Moving Forward with Randomized Controlled Trials

A randomized controlled trial (RCT) is the most powerful tool for determining the cause-effect relationship between an intervention and an outcome. RCTs typically include random allocation to intervention and control groups, a blinding plan for trialists, assessors and/or participants, identical treatment groups except for the experimental ingredients, and an intent-to-treat analysis. RCTs are commonly used to determine the efficacy of newly developed pharmacological treatments, but they are also becoming popular in behavioral research, including nursing.

My research team recently began a two-arm RCT exercise study in community-dwelling older adults with cognitive impairment. We encountered many bumps in the road when designing and implementing our RCT, including challenges in maintaining a good blinding plan and in selecting and retaining a control group. This learning experience made me think about how we can prepare our PhD students and junior researchers to help them avoid experiencing these difficulties.

A quick search of the PubMed database, using nursing as a keyword to search for affiliations, randomized controlled trial, randomly assigned, randomized, or random allocation as keywords to search for abstracts or titles, and limiting the search to clinical trial or randomized control trial, yielded more than a thousand publications. These numbers suggest that nurse researchers are aware of RCTs and are using RCTs to investigate their areas of interest. However, it is not clear to what extent they follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines for conducting and reporting RCTs (http://www.consort-statement.org/).

Nursing is a practice profession, and we try to maintain or improve our clients’ health and well-being through nursing intervention research. RCTs should be used to test the efficacy or effectiveness of nursing interventions because RCTs are the gold standard. However, the RCT is rarely presented in current nursing doctoral curricula or in training programs for nurse scientists, making it difficult for junior scientists to understand the importance of RCTs and their design. Nursing doctoral programs with an emphasis on research should at least familiarize students with RCTs. In training nurse scientists who plan to test interventions, RCT content should be incorporated into the training program. In addition, more sharing among nurse researchers through workshops and publications that discuss practical issues in designing and conducting RCTs may help fill the knowledge gap.

In addition, for those interested in RCTs, I recommend attending the week-long Summer Institute on the Design and Conduct of Randomized Clinical Trials, funded by the National Institutes of Health (http://obssr.od.nih.gov/Content/Training_and_Career_Development/). This content is also discussed in the preconference for nurse researchers at the Summer Institute on Aging Research, a National Institute on Aging event in collaboration with the American Academy of Nursing/John A. Hartford Foundation Building Academic Geriatric Nursing Capacity program. Designing and conducting RCTs require a special set of knowledge and experiences. Incorporating sufficient information on RCTs in the doctoral curriculum and training programs for junior scientists will help to speed up the progress of nursing science.

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