

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

Section/Topic	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	Title (p.1)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) ^{1,2}	See table 2	Abstract (p. 1)
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	Design sub-section of Methods section (p.7)
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	Introduction (pp.6-7) – objectives and hypotheses both at individual level
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	Design sub-section of Methods section (p.7)

	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		NA
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	Participants sub-section of Methods section (pp.7-8)
	4b	Settings and locations where the data were collected		Procedures sub-section of Methods section (pp.11-12)
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	The HSS model in the Introduction section (pp.3-6), The intervention sub-section in the Methods section (pp. 13-14) Tables 1 and 2
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	Introduction (p.6) Measures sub-section of Methods section
	6b	Any changes to trial outcomes after the trial		NA

		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 <i>k</i>), and an indication of its uncertainty	Participants subsection of Methods section (p. 8)
	7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		Procedures subsection of Methods section (p.12)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	No restriction or matching
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster	Procedures subsection of Methods section (p.12)

		containers), describing any steps taken to conceal the sequence until interventions were assigned	level, the individual participant level or both	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	Procedures sub-section of Methods section (p.12)
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	Procedures sub-section of Methods section (p.12)
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	Procedures sub-section of Methods section (p. 12)
	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	Procedures sub-section of Methods section (p.12)

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		No blinding Design sub-section of Methods section (p.7) Procedures sub-section of Methods section (pp.12-13)
	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	Data analysis sub-section of Method section (pp.14-15)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		Data analysis sub-section of Method section (pp. 14-15) – analysis of follow-up data
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 each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1 The sample sub-section of Results section (pp.15-16)

		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	Figure 1 The sample subsection of Results section (pp.15-16)
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Procedures subsection
	14b	Why the trial ended or was stopped		NA
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	Table 3
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	Table 5
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Result section

		as 95% confidence interval)	
	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	Results section
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms ³)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Eighth paragraph of Discussion and Application to Practice section (p.30)

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	Discussion and Application to Practice section
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		Discussion and Application to Practice section
Other information				
Registration	23	Registration number and name of trial registry		Methods section (p.12) This study was registered with ISRCTN Registry (ISRCTN16238864).
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		Quality Education Fund (included in submission information)

* Note: page numbers optional depending on journal requirements

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- ¹ Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283
 - ² Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20
 - ³ Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.