



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	Reported on page No
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	3
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	3-4
Introduction			
Background and objectives			
2a	Scientific background and explanation of rationale	Rationale for using a cluster design	6-7
2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level, or both	7
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	8
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		N/A
Participants			
4a	Eligibility criteria for participants	Eligibility criteria for clusters	8
4b	Settings and locations where the data were collected		7
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	9-10
Outcomes			
6a	Completely defined pre-specified 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	10-11
6b	Any changes to trial outcomes after the trial commenced,		N/A

with reasons			
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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	8
7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
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Randomisation:			
Sequence generation			
8a	Method used to generate the random allocation sequence		8-9
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	8-9
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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	9
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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	9
10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	8
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	7-8
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Blinding			

11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		9
11b	If relevant, description of the similarity of interventions		N/A
Statistical methods			
12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	12
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		12
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	13; Figure 1
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	Figure 1
Recruitment			
14a	Dates defining the periods of recruitment and follow-up		8
14b	Why the trial ended or was stopped		N/A
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	13, 20
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	20-23; Figure 1
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	22-23
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 pre-specified from exploratory		17; eTables 5-6
Harms			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms ¹⁰⁶)		13
Discussion			
Limitations			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		28
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		24-28
Other information			
Registration			
23	Registration number and name of trial registry		HKUCTR-1964, HKU Clinical Trials Registry (EA1511048)
ProtocolN/A			
24	Where the full trial protocol can be accessed, if available		N/A
Funding			
25	Sources of funding and other support (such as supply of drugs), role of funders		Title page