

Trustworthiness assessment as an inclusion criterion for systematic reviews – what is the impact on results?

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Abstract

BACKGROUND There is increasing concern that a significant proportion of randomised controlled trials (RCTs) included in Cochrane reviews may not be trustworthy. Applying a trustworthiness screening tool (TST) has already had a clinically important effect on several reviews published by the Cochrane Pregnancy and Childbirth Group. **OBJECTIVES** We wanted to assess the impact of removing untrustworthy RCTs from already- published Cochrane reviews on a defined clinical area (ante- and post-natal nutritional interventions). **METHODS** We applied the tool to 18 Cochrane reviews (375 RCTs). The tool had four domains: i) is the research governance trustworthy; ii) are the baseline characteristics trustworthy; iii) is the study feasible; iv) are the results plausible?). When additional information was needed, authors were contacted using a standard template. At least two attempts were made to contact the authors. At the end of the evaluation process each study was classified as: i) included (YES to all domains); ii) excluded (retracted study); or iii) awaiting classification (any NO to the TST questions). **RESULTS** 95/375 studies (25%) were removed, affecting 14/18 (78%) reviews. 13/18 reviews (72%) showed a difference in the Summary of Findings tables (direction and size of effects and/or GRADE ratings). 6/18 Cochrane reviews (33%) were judged to require updating because of important differences in either in their conclusions, implication for practice, and/or implication for research. **CONCLUSIONS** Formal assessment of trustworthiness and inclusion only of studies that satisfy prespecified criteria for trustworthiness affect conclusions in a relatively large number of Cochrane reviews, with potentially important clinical implications for practice and research. The lack of consensus regarding the best tool(s) for assessing trustworthiness cannot be an excuse for ignoring this issue in future Cochrane reviews.

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