International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Cluster-level characteristics reported in cluster randomised trials evaluating complex health intervention

INPLASY202630067
doi: 10.37766/inplasy2026.3.0067
Received: 18 March 2026
Published: 18 March 2026

Corresponding author:
Florian Manneville

florian.manneville@univ-lorraine.fr

Author Affiliation:
Université de Lorraine, Inserm, INSPIIRE, F-54000, Nancy, France
Université de Lorraine.

Manneville, F; Fournel, M; Giraud, V; Buzzi, M; Minary, L; Giraudeau, B; Agrinier, N.

ADMINISTRATIVE INFORMATION

Support - ANR : ANR-21-CE36-0007.

Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202630067

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 March 2026 and was last updated on 18 March 2026.

INTRODUCTION

Study aim To describe the reporting of cluster-level characteristics in CRTs evaluating complex health interventions, using a random sample of published CRTs.

Background Complex health interventions are increasingly used in health service, public health practice, and other areas of social policy that have consequences for health. Such interventions are characterised by several dimensions of complexity, including the presence of multiple interacting components, the number and difficulty of behaviours required from those delivering or receiving the intervention, the number of organisational levels or groups targeted, the multiplicity and variability of outcomes, and the degree of flexibility or tailoring permitted in their implementation. Because of their complexity and their strong interaction with the environments in which they are delivered, the effect of complex health interventions is often highly context-dependent.

Cluster randomized controlled trials (CRTs) are one solution commonly used to evaluate complex health interventions, particularly when interventions are delivered at the level of healthcare organizations, communities, schools, or geographical areas. In these trials, clusters (such as hospitals, primary care practices, schools, cities or communities) rather than individuals are randomized to intervention or control conditions. This design is appropriate for interventions applies naturally to the cluster (e.g., healthcare policy); when it is most ethical to apply an intervention to all within a group (e.g., school-level immunization); when lack of independence among participants may occur (e.g;., interactions between individuals within the same setting may lead to contamination between intervention and control groups).
Reporting guidelines such as the CONSORT statement extension for CRTs recommend describing both cluster-level and participant-level characteristics at baseline. In particular, item 15 of the checklist states that “baseline characteristics for cluster and individual participant levels, as applicable for each group” should be reported.

This recommendation is justified by the higher risk of chance imbalances in CRTs, as clusters rather than individuals are randomized and the number of clusters is often limited, although imbalances may also occur when the number of clusters is larger.
However, in CRTs evaluating complex health interventions, describing cluster characteristics serves an additional purpose, particularly related to the role of context, i.e., the set of characteristics and circumstances that consist of active and unique factors, within which the intervention is embedded). In CRTs, clusters represent not only units of randomization but also the context in which interventions are implemented. Characteristics of clusters such as their size, location, area deprivation level, organizational structure, population, or local health system context could interact with the intervention, and influence how interventions are delivered, adopted, and sustained, and could ultimately shape the effects they produce. In addition, because clusters reflect the contexts in which interventions are implemented, understanding their characteristics is essential for interpreting CRTs results and assessing the transferability of its findings, i.e., the extent to which its effects in a given context could be observed in another context. Decision-makers and researchers need to understand the contexts in which interventions were evaluated in order to judge whether results could apply to other contexts. Without adequate information about clusters and their contextual characteristics, it becomes difficult to determine whether variations in effect across studies reflect the intervention itself or differences in contextual conditions.
Despite these considerations, the quality of reporting of CRTs remains suboptimal. While one review showed that individual characteristics were reported in nearly 98% of CRTs, another review including a random sample of CRTs published between 2000 and 2008 found that reporting quality improved for only five of the fourteen reporting criteria following publication of the CONSORT extension for CRTs. In a related review using the same sample, only 27.3% of CRTs reported baseline cluster-level characteristics. However, this review was not specific to CRTs evaluating complex health interventions, and its findings may be outdated and not reflect current reporting practices.

METHODS

Search strategy Pubmed: ("cluster randomi* controlled trial"[Title/Abstract]) NOT ("drug*"[Title/Abstract] OR "Pharmacologic Actions"[Mesh] OR "Chemicals and Drugs Category"[Mesh] OR "protocol"[Title/Abstract] OR "Clinical Trial Protocol" [Publication Type] OR "process evaluation*"[Title/Abstract] OR "Systematic Review" [Publication Type] OR "Systematic Reviews as Topic"[Mesh] OR "Systematic Review" [Title/Abstract] OR "Meta-Analysis as Topic"[Mesh] OR "Meta-Analysis" [Publication Type] OR "Meta-Analysis" [Title/Abstract] OR "Review Literature as Topic"[Mesh]) AND ("2019/06/30"[Date - Publication] : "2024/06/30"[Date - Publication])
⍰ + filter: « Randomized Controlled trial »
Embase: 'cluster randomi* controlled trial':ab,ti NOT ('drug* therap*':ab,ti OR 'drug*':ab,ti) NOT 'process evaluation*':ab,ti NOT 'protocol*':ab,ti NOT ('systematic review':ab,ti OR 'literature':ab,ti OR 'meta analysis':ab,ti) NOT 'implementation science':ab,ti AND [randomized controlled trial]/lim AND [30-06-2019]/sd NOT [01-07-2024]/sd
+ filter: “article”

PsycInfo: (TI "cluster randomi* controlled trial" OR AB "cluster randomi* controlled trial") NOT (TI "drug* therap*" OR AB "drug* therap*" OR "drug*" OR AB "drug*") NOT (TI "process evaluation*" OR AB "process evaluation*") NOT (TI "protocol" OR AB "protocol") NOT (DE "Literature Review" OR DE "Systematic Review" OR TI "Literature Review" OR TI "Systematic Review" OR AB "Literature Review" OR TI "Systematic Review" OR AB "Meta Analysis" OR TI "Meta Analysis" OR DE "Meta Analysis") NOT (DE "Literature Review" OR DE "Systematic Review") NOT (DE "Drug Therapy" OR DE "Chemotherapy" OR DE "Drug Administration Methods" OR DE "Drug Augmentation" OR DE "Drug Dosages" OR DE "Drug Repurposing" OR DE "Hormone Therapy" OR DE "Immunotherapy" OR DE "Narcoanalysis" OR DE "Polypharmacy" OR DE "Prescribing (Drugs)" OR DE "Prescription Drug Misuse" OR DE "Prophylactic Drug Therapy" OR DE "Psychedelic Assisted Therapy" OR DE "Self-Medication" OR DE "Vitamin Therapy")
+ filter: “journal article”

Web of Science: (TI=(“cluster randomi* controlled trial”) OR AB=(“cluster randomi* controlled trial”)) NOT TI=(drug*) NOT AB=(drug*) NOT TI=(drug* therap*) NOT AB=(drug* therap) NOT TI=(process evaluation*) NOT AB=(process evaluation*) NOT TI=(protocol*) NOT AB=(protocol*) NOT TI=(implementation science*) NOT AB=(implementation science*) NOT AB=(systematic review) NOT TI=(systematic review) NOT AB=(meta-analysis) NOT TI=(meta-analysis).

Eligibility criteria Eligible articles were published in peer-reviewed journal whatever language. To cover current reporting practices, we retained articles published between June 30, 2019, and

June 30, 2024, corresponding to a five-year period. Articles reporting princeps results of CRTs evaluating complex health care interventions were included. Drug trial, articles different from original articles (e.g., briefs, reviews, editorials, comments, research protocols, conference abstracts), stepped-wedge trials, pilot studies, ancillary studies, process evaluation studies, and implementation studies were excluded.

Data extraction Two reviewers (FM and MF) independently extracted data of included studies. Disagreements were resolved by discussion. Information extracted pertained to the article (i.e., first author, year of publication, journal, trial registration number), the study objectives (effectiveness, efficacy, other), the type of the intervention (individual-cluster [i.e., primarily targeted at individuals], professional-cluster [i.e., primarily targeted at health professional with downstream consequences for individuals], external-cluster [i.e., targeted at the organizational level of the cluster], cluster-cluster [i.e., targeted at the cluster as a whole]). In addition, data on the population and sampling (i.e., recruitment area, number of cluster levels, nature of the cluster as random unit, number of clusters selection criteria, number of participants selection criteria), the type of analysis (i.e., at cluster level, individual level), and the results (i.e., number of cluster included, number of characteristics of cluster included [subdivided by purpose : randomization and/or descriptive], and number of characteristics of participants) were extracted.
The quality of the included studies was independently assessed by two reviewers (FM and MF) using the four items proposed by Eldridge et al. pertaining to the appropriate conduct of CRTs. The first item concerned the use of restricted randomization (e.g., block randomization, stratification, minimization, constrained randomization); the second, the allocation of at least four clusters per arm; the third, accounting for clustering in the sample size calculation (e.g., intraclass correlation coefficient, design effect); and the fourth, accounting for clustering in the statistical analysis (e.g., random effect at cluster level). Overall quality of included studies was describe using number and percentage.

Strategy of data synthesis / Statistical analysis Extracted data were synthesis using number and percentage.

Country(ies) involved France.

Keywords complex health intervention; cluster randomized trial; baseline characteristics; reporting.

Dissemination plans Publication in an international peer-reviewed journal, oral presentations at seminars and scientific conferences.

Contributions of each author

Author 1 - Florian Manneville - Screening and data extraction; data analysis; interpretation of results; drafting of the original manuscript.
Email: florian.manneville@univ-lorraine.fr
Author 2 - Mathieu Fournel - Data extraction; data analysis; interpretation of results; manuscript revision.
Email: fournel.mr@gmail.com
Author 3 - Victorien Giraud - Screening; manuscript revision.
Email: victorien.giraud@etu.unilim.fr
Author 4 - Marie Buzzi - interpretation of results; manuscript revision.
Email: marie.buzzi@univ-lorraine.fr
Author 5 - Laetitia Minary - study conception; interpretation of results; manuscript revision.
Author 6 - Bruno Giraudeau - study conception; interpretation of results; manuscript revision; guarantor.
Email: bruno.giraudeau@univ-tours.fr
Author 7 - Nelly Agrinier - study conception; interpretation of results; manuscript revision; guarantor.
Email: nelly.agrinier@univ-lorraine.fr