



Designing nursing interventions

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Summary The development of nursing interventions that demonstrate the link between nursing actions and patient outcomes is a high priority for nursing research. The development of intervention research frequently focuses on the methods used to test the intervention while less attention is placed on rigor in intervention development and design. The purpose of this paper is to provide thinking points for researchers considering the development of nursing interventions. The thinking points were developed from the limited literature on this topic in synthesis with the authors own experiences of designing nursing interventions. Adoption of a systematic approach to intervention testing is advocated along with a step-wise intervention development process. This process calls for attention to problem definition, conceptual underpinnings, desired outcomes and measures and evidence-based content along with careful consideration of delivery methods, dose and attention to protecting the integrity of the intervention during testing. The approach advocated will help to ensure that nursing intervention research makes a useful contribution to the development of nursing practice.

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Background

The role of nurses in the delivery of health services is becoming increasingly complex as the burden of chronic disease in our aging community begins to outstrip available resources. The real constraints on health funding mean that nurses and other health professionals need to demonstrate the benefits of the services they provide in direct relationship to patient outcomes. However, this relationship is complex and mediated by factors associated with the

environment, the patient population and the model of care delivery. Attempts to develop best evidence approaches to common patient problems expose significant deficits in current nursing intervention research largely as a result of a non-systematic approach to the development of nursing interventions. The purpose of this paper is to explore the characteristics of well-developed nursing interventions in order to guide researchers seeking to contribute to this area of nursing research and practice development. The focus of the paper is on intervention design specifically but a development approach utilizing methods testing in pharmacological research is advocated.

Establishing how nursing interventions impact on patient outcomes is an identified research priority in nursing (Hinshaw, 2000), yet limited attention has focused on the design of interventions (Conn, Rantz, Wipke-Tevis, & Maas,

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2001). Several authors (Conn et al., 2001; Whittemore & Grey, 2002) outline systematic approaches to nursing intervention development, including use of those advocated in the testing of pharmacological interventions. Conn et al. (2001) also outline key features of design that help researchers and clinicians to develop effective interventions. Still other authors have characterized how interventions might reflect nursing values such as being patient-centered (Lauver et al., 2002). This paper attempts to provide a synthesis of this work together with the experiences of conducting nursing intervention research in the clinical environment of a cancer centre. The aim is to provide guidance to researchers considering intervention research.

Drawing on approaches in pharmacological research

The development of pharmacological interventions follows a well-recognized path from phase 1 to phase 4 studies. This path helps to determine the safety, efficacy and effectiveness of new interventions from the time the drug is first used in humans. Each phase in pharmacological research can be applied to nursing intervention testing in helpful ways. Nurse researchers are encouraged to adopt this approach to developing and testing interventions in order to increase the credibility and strength of the findings. This approach cautions against leaping quickly into randomized controlled studies and advocates a planned program of work that may move several times between phases 1 and 2 until the intervention is ready for formal evaluation.

Phase 1 pharmacological studies seek to determine the maximum dose of a drug including establishment of side effect and toxicity profiles. In other words they assess patient tolerance and safety of the intervention. In nursing intervention research a similar concept would be to establish the acceptability of the intervention to patients, the level of burden involvement in the intervention has and the likely attrition rates. In nursing such studies would involve small numbers of patients and data collection would focus on qualitative experiences of the intervention to assist with refinement of the approach.

Phase 2 pharmacological research seeks to determine the response rate, side effect profile and feasibility of use, e.g. does toxicity outweigh benefit. The nursing research equivalent would be to determine the amount of benefit the patient gains from the intervention and to assess the degree to which the patient believes the effort of involvement is worth the benefits gained. Phase 2 studies would also seek to determine environmental factors that might impact on delivery of the intervention and other issues of feasibility such as patient recruitment. Phase 2 intervention experiences also assist in refinement of the intervention and protocols for delivery and determines the ability to measure intervention effects, providing data helpful for sample size calculations. For example, we have recently conducted a phase 2 study to develop a cognitive-behavioural intervention for women with bothersome hot flushes following breast cancer treatment (Sheeran, Ftanou, Tremblay, & Aranda, 2007). The intervention was identified by women as highly acceptable and appropriate but the study identified signif-

icant feasibility issues. The intervention was group based and recruitment of sufficient numbers of women to groups was problematic. Not only did this flag a potential problem in recruitment for the planned phase 3 trial but also raised important dissemination challenges if the intervention proved to be effective.

Phase 3 pharmacological studies involve prospective randomized trials to assess the efficacy of the intervention in controlled situations. The conditions of the intervention delivery are tightly managed as are the characteristics of the patients recruited to the study. Features of these studies include randomization and other elements that seek to remove the potential for bias in study outcomes. While nursing interventions are much more complex and inherently difficult to control, this approach remains the gold standard of intervention testing and should be used where possible. The purpose of phase 3 studies is to test if the intervention is effective against the outcome to which it is targeted. Conn et al. (2001) argue that initial phase 3 studies must test a clinically effective intervention and it is in subsequent studies that efforts might be made to achieve the same effect with a less intense intervention or using different delivery methods.

Phase 4 pharmacological studies assess the effectiveness of interventions in the real world. These studies seek to determine if the efficacy of the intervention is sustained in uncontrolled use. This is a major area of neglect in nursing research and one where attention is required. The factors that may contribute to reduce effectiveness of nursing interventions in real life include differences in nursing skill in delivery of the intervention, loss of integrity of the intervention as nurses adapt it to local environments and differences in effect due to differences in the model of care delivery. Phase 4 studies might also consider factors such as cost effectiveness. For example, we are currently testing a patient education intervention for patients commencing chemotherapy (Aranda, Schofield, Jefford, & Yates, 2007). The intervention has been found to be slightly longer than the usual care condition, implying additional cost. While the phase 3 study will determine if this additional cost is balanced by patient benefit it can only be determined if the intervention is cost effective if the phase 4 study shows acceptable costs and a retention of the benefits.

What is a nursing intervention?

According to McCloskey and Bulechek (1996) "A nursing intervention is any direct care treatment that a nurse performs on behalf of a client. These treatments include nurse-initiated treatments resulting from nursing diagnoses, physician-initiated treatments resulting from medical diagnoses, and performance of the daily essential functions for the client {who} cannot do these" (p. 21).

Interventions can be simply or complex. A simple intervention might consist of a single action by the nurse in response to common patient problem. For example where the patient is getting up for the first time after surgery and the nurse provides medication to ensure adequate pain control to enable the patient to mobilize. A complex intervention would normally be in response to a complex problem and might be delivered over more than one interaction, such

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