**Additional file 1**

**Table S1: 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 | 1 |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)1,2 | See table 2 | 3-4 |
| Introduction |  |
| Background and objectives | 2a | Scientific background and explanation of rationale | Rationale for using a cluster design | 5-6 |
| 2b | Specific objectives or hypotheses | Whether objectives pertain to the the cluster level, the individual participant level or both | 6 |
| 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 | 6 |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  | 7 |
| Participants | 4a | Eligibility criteria for participants | Eligibility criteria for clusters  | 7  |
| 4b | Settings and locations where the data were collected |  | 7 |
| 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 | 8-10 |
| 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 | 11-12 |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |  | NA |
| 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 | 13 |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines |  | NA |
| Randomisation: |  |
|  Sequence generation | 8a | Method used to generate the random allocation sequence |  | 8 |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Details of stratification or matching if used | 8 |
|  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 | 8 |
|  Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Replace by 10a, 10b and 10c |  |
|  | 10a |  | Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions | 7-8 |
|  | 10b |  | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling) | 7 |
|  | 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 | 7 |
|  |  |  |  |  |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |  | 8 |
| 11b | If relevant, description of the similarity of interventions |  | 6, 8-10 |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | How clustering was taken into account | 13-14 |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |  | 13-14 |
| 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 | Figure 1 |
| 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 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |  | Supplementary File 3 |
| 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 & Supplementary File 6 |
| 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 | Figure 1 |
| 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 | 16-18, Tables 3-5, Supplementary File 6 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |  | NA |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |  | 19 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms3) |  | 19 |
| Discussion |  |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |  | 23-24 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Generalisability to clusters and/or individual participants (as relevant) | 23 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |  | 19-22 |
| Other information |  |  |
| Registration | 23 | Registration number and name of trial registry |  | 7 |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |  | 7 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders |  | 26 |

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

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| --- | --- | --- | --- |
| Item | Standard Checklist item | Extension for cluster trials |  |
| Title | Identification of study as randomised | Identification of study as cluster randomised  | Page 1 |
| Trial design | Description of the trial design (e.g. parallel, cluster, non-inferiority) |  | Page 3 |
| Methods |  |  |  |
| Participants | Eligibility criteria for participants and the settings where the data were collected | Eligibility criteria for clusters  | Page 3 |
| Interventions | Interventions intended for each group |  | Page 3 |
| Objective | Specific objective or hypothesis | Whether objective or hypothesis pertains to the cluster level, the individual participant level or both  | Page 3 |
| Outcome | Clearly defined primary outcome for this report | Whether the primary outcome pertains to the cluster level, the individual participant level or both  | Page 3 |
| Randomization | How participants were allocated to interventions | How clusters were allocated to interventions | Page 3 |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment |  | Participants not blinded. In manuscript page 8.  |
| Results |  |  |  |
| Numbers randomized | Number of participants randomized to each group | Number of clusters randomized to each group  | Page 3 |
| Recruitment | Trial status[[1]](#footnote-1) |  | NA |
| Numbers analysed | Number of participants analysed in each group | Number of clusters analysed in each group | Page 3 |
| 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 outcome | Page 3 |
| Harms | Important adverse events or side effects |  | Adverse events reported page 19 in manuscript.  |
| Conclusions | General interpretation of the results |   | Page 3 |
| Trial registration | Registration number and name of trial register |  | Page 3 |
| Funding | Source of funding |  | In manuscript page 26.  |
|  |  |  |  |

**Table S2: Extension of CONSORT for abstracts,**2**to reports of cluster randomised trials**

**REFERENCES**

 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.

**The TIDieR (Template for Intervention Description and Replication) Checklist\*:**

 Information to include when describing an intervention and the location of the information

|  |  |  |
| --- | --- | --- |
| **Item number** | **Item**  | **Where located \*\*** |
|  | Primary paper(page or appendixnumber) | Other † (details) |
|  | **BRIEF NAME** |  |  |
| **1.** | Provide the name or a phrase that describes the intervention. | \_\_\_\_6\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **WHY** |  |  |
| **2.** | Describe any rationale, theory, or goal of the elements essential to the intervention. | \_\_\_\_5-6\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **WHAT** |  |  |
| **3.** | Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL). | \_\_\_\_8-10\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.** | Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. | \_\_\_\_10-11\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **WHO PROVIDED** |  |  |
| **5.** | For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given. | \_\_\_\_8\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **HOW** |  |  |
| **6.** | Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. | \_\_\_\_8-10\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **WHERE** |  |  |
| **7.** | Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. | \_\_\_\_7\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **WHEN and HOW MUCH** |  |  |
| **8.** | Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose. | \_\_\_\_8-10\_\_\_\_\_ | Table 1 |
|  | **TAILORING** |  |  |
| **9.** | If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. | \_\_\_\_8-10\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **MODIFICATIONS** |  |  |
| **10.ǂ** | If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). | \_\_\_\_\_NA\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **HOW WELL** |  |  |
| **11.** | Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. | \_\_\_\_11\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **12.ǂ** | Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned. | \_\_\_\_15-16\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_ |

\*\* **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

ǂ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

\* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

\* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see [www.consort-statement.org](http://www.consort-statement.org)) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial** **protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see [www.spirit-statement.org](http://www.spirit-statement.org)). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see [www.equator-network.org](http://www.equator-network.org)).

1. Relevant to Conference Abstracts [↑](#footnote-ref-1)