconduct.[8] However, standardised research integrity checks for systematic reviews are not routinely used, which may mean that flawed data are being used in treatment decisions and recommendations and to inform future research and justify potentially harmful trials. Therefore, determining the trustworthiness of randomised trials used in systematic reviews is of the utmost importance for the provision of quality patient care and research. As the number of systematic reviews published continues to grow, there has also been an increase in the evidence-base for how we plan, carry out, and publish the findings of reviews.[9,10] Undertaking a Study Within A Review (SWAR) is a resource-efficient method of conducting these methodology evaluations.[11]

This SWAR will examine the effect of applying research integrity checks, specifically The Cochrane Pregnancy and Childbirth Trustworthiness Screening Tool (CPC-TST), on "The effects of presenting diagnostic accuracy and intervention efficacy statistics in different numerical formats: a systematic review", which includes a number of criteria that require contacting corresponding authors for clarifications or specific information (e.g. the protocol or ethics approval letter, or individual participant data). Included trials will be assessed for research integrity by two reviewers independently, using the CPC-TST. Disagreements will be resolved by consensus opinion, including a third party not involved in the initial assessment. The two reviewers will decide whether to contact original authors and final decisions will use the replies, where relevant.

Interventions and comparators
Intervention 1: Application of the CPC-TST to studies judged eligible for the review after full-text screening.
Intervention 2: Usual systematic review processes for data extraction and assessment of risk of bias.

Index Type: Other

Method for allocating to intervention or comparator
Non-Random

Outcome measures
Primary: Proportion of studies within the systematic review to which we assign the terms 'included', 'excluded', or 'awaiting classification'.
Secondary: (1) proportion of studies within the systematic review to which we assign the terms 'included', 'excluded', or 'awaiting classification', for each of the 10 domains of the CPC-TST; (2) impact of including/excluding studies according to the CPC-TST on the pooled effect estimates and their 95% CI; (3) impact of including/excluding studies according to the CPC-TST on the overall certainty of evidence; (4) impact of including/excluding studies according to the CPC-TST on the overall conclusions of the study; (5) reasons for classification as 'excluded' or 'awaiting classification'; (6) characteristics of assessed trials; and (7) inter-observer levels of agreement between the two reviewers.

Analysis plans
Primary outcome: comparison of the proportion of included studies in each SWAR group
Secondary outcomes: inter-observer levels of agreement between the two reviewers using Kappa; comparison of pooled effect estimates and 95% CI for meta-analyses in each SWAR group; and comparison of certainty of evidence judgements in each SWAR group.

Possible problems in implementing this SWAR
Published papers considered for the review may contain insufficient explanation of their methodology and justification for us to fully use the CPC-TST. The CPC-TST may have subjective criteria which may lead to difficulty in categorising trustworthiness in some cases. It may be difficult to contact authors of studies published some time ago.

References
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11. Devane D, Burke NN, Treweek S, et al. Study within a review (SWAR). Journal of Evidence-Based Medicine 2022;15:328-32.

Publications or presentations of this SWAR design

Examples of the implementation of this SWAR

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Revisions made by:
Date of revisions: