# CONSORT Statement

**Checklist of items to include when reporting a cluster randomised trial**
**(adaptations from standard guidelines in italic)**

| ***PAPER SECTION*** **And topic** | **Item** | **Descriptor** | **Reported in section** |
|---|---|---|---|
| *TITLE & ABSTRACT* | 1 | How participants were allocated to interventions (eg random allocation, randomised, or randomly assigned), *specifying that allocation was based on clusters.* | Title |
| *INTRODUCTION* Background | 2 | Scientific background and explanation of rationale, *including the rationale for using a cluster design* | Introduction |
| *METHODS* Participants | 3 | Eligibility criteria for participants *and clusters* and the settings and locations where the data were collected | Methods: Site and population, Design; Fig. 1 |
| Interventions | 4 | Precise details of the interventions intended for each group, *whether they pertain to the individual level, the cluster level, or both,* and how and when they were actually administered. | Methods: Implementation of the intervention; Fig. S1 |
| Objectives | 5 | Specific objectives and hypotheses *and whether they pertain to the individual level, the cluster level, or both.* | Introduction |
| Outcomes | 6 | Report clearly defined primary and secondary outcome measures, *whether they pertain to the individual level, the cluster level, or both*, and, when applicable, any methods used to enhance the quality of measurements (eg multiple observations, training of assessors) | Methods: Outcome, Data collection and field staff |
| Sample size | 7 | How *total* sample size was determined *(including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty*) and, when applicable, explanation of any interim analyses and stopping rules. | Methods: Design |
| Randomization -- Sequence generation | 8 | Method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, *matching*) Allocation. | Methods: Design |
| Randomization -- Allocation concealment | 9 | Method used to implement the random allocation sequence, *specifying that allocation was based on clusters rather than individuals and* clarifying whether the sequence was concealed until interventions were assigned. | Methods: Design |
| Randomization -- Implementation | 10 | Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups. | Methods: Design |
| 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. | Methods: Design; Discussion |
| Statistical methods | 12 | Statistical methods used to compare groups for primary outcome(s) *indicating how clustering was taken into account*; methods for additional analyses, such as subgroup analyses and adjusted analyses. | Methods: Statistical analysis |
| *RESULTS* Participant flow | 13 | Flow of *clusters and* individual participants through each stage. Specifically, for each group report the numbers of *clusters and* 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. | Results: Participant flow and recruitment; Fig. 1 |
| Recruitment | 14 | Dates defining the periods of recruitment and follow up. | Results: Participant flow and recruitment; Figs. 1, S1 |
| Baseline data | 15 | Baseline information for each group *for the individual and cluster levels as applicable.* | Methods: Baseline characteristics; Table 2 |
| Numbers analyzed | 16 | Number of *clusters and* participants (denominator) in each group included in each analysis and whether the analysis was by intention to treat. | Methods: Statistical analysis; Fig. 1; Table 3 |
| Outcomes and estimation | 17 | For each primary and secondary outcome, a summary of results for each group *for the individual or cluster level as applicable*, and the estimated effect size and its precision (eg 95% confidence interval) *and a coefficient of intracluster correlation (ICC or k) for each primary outcome.* | Results: Diarrhoeal illness in the control and intervention arm; Table 3 |
| Ancillary analyses | 18 | Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory. | Methods: Statistical analysis; Results: Diarrhoeal illness by compliance; Table 3 |
| Adverse events | 19 | All important adverse events or side effects in each intervention group. | na |
| *DISCUSSION* 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. | Discussion |
| Generalizability | 21 | Generalisability (external validity) *to individuals and/or clusters (as relevant)* of the trial findings. | Discussion |
| Overall evidence | 22 | General interpretation of the results in the context of current evidence. | Discussion |