CONSORT 2010 checklist

# Title:

No:

Date:

Type of article:

🞎 Review article

🞎Original article

🞎Short communication

🞎Case report

🞎 National Report

🞎Letter to Editor

🞎RCT

Referee name:

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| **Section/topic** | **Item No.** | **Checklist item** | Yes | **No** | **Comments** | |
| **Title** | | |  |  |  | |
| **Is the title …** | 1 | Identification as a randomized trial in the title? |  |  |  | |
| **Abstract** | | |  |  |  | |
| **Is structured summary ….** | 2 | Structured summary of trial design, methods, results, and conclusions? |  |  |  | |
| **Introduction** | | |  |  |  | |
| **Is rationale …** | 3 | Scientific background and explanation of rationale? |  |  |  | |
| **Is objectives ….** | 4 | Specific objectives or hypotheses? |  |  |  | |
| **Methods** | | |  |  |  | |
| **IsTrial design….** | 5 | Description of trial design (such as parallel, factorial) including allocation ratio?  Important changes to methods after trial commencement (such as eligibility criteria), with reasons? |  |  |  | |
| **Is Participants…** | 6 | Eligibility criteria for participants?  Settings and locations where the data were collected? |  |  |  | |
| **Is Interventions….** | 7 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered? |  |  |  | |
| **Is Outcomes….** | 8 | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed?  Any changes to trial outcomes after the trial commenced, with reasons? |  |  |  | |
| **Is Sample size….** | 9 | How sample size was determined? |  |  |  | |
|  | 10 | When applicable, explanation of any interim analyses and stopping guidelines? |  |  |  | |
| Is Randomisation? | 11 | 1-Method used to generate the random allocation sequence?  2-Type of randomisation; details of any restriction (such as blocking and block size)?  3-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  ?  4-Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions?  5-If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how?  6-If relevant, description of the similarity of interventions?  7- Statistical methods used to compare groups for primary and secondary outcomes?  8- Methods for additional analyses, such as subgroup analyses and adjusted analyses? |  |  |  | |
| **RESULTS** | | |  |  |  | | |
| **Is Results?** |  | 1- For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome?  2- For each group, losses and exclusions after randomisation, together with reasons?  3- Dates defining the periods of recruitment and follow-up?  4- Why the trial ended or was stopped?  5- A table showing baseline demographic and clinical characteristics for each group?  6- For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups?  7- For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)?  8- For binary outcomes, presentation of both absolute and relative effect sizes is recommended?  9- Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory?  10- All important harms or unintended effects in each group? |  |  |  | | |
| **DISCUSSION** | | |  |  |  | | |
| **Is Limitations..** | 24 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses? |  |  |  | | |
| **Is Generalisability..** | 25 | Generalisability (external validity, applicability) of the trial findings?  Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence? |  |  |  | | |
| **Is conclusions ….** | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research? |  |  |  | | |
| **FUNDING** | | |  |  | |  | |
| **Is funding ……** | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review? |  |  | |  | |

Additional comments

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Which of the following do you suggest about the publication of this article in the university scientific journal?

🞎Accept in present form

🞎Accept with minor changes

🞎Accept with major changes

🞎Reject

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