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	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[11 12]	See table 2	See section “Abstract”
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Rationale for using a cluster design	See section “introduction”
2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level, or both	See section “introduction”, paragraph 3
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	See section “study design and participants”, paragraph 1-2. Section “Randomisation and masking”, paragraph 1.
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		See section “study design and participants”, paragraph 3

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Participants:			
4a	Eligibility criteria for paticipants	Eligibility criteria for clusters	See section “study design and participants”, paragraph 2.
4b	Settings and locations where the data were collected		See section “study design and participants”, paragraph 1. See section “Data collection”, paragraph 1
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	See section “procedure”, paragraph 1.
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	See section “outcomes”, “Secondary neonatal outcomes”, “Exploratory neonatal outcomes”, “Secondary maternal outcomes”, “Exploratory maternal outcome” Section “Sample size and statistical analysis” paragraph 1.
6b	Any changes to trial outcomes after the trial commenced, with reasons		See section “Data collection”
Sample size:			
7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or	See section “Sample size and statistical analysis”, paragraph 1

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		unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	See section “Randomisation and masking”
7b	When applicable, explanation of any interim analyses and stopping guidelines		See section “Procedures”, paragraph 3
Randomisation			
Sequence generation:			
8a	Method used to generate the random allocation sequence		See section “Randomisation and masking”
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	See section “Randomisation and masking”
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	See section “Randomisation and masking”
Implementation:			
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replaced by 10a, 10b, and 10c	See section “Randomisation and masking” See section “procedure”, paragraph 2.

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10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	See section “Randomisation and masking” and “procedure”
10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	See section “Study design and participants”, paragraph 2
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	See section “Study design and participants”, paragraph 4
Blinding:			
11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		See section “Study design and participants”, paragraph 1 See section “Randomisation and masking”
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	See section “Sample size and statistical analysis”, paragraph 2-3

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12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		See section “Sample size and statistical analysis”, paragraph 2-3
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	See figure 1 and figure S1. See section “results”, paragraph 1-2.
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	See figure 1 and figure S1. See section “results”, paragraph 1-2.
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		See section “results”, paragraph 1
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	See table 1, table S12 and S16.
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the	For each group, number of clusters included in each analysis	See section “results”, paragraph 1-2.

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	analysis was by original assigned groups		
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	See table 2 and 3.
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		See table 2 and 3.
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory		See table 2 and 3.
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms106)		See section “results”, paragraph 5
Discussion			
Limitations:			

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20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		See section “discussion”, paragraph 6
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	See section “discussion”, paragraph 5
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		See section “discussion”, paragraph 8 See section “conclusion”
Other information			
Registration:			
23	Registration number and name of trial registry		See section “Trial registration”
Protocol:			
24	Where the full trial protocol can be accessed, if available		See section “methods”, paragraph 1
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		See section “funding”

*Page numbers optional depending on journal requirements.