Randomized and controlled clinical trials

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Abstract

Randomized clinical trials, placebo-controlled are the best design for obtaining reliable results in clinical trials.

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Clinical Protocols,
Randomized Controlled Trials as Topic,
Double-Blind Method,
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INTRODUCTION

The history of clinical trials dates back to biblical times, and famous were the introduction of the smallpox vaccine by Jenner in the eighteenth century, and James Lind, who demonstrated the cure of scurvy in sailors aboard the Alisbury in 1747, by feeding them oranges and lemons.

Credit for modern clinical trials is given to Sir Austin Bradford Hill for the historic trial of streptomycin for pulmonary tuberculosis, considered a milestone in the new age of medicine.\(^1\)

The Cochrane Library’s Registered Controlled Trials Registry Center (CENTRAL) is a highly concentrated source of randomized or near-randomized clinical trials from PubMed, Embase, and ClinicalTrials.gov bibliographic databases. CENTRAL started publications in 1996. Updated data show that 1,285,036 clinical trials and 7,770 reviews Cochrane.\(^2\) were recorded.

These numbers demonstrate the importance of scientifically reliable clinical research for the benefit of the population.

OBJECTIVES

The text addresses the definition of randomized clinical trials, types of blinding design and the desirability of controlled studies.

DISCUSSION

Randomized Clinical Trial (RCT) is a revolutionary, simple, and the most robust research instrument of all. It is essentially the study in which participants are randomly allocated to receive one or more interventions. Random is synonymous with chance. It is a randomly derived Anglicism, which is a selection process in which each item or individual is just as likely to be selected unpredictably. There are tables of random numbers, or numbers generated by computer programs. The advantage of randomizing participants is to have the same probability (chance) among groups before starting a study.\(^3\)

There are variations in randomized trials to evaluate the effectiveness of interventions, for example, whether participants are exposed to interventions in parallel or cross-groups.

In addition to randomization, which helps control selection biases, a trial may incorporate the strategy known as blinding or masking. If the participant knows or thinks he or she is receiving the active drug, a psychological response may determine physical changes such as blood pressure, biochemical response, suggestion of improvement, or adverse effects.\(^1,3\)

Blinding is an attempt to make participants, investigators, and staff responsible for assessing outcomes, not interfere with outcomes, not knowing the intervention being evaluated. The participant’s evaluation bias, by the investigator is circumvented by blinding. It is not always possible, for example, for active drug formulations and placebos to have exactly the same appearance, color, size, taste, etc. When the experimental intervention is new or if there is no effective standard intervention that could be used as a control, the protocol may include an inert substance or placebo that looks similar to the experimental drug (placebo-controlled study).

A trial comparing new treatments to an existing standard may require the use of more than one placebo, known as double dummy. Each group of participants receives one of the interventions and a placebo that looks identical to the other intervention. For instance, a study comparing oral medication with parenteral medication. One group would receive the active substance tablet and a placebo injection while the other group would receive placebo tablet and an injection with the active substance.

According to the degree of blinding, the RCTs can be classified into:

1- Open; everyone involved in the clinical study knows what goes on with the interventions.
2- Single-blinded: participants do not know if they are receiving the active substance or a placebo.
3- Double-blinded: No one involved in the study protocol can identify the administered or evaluated intervention.
4- Other: Specific blindness for each party involved, investigators, who administer the medication, who evaluate the participant during the study, who evaluate the outcomes of interventions, who analyze the data obtained and who write the results and the article for publication.

CONCLUSION

Randomized, controlled clinical trials represent the best design to produce the most reliable results. The popularity of currently designed RCTs is understandable as they are convenient for researchers, pharmaceutical companies, funding agencies, regulatory agencies and publishers.

REFERENCES