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

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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
1. Acupuncture rationale	1a) Style of acupuncture (e.g. Traditional Chinese Medicine, Japanese, Korean, Western medical, Five Element, ear acupuncture, etc) (page 1, line 1-2)
	1b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate (page 4-5, line 85-110)
	1c) Extent to which treatment was varied (page 4-5, line 85-110)
2. Details of needling	2a) Number of needle insertions per subject per session (mean and range where relevant) (page 6, line 141)
	2b) Names (or location if no standard name) of points used (uni/bilateral) (page 6, line 141)
	2c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level (page 6, line 144-146)
	2d) Response sought (e.g. *de qi* or muscle twitch response) (page 6, line 144-146)
	2e) Needle stimulation (e.g. manual, electrical) (page 6-7, line 149-151)
	2f) Needle retention time(page 7, line 151-152)
	2g) Needle type (diameter, length, and manufacturer or material) (page 6, line 141-144)
3. Treatment regimen	3a) Number of treatment sessions (page 7, line 152)
	3b) Frequency and duration of treatment sessions(page 7, line 152)
4. Other components of treatment	4a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice) (page 7, line 170-171)
	4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients (page 4-5, line 85-110)
5. Practitioner background	5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)(page 7, line 153-154)
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 (page 4-5, line 85-110)
	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. (page 7, line 166-171)

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.

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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 #	CONSORT 2010 Statement*: Checklist item[10]. Describe:	Additional items from the Non-pharmacological Trials Extension to CONSORT[14]. Add:
TITLE AND ABSTRACT			
	1.a	Identification as a randomized trial in the title (NA, this was not a randomized trial)	In the abstract, description of the experimental treatment, comparator, care providers, centres and blinding status.
	1.b	Structured summary of trial design, methods, results, and conclusions; for specific guidance see CONSORT for Abstracts [58,59] (page 3-4 line 51-80)	
INTRODUCTION			
Background and objectives	2.a	Scientific background and explanation of rationale (page 4-5, line 85-106)	
	2.b	Specific objectives or hypotheses (page 5, line 107-109)	
METHODS			
Trial design	3.a	Description of trial design (e.g., parallel, factorial) including allocation ratio (page 5, line 112-117)	
	3.b	Important changes to methods after trial commencement (e.g. eligibility criteria), with reasons (NA, this study had no change)	
Participants	4.a	Eligibility criteria for participants (page 5-6, line 119-130)	When applicable, eligibility criteria for centers and those performing the interventions.
	4.b	Settings and locations where the data were collected (page 5, line 114-115)	
Interventions	**5**	**The interventions for each group with sufficient details to allow replication, including how and when they were actually administered (page 6-7, line 133-170)**	**Precise details of both the experimental treatment and comparator - see Table 1 for details**
Outcomes	6.a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed (page 7-8, line 172-186)	
	6.b	Any changes to trial outcomes after the trial commenced with reasons (NA, the outcomes of this study had no changes)	
Sample size	7.a	How sample size was determined (NA, this was a cohort study, not a RCT, the sample size was determined by previous study)	When applicable, details of whether and how the clustering by care providers or centers was addressed.

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Section/Topic	Item #	CONSORT 2010 Statement*: Checklist item[10]. Describe:	Additional items from the Non-pharmacological Trials Extension to CONSORT[14]. Add:
	7.b	When applicable, explanation of any interim analyses and stopping guidelines (NA)	
Randomization			
Sequence generation	8.a	Method used to generate the random allocation sequence (NA, this was not a randomized trial)	When applicable, how care providers were allocated to each trial group.
	8.b	Type of randomization; details of any restriction (e.g., blocking and block size) (NA, this was not a randomized trial)	
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 (NA, this was not a randomized trial)	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions (NA, this was not a randomized trial)	
Blinding	11.a	If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how (NA, this was a open-label trial)	Whether or not those administering co-interventions were blinded to group assignment. If blinded, method of blinding and description of the similarity of interventions.
	11.b	If relevant, description of the similarity of interventions (NA, this was a open-label trial)	
Statistical methods	12.a	Statistical methods used to compare groups for primary and secondary outcomes (page 8-9, line 199-207)	When applicable, details of whether and how the clustering by care providers or centers was addressed.
	12.b	Methods for additional analyses, such as subgroup analyses and adjusted analyses (NA, this study did not include subgroups)	
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 (page 9, line 210-220)	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.
	13.b	For each group, losses and exclusions after randomization, together with reasons (NA, this situation did not happen in this study)	
Implementation of intervention			Details of the experimental treatment and comparator as they were implemented.

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Section/Topic	Item #	CONSORT 2010 Statement*: Checklist item[10]. Describe:	Additional items from the Non-pharmacological Trials Extension to CONSORT[14]. Add:
Recruitment	14.a	Dates defining the periods of recruitment and follow-up (page 9, line 211-213)	
	14.b	Why the trial ended or was stopped (NA, this situation did not happen in this study)	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group (table 1)	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group.
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups (page 9, line 211-215)	
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) (page 9-13, line 222-315)	
	17.b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended (NA, this situation did not happen in this study)	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory (NA, this study did not include analyses mentioned above)	
Harms	19	All important harms or unintended effects in each group; for specific guidance see CONSORT for Harms [60] (page 13, line 311-315)	
DISCUSSION			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses (page 17, line 409-415)	
Generalizability	21	Generalizability (external validity, applicability) of the trial findings (page 17, line 401-405)	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients and care providers and centers involved in the trial.
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence (page 13-16, line 317-400)	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.
OTHER INFORMATION			
Registration	23	Registration number and name of trial registry (NA, this was not a randomized trial)	

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Section/Topic	Item #	CONSORT 2010 Statement*: Checklist item[10]. Describe:	Additional items from the Non-pharmacological Trials Extension to CONSORT[14]. Add:
Protocol	24	Where the full trial protocol can be accessed, if available (NA, the trial protocol is not online)	
Funding	25	Sources of funding and other support (e.g., supply of drugs); role of funders (page 2, line 28-36)	

* We strongly recommend reading this Statement in conjunction with the CONSORT 2010 explanation and elaboration [11] for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials [61], noninferiority and equivalence trials [62], herbal interventions [63], and pragmatic trials [16]. 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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*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.