

AGREMA: a guideline for reporting mechanism evaluations in randomised controlled trials

If endorsed by CONSORT group as an official extension:

CONSORT-Mechanism: an extension for randomised controlled trials of mechanism evaluations

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Background: Studies investigating causal mechanisms from randomised controlled trials (RCTs) are becoming increasingly common. Despite growing numbers of publications and trialist embedding mechanism evaluations into RCTs, the reporting accuracy and consistency of mechanism studies is suboptimal. The heterogeneity in the reporting of mechanism evaluations stifles systematic reviews, complicates meta-analyses, and limits transparency and replication. The aim of this initiative is to develop a reporting guideline for mechanism evaluations in RCTs. We also plan to develop an accompanying explanation and elaboration (E&E) paper.

Methods: This project will be conducted in 5 phases. The first phase will be the project launch, consisting of: establishing a project executive and an international advisory group, and engagement with journal editors and the CONSORT Group. The second phase will be a Delphi process to identify a priority list of items that should be considered for inclusion in the reporting guideline. The third phase will involve an online consensus meeting to vote on the items to be included in the guideline. The fourth phase will be the write-up of the guideline and E&E documents. In the final phase we will disseminate and implement the guidelines. This will consist of simultaneous publications and requests to journal editors to endorse the guideline. The project executive will present the guideline at international conferences, professional bodies, and organisations across multiple disciplines.

Conclusion: The development of this reporting guideline should improve standardisation, accuracy, transparency, and completeness in reporting mechanism evaluations in RCTs. This will facilitate more comprehensive systematic reviews of mechanisms, and guide researchers, editors, and policy makers in evaluating evidence for causal mechanisms.