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Review Article

The CONSORT statement

ABSTRACT

Randomized control trials (RCT's) are the gold standard in evaluating and efficiently translating research data into clinical practice. The CONSORT statement was conceptualized in order to help ascertain standardization and reproducibility of RCT's. The articles publishing the CONSORT 2010 statement along with their bibliographies were identified and thoroughly reviewed. The CONSORT statement is made up of a 25-item checklist that provides the author with a solid backbone around which to construct and present an RCT. It sets standards on the trial's design, analysis, and interpretation of the results.

Key words: Data reporting; epidemiology; publishing; research; research design

Introduction

Different epidemiological study designs are available, one of which is the randomized control trial (RCT). RCTs are the gold standard in evaluating and efficiently translating research data into clinical practice. In fact, this type of study provides the fundamentals of evidence-based medicine and is the most reliable research design out of all of the epidemiological studies available.[1] Therefore reporting of these invaluable interventions require high-quality reporting techniques, which allow transparency while enabling the readers to critically appraise the trial findings. In order to avoid systematic reporting errors while ascertaining the high-quality reporting standards of RCTs, the CONSORT statement was coined in 1996.[2] The CONSORT was revised over the years to provide clearer explanations and elaborations of the CONSORT principles. The last version was established in 2010 (available at www.consort-statement.org), on which this article will be based.[2] In fact, the original articles publishing the CONSORT 2010 statement together with their bibliographies were identified and thoroughly reviewed.

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The CONSORT Statement

The CONSORT stands for "Consolidated Standards of Reporting Trails" and was developed to aid authors to present the RCTs in a clean, transparent and complete manner, and not to act as a quality assessment tool. The CONSORT is composed of a 25-item checklist, which focuses on the reporting of the trial design, analysis, and interpretation, as seen in Table 1.[2–4] A CONSORT flowchart is also available, which displays the progress of all participants through the trail, as seen in Figure 1.[4]

The CONSORT checklist

A brief description of each checklist item is provided below.[2,3]

Item 1: Title and abstract

The manuscript title should include the words "randomized trial" in order to ensure correct indexing of the manuscript in electronic databases. Indexing of the published manuscript is of utmost importance to ensure identification of the

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Table 1: The CONSORT 2010 checklist

CONSORT 2010 checklist		
Section/topic	**Item number**	**Checklist item**
Title and abstract	1a	Identification as a randomized trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions
Introduction		
Background and objectives	2a	Scientific background and explanation of the 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
Randomization		
Sequence generation	8a	The method used to generate the random allocation sequence
	8b	Type of randomization; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	The 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
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 (e.g., 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 analyzed for the primary outcome
	13b	For each group, losses and exclusions after randomization, 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 the baseline demographic and clinical characteristics for 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
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, the multiplicity of analyses
Generalizability	21	Generalizability (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 the supply of drugs), the role of funders

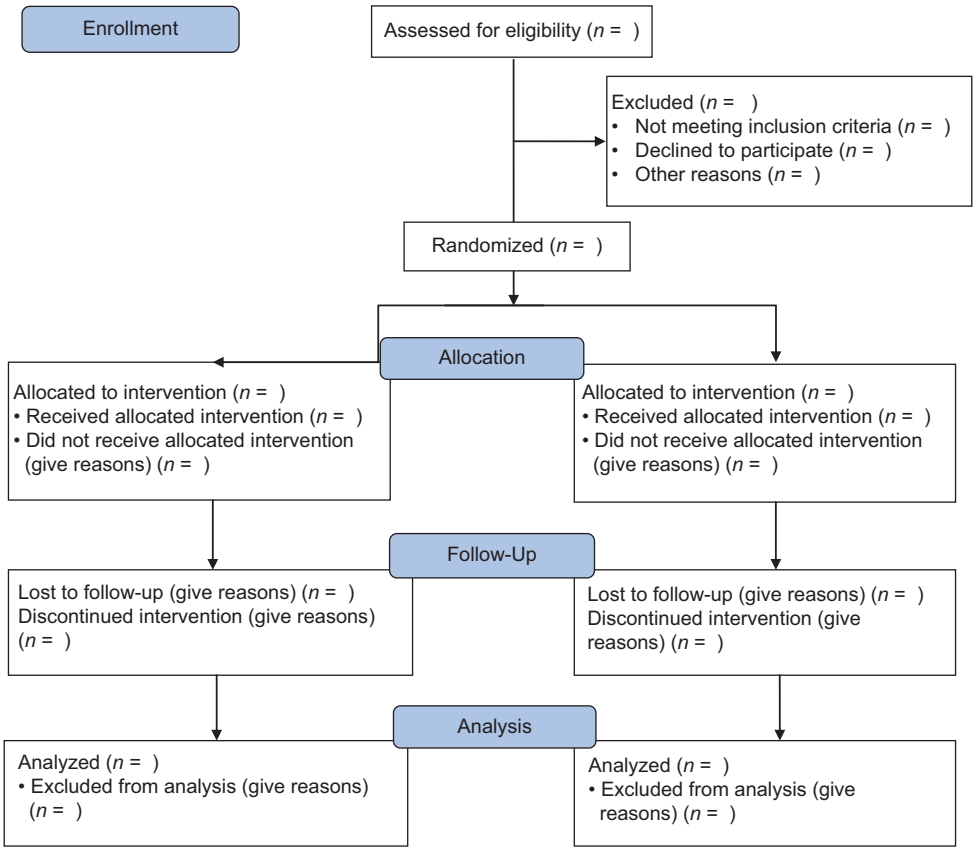

Figure 1: The CONSORT 2010 flowchart

manuscript as describing a trial. Furthermore, correct indexing also enhances the visibility of a researcher's work and increases the citation potential of the published manuscript. Citation of published manuscripts is imperative for the enhancement of the researcher's research metrics and for increasing the prestigious acknowledgment of the researcher and his/her work within the scientific community.[5]

The abstract should include a structured, brief, and clear summary of the study while presenting information found within the actual body of the manuscript. The abstract needs to be well written, since readers tend to assess the overall quality of the trial just by reading the abstract. Furthermore, since not all trial reports are fully freely available for readers, the abstract may be the only source of initial information accessible to readers.[3]

Item 2: Introduction

The Introduction section sets the scientific scene and rational as to why the trial was essential. Trials involving human subjects should have an ethical clearance and exhibit substantial benefit toward mankind.

The objective and hypothesis set out to be investigated in the trial should be reported clearly in this section.

Item 3 to 12: Methods

The Methods section should include a detailed report of how the trial was conducted including the type of design followed and the description of the protocol followed. The type of trial conducted needs to be noted clearly i.e., whether it consisted of a parallel group design or a factorial design.[3] The most common trial design followed is a randomized parallel group design, and in fact the CONSORT statement focuses mainly on such a trial design.[6] It is essential that all the eligibility criteria utilized in the trial protocol are clearly defined since this will enable the reader to interpret the study results adequately. Furthermore, the setting and location (county, city, hospital, and clinic) of the trial needs to be reported, since such information impacts on the study's validity.[3]

Sufficient detail on the intervention and the control groups are required to enable the reproducibility of the trial. When a drug intervention trial is being reported, it is essential that the drug name, dose, mode of administration, timing, and duration details are provided.

The outcome measures, be it primary or secondary outcome, should be identified and defined as part of the Methods section in order to allow readers to use the same outcomes for their own setting.[7] It is not uncommon that the initial

objective and protocol are amended throughout the course of the trial. In which case, this change should be reported.

The process of establishing an ethically and scientifically approved trial sample size needs to be noted and justified. Such information needs to provide evidence of the statistical power of the sample population under study. Furthermore, the randomization protocol of the sample population into the intervention and the control groups must be noted. Trials that follow a blinding protocol need to ensure the following: how such blinding was done, who knew about the blinding, was blinding initiated from the start of the trial, among other details. This is to ensure that any potential bias in the results is identified and accounted for.[3]

A detailed description of all the statistical analyses of the data obtained from all stages of the trial needs to be reported.

Item 13 to 19: Results

The CONSORT flowchart, as seen in Figure 1, is provided to guide the author to the details required in the Results section. It is strongly recommended that the author utilizes the CONSORT flowchart to illustrate the trial outcomes. A detailed account of the intervention and the control groups are required including any loss of follow-up and any individual exclusion that occurred during the trial. If the trial ended prematurely, the reasons contributing to this need to be reported. It is suggestible to illustrate the baseline characteristics of the population under study followed by the primary and secondary outcomes of the study. Furthermore, any harms or unintended effects originating from the trial need to be reported.

Item 20 to 22: Discussion

The Discussion section should include supporting evidence to the trial's findings along with the pros and cons of the results obtained. Any external validation performed needs to be reported and discussed.

Item 23: Other information

The clinical trial should be registered at the very beginning in order to avoid any patency or infringement issues. Such details are required to be included in the manuscript reporting the clinical trial. The details of where a reader can access the full trial protocol needs to be included as well. Clinical trials are very expensive to conduct and funding will be required for it to be successful. All funding sources and the role of the funders in the trial's protocol are imperative to be stated in manuscripts.

Conclusion

The CONSORT statement is a constantly updated guideline developed to aid RCTs authors in adequately reporting any trial. A 25-checklist and a flowchart comprise the CONSORT statement. Reporting and publishing trials in any journal require the authors to follow the CONSORT statement while writing their manuscript to ensure publication consideration.

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Conflicts of interest

There are no conflicts of interest.

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