

2017 CONSORT checklist of information to include when reporting a randomized trial assessing nonpharmacologic treatments (NPTs)*. Modifications of the extension appear in italics and blue.

Section/Topic Item	Check list item no.	CONSORT item	Extension for NPT trials	DESCRIBE
Title and abstract				Pag. 1-2
	1a	Identification as a randomized trial in the title		X
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	<i>Refer to CONSORT extension for abstracts for NPT trials</i>	Page 2 lines 1-21
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale		Pag 3, lines 1-38
	2b	Specific objectives or hypotheses		Pag. 3 lines 39-42
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	When applicable, how care providers were allocated to each trial group	Pag 4 lines 2-7 Lines 19-22
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		NA
Participants	4a	Eligibility criteria for participants	When applicable, eligibility criteria for centers and for <i>care providers</i>	Pag 4. Lines 13-18
	4b	Settings and locations where the data were collected		Pag 4 lines 9-12
Interventions†	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Precise details of both the experimental treatment and comparator	Pag 4 lines 23-38 Pag 5 lines 1-9
	5a		Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants.	NA
	5b		Details <i>of whether and</i> how the interventions were standardized.	Pag 4 lines 24-26 Pag 4 lines 33-38 Pag 5 lines 1-7

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	5c.		Details <i>of whether and</i> how adherence of care providers to the protocol was assessed or enhanced	NA
	5d		<i>Details of whether and how adherence of participants to interventions was assessed or enhanced</i>	NA
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed		Pag. 5 lines 16-18 Pag.6 lines 1
	6b	Any changes to trial outcomes after the trial commenced, with reasons		NA
Sample size	7a	How sample size was determined	When applicable, details of whether and how the clustering by care providers or centers was addressed	Pag 6 lines 28-31
	7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomization:				
- Sequence generation	8a	Method used to generate the random allocation sequence		Pag 5 lines 16-19
	8b	Type of randomization; details of any restriction (such as blocking and block size)		Pag 4 lines 35-38
- 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		Pag 4 lines 19-22
- Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		Pag 4 lines 19-20

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Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Whether or not those administering co-interventions were blinded to group assignment If done, who was blinded after assignment to interventions (e.g., participants, care providers, <i>those administering co-interventions</i> , those assessing outcomes) and how	Pag 6 lines 24-25
	11b	If relevant, description of the similarity of interventions	If blinded, method of blinding and description of the similarity of interventions	
	11c		<i>If blinding was not possible, description of any attempts to limit bias</i>	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	When applicable, details of whether and how the clustering by care providers or centers was addressed	Pag 6 lines 27-37
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		NA
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 analyzed for the primary outcome	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	Figure 2
	13b	For each group, losses and exclusions after randomization, together with reasons		Figure 2 Pag 7 lines 06-09
	13c		<i>For each group, the delay between randomization and the initiation of the intervention</i>	Pag 4 lines 33-35
	new		Details of the experimental treatment and comparator as they were implemented	Pag 5 lines 3-10
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Pag 4 lines 11-12

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	14b	Why the trial ended or was stopped		NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group.	Table 1 and 2
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups		Figure 2 Pag 7 lines 06-09
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)		Figures 3-4
	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		NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		Pag 7 lines 14-15
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	Pag 10 lines 35-38
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	Pag 10 lines 39-40
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		Pag 10 lines 9-34

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Other information				
Registration	23	Registration number and name of trial registry		Pag. 1 lines 17-19
Protocol	24	Where the full trial protocol can be accessed, if available		NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		Pag 11, lines 10-11

*Additions or modifications to the 2010 CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials

†The items 5, 5a, 5b, 5c, 5d are consistent with the Template for Intervention Description and Replication (TIDieR) checklist