**Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial**

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| 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 Page 1 |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[[1]](#endnote-1),[[2]](#endnote-2) | See table 2 | Abstract “Methods and Findings” section  |
| Introduction |  |
| Background and objectives | 2a | Scientific background and explanation of rationale | Rationale for using a cluster design | Background 3rd to last paragraphs |
| 2b | Specific objectives or hypotheses | Whether objectives pertain to the the cluster level, the individual participant level or both | Background last paragraph |
| 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 | Abstract, “Methods and Findings” 2nd paragraph. background last paragraph and Methods 1st &2nd paragraphs |
| 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  | “Recruitment and participants” 1st &2nd paragraphs |
| 4b | Settings and locations where the data were collected |  | Discussion subheading ” strength and limitations” towards end of 1st paragraph. |
| 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 | Methods under Subheadings “Intervention” “the control condition” and “Participants involvement”. Discussion “strength and limitations” 2nd paragraph.  |
| 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 | Methods subheading “Primary outcome measures” Secondary outcome measures”. In “Statistical analysis” both levels (individual and cluster were considered) see 1st paragraph  |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |  | We did not report on the Stepping choice Reaction Time mentioned in trial published protocol due to instrument problem. Reporting these tests will reduce substantially the sample |
| 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 | Methods, subheading “Sample size” We did report two calculation based on small cluster size (worst case) and a larger cluster size more likely to be manageable.  |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines |  | **NA** |
| Randomisation: |  |
|  Sequence generation | 8a | Method used to generate the random allocation sequence |  | Methods under the subheading “randomisation and blinding” 1st paragraph. |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Details of stratification or matching if used | Methods under the subheading “randomisation and blinding” 1st paragraph. |
|  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 |  Methods under the subheading “randomisation and blinding” last part of the 1st paragraph. |
|  Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Replace by 10a, 10b and 10c | Methods under the subheading “randomisation and blinding” 1st paragraph. |
|  | 10a |  | Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions | Methods under the subheading “randomisation and blinding” 1st paragraph. |
|  | 10b |  | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling) | Fig 1 explain cluster recruitment and complete enumeration of those assessed, excluded and randomised. Table 1 give enumeration of village size, cluster size at randomisation and at follow-up.  |
|  | 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 | Methods subheading “Recruitment and participants” – we sought Individual consent, including GP appoval.  |
|  |  |  |  |  |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |  | Methods under the subheading “randomisation and blinding” 1st and 2nd paragraphs. |
| 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 | Methods subheading “Statistical analysis” 1st paragraph.  |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |  | Methods subheading “Statistical analysis” 2nd paragraph. |
| 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 | Flow chart (Fig1) and Table 1 for clusters |
| 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 | Flow chart (Fig 1) |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |  | Methods, 1st paragraph. |
| 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 2  |
| 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 | In all tables (Table 1- 4) and Supplementary tables  |
| 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 | ICC not reported |
| 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 |  | Sub group analysis included in Table 3 and supplementary exploratory analyses S2-S4 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[[3]](#endnote-3)) |  | No harm was reported  |
| Discussion |  |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |  | Abstract 4th paragraph.Discussion subheading “Strengths and limitations” 1st and 2nd paragraphs. |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Generalisability to clusters and/or individual participants (as relevant) | Discussion subheading “Strengths and limitations” start of 1st paragraph. |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |  | Discussion subheading “Main results in the context of other research” 1st to 4th paragraphs.  |
| Other information |  |  |
| Registration | 23 | Registration number and name of trial registry |  | Methods end of 1st paragraph.  |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |  | Yes ACTRN12612000889853 Supplementary file  |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders |  | In the submission online section |

*\* Note: page numbers optional depending on journal requirements*

**Table 2: Extension of CONSORT for abstracts**1**,**2**to reports of cluster randomised trials**

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| Item | Standard Checklist item | Extension for cluster trials |
| Title | Identification of study as randomised | Identification of study as cluster randomised |
| Trial design | Description of the trial design (e.g. parallel, cluster, non-inferiority) |  Abstract 2nd paragraph. Methods 1st paragraph. |
| Methods |  |  |
| Participants | Eligibility criteria for participants and the settings where the data were collected | Eligibility criteria for clusters: Fig 1 and Methods subheading “Recruitment and participants”  |
| Interventions | Interventions intended for each group |  |
| Objective | Specific objective or hypothesis | Whether objective or hypothesis pertains to the cluster level, the individual participant level or both Individual level taking into account cluster In Methods sample size calculation and Statistical analysis 1st paragraph.  |
| Outcome | Clearly defined primary outcome for this report | Whether the primary outcome pertains to the cluster level, the individual participant level or both Both - See Methods “statistical analysis” 1st paragraph. |
| Randomization | How participants were allocated to interventions | How clusters were allocated to interventionsRandom allocation; within Dance group there were two styles allocated based on pragmatic consideration and not at random (see Methods “intervention” and study limitations) |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | Methods subheading “Randomisation and blinding”  |
| Results |  |  |
| Numbers randomized | Number of participants randomized to each group | Number of clusters randomized to each group – Table 1 Fig. 1 |
| Recruitment | Trial status[[4]](#footnote-1) |  |
| Numbers analysed | Number of participants analysed in each group | Number of clusters analysed in each group – remained the same at randomised |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | Results at the cluster or individual participant level as applicable for each primary outcomeAll unadjusted and adjusted results account for cluster level.  |
| Harms | Important adverse events or side effects | No adverse events were noted  |
| Conclusions | General interpretation of the results |   |
| Trial registration | Registration number and name of trial register | Yes Methods 1st paragraph |
| Funding | Source of funding | Yes- on submission site |
|  |  |  |

**REFERENCES**

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 [↑](#endnote-ref-1)
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 [↑](#endnote-ref-2)
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. [↑](#endnote-ref-3)
4. Relevant to Conference Abstracts [↑](#footnote-ref-1)