CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract				
	1a	Identification as a randomised trial in the title	Pg. 1 / Line 2	Title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Pg. 2 / Lines 1-22 Pg. 3 / Line 1-2	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Pg. 3 / Lines 3-21 Pg. 4 / Lines 1-17	Introduction – P. 1-6
	2b	Specific objectives or hypotheses	Pg. 4 / Lines 14-22	Introduction – P. 6-7
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Pg. 5 / Lines 2-3	Materials and Methods – P.1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Pg. 5 / Lines 19-20 Pg. 6 / Lines 4-5	Materials and Methods – P.5-6
Participants	4a	Eligibility criteria for participants	Pg. 5 / Lines 9-10	Materials and Methods – Participants and enrollment - (Figure 1)
	4b	Settings and locations where the data were collected	Pg. 5 / Lines 3-7	Materials and Methods – P.1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pg. 5 / Lines 18-22 Pg. 6 / Lines 1-5	Materials and Methods – P.4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Pg. 2 / Lines 8-10 Pg. 7 / Lines 15-22	Abstract – Methods Materials and Methods - Statistics
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A	N/A
Sample size	7a	How sample size was determined	Pg. 5 / Lines 9-10 Pg. 7 / Lines 15-22	Materials and Methods – Participants and enrollment, Statistics
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A	N/A
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	Pg. 5 / Lines 12-13	Materials and Methods – Participants and Enrollment
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Pg. 5/ Lines 2-3, Lines 10-13	Materials and Methods – P.1- Participants and Enrollment

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	Pg. 5 / Lines 12-13 Pg. 6 / Lines 20-21	Materials and Methods – Participants and Enrollment, Data Collection

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Pg. 5 / Lines 10-13	Materials and Methods – Participants and Enrollment
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Pg. 5 / Line 18 Pg. 6 / Lines 20-21	Materials and Methods – P.6 - Data Collection
	11b	If relevant, description of the similarity of interventions	Pg. 4 / Lines 7-11	Introduction – P. 5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Pg. 7 / Lines 15-22	Materials and Methods - Statistics
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Pg. 7 / Lines 4-22	Materials and Methods – Data Collection - Statistics
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 analysed for the primary outcome	Pg. 5 / Lines 9-12, 16-17	Materials and Methods – Participants and Enrollment - Figure 1, Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	Pg. 6 / Lines 4-5	Materials and Methods – P.7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Pg. 9 / Lines 11-12	Results – Opioid use
	14b	Why the trial ended or was stopped	Pg. 9 / Lines 2-3	Results – Pain – Table 4
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Pg. 8 / Line 6	Results – P. 2 – Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Pg. 2 / Lines 6-8	Abstract - Methods
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)	Pg. 7 / Lines 15-22 Pg. 8 / Lines 7-20 Pg. 9 / Lines 1-15	Materials and Methods – Statistics Results
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Pg. 8 / Line 6	Results – P. 2 – Table 1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Pg. 8 / Lines 7-13	Results – Side effects related to treatment
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pg. 11 / Lines 8-22 Pg. 12 / Lines 1-10	Discussion – P. 8-11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Pg. 3 / Lines 19-21 Pg. 4 / Lines 1-2	Introduction – P. 4
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Pg. 12 / Lines 11-16	Conclusion
Other information				

Registration	23	Registration number and name of trial registry	Pg. 2 / Lines 11-12	Abstract – Methods

Protocol	24	Where the full trial protocol can be accessed, if available	Pg. 13 / Lines 15 -17	Footnote – Ethical Statement
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Pg. 12 / Line 22 Pg. 13 / Lines 5-9	Acknowledgements – Funding Footnote – Conflicts of Interest

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Table 2 Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	Identification of the study as randomized	Pg. 1 / Line 2	Title
Authors *	Contact details for the corresponding author	Pg. 1 / Lines 17-19	P.4
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	Pg. 5 / Lines 2-3	Materials and Methods
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	Pg. 5 / Lines 3-7, 9-10	Materials and Methods – Participants and Enrollment – Figure 1
Interventions	Interventions intended for each group	Pg. 2 / Lines 7-8	Abstract - Methods
Objective	Specific objective or hypothesis	Pg. 4 / Lines 14-17	Introduction – P.6
Outcome	Clearly defined primary outcome for this report	Pg. 2 / Lines 8-10 Pg. 8 / Lines 6-20 Pg. 9 / Lines 1-15	Abstract - Methods Results
Randomization	How participants were allocated to interventions	Pg. 2 / Line 7 Pg. 5 / Lines 12-13	Abstract – Methods Materials and Methods – Participants and Enrollment
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Pg. 5 / Line 18 Pg. 6 / Lines 20-21	Materials and Methods –P.3 Materials and Methods – Data collection
Results			
Numbers randomized	Number of participants randomized to each group	Pg. 2 / Lines 6-8 Pg. 5 / Lines 9-13	Abstract – Methods Materials and Methods – Participants and enrollment

			– Figure 2
Recruitment	Trial status	Pg. 5 / Lines 9-15 and 19-22 Pg. 6 / Lines 1-3	Materials and Methods – Participants and Enrollment
Numbers analysed	Number of participants analysed in each group	Pg. 2 / Lines 6-8 Pg. 5 / Lines 9-13	Abstract – Methods Materials and Methods – Participants and enrollment – Figure 2
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Pg. 8 / Lines 7-20 Pg. 9 / Lines 1-15	Results – Differences in postoperative outcomes
Harms	Important adverse events or side effects	Pg. 8 / Lines 7-13	Results – Side effects related to treatment

Conclusions	General interpretation of the results	Pg. 12 / Lines 11-16	Conclusion
Trial registration	Registration number and name of trial register	Pg. 2 / Lines 11-12 Pg. 13 / Lines 15-17	Abstract – Methods Footnote – Ethical Statement
Funding	Source of funding	Pg. 12 / Line 22	Acknowledgements - Funding

** this item is specific to conference abstracts*

From: Hopewell S, Clarke M, Moher D, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5(1):e20

Article information: https://dx.doi.org/10.21037/aoj-22-33
*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.