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Review Article

Clinical trial publications

ABSTRACT

Clinical trials are observations or experiments performed in clinical research. It is customary for researchers to publish their interim findings during the course of the trial. However, publishing the final results and outcomes is imperative. The CONSORT statement was developed to aid the randomized control clinical trial's authors to standardize the reporting of the trial's design, analysis, and interpretation of the results. Readers need to understand all the trial outcomes irrespective of whether they are beneficial or harmful as these impact future research. Well-reported clinical trials are a must as these provide the basis for systemic reviews, meta-analyses, and eventual clinical guidelines.

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

Introduction

A clinical trial is a prospective biomedical or behavioral research study that involves the participation of humans. The trial is designed to answer questions about particular interventions such as new medications, vaccines, dietary supplements, and medical devices, amongst others. The most common type of clinical trial is a randomized control trial (RCT). RCTs are the gold standard research design to evaluate and efficiently translate research data into clinical practice.[1] In such a clinical trial, the participants are randomly allocated to either the "intervention group," which is the group receiving the treatment under study, or else allocated to the "control group." The latter group receives standard treatment or else a placebo treatment. It is customary for the process to be blinded (single or double) apart from being randomized.

A clinical trial is set to progress through four phases; however, not all trials reach the end phase due to various reasons such as the development of an unexpected complication(s) or mortality, amongst others.

It is important that clinical trials get registered to national clinical trial registers and obtain an authentic trial number. Trials can be registered to more than one register simultaneously. Such a registering process ensures transparency of the trial design while the outcomes are authenticated and patented to the research body.

Publishing Clinical Trials

It is common practice that during the ongoing trial phases, the researchers start to publish interim findings. In order to aid such reporting, the CONSORT statement has been developed for the reporting of RCTs. The CONSORT statement is made up of a 25-checklist guideline and a flowchart that aids the author to present the trial's protocol, results, and outcomes in a scientific and ethical manner.[2,3] In fact, a number of journals are considering the CONSORT

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statement as a requisite for submitting RCT articles for publication.

When publishing interim findings, researchers should ensure that such publications are limited to the protocol of specified analyses that enabled the identification of statistically stable outcome(s). It is further suggested that when publishing such findings, the article title should include the word "interim." Meanwhile within the article, justification for publishing interim results should be provided.[4]

Regretfully, a percentage of the clinical trials (more than a third) only publish interim findings and fail to report the final results and outcomes. Furthermore, it is not uncommon that the final outcome(s) and conclusion(s) are altered from the initial setout plan.[5] It is essential for the trial's final results to be published in scientific journals since these provide the evidence to whether the trial obtained a beneficial or harmful or no outcome(s).[4] In addition, the readers will not be able to adequately critically appraise the clinical trial unless the end results are published. Furthermore, it is an obligation of the trial researchers to publish the clinical trial full results. The trial would have exposed humans to potential risks during its course and failing to publish the results would be ethically unacceptable as well as violating the Helsinki Declaration.[6,7] Unfortunately, it was reported that only 60% of the RCTs are fully published in scientific journals.[8] Regretfully, trials that obtain a positive outcome are more likely to be published than those obtaining a negative outcome.[8] However, such editorial practice is perilous since negative outcomes do not imply a failed trial. Rather, reporting of negative outcomes would enable other researchers to improve future protocol(s) or avoid pertaining the same research protocol.

Clinical trial data provide the basis of systemic reviews and meta-analyses, leading to the development of clinical guidelines.[6] Hence, publishing of the clinical trial results throughout the different trial phases and eventually reporting the final outcome(s) would enhance the effectiveness of systemic reviews, meta-analyses, and clinical guidelines.

Visibility of Clinical Trial Publications

When a clinical trial is published, it is recommended that the manuscript title includes the words "clinical trial" in order to ensure correct indexing of the manuscript in electronic databases. Correct indexing of the published manuscript is of utmost importance to ensure identification of the manuscript as describing a clinical 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.[9]

Conclusion

Clinical trials should have their interim and final outcomes published in scientific journals. Journal editors should permit the publication of the trial's outcome(s) irrelevant of its beneficial or harmful nature. Clinical trial publications provide the basis for systemic reviews, meta-analyses, and eventual clinical guidelines.

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Conflicts of interest
There are no conflicts of interest.

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