Editorial

Reporting of Clinical Trials: Should we adopt CONSORT Statement?

Ijaz Hussain
Department of Dermatology, King Edward Medical College/Mayo Hospital, Lahore

Reports of clinical trials especially randomized, controlled trials (RCT) are subjected to a good deal of controversy. The bias may be in the recruitment of patients, methodology or the assessment of efficacy and safety. To circumvent these pitfalls in the objectives and conduct of a study and reliability, relevance and validity of its results, a uniform system of reporting RCTs, later termed as CONSORT statement, was formulated.[1,2]

CONSORT, an acronym for *Con*solidated *S*tandards *o*f *R*eporting *T*rials, was developed by an international group of clinical trialists, statisticians, epidemiologists and biomedical editors in the mid-1990s. The philosophy behind its development was to improve reporting of RCTs by using certain fundamental standards in the form of a checklist and a flow diagram. For convenience the checklist and diagram are called simply CONSORT. This has been a continuous evolving process and since its first draft, CONSORT statement has been periodically revised, few new items added and certain old ones deleted. The revised statement comprises a 22-item checklist (**Table 1**) and a flow diagram (**Figure 1**).[2] The checklist evidence-based items need to be addressed in the report whereas the flow diagram depicts a clear picture of the progress of all participants in the trial from the time of randomization until the end of their involvement. In addition to English, CONSORT is also published in Dutch, French, German, Japanese and Spanish languages.[1]

The basic objective of using CONSORT is to present an RCT in such a transparent manner that it is easy for the reader to comprehend and apply into practice. It may be taken as an evidence-based approach to ensure the integrity, validity and reliability of results of any study so that they can be confidently applied for the benefits of the patient. It is of crucial value not only to researchers, but also health care providers, peer reviewers and journal editors.

CONSORT has been supported by a growing number of medical journals and editorial groups including *I*nternational *C*ommittee of *M*edical *J*ournal *E*ditors (ICMJE, Vancouver group), the *C*ouncil of *S*cience *E*ditors (CSE), and the *W*orld *A*ssociation of *M*edical *E*ditors (WAME). Many top medical journals e.g. the British Medical Journal, Journal of the American Medical Association, Annals of Internal Medicine, Lancet etc. and dermatological journals e.g. Archives of Dermatology and British Journal of Dermatology require their authors to submit RCTs conforming to CONSORT. A copy of checklist is desired to identify that all items are given where to find them. Should *JPAD* also join the CONSORT club? We hold the viewpoint that good changes in the medical journalism should be adopted, the earlier the better.[1,2]

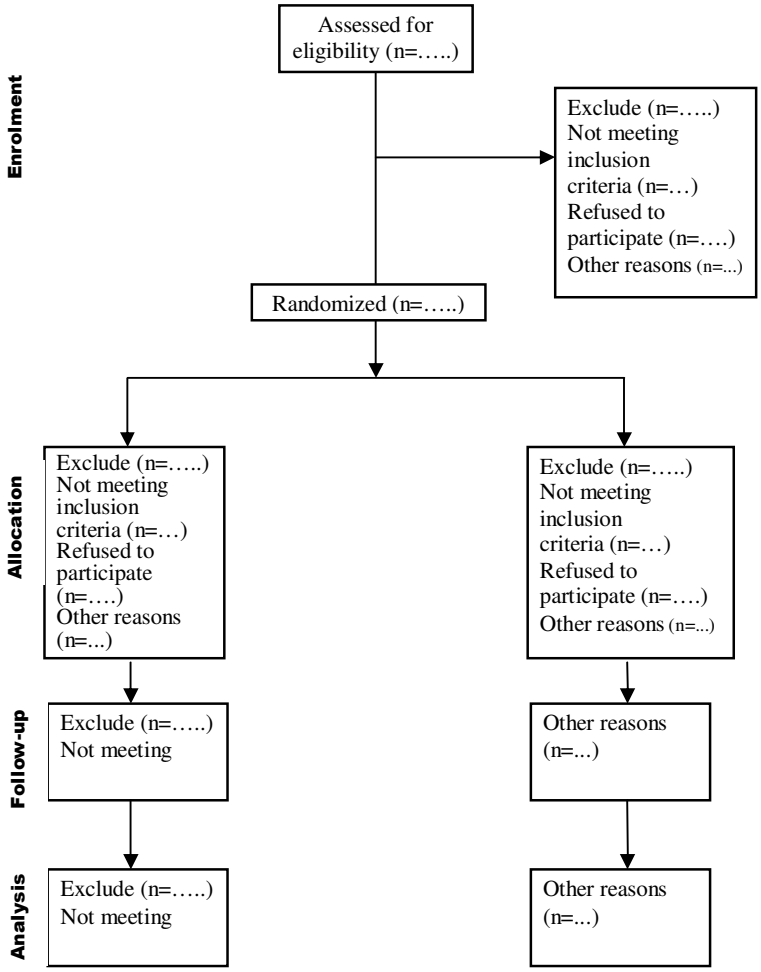
Address for Correspondence
Dr. Ijaz Hussain,
Associate Professor,
Dermatology Department,
KEMC/Mayo Hospital, Lahore.

Table 1

Checklist of items to include when reporting a randomized trial

Paper Section and Topic	Item Number	Descriptor	Reported on page number
Title and abstract	1	How participants were allocated to interventions (e.g. "random allocation", "randomized", or "randomly assigned").	
Introduction			
Background	2	Scientific background and explanation of rationale.	
Methods			
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objectives	5	Specific objectives and hypotheses.	
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g. multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomization			
Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g. blocking, stratification).	
Allocation concealment	9	Method used to implement the random allocation sequence (e.g. numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were aware of group assignment. If not, how the success of masking was assessed.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.	
Results			
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention to treat". State the results in absolute numbers when feasible (e.g. 10/20, not 50%).	
Outcomes & estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g. 95% CI).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	
Adverse events	19	All important adverse events or side-effects in each intervention group.	
Discussion			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

Figure 1
Flow diagram of subject progress through the phases of a randomized trial



For authors, the best time to consult the CONSORT is the stage of planning a trial in order to improve the conduct of study. Similarly, it would help in analyzing the results and preparing the manuscript and ensuring increased chances of getting the paper accepted. CONSORT may also be used for reviewing and evaluating reports of RCTs.

CONSORT was primarily devised for two parallel-group RCTs. However, not all trials will conform to the two-parallel-group model on which CONSORT is based. The basic principles of CONSORT can be adapted with a little interventiveness to left-right comparative studies and multiple groups. For small pilot studies, statistical power calculations are not appropriate and should not declare a treatment ineffective if they don't have power to detect an effect.

References

1. http://www.consort-statement.org (accessed 04/04/2003).

2. Moher D, Schulz KF, Altman D. The CONSORT statement: Revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001; **285**: 1987-91.