# Avoidable Research Waste related to Inadequate Methods and Incomplete Reporting in Pediatric Randomized Controlled trials (RCTs) published in 2007, 2012 and 2017

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## INTRODUCTION

Randomized controlled trials (RCTs) are the universal gold standard for gathering evidence about the effectiveness of clinical interventions and they are needed to improve child health care. However, inadequate methods and incomplete reporting of interventions can prevent the transposition of research in practice which leads waste of research.

Failure to document critical elements of RCT can result in inaccurate assessments of findings and subsequent misinformed and potentially harmful and wrong clinical decision-making.

## AIM

The primary objective is to evaluate changes in risk of bias (RoBs) assessment reporting in the child health RCTs published in 2007, 2012 and 2017.

## METHOD

We performed a methodological systematic review of a representative sample of randomly selected 900 child health RCTs, using three sets of studies previously identified by our team the Cochrane Central Register of Controlled Trials. Each set consists of 300 trials published in cohorts of 2007, 2012, and 2017.

Details of the search strategy and selection methods are outlined in previous publications (Gates et al., 2018; Hamm et al., 2010).

We used the 2010 Cochrane RoB tool to assess RoB for the primary outcome among 7 domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, other bias and overall RoB. We assessed each domain as low scored as 1, unclear scored as 2, or high risk scored as 3 following Cochrane procedures and internal decision rules. Two reviewers assessed each record and discussed the judgments until consensus was reached or a third party provided arbitration.

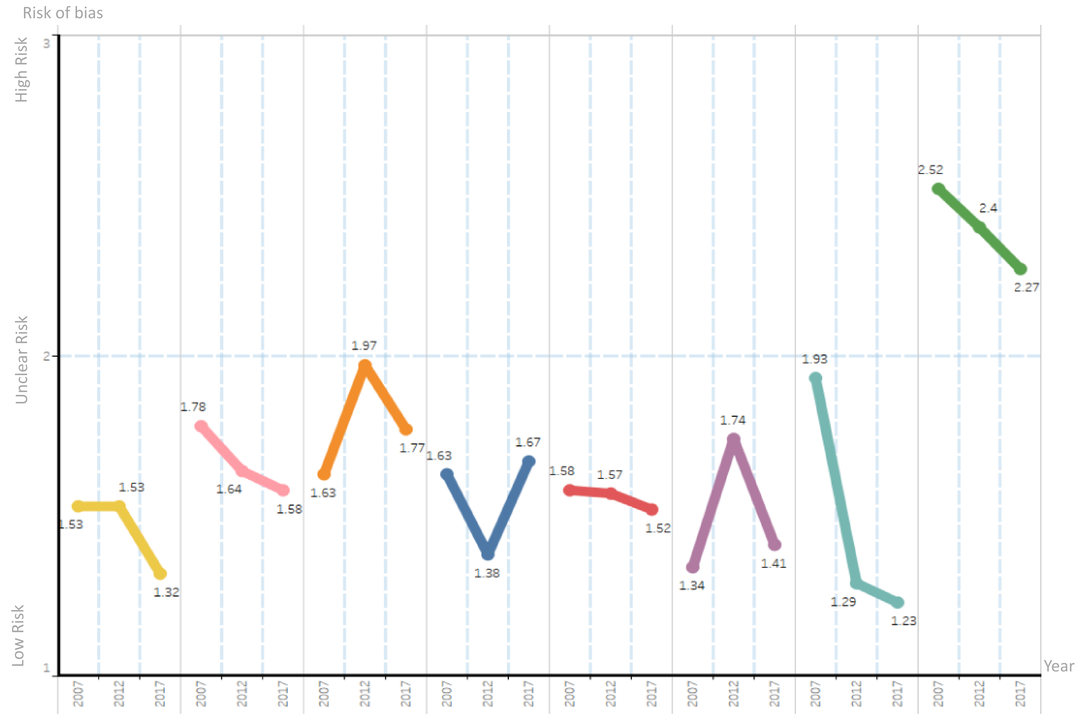
We tested for presence of a change in trend in each RoB domain using Cuzick's test across the 2007, 2012 and 2017 cohorts.

## RESULTS

We found significant trend decreases in 5 out of 7 (71.4%) RoB domains (from relatively higher risk to relatively lower risk) in the selected RCTs published (Figure 1) and the changes in each RoB domain (Table 1) in the three studied cohorts.

## RESULTS

***Figure* 1. Trend Changes in the Risk of Bias (RoBs) in Child Health RCTs published in 2007, 2012 and 2017**




| | Random Sequence Generation | Allocation Concealment | Blinding of Participation and Personnel | Blinding of Outcome Assessors | Incomplete Outcome Data | Selective Reporting | Other Bias | Overall RoB |
|---|---|---|---|---|---|---|---|---|
| 2007 (mean, sd) | 1.53, .03 | 1.78, .03 | 1.63, .04 | 1.63, .04 | 1.58, .05 | 1.34, .04 | 1.93, .04 | 2.52, .04 |
| 2012 (mean, sd) | 1.53, .03 | 1.64, .03 | 1.97, .05 | 1.37, .03 | 1.57, .04 | 1.75, .03 | 1.29, .03 | 2.41, .04 |
| 2017 (mean, sd) | 1.33, .03 | 1.57, .03 | 1.77, .04 | 1.66, .04 | 1.52, .04 | 1.41, .03 | 1.23, .02 | 2.27, .03 |
| Cuzick's trend test | p<.001 | p<.001 | p<.05 | p=.54 | p=.92 | p<.001 | p<.001 | p<.001 |

***Table* 1. Descriptive statistics of each RoB domain in Child Health RCTs published in 2007, 2012 and 2017**

## DISCUSSION

While a lot of waste of research seems to be avoidable with simple and inexpensive adjustments (Yordanov et al., 2018), the impact of current study highlights the importance of methodological rigors by identifying how research waste was formed and turning the "waste" into valuable resources.

## CONCLUSION

Though the trend for improvements with respect to most of the RoB domains were observed, domains of blinding of outcome assessors and incomplete outcome data were unchanged in the past decade. The present study has identified the key design elements that need further improvement.

To conclude, optimizing the design, conduct, and reporting of pediatric trials may reduce research waste in the field.

## ACKNOWLEDGEMENTS

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