


REVIEW ARTICLE

Open Access

A guide to do randomized controlled trials in the field of otolaryngology



Sameh M. Zamzam^{*} , Mosaad Abdel-Aziz, Ahmed Atef, Usama Abdel-Naseer, Mostafa Hamoda, Mohamed Salah, Hazem Dewidar, Louay Elsharkawy and Mena E. Abdelmalek

Abstract

Background: Randomized controlled trials (RCTs) are prospective comparative studies in which study groups are allocated randomly to intervention or serve as controls. RCT is the mainstay to achieve evidence in the literature in clinical research. A RCT is the main research design to study the effect of an intervention and the only way to confirm the value of a new treatment.

Main body: RCT also gives the way to generate meta-analyses and systematic reviews giving a stronger evidence for clinical practice. Evidence-based medicine (EBM) is crucial for safe, effective, and standardized patient care. Although there is an agreement on the importance of performing RCT, it can be challenging to do it efficiently including different aspects like study design, funding, randomization, blinding, follow-up, data analysis, statistics, generalization of results, and reporting of quality of the studies.

Conclusion: In this article, we gave a comprehensive review for RCT in otolaryngology discussing their importance, advantages, and drawbacks, types, steps, challenges, reporting their quality and their prevalence in the literature.

Keywords: Study design, Randomized clinical trials, Otolaryngology, Research

Background

RCT is a study in which subjects are randomly assigned into groups including a control group, to receive or not receive intervention under study. The study results are determined by comparing outcomes of interest between different groups and their statistical analysis to determine whether the difference is clinically significant or not. The terms “randomized control trial” and “randomized trial” are usually used interchangeably. However, “randomized control trial” refers to the comparison between intervention and control groups while “randomized trial” refers to the comparison between multiple intervention groups [1].

Sir Bradford Hill (1897–1991) was the first to publish RCT in medicine. He is a British epidemiologist and statistician and is considered to be the father of modern RCT. There is a progressive increase in the number of

published articles in otolaryngology. This opened the way for more evidence-based treatment recommendations and well-settled guidelines. However, this provided new challenges for otolaryngologists including continuous review for updates in the published research, ability to assess its quality, provide continuously updated treatment guidelines, and individualizing patient care according to the most recent available evidence in the literature [2, 3].

Main text

Importance of RCTs

Evidence from RCTs and subsequently systematic reviews lies at the top of the pyramid of evidence and is considered the most important source for evidence-based clinical decisions. On contrary, in observational studies, there are often differences in characteristics between study groups, this will result in bias because the outcome may differ due to such differences not due to the intervention itself. The only way to overcome this

* Correspondence: samehzamzam@hotmail.com

ENT Department, Kasr Alainy Hospital, Garden city, Cairo, Egypt