Challenges of clinical research in dentistry

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Declaration of Interests: The authors certify that they have no commercial or associative interest that represents a conflict of interest in connection with the manuscript.

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https://doi.org/10.1590/1807-3107bor-2020.vol34.0092

Randomized controlled trials (RCTs) are the most reliable primary study for treatment decisions.[1] They occupy an important place near the top of the evidence-based pyramid. However, evidence provided from RCTs can be influenced by the presence of bias.[2] Furthermore, planning and conduction of an RCT can be associated with some limitations that may undermine the evidence provided by this study design. Probably, the most well-know limitation of an RCT is its external validity.[3] Most of the RCTs present strict eligibility criteria, which makes it difficult to extrapolate their findings to other populations. It is also important to mention that RCTs are conducted under ideal situations that do not simulate the "real" world settings.

Another limitation is the frequent use of surrogate outcomes and the reliance on secondary outcomes. This is especially true in Dentistry, where only a small fraction of the trials uses clinically relevant outcomes (CROs), such as tooth loss, implant success or retention of restorations. On the other hand, most CROs in Dentistry require many years to manifest and the number of events is usually very low, which makes the use of these outcomes particularly challenging.

Other challenges in conducting an RCT include the choice of a proper trial design, data management, financial constraints and communication of the study findings to the society. Many questions may arise in the mind of clinical researchers when planning, conducting or interpreting clinical trials. How does an intervention work under usual conditions? Which is the best trial design to answer my research question? What constitutes a relevant outcome? How can I associate an economic evaluation to a clinical trial? Should I trust an industry- sponsored study? How can I communicate the benefits of tested interventions to the population?

In order to address these questions, the scientific meeting "Great Challenges in Dental Clinical Research" was held on the 06–07th June 2019, in São Paulo, Brazil. The meeting was conceived by the Center of Clinical Research of the School of Dentistry of the University of São Paulo (CEPEC-FOUSP) and was organized by the three renowned Schools of Dentistry of the University of São Paulo: Faculdade de Odontologia (FOUSP), Faculdade de Odontologia de Ribeirão Preto (FORP) and Faculdade de Odontologia de Bauru (FOB). The event was funded by the Coordination for the Improvement of Higher Education Personnel (CAPES), the Dean's Office for Research Studies of the University of São Paulo (PRP/USP) and the School of Dentistry Foundation (FFO).

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The meeting aimed to bring together researchers from all over Brazil for an in-depth discussion about designing RCTs, its conduction, limitations and challenges. The meeting featured 12 lectures along two days. Some speakers have kindly written critical reviews for this Special Issue of the Brazilian Oral Research.

This special issue contains papers written by eight speakers and their colleagues. Demarco et al. presented the advantages and limitations of practice-based research, which is an approach where clinical interventions are tested under settings closer to the "real-world" conditions. Honorio et al. described particularities of non-inferiority randomized trials, a type of RCT that aims to test if a new intervention is not less effective than the reference intervention. Pannuti et al. offered an overview about indications and limitations of the use of clinically relevant outcomes in dental trials and presented proposals to overcome challenges in the adoption of this type of outcome. Pedrazzi et al. showed the advantages, disadvantages and indications of the use of surrogate outcomes. Perazzo et al. discussed the applications of Patient Report Outcome Measures (PROMs) and Patient Report Experience Measures (PREMs), which are outcomes that express how patients feel and function about their health and life. Braga et al. approached on how to associate economic evaluations to dental clinical trials, presenting important items of it, such as time horizon and perspective, health effects, costs and data analysis. Cortelli et al. reported some aspects related to industry-sponsored studies, such as confidentiality, authorship, agreement and budget. Finally, Nadanovsky et al. cited limitations in the communication of diagnostic test accuracy and benefits of interventions, and suggested strategies for improving risk communication in clinical researches.

We do believe that these critical reviews will provide information of outmost importance for researchers and students interested in the knowledge to support the planning, development, and interpretation of clinical research in dentistry.

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