Understanding Research

Randomized Controlled Trials

In this issue, Gross, Jennings, and Clark (2016) reported results of a randomized controlled trial (sometimes called a randomized clinical trial) of three different ways of dressing a chest tube insertion site. Often abbreviated as RCT, this type of experiment is considered the most powerful quantitative research method for determining effectiveness of a treatment or which of two or more treatments is the best one (Polit & Beck, 2016). An RCT must have three different components: controlled manipulation of at least one variable, use of a control or comparison group, and random assignment to the treatment groups. In this column, each of these components will be discussed.

Intervention

In experimental research, the intervention (independent variable) under study is isolated and controlled (Polit & Beck, 2016). Researchers are active agents in the research, not simply observing. The intervention is manipulated, meaning it is specifically planned to make a difference in the situation under study. For example, Gross and colleagues (2016) tried two different dressings and no dressing and compared them on several dependent variables (air leaks, pain, skin integrity). Researchers expect outcome or dependent variables to be affected (usually positively) by the intervention.

In this type of research, researchers study a hypothesis that one intervention (A) is better than another (B). This is tested statistically using the null hypothesis that no difference exists between the two interventions (Bench, Day, & Metcalfe, 2013). If researchers find a significant difference exists between one intervention and another, support exists for the idea one intervention is better than the other. This is considered support rather than proof, as interventions may need to be tested with different groups and different conditions, and at different clinical sites.

Control or Comparison Groups

In a classic experiment, researchers introduce an intervention to the experimental group and withhold the intervention in the control group to observe the effect of the manipulation (Polit & Beck, 2016). In clinical research, withholding treatment often is considered unethical so at least one comparison group is used. The comparison group typically is given the current standard of care to determine if the new treatment is better or at least as good as the comparison. Thus the term clinical trial is used in medical and nursing research. Gross and co-authors (2016) compared two dressings and no dressing at all.

Random Assignment to Groups

Random assignment involves placing each subject in the study in a group by using a procedure based on chance. Each person in the sample thus has an equal chance to be in the experimental group (also known as the study arm) or the control/comparison group (control arm) so comparisons can be made (Bench et al., 2013). This is usually accomplished by use of a random number table or a computer random number generator. Clinicians should not try to place certain patients in the treatment or comparison group in an effort to help them, as this can invalidate the study.

Random assignment is important for equal distribution of subject characteristics that could affect the experiment (confounding variables) to all groups, thus reducing bias. In the study by Gross and colleagues (2016), characteristics, such as the location of the chest tube, age, and sex of patients, weight, and skin texture, likely would be distributed equally across groups with randomization. Therefore, any differences between the two groups can be ascribed to the intervention or independent variable (Bench et al., 2013). Even with random assignment, one group might be somewhat different than the other (e.g., older on average), so researchers collect demographic data and other information to be able to describe the subjects in a study. In addition, readers can determine if the subjects are similar to patients in their practice. Attrition or loss of subjects in a study also may affect the equivalency of groups (Hewitt, Kumaravel, Durnville, & Torgerson, 2010).

Other Issues

Gross and co-authors (2016) indicated the interventions were not blinded because there was no practical way to do so. In RCTs, researchers often will try to blind the people involved in the study so they do not know which intervention is the experimental and which is the control. A study can be blinded to the patients and/or to the people administering the treatment. When studying
medications, pharmacists can create a placebo made of an inactive substance. No one knows who received which medication until a sealed envelope is opened. However, in the case of dressings, it clearly is impossible to blind nurses about which dressing or lack of dressing the patient is receiving. Studies done at more than one site, especially international studies, have more external validity than single-site studies. For example, Apóstolo, Cardoso, Rosa, and Paúl (2014) conducted a study of cognitive stimulation with elders at four nursing home sites in Portugal. However, it is more difficult to control studies conducted at multiple sites (Bench et al., 2013). Gross and colleagues (2016) listed the single site as a limitation of their study. Often, researchers hope others will try to replicate the study at other sites.

Different types of RCTs include explanatory, pragmatic/management, and equivalence. Explanatory RCTs are conducted to determine if an intervention works, a pragmatic RCT tests if an intervention works in a real clinical situation under normal conditions, and an equivalency RCT compares a new intervention to a current gold standard to determine if it is at least as good as the standard (Bench et al., 2013). Further detail is beyond the scope of this column; readers are referred to the references or other readings on the topic. Some patients may not understand what it means to be in a RCT (Leroy, Christophe, Penel, Antoine, & Clisant, 2011) and require some explanation. Nurse researchers, readers of research, and nurses caring for patients in an RCT should understand the components of this type of research.

REFERENCES