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

Megan Pinette[1], Clara Tam[1], Terry P. Klassen[1,2], Alex Aregbesola[1,2*]

[1]The Children's Hospital Research Institute of Manitoba, Winnipeg, MB, Canada
[2]Department of Pediatrics and Child Health, Max Rady College of Medicine, Rady Faculty of Health Sciences, University of Manitoba, Winnipeg, MB, Canada

INTRODUCTION

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

AIM

- To investigate the sources of bias and examine if the proportion of bias has changed in a sample of child health cluster RCTs published in 2007 and 2017.

METHODS

Study eligibility

Cluster RCTs in health research conducted among individuals aged 21 years and below published in 2007 and 2017.

Search strategy

Searched the Cochrane Central Register of Controlled Trials [1,2].

Study selection

Identified from a pre-existing sample of child health RCTs in 2007 and 2017 [3].

Data extraction

Extracted data pertaining to trial characteristics and for risk of bias assessment.

Data analysis

We performed Pearson/Fisher Exact tests to assess the change in proportion of trial characterics and level of bias. Determined the association between trial characteristics and evidence of bias using a logistic regression model.

RESULTS

PROPORTION OF CLUSTER RCTS BY CONTINENTS IN 2007 AND 2017

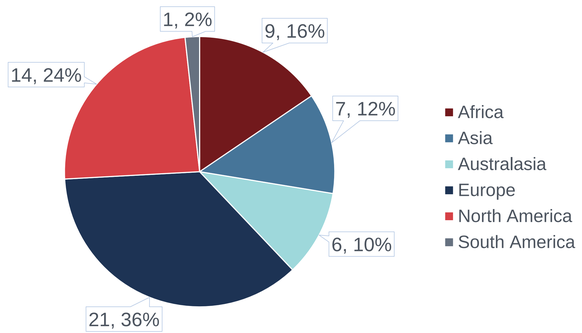

Figure 1. Proportion of published cluster RCTs by continent. Most of the cluster RCTs were from Europe (21, 36.2%) and North America (14, 24.1%).

PROPORTION OF CLUSTER RCTS BY CLUSTER TYPE IN 2007 AND 2017

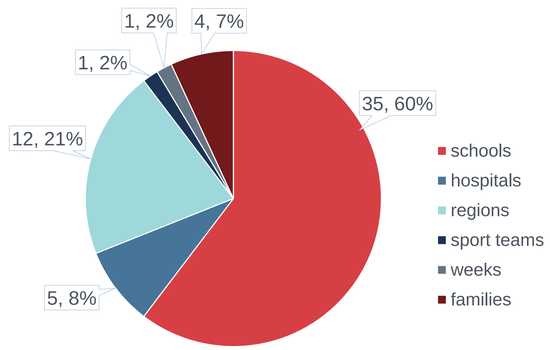

Figure 2. Cluster type distribution. Majority of the cluster RCTs (35, 60%) in our sample grouped participants by schools.

NUMBER OF CLUSTER RCTS BY YEAR OF PUBLICATION

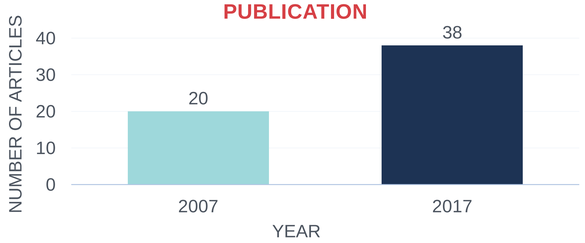

Figure 3. Cluster RCT distribution by publication year. Of the 58 trials, 35% of cluster RCTs were published in 2007 and 65% were published in 2017.

PROPORTION OF CLUSTER RCTS WITH EVIDENCE OF RISK OF BIAS IN 2007 AND 2017

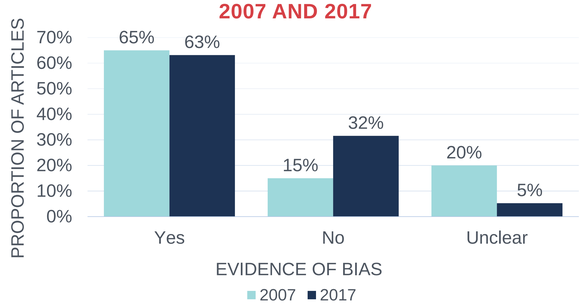

Figure 4. Proportion of cluster RCTs with evidence of risk of bias. Of the 58 trials, 37 (63.7%) showed evidence of bias with the proportion of bias observed in 2007 (65%) similar to 2017 (63%).

SOURCE OF BIAS FOR CLUSTER RCTS IN 2007 AND 2017

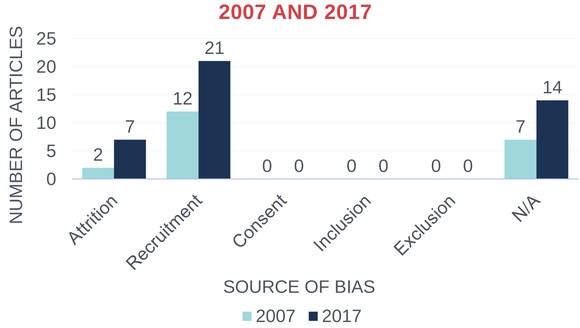

Figure 5. Source of bias distribution. Of the sources of bias investigated, recruitment bias (33, 57%) accounted for most of the bias observed with an increase between 2007 (12, 20.6%) and 2017 (21, 36.2%).

OVERALL OF RISK OF BIAS FOR CLUSTER RCTS IN 2007 AND 2017

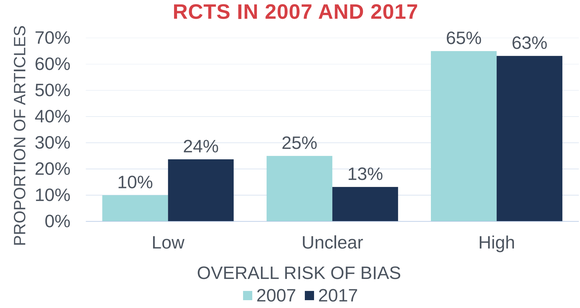

Figure 6. Over risk of bias distribution. Proportion of trials exhibiting high risk of bias observed in 2007 (65%) was similar to 2017 (63%).

CONCLUSION

- The level of bias has not changed within the studied timeframe.
- Recruitment bias is the main source of bias in cluster RCTs.

There is a need to improve the quality of cluster RCTs.

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ACKNOWLEDGEMENTS

The authors would like to thank Dr. Michele Dyson, Dr. Allison Gates, and the ARCHE group for their contribution to the 2007 and 2017 samples used in this study. We also want to thank the administrative staff of the Children's Hospital Research Institute of Manitoba and Translating Emergency Knowledge for Kids (TREKK).