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The Development of Risk of Bias Instrument for Use in Systematic Reviews for Cluster Randomized Controlled Trials (ROBUST-CRT)

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Background

- **ROBUST-RCT** recently developed, methodologically rigorous, and user-friendly tool for assessing RoB in individually parallel RCTs.

- Does not address methodological issues specific to cluster RCTs

Key cluster-specific concerns include:

  - Loss of entire clusters
  - Failure to account for clustering in the analysis

- Existing SRs use ad hoc approaches, including referring to methodological papers/handbooks, modified tools, and informal assessments.

Aims

To enhance the scope and usefulness of ROBUST-RCT by developing an extension that will address RoB in cluster RCTs included in SRs

Methods

1. Systematic survey of SRs (Completed)

- Captured tools used, guidance cited, response options, and cluster-specific items.

2. Systematic survey of methodological guidance (In Progress)

- Identifying recommendations relevant to bias in cluster RCTs.

3. Item consolidation (Planned)

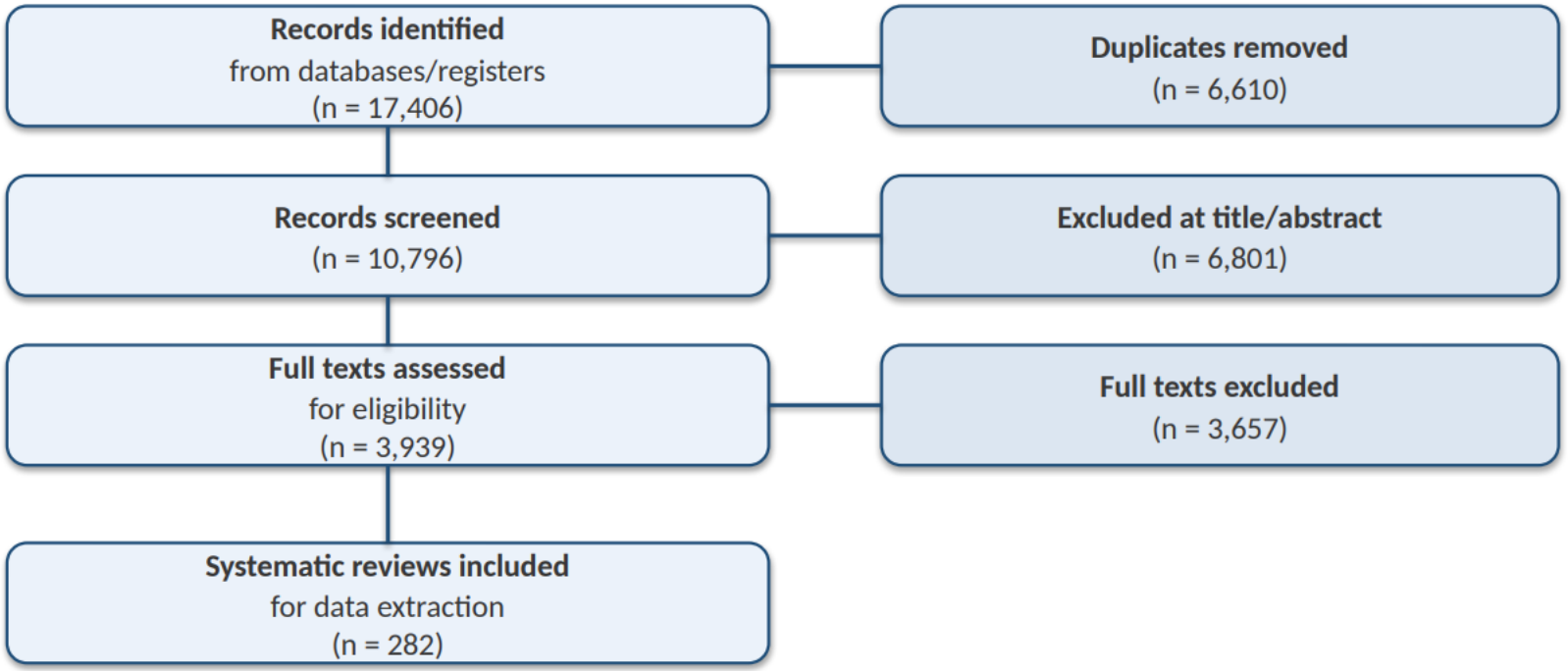
- Will remove duplicates & group items into cluster-specific domains.

4. Consensus and user testing (Planned)

- Expert panel consensus process
- User testing with reviewers to improve clarity and usability.

Results

- **Systematic Survey of SRs (Project 1)**



- Publications between 1995 and 2025.
- 207 (73.4%) Cochrane and 75 (26.6%) non-Cochrane reviews.
- 230 (81.6%) included cluster RCTs alongside other RCT designs, while 52 (18.4%) included only cluster RCTs.

Results- Ad Hoc Sources

- **Systematic Survey of SRs (Project 1)**

Sources of Items	Reviews, n (%)
Methodological guidance or handbooks	176 (62.4%)
Generated items themselves	77 (27.3%)
Modified existing RoB tools	9 (3.2%)
Reporting guideline	9 (3.2%)
Multiple approaches	15 (5.3%)

Results- Ad hoc Concepts

Ad hoc Concept	How SRs interpreted the concept
Selection / recruitment bias	• Simultaneous randomization of all sites. • Geographical separation limiting allocation awareness.
Baseline imbalance	• Addressed through stratified or pair-matched randomization or analysis. • Risk of imbalance with few randomized clusters.
Loss of clusters	• Loss or exclusion of entire clusters during follow-up or analysis

Results- Ad hoc Concepts

Ad hoc Concept	How SRs interpreted the concept
Comparability with individually randomized trials	• Herd effects may increase treatment benefits across a cluster.
Allocation Concealment	• Participants recruited after allocation was known.
Contamination	• Providers treating both arms • Participants accessing services outside assigned clusters.

Limits- First Systematic Surv

- **Inconsistent reporting:** SRs often reported broad concepts and ad hoc interpretations rather than explicit signaling questions or decision rules.

- **Subjectivity in consolidation:** Grouping overlapping concepts required judgment, some concepts may not represent genuine RoB concerns.

Conclusions

- Systematic survey identified a broad pool of cluster-specific RoB concepts and ad hoc interpretations reported in SRs.

- **Next steps**: Complete the second systematic survey of methodological guidance papers, consolidate and refine identified items with international expert consensus, develop draft ROBUST-CRT tool, user testing to improve clarity and usability.