Consort 2010 statement: extension to cluster randomised trials

Marion K Campbell,[1] Gilda Piaggio,[2] Diana R Elbourne,[2] Douglas G Altman,[3] for the CONSORT Group

[1]Health Services Research Unit, University of Aberdeen, Aberdeen AB25 2ZD, UK
[2]Department of Medical Statistics, London School of Hygiene and Tropical Medicine, London, UK
[3]Centre for Statistics in Medicine, University of Oxford, Oxford, UK
Correspondence to: M K Campbell
m.k.campbell@abdn.ac.uk
Accepted: 5 July 2012
Cite this as: *BMJ* 2012;345:e5661
doi: 10.1136/bmj.e5661

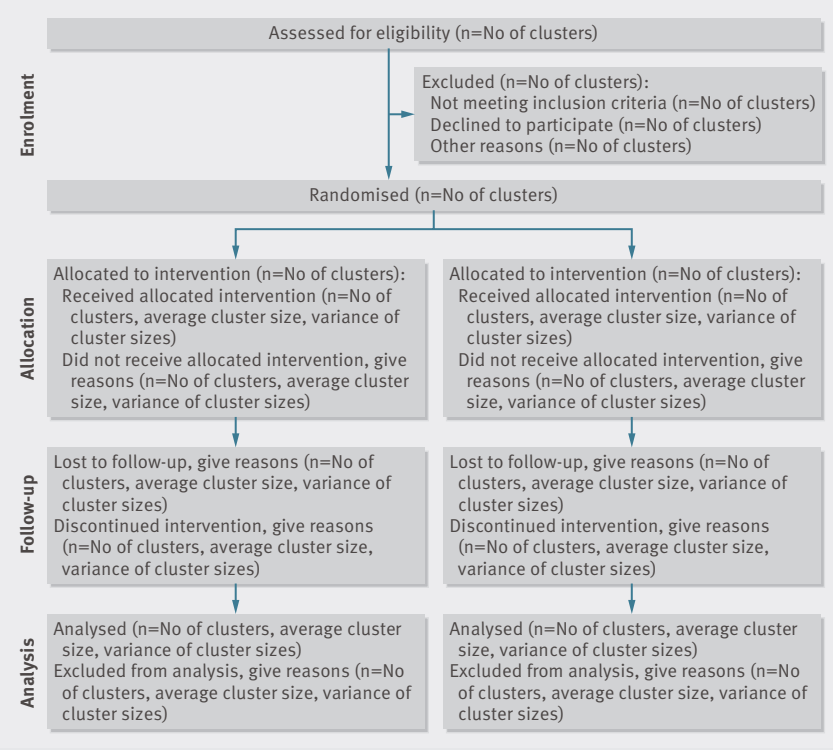
The Consolidated Standards of Reporting Trials (CONSORT) statement was developed to improve the reporting of randomised controlled trials. It was first published in 1996[1] and was revised in 2001,[2] with a further update in 2010.[3] The statement includes a checklist of items that should be included in the trial report. These items are evidence based whenever possible and are regularly reviewed.[4] The statement also recommends including a flow diagram to show the progression of participants from group assignment through to the final analysis.

The standard CONSORT statement focuses on reporting parallel group randomised controlled trials in which individual participants are randomly assigned to study groups. However, in some situations it is preferable to randomly assign groups of people (such as communities, families, or medical practices) rather than individuals. Trials with this design are variously known as field trials, community based trials, group randomised trials, place based trials, or cluster randomised trials.[5]

In earlier papers we considered the implications of the CONSORT statement for the reporting of cluster randomised trials.[6 7] Here we present updated guidance, based on the 2010 revision of the CONSORT statement[3] and the 2008 CONSORT extension for the reporting of abstracts.[8 9] The full version of this paper on bmj.com outlines the rationale for specific checklist items and presents examples of good practice.

SUMMARY POINTS

- Reports of randomised trials should include key information on their methods and findings
- Cluster randomised trials have additional reporting considerations; we previously provided guidance on these in 2004
- This paper provides updated guidance on the reporting of cluster randomised trials based on the 2010 revision of the CONSORT statement
- New guidance is provided on the reporting of abstracts of cluster randomised trials
- Routine use of this guidance should lead to improved quality of reporting



Recommended format for flow diagram of progress of clusters and individuals through phases of randomised trial

Scope of this paper

Cluster randomised trials are characterised by their multilevel nature. Most often cluster trials involve two levels—the cluster and its individual members, such as general practice and patient—although trials of more than two levels, such as hospital-ward-patient, do exist. In this paper we focus on two level cluster trials for simplicity and refer to the groups that are randomised as "clusters" (these could be families, wards, etc) and we refer to the individual members of the clusters as "participants" (as they are usually individual people) unless there is ambiguity in a particular context. On occasion, however, a single person may be a cluster, with their teeth or eyes or limbs or multiple lesions as the members of the cluster. Measurements of these teeth, eyes, etc, within one individual will be correlated and so should not be treated as independent observations. These studies have additional considerations relating to the randomisation and the comparisons being within individuals. We do not consider them in detail in this paper.

In some situations another form of clustering can be observed in individually randomised trials—for example, several patients receiving care from the same therapist or surgeon.[10] This type of clustering is also not the focus of this paper—it is discussed in the CONSORT extension for non-pharmacological treatments.[11] Nor are we interested in trials with one cluster per intervention. We further note that cluster randomised trials have no connection to cluster analysis; an exploratory multivariate statistical technique used to define clusters of similar people. Nor are they connected to the concept of cluster sampling, in which natural clusters such as geographical areas are identified and some clusters are chosen to be studied, preferably at random.

In summary, our focus is on trials that are cluster randomised by design and have two or more clusters per arm.

Table 1 | CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/topic and item No	Standard checklist item	Extension for cluster designs	Page No*
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[8 9]	See table 2	
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Rationale for using a cluster design	
2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level, or both	
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		
Participants:			
4a	Eligibility criteria for participants	Eligibility criteria for clusters	
4b	Settings and locations where the data were collected		
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level, or both	
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level, or both	
6b	Any changes to trial outcomes after the trial commenced, with reasons		
Sample size:			
7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	
7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation			
Sequence generation:			
8a	Method used to generate the random allocation sequence		
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level, or both	
Implementation:			
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replaced by 10a, 10b, and 10c	
10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	
10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	
10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both) and whether consent was sought before or after randomisation	
Blinding:			
11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		
11b	If relevant, description of the similarity of interventions		
Statistical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	
13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	

Table 1 continued on next page

Table 1 continued | CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/topic and item No	Standard checklist item	Extension for cluster designs	Page No*
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		
14b	Why the trial ended or was stopped		
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or *k*) for each primary outcome	
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory		
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[15])		
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		
Other information			
Registration:			
23	Registration number and name of trial registry		
Protocol:			
24	Where the full trial protocol can be accessed, if available		
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		

*Page numbers optional depending on journal requirements.

Table 2 | Extension of CONSORT for abstracts[8 9] to reports of cluster randomised trials

Item	Standard checklist item	Extension for cluster trials
Title	Identification of study as randomised	Identification of study as cluster randomised
Trial design	Description of the trial design (for example, parallel, cluster, non-inferiority)	
Methods:		
Participants	Eligibility criteria for participants and the settings where the data were collected	Eligibility criteria for clusters
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	Whether objective or hypothesis pertains to the cluster level, the individual participant level, or both
Outcome	Clearly defined primary outcome for this report	Whether the primary outcome pertains to the cluster level, the individual participant level or both
Randomisation	How participants were allocated to interventions	How clusters were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomised	Number of participants randomised to each group	Number of clusters randomised to each group
Recruitment	Trial status*	
Numbers analysed	Number of participants analysed in each group	Number of clusters analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Results at the cluster or individual level as applicable for each primary outcome
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

*Relevant to conference abstracts.

bmj.com/podcasts

Research: Effect of editors' implementation of CONSORT guidelines on the reporting of abstracts in high impact medical journals (*BMJ* 2012;344:e4178)

Noteworthy changes from CONSORT 2004 extension for cluster randomised trials

- The standard CONSORT checklist items and extension specific to cluster trials (table 1) presented separately
- Updated examples of good reporting practice provided
- An augmented checklist for abstracts of cluster randomised controlled trials provided
- Item 7a (sample size) expanded to include the possibility of unequal cluster sizes
- Item 10 (generation of random allocation sequence for participants) replaced by items 10a, 10b, and 10c

Updating the CONSORT extension for cluster randomised trials

To identify papers relevant to the methodology for cluster randomised trials published between 2004 and 2010, we undertook an electronic search. We also reviewed all correspondence that had been received after the publication of the 2004 extension for cluster trials. We reformatted the checklist for cluster trials in line with the style currently promoted by the CONSORT Group for the extensions for non-pharmacological interventions[11] and pragmatic trials,[12] with additions to the main CONSORT checklist items presented in a separate column.

In 2008 the CONSORT Group also produced a separate reporting checklist for abstracts of reports of randomised controlled trials,[8 9] which presented a minimum list of essential items that should be reported within a trial abstract. As part of the update process for this extension paper therefore we also reviewed the CONSORT extension for abstracts and highlighted the key areas where cluster trial specific reporting requirements would apply.

As for previous CONSORT checklists, we have included only those items deemed fundamental to the reporting of a cluster randomised controlled trial. Moreover, a few items may be crucial to a trial but not included, such as approval by an institutional ethics review board as medical journals usually address reporting ethics review in their instructions for authors. The box presents the noteworthy changes from the 2004 cluster extension paper. Table 1 presents the revised checklist for the reporting of a cluster randomised controlled trial. In table 2 we provide an augmented checklist for abstracts as it applies to cluster randomised controlled trials. The figure shows the updated flow diagram.

Discussion

Reports of randomised controlled trials should include key information on the methods and findings to allow readers to accurately interpret the results. This information is particularly important for meta-analysts attempting to extract data from such reports.

Use of the CONSORT statement for the reporting of two group parallel trials is associated with improved reporting quality.[13] We believe that the routine use of this proposed extension to the CONSORT statement will eventually result in similar improvements for cluster trials.

When reporting a cluster randomised trial, authors should address all 25 items on the CONSORT checklist using this document in conjunction with the main CONSORT guidelines.[3] Depending on the type of trial conducted, authors may also find it useful to consult the CONSORT extensions for non-pharmacological treatments[11] and non-inferiority trials.[14] The most up to date versions of all CONSORT recommendations can be found at www.consort-statement.org.

We thank Cynthia Fraser for undertaking the electronic searches, the members of the CONSORT Group for comments on drafts, and Monica Taljaard for comments on consent issues.

Contributors: MKC, DRE, DGA, and GP each took lead responsibility for the writing of different components of the manuscript. All authors then input to, and commented on, the overall draft and subsequent revisions. MKC is guarantor.

Funding: The Health Services Research Unit is core funded by the Chief Scientist Office of the Scottish Government Health Directorates. DGA is supported by a Cancer Research UK programme grant (C5529). The views expressed in this paper are those of the authors alone.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Provenance and peer review: Not commissioned; externally peer reviewed.

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