

**Table 1 2017 CONSORT checklist of information to include when reporting a randomized trial assessing nonpharmacologic treatments (NPTs)\***

Section/Topic	Checklist item no.	Item	Reported on Page Number/Line Number	Reported on Section/Paragraph
<b>Title and abstract</b>				
	1a	Identification as a randomized trial in the title	Page1/Line6-7	Abstract/Paragraph2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see <i>Table 2</i> )	Page1/Line6-Page2/Line2	Abstract/Paragraph2-4
<b>Introduction</b>				
Background and objectives	2a	Scientific background and explanation of rationale	Page2/Line3-5	Introduction/Paragraph1
	2b	Specific objectives or hypotheses	Page3/Line5-6	Introduction/Paragraph1
<b>Methods</b>				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio <b>(When applicable, how care providers were allocated to each trial group )</b>	Page3/Line3-4	Methods/Paragraph1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page3/Line29-34	Methods/Paragraph2
Participants	4a	Eligibility criteria for participants <b>(When applicable, eligibility criteria for centers and for care providers )</b>	Page3/Line5-13	Methods/Paragraph1
	4b	Settings and locations where the data were collected	Page3/Line1-2	Methods/Paragraph1
Interventions†	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered <b>(Precise details of both the experimental treatment and comparator)</b>	Page3/Line46-50	Methods/Paragraph2
	5a	<b>Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants.</b>	Page3/Line46-48	Methods/Paragraph2
	5b	<b>Details of whether and how the interventions were standardized.</b>	Page3/Line49-51	Methods/Paragraph2
	5c.	<b>Details of whether and how adherence of care providers to the protocol was assessed or enhanced</b>	Page3/Line29-34	Methods/Paragraph2
	5d	<b>Details of whether and how adherence of participants to interventions was assessed or enhanced</b>	Page3/Line29-34	Methods/Paragraph2

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page4/Line1-Page5/Line8	Methods/Paragraph3-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Page4/Line1-Page5/Line8	Methods/Paragraph3-7
Sample size	7a	How sample size was determined <b>(When applicable, details of whether and how the clustering by care providers or centers was addressed )</b>	N/A	The larger the sample size within the test time range, the better
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Page5/Line19	Results/Paragraph1
Randomization:				
Sequence generation	8a	Method used to generate the random allocation sequence	Page3/Line15-16	Methods/Paragraph1
	8b	Type of randomization; details of any restriction (such as blocking and block size)	Page3/Line15-16	Methods/Paragraph1
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	Page3/Line15-16	Methods/Paragraph1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page3/Line15-16	Methods/Paragraph1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how <b>[If done, who was blinded after assignment to interventions (e.g., participants, care providers, those administering co-interventions, those assessing outcomes) and how]</b>	Page3/Line15-16	Methods/Paragraph1
	11b	If relevant, description of the similarity of interventions	Page2/Line29-34	Methods/Paragraph2
	11c	<b>If blinding was not possible, description of any attempts to limit bias</b>	Page2/Line29-34	Methods/Paragraph2
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes <b>(When applicable, details of whether and how the clustering by care providers or centers was addressed)</b>	Page5/Line10-15	Methods/Paragraph8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page5/Line10-15	Methods/Paragraph8

<b>Results</b>				
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 <b>(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 )</b>	Page5/Line1-5	Results/Paragraph1
	13b	For each group, losses and exclusions after randomization, together with reasons	Page5/Line2-3	Results/Paragraph1
	13c	<b>For each group, the delay between randomization and the initiation of the intervention</b>	Page5/Line2-3	Results/Paragraph1
	new	<b>Details of the experimental treatment and comparator as they were implemented</b>	Page5/Line2-3	Results/Paragraph1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page3/Line1-2	Methods/Paragraph1
	14b	Why the trial ended or was stopped	Page3/Line1-2	Methods/Paragraph1
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group <b>[When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group.]</b>	Table2	Table2
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Page5/Line3	Results/Paragraph1
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)	Page5/Line4-5	Results/Paragraph1
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Page5/Line2	Statistical
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page5/Line4-5	Results/Paragraph1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page5/Line4-5	Results/Paragraph1
<b>Discussion</b>				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses <b>(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)</b>	Page8/Line1-6	Discussion/Paragraph4
Generalizability	21	Generalizability (external validity, applicability) of the trial findings <b>[Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial]</b>	Page7/Line2-4	Discussion/Paragraph1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page7/Line14-17	Discussion/Paragraph2

Other information				
Registration	23	Registration number and name of trial registry	Page3/Line11-13	Methods/Paragraph1
Protocol	24	Where the full trial protocol can be accessed, if available	Page3/Line11-13	Methods/Paragraph1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page8/Line5-6	Acknowledgments/Paragr

\* 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

Cite as: Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P. CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. *Annals of Internal Medicine*. 2017 Jul 4;167(1):40–7.

**Table 2 Items to include when reporting an RCT assessing NPT in a journal or conference abstract\***

Section	Item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	Identification of the study as randomized	Page1/Line2-4	Title/Paragraph1
Authors	Contact details for the corresponding author	Page1/Line19-20	Correspondence/Paragraph5
Trial design	Description of the trial design (e.g. parallel, cluster, noninferiority)	Page1/Line2-4	Title/Paragraph1
<b>Methods</b>			
Participants	Eligibility criteria for participants and the settings where the data were collected <b>(When applicable, report eligibility criteria for centers where the intervention is performed and for care providers)</b>	Page3/Line14-26	Methods/Paragraph1
Interventions	Interventions intended for each group	Page3/Line29-34	Methods/Paragraph2
Objective	Specific objective or hypothesis	Page3/Line5-10	Introduction/Paragraph1
Outcome	Clearly defined primary outcome for this report	Page5/Line18-Page6/Line26	Results/Paragraph1-6
Randomization	How participants were allocated to interventions	Page3/Line15-16	Methods/Paragraph1
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Page3/Line14-26	Methods/Paragraph1
<b>Results</b>			
Number randomized	Number of participants randomized to each group	Page3/Line14	Methods/Paragraph1
Recruitment	Trial status	Page3/Line14-26	Methods/Paragraph1
	<b>Report any important changes to the intervention delivered from what was planned</b>	Page3/Line29-34	Methods/Paragraph2
Number analyzed	Number of participants analyzed in each group	Page5/Line4-5	Results/Paragraph1
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Page5/Line18-Page6/Line26	Results/Paragraph1-6
Harms	Important adverse events or side effects	Page5/Line4-5	Results/Paragraph1
Conclusions	General interpretation of the results	Page5/Line18-Page6/Line26	Results/Paragraph1-6

Trial registration	Registration number and name of trial register	Page8/Line33	Footnote/Paragraph2
Funding	Source of funding	Page8/Line12-13	Acknowledgments/Paragraph2

\* CONSORT = Consolidated Standards of Reporting Trials; NPT = nonpharmacologic treatment; RCT = randomized controlled trial

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Article Information: <http://dx.doi.org/10.21037/apm-20-913>

\*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.