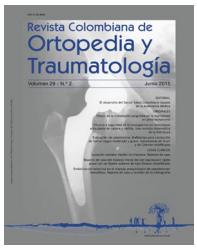
Revista Colombiana de
Ortopedia y
Traumatología
www.elsevier.es/rccot



EDITORIAL

Revista Colombiana de Ortopedia y Traumatología adopts the CONSORT statement

La Revista Colombiana de Ortopedia y Traumatología adopta formalmente la declaración CONSORT para estudios clínicos aleatorizados

Juan Manuel Herrera-Arbelaez

Chief-Editor, Revista Colombiana de Ortopedia y Traumatología

Received 28 April 2021; accepted 30 April 2021

''*Thou shalt randomize*''[1]

Martin A. Weinstock

With this scientific command, researchers illuminate the rest of the world with the most rigorous and reliable type of evidence about the usefulness of therapies and other interventions for patient care and public health. However, randomization poses a mathematical challenge widely known and described in probability more than a hundred years ago as the Bertrand paradox, Count Buffon needle problem (Geoeges-Louis Leclerc) and several others. Therefore randomization ''per se'' does not imply that the evidence is better, more rigorous, or more reliable. In fact, when the randomization method is not correctly described in probability, a default bias is created. Ultimately, this bias makes a study neither reproducible nor controversial, events that are both indisputable pillars of the scientific method.

In order for both reviewers and readers to adequately assess critical pillars of the scientific method and decision-making in patients based on the evidence, the structure and findings of each randomized trial must be presented to them as clearly as possible. Frequently, medical journals and manuscript authors do not present all the details of randomized trials clearly and transparently. In fact, important details are often omitted from the randomized experiment, creating a perceptual bias that may also be even amplified in meta-analysis.

To critically asses published randomized manuscript, readers need complete, clear, and transparent information about the methodology and findings of that clinical trial. The same occurs with peer reviewers during the manuscript acceptance process. With the intention of correcting this problem, several journal editors made what is known as the CONSORT statement (Consolidation of Standards Of Reporting Trials).[2,3]

Although the journal (Revista Colombiana de Ortopedia y Traumatología) includes the suggestion to follow the recommendations of the CONSORT statement in its guidelines for authors since 2013, as of July 1, 2021, it will be mandatory for authors of Randomized trials reports to include a complete checklist of the key elements of a randomized trial report, and indicate for each element the page on which that element is documented in the manuscript according to with the 2010 revision of the CONSORT statement. (Fig. 1) The checklist (verification) will not be published, but will be included in the material provided to the reviewers of the manuscript.

Authors also will be required to include a flow chart in the manuscript that clearly documents the

DOI of original article: https://doi.org/10.1016/j.rccot.2021.05.001
E-mail address: jmherreraarbelaez@gmail.com

https://doi.org/10.1016/j.rccot.2021.05.002

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

Figure 1 CONSORT 2010 checklist of information to include when reporting a randomised trial*.
*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.

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
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	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
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)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

number of patients who were eligible, recruited, randomized, operated on, withdrawn, or lost to follow-up, and the number evaluated at the end of the study test. (Fig. 2) Based on this, all readers can better interpret the value and applicability of the results in the publication.

You can also obtain the official translations of the checklist (verification) and the sample flow diagram in other languages, including Spanish, by downloading them from the following link:

http://www.consort-statement.org/downloads/translations

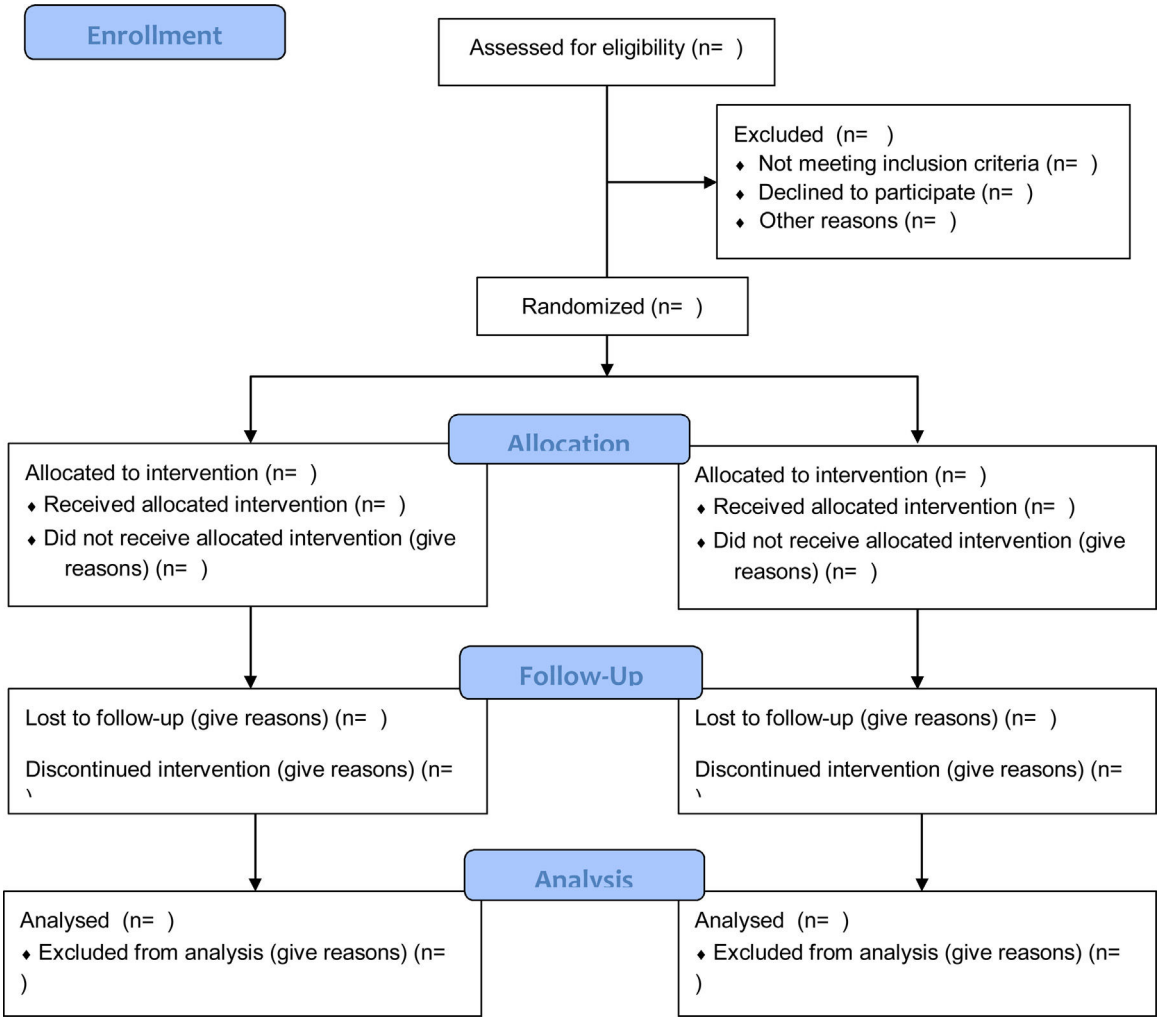


Figure 2 CONSORT 2010 Flow Diagram.

This policy will apply to all manuscripts that are reported as randomized trials, regardless of the section of the journal in which they appear or whether they appear in a sponsored supplement. Authors can obtain a copy of the checklist and sample flowchart in English by downloading it from the following link: http://www.consort-statement.org.

References

1. Weinstock MA. The J.A.A.D.adopts the consort Statement. J Am Acad Dermatol. 1999;41:1045–7, http://dx.doi.org/10.1016/s0190-9622(99)70267-7.
2. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials.BMJ. 2010 Mar 23;340:c332, http://dx.doi.org/10.1136/bmj.c332.
3. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF. JAMA. 1996;276:637–9, http://dx.doi.org/10.1001/jama.276.8.637.