Focus on Research Methods
Designing Effective Nursing Interventions

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Abstract: The purpose of this article is to present issues scientists must consider to design effective experimental interventions. The efforts of nurse-researchers to test diverse interventions are consistent with the central role of interventions for the nursing discipline. Despite the importance of interventions, limited literature has addressed the actual design of these interventions. Many experimental interventions lack content validity, and others are inadequate to affect outcomes. Eight issues to consider in the development of interventions are discussed, including the conceptual basis of the intervention, descriptive research linking key concepts to the proposed outcome, previous intervention literature testing similar or related interventions, the intervention target, intervention specificity/generality, single or bundled interventions, intervention delivery, and intervention dose. Strategies are recommended for designing effective experimental interventions.

Keywords: experimental methods; intervention design

The interest of nurse-researchers in testing interventions reflects the pivotal role of interventions in the discipline (Snyder, 1992; Tolson, 1996; Tripp-Reimer, Woodworth, McCloskey, & Bulechek, 1996). Designing interventions can be challenging. The nature and strength of nursing interventions are often questioned by proposal reviewers. Researchers reporting on interventions that did not achieve the intended results often speculate that a “larger dose” of their intervention might affect the outcome variables. The methodological literature generally has focused on the study design and internal validity of experiments (Fogg & Gross, 2000), not on the intervention design. Nursing texts extensively address study design considerations. However, the nursing literature, including published articles and research books, is largely silent regarding the creation of experimental interventions. In this article we discuss dimensions of interventions that should be considered in the design phase and some strategies for creating effective interventions.

CONCEPTUAL BASIS OF THE INTERVENTION

Effective treatments contain large quantities in pure form of those contents producing the desired changes (Yeaton & Sechrest, 1981). The content of the intervention is most often determined by the selected conceptual framework.

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Despite widespread agreement about the importance of conceptual frameworks, researchers often attend more to the internal validity of experiments than to the construct validity of the intervention (Sechrest, West, Phillips, Redner, & Yeaton, 1979). Yet it is impossible to address treatment integrity without considering the conceptual basis of the treatment (Gross, Fogg, & Conrad, 1993). Theories that describe the phenomenon in nursing language without specific predictions have limited utility in preparing interventions effective in producing measurable differences in outcomes (Fawcett & Downs, 1992; Tolson, 1996). Theories that make specific predictions are important for effective interventions. Interventions based on general notions will likely be weak (Sechrest et al.). For example, interventions to enhance smoking cessation will likely be more useful if they are based on theories specifically focused on the processes of changing smoking behavior or health-behavior change, such as the transtheoretical model or reversal theory (Cook, Gerkovich, Hoffman, McClernon, & O'Connell, 1996; Prochaska & Goldstein, 1991), than would interventions based on the much more general self-care nursing theory (Orem, 1991).

Researchers will have difficulty developing effective interventions when selected conceptual frameworks emphasize constructs not readily amenable to nursing intervention. For example, the theory of reasoned action (Ajzen & Fishbein, 1980) postulates that behavior is based on behavioral and normative beliefs. Normative beliefs, that is, significant others’ expectations, are a central construct of this theory that would be difficult to change. Several investigators who have conducted studies based on the theory of reasoned action have found interventions to change normative beliefs ineffective in changing behavior (Lierman, Young, Powell-Cope, Georgiadou, & Benoliel, 1994; Miller, Wikoff, McMahon, Garrett, & Ringel, 1988; Wrenn, 1997).

Theoretical frameworks that have received considerable empirical support, such as the self-regulation theory for designing interventions to help people cope with physical illness (Johnson, 1999) or social cognitive theory for health-behavior change (Conn, 1998), are more likely to produce measurable differences in outcomes than theories with limited empirical support. Table 1 summarizes strategies for constructing experimental interventions most likely to produce changes or differences in outcomes.

The intervention should definitively reflect the key constructs of interest specified in the conceptual framework (Heppner, Kivlghan, & Wampold, 1999). Careful conceptualization of an intervention is essential for credible interpretation of the success or failure of a treatment (Sechrest et al., 1979). Inadequate construct validity of an intervention leads to misinterpretation of findings (Cook & Campbell, 1979; Sechrest et al., 1979). For example, in an intervention designed to provide social support, but where the main intervention activity was the provision of instrumental information, the effectiveness of social support might be obscured.

The absence of a conceptual framework often is associated with weak intervention effects and with missing explanations of causal processes between the intervention and outcomes (Goldenhar & Schulte, 1996). Mediating variables specified in conceptual frameworks and measured with sound instruments provide possible explanations for findings regarding intervention effects (Goldenhar & Schulte). For example, social cognitive theory suggests four sources of efficacy beliefs through which self-efficacy is enhanced and thus behavior is changed. This theory can be tested by manipulating one or more of the efficacy sources as the independent variable and measuring both the mediating construct of self-efficacy and the behavioral outcome (Bandura, 1977). Research examining only the efficacy-based intervention and behavioral outcome would provide less support for the social cognitive theory.

Effective interventions are possible when the conceptual relevance of the intervention for the particular problem is clear (Yeaton & Sechrest, 1981). Interventions successful for some problems, such as relaxation, should be applied to problems where conceptual frameworks suggest reasonable application of the intervention. Testing interventions based on clear conceptual links between the intervention and the phenomenon will lead to more rapid development of knowledge than will tests of other interventions. Lack of conceptual relevance may delay identification of effective interventions and in turn result in a lack of efficiency in the research and theory revision iterative process (Eddy, Dishion, & Stoolmiller, 1998).

Efforts to maximize the impact of an intervention often involve increasing any possible intervention or treatment differences between the experimental and control group, sometimes regardless of the conceptual fit between the intervention and the theoretical framework (Buckwalter, Maas, & Wakefield, 1998; Heppner et al., 1999). Differences between treatment and control groups that are unrelated to the conceptual
foundation of the intervention will impede interpretation of findings. For example, a researcher might intend to test a theory specifying that feedback information improves nursing-care quality. If the single experimental group were to receive both feedback and advanced-practice nurse consultation, the content validity of the intervention would be questionable. If the nursing-care quality improved in response to the intervention, it would be impossible to determine whether the feedback or the advanced-practice nurse was the important component of the intervention. Thus, the experiment would not have provided a valid test of the theory.

### Table 1. Considerations in Designing Interventions

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<tr>
<th>Attribute</th>
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<tr>
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<tr>
<td>for population</td>
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<td>Specificity/generality</td>
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<td></td>
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Completed descriptive research provides the foundation for intervention development. Extensive reviews of the literature, such as those published in the *Annual Review of Nursing Research* series, are useful in identifying the research base for proposed interventions. Quantitative syntheses of existing research using meta-analytic methods are particularly informative (Conn & Armer, 1994; Conn, Valentine, & Cooper, 2001). Interventions based on constructs that have consistently explained sizable amounts of variance in dependent variables probably will be more effective than interventions based on constructs that are weakly correlated with the outcomes of interest (Gross et al., 1993). It is possible to obtain statistically significant predictors of outcomes given sufficiently large samples and a consistent but weak association between the predictor and outcome. Generally predictors that account for more of the variance in outcomes, such as an $R^2$ of .40, will result in more effective interventions to change the outcome than will interventions based on predictors that account for an $R^2$ of .15. Self-efficacy is an
example of a construct that consistently accounts for large amounts of the variance in behaviors across diverse measurement tools and health behaviors (Conn, 1998). In contrast, perceived benefits of health behaviors is an inconsistent predictor of health behavior, often accounting for only small amounts of variance (Conn). Interventions based on self-efficacy are more likely to result in significant changes in outcomes than are those based on perceived benefits. Empirical evidence has documented changes in health behaviors following self-efficacy-based interventions (Becker, 1990).

Comparing the proposed intervention to identical or similar interventions in similar or different populations can offer insights about potential intervention effectiveness. For example, if most previous research has found 10 treatments necessary to establish improved outcomes, the potential adequacy of a similar intervention with four treatments should be considered carefully.

Attention to meta-analytic reviews of existing intervention studies can be especially valuable. This is particularly true for some nursing intervention research in which limited sample size has been common. Although synthesis is always limited by the quality of the extant research, rigorous meta-analyses can inform intervention design. For example, a recent meta-analysis of interventions to increase physical activity among 33,000 aging adults by Conn et al. (2001) found effect sizes were larger when interventions targeted only activity behavior, excluded general health education, incorporated self-monitoring, used center-based exercise, recommended moderate intensity activity, were delivered in groups, used intense contact between interventionists and participants, and targeted patient populations. Conn et al. found that components of questionable value for aging adult populations included cognitive modification, social modeling, and social support, and they documented the following specific intervention components found too infrequently for meaningful meta-analytic comparison: contracting, decisional balance activities, feedback, fitness testing, goal setting, and stimulus control. These meta-analysis findings provide valuable information for the design of future experimental interventions intended to increase physical activity among aging adults. Researchers designing interventions should consider meta-analysis results along with conceptual frameworks.

The evaluation of completed research to determine dose or other intervention parameters also should incorporate unpublished literature. This should happen because despite the prevalent belief that unpublished studies are of lower quality and are not peer reviewed, evidence documents that the main difference between published and unpublished studies is the statistical significance of the results (Cook et al., 1993; Dickersin, Min, & Meinert, 1992; Easterbook, Berlin, Gopalan, & Matthews, 1991). Reviewing only published literature is problematic because of the potential publication bias in favor of significant treatment effects. An extensive review of both published and unpublished studies might contribute to identification of a minimum “dose” that must be exceeded to produce measurable outcomes. For example, if an investigator reviewing the literature found that studies with at least eight treatments resulted in significant outcomes but that studies with less than six treatments showed a lack of significant change in outcome variables, that investigator would likely design an intervention with at least eight treatments. Thus, a careful review of the existing literature may contribute to identification of possible sources of confounding in previous works that may be addressed in the planned experimental design.

In addition to expertise recorded in the literature, expert opinion is extremely helpful in formulating effective interventions. Sechrest et al. (1979) found that carefully selected experts—those with expertise with the target population, the conceptual framework, or similar interventions—can accurately predict the ability of interventions to affect outcome variables. When selecting interdisciplinary research team collaborators and consultants, this need for expertise should be attended to early in the process of developing interventions.

Researchers designing interventions should examine the published and unpublished primary and meta-analytic research to identify those constructs that are amenable to intervention and that have accounted for large amounts of variance in the proposed outcome variables and to determine the characteristics of effective interventions, such as dose, that were used for similar problems. Interventions may be enhanced by careful consultation with both scientific and consumer experts.

**INTERVENTION TARGETED FOR POPULATION**

Population-specific interventions are consistent with the attributes of the targeted persons. Developmentally appropriate and culturally sensitive
interventions enhance the potential effects of the interventions (Stanton, Kim, Galbraith, & Parrott, 1996; Varricchio, 1995). For example, Harris, Bausell, Scott, Hetherington, and Kavanagh (1998) designed an intervention specifically for methadone-dependent African American women that was intended to enhance safe-sex practices. Clarity regarding the intervention’s target may include descriptions of individuals, dyads, families, components of organizations, or communities. The conceptual framework and problem determine the appropriate target(s) for interventions. For example, Tolson (1996) designed an intervention to enhance hearing for elders in long-term care. Hearing was conceptualized as an interaction between individual and environmental factors. The intervention targeted both the characteristics of individual elders and aspects of the physical environment, which is consistent with the theoretical framework.

Members of the target population where the intervention will be tested are a valuable source of expertise for intervention development. People who have experienced the situation the intervention is designed to address can provide insight about possible interventions. Also, they can assess realistically the respondent burden associated with completing the intervention and suggest ways to minimize burden. For example, Rogers and Aldrich (1993) found participants with narcolepsy were unable to complete the planned napping intervention because of other commitments. The involvement of population members will likely reduce adherence and attrition problems that can seriously impede intervention research. An illustration of this was reported by Ziemer, Cooper, and Pigeon (1995), who found high attrition in a treatment group using a dressing to treat breastfeeding nipple pain and skin disturbance. The investigators hypothesized that dressing removal for feeding episodes was sufficiently painful to cause subject attrition. The use of a consumer advisory group representing the population of interest could assist with intervention design and burden, as well as subject recruitment and retention.

**INTERVENTION SPECIFICITY/GENERALITY AND INDIVIDUALIZED TREATMENTS**

A diffuse intervention targeting a broad problem requires careful description to prevent the appearance of “fuzziness” (Polit & Hungler, 1999). The results of a study using an amorphous intervention will be difficult to interpret because the intervention lacks specificity. Furthermore, a lack of specificity hampers replication as well as practical use of the intervention.

A related issue is whether the intervention can be modified to fit the needs of individual participants (Woods, 1988). Clearly, many interventions cannot be individually tailored and still retain treatment integrity. Some interventions can be matched to individual attributes. Generally, interventions with differential assignment are more effective (Sechrest et al., 1979). For example, Schnelle, Cruise, Alessi, Al-Samarrai, and Ouslander (1998) successfully individualized nighttime incontinence care in nursing home residents in order to minimize sleep disturbance.

**SINGLE OR BUNDLED INTERVENTIONS**

Researchers often make decisions about testing single interventions or groups of interventions. It is probable that complex problems are more likely to require bundled interventions to achieve desired outcomes. And some interventions are not easily separated into components, thus requiring treatment packages. Other interventions are easily separated.

Piantadosi (1997) argued for testing individual interventions in factorial designs to determine effective components. Cook and Campbell (1979) suggested that efforts to detect causally efficacious components of complex treatment packages require unbundled interventions, whereas attempts to determine the most potent treatments may require combinations of interventions. It is possible that some interventions with no detectable effect individually can be effective when grouped with other interventions. For example, Taylor (1999) tested bundled interventions for premenstrual syndrome after noting that single nonpharmacologic interventions were ineffective.

The nature of the problem and the conceptual framework provide the justification for deciding whether to test single interventions or bundled interventions. Shotgun approaches may reflect a lack of understanding of the problem, a lack of adequate conceptual framework, or a lack of adequate experimental control. Bundled interventions are appropriate when a multidimensional problem is located in a conceptual framework that suggests combining multiple interventions. For some phenomena bundled interventions may be essential. For example, White-Traut et al. (1999) delivered bundled interventions to preterm
interventions delivered to adolescents by adults may have weaker effects than content-identical interventions delivered by peers (Stanton et al., 1996). The purpose of the research may determine the appropriate intervener. Nurse interventionists may be used in early testing of a wound-care protocol, whereas in later research investigators might seek to determine if patient/family performance of the wound care yields intended outcomes.

Intervention studies vary in the extent of intervention burden imposed on participants. Although researchers more commonly address respondent burden in relationship to measures, some interventions place large responsibilities on participants. The potential for interaction of subject retention and treatment group looms large when selective attrition occurs in response to burdensome interventions (Cook & Campbell, 1979). For example, a complex wound-management intervention requiring participants to perform frequent elaborate dressing changes, to alter diet to achieve several particular nutritional goals, and to maintain certain positions for specified amounts of time may lead to accelerated attrition in the treatment group. A powerful treatment may be concealed by selective attrition in response to intervention burden on participants. Pilot-testing interventions with members of the population may help reveal the extent of intervention burden, as well as other participant suggestions to make the intervention more acceptable.

Variable subject performance of the intervention behavior can significantly weaken the intervention such that control and experimental groups become more similar than planned (Woods, 1988). For example, testing the effects of exercise on disease-specific symptoms may be difficult if participants perform the intervention in variable amounts. Identifying acceptable subject-adherence rates will ensure that adequate intervention integrity and concentration are maintained. An alternative analysis plan that measures intervention “dose” or subject adherence and examines the impact of a “dose” on outcome variables is another approach to handling this difficult problem. In the stated example, participants could wear a programmable motion detector to record exercise performance. Two analyses could be conducted. One could be an intention-to-treat analysis comparing those assigned to the treatment group to those assigned to the control group. A second analysis could examine the impact of amount of exercise performance on the outcome variables. This second analysis would be particularly important if group differences were detected in the intention-to-treat primary analysis. Information about the required dose
to achieve the intended outcomes is especially important in determining best practices.

Interventions can be delivered in person or by phone, mail, printed materials, e-mail, or Internet. Clarity is important regarding whether the delivery medium constitutes the intervention, if intervention content is being tested, or if both are being tested. The significance of testing the latest technological device for intervention delivery must be clearly explicated beyond the inherent desire to manipulate new gadgets. Factorial designs may be essential when researchers want to examine both the content and delivery medium. For example, Parker, McFarlane, Soeken, Silva, and Reel (1999) tested an intervention to reduce physical abuse of pregnant women. They delivered the intervention by face-to-face contact with pregnant women. If they had delivered the intervention via the Internet, it would have been difficult to determine whether it was the content or the mode of delivery that was important. It is possible that any intervention delivered via the Internet could be effective in this population if it were of enormous importance to have the ability to receive the intervention discreetly when the participant has available time. A factorial design would efficiently test both the intervention designed by Parker et al. and the delivery medium.

The setting of interventions may make them difficult to implement and can alter effectiveness (Phillips & Van Ort, 1995). It may be necessary to consider the setting as a dimension of the intervention. For example, Stein (1991) noted that intervention trials in which investigators attempt to provide social support through relationships developed during phone conversations may lack the social setting necessary to achieve a social relationship.

Interventions often are delivered at a particular time in relationship to a specific event (Clark, 1996). The conceptual framework most often suggests the appropriate timing. For example, smoking cessation interventions based on the transtheoretical model of health behavior change will include specific interventions before ceasing smoking and different interventions in the 6 months following initial abstinence (Conn, 1994; Prochaska & Goldstein, 1991). Timing interventions in relationship to health events can be challenging. For example, testing a fatigue intervention among patients with cancer is difficult because changes in health status–related fatigue occur over time regardless of the intervention (Porock, Kristjanson, Tinnelly, & Blight, 2000).

TREATMENT DOSE ISSUES

A content-appropriate intervention delivered in insufficient doses obscures the potential effectiveness of the intervention. For example, Kim et al. (1993) speculated that insufficient training intensity accounted for their lack of success in increasing respiratory muscle strength. Intervention intensity, the amount of treatment per unit time, includes both session duration and frequency (Sechrest et al., 1979). Duration of delivery over hours, days, or weeks is the other important dimension of dose. Increasing treatment dose is one way of constructing robust interventions. Increasing treatment dose to enhance the likelihood of achieving significant changes in outcomes must be balanced with the increased demand on the participants because of a more intense intervention. Interventions with high subject demand may be associated with increased attrition.

Dose considerations can be addressed by establishing an acceptable dose for study inclusion. For example, a study of vitamin effects could require participants to consume 80% of the intended vitamin administrations for continued inclusion in the research. Dose–response function, examining the variations in responses associated with varied treatment levels, is another alternative for interventions amenable to unidimensional dosage considerations (Lipsey, 1990; Sidani, 1998). For instance, Maas et al. (1994) examined dose–response function in a study of the effects of family involvement in care intervention on outcomes for residents in long-term care settings and their family and staff caregivers.

Testing variations in dose, that is, intervention intensity, may be the major thrust of the research. For example, Rothert et al. (1997) held the content of interventions constant in a study of the empowerment of menopausal women. The intervention intensity was systematically varied by providing information only in written format, by supplementing written information with didactic and discussion experiences, and, for the most intense group, by providing additional activities.

OTHER CONSIDERATIONS IN DESIGNING AND TESTING INTERVENTIONS

Research design determines the nature of the information obtained about experimental nursing interventions. Study design is determined based
on the purpose of the research. Pharmacological research is traditionally divided into Phases I, II, III, or IV, reflecting study purpose. In Phase I studies researchers attempt to identify the maximally tolerated dose in terms of side effects and toxicity. Limited numbers of nursing interventions require Phase I testing. During Phase II research investigators attempt to estimate the beneficial response rate, quantify adverse events, and appraise the feasibility of implementing the intervention. Phase II studies often do not include comparison groups. Many nursing intervention pilot studies are similar to Phase II research. In Phase III studies researchers use randomized trials to test the effectiveness of new interventions by comparing the experimental intervention to standard therapy or to some type of control group. Subsequent Phase III studies may involve researchers’ attempts to determine the lowest dose that achieves the desired outcomes. These studies are pivotal in determining the clinical consideration of the intervention. Most nursing intervention trials closely approximate Phase III trials. Phase IV studies include long-term surveillance of the intervention to detect long-term consequences and identify uncommon side effects. In Phase II studies, the initial testing of interventions, researchers should test the intervention that contains the largest amount of content feasible to be delivered so as to determine potential usefulness (Sechrest et al.). If weak interventions are tested initially, it may lead to the erroneous conclusion that the interventions are not useful. Interventions found to be effective may be tested further to determine ideal dose. Later testing may include lower doses of the intervention or comparisons of doses (Sechrest et al., 1979). This is important because one of the ultimate goals of research is to identify the minimum treatment that produces the desired effects (Woods, 1988).

Questions often arise about the feasibility of some potent interventions for practice. Phase II pilot testing of interventions may reveal insurmountable feasibility problems that prevent further testing of a planned intervention. For some interventions it may not be wise to prematurely abandon potentially effective interventions because of questions about practice feasibility. A historical example illustrates this point. Early tests with artificial kidneys documented potential benefits despite costs that prevented widespread use. Documented effectiveness was necessary to encourage technological advances that made the treatment feasible outside research studies. The discovery of effective interventions, including those with prohibitive costs for general practice, does provide information that is useful in designing other interventions (Sechrest et al., 1979).

Issues related to experimental design are generally beyond the scope of this discussion and are well addressed elsewhere (Egan, Snyder, & Burns, 1992; Fogg & Gross, 2000; Friedman et al., 1996; Geligns, 1990; Piantadosi, 1997). Rigorous experiments designed to detect differences attributable to the independent variable are essential to determine if interventions are effective. Sensitive and accurate measures of dependent variables are vital to detect changes in predicted outcomes (Stewart & Archbold, 1993a, 1993b). Interventions must be tested in well-designed experiments to advance the scientific basis of nursing interventions.

Clinical and field realities often impose restraints on the research designs that may be implemented. For example, sometimes it is necessary to risk possible differences in experimental group environments by randomizing using units other than individuals so as to avoid issues of cross-contamination. At times researchers must give up control over one aspect of an experiment in order to gain control of a more important source of extraneous variation. Deliberate decisions with full awareness of the potential effects of compromises will lead to balanced decisions that advance knowledge.

Nursing interventions are as diverse as the discipline. Experimental studies testing interventions are essential to move the quality of care forward. There is an abundance of literature on how to design studies. Unfortunately, little nursing literature has been focused on how to design interventions. This article has raised issues about intervention design that should stimulate the thoughtful deliberation that may move our science forward. Careful consideration of the multiple attributes of interventions will enhance the quality of nursing research.

REFERENCES


