STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT Statement

Table 1: STRICTA 2010 checklist of information to include when reporting interventions in a clinical trial of acupuncture (Expansion of Item 5 from CONSORT 2010 checklist)

Item	Detail	Reported on Page Number/Line Number	Reported on Section/ Paragraph
1. Acupuncture rationale	1a) Style of acupuncture (e.g. Traditional Chinese Medicine, Japanese, Korean, Western medical, Five Element, ear acupuncture, etc)	Page3/Line13-15	Introduction/Paragraph1
	1b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate	Page3/Line13-15	Introduction/Paragraph1
	1c) Extent to which treatment was varied	Page5/Line5-6	Methods/Paragraph2
2. Details of needling	2a) Number of needle insertions per subject per session (mean and range where relevant)	Page5/Line5-7	Methods/Paragraph2
	2b) Names (or location if no standard name) of points used (uni/bilateral)	Page5/Line5-6	Methods/Paragraph2
	2c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level	Page5/Line5-6	Methods/Paragraph2
	2d) Response sought (e.g. de qi or muscle twitch response)	Page5/Line5-6	Methods/Paragraph2
	2e) Needle stimulation (e.g. manual, electrical)	Page5/Line5-6	Methods/Paragraph2
	2f) Needle retention time	Page5/Line6-7	Methods/Paragraph2
	2g) Needle type (diameter, length, and manufacturer or material)	Page5/Line5-6	Methods/Paragraph2
3. Treatment regimen	3a) Number of treatment sessions	Page5/Line6-7	Methods/Paragraph2
	3b) Frequency and duration of treatment sessions	Page5/Line6-7	Methods/Paragraph2
4. Other components of treatment	4a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)	Page5/Line8-15	Methods/Paragraph2
	4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients	Page5/Line16-19	Methods/Paragraph3
5. Practitioner background	5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)	Page4/Line27	Methods/Paragraph2
6. Control or comparator interventions	6a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice	Page3/Line8-10	Introduction/Paragraph1
	6b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above.	Page4/Line20-27	Methods/Paragraph1

Note: This checklist, which should be read in conjunction with the explanations of the STRICTA items provided in the main text, is designed to replace CONSORT 2010's item 5 when reporting an acupuncture trial.

Table 2: CONSORT 2010 checklist with the Non-pharmacological Trials Extension to CONSORT (with STRICTA 2010 extending CONSORT Item 5 for acupuncture trials)

Section/Topic	Item No	CONSORT 2010 Statement*: Checklist item[1]. Describe:	Additional items from the Non-pharmacological Trials Extension to CONSORT[2]. Add:	Reported on Page Number/Line Number	Reported on Section/Paragraph
TITLE AND ABSTRACT					
	1.a	Identification as a randomized trial in the title	In the abstract, description of the experimental treatment, comparator, care providers, centres and blinding status.	Page2/Line3-4	Abstract/Paragraph2
	1.b	Structured summary of trial design, methods, results, and conclusions; for specific guidance see CONSORT for Abstracts [3,4]		Page2/Line1-24	Abstract/Paragraph2-4
INTRODUCTION					
Background and objectives	2.a	Scientific background and explanation of rationale		Page3/Line13-18	Introduction/Paragraph1
	2.b	Specific objectives or hypotheses		Page3/Line18-22	Introduction/Paragraph1
METHODS					
Trial design	3.a	Description of trial design (e.g., parallel, factorial) including allocation ratio		Page3/Line27-29	Methods/Paragraph1
	3.b	Important changes to methods after trial commencement (e.g. eligibility criteria), with reasons		Page4/Line27	Methods/Paragraph2
Participants	4.a	Eligibility criteria for participants	When applicable, eligibility criteria for centers and those performing the interventions.	Page4/Line8-12	Methods/Paragraph2
	4.b	Settings and locations where the data were collected		Page3/Line27	Methods/Paragraph1
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 - see Table 1 for details**	Page4/Line20-Page5/Line15	Methods/Paragraph4
Outcomes	6.a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed		Page5/Line21	Observation indicators/Paragraph1-3
	6.b	Any changes to trial outcomes after the trial commenced with reasons		Page5/Line21	Observation
Sample size	7.a	How sample size was determined	When applicable, details of whether and how the clustering by care providers or centers was addressed.	Page3/Line27	Methods/Paragraph1
	7.b	When applicable, explanation of any interim analyses and stopping guidelines		Page4/Line14	Methods/Paragraph3

Randomization					
Sequence generation	8.a	Method used to generate the random allocation sequence	When applicable, how care providers were allocated to each trial group.	Page3/Line29	Methods/Paragraph1
	8.b	Type of randomization; details of any restriction (e.g., blocking and block size)		Page3/Line29	Methods/Paragraph1
Allocation concealment	9	Mechanism used to implement the random allocation sequence (e.g., sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		Page3/Line29-31	Methods/Paragraph1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		Page3/Line29-31	Methods/Paragraph1
Blinding	11.a	If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how	Whether or not those administering co-interventions were blinded to group assignment. If blinded, method of blinding and description of the similarity of interventions.	Page3/Line29-31	Methods/Paragraph1
	11.b	If relevant, description of the similarity of interventions		Page4/Line20-Page5/Line15	Methods/Paragraph4
Statistical methods	12.a	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.	Page6/Line28-30	Statistical analysis/Paragraph1
	12.b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		Page6/Line28-30	Statistical analysis/Paragraph1
RESULTS					
Participant flow (A diagram is strongly recommended)	13.a	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.	Page3/Line27	Methods/Paragraph1
	13.b	For each group, losses and exclusions after randomization, together with reasons		Page4/Line14	Methods/Paragraph3
Implementation of intervention			Details of the experimental treatment and comparator as they were implemented.	Page4/Line20-Page5/Line15	Methods/Paragraph4
Recruitment	14.a	Dates defining the periods of recruitment and follow-up		Page3/Line27	Methods/Paragraph1
	14.b	Why the trial ended or was stopped		Page4/Line14	Methods/Paragraph3
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.	Table1-3	Table1-3

Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups		Page7/Line4	Results/Paragraph1
Outcomes and estimation	17.a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval)		Page7/Line4	Results/Paragraph1
	17.b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Page6/Line28-30	Statistical analysis/Paragraph1
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		Page7/Line4	Results/Paragraph1
Harms	19	All important harms or unintended effects in each group; for specific guidance see CONSORT for Harms [5]		Page7/Line5-7	Results/Paragraph1
DISCUSSION					
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		Page8/Line12	Discussion/Paragraph2
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.	Page8/Line25-30	Discussion/Paragraph2
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	In addition, take into account the choice of the comparator, lack of or partial blinding, unequal expertise of care providers or centers in each group.	Page8/Line25-30	Discussion/Paragraph2
Other Information					
Registration	23	Registration number and name of trial registry		Page3/Line27	Methods/Paragraph1
Protocol	24	Where the full trial protocol can be accessed, if available		Page3/Line27	Methods/Paragraph1
Funding	25	Sources of funding and other support (e.g., supply of drugs); role of funders		Page4/Line20-Page5/Line15	Methods/Paragraph4

* We strongly recommend reading this Statement in conjunction with the CONSORT 2010 explanation and elaboration [6] for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials [7], noninferiority and equivalence trials [8], herbal interventions [9], and pragmatic trials [10]. Moreover, additional extensions are forthcoming. For those and also for up-to-date references relevant to this checklist, see http://www.consort-statement.org.

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1. Schulz KF, Altman DG, Moher D for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332–c332.
2. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med 2008. 2008;148:295–309.
3. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, et al. CONSORT for reporting randomised trials in journal and conference abstracts. Lancet. 2008;371:281–3.
4. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5:e20.
5. Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, et al. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med. 2004;141:781–8.
6. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c869–c869.
7. Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. BMJ. 2004;328:702–8.
8. Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJ. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. JAMA. 2006;295:1152–60.
9. Gagnier JJ, Boon H, Rochon P, Moher D, Barnes J, et al. Reporting randomized, controlled trials of herbal interventions: an elaborated CONSORT statement. Ann Intern Med. 2006;144:364–7.
10. Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ. 2008;337:a2390.

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*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.