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Abstract Title

Risk of bias in cluster randomized-controlled trials: a methodological review of child health trials published in 2007, 2017, and 2022

Authors

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Background

Cluster randomized-controlled trials (RCTs) are preferable when the individual unit of allocation is not feasible to address research questions. Evidence suggests that cluster RCTs are often poorly designed and executed, leading to a potential risk of bias (ROB).

Objective

Using a sample of child health cluster RCTs published across three time points, we characterized these trials and assessed the prevalence, source, and temporal trends in ROB.

Methods

We leveraged an existing dataset of 900 child health RCTs across three publication cohorts (2007, 2017, and 2022; n=300 each), selecting all cluster RCTs for inclusion (n=77). Trial characteristics and ROB were independently assessed in duplicate, with discrepancies resolved through consensus. ROB was assessed using the Cochrane ROB2 tool for cluster-randomized trials. Trial characteristics and ROB were compared across cohorts using Fisher's exact test, with Cochrane-Armitage trend testing for linear trends over time. Associations between trial characteristics and high overall ROB were assessed using logistic regression.

Results

Most trials (60, 78%) used two randomized arms with a median of 23 clusters (IQR 12–40). Accounting for clustering in sample size estimation increased from 40% (2007) to 73% (2017) and 63% (2022); stratified allocation increased from 20% to 46%; participant identification before randomization remained low and stable (29–30%) across all three cohorts. Most trials were rated high overall ROB (75%, 58%, 67%, respectively), with no significant difference across cohorts (Fisher's exact $p=0.38$) or linear trend (Cochran-Armitage $Z=0.75$, $p=0.45$). Outcome measurement was the dominant contributor to high ROB across all cohorts. No trial characteristic was significantly associated with high overall ROB, though failure to identify participants before randomization showed the largest effect, odds ratio, (OR)=2.21, 95% CI 0.79–6.32, $p=0.13$.

Conclusion

ROB in child health cluster RCTs remains high and has not significantly changed between 2007 and 2022, driven primarily by outcome measurement bias.