COCHRANE INFECTIOUS DISEASES GROUP

Cluster randomised trials: A study to help recommendations for better reporting in Cochrane reviews

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Background

Cluster-randomised controlled trials (CRCTs) differ in design to RCTs; clusters of subjects (e.g. schools, communities, clinics) are randomly assigned to intervention groups. Reviews should report various details about the CRCT, assess risk of bias appropriately, and perform analyses correctly. Failure to consider these issues may lead to serious misinterpretation.

AIM: To identify areas of concern, and inform review authors in appropriate methodology when including CRCTs.

Methods

Search: Cochrane Database of Systematic Reviews for reviews including CRCTs published in the last 2 years

We assessed eligibility[1] using a form and obtained the review and trial reports

We assessed each review on criteria[2] relating to: reporting of CRCTs, assessment of risk of bias, and statistical analyses.

[1]**Inclusion:** Reviews; included ≥1 CRCT; past 2 years.
Exclusion: Protocols/abstracts; DTA reviews; methodological publications; cost-effectiveness reviews.

[2]Criteria for identifying, reporting and analyses of CRCTs were constructed after consultation with statisticians and the Cochrane Handbook. Risk of bias criteria are listed in the Cochrane Handbook.

Results

- 50 reviews (232 trials) were identified.
- Most (94%) reported CRCTs in "Characteristics of included studies"; fewer under "Types of studies" (56%) (Fig. 1).
- Authors often failed to report (Fig. 2) the intra-cluster correlation coefficient (ICC) and method of adjustment, even after excluding reviews where no trials reported these ("Not reported in any of original trial reports" series).
- Completion of the five risk of bias criteria were low (Fig. 3).
- 64% of reviews did not identify CRCTs in the meta-analysis, and 74% did not state whether CRCT results were adjusted. 42% included unadjusted results in meta-analyses (Fig. 4).

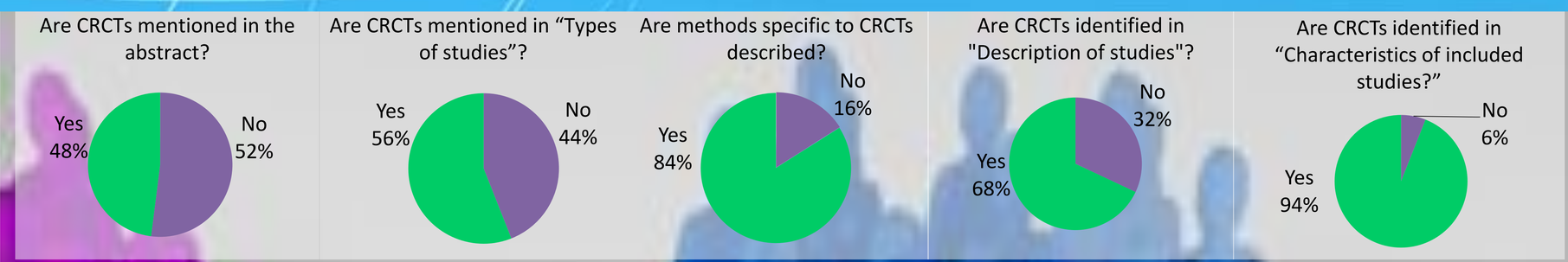

Figure 1: Identifying CRCTs

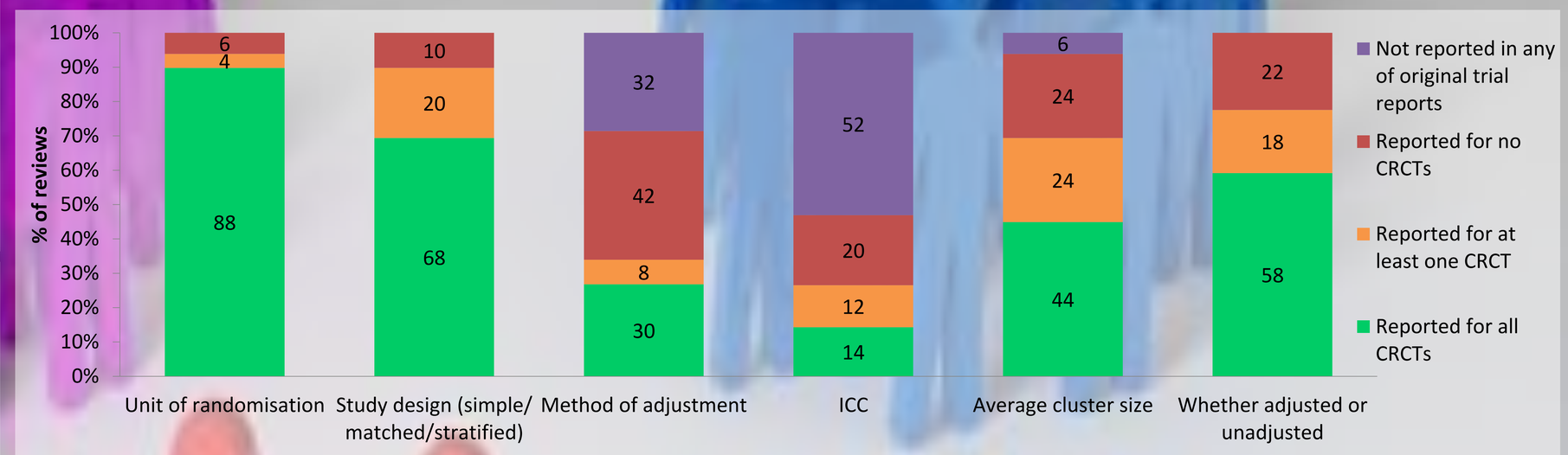

Figure 2: Reporting of key trial characteristics

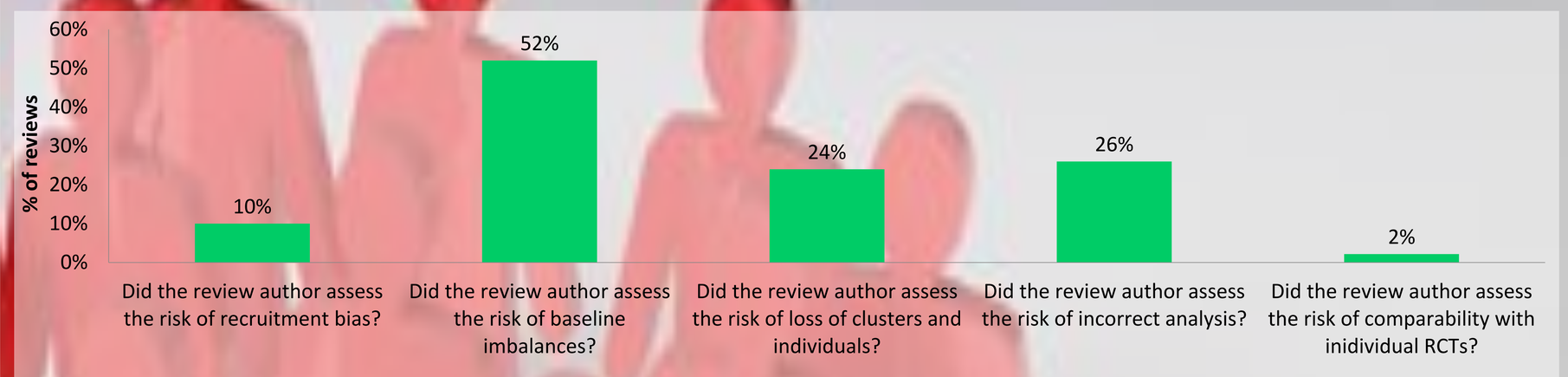

Figure 3: Assessment of risk of bias

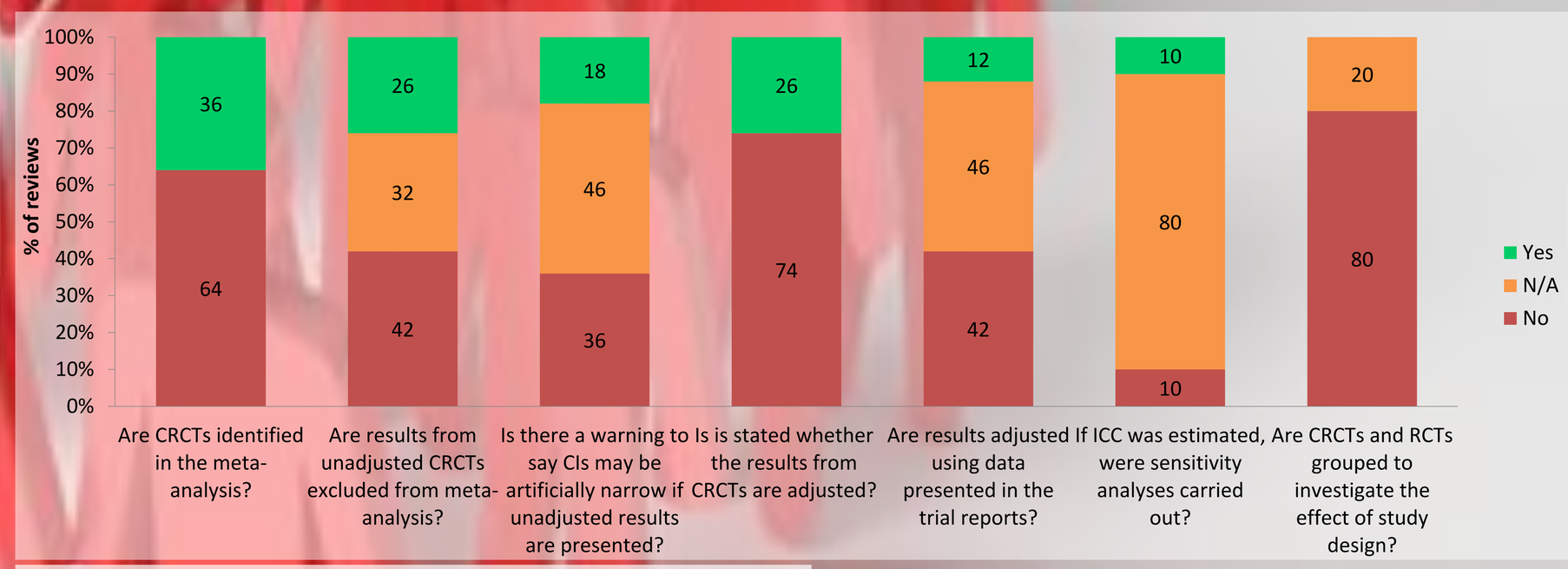

Figure 4: Analyses and interpretation

Conclusions

- It is desirable for CRCTs to be identified and reported well, but more crucial that analyses are correct, and risk of bias assessed well. These issues may greatly affect results, and influence heath-care decisions.
- Reporting of trial characteristics is often poor in trial reports; authors should report these absences. Many reviews do not report key characteristics for any included CRCTs, despite trial reports providing this information.
- Review authors should refer to the Cochrane Handbook for assessment of risk of bias when including CRCTs.
- The criteria used in this study could contribute to guidelines for producing high quality reviews including CRCTs, to overcome major flaws in the analyses, such as including unadjusted CRCT results in meta-analyses.

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