

Randomized Clinical Trials: why do we need to appropriate this method?

Ensaio clínico randomizado: porque precisamos nos apropriar deste método?

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Randomized Clinical Trials (RCTs) are studies designed to assess the efficacy of a therapeutic or prophylactic intervention on a given outcome. They are considered the gold standard for testing the effects of a pharmacological treatment, an educational action, an exercise, a care measure, a behavior or a lifestyle. The effects tested can include reduction in mortality and morbidity rates, relief of clinical symptoms, improvement in quality of life, improvement in functional capacity, gain in knowledge, change in behavior, effect on healing, and reduction of parameters such as weight, blood pressure, lipid profile and blood glucose, among many other outcomes that matter to patients, individuals and the community.

The complexity involved in conducting RCTs requires from researchers extreme scientific rigor, critical sense, discipline, organization, time and in-depth knowledge of the guidelines that underlie their development. Nurses are professionals with exemplary capacity for organization, discipline and determination and I believe that these characteristics are fundamental for the planning, conduction, execution and success of an RCT; therefore, we can! In this context, for those who have not yet experienced guidance or conduction of an RCT, we recommend that they take ownership and establish a goal to start as soon as possible. Science needs robust studies and evidence-based knowledge, and our contribution is necessary.

In our practice, we are daily faced with care processes that do not add to the team, the patients or the family members, as well as with care measures that imply a waste of time, personnel or material. Teams follow protocols that are not updated in the light of diverse evidence due to lack of time or because there are no people who are encouraged to modify them. We need to incorporate the academic sphere into health institutions in an "immersive" way to live day-to-day and, thus, question the environment, the people and the processes. This process is often misconducted (in our opinion) from the "academy" to the inside, and this does not work in the practice. Student researchers, or guiding professors, need to experience the research scenario or context by themselves, as that is where the most interesting and necessary research hypotheses and questions reside. In this favorable scenario, we test the hypotheses, and when we answer a research question, new doubts arise and, in this way, the dynamics inherent to this process that we call research becomes continuous, lasting, evolving and exciting⁽¹⁾.

But where to start? Initially, we want to say that the path is slightly easier than it may seem. We suggest starting by reading materials that we already have available in the literature, such as the methodological

evidence guidelines set forth in the Consolidated Standards of Reporting Trials (CONSORT), which contain, among other documents, a list of 25 items to be included in RCT reports⁽²⁾. Following this list is important since writing of the research project, as it allows the project itself to be built to the recommended standard, which may come to help us avoid future errors in report writing. Therefore, our first tip is: read a lot. It is also interesting to participate in research groups, in order to seek diverse information and news about courses, seminars and other events, which are excellent ways to better understand the topic, meet people with common interests and, perhaps, identify with some research topic.

When we identify our topic of interest, we will need to think about important points to ensure the quality of our RCT. Some of these points are as follows: (a) choosing a feasible research question; (b) careful selection of the participants, variables and outcomes of interest; (c) definition of the adequate type of RCT and sample size; (d) planning of randomization, blinding and intervention protocol; (e) control of co-interventions and contamination; (f) accurate and precise data analysis; and (g) registration of the study protocol⁽³⁾.

If these steps are followed, we will have strong evidence to support our decision-making in clinical care, as well as in the educational and managerial practice. For these reasons, we need to invest in RCT coordination, development and execution. When researching the number of RCTs published by nurses in the last 10 years, we were able to identify thousands of publications in the world; however, when filtering by research studies conducted in Brazil, these numbers are still incipient. This further reinforces the need to fill our prominent place and seek support from our colleagues, even from other disciplines, as well as financial support from funding agencies, in order to be able to turn our efforts into facts and increase our levels of evidence.

Finally, our major challenge as nurse researchers is knowing how to apply robust research methodologies in the pursuit of advancing knowledge to improve the Nursing practice, shape public policies, and provide health impacts that reach individuals and communities alike.

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