

STandards for **R**eporting **I**nterventions in **C**linical **T**rials of **A**cupuncture (STRICTA):
extending the CONSORT Statement

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:
<i>TITLE AND ABSTRACT</i>			
	1.a	Identification as a randomized trial in the title	p1 (L 1-2)
	1.b	Structured summary of trial design, methods, results, and conclusions; for specific guidance see CONSORT for Abstracts [58,59]	p8 (L 137) - p9 (L 176)
<i>INTRODUCTION</i>			
Background and objectives	2.a	Scientific background and explanation of rationale	p10 (L 182) - p12 (L 229)
	2.b	Specific objectives or hypotheses	
<i>METHODS</i>			
Trial design	3.a	Description of trial design (e.g., parallel, factorial) including allocation ratio	p12 (L 231-236)
	3.b	Important changes to methods after trial commencement (e.g. eligibility criteria), with reasons	N/A
Participants	4.a	Eligibility criteria for participants	p12 (L 238) – p13 (246)
	4.b	Settings and locations where the data were collected	p14 (L 282) – p15 (286)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	p13 (L 257) - p14 (L 280)
Outcomes	6.a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	p15 (L 288 - 300)
	6.b	Any changes to trial outcomes after the trial commenced with reasons	N/A
Sample size	7.a	How sample size was determined	p16 (L 308 - 315) N/A
	7.b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization			
<i>Sequence generation</i>	8.a	Method used to generate the random allocation sequence	p13 (L 252)
	8.b	Type of randomization; details of any restriction (e.g., blocking and block size)	p13 (L 253)

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<i>Allocation concealment</i>	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	p13 (L 253)
<i>Implementation</i>	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	p13 (L 253)
Blinding	11.a	If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how	p13 (L 254 - 255)
	11.b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12.a	Statistical methods used to compare groups for primary and secondary outcomes	p16 (L 317 - 323)
	12.b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
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	Figure 4
	13.b	For each group, losses and exclusions after randomization, together with reasons	Figure 4
Implementation of intervention			
Recruitment	14.a	Dates defining the periods of recruitment and follow-up	p13 (L 248 - 250)
	14.b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 4. p17 (L 339 - 343)
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)	Table 2 & Table 3
	17.b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A

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Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group; for specific guidance see CONSORT for Harms [60]	p20 (L 399 - 401)
<i>DISCUSSION</i>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	p22 (L 448) – p23 (L 459)
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	p22 (L 452 - 454)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	p 20 (L 403) – p23 (L 467)
<i>OTHER INFORMATION</i>			
Registration	23	Registration number and name of trial registry	p9 (L 168 - 173) p25 (L 510 – 515) p26 (530-533)
Protocol	24	Where the full trial protocol can be accessed, if available	p17 (L 335-336) p26 (L 522-525)
Funding	25	Sources of funding and other support (e.g., supply of drugs); role of funders	p9 (L 175 – 176) p26 (535) – p27 (539)

* 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>.