Using Research to Advance Nursing Practice
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Research Intervention Fidelity

Tips to Improve Internal Validity of Your Intervention Studies

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The clinical nurse specialist is often involved in intervention studies to determine whether a specific treatment or program improves some important outcome. However, a common problem with all intervention studies is the possibility of a type I or II error that is attributable to how the intervention is administered rather than how well the intervention worked.[1] A type I error occurs when the researcher incorrectly concludes that there is a difference between groups (those who receive the intervention and those who do not receive the intervention), when the difference may be caused by the introduction of unintentional bias into the protocol.[1] In contrast, a type II error occurs when the researcher concludes that there is no difference between groups, although there actually is a difference.[1] Any variation in how the intervention is administered will decrease power and make it difficult to find a difference, although a difference may actually exist.[1,2]

Understanding how to prevent or minimize intervention variation is a key factor when designing a sound and rigorous research study. Ultimately, researchers want to accurately assess the impact of an intervention on an outcome of interest. The purpose of this article was to identify issues associated with intervention fidelity and to provide tips that researchers can use to enhance the validity of intervention study findings.

INTERVENTION FIDELITY

Intervention fidelity means that the research study groups (both the experimental and control groups) receive the intervention or instructions exactly as described in the study protocol.[1,2] Lack of intervention fidelity is a threat to the internal validity of a study. Threats to the internal validity of an intervention study make it difficult to rationalize and discuss findings.[3] Essentially, it will be difficult to truly know whether significant or nonsignificant findings between the intervention and control (usual care) groups are due to variation in how the intervention was administered or due to the intervention itself.

The likelihood that intervention infidelity will occur increases with complexity and duration of the intervention.[1–3] Complexity is associated with the number of technical steps in the intervention, the number of times the intervention is administered, and the number of people responsible for administering the intervention.[2,4] Duration of the intervention is associated with a phenomenon referred to as "drift." Drift occurs when there are unplanned changes or modifications in the way the intervention is delivered. Even seemingly small modifications will add up over time and could result in major deviations from the original protocol. In this case, subjects enrolled at the end of a study may not receive the intervention in the same way that those in the beginning of the study received it.

INCREASING AWARENESS OF AND SOLUTIONS THAT PROMOTE HIGH-FIDELITY INTERVENTIONS

Two research studies are provided with examples of threats to intervention fidelity, potential solutions, and the strengths and limitations of each solution. The first scenario (Table 1) explores an educational intervention, and the second scenario (Table 2) explores the impact of a new protocol on a specific patient outcome. In both scenarios, there are multiple possible solutions that have strengths and limitations. Based on the option selected, researcher time and effort may increase or decrease, and in both scenarios, there is still a possibility of intervention variability and drift over time.

Scenario 1

The clinical nurse specialist decides to explore the impact of an education course on some important outcome using a

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Table 1. Scenario 1: Effect of an Educational Program Delivered by a Nurse Researcher to Clinical Nurses[2,3]

Issue and Potential Threat to Intervention Fidelity	Potential Solutions	Strengths	Limitations
1. Variation in teaching style between 4 educators 2. Potential for program content to change over time (drift) 3. Attention of nurses varies (because of the time the educational program was offered).	Solution 1 • Use a standard PowerPoint presentation with "notes" for the instructor • Provide time for educators to practice together, so they all relate content in the same way • The principal investigator assesses for variation in teaching of content and provides additional time for practice as needed • Researcher attends presentations led by each educator to assess content variations at regular intervals during the study and provides time for retraining	Solution 1 • Addresses some variation between educators • Researchers can assess for and manage drift • May strengthen the education delivered for all because practice and discussion of potential issues may lead to enhancements that improve the program	Solution 1 • Some variation and drift will still occur • Time intensive for researchers and educators • Costly in terms of personnel (educators and nurses' time) • Will not address variation in emotional responses of nurses because of the timing of their attendance at the educational session
	Solution 2 • Change the design of the intervention from in-person lecture format to an online program that nurses can view at a time and place that allow them to attend to the content	Solution 2 • Addresses variation • Minimizes drift • Efficient use of educator and researcher time	Solution 2 • Requires resources for developing the teaching program and placing it online • Online programs may not be as effective as in-person educational programs

1-group quasi-experimental design and collects baseline data on the outcome of interest before offering the educational program. In this study, 800 nurses will need to be educated. Four nurse educators are asked to develop and deliver the course content. Courses will be offered to nurses before their shift, after their shift, or on their days off. With 4 instructors, it will take approximately 6 months to educate the entire nursing staff. The postintervention data collection is planned for 7 months after the study begins (see Table 1).

Scenario 2

A clinical nurse specialist is assessing the impact of a new oral care protocol on an outcome. The study involves 2 medical surgical units; each has approximately 20 nursing assistants and 24 clinical nurses who will be responsible for implementing the oral care protocol twice daily (morning and night) to all enrolled patients. The oral care procedure varies depending on the abilities of the patient (dependent or independent) and their dentation (teeth or dentures); however, each protocol includes cleaning of the teeth and tongue and moistening of the lips (see Table 2).

POTENTIAL SOLUTIONS

Techniques that can enhance intervention fidelity include adequate education, training, and resources (copy of protocol or use of an intervention manual) of investigators and clinicians delivering the intervention.[2–4] Intervention implementation personnel should be monitored during the enrolment/intervention period to ensure all subjects receive the intervention in the same way and with the same methods.[2–4] Investigators must prepare for unintentional differences between individuals who will implement interventions. Furthermore, the number of intervention implementers may affect intervention fidelity and needs to be accounted for before study start-up. Because variation can also occur because of drift, nurses must consider the length of time and complexity of the intervention to minimize small seemingly insignificant changes in protocol delivery. Careful attention to fidelity during the planning stages of a study and careful monitoring of intervention fidelity during the study will increase the validity of the study and improve the likelihood that any differences you do or do not see are due to the intervention and not some variation in how the intervention was administered.[2]

STRENGTHS AND LIMITATIONS

Every study is different, and there is no 1 single solution that will be appropriate for all intervention studies. Each solution has strengths and limitations, and the researcher must consider these when making decisions related to the study protocol. Some solutions are more expensive than others, some are more time intensive than others, and some

Table 2. Scenario 2: Oral Care Intervention Delivery Twice Daily[2,3]

Threats to Intervention Fidelity	Potential Solutions	Strengths	Limitations
1. Variation in implementation of protocol that requires twice-daily oral care 2. Time spent on oral care may vary; techniques may vary 3. Missed treatments 4. Extra treatments by patient, other healthcare personnel, or family	Solution 1 • Train all personnel and assess their skills after training is completed • Provide reminders and a flyer of the intervention steps and posts in rooms of all study subjects • Researcher verbally thanks nurses every time they complete actions independently • Researcher performs observational assessments throughout the study to identify lapses in protocol implementation and reeducates caregiver staff as needed	Solution 1 • May minimize protocol deviations and catch drift when it occurs • Minimally interferes with usual care • Takes advantage of existing caregiver education on oral care protocol • Cost effective; provides a true reflection of the impact of usual care	Solution 1 • Variation in implementation may still occur as reeducation does not equal action • Time intensive for researchers • Missing and extra treatments may still occur
	Solution 2 • Limit the number of caregivers who will deliver the intervention or have research team deliver the oral care. • Train all personnel and assess their skills after training is completed and periodically during study • Place study flyer in room and orient patient, family, and nursing personnel about study daily during rounds	Solution 2 • Minimizes implementation variation • May minimize time researcher spends monitoring and reeducating caregivers • May minimize missing treatments	Solution 2 • Costly to hire and train study staff • Drift and variation in technique and time spent may still occur • Intervention may not be a true reflection of the impact of usual care because of the added controls • May have a little impact on extra treatments

may or may not be feasible. In addition, none of the solutions can prevent infidelity; rather, they can only be used to limit the threat of infidelity.

CONCLUSION

Intervention fidelity is an important factor to consider when planning an intervention study. Low variation in the implementation of a study intervention increases the likelihood that results will be valid and therefore generalizable to others because they will reflect the true effect of the intervention on the outcome of interest.[1,2] Intervention variation may be subtle or obvious and may become more or less intense over time. In some cases, it is cyclic and becomes more intense as the enrolment and intervention period drags on and investigators and caregivers become more relaxed in following expected protocols. Intervention fidelity can also be influenced by day-to-day nonnurse caregivers (including family), students completing clinical practicums, and other untrained support people assisting in care delivery. It is therefore important for the researcher to consider all of the potential threats to the fidelity of the intervention during the initial stages of study planning. Careful planning is the most effective way to prevent intervention fidelity from impacting the validity of your research results.

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