

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic No Checklist item Reported Page No Title and abstract 1a Identification as a randomised trial in the title 1 Structured summary of trial design, methods, results, and conclusions (or specific pullifunce see CONSORT for sharkarsh) 2 2 2 2 2 2 2 2 2				
that Identification as a randomised trial in the title 1a Identification as a randomised trial in the title 1b Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts). 2a Scientific background and explanation of rationale 2b Specific objectives or hypotheses 3a Description of trial design (such as parallel, factorial) including allocation ratio Important changes to methods after trial commencement (such as eligibility criteria), with reasons 4b Settings and locations where the data were collected The interventions for each group with sufficient details to allow replication, including how and when they were actually administered 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 7b When applicable, explanation of any interim analyses and stopping guidelines 7b When applicable, explanation of any interim analyses and stopping guidelines 7c Method used to generate the random allocation sequence 8d Type of randomisation; details of any restriction (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Section/Topic	Item No	Checklist item	Reported on page No
1 Identification as a randomised trial in the title 1 Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) 1 Scientific background and explanation of rationale 2 Scientific background and explanation of rationale 2 Specific objectives or hypotheses 3 Description of trial design (such as parallel, factorial) including allocation ratio 3 Important changes to methods after trial commencement (such as eligibility criteria), with reasons 4 Eligibility criteria for participants 5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered 6 Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6 Any changes to trial outcomes after the trial commenced, with reasons 7 How sample size was determined 8 Method used to generate the random allocation sequence 9 Method used to generate the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned participants to interventions 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11 If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Title and abstract			,
2b Scientific background and explanation of rationale 2b Specific objectives or hypotheses 2b Specific objectives or hypotheses 3c Description of trial design (such as parallel, factorial) including allocation ratio 3b Important changes to methods after trial commencement (such as eligibility criteria), with reasons 4b Eligibility criteria for participants 4c Eligibility criteria for participants 5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered 6c Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6c Any changes to trial outcomes after the trial commenced, with reasons 7d How sample size was determined When applicable, explanation of any interim analyses and stopping guidelines 7b When applicable, explanation of any interim analyses and stopping guidelines 7c When applicable, explanation of any restriction (such as blocking and block size) 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 participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those		1 1 1 1	Identification as a randomised trial in the title Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
2b Specific objectives or hypotheses 3a Description of trial design (such as parallel, factorial) including allocation ratio Important changes to methods after trial commencement (such as eligibility criteria), with reasons 4a Eligibility criteria for participants 4b Settings and locations where the data were collected 5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered 6a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6b Any changes to trial outcomes after the trial commenced, with reasons 7a How sample size was determined 7b When applicable, explanation of any interim analyses and stopping guidelines 7a How sample size was determined 8b Type of randomisation; details of any restriction (such as blocking and block size) 9 Method used to generate the random allocation sequence (such as sequentially numbered containers), 11 Method used to implement the random allocation sequence until interventions were assigned 10 Who generated the random allocation sequence until interventions were assigned participants to interventions 11 If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Introduction Background and	2a	Scientific background and explanation of rationale	ഗ
Description of trial design (such as parallel, factorial) including allocation ratio limportant changes to methods after trial commencement (such as eligibility criteria), with reasons Eligibility criteria for participants Completed participants Eligibility criteria for participants Eligibility criteria for participants Completed participants Eligibility criteria for participants for participants to interventions Eligibility criteria for participants for participants to interventions Eligibility criteria for participants for parti	objectives	2b	Specific objectives or hypotheses	6
Description of trial design (such as parallel, factorial) including allocation ratio Important changes to methods after trial commencement (such as eligibility criteria), with reasons Heligibility criteria for participants Legibility criteria for participants to interventions Legibility criteria for methods after trial commenced for participants to interventions Legibility criteria for methods after trial commenced, with reasons Legibility criteria for participants to interventions Legibility criteria for methods after assignment to interventions were assigned participants to interventions Legibility criteria for methods after assignment to interventions (for example, participants, care providers, those	Methods			
Important changes to methods after trial commencement (such as eligibility criteria), with reasons Eligibility criteria for participants 4b Settings and locations where the data were collected The interventions for each group with sufficient details to allow replication, including how and when they were actually administered 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 How sample size was determined The When applicable, explanation of any interim analyses and stopping guidelines Method used to generate the random allocation sequence Ba Method used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned interventions Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions The fonce, who was blinded after assignment to interventions (for example, participants, care providers, those	Trial design	3a		6-7-8
4a Eligibility criteria for participants 4b Settings and locations where the data were collected 5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered 6a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6b Any changes to trial outcomes after the trial commenced, with reasons 7a How sample size was determined 7b When applicable, explanation of any interim analyses and stopping guidelines on: 8a Method used to generate the random allocation sequence 15 Type of randomisation; details of any restriction (such as blocking and block size) 16 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 participants to interventions 16 If done, who was blinded after assignment to interventions (for example, participants, care providers, those		<u>3</u> b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
4b Settings and locations where the data were collected 5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered 6a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6b Any changes to trial outcomes after the trial commenced, with reasons 7a How sample size was determined 7b When applicable, explanation of any interim analyses and stopping guidelines on: 8a Method used to generate the random allocation sequence tion 8b Type of randomisation; details of any restriction (such as blocking and block size) 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 isim 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Participants	4a	Eligibility criteria for participants	6-7-8
The interventions for each group with sufficient details to allow replication, including how and when they were actually administered 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 How sample size was determined When applicable, explanation of any interim analyses and stopping guidelines on: Method used to generate the random allocation sequence tion When applicable, explanation; details of any restriction (such as blocking and block size) 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 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions If done, who was blinded after assignment to interventions (for example, participants, care providers, those		46	Settings and locations where the data were collected	6-/-8
actually administered actually administered 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 size 7a How sample size was determined 7b When applicable, explanation of any interim analyses and stopping guidelines iisation: 8a Method used to generate the random allocation sequence neration 8b Type of randomisation; details of any restriction (such as blocking and block size) 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 who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were	i
completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6b Any changes to trial outcomes after the trial commenced, with reasons size 7a How sample size was determined 7b When applicable, explanation of any interim analyses and stopping guidelines sisation: ance 8a Method used to generate the random allocation sequence neration 8b Type of randomisation; details of any restriction (such as blocking and block size) 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 achanism Morthod used to generate the random allocation sequence (such as sequentially numbered containers), interventions 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those			actually administered	6-7-8
were assessed Any changes to trial outcomes after the trial commenced, with reasons Any changes to trial outcomes after the trial commenced, with reasons How sample size was determined The When applicable, explanation of any interim analyses and stopping guidelines Institution Method used to generate the random allocation sequence Type of randomisation; details of any restriction (such as blocking and block size) 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 interventions Type of randomisation; details of any restriction (such as blocking and block size) 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 participants to interventions Type of randomisation; details of any restriction (such as blocking and block size) 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 participants to interventions Type of randomisation; details of any restriction (such as blocking and block size) Mechanism of the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned containers), describing any steps taken to conceal the sequence of the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence of the random allocation sequence (such as blocking and block size)	Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they	
Size Any changes to trial outcomes after the trial commenced, with reasons How sample size was determined When applicable, explanation of any interim analyses and stopping guidelines Insation: Ba Method used to generate the random allocation sequence neration Bb Type of randomisation; details of any restriction (such as blocking and block size) 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 Method used to generate the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions If done, who was blinded after assignment to interventions (for example, participants, care providers, those			were assessed	6-7-8
size 7a How sample size was determined 7b When applicable, explanation of any interim analyses and stopping guidelines iisation: 8a Method used to generate the random allocation sequence neration 8b Type of randomisation; details of any restriction (such as blocking and block size) ncealment 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 mentation 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those		6b		ı
7b When applicable, explanation of any interim analyses and stopping guidelines ance 8a Method used to generate the random allocation sequence neration 8b Type of randomisation; details of any restriction (such as blocking and block size) 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 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Sample size	7a	How sample size was determined	6-7
isation: 8a Method used to generate the random allocation sequence neration 8b Type of randomisation; details of any restriction (such as blocking and block size) 11a Method used to generate the random allocation sequence 12 Method used to generate the random allocation sequence 13 Method used to generate the random allocation sequence (such as sequentially numbered containers), 14 describing any steps taken to conceal the sequence until interventions were assigned 15 Method used to generate the random allocation sequence (such as sequentially numbered containers), 16 describing any steps taken to conceal the sequence until interventions were assigned 17 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 18 Method used to generate the random allocation sequence (such as sequentially numbered containers), 18 describing any steps taken to conceal the sequence until interventions were assigned 19 Mechanism used to implement the random allocation sequence (such as blocking and block size) 10 Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), 10 describing any steps taken to conceal the sequence until interventions were assigned 10 interventions		7b	When applicable, explanation of any interim analyses and stopping guidelines	1
meration 8b Type of randomisation; details of any restriction (such as blocking and block size) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), ncealment describing any steps taken to conceal the sequence until interventions were assigned Method used to generate the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned Method used to generate the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned Method used to generate the random allocation sequence (such as blocking and block size) Mechanism of the random allocation sequence until interventions assigned participants to interventions Interventions Interventions Interventions (for example, participants, care providers, those	Randomisation:			
neration 8b Type of randomisation; details of any restriction (such as blocking and block size) ntion 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 sechanism 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Sequence	8a	Method used to generate the random allocation sequence	6-7
ncealment 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 schanism 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those	generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6-7
ncealment describing any steps taken to conceal the sequence until interventions were assigned schanism The provider of the random allocation sequence, who enrolled participants, and who assigned participants to interventions The provider of the random allocation sequence, who enrolled participants, and who assigned participants to interventions The provider of the participants of	Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	
mentation 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11 If done, who was blinded after assignment to interventions (for example, participants, care providers, those	concealment		describing any steps taken to conceal the sequence until interventions were assigned	7
mentation 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those	mechanism			6-7
11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Implementation	10		6-7
	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6-7

CONSORT 2010 checklist

Page 1

14	Sources of funding and other support (such as supply of drugs), role of funders	25	Funding
4-6	Where the full trial protocol can be accessed, if available	24	Protocol
4-6	Registration number and name of trial registry	23	Registration
			Other information
11-12	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	22	Interpretation
11-12	Generalisability (external validity, applicability) of the trial findings	21	Generalisability
12	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20	Limitations
			Discussion
9	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	19	Harms
9	pre-specified from exploratory		
	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	18	Ancillary analyses
9	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	17b	
9	precision (such as 95% confidence interval)		estimation
	For each primary and secondary outcome, results for each group, and the estimated effect size and its	17a	Outcomes and
8-9	by original assigned groups		
	For each group, number of participants (denominator) included in each analysis and whether the analysis was	16	Numbers analysed
yes	A table showing baseline demographic and clinical characteristics for each group	15	Baseline data
7-8	Why the trial ended or was stopped	14b	
8-9	Dates defining the periods of recruitment and follow-up	14a	Recruitment
8-9	For each group, losses and exclusions after randomisation, together with reasons	13b	recommended)
8-9	were analysed for the primary outcome		diagram is strongly
	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	13a	Participant flow (a
			Results
8	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12b	
8	Statistical methods used to compare groups for primary and secondary outcomes	12a	Statistical methods
	If relevant, description of the similarity of interventions	11b	
	assessing outcomes) and how		

recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist Page 2