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:

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?			

<u>Additional comments</u>

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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