Editorial

Standardization of clinical trials

A paradigm shift has occurred in conducting the clinical trials.[1] Minimum accepted protocol for conducting the *in vivo* and clinical trials has been proposed, published by standard organizations. It is essential that these research protocols are followed in conducting and reporting the trials for wider acceptance. The clinical research starts with the research question alike any other study design and preferably it must be stated as a need for future research in recent systematic reviews. The title of the manuscript should identify it as clinical trial with a structured abstract. The study design should have an explanation on the rationale with more specific orientation toward the problem and the objective of the study. The participants must be recruited with a distinct inclusion and exclusion criteria. The merits and limitations of the study should be explained to patients before recruiting them and appropriate consent (ICMR guidelines) should be obtained.

The trial design should have a clear description on the type of design, allocation ratio, and the alternations in the protocol with justifications. The studies should report with the identifiable clinical trial registration number, method, type, mechanism of randomization sequence source of funding, protocol assessment, and a detailed protocol is mandatory for reporting clinical trials.

Majority of the studies lack the randomization, blinding, and standard analytical procedures. Not all randomization methods can be adapted for prosthodontic research. It is mandatory that suitable and applicable method is followed among the randomization.

The blinding improves research impact. Conventionally, single or double blinding is followed. The maximum blinding of research protocol should be followed to avoid the bias in research. Utmost care is taken in avoiding the bias in the research design. The amount of care followed in avoiding the bias and blinding can provide better appreciable research design. The details of participant enrollment, individual performing the intervention, and evaluator should be provided. The interventions done on patients should allow replication and should have all the details of method of data collection. The information on settings and location of environment can provide more external validity. The most updated, acceptable, and standardized protocol can provide better validity for the research. Outdated methodology and impactless protocol should be avoided to reduce the research waste. The trials alike any study design should start with definitive primary and secondary outcomes. The outcome becomes evidence for future systematic reviews and the research develops into a considerable evidence for a problem. If there are deviations made from the initial protocol, the details of it should be clearly defined with justifications on the changes made.

The clinical trial or *in vivo* studies are becoming the order of the day. They provide better research impact benefiting the patients, health-care providers, researchers, journals, and to the organizations. In comparison to earlier decades, more clinical research is being done in the past few years.[2] More likely, the significant research protocol makes it essential to follow the guidelines. Many standard guidelines are proposed to obtain a globally acceptable research. Consort guidelines were proposed to obtain the same. Any manuscript or research design has to follow these guidelines to be more acceptable for publication. The Consort provides a checklist of items that helps us to cross-check the factors that can help us to understand, improve in conducting the clinical trial or *in vivo* studies, and also aid in better appreciation.[3]

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