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ever-evolving tool and the CONSORT group welcomes suggestions to further improve the quality of reports of randomized controlled trials. Unfortunately, in this instance, Chan and colleagues have apparently overlooked the existing CONSORT documents. Nevertheless, we congratulate them for their excellent study and for highlighting the issue of clinical importance.

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References


C onsidering their study’s objectives, I was surprised that Karen Chan and colleagues did not explain why they evaluated only 10% (27/266) of available randomized controlled trials. This is especially interesting as both previous studies they referenced evaluated more studies, 102 and 45 respectively, and therefore were more precise.

Further, why weren’t the proportions in Table 3 accompanied by 95% confidence intervals, particularly when the reporting of confidence intervals was one of the criteria Chan and colleagues used to evaluate randomized controlled trials?

When one refers to Diem and Lentner’s Scientific Tables, it is troubling to note the imprecision of the proportions reported by Chan and colleagues (e.g., 22/27 = 81%, confidence interval [CI] 62–94%; 20/27 = 74%, CI 54–89%; 18/20 = 90%, CI 68–99%; 2/18 = 11%, CI 1–35%; 13/18 = 72%, CI 47–90%; 17/27 = 63%, CI 42–81%; 11/27 = 41%, CI 22–61%; 10/20 = 50%, CI 27–73%; 15/20 = 75%, CI 51–91%). Apparently, the upper and lower limits of many of these confidence intervals could lead to differing conclusions. For example, although Chan and colleagues found that 74% of investigators (20/27) discussed the clinical significance of their findings, this estimate is also consistent with values as low as 54% and as high as 89%.

In closing, I would argue that the determination of study precision should be part of the planning process for all studies, not just randomized controlled trials. Such as step would strengthen both the statistical and clinical integrity of any planned study.

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[The authors respond:]

Upon rereading the revised CONSORT statement, we do still not see an explicit recommendation that authors should discuss the clinical importance of their study results. We do not believe that the discussion of such an important component of the reporting of randomized controlled trials should have been relegated to the accompanying explanation and elaboration paper. We are delighted that the CONSORT statement is an ever-evolving tool and suggest that in the next version the checklist explicitly state that authors should (1) report and justify the magnitude of the minimal clinically important difference and (2) discuss and justify their interpretation of the clinical importance of the study result in relation to that difference.

We agree with Bart Harvey’s comment. However, the goal for our study was to highlight an important shortcoming in the reporting of randomized controlled trials rather than to document the precise frequency of this phenomenon. We believe that we were able to accomplish this goal with our relatively small sample size.

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References


