

CONSORT - CHECKLIST OF ITEMS TO INCLUDE WHEN REPORTING A CLUSTER RANDOMISED TRIAL	
DETAILS	REPORTED ON PAGE NO
<b>Title and abstract</b>	
Design 1* How participants were allocated to interventions (eg random allocation, randomised, or randomly assigned), <i>specifying that allocation was based on clusters</i>	2
<b>Introduction</b>	
Background 2* Scientific background and explanation of rationale, <i>including the rationale for using a cluster design</i>	3, 5
<b>Methods</b>	
Participants 3* Eligibility criteria for participants <i>and clusters</i> and the settings and locations where the data were collected	4,5
Interventions 4* Precise details of the interventions intended for each group, <i>whether they pertain to the individual level, the cluster level, or both</i> , and how and when they were actually administered	4
Objectives 5* Specific objectives and hypotheses <i>and whether they pertain to the individual level, the cluster level, or both</i>	3,4
Outcomes 6* Report clearly defined primary and secondary outcome measures, <i>whether they pertain to the individual level, the cluster level, or both</i> , and, when applicable, any methods used to enhance the quality of measurements (eg multiple observations, training of assessors)	3,4
Sample size 7* How <i>total</i> sample size was determined ( <i>including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty</i> ) and, when applicable, explanation of any interim analyses and stopping rules	6
Randomisation:	
Sequence generation 8* Method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, <i>matching</i> )	5
Allocation concealment 9* Method used to implement the random allocation sequence, <i>specifying that allocation was based on clusters rather than individuals</i> and clarifying whether the sequence was concealed until interventions were assigned	5
Implementation 10 Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups	5
Blinding (masking) 11 Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated	5
Statistical methods 12* Statistical methods used to compare groups for primary outcome(s) <i>indicating how clustering was taken into account</i> ; methods for additional analyses, such as subgroup analyses and adjusted analyses	6
<b>Results</b>	
Participant flow 13* Flow of <i>clusters and</i> individual participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of <i>clusters and</i> participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome. Describe protocol deviations from study as planned, together with reasons	7, 13
Recruitment 14 Dates defining the periods of recruitment and follow up	7
Baseline data 15* Baseline information for each group <i>for the individual and cluster levels as applicable</i>	7,15

Numbers analysed 16* Number of <i>clusters and</i> participants (denominator) in each group included in each analysis and whether the analysis was by intention to treat. State the results in absolute numbers when feasible (eg 10/20 not 50%)	7,13, 16-19
Outcomes and estimation 17* For each primary and secondary outcome, a summary of results for each group <i>for the individual or cluster level as applicable</i> , and the estimated effect size and its precision (eg 95% confidence interval) <i>and a coefficient of intracluster correlation (ICC or k) for each primary outcome</i> .	7,8, 16-19
Ancillary analyses 18 Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory	3,4
Adverse events 19 All important adverse events or side effects in each intervention group	7,8
<b>Discussion</b>	
Interpretation 20 Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	8-10
Generalisability 21* Generalisability (external validity) <i>to individuals and/or clusters (as relevant)</i> of the trial findings	10
Overall evidence 22 General interpretation of the results in the context of current evidence	9-10

\*Addition to CONSORT guidelines 2001