Volume 41 N° 4 CJNR December / décembre 2009

CONTENTS / TABLE DES MATIÈRES

## Nursing Intervention Research / *Recherches en matière d'interventions infirmières*



McGill University School of Nursing

*CJNR 2009, Vol. 41 Nº 4, 3–6*

# *Guest Editorial*

# Nursing Intervention Research

**Nancy Feeley and José Côté**

This is the first time that *CJNR* has devoted an issue to the topic of nursing intervention research. Nursing intervention research is essential not only to determine whether existing care practices in Canada are efficacious, but also to develop and evaluate novel interventions. Researchers, clinicians, and administrators need to work in concert to pursue intervention research that will produce evidence for and develop clinical practice. This special issue of the Journal addresses some of the challenges and issues surrounding the development and evaluation of nursing interventions as well as the application of these interventions in clinical practice.

The development of nursing intervention research is clearly coming into its own. Nurses are exploring the numerous and varied methodological and practical challenges of conducting studies that assess the efficacy of interventions provided by nurses. Sidani and colleagues address the topic of treatment preference, and how participants' favouring of a particular group assignment can affect the external and internal validity of a study. They describe alternative designs that take participants' preferences into account. These alternative designs are well suited to the nature and realities of the clinical setting, the needs of participants, and the values and goals of the discipline. Campbell-Yeo and colleagues review possible sources of bias in clinical trials and provide a checklist that students and new investigators can use as a guide when designing such studies.

The articles included in this issue of the Journal shed light on the current state of development in this domain, and point to some of the gaps. Both quantitative and qualitative methods are being used to address research questions. The contribution of Beal and colleagues underscores the value of using mixed methods to evaluate an intervention and to demonstrate how it might bring about change. These authors report on a study that employed qualitative methods to explore participants' perceptions of their experience in the experimental and control groups of a clinical trial. The findings provide interesting insights concerning the

mechanism of change as well as verification that the intervention functioned as the researchers anticipated it would. Sobieraj and colleagues conducted a quasi-experimental study that tested the effects of a simple, inexpensive music intervention for the parents of children undergoing laceration repair.

We find it noteworthy that we did not receive any submissions related to intervention development research — that is, studies whose purpose is to develop an intervention that will be tested in a clinical trial. This is a relatively new and underdeveloped aspect of intervention research. We do not know the extent to which such work is being conducted in nursing, nor whether funding exists to support this type of study.

Researchers who have developed a program or intervention and determined its efficacy are eager to have it adopted in clinical practice. Several well-established researchers who study different populations in various clinical arenas agreed to share their personal experiences with us. Gina Browne, Francine Ducharme, Ruth O'Brien, and Bonnie Stevens all reaffirm the need for researchers to engage stakeholders, clinicians, and patients in a partnership through all phases of intervention development and evaluation. The reflections of these authors underscore the importance of providing support to clinicians and administrators who seek to adopt efficacious programs and the role of that support in the ability of clinicians and administrators to do so successfully. A critical mass of change agents or adopters appears to be another essential ingredient in success. Finally, researchers must be able to communicate their findings to a variety of audiences, including politicians and patients and their families, effectively and in a multitude of ways.

Robin Whittemore's Discourse highlights a few of the challenges that we confront at this time. Whittemore discusses the need for balance between intervention fidelity and the adaptability of the intervention to the clinical milieu. Interestingly, the challenge of achieving balance between intervention fidelity and fit in the clinical context is evident in the reflections of Browne, O'Brien, and Stevens, as is the value of program flexibility. Whittemore also discusses the need to achieve balance between internal and external validity when evaluating nursing interventions. She states that practical clinical trials may help to achieve this balance.

In our Happenings contribution, the leaders of a new research group for nurse researchers in Quebec (GRIISIQ) involved in conducting intervention studies describe the development and activities of their unique group. The group provides important opportunities for training the next generation of nurses who possess the knowledge and skills needed to conduct intervention studies. An international conference

dedicated to the topic is currently being planned, and it could be an important forum for researchers to discuss the challenges we face, share their findings, and advance the development of knowledge in this area. We encourage clinicians and researchers involved in this work to come to Montreal in 2011 for this exciting event.

If we look to the future, we will certainly see a number of challenges. Intervention development research is clearly an area that requires our attention. The nursing literature includes very little on this topic. Health promotion and behavioural scientists are clearly ahead of us in this respect. We need to develop methodology for the development of nursing interventions. Researchers will need to enhance their knowledge of a wider range of study designs to evaluate interventions, including the practical clinical trials that Whittemore discusses and the partially randomized trials described by Sidani.

Innovative partnerships between decision-makers, clinicians, researchers, and patients will be essential to the processes of intervention development, evaluation, and adoption, if we are to develop the knowledge needed to enhance health and health care.

We are optimistic about the future of nursing intervention research. The Canadian Institutes of Health Research (2009) has adopted a strategic plan for 2009–14 that identifies enhanced patient-centred care and improved clinical outcomes through scientific innovations as one of five priorities for the next 5 years. Furthermore, the report of this year's Nursing Research Symposium, submitted by the Canadian Association of Schools of Nursing to the Office of Nursing Policy, Health Canada (Pringle, Rukholm, & Sabourin, 2009), indicates that intervention studies are a priority for the advancement of nursing science. Nurses who conduct intervention research are extremely well positioned at the moment to take advantage of this focus on patient-oriented research and to play a part in developing the knowledge needed to improve health and health care.

## References

Canadian Institutes of Health Research. (2009). *Health research roadmap: Creating innovative research for better health and health care. CIHR's Strategic Plan, 2009/10–2013/14.* Ottawa: Author.

Pringle, D., Rukholm, E., & Sabourin, H. (2009). *Advancing nursing science and research capacity in Canada. Report of the Nursing Research Symposium.* Ottawa: Office of Nursing Policy, Health Canada.

## Acknowledgements

Both authors are supported by a Clinical Research Scholar Award from the Fonds de la recherche en santé du Québec (FRSQ).

*Nancy Feeley, RN, PhD, is Assistant Professor, School of Nursing, McGill University, and Researcher, Centre for Nursing Research, Sir Mortimer B. Davis Jewish General Hospital, and Quebec Interuniversity Nursing Intervention Research Group (GRIISIQ), Montreal, Quebec, Canada. José Côté, RN, PhD, is Associate Professor and Chaire de recherche sur les nouvelles pratiques de soins infirmiers, Faculté des sciences infirmières, Université de Montréal, and Researcher, Centre de recherche du Centre hospitalier de l'Université de Montréal.*

*CJNR 2009, Vol. 41 Nº 4, 7–15*

*Discourse*

# How Can Nursing Intervention Research Reduce the Research-Practice Gap?

**Robin Whittemore**

Nursing intervention research is defined as "studies either questioning existing care practices or testing innovations in care that are shaped by nursing's values and goals, guided by a strong theoretical basis, informed by recent advances in science, and designed to improve the quality of care and health of individuals, families, communities, and society" (Naylor, 2003, p. 382). Because nursing interventions often encompass multiple components, a systematic approach to intervention development and evaluation has been proposed. The phases of nursing intervention development and evaluation are as follows: conceptualization of the intervention, feasibility and pilot tests, efficacy trials, effectiveness trials, and widespread dissemination (Whittemore & Grey, 2002). It is important that a clear understanding of mediators and moderators of intervention effectiveness be determined during development and evaluation. Other models of intervention development and evaluation for complex health-care interventions and behavioural interventions propose similar phases (Campbell et al., 2000; Flay, 1986; Glasgow, Davidson, Dobkin, Ockene, & Spring, 2006).

Great strides have been made in nursing intervention research in the past several decades, producing evidence on the efficacy of a wide range of interventions. Yet, moving evidence from efficacy trials into clinical practice remains problematic across health-care disciplines. In the United States, the Institute of Medicine has issued a report highlighting the wide gap between evidence-based, efficacious interventions and clinical practice (Institute of Medicine, 2006). Coupled with this persistent research-practice gap are the continued health-care disparities facing health-care systems worldwide; many people lack access to evidence-based health care (Institute of Medicine, 2003; World Health Organization, 2008).

Addressing the research-practice gap will require a multifaceted and concerted effort by clinicians, scientists, communities, health-care systems,

and policy-makers. What are intervention scientists to do? Some scientists have stated that the research enterprise is at fault for failing to provide research adequate to inform clinical and health-policy decision-making and for developing interventions that are difficult to implement in diverse settings, particularly low-resource settings with vulnerable populations (Glasgow, 2008; Tunis, Stryer, & Clancy, 2003). A framework to guide intervention development and evaluation proposed by Glasgow and colleagues (1999) has the potential to address the research-practice gap. The RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) framework highlights the need for health-care interventions to demonstrate more than efficacy; they must also reach the targeted population, be readily adopted by providers and health-care systems, be able to be consistently implemented by providers, and be able to be maintained over time (Glasgow, Vogt, & Boles, 1999; RE-AIM, 2009).

While there are many challenges to achieving the objectives of the RE-AIM framework, two are particularly relevant to the development of nursing interventions. One challenge centres on the need for intervention fidelity in contrast to intervention adaptability; the other centres on the need for internal validity in contrast to external validity in developing and evaluating interventions. Both of these challenges greatly influence the ability of efficacious or evidence-based interventions to be implemented in clinical practice, reach the targeted population, and be effective across providers and settings.

## Intervention Fidelity – Intervention Adaptability

When the efficacy of an intervention is being developed and tested, it is essential that intervention fidelity be maintained across participants and/or providers so that causal outcomes can be attributed to the intervention (Bellg et al., 2004; Santacroce, Maccarelli, & Grey, 2004). However, in implementing efficacious interventions, particularly in low-resource settings, adaptability to the local context may be necessary (Green & Glasgow, 2006). This requires an elusive balance between intervention fidelity and intervention adaptability. Highly structured protocols may be impossible to implement as intended (Glasgow & Emmons, 2007) and thus may not be effective. Highly adapted interventions may not include key components of an efficacious or evidence-based intervention and thus may not be effective (Oakley, Strange, Bonell, Allen, & Stephenson, 2006).

Some interventions may have a well-specified protocol that requires standardized delivery across providers and settings (Craig et al., 2008). This condition may be effective in some settings and with some inter-

ventions. However, many settings fail in their implementation efforts despite enthusiasm on the part of clinicians for a particular intervention. An intervention may be complex and difficult to learn, may be highly specific to a particular setting, may be not modularized or adaptable, or may be difficult to implement because of limited resources (Glasgow & Emmons, 2007).

While there is ongoing debate, current recommendations call for interventions that are adaptable to local contexts. However, adaptability cannot be treated haphazardly. Strategies for addressing the fidelity-adaptability tension in intervention evaluation include: clearly identifying a limited set of key components of the intervention; specifying the theoretical link between the intervention's components and mechanisms of change; and identifying a range of reasonable adaptations of the intervention — those that retain essential elements of the original protocol (Green & Glasgow, 2006; Michie, Fixsen, Grimshaw, & Eccles, 2009). Clearly defined core components of interventions are more likely to be successfully implemented across settings. In addition, clarity in the components of interventions and mechanisms of change will facilitate adaptation to clinician, patient, or setting characteristics (Michie et al., 2009). Adaptation can thus become systematic and can result in interventions that are suitable for wide dissemination, that are responsive to a community's cultural needs, and that are effective (Castro, Barrera, & Martinez, 2004).

It is therefore important that the processes and outcomes of intervention adaptation be described and systematically evaluated. Castro and colleagues (2004) propose a process of intervention adaptation that is systematic in addressing the intervention fidelity-adaptability tension. Intervention fidelity is addressed by carefully considering the core components of the intervention and consulting with its developers. Intervention adaptability is addressed by considering the characteristics of the setting and including stakeholders (i.e., clinicians, patients, policymakers) in the adaptation process.

The process of adaptation has relevance for the development of nursing interventions. It is critical that researchers conduct carefully planned pilot studies prior to undertaking an efficacy trial, to determine the feasibility, acceptability, and preliminary efficacy of the intervention (Feeley et al., 2009). Pilot studies can also be designed to determine the key components and adaptable components of an intervention, thus facilitating future dissemination. It may be that the early stages of intervention development will need to include a participatory research approach with key stakeholders convened to provide different perspectives on core/adaptable components. Participatory research conducted early in the development process may also facilitate dissemination to clinical practice

by ensuring that the intervention accurately reflects the context in which it will be applied (Green & Glasgow, 2006).

## Internal Validity – External Validity

Another challenge in meeting the objectives of the RE-AIM framework, and thus in narrowing the research-practice gap, is the emphasis on internal as opposed to external validity in evaluating interventions. As stated above, the trajectory of intervention development and evaluation specifies a development phase, then an efficacy trial followed by an effectiveness trial. Efficacy trials are essential and are aimed at determining cause and effect — assessing whether the intervention does more good than harm when delivered under optimal conditions. The emphasis of the research design is on experimental control with high standards of internal validity. If an intervention demonstrates efficacy, an effectiveness trial is conducted to assess whether the intervention does more good than harm under typical or real-world conditions (Glasgow, Lichenstein, & Marcus, 2003; Green & Glasgow, 2006). However, this intervention development and evaluation trajectory has not produced good evidence for clinical practice and policy-making (Tunis et al., 2003). Very few efficacy trials have been followed by effectiveness trials. When effectiveness trials *have* been undertaken, problems have occurred with implementation of the intervention — the intervention failing to produce the outcomes achieved in the efficacy trial (Hallfors & Cho, 2007). Thus research sometimes fails to translate into practice, particularly in low-resource settings, because interventions and methods of evaluation do not necessarily address critical contextual factors in clinical practice (Glasgow & Emmons, 2007).

While research is necessary to determine the efficacy of interventions, there is also a need for interventions that are robust across settings and can address a diversity of clinicians, patients, and settings (Braslow et al., 2005; Glasgow, 2008). Greater attention to contextual issues in feasibility and pilot studies is needed. In addition, researchers in medicine, the behavioural sciences, and psychology have recently called for "practical clinical trials" (Glasgow, Magid, Beck, Ritzwoller, & Estabrooks, 2005; March et al., 2005; Tunis et al., 2003). Practical clinical trials are distinguished from efficacy trials in that they include characteristics of effectiveness research, thus increasing the external validity or generalizability of the study. They reflect more of the complexity and context of clinical practice (Glasgow & Emmons, 2007). Key characteristics of practical clinical trials are identified in Table 1. Depending on the state of the science, more or fewer of these characteristics may be incorporated into an efficacy trial. For example, the testing of a novel intervention will require

**Table 1** ***Characteristics of Practical Clinical Trials***

- Answer the questions of clinicians, decision-makers, and policy-makers.
- Use a randomized clinical trial design.
- Evaluate multiple outcomes, including cost, satisfaction, and quality of life.
- Evaluate processes of implementation.
- Compare clinically meaningful alternatives (comparative effectiveness research).
- Recruit a diverse, heterogeneous sample.
- Include multiple settings and interventionists.
- Specify training and expertise of interventionists.
- Delineate the intervention's core components and components that are amenable to modification.

greater attention to internal validity than the testing of an intervention based on an established theoretical framework being applied in a new setting (or with a different dose or with an interventionist possessing a different skill set). Practical trials offer a mechanism for merging efficacy and effectiveness research, potentially leading to evidence that meets the goals of the RE-AIM framework — interventions that reach diverse patients, interventions that can be implemented by different clinicians and in different settings, and interventions that improve health outcomes.

## Development and Evaluation Models

What does all of this mean for intervention science and the process of developing and evaluating nursing interventions? Development and evaluation models that specify phases of the process remain important. Interventions need to be developed systematically and need to be tested for efficacy before being widely disseminated. However, a less discrete categorization of phases and a less linear model of evaluation have been proposed (Campbell et al., 2007; Glasgow et al., 2006). The Medical Research Council in the United Kingdom recently revised its guidelines for evaluating complex interventions (www.mrc.ac.uk/complexinterventionsguidance). Its new guidelines include greater attention to early pilot and development research, a less linear model of intervention evaluation, and the recognition that complex interventions may be most effective if adapted to local contexts (Craig et al., 2008). A systematic approach to intervention development remains critical. However, the context in

which the intervention is delivered needs greater consideration in all phases of development and evaluation (Craig et al., 2008). Also essential is greater attention to external validity during the intervention evaluation process (Green & Glasgow, 2006). Table 2 provides suggestions for intervention research aimed at meeting the goals of the RE-AIM framework.

Table 2 ***Directions for Future Research in Intervention Development and Evaluation***

| **Phase of Intervention Research** | **Directions for Future Research** |
|---|---|
| Development | Identify theoretical mechanisms of change. |
| | Identify key components and adaptable components of the intervention. |
| | Include participatory research with key stakeholders. |
| | Identify potential barriers to implementation, particularly in low-resource settings. |
| | Determine the feasibility, acceptability, and preliminary efficacy of the intervention. |
| | Estimate the effect size of the intervention. |
| | Identify moderators of intervention efficacy. |
| Efficacy | Monitor treatment fidelity and effect on outcomes. |
| | Report on some aspects of generalizability. |
| | Determine mediators of intervention efficacy. |
| | Consider a practical clinical trial design. |
| | Incorporate some characteristics of effectiveness research (e.g., diverse sample, multiple settings, evaluation of cost). |
| | Include process and outcome evaluation (mixed-method research). |
| Effectiveness | Consider conducting a pilot study to evaluate adaptation before conducting an effectiveness trial. |
| | Compare clinically meaningful interventions. |

## Conclusion

If nursing interventions are to improve the quality of care and the health of individuals, families, communities, and society, they will have to reach a diversity of clinicians, patients, and settings. Proposed new scientific approaches to intervention development and evaluation have the potential to enhance the reach, efficacy, adoption, implementation, and maintenance of interventions. Greater attention to possible implementation challenges during the intervention development phase and increased use of practical clinical trials during the evaluation phase are recommended. Attending to these challenges may ultimately serve to narrow the research-practice gap.

## References

Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, J., et al. (2004). Enhancing treatment fidelity in behavior change studies: Best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology, 23,* 443–451.

Braslow, J. T., Duan, N., Starks, S. L., Polo, A., Bromley, E., & Wells, K. B. (2005). Generalizability of studies on mental health treatment and outcomes, 1981 to 1996. *Psychiatry Service, 56,* 1261–1268.

Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter, D., et al. (2000). Framework for design and evaluation of complex interventions to improve health. *British Medical Journal, 321,* 694–696.

Campbell, N. C., Murray, E., Darbyshire, J., Emery, J., Farmer, A., Griffiths, F., et al. (2007). Designing and evaluating complex interventions to improve health care. *British Medical Journal, 334,* 455–459.

Castro, F. G., Barrera, M., & Martinez, C. R. (2004). The cultural adaptation of prevention interventions: Resolving tensions between fit and fidelity. *Prevention Science, 5,* 41–45.

Craig, P., Dieppe, P., Macintyre, S., Mitchie, S., Nazareth, I., & Petticrew. (2008). Developing and evaluating complex interventions: The new Medical Research Council guidance. *British Medical Journal, 337,* 979–983.

Feeley, N., Cossette, S., Côté, J., Héon, M., Stremler, R., Martorella, G., et al. (2009). The importance of piloting an RCT intervention. *CJNR, 41*(2), 84–99.

Flay, B. R. (1986). Efficacy and effectiveness trials in the development of health promotion programs. *Preventive Medicine, 15,* 451–474.

Glasgow, R. E. (2008). What types of evidence are most needed to advance behavioral medicine? *Annals of Behavioral Medicine, 35,* 19–25.

Glasgow, R. E., Davidson, K. W., Dobkin, P. L., Ockene, J., & Spring, B. (2006). Practical behavioral trials to advance evidence-based behavioral medicine. *Annals of Behavioral Medicine, 31,* 5–13.

Glasgow, R. E., & Emmons, K. M. (2007). How can we increase translation of research into practice? Types of evidence needed. *Annual Review of Public Health, 28,* 413–433.

Glasgow, R. E., Lichtenstein, E., & Marcus, A. C. (2003). Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *Public Health Matters, 93,* 1261–1267.

Glasgow, R. E., Magid, D. J., Beck, A., Ritzwoller, D., & Estabrooks, P. A. (2005). Practical clinical trials for translating research to practice: Design and measurement recommendations. *Medical Care, 43,* 551–557.

Glasgow, R. E., Vogt, T. M., & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *American Journal of Public Health, 89,* 1322–1327.

Green, L. W., & Glasgow, R. E. (2006). Evaluating the relevance, generalization, and applicability of research: Issues in external validation and translation methodology. *Evaluation and the Health Professions, 29,* 126–153.

Hallfors, D., & Cho, H. (2007). Moving behavioral science from efficacy to effectiveness. *International Journal of Behavioral Consultation and Therapy, 3*(2), 236–250.

Institute of Medicine. (2003). *Unequal treatment: Confronting racial and ethnic disparities in healthcare* (B. D. Smedley, A. Y. Stith, & A. R. Nelson, Eds.). Washington: National Academy Press.

Institute of Medicine. (2006). *Community quality health care in America 2001. Crossing the quality chasm: A new health system for the 21st century.* Washington: National Academy Press.

March, J. S., Silva, S. G., Compton, S., Shapiro, M., Califf, R., & Krishnan, R. (2005). The case for practical clinical trials in psychiatry. *American Journal of Psychiatry, 162,* 836–846.

Michie, S., Fixsen, D., Grimshaw, J. M., & Eccles, M. P. (2009). Specifying and reporting complex behavior change interventions: The need for a scientific method. *Implementation Science, 4*(1), 40. Available online: http://www.implementationscience.com/content/4/1/40.doi:10.1186/1748-5908-4-40.

Naylor, M. D. (2003). Nursing intervention research and quality of care. *Nursing Research, 52,* 380–385.

Oakley, A., Strange, V., Bonell, C., Allen, E., & Stephenson, J. (2006). Process evaluation in randomized controlled trials of complex interventions. *British Medical Journal, 332,* 413–416.

RE-AIM. (2009). *Applying the RE-AIM framework to health behavior interventions.* Retrieved September 30, 2009, from http://www.re-aim.org/2003/researchers/framework_res.html.

Santacroce, S. J., Maccarelli, L. M., & Grey, M. (2004). Intervention fidelity. *Nursing Research, 53,* 63–66.

Tunis, S. R., Stryer, D. B., & Clancy, C. M. (2003). Practical clinical trials: Increasing the value of clinical research for decision making in clinical and health policy. *Journal of the American Medical Association, 290,* 1624–1632.

Whittemore, R., & Grey, M. (2002). The systematic development of nursing interventions. *Journal of Nursing Scholarship, 34,* 115–120.

World Health Organization. (2008). *The world health report 2008 – Primary health care (now more than ever).* Retrieved September 8, 2009, from www.who.int/whr/2008/en/.

---

*Robin Whittemore, PhD, APRN, is Associate Professor, School of Nursing, Yale University, New Haven, Connecticut, United States.*

*Résumé*

# L'expérience/les perceptions des femmes en tant que participantes à un groupe témoin avec attention et à un groupe d'intervention expérimentale, dans le cadre d'un essai clinique randomisé

**Claudia C. Beal, Alexa Stuifbergen, Deborah Volker et Heather Becker**

Un groupe témoin avec attention peut être utilisé pour contrôler l'effet placebo lors de l'évaluation d'interventions psychosociales et comportementales. Les auteures ont réalisé une étude descriptive qualitative afin de cerner les perceptions de femmes atteintes du syndrome de fibromyalgie concernant leur participation/expérience au sein d'un groupe témoin avec attention et d'un groupe d'intervention expérimentale, à la suite d'un essai clinique randomisé. Des entrevues semi structurées ont été réalisées auprès de 18 femmes (12 du groupe d'intervention expérimentale et six du groupe témoin avec attention). Les participantes du groupe témoin ont signalé certains bienfaits mais peu de changements comportementaux découlant de la participation à l'essai clinique. Certaines participantes ont été déçues de ne pas avoir bénéficié de ce type d'intervention. Des perceptions de changements dans les attitudes concernant le syndrome de fibromyalgie et certains comportements rapportés par le groupe d'intervention semblent conformes à la théorie sous-jacente à l'intervention. Des interactions sociales négatives et positives avec les autres participantes figurent parmi les effets placebos possibles relevés chez les deux groupes.

Mots clés : groupe témoin, effets placebos, fibromyalgie

*CJNR 2009, Vol. 41 Nº 4, 16–31*

# Women's Experiences as Members of Attention Control and Experimental Intervention Groups in a Randomized Controlled Trial

**Claudia C. Beal, Alexa Stuifbergen, Deborah Volker, and Heather Becker**

Attention control groups are often used in research testing the efficacy of psychosocial and behavioural interventions in order to control for placebo effects. The authors conducted a descriptive qualitative study to investigate how participants viewed their experiences in attention control and experimental intervention groups following a randomized controlled trial for women with fibromyalgia syndrome. Moderately structured interviews were conducted with 18 women (12 from the experimental intervention group and 6 from the attention control group). Members of the control group reported some benefits but few behavioural changes as a result of participating in the RCT, and some participants expressed disappointment at not receiving the intervention. Perceptions of changes in attitudes towards fibromyalgia syndrome and behaviours reported by the intervention group appear to be consistent with the theory underlying the intervention. Possible placebo effects identified in both groups include negative and positive social interactions with other participants.

Keywords: control groups, placebo effects, intervention research, fibromyalgia

An important area of chronic illness research is testing experimental interventions consisting of patient education and/or cognitive-behavioural strategies aimed at self-management and health promotion (Burckhardt, 2002). The use of control groups in randomized controlled trial (RCTs) of patient education and behavioural interventions enables researchers to distinguish between the effect of the hypothesized mechanism of an intervention and the effect of other components of the intervention (Street & Luoma, 2002). Among the challenges associated with the use of control groups in nursing intervention research is the fact that placebo effects may cause difficulty interpreting the results of an RCT if both control and intervention groups show improvement (Fogg & Gross, 2000).

Between January 2004 and December 2006 we conducted an RCT with attention control groups to test a wellness intervention for women with the chronic condition of fibromyalgia syndrome (FMS). The objective of the RCT was to examine the effect of the intervention on the

level of self-efficacy for health promoting behaviours, health promoting activity, and perceived quality of life. Participants in the RCT were randomized to a group in which they would develop skills to engage in health promoting behaviours (intervention group) ($N = 98$) or a group that would receive information about other health-related topics (attention control group) ($N = 89$). Participants were not informed which group they were assigned to. Research activities for the two groups were held concurrently at a women's health centre but on different days, to avoid contact between the two groups. The groups had different facilitators. During the study period 10 intervention and 10 attention control cohorts were formed, each containing 8 to 12 participants.

The Lifestyle Counts intervention was based on a theoretical framework incorporating concepts from the Health Belief Model (Becker, 1974), Pender's (1987) model of health promotion and self-efficacy theory (Bandura, 1982). It was first tested among women with multiple sclerosis (Stuifbergen, Becker, Blozis, Timmermann, & Kullberg, 2003) and later adapted for use among women with FMS (Stuifbergen, Harrison, Becker, & Carter, 2004). Lifestyle Counts consisted of eight 2-hour lifestyle change classes followed by a supportive environment component. The facilitators for the Lifestyle Counts intervention were a clinical nurse specialist experienced in working with persons with chronic conditions and a woman with a doctoral degree in social work who had FMS. The lifestyle change classes included patient education about health promoting behaviours in the context of FMS, including physical activity, nutrition and stress management, discussions about resources and about barriers to health behaviours, a self-assessment of health behaviours, and the development of strategies for building self-efficacy with respect to health behaviours. The supportive component consisted of bi-monthly phone calls for 3 months during which the facilitators used motivational techniques to assist and support participants as they strove to achieve individual health behaviour goals and develop solutions to perceived barriers to health behaviours.

The attention control group received eight 2-hour classes consisting of information on health topics not covered in the lifestyle change classes. Topics included medications used to treat FMS, heart health, enhancing memory, and understanding health information. The protocol for the control group followed a lecture format and specified that the facilitator, a nurse with a master's degree and experience working with persons with chronic conditions in a research environment, not engage participants in discussions of ways to improve self-efficacy for health behaviours or discuss topics covered in the lifestyle change classes. During follow-up phone calls, made at the same frequency as for the intervention group, participants were asked if they had questions about class content.

The results of the RCT indicated that the attention control and experimental intervention groups demonstrated significant improvement ($p < .05$) on measures of self-efficacy, health promoting behaviours, and quality of life (Stuifbergen et al., in press). In order to gain a better understanding of how the research groups functioned, we conducted a qualitative descriptive study to answer the following research question: *How did attention control and experimental treatment group participants view their experiences in an RCT to test the effects of a wellness intervention for women with FMS?*

## Literature Review

### *Rationale for Attention Control Groups*

Activities for the attention control groups are similar to those for the intervention but without the components of the intervention theorized to have an effect on dependent variables (Bickman & Rog, 1998). An assumption underlying the use of control groups in patient education and behavioural intervention research is that the interventions contain specific factors theorized to affect outcome variables as well as non-specific factors, such as social support, that may be therapeutically active ingredients (Schwartz, Chesney, Irvine, & Keefe, 1997). The total effect of an experimental intervention derives from both specific and non-specific factors (Vickers & de Craen, 2000). Random assignment to the control or intervention group is thought to control for the effect the non-specific factors may have on study outcomes such that the magnitude of the between-group differences reflects the efficacy of the specific factors in the experimental treatment (Hakim, 1987).

### *Placebo Effects*

Placebo effects are defined as a change in the dependent variable not attributable to the specific components of the intervention under investigation (Vickers & de Craen, 2000). They likely occur due to a combination of factors, including the nature of the relationship between the participants and members of the research team and the personal characteristics of these individuals, the condition under study, and the research environment (Shapiro, 1964). Participant factors that may account for placebo effects include expectations about the outcome of a study, conditioned responses to the health-care milieu, and personality characteristics (Crow et al., 2001). Personal attributes of members of the research team, such as warmth and empathy towards participants, may influence participants' perceptions of the intervention; also, researchers may unknowingly communicate their attitudes about the study (Street & Luoma, 2002). Because the factors that contribute to placebo effects are

complex and vary from study to study, the placebo effect is not considered a unitary phenomenon that can be reliably replicated (Shapiro & Morris, 1978).

### *Design of Attention Control Groups*

Lindquist, Wyman, Talley, Findorff, and Gross (2007) specify several principles as important to the design of control groups: equivalence of the interventions, distinctiveness versus comparability of interventions, and attractiveness of the control condition. The control group should be equivalent to the experimental group in terms of the time commitment required of participants, amount of attention paid by the researchers, format of activities, and scheduling of follow-ups. The two groups should be conducted contemporaneously to control for history and maturation effects. The control group should not be comparable to the experimental group, meaning that it should not contain elements that may have an effect on study outcomes through a mechanism that differs from that of the experimental intervention. Also, the control group should offer something of value and interest so that it is attractive to participants. Control groups that are attractive to participants and structurally equivalent but not comparable to the experimental intervention contribute to the internal validity of an RCT (Lindquist et al., 2007).

Health information control groups have been used in several intervention studies testing the efficacy of patient education and/or cognitive-behavioural strategies for FMS (Buckelew et al., 1998; Nicassio et al., 1997). In these groups, participants receive information about health-related topics but there are no strategies for changing behaviour. A health information control group differs from a patient education intervention, which consists of "planned, organized learning experiences designed to facilitate voluntary adoption of behaviors or beliefs conducive to health" (Burckhardt, 1994, p. 2). The rationale for using a health information control group is that health information alone does not lead to change in behaviour (Bucklew et al., 1998).

## Methodology

### *Design and Procedures*

Qualitative description was chosen as the methodology for the study. This method is appropriate when a researcher aims to obtain a comprehensive summary of an event or experience and convey it "in everyday language" (Sandelowski, 2000, p. 336). Sandelowski (2000) describes this approach as not highly interpretive and as instead yielding "largely unadorned answers" to a research question.

After Internal Review Board approval was received, participants who had completed the RCT in the preceding year ($n$ = 63) were invited by letter to participate in an interview about their experiences in the research group. A total of 20 participants contacted the research office to express an interest in the study, 14 from the intervention group and 6 from the control group. A member of the research staff contacted these individuals by phone to describe the purpose of the study and to schedule interviews. The final sample consisted of 6 participants from the control group and 12 from the intervention group, because 2 women from the intervention group were unable to schedule interviews. Recruitment and interviewing took place over a 7-month period (September 2006 through March 2007).

Verbal and written informed consent was obtained at the time of the interview by the first author, who conducted the interviews. All interviews took place in a private room at a women's health centre, with the exception of one interview, which took place in the participant's home. The interviews lasted approximately 45 to 60 minutes. The interview schedule consisted of six open-ended questions (Figure 1). Consistent with Sandelowski's (2000) approach, interview questions were crafted to uncover the basic nature of participants' experiences in the RCT. The interviews were audiorecorded and transcribed verbatim. Each participant received a $20 gift card to a national chain store for taking part in the study.

**Figure 1** ***Interview Schedule***

1. What was it like being in the research group?
2. Why did you decide to join the research group?
3. What was the most valuable thing about being in the research group for you?
4. How has being in the research group affected how you think about having FMS?
5. How has being in the research group affected your life?
6. What would have made the research study a better experience for you?

### *Sample*

The 18 women who made up the sample ranged in age from 34 to 71. The average time since diagnosis of FMS was 8.94 years. Fifteen participants were White, two were African American, and one was Hispanic. Most of the participants (13) were married, one was widowed, two were

divorced, and two indicated that they had never married. The average number of years of education for the sample was 15. The majority of participants (15) were not employed. The average number of classes attended was 6.88 for the intervention group and 6.66 for the control group.

### *Data Analysis*

The transcripts were sorted by research group and the data set for each group was analyzed separately in order to identify similarities and differences in participants' experiences in the two groups. Qualitative content analysis was used to analyze each data set (Morse & Field, 1995; Sandelowski, 2000). This method consists of carefully reading and rereading the transcripts to identify the main topics in the data. The transcripts were coded by hand, which involved marking phrases, sentences, or larger segments and noting, in the margins, the corresponding topics. This process continued until no new topics were identified. Then a description for each topic was developed, which became the category label. Some categories were combined and in some cases subcategories were created. A table was drawn up in a Microsoft Word document in which the marked segments of the transcripts were sequestered under each category label. The next step in the analysis was to construct paragraphs to describe the categories and the relationships between categories. In the final analytic step, the descriptive summaries of the categories were compared across the two data sets.

### *Trustworthiness of the Data*

The trustworthiness of the results of a qualitative research study is assessed by measuring their persuasiveness in convincing readers that they merit attention (Lincoln & Guba, 1985, p. 290). One way to present evidence for trustworthiness is to clearly describe all research activities so that readers can decide if the researcher's conclusions are congruent with the methods and procedures used (Mischler, 1986). Trustworthiness is also enhanced through procedures designed to reduce researcher bias. In the present study, the research team member who conducted the interviews and data analysis was not a facilitator for either of the research groups. At the time of the interviews, she had not been informed about which group the participant had been assigned to, in order to minimize any possible effect of this knowledge on the interview. She discussed her findings with the research team and solicited their perspectives on her conclusions. Finally, the results of the data analysis were reviewed by a researcher with experience in qualitative methods who had not been involved in the RCT (Kahn, 2000).

## Findings

Three main categories were identified in each data set. These had to do with participants' interactions with other research participants, perceptions about the classes, and perceived effects of participating in the RCT.

### *Interactions With Other Research Participants*

During the interviews the participants in both groups made many observations about the other women in their research group. This category contained four subcategories that reflected different dimensions of participants' interactions.

***"There's somebody out there who understands."*** Most participants in both groups characterized the opportunity to spend time with other women with FMS as the most valuable part of their experience in the RCT. The women described feeling alone having FMS, which they attributed to the fact that persons close to them often did not understand the diagnosis or its effect on their lives. This perception extended to experiences with physicians, who were described as frequently sceptical of participants' symptoms. "Knowing that I wasn't the only one . . . just being able to relate to others and hear their anxiety and their pain and to realize you're not the only one, that's comforting to know."

***"We trade ways of doing things that help us."*** The exchange of symptom-management strategies and health-care resources was integral to participants' interactions in both groups. The women reported that they had tried or were currently using a variety of pharmacological and non-pharmacological modalities to manage their symptoms, and they were eager to learn about and try strategies that were effective for the other women. One participant likened the process of exchanging symptom-management strategies and resources to "a quilt show where you go and put all your pieces on the table."

***"All of us are in different places."*** Despite commonalities in their experiences as women with FMS, participants in both groups were aware of differences among them. Some of these differences had to do with personal and sociodemographic characteristics. For example, participants remarked that with FMS there is "no distinction between race, colour, religion, age" and that the women in the RCT ranged from "redneck to . . . white-collar worker." They expressed surprise that the group included younger women, because they had assumed that only older individuals had FMS. One woman indicated that the diversity of the participants was reassuring in that "you don't place blame on yourself that you were singled out."

Differences in socio-economic status gave rise to reflection on how economic circumstances affect one's ability to manage symptoms and/or obtain health services. One participant said, "It's easier for people who have money to deal with this disease than it is for people who don't." Another commented that women of financial means in her group had access to medical specialists and could afford prescription medications and self-management strategies such as water exercise classes. Despite these differences, a participant who described herself as of modest financial means said she "never felt any tension along those lines" in her group.

A frequent topic in the interviews was different attitudes towards FMS among the participants. One woman divided her group into "self-starters" who were making an effort to improve their situation and individuals who were waiting "for the doctors to find the magic pill." Another woman commented that some of her fellow participants did not seem to be "doing anything to make their situation better."

Perceived differences in attitude towards FMS sometimes led women to compare themselves to their fellow participants. For example, one woman felt "a little bit of pride" for having discovered and used strategies, unlike the other women in her group, to cope with her symptoms. Although they were frustrated with participants who did not, in their view, do enough to improve their situation, the women expressed compassion for those participants who had adverse life circumstances and more severe symptoms. Several women expressed a sense of gratitude that their FMS was "not as severe as [that of] others."

***The "Leavers."*** Only participants from the control group expressed concern or opinions about women who missed classes or left the group altogether. One participant, who referred to these individuals as "leavers," described the absences as "mysterious" and seemed bothered that "nobody ever said anything and it was like they just didn't exist." She wondered why it was so hard for people to invest a few weeks of their time to try to get help. Another participant wanted to know the reasons for the absences and assumed that confidentiality issues prevented the facilitators from discussing the absences. Concern about absences may have been reflective of the women's feelings about attending weekly classes themselves. For example, one woman mentioned that there were times when she was physically unwell or the scheduled topic was not of interest to her but she went to the class anyway.

### *Perceptions About the Classes*

In both groups the interviewees' opinions about the classes were mainly positive. Comments by members of the intervention group revealed that they thought the topics discussed in the Lifestyle Counts classes were "very educational" and that the classes "pretty well covered everything."

One participant said that the classes "made you think about things you might not be doing that you could do, or that you should stop doing."

The control group interviewees indicated that they acquired new information in the weekly classes, such as medical conditions associated with FMS and how to research health topics online. Several participants questioned the inclusion of information about disability and long-term-care insurance because these topics were not relevant to their situation or because the emphasis should have been on "being as healthy and independent and self-sufficient as possible." However, one woman said that this information would have been helpful to her when she was trying to obtain disability benefits.

Several control group interviewees expressed regret that they were not in the intervention group, primarily because they did not gain new symptom-management strategies as a result of participating in the RCT: "I was disappointed that I was in the control group, because I wanted to learn something that would be really useful. . . . I wanted some concrete advice that was going to make things better." This sentiment was echoed by another woman, who said that after she reviewed the materials from the other group at the end of the RCT she concluded that the intervention group "would have been more useful." However, the control group interviewees all expressed positive feelings about their participation in the RCT. For example, one woman said that she was glad she was in the trial because it was "a kind of giving, and it's also kind of growing [because] the things I've learned can be a resource to others."

Another difference between the two groups concerned perceptions about the facilitators and guest speakers. Two members of the control group mentioned that they liked the facilitator and were complimentary about how she performed her role. The women who received the Lifestyle Counts intervention discussed the facilitators/guest speakers to a greater extent, often recalling specific information that a particular individual presented in class. Several women from the intervention group described the facilitators and speakers as "good examples" and commented that the facilitators were "slender" and were achieving their goals despite their chronic health condition. One woman noted that it was a very positive thing that the facilitators and guest speakers were not "poor [me], pity me types."

### *Perceived Effects of Participation in the RCT*

The third category consisted of findings related to the women's perceptions of changes in their lives as a result of their participation in the RCT. Shifts in attitudes about FMS and alterations in health behaviour were noted by participants in both groups, although the reports were more extensive among the intervention group interviewees. One member of

the intervention group said that, as a result of her experiences in the RCT, she felt "in control of my illness and my illness isn't controlling me." Another Lifestyle Counts participant had a more hopeful outlook on living with FMS because "doing some of the things they had been saying in class and then seeing a change . . . altered my way of thinking what's going to happen to me down the line." Other intervention group participants said that the classes helped them to set realistic goals, pace themselves, follow a more healthful diet, and employ stress- and time-management techniques.

The changes reported by the control group participants were fewer. One woman said she had "blamed myself for having it [FMS] . . . because I'm fat" but after the trial did not feel "so bad and so useless." Another woman thought she was noticing her symptoms sooner.

Participants in both groups attributed changes in attitude towards FMS or in health behaviours to interactions, whether positive or negative, with other women in their group. One participant said that she had learned to manage FMS better because she "pulled the experiences from some of the other ladies." Another indicated that she started taking better care of herself as a result of the example set by a woman in her group. Some changes were attributed to perceptions about the negative qualities of other participants: "It made me say, 'I'm not going there,' because there are still so many women, I think, that left there, like, 'well, this is what I have and this is what I'm going to have and I can't get any better'." The only person in the control group who reported a change in health behaviour after the trial had started lifting weights because the women in her group were "such a lot of whiners that I don't want to be like that."

Only participants in the intervention group attributed changes in attitudes and health practices to their interactions with the facilitators and guest speakers. These changes had to do with the personal characteristics of the facilitators and speakers as well as their credibility as experts in their fields. One woman said that although she knew about some health practices discussed in her group before she entered the trial, "hearing it from the experts up there and knowing this is something you need to be doing, you know it. Get on the ball and do it. And I did."

## Discussion

Our study had several limitations. Some of the characteristics of women who volunteered for the study may have differed from those of women who did not volunteer. In addition, approximately twice as many intervention group participants as control group participants volunteered for the study, resulting in unequal sample sizes. The reason for this disparity

is not clear, but it may reflect the feelings of control group participants about their experiences in the RCT. Several control group participants expressed disappointment about not being assigned to the intervention group; it is possible that other control group participants who felt this way were disinclined to volunteer for the study.

The findings provide insight into the mechanisms by which non-specific yet therapeutically active ingredients in patient education and behavioural interventions may give rise to placebo effects. The exchange of social support by participants is considered to be an important ingredient in group interventions (Lepore, Helgeson, Eton, & Schulz, 2003). The enthusiasm shown by participants in both groups for the opportunity to interact with other women with FMS is not surprising given that FMS is a stigmatizing condition in which one feels that the legitimacy of one's symptoms is called into question by the absence of external signs and definitive diagnostic tests (Åsbring & Närvänen, 2002). Our findings suggest that the emotional validation and symptom-management techniques exchanged by participants led to behavioural change. There is also evidence that some participants were motivated to make changes by the actions of other women in their group. This is consistent with Bandura's (1982) self-efficacy theory, whereby an individual's belief that they will succeed in a pursuit is strengthened by the success of another person they perceive as similar.

One intriguing finding is that individuals in both groups attributed changes in attitudes towards FMS and health behaviours to negative perceptions of other participants. Placebo effects associated with negative role models in research groups apparently receive less attention in the literature than social support and positive role models. This finding suggests the need to explore the mechanisms by which negative interpersonal interactions in research groups affect study outcomes.

Another finding of relevance to the RCT outcome concerns interactions between the facilitators and the participants. Whereas members of the intervention group indicated that the facilitators and guest speakers were catalysts for change in health behaviour and attitudes towards FMS, there was no evidence of this phenomenon in the control group. This result is congruent with the design of the Lifestyle Counts intervention: The facilitators were in a collaborative goal-setting relationship with participants, and a facilitator and guest speaker with chronic health conditions may have served as role models. However, it is possible that the control group facilitator exerted an influence on participants that resulted in behavioural change, even though this is not apparent in our findings. An "experimenter" can unintentionally affect the behaviour of research participants (Rosenthal, 2002). For example, experimenters may sense reactions by research participants early in an RCT, which can influence

their subsequent interactions with participants (Rosenthal, 2002). It is possible that the control group facilitator sensed participants' disappointment about their group assignment and responded in a manner that influenced outcomes. Additionally, the facilitator was a nurse, and health practitioner-client interactions can be therapeutic without the practitioner intending them to be so (Moerman & Jonas, 2002, p. 473).

The fact that several members of the control group were disappointed with their group assignment highlights the challenges associated with designing attractive control conditions. The health information control group was designed to be of value and interest to the study population (e.g., women of various ages with FMS), and evidence from the qualitative study indicates that this goal was largely met. However, it is clear that some members of the control group hoped to learn symptom-management strategies during the RCT, other than the ones they learned in their group. This is not surprising given that existing medical treatment may provide incomplete relief of FMS symptoms (Goldenberg, Burckhardt, & Crofford, 2004).

In some pharmacological or physiological intervention trials, it is possible for research participants to remain unaware of their group assignment. In patient education and behavioural intervention studies, however, participants may surmise which group they have been assigned to and, further, form opinions about the attractiveness of the groups. With respect to the present study, it is not known when the control group participants who expressed a preference for the other group surmised their group assignment. At the conclusion of the RCT, all participants were offered a copy of the materials from both research groups. It is therefore possible that opinions about group assignment, and the relative attractiveness of each group, were formed at this time. It is also possible that participants surmised their group assignment during the RCT as they compared the information they were receiving in class with the description of the groups that was provided in the consent document.

RCT participants who perceive that they are not receiving the experimental intervention can have feelings of demoralization (Street & Luoma, 2002). Street and Luoma (2002) posit that it is an ethical responsibility of researchers to ensure that participants are not worse off at the conclusion of a trial than at its start, and that if a participant's normal functioning is adversely affected by randomization to a control group this responsibility may not have been met. There is no indication that the control group participants in our study experienced demoralization related to their group assignment. In fact, these women reported that they enjoyed the weekly classes and derived benefits from their participation in the RCT.

An ethical issue in intervention research is the responsibility of researchers to provide participants with some form of symptom management or standard of care (O'Brien, 1997). In our RCT, members of the attention control group did receive information about symptom-management strategies. Background information gathered prior to the RCT revealed that there was no single standard of care for FMS in this community. In fact, many participants said they had difficulty obtaining health care that they viewed as responsive to their needs. In addition, data collected during the study indicated that participants were availing themselves of a wide array of prescription medications, nutritional supplements, and lifestyle strategies to manage their symptoms. Our participants were not asked to alter their usual symptom-management strategies or medical treatments during the RCT, as we wished to mimic what would happen in the real world if women with FMS attended wellness classes.

## Conclusion

The findings of this qualitative investigation of women's experiences in attention control and intervention groups of an experimental wellness intervention RCT indicate that the two research groups functioned largely as expected. Members of the control group reported gaining something of benefit from the RCT but making few behavioural changes as a result of their participation. Perceptions of change in attitudes towards FMS and behaviours reported by the intervention group appeared to be a result of the focus on skill-building and the positive role modelling of facilitators, consistent with the theory underlying the intervention. Possible placebo effects in both groups, including positive and negative social interaction among participants, may have obscured any effect of the intervention. As recommended by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium (Bellg et al., 2004), future studies should continue to explore participants' perceptions of treatments across intervention and control conditions.

## References

Åsbring, P., & Närvänen, A. (2002). Women's experiences of stigma in relation to chronic fatigue syndrome and fibromyalgia. *Qualitative Health Research, 12*(2), 148–160.

Bandura, A. (1982). Self-efficacy mechanism in human agency. *American Psychologist, 37,* 122–147.

Becker, M. H. (1974). *The Health Belief Model and personal health behavior.* Thorofare, NJ: Slack.

Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., et al. (2004). Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology, 23*(5), 443–451.

Bickman, L., & Rog, D. (1998). *Handbook of applied social research methods*. Thousand Oaks, CA: Sage.

Buckelew, S. P., Conway, R., Parker, J., Deuser, W. E., Read, J., Witty, T. E., et al. (1998). Biofeedback/relaxation training and exercise interventions for fibromyalgia: A prospective trial. *Arthritis Care and Research 11*(3), 196–209.

Burckhardt, C. S. (1994). Arthritis and musculoskeletal patient education standards. *Arthritis Care and Research,* 7(1), 1–4.

Burckhardt, C. S. (2002). Nonpharmacologic management strategies in fibromyalgia. *Rheumatic Disease Clinics of North America, 28,* 291–304.

Crow, H., Gage, H., Hampson, S., Hart, J., Kimber, A., & Thomas, H. (2001). The placebo effect: Methodological process and implications of a structured review. In A. Stevens, K. Abrams, J. Brazier, R. E. Fitzpatrick, & R. Lilford (Eds.), *The advanced handbook of methods in evidence based health care* (pp. 73–89). London: Sage.

Fogg, L., & Gross, D. (2000). Threats to validity in randomized clinical trials. *Research in Nursing and Health, 23,* 79–87.

Goldenberg, D. L., Burckhardt, C., & Crofford, L. (2004). Management of fibromyalgia syndrome. *Journal of the American Medical Association, 292*(19), 2388–2395.

Hakim, C. (1987). *Research design: Strategies and choices in the design of social research*. London: Allen & Unwin.

Kahn, D. L. (2000). Reducing bias. In D. L. Kahn, M. Z. Cohen, & R. H. Steeves (Eds.), *Hermeneutic phenomenological research* (pp. 85–92). Thousand Oaks, CA: Sage.

Lepore, S. J., Helgeson, V. S., Eton, D. T., & Schulz, R. (2003). Improving quality of life in men with prostate cancer: A randomized controlled trial of group education interventions. *Health Psychology, 22*(5), 443–452.

Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*. Newbury Park, CA: Sage.

Lindquist, R., Wyman, J. F., Talley, K. M. C., Findorff, M. J., & Gross, C. R. (2007). Design of control-group conditions in clinical trials of behavioral interventions. *Journal of Nursing Scholarship, 39*(3), 214–221.

Mischler, E. G. (1986). *Research interviewing*. Cambridge, MA: Harvard University Press.

Moerman, D. E., & Jonas, W. B. (2002). Deconstructing the placebo effect and finding the meaning response. *Annals of Internal Medicine, 136,* 471–476.

Morse, J., & Field, P. (1995). *Qualitative research methods for health professionals,* 2nd ed. Thousand Oaks, CA: Sage.

Nicassio, P. M., Radojevic, V., Weisman, M. H., Schuman, C., Kim, J., Schoenfeld-Smith, K., et al. (1997). A comparison of behavioral and educational interventions for fibromyalgia. *Journal of Rheumatology, 24*(10), 2000–2007.

O'Brien, B. (1997). Debating the power of the placebo – experimental error or expectation mediated? *Western Journal of Nursing Research, 19*(5), 551–553.

Pender, N. J. (1987). *Health promotion in nursing practice*. East Norwalk, CT: Appleton & Lange.

Rosenthal, R. (2002). Experimental and clinician effects in scientific inquiry and clinical practice. *Prevention and Treatment, 5*(38), 1–11.

Sandelowski, M. (2000). Whatever happened to qualitative description? *Research in Nursing and Health, 23,* 334–340.

Schwartz, C. E., Chesney, M. A., Irvine, M. J., & Keefe, F. J. (1997). The control group dilemma in clinical research: Applications for psychosocial and behavioral medicine trials. *Psychosomatic Medicine, 59,* 362–371.

Shapiro, A. K. (1964). Factors contributing to the placebo effect. *American Journal of Psychotherapy, 18*(suppl 1), 73–88.

Shapiro, A. K., & Morris, L. A. (1978). The placebo effect in medical and psychological therapies. In S. L. Garfield & A. E. Bergen (Eds.), *Handbook of psychotherapy and behavior change,* 2nd ed. (pp. 369–410). New York: John Wiley.

Street, L. L., & Luoma, J. B. (2002). Control groups in psychosocial intervention research: Ethical and methodological issues. *Ethics and Behavior, 12*(1), 1–30.

Stuifbergen, A. K., Becker, H., Bloizis, S., Timmermann, G., & Kullberg, V. (2003). A randomized clinical trial of a wellness intervention for women with multiple sclerosis. *Archives of Physical Medicine and Rehabilitation, 84*(4), 467–476.

Stuifbergen, A. K., Blozis, S., Becker, H., Phillips, L., Timmerman, G., Kullberg, V., et al. (in press). A randomized controlled trial of a wellness intervention for women with fibromyalgia syndrome. *Clinical Rehabilitation.*

Stuifbergen, A. K., Harrison, T. C., Becker, H., & Carter, P. (2004). Adaptation of a wellness intervention for women with chronic disabling conditions. *Journal of Holistic Nursing, 22*(1), 12–31.

Vickers, A. J., & de Craen, A. J. M. (2000). Why use placebos in clinical trials? A narrative review of the methodological literature. *Journal of Clinical Epidemiology, 53,* 157–161.

## Acknowledgements

This study was supported by grant 2 RO1HD035047, National Center for Medical Rehabilitation Research, National Institute of Child Health and Human Development, National Institutes of Health.

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Child Health and Human Development or the National Institutes of Health.

---

*Claudia C. Beal, MN, RN, is a doctoral candidate in the School of Nursing, University of Texas at Austin, United States. Alexa Stuifbergen, PhD, RN, FAAN, is James R. Dougherty Jr. Centennial Professor in Nursing, School of Nursing, University of Texas at Austin. Deborah Volker, PhD, RN, is Associate Professor, School of Nursing, University of Texas at Austin. Heather Becker, PhD, is Research Scientist, School of Nursing, University of Texas at Austin.*

*CJNR 2009, Vol. 41 N° 4, 32–50*

*Résumé*

# L'identification de biais dans les recherches sur les interventions infirmières complexes : une liste de vérification

**Marsha Campbell-Yeo, Manon Ranger, Celeste Johnston et Dean Fergusson**

Un biais est défini comme étant toute erreur systématique faussant une estimation des résultats de recherche. Dans des études portant sur des interventions infirmières complexes, les biais sont particulièrement difficiles à repérer en raison de problématiques liées à l'anonymat et au choix des outils d'évaluation. Les auteurs identifient des stratégies de dépistage de biais dans les recherches sur les interventions. Une analyse documentaire et une consultation auprès d'experts révèlent six volets liés au développement de protocoles de recherche qui offrent des possibilités quant à la réduction de biais : le concept de recherche; la définition de l'intervention; le choix des comparaisons; la randomisation/l'allocation; l'intégrité de l'intervention; et la détermination des résultats. Les auteurs proposent une liste de vérification qui aidera les chercheurs à réduire le risque de biais dans le cadre de la préparation de protocoles d'essais portant sur des interventions infirmières complexes. Le recours à une telle liste peut bonifier la rigueur scientifique et assurer aux cliniciens l'accès à une information fiable.

Mots clés : biais, intervention complexe

*CJNR 2009, Vol. 41 Nº 4, 32–50*

# Controlling Bias in Complex Nursing Intervention Studies: A Checklist

**Marsha Campbell-Yeo, Manon Ranger, Celeste Johnston, and Dean Fergusson**

Bias is defined as any systematic error resulting in an inaccurate estimate of the outcome of a study. In studies of complex nursing interventions, bias is particularly difficult to control because of issues related to blinding and choice of controls. The authors identify strategies to control bias in intervention studies. They conduct a literature review and consult expert opinion to identify 6 areas of study protocol development that have potential for reducing bias: study concept, definition of intervention, selection of comparisons, randomization/allocation, integrity of intervention, and ascertainment of outcomes. They provide a checklist to help researchers reduce the potential for bias in preparing protocols for complex nursing intervention trials. Use of the checklist can enhance scientific rigour and thus help to ensure that clinicians are ultimately provided with reliable information.

Keywords: bias, complex intervention, nursing research

Study bias can be defined as any design error that results in an over- or under-estimation of the effect of an intervention, thus threatening the validity of the findings (Norman & Streiner, 2000). When properly conducted, the double-blind, randomized, placebo-controlled trial (RCT) has been identified as the gold standard for controlling bias in health research (Rees, Wade, Levy, Colford, & Hilton, 2005). However, this type of trial faces challenges for determining the effectiveness of complex nursing intervention trials, for three reasons. First, in intervention trials it can be difficult to blind investigators and participants to the intervention (Bang, Ni, & Davis, 2004). Second, in these trials, significant issues related to the appropriate choice of a comparison group can arise, given that the use of placebos is often impossible or unethical (Mann, 2007). Third, RCTs are usually limited to a single intervention, such as a drug, and are not designed to address issues that arise with more complex interventions, such as nursing interventions composed of interrelated elements (Hawe, Shiell, & Riley, 2008).

While controlling bias is only one of many aspects that must be considered in conducting research, it merits special attention in the context of complex nursing intervention trials, given the above-mentioned limitations of the classical RCT. It is therefore necessary to identify methods

for eliminating study bias. One such method is the development of carefully planned study protocols.

There are no concise guidelines for designing protocols that minimize the potential for bias in intervention studies. Therefore, the aim of this article is to develop a bias-control checklist to aid nurse researchers and health-care professionals in the planning of study protocols.

A computerized search of CINAHL, Pubmed, PsycINFO, Web of Science, and the Cochrane Collaboration Libraries was conducted for the years 1990 to 2009. Keywords included bias, complex interventions, clinical trials, and nursing research. The search was limited to English-language articles. Articles were excluded if they did not discuss at least one concept/issue that can contribute to the generation of study bias in intervention research. Relevant articles were reviewed. Expert opinion was elicited from clinical intervention researchers from three universities who came together to discuss the issue. Six areas of concern were identified and formed the basis for the checklist. The literature was searched based on keywords related to each topic.

The initial search found 38 articles in CINHAL, 14 in Pubmed, 14 in PsychInfo, 18 in Web of Science, and 18 in the Cochrane Libraries. Numerous articles overlapped among databases and for several articles the primary focus was not controlling bias in an intervention trial. A total of 10 articles were retained. Using this literature and expert input, we identified six primary points to be addressed in order to reduce the potential for bias during protocol development: (1) study concept, (2) definition of the intervention, (3) selection of comparisons, (4) randomization/allocation, (5) integrity of the intervention, and (6) ascertainment of outcomes. Each primary point is summarized in the checklist (Figure 1) and described below.

## Study Concept

Examination of the study concept presents the first real opportunity for researchers to identify and control bias. We define study concept as the issues and ideas that need to be considered, weighed, defined, and formalized in developing and justifying a study protocol. These include: determining the study topic, purpose, and hypothesis; determining the need for such a study; justifying its need; and seeking input, feedback, and buy-in from all study stakeholders. While an examination of the study concept will not target a specific form of bias per se, it is a platform from which investigators can both identify and minimize the potential for a multitude of biases.

The study concept should be based on a thorough literature review, at which time constructs related to the topic of interest may be identified as potential sources of bias. For example, if post-operative pain is the study

**Figure 1** ***Controlling Bias in Complex Intervention Trials: A Checklist***

| Key Points | Strategies | Purpose |
|---|---|---|
| Study Concept | ☐ Conduct systematic literature review/ meta-analysis<br>☐ Survey experts and colleagues; administer usual care<br>☐ Conduct pilot test(s) | • Creates basis for hypothesis<br>• Predicts possible contaminates, co-founders, and co-interventions<br>• Provides link between clinical practice and existing evidence<br>• Establishes feasibility |
| Definition of Intervention | ☐ Clearly define intervention<br>a. *Timing, duration, interval between each exposure*<br>b. *Resources required and setting*<br>c. *Characteristics and education of the provider* | • Ascertains replicability, generalizability, and uniformity of delivery |
| Selection of Controls | ☐ Differentiate between best and usual care<br>a. *Conduct a survey and document usual care*<br>b. *Conduct a pilot study*<br>c. *Apply protocol-driven controls*<br>d. *Consider a range of control arms* | • Allows for isolation of direct versus indirect effects of intervention<br>• Ensures greater consistency and comparability between groups |
| Randomization and Allocation<br>*(continued)* | ☐ Ensure true randomization<br>a. *Use opaque, sequentially numbered envelopes*<br>b. *Use off-site randomization, by phone or computer* | • Creates balance between the groups |

| Key Points | Strategies | Purpose |
|---|---|---|
| Randomization and Allocation | ☐ Conceal allocation<br>a. *Permuted variable blocks*<br>☐ Ensure unpredictability of groups<br>a. *Identify the means of recruitment and the recruiters*<br>b. *Maintain records for all those eligible to participate: those approached, those enrolled, and those refused*<br>☐ Clearly outline all steps in study protocol manual | • Limits differences in potentially confounding variables at baseline<br>• Decreases subversion bias<br>• Decreases research-staff manipulation of group assignment |
| Integrity of Intervention | ☐ Monitor intervention fidelity<br>a. *Address design, training, delivery, receipt, and enactment of intervention(s)*<br>b. *Use intervention-monitoring tools/ inter- and intra-rater coder reliability*<br>☐ Identify potential co-interventions<br>a. *Conduct random surveys to monitor standard care*<br>☐ Monitor for contamination<br>a. *Conduct random checks to determine whether participants have discussed the study with other participants or with nurses*<br>b. *Consider cluster randomization*<br>c. *Compensate for intra- or within-cluster correlation* | • Ensures that the study intervention remains stable across time, places, and persons<br>• Limits participant awareness of the treatment being received by the other group |

| | | |
|---|---|---|
| Analysis | ☐ Limit loss to follow-up<br>a. *Identify potential participant burden*<br>☐ Conduct intention-to-treat analysis | • Limits attrition, maintains sample size, and maintains statistical power<br>• Maintains group allocation, allowing for the balancing of confounding factors across groups |
| Ascertainment of Outcome | ☐ Choose a blind design<br>a. *Blind participants, care providers, and investigators where possible*<br>b. *Blind evaluator(s) of outcomes*<br>c. *Consider videotaped participant responses or direct entry of responses into computerized databanks*<br>☐ Choose objective outcomes<br>☐ Provide clear and precise written procedures for data collection<br>☐ Monitor adherence to study interventions | • Minimizes variations in interpretation of data and outcomes<br>• Controls for Hawthorne effect |

topic, pre-operative anxiety may be a related construct. If participants receive pre-operative care for their anxiety, this may affect post-operative pain, and it therefore becomes a source of bias. The identification of this source of bias in advance allows the researcher to incorporate measures to reduce bias during the development of the protocol. In the same way, the researcher can predict possible contaminates, confounders, and co-interventions that have been identified or summarized in previous studies (Blair, 2004).

**Definition of the Intervention**

The potential for exposure bias can arise when researchers fail to adequately define or fully describe interventions being examined (Campbell et al., 2000). Complex clinical interventions are particularly vulnerable to this type of bias, given their multi-faceted nature (Glasziou, Meats, Heneghan, & Shepperd, 2008). A precise definition of the intervention can ensure uniform delivery of the intervention, thus reducing the chance of exposure bias (Lindsay, 2004). A clear and complete definition of the intervention also allows for easy replication of the study, improves generalizability, and enhances the clinical utility of the findings (Campbell et al., 2000). In order to allow access to the definition of the intervention by granting agencies, those providing the study intervention, and those interested in utilizing the results, a precise definition should be included in the study protocol, included in a study manual for research personnel and staff, and reviewed during dissemination of the results.

In a review of 47 RCTs of nursing interventions published in 2000–01, inadequate definition was identified as the most common source of bias (Lindsay, 2004). Reflecting the significance of this issue, these trials originated in eight countries, focused on 14 different health fields (hospital and community populations), and included nursing, specialty, and high-impact general medical journals (e.g., *Lancet, British Medical Journal*). Similarly, a recent review including 27 nursing journals found that 141 research articles published in 2005 reported suboptimal definition of interventions (Conn, Cooper, Ruppar, & Russell, 2008). While the intervention definition accounted for an average 7.3% of article space, the space given to methodological descriptions accounted for over 20.7%. Moreover, only 38 articles (27.0%) reported sufficient detail about the intervention to allow for replication of the study or for translation of the intervention into practice.

Complete definition of the intervention should include not only details on the nature of the treatment but also information about its delivery (i.e., timing, duration, and interval of each exposure); materials needed (such as patient handouts or devices); the setting; and the characteristics and education of the provider (Glasziou, Meats, Henehan, &

Sheppard, 2008). For instance, in a recent study examining the efficacy of maternal skin-to-skin care during heelstick in very preterm neonates, infant condition, position, duration of the intervention, and maternal interaction were clearly defined and the five phases of blood collection were delineated (Johnston et al., 2008). Additionally, measures were taken to control potential sources of bias such as the technical skills and education of the provider, the setting, and the urgency of blood work.

## Selection of Appropriate Comparisons

In the evaluation of interventions, the primary purpose of a comparison group is to distinguish between the direct effects of the intervention and the indirect effects of participation in the study (Paterson & Dieppe, 2005). The lack of an appropriate comparison group increases the potential for bias. For instance, participants' symptoms may improve merely due to the passage of time, regression of an acute flare-up, or altered perception because they have been cared for or have been told that they should feel better. Therefore, the use of a comparison group that differs, ideally, only in that it does not receive the intervention is important in order to control for these confounding variables.

Two issues are important in choosing an appropriate comparison group: knowledge of the evidence-based recommendations and guidelines for treating a condition (best care), and current practice (usual care) in the clinical setting (Mann & Djulbegovic, 2003).

### *Best Versus Usual Care*

In intervention studies, the researcher's primary aim is to determine whether a treatment or intervention improves outcomes. Thus, if the intervention is being compared to usual care, it is important to determine whether usual care is reflective of the most recent findings in the literature. If usual care deviates significantly from best care, or if there is inconsistency in the usual care that is provided, then protocol-driven control treatments can ensure greater consistency and improved comparability between the groups (Silverman & Miller, 2004). If protocolized care is used as a comparison, measures are required to determine and ensure protocol compliance of both participants and care providers, in the same manner as in the intervention arm. A pre-trial observational survey, pilot study, or run-in phase could determine the feasibility of the protocolized group and the acceptability of the proposed intervention to staff and participants at all potential sites.

In cases where there is a lack of sufficient evidence to define best practice, great diversity of care, or significant staff reluctance to support new interventions, protocolized comparison alone may not be sufficient.

In such circumstances, the investigator may choose to consider a three-arm trial: a treatment group, a protocolized group reflective of one accepted form of care, and a comparison or usual-care arm reflective of current practice on the unit. Using this design, the researcher compares the efficacy of the new intervention to two alternatives rather than one. Every attempt should be made to ensure that each group is matched with respect to the experience of the health-care provider and number of interactions, thus ensuring that the intervention is the only difference between them (Silverman & Miller, 2004). Protocolized comparison groups enhance scientific validity because they limit inconsistencies between groups. However, if they do not adequately represent current practice, they are less generalizable and may be of little clinical value. The choice of losing generalizability in order to increase the scientific validity of a study should depend on the research purpose and question.

## Randomization and Allocation

Selection bias can occur if comparison groups are not considered equal at baseline, prior to the commencement of the intervention. Bias-reducing strategies such as randomization and allocation concealment are important because their exclusion has been associated with amplified treatment outcomes of 20–45% (Balk et al., 2002; Kunz, Vist, & Oxman, 2007).

### *Randomization*

Randomization is considered an optimal method for ensuring balance between groups because it limits differences in potentially confounding variables at baseline (Kunz et al., 2007), enhances the validity of statistical methods of analysis (Bridgman et al., 2003), and reduces the chance of mal-distribution of key predictors (Blair, 2004). True randomization occurs when participants have an equal chance of being assigned to the intervention or the comparison group, without interference from the investigators. Pseudo-randomization, or systematic assignment, has been mistakenly referred to as true randomization in some clinical research trials (Bridgman et al., 2003). In this instance, group assignment may be dictated by factors such as birth date, day of clinic visit, or room assignment. This type of allocation, which is easily predicted by investigators and participants, can lead to potential tampering with participant assignment.

There are several acceptable methods of randomization. One of the simplest, most straightforward, and least expensive is the use of sequentially numbered, opaque, sealed envelopes (SNOSE). This is a reasonable choice, especially for smaller single-centre trials (Doig & Simpson, 2005),

while pharmacy-controlled randomization and 24-hour central randomization by phone-in or Internet have been particularly useful in larger trials or in trials with more than one centre (Schulz & Grimes, 2002).

### *Allocation Concealment*

The most important aspect of randomization is the unpredictability of group allocation, which is referred to as allocation concealment. Inadequate concealment has been associated with an increase of up to 40% in effect sizes (Juni, Altman, & Egger, 2001). Unlike blinding, which controls bias during the course of the study, allocation concealment prevents selection bias and preserves allocation sequence before and until group assignment. Therefore, allocation concealment must be a priority in all studies where participants are randomized (Forder, Gebski, & Keech, 2005).

For the majority of randomization methods, large sample sizes are needed to ensure groups of equal size and of evenly distributed participants. However, in the case of trials with smaller sample sizes, such as many nursing intervention trials, the use of block randomization is helpful. Blocking is used to ensure that, at specific points of enrolment, equal numbers of participants have been assigned to receive either treatment. In unblinded studies it is vital that more than one block size be used, to prevent the anticipation of allocation sequence by the investigators (Schulz & Grimes, 2002). Permuted block randomization is a variation that alters the allocation sequence of specific blocks sizes. For example, blocks of four might consist of AABB, ABAB, ABBA, BABA, and so forth.

Subversion bias, a type of selection bias, occurs when research staff manipulate recruitment to enable the enrolment of specific participants in either the comparison or the experimental group. To avoid this, the randomization sequence should be prepared and conducted by an independent person preferably not linked with the field of study. Thus, telephone or Web-based sequence generation is an excellent choice, especially for multi-centre studies.

In keeping with the CONSORT guidelines (http://www.consort-statement.org), investigators are obliged to give details of all aspects of randomization and allocation concealment, including the individuals responsible for group assignment. Study protocols should include a process for accurately recording all eligible participants, those who are enrolled and those who refuse, and any participants who withdraw during the course of the study. Data on reasons for refusal or withdrawal and missed eligible participants should also be systematically collected.

## Integrity of Intervention

Throughout the course of a study, researchers must constantly verify that the intervention remains stable over time as well as from place to place and person to person (participants, caregivers, researchers, etc.). When trials involve human subjects or complex interventions, many uncontrollable psychological effects and non-specific treatment effects can occur. To minimize these unintended effects, one must first be aware of them. The following section describes biases that could affect the integrity of interventions and how they can be minimized.

## Intervention Fidelity

Intervention fidelity can be defined as the extent to which an intervention is carried out consistently, as planned, throughout all stages of the study (Bellg et al., 2004). It is considered central to the evaluation, comparison, and dissemination of all intervention research (Horner, Rew, & Torres, 2006). The effects of even the most well-defined intervention cannot be fully interpreted unless specific processes to ensure receipt and evaluation of the intervention have been put in place. Consistency in intervention delivery is often directly correlated with the complexity of the intervention, the number of sites, and the duration of the study. Several aspects of an intervention can affect fidelity. These include design, training, delivery, receipt, and enactment (Dumas, Lynch, Laughlin, Phillips Smith, & Prinz, 2001). To ensure fidelity, researchers should ask themselves: Have I provided a detailed definition using a combination of verbal, written, and electronic means that convey all aspects of the intervention to those providing the intervention? Can I guarantee that all the providers will be trained in a consistent manner? Have I included specific criteria to assess delivery outcomes? Have I incorporated ways to maintain provider competence and consistency over time by including an evaluation and feedback process? How will I know if the participants received the appropriate intervention?

Intervention-monitoring tools can be quantitative and/or qualitative in nature. They may consist of simple questions (*yes/no*) or be more descriptive (*none, adequate, excellent*) (Dumas et al., 2001). Providers and participants may simply be asked on a random basis about the delivery of the intervention (Orwin, 2000), or there may be a more sophisticated system. For example, in a large study examining methods for improving diabetes management in the community, a virtual networking system was used (Minnick, Catrambone, Halstead, Rothschild, & Lapidos, 2008). Similarly, in a large-scale prevention trial testing the effectiveness of family, peer, and school interventions for conduct disorder, substance abuse, and school failure, researchers incorporated an extensive fidelity

check that included a review of randomly selected videotaped sessions. Trained coders recorded adherence to the intervention protocol and evaluated the delivery technique of the provider, to ensure that the fidelity of both content and process was evaluated (Dumas et al., 2001). If coders are to be used in this manner, the researcher must also incorporate inter- and intra-rater coder reliability checks into the proposal (Santacroce, Maccarelli, & Grey, 2004).

***Co-interventions***

The addition of other treatments that are not included in the study protocol could influence the study's outcomes. These are known as co-interventions. In general, a balance of co-intervention use across study groups will dilute the observed treatment effect and an imbalance will introduce bias. Take the example of a study that evaluated the effect of kangaroo care as non-pharmacological pain relief for painful procedures in preterm infants. The introduction of a practice policy that allowed the administration of a 24% sucrose solution to the infants prior to such procedures was a co-intervention that could possibly have interacted with the study outcome (Johnston et al., 2008). Specifically, if the possibility of a co-intervention was not recognized prior to study commencement, the researcher could not incorporate methods to monitor for or prevent its use during the study. A pilot test is a valuable means of identifying such co-interventions and can help researchers in controlling this type of bias throughout the trial. Once it is identified, the researcher may choose to measure and control for the co-intervention (a priori) in the analysis, or may include its use as part of the intervention definition to ensure a balance between groups.

***Contamination***

Contamination can occur when participants in either group become aware of the treatment that the other group is receiving (Torgerson, 2001). This is especially relevant in trials where the intervention cannot be blinded, and if it occurs more than minimally it can destroy the internal validity of the trial. Consider a trial in a postpartum unit where some mothers are in the experimental group and others are in the comparison group. Bearing in mind that most mothers do not have a private room, contamination between these participants could occur when they talk among themselves or witness differences between their treatments. One method for minimizing this type of contamination is cluster randomization. In a cluster trial, groups of participants, rather than individuals, are randomized to the intervention or comparison group (Torgerson, 2001). Cluster allocation is not without its drawbacks. The randomization of groups requires much larger sample sizes, which could increase the length

and complexity of the trial, as well as its costs (Torgerson, 2001). Torgerson (2001) argues that unless the anticipated contamination rate is greater than 30%, contamination is more efficiently dealt with by individual randomization of an increased sample size — thus avoiding the above-mentioned disadvantages. Researchers should thoroughly reflect on the pros and cons of the cluster approach before applying it to their study design. Alternatively, researchers may include qualitative analysis to assess participants' views on treatment credibility as a means to quantify the effect of potential contamination influence on outcomes (Licciardone & Russo, 2006).

## Analysis

### *Attrition*

When participants drop out before the end of a trial or before the end of the experimental phase, bias can occur. This type of bias is known as sample attrition, and it may affect both the external and the internal validity of a trial (Barry, 2005). Attrition rates that are well balanced between groups can contribute to reduced statistical power and generalizability of outcomes (Leon et al., 2006). However, imbalanced attrition is more problematic. When this happens, the characteristics of the remaining participants, both within and between groups, differ significantly from those of the participants who have dropped out. This creates difficulties in determining whether outcomes are related to the intervention or to attrition. Prevention of attrition is a key factor in all studies and is especially important in studies where participants are not blinded to the intervention being tested (Leon et al., 2009).

Qualitative research is an excellent way to determine the potential for attrition, because it is suited to studying the variations of complex human behaviour. The use of interview or focus groups with potential participants prior to the study, or with those who have failed to complete the study, offers valuable insights into why people do not wish to enrol in a study or why participants choose to drop out (Lewin, Glenton, & Oxman, 2009). For example, if used prior to the study, qualitative research methods can determine the degree of participants' preconceived likes and dislikes regarding the intervention. Additional incentives or an alteration in the protocol can then be used to reduce potential attrition. Alternatively, qualitative methods can be used to explain the specific reasons for dropping out and possible variations between those who continue with the study and those who do not.

Attrition bias can also result from missing and incomplete data. For example, it may result from participants failing to answer all questions on a questionnaire. A pilot study to pre-test the questionnaire or the inclusion of follow-up phone calls may prevent this type of bias (Hayward

et al., 2007). Nonetheless, when it occurs, researchers may deal with it by using a variety of approaches, including creating an imputed data set (Donders, van der Heijden, Stijnen, & Moons, 2006). Although this approach can introduce additional bias, if missing items make up less than 5% of data this method has a minimal effect on overall results.

### *Intention to Treat*

According to Eysenbach (2005), intention to treat (ITT) analysis is the only reliable way to avoid attrition bias. However, ITT analysis is not a perfect solution, since it significantly decreases a study's power to identify differences between groups. It is used to analyze all patients assigned to a study group, regardless of whether there was contamination, whether they complied with treatment, or whether they completed the trial (Fergusson, Aaron, Guyatt, & Hebert, 2002). There are various definitions of ITT, and there is no consensus among researchers on when it should or should not be applied. The benefit of using ITT analysis is that it maintains group allocation, allowing confounding factors to be balanced across groups. For example, if someone who was allocated to receive the treatment intervention was missed and received usual care, he or she would still be included in the analysis as part of the treatment group. This method ensures that although the oversight may have been random, any unknown sources of bias, such as timing of the intervention or differences in care providers, that could falsely influence the outcomes are controlled for. In their survey of published RCTs, Hollis and Campbell (1999) found that about half of these had used ITT analysis but had applied it in various ways. In addition, several studies used inadequate methods to deal with missing data on the primary outcome variable. Intention to treat analysis is best applied when complete outcome data are available for all randomized participants. The authors recommend that researchers make every attempt to follow up on all participants who have abandoned the trial, in order to decrease the rate of missing data for the primary outcome.

## Ascertainment of Outcome

Ascertainment bias occurs when outcomes are erroneously attributed to the phenomenon under study. It can be introduced by the people who deliver the intervention, the participants, or the people collecting and analyzing the data. Ascertainment bias may be introduced if the research assistant or principal investigator has certain beliefs about the study or is not blinded to the allocation of participants to the different treatment groups. In addition, participants who know which group they have been allocated to could influence the outcomes of the study (non-blinded allocation).

Various strategies are recommended at different points within the trial to minimize ascertainment bias. During the data-collection phase, the best approach is to blind the investigator and participants. This method is known as double-blinding. While double-blinding is standard practice for most experimental trials, it is often unfeasible in nursing intervention trials because both the use of a placebo and the blinding of the caregiver can rarely be achieved. Thus, single-blinded designs, with the investigator or, more importantly, the evaluator of the outcome remaining blinded, are more common. Examples include videotaping of participant responses that are objectively scored by blinded and trained coders (Johnston et al., 2009) and direct entry of patient responses into computerized databanks followed by analysis, without knowledge of group allocation.

### *Hawthorne Effect*

It is recognized that merely participating in a study can influence a participant's behaviour, thereby affecting the outcome. This phenomenon, known as the Hawthorne effect, is a result of the increased attention and support that participants receive with trial participation. Given the complexity of nursing and therapeutic relationships, nursing intervention trials are prone to the Hawthorne effect. However, this effect can be limited by means of a protocol design that allows for equal time spent with participants in the two groups (McCarney et al., 2007).

## Summary

We have argued that the internal validity of any study is dependent on the level of bias that is introduced. Our checklist provides an overview to assist researchers in anticipating and controlling bias during the design and conduct of intervention trials. This checklist is intended for nurse researchers who wish to use a systematic approach in the preparation of research protocols, so that potential sources of bias can be avoided. Despite considerable progress in reducing bias in clinical trials, current tools focus on double-blind RCTs and on reporting rather than trial planning. While our checklist does include similar concepts, such as sequence generation, allocation, blinding, and incomplete outcome data (www.consort-statement.org), we have included additional concepts, in particular study design, selection of comparisons, and definition and integrity of interventions. These concepts are especially relevant for preparing and conducting complex intervention studies. Their inclusion complements the work of other authors who have highlighted differences in the reporting of non-pharmacological trials (Boutron & Ravaud, 2009) and pragmatic trials (Zwarenstein et al., 2008) when compared to a

double-blind randomized controlled drug trial. In a recent review highlighting strategies for improving the quality and explanatory power of nursing science, Borglin and Richards (in press) found that randomization alone was a necessary but insufficient method for reducing bias in intervention trials. They argue the importance of careful participant selection, consistent performance of the intervention, reduction of attrition, and blinding of assessors. We anticipate that adherence to this checklist will lead to improvements in the scientific rigour of intervention trials. We hope it will also serve to strengthen the impact of complex nursing intervention studies in the wider field of medicine.

Although this article focuses on nursing interventions, it is also relevant for other disciplines conducting similar types of complex intervention research — for example, surgery, complementary medicine, physical therapy, or the social and health sciences, all of which can present similar challenges.

## References

Balk, E. M., Bonis, P. A., Moskowitz, H., Schmid, C. H., Ioannidis, J. P., Wang, C., et al. (2002). Correlation of quality measures with estimates of treatment effect in meta-analyses of randomized controlled trials. *Journal of the American Medical Association, 287*(22), 2973–2982.

Bang, H., Ni, L., & Davis, C. E. (2004). Assessment of blinding in clinical trials. *Controlled Clinical Trials, 25*(2), 143–156.

Barry, A. E. (2005). How attrition impacts the internal and external validity of longitudinal research. *Journal of School Health, 75*(7), 267–270.

Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., et al. (2004). Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology, 23*(5), 443–451.

Blair, E. (2004). Gold is not always good enough: The shortcomings of randomization when evaluating interventions in small heterogeneous samples. *Journal of Clinical Epidemiology, 57*(12), 1219–1222.

Borglin, G., & Richards, D. (in press). Bias in experimental nursing research: Strategies to improve the quality and explanatory power of nursing science. *International Journal of Nursing Studies.*

Boutron, I., & Ravaud, P. (2009). Improving the reporting of clinical research. *British Journal of Surgery, 96*(5), 449–450.

Bridgman, S., Engebretsen, L., Dainty, K., Kirkley, A., Maffulli, N., & ISAKOS Scientific Committee. (2003). Practical aspects of randomization and blinding in randomized clinical trials. *Arthroscopy: Journal of Arthroscopic and Related Surgery, 19*(9), 1000–1006.

Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter, D., et al. (2000). Framework for design and evaluation of complex interventions to improve health. *British Medical Journal, 321*(7262), 694–696.

Conn, V. S., Cooper, P. S., Ruppar, T. M., & Russell, C. L. (2008). Searching for the intervention in intervention research reports. *Journal of Nursing Scholarship, 40*(1), 52–59.

Doig, G. S., & Simpson, F. (2005). Randomization and allocation concealment: A practical guide for researchers. *Journal of Critical Care, 20*(2), 187–193.

Donders, A. R., van der Heijden, G. J., Stijnen, T., & Moons, K. G. (2006). Review: A gentle introduction to imputation of missing values. *Journal of Clinical Epidemiology, 59*(10), 1087–1091.

Dumas, J. E., Lynch, A. M., Laughlin, J. E., Phillips Smith, E., & Prinz, R. J. (2001). Promoting intervention fidelity: Conceptual issues, methods, and preliminary results from the EARLY ALLIANCE prevention trial. *American Journal of Preventive Medicine, 20*(Suppl 1), 38–47.

Eysenbach, G. (2005). The law of attrition. *Journal of Medical Internet Research, 7*(1), e11.

Fergusson, D., Aaron, S. D., Guyatt, G., & Hebert, P. (2002). Post-randomization exclusions: The intention to treat principle and excluding patients from analysis. *British Medical Journal, 325*(7365), 652–654.

Forder, P. M., Gebski, V. J., & Keech, A. C. (2005). Allocation concealment and blinding: When ignorance is bliss. *Medical Journal of Australia, 182*(2), 87–89.

Glasziou, P., Meats, E., Heneghan, C., & Shepperd, S. (2008). What is missing from descriptions of treatment in trials and reviews? *British Medical Journal, 336*(7659), 1472–1474.

Hawe, P., Shiell, A., & Riley, T. (2008). In response to Spillane V., Byrne M.C., Byrne M., Leathem C.S., O'Malley M. & Cupples M.E. (2007). Monitoring treatment fidelity in a randomized trial of a complex intervention. *Journal of Advanced Nursing, 60*(3), 343–352. Important considerations for standardizing complex interventions. *Journal of Advanced Nursing, 62*(2), 267.

Hayward, K., Campbell-Yeo, M., Price, S., Morrison, D., Whyte, R., Cake, H., et al. (2007). Co-bedding twins: How pilot study findings guided improvements in planning a larger multicenter trial. *Nursing Research, 56*(2), 137–143.

Hollis, S., & Campbell, F. (1999). What is meant by intention to treat analysis? Survey of published randomized controlled trials. *British Medical Journal, 319*(7211), 670–674.

Horner, S., Rew, L., & Torres, R. (2006). Enhancing intervention fidelity: A means of strengthening study impact. *Journal for Specialists in Pediatric Nursing, 11*(2), 80–89.

Johnston, C. C., Filion, F., Campbell-Yeo, M., Goulet, C., Bell, L., McNaughton, K., et al. (2008). Kangaroo mother care diminishes pain from heel lance in very preterm neonates: A crossover trial. *BMC Pediatrics, 8*(13). Online: http://www.biomedcentral.com/1471-2431/8/13.

Johnston, C. C., Filion, F., Campbell-Yeo, M., Goulet, C., Bell, L., McNaughton, K., et al. (2009). Enhanced kangaroo mother care for heel lance in preterm neonates: A crossover trial. *Journal of Perinatology, 29*(1), 51–56.

Juni, P., Altman, D. G., & Egger, M. (2001). Systematic reviews in health care: Assessing the quality of controlled clinical trials. *British Medical Journal, 323*(7303), 42–46.

Kunz, R., Vist, G., & Oxman, A. D. (2007). Randomization to protect against selection bias in healthcare trials. *Cochrane Database of Systematic Reviews* (Online), *2*(2), MR000012.

Leon, A. C., Mallinckrodt, C. H., Chuang-Stein, C., Archibald, D. G., Archer, G. E., & Chartier, K. (2006). Attrition in randomized controlled clinical trials: Methodological issues in psychopharmacology. *Biological Psychiatry, 59*(11), 1001–1005.

Lewin, S., Glenton, C., & Oxman, A. D. (2009). Use of qualitative methods alongside randomized controlled trials of complex healthcare interventions: Methodological study. *British Medical Journal, 339*(3496), 732–735.

Licciardone, J. C., & Russo, D. P. (2006). Blinding protocols, treatment credibility, and expectancy: Methodologic issues in clinical trials of osteopathic manipulative treatment. *Journal of the American Osteopathic Association, 106*(8), 457–463.

Lindsay, B. (2004). Randomized controlled trials of socially complex nursing interventions: Creating bias and unreliability? *Journal of Advanced Nursing, 45*(1), 84–94.

Mann, H. (2007). Deception in the single-blind run-in phase of clinical trials. *IRB: Ethics and Human Research, 29*(2), 14–17.

Mann, H., & Djulbegovic, B. (2003). Choosing a control intervention for a randomized clinical trial. *BMC Medical Research Methodology, 3*(7). Online: www.biomedcentral.com/1471-2288/3/7.

McCarney, R., Warner, J., Iliffe, S., van Haselen, R., Griffin, M., & Fisher, P. (2007). The Hawthorne effect: A randomized controlled trial. *BMC Medical Research Methodology,* 7(30). Online: www.biomedcentral.com/1471-2288/7/30.

Minnick, A., Catrambone, C. D., Halstead, L., Rothschild, S., & Lapidos, S. (2008). A nurse coach quality improvement intervention: Feasibility and treatment fidelity. *Western Journal of Nursing Research, 30*(6), 690–703.

Norman, G. R., & Streiner, D. L. (Eds.). (2000). *Biostatistics: The bare essentials,* 2nd ed. London: B. C. Decker.

Orwin, R. G. (2000). Assessing program fidelity in substance abuse health services research. *Addiction, 95*(Suppl 3), S309–S327.

Paterson, C., & Dieppe, P. (2005). Characteristic and incidental (placebo) effects in complex interventions such as acupuncture. *British Medical Journal, 330*(7501), 1202–1205.

Rees, J. R., Wade, T. J., Levy, D. A., Colford, J. M. Jr., & Hilton, J. F. (2005). Changes in beliefs identify unblinding in randomized controlled trials: A method to meet CONSORT guidelines. *Contemporary Clinical Trials, 26*(1), 25–37.

Santacroce, S. J., Maccarelli, L. M., & Grey, M. (2004). Intervention fidelity. *Nursing Research, 53*(1), 63–66.

Schulz, K. F., & Grimes, D. A. (2002). Allocation concealment in randomized trials: Defending against deciphering. *Lancet, 359*(9306), 614–618.

Silverman, H. J., & Miller, F. G. (2004). Control group selection in critical care randomized controlled trials evaluating interventional strategies: An ethical assessment. *Critical Care Medicine, 32*(3), 852–857.

Torgerson, D. J. (2001). Contamination in trials: Is cluster randomization the answer? *British Medical Journal, 322*(7282), 355–357.

Zwarenstein, M., Treweek, S., Gagnier, J. J., Altman, D., Tunis, S., Haynes, B., et al. (2008). Improving the reporting of pragmatic trials: An extension of the CONSORT statement. *British Medical Journal, 337*(2390).

**Acknowledgements**

The authors thank Kate Johnson for editorial assistance.

Marsha Campbell-Yeo is supported by a Clinical Initiative Fellowship from the Canadian Institutes of Health Research (CIHR). Manon Ranger is supported by Fonds de la recherche en santé du Québec (FRSQ). Both of these authors are supported by the Quebec Inter-university Nursing Intervention Research Group (GRIISIQ). Dean Fergusson is the recipient of a CIHR New Investigator Award.

Conflict of interest and financial disclosure: none to declare.

---

*Marsha Campbell-Yeo, RN, MN, NNP, is Neonatal Nurse Practitioner, IWK Health Centre, Halifax, Nova Scotia, Canada; and a PhD candidate at the School of Nursing, McGill University, Montreal, Quebec, Canada. Manon Ranger, RN, MSc, is a PhD candidate at the School of Nursing, McGill University. Celeste Johnston, RN, DEd, is Professor, School of Nursing, McGill University. Dean Fergusson, MHA, PhD, is Senior Scientist and Deputy Director, Ottawa Health Research Institute, and Associate Professor, Faculty of Medicine and Department of Epidemiology and Community Medicine, University of Ottawa, Ontario, Canada.*

*CJNR 2009, Vol. 41 N° 4, 52–67*

*Résumé*

# L'influence des préférences de traitements sur la validité : une étude

**Souraya Sidani, Joyal Miranda, Dana Epstein, Mary Fox**

L'affectation au hasard de participants à des traitements expérimentaux et comparatifs est censé améliorer la comparabilité des groupes d'étude quant aux caractéristiques de base. Malgré ses avantages, l'affectation au hasard entraîne des problèmes de validité. Cette approche ne tient pas compte des préférences de traitements exprimées par les participants. Si l'affectation est faite sans prendre en compte ces préférences, celles-ci influeront sur l'adhésion à l'étude, la représentativité de l'échantillonnage accumulé, l'occurrence d'attrition, l'adhérence au traitement et les résultats. Cet article méthodologique décrit les mécanismes qui sous-tendent l'influence des préférences de traitements sur la validité externe et interne d'une étude d'évaluation d'interventions. Les auteures présentent des preuves empiriques en soutien à leur argumentation et proposent des modèles de recherche alternatifs qui tiennent compte des préférences de traitements à des fins de futures recherches en sciences infirmières.

Mots clés : préférences de traitements, modèles de recherche alternatifs, problèmes de validité.

*CJNR 2009, Vol. 41 Nº 4, 52–67*

# Influence of Treatment Preferences on Validity: A Review[1]

**Souraya Sidani, Joyal Miranda, Dana Epstein, Mary Fox**

Random assignment of participants to experimental and comparison treatments is believed to enhance the comparability of the study groups on baseline characteristics. Despite its benefits, random assignment presents threats to validity. It ignores participants' treatment preferences. If not accounted for when participants are allocated to treatments, preferences influence enrolment in the study, representativeness of the accrued sample, attrition, adherence to treatment, and outcomes. This methodological article describes the mechanisms underlying the influence of treatment preferences on the external and internal validity of an intervention evaluation study. The authors present empirical evidence to support the points of discussion. They describe alternative research designs that account for treatment preferences, for use in future nursing intervention research.

Keywords: treatment preferences, research designs, randomized clinical trial, partially randomized clinical trials, threats to validity

## Introduction

The randomized controlled trial (RCT) is considered the gold standard design for evaluating the effects of interventions on intended outcomes (Richardson, 2000; Shadish, Cook, & Campbell, 2002). Random assignment, a key feature of the RCT, is believed to minimize selection bias and ensure internal validity. Allocating participants on the basis of chance enhances the comparability of participants in the experimental and comparison groups on measured and unmeasured variables, before implementation of the treatment under evaluation. This initial group comparability reduces the potential confounding influence of baseline characteristics on the post-treatment outcomes. This in turn strengthens confidence in attributing the changes in the outcomes, observed following treatment delivery, to the intervention (Abel & Koch, 1999; Cook, 1993). Despite its benefits, random assignment presents threats to validity in intervention evaluation research. Participants, especially those with preferences for treatment options (experimental or comparison), may resent randomization. They may feel it is unfair, decreases their sense of control, and reduces

[1] The contents of this article do not represent the views of the US Department of Veterans Affairs or the United States government.

their chances of receiving the preferred treatment option (Bradley, 1993; Ellis, 2000; Stevens & Ahmedzai, 2004). Preferences for treatment are increasingly being implicated as threats to internal and external validity (Howard & Thornicroft, 2006; McPherson & Britton; 2001; TenHave, Coyne, Salzer, & Katz, 2003).

In this article we focus on the mechanisms that underlie the influence of treatment preferences on external and internal validity. We present empirical evidence, synthesized from the relevant literature, to support the points of discussion. We describe alternative research designs that account for treatment preferences, to guide their use in studies evaluating nursing interventions. We first introduce a conceptualization of treatment preferences in order to define this concept.

## Conceptualization of Treatment Preferences

Treatment preferences represent persons' choices of treatment; that is, they reflect the specific intervention or treatment option they want to receive (Stalmeier et al., 2007) to address a clinical problem or promote their health. Preferences are derived from the persons' understanding of, experience with, and attitudes towards the treatment option (Corrigan & Salzer, 2003; Sidani, Epstein, Bootzin, Moritz, & Miranda, 2009; Wensig & Elwyn, 2003).

Individuals gain an understanding of the treatment options through exposure to relevant information. This information is obtained prior to or upon enrolment in the study. Prior to enrolment, it is obtained directly from different sources, including health-care professionals, family members, or friends; from written materials available in print or online; and from media presentations. Upon enrolment in a trial, persons are informed of the treatment options offered within the study context, as part of the process for obtaining informed consent. Regardless of its accuracy, the knowledge gained contributes to the formulation of preferences. Experience with the treatment, whether personal or vicarious, refers to the exposure to and application of the treatment option. Experience has been found to shape preferences: Persons who previously used an option are likely to select it, particularly if they found it effective; otherwise, they tend to choose alternative treatments (Awad, Shapiro, Lund, & Feine, 2000; Gum et al., 2006; Jansen et al., 2001; Miranda, 2004).

Attitude towards treatment represents the person's appraisal of the treatment options as acceptable or unacceptable (Van der Berg et al., 2008). Attitudes are based on careful consideration of the following treatment attributes: appropriateness for addressing the clinical problem or promoting health, suitability to individual lifestyle, effectiveness, severity

of side effects, and convenience (Sidani et al., 2009). Acceptable treatments are those perceived as appropriate, suitable, effective, convenient, and having minimal side effects of low severity. Persons develop preferences for treatment options they view as acceptable.

Treatment preferences influence engagement in and adherence to treatment as well as the outcomes (Kiesler & Auerbach, 2006; Lang, 2005; Mills et al., 2006; Tacher, Morey, & Craighead, 2005). They therefore represent factors that confound treatment effectiveness and weaken the validity of study conclusions.

## Influence of Preferences on Validity

Preferences for treatment influence individuals' decision to enrol in a trial, which affects external validity. Preferences also influence attrition, adherence to treatment, and outcomes, which weaken internal validity.

### *Influence on External Validity*

Two interrelated mechanisms explain the influence of treatment preferences on external validity: low enrolment rate, and non-representativeness of the sample. Preferences are emerging as a reason for non-enrolment in an RCT (Thomas, Croft, Paterson, Dziedzic, & Hay, 2004). Eligible individuals have a preference for the experimental or comparison treatment under evaluation. Results of a large number of descriptive and experimental studies show that 60% to 100% of participants have clear preferences for one of the treatment options offered within the context of the study. Persons with a preference may decline enrolment in an RCT because they are unwilling to risk being randomly assigned to their non-preferred treatment (Ellis, 2000; McPherson & Britton, 2001; TenHave et al., 2003). Individuals with a preference resent allocation to treatment on the basis of chance and wish to be actively involved in treatment decision-making (Jenkins & Fallowfield, 2000). The results obtained by Arega et al. (2006) indicate a strong association between preferences and willingness to be randomized. The results of four other studies support this association. Patients who perceived the intervention under evaluation as improper treatment for their condition declined enrolment in an RCT of adjuvant therapy for breast cancer (Stevens & Ahmedzai, 2004). About 10% of schools taking part in an RCT of peer-led sex education withdrew from the trial because of random assignment to the non-preferred treatment (Oakley et al., 2003). In an RCT evaluating the effectiveness of a brief physiotherapy intervention, 45% of eligible persons refused to be randomized to treatment because of preferences and decided not to enrol in the trial (Klaber Moffett et al., 1999). In another study (Macias et al., 2005), 30% of eligible individuals

declined participation because they wanted to avoid the risk of receiving the non-preferred treatment for managing mental health problems. With such a high refusal rate (up to 45%), the rate of enrolment decreases; this in turn may increase the length of the enrolment period or, with limited funds and resources to accommodate a prolonged enrolment period, may yield a sample size smaller than required to attain adequate statistical power.

Persons with preferences form a subgroup of the target population. If these individuals decline enrolment in an RCT, then the accrued sample may not be representative of all subgroups making up the target population (Howard & Thornicroft, 2006; Millat, Borie, & Fingerhut, 2005). Thus participants differ from non-participants on at least two characteristics: preference for treatment, and willingness to be randomized. As indicated by the results of previous studies, non-participants have clear treatment preferences and are unwilling to be randomly assigned to treatment. Accumulating empirical evidence indicates differences in sociodemographic characteristics and severity of the presenting problem between individuals who have preferences and are unwilling to be randomized and those who have no preferences and are willing to be randomized. King et al. (2005) conducted a systematic review of studies that investigated preferences for medical treatments. They found that participants with preferences were more likely than those with no preferences to be women, well-educated, White, and employed. The results of five additional studies (Bedi et al., 2000; Cooper et al., 2003; Gum et al., 2006; Heit et al., 2003; Vuorma et al., 2003) consistently support the relationship between perceived severity of the presenting problem and treatment preferences. Participants reporting high levels of problem severity tend to select intensive, invasive treatment. The observed differences in sociodemographic characteristics and perceived severity of the presenting problem between persons with preferences who decline enrolment and persons with no preferences who participate in an RCT may compromise sample representativeness. The sample consists of a subgroup of the target population, which limits the generalizability of the RCT findings to all subgroups making up the target population (Lambert & Wood, 2000; Millat et al., 2005).

### *Influence on Internal Validity*

Persons with preferences for the experimental or comparison treatment under evaluation may decide to enrol in an RCT. They may consider participation in the RCT their only opportunity to obtain their preferred treatment since they have a 50% chance of being assigned to it (Bradley, 1993). The enrolment of participants in the RCT threatens

internal validity because these participants react differently depending on the treatment option to which they are allocated.

In an RCT, participants are randomly allocated to the experimental or comparison treatment group, regardless of their preference. Thus randomization creates two subgroups within each experimental and comparison group. One subgroup represents participants who are randomly assigned to the treatment of their preference. The other subgroup comprises participants who are allocated to the non-preferred treatment. Participants assigned to the preferred intervention are satisfied with the treatment they receive. Accordingly, they develop enthusiasm for treatment, actively engage in the treatment activities, and comply with the treatment as prescribed. Consequently, they may demonstrate the expected improvement in the oucomes. In contrast, participants assigned to the non-preferred treatment experience disappointment because they are deprived of their treatment of choice. They respond in two possible ways.

First, they may decide to withdraw from the study. Attrition weakens the validity of the RCT findings. It reduces the sample size included in the "as treated" analysis, thereby decreasing the statistical power to detect significant treatment effects. Attrition can lead to non-comparability on baseline characteristics of the experimental and comparison treatment groups; this can result in uncontrolled confounding variables that influence the outcomes. Thus the changes in outcomes, observed after treatment implementation, cannot be attributed with confidence to the treatment (Shadish et al., 2002).

Second, participants assigned to the non-preferred treatment may experience a sense of demoralization that shapes their subsequent reaction. This subgroup of individuals has low motivation to engage in and adhere to treatment. Non-adherence to treatment is associated with poor outcomes (Halpern, 2003; Huibers et al., 2004; McPherson & Britton, 2001).

The location of these two subgroups within the experimental and comparison groups will bias the estimates of the treatment effects, thereby threatening the validity of the RCT conclusions. For instance, when the participants randomly assigned to their preferred treatment are equally distributed across the experimental and comparison groups, the within-group variance in the outcomes observed at post-test is high and the power to detect significant treatment effects is reduced. When the number of participants with a preference for the experimental treatment who are randomly allocated to their treatment of choice is larger than the number of participants with no preference who are assigned to the comparison group, the between-group variance in the post-test outcomes is

high, potentially leading to overestimation of the treatment effects (Sidani, 2006).

The influence of treatment preferences on attrition, adherence to treatment, and outcome has been investigated in several studies (e.g., Adamson, Sellman, & Dore, 2005; Bedi et al., 2000; Gum et al., 2006; Klaber Moffett et al., 1999; Mills et al., 2006) and is synthesized in three recent systematic reviews (King et al., 2005; Preference Collaborative Review Group, 2009; Swift & Callahan, 2009). The results pertaining to the influence of treatment preferences on attrition differ across the three reviews. King et al. (2005) found no significant differences in attrition rates for participants assigned to treatment groups based on chance (i.e., random) or on preference. The Preference Collaborative Review Group (2009) reports lower attrition rates for participants who were randomly assigned to treatment groups compared to those who were allocated to the treatment of preference; this finding is contrary to expectations. In contrast, Swift and Callahan (2009) estimated an overall effect size of 0.58, whereby lower attrition rates were observed for participants allocated to treatment of choice, as hypothesized. The exact reason for the inconsistent findings is unclear, but it could be related to differences in the target populations and treatments investigated.

Four studies examined the influence of treatment preferences on adherence to the intervention. The results are consistent. They show higher rates of attendance at the planned treatment sessions (Bedi et al., 2000; Hitchcock Noël et al., 1998; Janevic et al., 2003) and of engagement in treatment activities (Macias et al., 2005) for participants allocated to the preferred treatment than participants randomly assigned to treatment.

The results of the three systematic reviews examining the influence of treatment preferences on outcomes varied slightly. In their review, King et al. (2005) focused on studies that evaluated medical treatments. Seven of the 19 studies included in the review reported significant outcome differences between participants allocated to treatment based on preference and those allocated based on chance. Better outcomes were observed for participants allocated to the treatment of preference in five of the seven studies and for those randomized to treatment in the other two studies. In their meta-analysis, the Preference Collaborative Review Group (2009) analyzed participants' data pooled from eight trials of treatment for musculoskeletal conditions (e.g., back and neck pain). Participants who received the treatment of their choice showed greater improvement than those randomized to the non-preferred treatment. The effect size was 0.15. Swift and Callahan (2009) reviewed 26 studies that investigated pharmacological, psycho-educational, and behavioural treatments for the management of psychological conditions (e.g., depression). The overall

effect size was 0.15 ($CI_{95}$: .09 to .21). Participants who received the preferred treatment exhibited more improvement than those who were randomized. The findings of the systematic reviews provide evidence supporting the influence of treatment preferences on outcome; however, the influence appears to be of small magnitude. The exact reason for the small effect of preferences on outcomes is unclear and requires further exploration. However, the method for assessing treatment preferences is a methodological factor that could account for the observed small effect. The reports of studies that were included in the systematic reviews and that investigated preferences provided minimal detail on the procedure used to elicit preferences for the treatments under evaluation. Specifically, the study report did not describe the treatment information that was provided to participants or the form in which this information was presented. Yet the nature and presentation of treatment-related information affect participants' perception of an intervention and their expressed preferences (Becker, Davis, & Schaumberg, 2007; Say & Thompson, 2003; Tarrier, Liversidge, & Gregg, 2006; Wragg, Robinson, & Lilford, 2000). Bowling and Rowe (2005) state that the results of these studies should be viewed with caution due to the non-standardized and non-rigorous method used to elicit treatment preferences. The expressed preferences are not well informed and do not accurately represent participants' choice. Error of measurement is known to attenuate the magnitude of a relationship between variables (Streiner & Norman, 2008). Future research should use a systematic procedure and validated measure for assessing preferences, as described by Sidani (2006) and Sidani et al. (2009).

In summary, the empirical evidence available to date suggests that treatment preferences contribute to the decision whether to enrol in an RCT, adherence to treatment, and achievement of outcomes. The evidence is not clear regarding the influence of treatment preferences on attrition. Accounting for preferences when allocating participants to the experimental and comparison treatments in an RCT may mitigate the influence of preferences and strengthen the validity of conclusions related to the effectiveness of the intervention under evaluation.

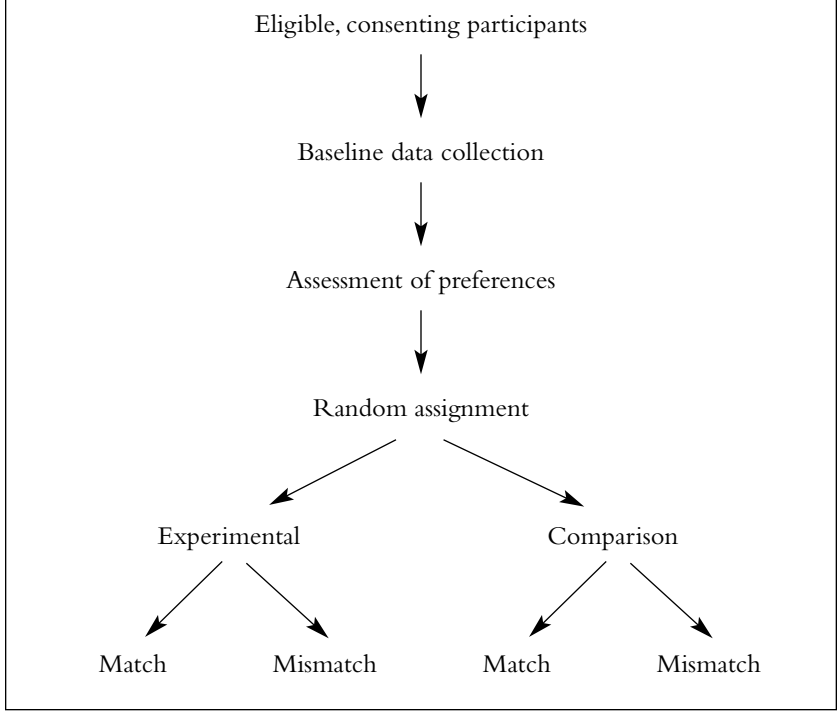
## Designs for Investigating Treatment Preferences

Three types of design are used to investigate treatment preferences: RCT, partially randomized clinical trial (PRCT), and two-stage PRCT. Each of these designs has its strengths and limitations, which guide their selection for future studies of preferences.

In the standard RCT, participants' preferences are assessed after consent is obtained but before randomization. A record is kept of each participant's expressed preferences. Participants are randomly assigned to

the treatment options offered within the context of the RCT, as is usually the case in this design. They are categorized into two groups (matched and mismatched), based on the treatment of preference and the treatment actually received. In the matched group, participants are randomly allocated to the preferred intervention; in the mismatched group, participants are randomly allocated to the non-preferred intervention (Figure 1). This design is illustrated in Klaber Moffett et al.'s (1999) study. The matched-mismatched group is included as a between-subject factor in the analysis aimed at determining the effectiveness of treatment. A significant treatment (i.e., experimental and comparison) by match (i.e., matched and mismatched) group interaction effect indicates differences in the outcomes among participants in the experimental group with matched and mismatched treatment and participants in the comparison group with matched and mismatched treatment. The strength of this design is the randomization of participants to treatment, which maintains the comparability of participants at baseline. Its limitations are (a) the fact

**Figure 1** ***RCT Design***



that random assignment ignores participants' preferences elicited at baseline, which may not be well received by participants and may be viewed as unethical; and (b) the sample size is often estimated to detect significant treatment effects and hence may not be adequate to detect significant interaction (i.e., treatment by match) effects reflecting the influence of preferences on outcome achievement (Preference Collaboration Review Group, 2009).

The partially randomized clinical trial (PRCT) was first described by Bradley (1993) and is well illustrated in the design implemented by Coward (2002). At baseline, participants' preferences for the treatment under study are elicited. Participants are requested to indicate whether they have a preference for a particular treatment. Those who express a preference are asked to identify their preferred treatment. Those who indicate that they have no preference are randomly assigned to the treatment options; those with a preference are allocated to the treatment of their choice (Figure 2). Comparison of the four resulting groups deter-

**Figure 2** ***PRCT Design***

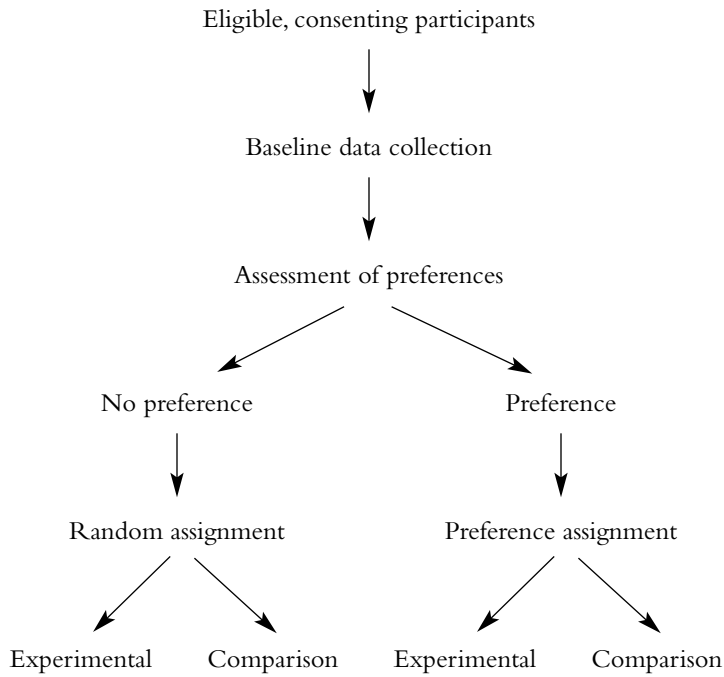
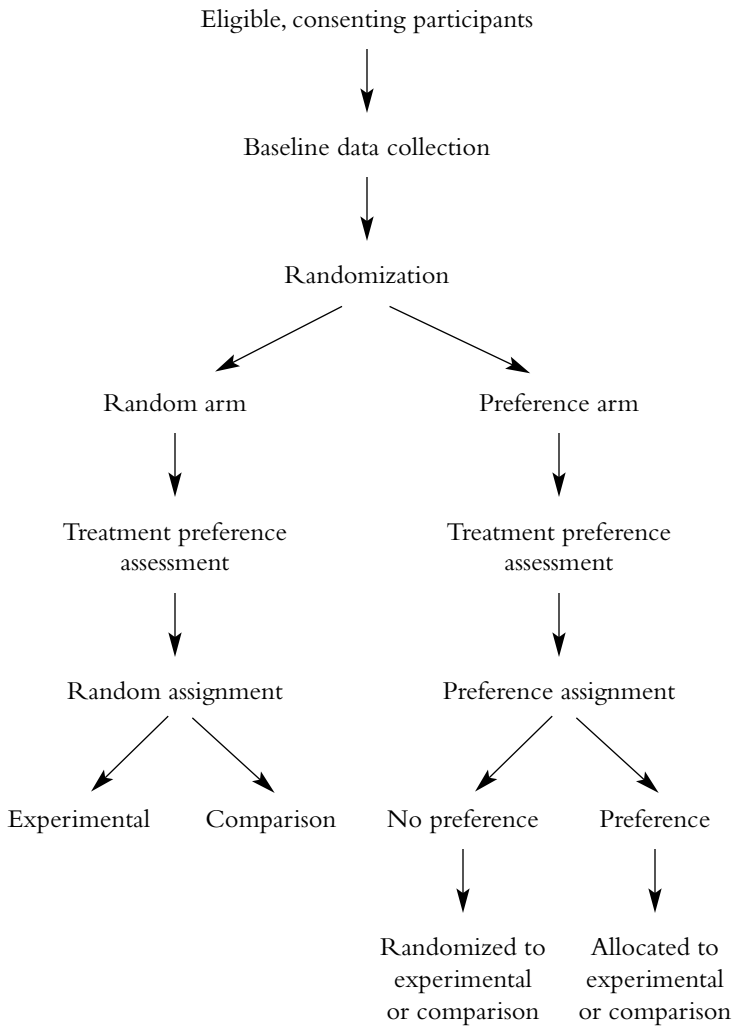


Figure 3 ***Two-Stage PRCT Design***




mines the extent to which preferences affect treatment outcomes. Specifically, significant differences in outcomes between participants who received the experimental treatment based on chance and those who received it based on preference indicate if and to what extent preferences contribute to treatment outcomes. Although accounting for preferences is advantageous, this design has two limitations. First, as observed in

several studies, in particular Coward (2002), most participants (≥ 60%) have preferences. Consequently, more participants are allocated to the treatment of their choice than are randomly assigned to treatment. The resulting unbalanced group size limits meaningful between-group comparison aimed at examining the influence of preferences. Second, participants with preferences may differ from those without preferences on baseline characteristics. Initial non-comparability of the groups may confound the effects of the treatment and preferences on the outcomes, thereby threatening the validity of the conclusions regarding treatment effectiveness.

The two-stage PRCT is meant to overcome the limitations of the PRCT. In this design, participants are randomized to the random or preference arm of the trial, thereby preserving initial comparability and balanced size of the groups. In the random arm, participants are randomly assigned to the treatment under investigation, as is usually done in an RCT. In the preference arm, participants indicate their preference; those with no preference are randomly allocated to treatment and those with a preference are allocated to their treatment of choice (Figure 3). Comparison of participants who received the same intervention in the random and preference arms determines the influence of preferences on outcomes. Therefore the two-stage PRCT is the most appropriate design for dismantling the contribution of treatment preference. Implementation of the two-stage PRCT may necessitate an increased sample size. This type of design has been used in some studies evaluating medical treatments that were included in the systematic review carried out by King et al. (2005).

## Conclusions

Although the contribution of treatment preferences has been investigated in the medical and behavioural sciences, it has not been extensively addressed in nursing. Accounting for treatment preferences has methodological advantages. It promotes enrolment in an intervention evaluation study, adherence to treatment, satisfaction with treatment, and improvement in outcomes (Lang, 2005; Mills et al., 2006). The methodological advantages of accounting for treatment preferences demand careful consideration of preferences when designing, implementing, and evaluating nursing interventions. Nurse researchers are encouraged to further investigate treatment preferences with the goals of developing interventions that are acceptable to the various groups making up the target population and promoting adherence to and satisfaction with treatment as well as outcome achievement in the context of research.

## References


Abel, U., & Koch, A. (1999). The role of randomization in clinical studies: Myths and beliefs. *Journal of Clinical Epidemiology, 52,* 487–497.

Adamson, S. J., Sellman, J. D., & Dore, G. M. (2005). Therapy preference and treatment outcome in clients with mild to moderate alcohol dependence. *Drug and Alcohol Review, 24,* 209–216.

Arega, A., Birkmeyer, N. J. O., Lurie, J. D. N., Tosteron, Y., Gibson, J., Taylor, B. A., et al. (2006). Racial variation in treatment preferences and willingness to randomize in the Spine Patient Outcomes Research Trial (SPORT). *Spine, 31,* 2263–2269.

Awad, M. A., Shapiro, S. H., Lund, J. P., & Feine, J. S. (2000). Determinants of patients' treatment preferences in a clinical trial. *Community Dental Oral Epidemiology, 28,* 119–125.

Becker, C., Davis, E., & Schaumberg, K. (2007). An analog study of patient preferences for exposure versus alternative treatments of posttraumatic stress disorder. *Behavior Research and Therapy, 45,* 2861–2873.

Bedi, N., Chilvers, C., Churchill, R., Dewey, M., Duggan, C., Fielding, K., et al. (2000). Assessing effectiveness of treatment of depression in primary care: Partially randomized preference trial. *British Journal of Psychiatry, 177,* 312–318.

Bowling, A., & Rowe, G. (2005). "You decide doctor." What do patient preference arms in clinical trials really mean? *Journal of Epidemiology and Community Health, 59,* 914–915.

Bradley, C. (1993). Designing medical and educational intervention studies. *Diabetes Care, 16,* 509–518.

Cook, T. D. (1993). A quasi-experimental theory of generalization of causal relationships. *New Directions for Program Evaluation, 57,* 39–82.

Cooper, L. A., Gonzales, J. J., Gallo, J. J., Rost, K. M., Meredith, L. S., Rubenstein, L. V., et al. (2003). The acceptability of treatment of depression among African-American, Hispanic and White primary care patients. *Medical Care, 41,* 479–489.

Corrigan, P. W., & Salzer, M. S. (2003). The conflict between random assignment and treatment preference: Implications for internal validity. *Evaluation and Program Planning, 26,* 109–121.

Coward, D. (2002). Partial randomized design in a support group intervention study. *Western Journal of Nursing Research, 24*(4), 406–421.

Ellis, P. M. (2000). Attitudes towards and participation in randomized clinical trials in oncology: A review of the literature. *Annals of Oncology, 11,* 939–945.

Gum, A. M., Arean, P. A., Hunkeler, E., Tang, L., Katon, W., Hitchcock, P., et al. (2006). Depression treatment preferences in older primary care patients. *Gerontologist, 4,* 14–22.

Halpern, S. D. (2003). Evaluating preference effects in partially unblended, randomized clinical trials. *Journal of Clinical Epidemiology, 56,* 109–115.

Heit, M., Rosenquist, C., Culligan, P., Graham, C., Murphy, M., & Shott, S. (2003). Predicting treatment choice for patients with pelvic organ prolapse. *American College of Obstetrics and Gynecology, 101,* 1279.

Hitchcock Noël, P., Marsh, G., Larme, A. C., Correa, A., Meyer, J., & Pugh, J. A. (1998). Patient choice in diabetes education curriculum. *Diabetes Care, 21,* 896–901.

Howard, L., & Thornicroft, G. (2006). Patient preference and randomized controlled trials in mental health research. *British Journal of Psychiatry, 188,* 303–304.

Huibers, M. J. H., Bleijenberg, G., Beurskens, A. J. H. M., Kant, I., Knottnerus, J. A., van der Windt, D. A. W. M., et al. (2004). An alternative trial design to overcome validity and recruitment problems in primary care research. *Family Practice, 21,* 213–218.

Janevic, M. R., Janz, M. K., Dodge, J. A., Lin, X., Pan, W., Sinco, B. R., et al. (2003). The role of choice in health education intervention trials: A review and case study. *Social Science and Medicine, 56,* 1581–1594.

Jansen, S. J. Y., Kievit, J., Nooij, M. A., de Haes, J. C. J. M., Overpelt, I. M. E., van Slooten, H., et al. (2001). Patients' preferences for adjuvant chemotherapy in early-stage breast cancer: Is treatment worthwhile? *British Journal of Cancer, 84,* 1577–1585.

Jenkins, V., & Fallowfield, L. (2000). Reasons for accepting or declining to participate in randomized clinical trials for cancer therapy. *British Journal of Cancer, 82*(11), 1783–1788.

Kiesler, D. J., & Auerbach, S. M. (2006). Optimal matches of patient preferences for information, decision-making and interpersonal behavior: Evidence, models, and interventions. *Patient Education and Counseling, 61,* 319–341.

King, M., Nazareth, I., Lampe, F., Bower, P., Chandler, M., Morou, M., et al. (2005). Impact of participant and physician intervention preferences on randomized trials: A systematic review. *Journal of the American Medical Association, 293,* 1089–1099.

Klaber-Moffett, J. K, Torgerson, D., Bell-Syer, S., Jackon, D., Llewlyn-Phillips, H., Farrin, A., et al. (1999). Randomised controlled trial of exercise for low back pain: Clinical outcomes, costs, and preferences. *British Medical Journal, 319*(7205), 279–283.

Lambert, M. F., & Wood, J. (2000). Incorporating patient preferences into randomized trials. *Journal of Clinical Epidemiology, 53,* 163–166.

Lang, A. J. (2005). Mental health treatment preferences of primary care patients. *Journal of Behavioral Medicine, 28,* 581–586.

Macias, C., Barreira, P., Hargreaves, W., Bickman, L., Fisher, W., & Aronson, E. (2005). Impact of referral source and study applicants' preference for randomly assigned service on research enrollment, service engagement, and evaluative outcomes. *American Journal of Psychiatry, 162,* 781–787.

McPherson, K., & Britton, A. (2001). Preferences and understanding their effects on health. *Quality in Health Care, 10,* i61–i66.

Millat, B., Borie, F., & Fingerhut, A. (2005). Patients' preference and randomization: New paradigm of evidence-based clinical research. *World Journal of Surgery, 29,* 596–600.

Mills, N., Metcalfe, C., Ronsmans, C., Davis, M., Lane, J. A., Sterne, J. A. C., et al. (2006). A comparison of socio-demographic and psychological factors

between patients consenting to randomisation and those selecting treatment (the ProtecT study). *Contemporary Clinical Trials, 27,* 413–419.

Miranda, J. (2004). An exploration of participants' treatment preferences in a partial RCT. *CJNR, 36*(3), 100–114.

Oakley, A., Strange, V., Toroyan, T., Wiggins, M., Roberts, I., & Stephenson, J. (2003). Using random allocation to evaluate social interventions: Three recent U.K. examples. *Annals of the AAPSS, 589,* 170–189.

Preference Collaborative Review Group. (2009). Patients' preferences within randomized trials: Systematic review and patient level meta-analysis. *British Medical Journal, 338,* 1864.

Richardson, J. (2000). The use of randomized control trials in complementary therapies: Exploring the issues. *Journal of Advanced Nursing, 32,* 398–406.

Say, R. E., & Thomson, R. (2003). The importance of patient preferences in treatment decisions: Challenges for doctors. *British Medical Journal, 327,* 542–545.

Shadish, W. R., Cook, T. D., & Campbell, D. T. (2002). *Experimental and quasi-experimental design for generalized causal inference*. Boston: Houghton-Mifflin.

Sidani, S. (2006). Random assignment: A systematic review. In R. R. Bootzin & P. E. McKnight (Eds.), *Strengthening research methodology: Psychological measurement and evaluation* (pp. 125–141). Washington: American Psychological Association.

Sidani, S., Epstein, D. R., Bootzin, R. R., Moritz, P., & Miranda, J. (2009) Assessment of preferences for treatment: Validation of a measure. *Research in Nursing and Health, 32*(4) 419–431.

Stalmeier, P. F. M., van Tol-Geerdink, J. J., van Lin, E. N. J. T., Schimmel, E., Huizenga, H., van Daal, W. A. J., et al. (2007). Doctors' and patients' preferences for participation and treatment in curative prostate cancer radiotherapy. *Journal of Clinical Oncology, 25,* 3096–3100.

Stevens, T., & Ahmedzai, S. H. (2004). Why do breast cancer patients decline entry into randomized trials and how do they feel about their decision later? A prospective, longitudinal, in-depth interview study. *Patient Education and Counseling, 52,* 341–348.

Streiner, D. L., & Norman, G. R. (2008). *Health measurement scales: A practical guide to their development and use,* 4th ed. Oxford: Oxford University Press.

Swift, J. K., & Callahan, J. L. (2009). The impact of client treatment preferences on outcome: A meta-analysis. *Journal of Clinical Psychology, 65,* 368–381.

Tacher, J. A., Morey, E., & Craighead, W. E. (2005). Using patient characteristics and attitudinal data to identify depression treatment preference groups: A latent-class model. *Depression and Anxiety, 21,* 47–54.

Tarrier, N., Liversidge, T., & Gregg, L. (2006). The acceptability and preference for the psychological treatment of PTSD. *Behaviour Research and Therapy, 44,* 1643–1656.

TenHave, T. R., Coyne, J., Salzer, M., & Katz, I. (2003). Research to improve the simple randomized clinical trial. *General Hospital Psychiatry, 25,* 115–123.

Thomas, E., Croft, P. R., Paterson, S. M., Dziedzic, K., & Hay, E. M. (2004). What influences participants' treatment preference and can it influence outcome?

Results from a primary care-based randomized trial for shoulder pain. *British Journal of General Practice, 54,* 93–96.

Van der Berg, M., Timmermans, D. R. M., Knol, D. L., van Eijk, J. M., de Smit, D., van Vugt, J. M. G., et al. (2008). Understanding pregnant women's decision making concerning prenatal screening. *Health Psychology, 27*(4), 430–437.

Vuorma, S., Teperi, J., Hurskainen, R., Aalto, A., Rissanen, P., & Kujansuu, E. (2003). Correlates of women's preferences for treatment of heavy menstrual bleeding. *Patient Education and Counseling, 49,* 125–132.

Wensig, M., & Elwyn, G. (2003). Methods for incorporating patients' views in health care. *British Medical Journal, 326,* 877–879.

Wragg, J. A., Robinson, E. J., & Lilford, R. J. (2000). Information presentation and decisions to enter clinical trials: A hypothetical trial of hormone replacement therapy. *Social Science and Medicine, 51,* 453–462.

**Acknowledgements**

This study was financially supported by the Canada Research Chairs Program and Ryerson University.

---

*Souraya Sidani, PhD, is Professor and Canada Research Chair, School of Nursing, Ryerson University, Toronto, Ontario, Canada. Joyal Miranda, PhD, RN, is Postdoctoral Fellow, Faculty of Nursing, Université de Montréal, Quebec, Canada. Dana Epstein, PhD, RN, is Associate Chief, Nursing Service/Research, Phoenix Veterans Affairs Health Care System, Phoenix, Arizona, United States. Mary Fox, PhD, RN, is Assistant Professor, School of Nursing, York University, Toronto.*

*CJNR 2009, Vol. 41 N° 4, 68–82*

*Résumé*

# L'effet de la musique sur la participation parentale dans le cadre de réparations pédiatriques de déchirures

**Gregory Sobieraj, Maala Bhatt, Sylvie LeMay, Janet Rennick et Celeste Johnston**

Cette étude quasi-expérimentale a pour objectif d'évaluer une intervention utilisant la musique pendant de simples réparations de déchirures avec l'intention de favoriser la participation de parents d'enfants âgées de un an à cinq ans. Des haut-parleurs ont diffusé des chansons pour enfants pendant la réparation de déchirures et les parents étaient invités à participer à l'intervention en distrayant leur enfant. Le taux de participation parentale a été déterminé et les procédures entourant la réparation ont été filmées sur vidéo et soumises à un pointage objectif à l'aide d'une liste de contrôle des comportements pendant les procédures. Au total, 57 enfants ont participé à l'étude. Aucune différence n'a été notée entre le groupe de contrôle et le groupe d'intervention en ce qui a trait à la participation parentale. Pour ce qui est des contrôles fondés sur l'âge, le sexe et l'état, les taux de détresse étaient significativement plus élevés lorsque les pères étaient présents dans la salle de soins, comparativement aux cas où seules les mères étaient présentes (43,68 contre 23,39, $t(54)$ 4,296, $p = <0{,}0001$). Les auteurs ont conclu que les taux de détresse varient selon l'âge de l'enfant et le parent présent pendant la prestation de soins. La présence de musique pendant de simples réparations de déchirures n'a pas favorisé de plus grands taux de participation parentale aux efforts de distraction.

Mots clés : déchirures, musique, pédiatriques

*CJNR 2009, Vol. 41 Nº 4, 68–82*

# The Effect of Music on Parental Participation During Pediatric Laceration Repair

**Gregory Sobieraj, Maala Bhatt, Sylvie LeMay, Janet Rennick, and Celeste Johnston**

The purpose of this quasi-experimental study was to test an intervention on the use of music during simple laceration repair to promote parent-led distraction in children aged 1 to 5. Children's songs were broadcast via speakers during laceration repair and parents were encouraged to participate in distracting their child. The proportion of parental participation was determined. Laceration procedures were videotaped and objectively scored using the Procedure Behavior Check List. A total of 57 children participated in the study. There was no difference in parental involvement between the control and intervention groups. When age, sex, and condition were controlled for, distress scores were significantly higher if the father was present in the procedure room than if only the mother was present (43.68 vs. 23.39, $t(54)$ 4.296, $p = < 0.001$). It was concluded that distress varies with the age of the child and the parent who is present during the procedure. Providing music during simple laceration repair did not increase the proportion of parents who were involved in distraction.

Keywords: lacerations, music, intervention studies, pediatrics, pain

## Introduction

In Canada more than 95,000 children visit emergency departments (EDs) annually because of injuries (Public Health Agency of Canada, 2002b) and lacerations and other open wounds account for 25% of injuries among children aged 1 to 4 (Public Health Agency of Canada, 2002a). Although laceration repair is a relatively painless procedure due to the use of topical anesthesia, children experience distress as a result of anticipatory fear. A child's fear, anxiety, and distress must be adequately addressed to ensure successful laceration repair and a positive hospital experience for parents and their children. The focus of this study was the testing of music as an intervention to increase parent-led distraction in the ED.

## Literature Review

There is a wealth of research supporting the notion that children who are undertreated for pain suffer long-term deleterious effects. For example,

Taddio, Katz, Ilersich, and Koren (1997) found that neonates who were circumcised without analgesia experienced more distress in subsequent routine immunizations than children who were circumcised with topical analgesia. Simple laceration repair, defined in this study as the application of tissue adhesives or sutures to repair torn or damaged tissue without the use of sedatives, is a relatively painless procedure. However, children under 5 years of age are unable to distinguish between the experience and the sensation of fear (Carr, Lemanek, & Armstrong, 1998; Goodenough et al., 1999). Therefore, intense fear experienced by the child during laceration repair may lead to long-term negative outcomes similar to those described by Taddio and colleagues. If we consider distress as "the sum of anxiety and pain" (Walco, Conte, Labay, Engel, & Zeltzer, 2005), any medical procedure resulting in distress in young children may lead to long-term deleterious effects. It should therefore be a priority for all pediatric health-care providers to implement distress reduction in their practice.

Age has been identified as a significant variable in studies assessing pediatric distress, especially during acute, painful procedures. A study by Goodenough and colleagues (1999) found that ratings of pain and unpleasantness during a painful medical procedure decreased with increasing age. An earlier study, similarly, found a negative correlation between pain (both subjective and objective) and age, indicating that the pain response is attenuated by age (Fradet, McGrath, Kay, Adams, & Luke, 1990).

Psychological interventions have been shown to have a positive effect on procedural distress. Techniques such as distraction have a clear benefit in procedures such as venous cannulation or lumbar puncture (Cohen, 2002; Uman, Chambers, McGrath, & Kisely, 2006). There are, however, very few studies exploring these benefits in painless procedures such as laceration repair using topical anesthesia. Sinha, Christopher, Fenn, and Reeves (2006) attempted to use music as a distraction during laceration repair in children aged 6 to 18. They found that music effectively reduced anxiety in both the children and their parents during the procedure but that it did not have an effect on the sensation of pain. Conversely, a recent Cochrane review concluded that music has a small but measurable effect on the sensation of pain; the authors recommend that although music should not be used as a first-line treatment for pain, it could serve as a useful adjunct to analgesia (Cepeda, Carr, Lau, & Alvarez, 2006). Its positive effect on distress and its unobtrusive nature make music an ideal intervention for testing in a busy environment such as an ED.

Child caregivers are often closely attuned to the child and consequently can have a considerable effect on levels of distress experienced by the child. When a parent is present in the treatment room during a

potentially painful event, positive effects include lower distress scores for the parent and the child (Wolfram & Turner, 1996), increased parent satisfaction, and a sense of being helpful (Piira, Sugiura, Champion, Donnelly, & Cole, 2005). Finally, it has been demonstrated that parental engagement in coping behaviours, such as use of humour and non-procedural talk directed at the child, serve to decrease the amount of distress experienced by the child (Blount et al., 1989).

Interestingly, some coping strategies used by parents, such as verbal reassurance (e.g., "it's okay," "don't worry"), empathy, criticism, and apologizing for the child's behaviour, have been shown to heighten the child's distress (Blount et al., 1989; Manimala, Blount, & Cohen, 2000; McMurtry, McGrath, & Chambers, 2006). It is unclear how these parental behaviours directed towards the child serve to increase distress. McMurtry and colleagues (2006) summarize the findings on reassurance and report that this coping strategy may increase distress via three mechanisms. First, reassurance may cue the child to prepare for an unpleasant event and incite fear and anxiety in the child. Second, it may reinforce and encourage distress behaviour: The more the child expresses feelings of distress, the more attention he receives from the parent. Finally, reassurance may provide validation for the child's feelings, effectively telling the child that it is "okay" to be distressed (McMurtry et al., 2006). Showing empathy and apologizing for the child's behaviour likely work via similar mechanisms. Further, it has been demonstrated that parental engagement in these distress-promoting behaviours can result in similar behaviours by those treating the child, such as nurses and physicians (Frank, Blount, Smith, Manimala, & Martin, 1995).

It is therefore important that strategies be developed whereby a parent can actively participate in a procedure and thus be made to feel helpful yet not engage in distress-promoting behaviour. Distress-promoting behaviours may be difficult to prevent, as a parent will intuitively attempt to reassure a child who is experiencing distress. Music, as a recommended adjunct for the treatment of pain, may be a useful tool for distracting the child and involving the parent in an activity that will prevent him or her from engaging in distress-promoting behaviours.

## Purpose

It has been demonstrated that distraction is an effective means of decreasing distress. The purpose of this study was to test an intervention using children's songs to promote parent-led distraction during simple laceration repair in children aged 1 to 5. Parents were encouraged to participate in their child's treatment by singing along to music being broadcast via speakers. A parent who actively participates by singing will have less

opportunity to engage in distress-promoting behaviour and, as reported by Sinha and colleagues (2006), may experience less anxiety during the procedure. Maternal behaviour could account for as much as 53% of the variance in distress experienced by a child (Frank et al., 1995). This finding supports the notion that an intervention targeting both parent and child could have a significant impact on the child's distress. This simple and easily implemented intervention provides parents with a medium through which to distract the child while simultaneously avoiding distress-promoting behaviours. Further, music is an inexpensive, easily implemented, low-burden intervention, requiring only the press of a button. This intervention could lead to a measurable reduction in distress during simple laceration repair by increasing parent-led distraction, thereby improving the hospital experience for both young children and their parents without placing an undue burden on professionals integrating the intervention into their practice.

We hypothesized that parents in the intervention group would demonstrate a greater degree of parent-led distraction than those in the control group. With this objective in mind, we formulated the following research question: *Does music broadcast via speakers have a measurable effect on parent-led distraction during simple laceration repair in children aged 1 to 5?*

## Methods and Materials

### *Design*

This quasi-experimental study was conducted in a pediatric ED located in a large city. This study design was chosen over randomization because no between-group differences were expected in children presenting at the ED, based on a review of the department's patient-tracking software conducted by one of the investigators. As the study site was experiencing a severe staff shortage at the time of the study, this method also served to minimize any burden associated with randomization (e.g., using randomization software) and to simplify study logistics for participating ED staff.

Recruitment took place in 2-week blocks. Those children presenting during the first 2 weeks of the study had laceration repair as per department protocol, without the music intervention. During the second 2 weeks, consenting patients received the intervention. Recruitment took place over an 8-week period, Monday to Friday from noon to 8 p.m. A review of the patient-tracking software used at the study site, which tracks the presenting complaint, demographic data, and discharge diagnosis, determined that these days and times would allow for the greatest recruitment potential, as they were when lacerations in the 1-to-5 age group were most likely to present at the ED.

### *Sample*

Children aged 12 to 71 months, inclusive, presenting at the ED with a single, simple laceration requiring repair with sutures or tissue adhesives and pretreated topically with lidocaine, epinephrine, and tetracaine (LET) were included in the study. This age range was selected so the intervention could be studied in a narrow developmental range and to facilitate standardization of the intervention and pre-procedural teaching. All children who required suturing received LET followed by injectable lidocaine to ensure that the procedure remained painless. Children were recruited regardless of prior experience with lacerations or laceration repair. Excluded were children who had more than one laceration, required sedation for their laceration repair, presented at the ED without a family member, or were accompanied by a family member who did not speak English or French.

Families were identified as eligible for the study by the triage nurse and flagged for the research assistant. The research assistant then approached the family and requested consent for participation prior to examination by the physician. Recruitment took place over the months of July and August 2008. Of the 69 families screened for the study, 68 agreed to participate (98%). Eleven of the families were excluded from the final analysis because the child did not meet inclusion criteria after being examined by the physician (e.g., required sedation, required complex laceration repair, had multiple injuries). One family did not provide a specific reason for refusal to consent. In total, 57 families were included in the final analysis, 27 of whom received the music intervention.

### *Intervention*

All consenting families were met by a Child Life Specialist (CLS), who provided pre-procedural teaching to the parent and child. The pre-procedural teaching was standardized between the two groups. Children assigned to the intervention group had audiorecorded children's songs played to them during the procedure. The song choices included lullabies, educational songs, and songs performed by popular television characters in both English and French. Three songs were selected by the CLS and the parents prior to the procedure. These were played throughout the procedure on a repeating basis, from the start of the procedure (child placed on bed) to the end of the procedure (bandage placed over laceration). The parents were encouraged to sing along with the music during the procedure. Participants in the non-intervention group (usual care) had no music played. All laceration-repair procedures were videotaped. The research assistant accompanied the physician, patient, and parents at

all the procedures and was responsible for proper positioning of video equipment and for starting the music at the beginning of the procedure.

Approval for the study was obtained from both the Nurse Manager and the Medical Director of the ED. Ethical approval was obtained from the ethical review board prior to implementation. Informed consent was obtained by the research assistant prior to videotaping the procedure. All taped procedures were transferred to a dedicated hard drive in a locked office at the end of each study week. Videotapes were accessed and viewed only by the researchers and objective scorers. Patient confidentiality was ensured through the replacement of patient names with codes on all study materials. Consent forms were kept separate from other study materials at all times.

### *Instruments*

***Parental participation.*** The video scorers determined the amount of time a parent spent distracting the child during the procedure. They were trained to recognize behaviours that distracted the child. Behaviours such as singing to the child, diverting the child's attention away from the laceration repair, or encouraging the child to sing were considered to be parental participation. The video scorers recorded the number of seconds spent on each distraction event. For example, they timed exactly how long a parent would sing along with the music being broadcast. A parental participation score was then derived by determining the proportion of time spent on distracting the child (time distracting/total procedure time). Interrater reliability for proportion of parental participation was determined (0.767, $p < 0.01$, CI 95% 0.632, 0.923) and judged to be acceptable.

Since the scores given by the two raters were similar, they were averaged to create an objective distress score and a parental participation score (in seconds), which were used in the subsequent analysis.

***Procedure Behavior Check List.*** Videotapes of all laceration repairs were objectively scored using the Procedure Behavior Check List (PBCL) (LeBaron & Zeltzer, 1984). The PBCL is an observational measure of distress that scores the presence and intensity of eight behaviours associated with child pain and anxiety (e.g., muscle tension, verbal stalling, crying). Each behaviour is rated on a Likert-type scale ranging from 0 to 5 (0 = no distress; 1 = very mild distress; 5 = extremely intense distress), for a score ranging from 0 to 40. This tool was originally used to measure observable distress during lumbar punctures in 67 pediatric oncology patients between the ages of 6 and 18 years. Concurrent validity was found to be acceptable, with a correlation of 0.80 ($p < 0.001$) to the children's self-reports of pain and anxiety (Lebaron & Zeltzer, 1984). Subsequent studies have shown the PBCL to be a reliable and valid

measure of behavioural distress in children (Cavender, Goff, Hollon, & Guzzetta, 2004; Luhmann, Schootman, Luhmann, & Kennedy, 2006), with observed distress significantly correlated with patient ratings of pain and anxiety (Langer, Chen, & Luhmann, 2005). Finally, a recent review of observational measures of pain rated the PBCL one of the most accurate measures of pain-related distress currently available, with a good balance of evidence, burden, and content validity (von Baeyer & Spagrud, 2007).

Videotapes were scored by two reviewers naive to the study purpose using the PBCL. The reviewers were trained in the use of the PBCL by study investigators prior to the study start date. Interrater reliability was established prior to the study by comparing rater and investigator scores on sample videotapes. Coding of the videotapes was begun by the raters only when reliability was greater than 0.80 on sample videotapes. Following data collection, interrater reliability was strong for the two video scorers on the objective measure of distress (0.884, $p < 0.01$, CI 95% 0.81, 0.93) and the time to complete the procedure (0.995, $p < 0.01$, CI 95% 0.991, 0.997).

## Results

The intervention and control groups were similar for age, location of laceration, length of laceration, and family member present, but dissimilar for gender. Children in the intervention group more frequently required sutures to repair the laceration (26% vs. 7%) (Table 1); however, this difference was not statistically significant.

Linear regression analysis was performed to determine whether parental involvement predicted distress scores and the degree to which age affected distress. In the control group ($n = 30$), 18 parents participated in distracting the child (60%) and the mean proportion of time spent participating in the laceration repair was low (0.0647). Of the 27 parents in the intervention group, 15 distracted their child (56%), with a similar mean proportion of time spent distracting the child (0.0669). There was no significant difference between the two groups in terms of parental participation.

There was no significant difference in distress scores based on parental participation. The greatest predictors of child distress were age ($\beta = -0.434$, $t = -4.017$, $p < 0.01$), with younger children being more distressed, and the presence of the father in the procedure room ($\beta = -0.419$, $t = -3.888$, $p < 0.01$). Children had a significantly higher mean distress score when the father was present (43/100) than when only the mother was present (23/100) ($F(1, 54) = 18.452$, $p < 0.01$). (See Table 2 for descriptive and comparative data on distress scores.)

**Table 1** ***Demographic and Procedural Characteristics of Intervention and Control Groups***

| | Control | Intervention | Chi-squared *p* |
|---|---|---|---|
| Age of child (months) | 43.5 ± 14.4 | 39.9 ± 18.7 | ns |
| Sex *(n)* | | | 0.047* |
| Male | 24 | 15 | |
| Female | 6 | 12 | |
| Parent present *(n)* | | | ns |
| Father | 4 | 4 | |
| Mother | 19 | 16 | |
| Both | 6 | 7 | |
| Other | 1 | 0 | |
| Location of laceration *(n)* | | | ns |
| Scalp | 9 | 3 | |
| Face | 17 | 21 | |
| Other | 3 | 3 | |
| Length of laceration (mm) | 13.2 ± 7.6 | 14.5 ± 7.7 | ns |
| Type of repair *(n)* | | | ns |
| Tissue adhesive | 28 | 20 | ns |
| LET[a] + sutures | 1 | | 1 |
| LET + lidocaine + sutures | 1 | | 6 |
| N | 30 | 27 | |

*Significant at 0.05.
[a] Topical anesthesia

**Table 2** ***Distress Score Data: Treatment Group by Parental Presence (Distress Scores 0–100)***

| | Control | Intervention | *Mean* | *F* | *p* |
|---|---|---|---|---|---|
| Mean distress *(n)* | 33.1 (29) | 28.6 (26) | | | ns |
| Parent present | | | | | |
| Mother *(n)* | 27.1 (19) | 19 (16) | 23.05 | (2,52) 9.516 | < 0.01 |
| Father *(n)* | 40.2 (4) | 44.7 (4) | 42.5 | | |
| Both *(n)* | 48.1 (6) | 43.4 (6) | 45.8 | | |

*Note:* Two cases were excluded; one child was accompanied by an aunt and one child was missing objective data.

## Discussion

There is a paucity of research on distress during laceration repair. Although this is a relatively simple, quick, and painless procedure, it is perceived by observers as extremely distressing (Babl, Mandrawa, O'Sullivan, & Crellin, 2008). As resolution of pain is an important predictor of high patient satisfaction in children (Magaret, Clark, Warden, Magnusson, & Hedges, 2002), it may be inferred that effective resolution of distress during simple laceration repair may also increase patient satisfaction. Further, reducing distress during laceration repair may decrease the need for sedatives such as midazolam, the use of which increases observation time (post-intervention) and the incidence of sequelae (Luhmann, Kennedy, Porter, Miller, & Jaffe, 2001). Our results indicate that the strongest predictors of distress are age and the parent who accompanies the child in the treatment room. The finding that distress is strongly correlated with age is in concordance with the results of several other studies examining pediatric distress (Carr et al., 1998; Goodenough et al., 1999).

Although the intervention did reduce distress in children (see Bhatt, Sobieraj, & Johnston, 2009), in the present study parental participation was not higher in the intervention group. Although parents were encouraged to distract their child during the procedure, the proportion of time spent distracting the child, regardless of condition, was extremely small (6.6% of total procedure time). The intervention may not provide sufficient stimulus to overcome the unpleasantness of seeing one's child in distress. In the future, more time with parents in pre-procedural teaching, to stress the importance of distraction, may serve to increase the proportion of time spent participating. If the proportion of time spent participating is increased, we might observe a lowering of distress scores, as had been expected, since the parents will have less opportunity to engage in distress-promoting behaviours.

Pre-procedural teaching has been demonstrated to reduce anxiety prior to a procedure (Claar, Walker, & Barnard, 2002; Spafford, von Baeyer, & Hicks, 2002). Presumably the older children in our sample had learned more from the pre-procedural teaching and applied the information more effectively. If distress is defined as the "sum of anxiety and pain" (Walco et al., 2005), then older children who are less anxious as a result of pre-procedural teaching will experience less distress. Therefore, we cannot rule out the possibility that the difference in distress levels between age groups is a result of an association between increasing age and pre-procedural teaching and is not in fact an accurate representation of distress scores. In the future it would be imperative to add a third group to the study, one in which no pre-procedural teaching has been

provided by a CLS, in order to control for this potential confounding variable.

A novel finding in our study was the difference in distress scores depending upon which family member accompanied the child during the procedure. Children were significantly more distressed if the father was in the treatment room. Although the mean age for the group in which the father was present was slightly lower (38.3 vs. 43.9 months), this is likely not a sufficiently large age difference to explain the stress differences. There are no prior studies reporting a similar finding. As different coping strategies are known to provoke varying degrees of distress (Manimala et al., 2000; McMurtry et al., 2006; Young, 2005), it may be that fathers in our study were using coping strategies known to increase distress, such as reassurance, criticism, or apologizing for the child's behaviour, more frequently than mothers, while mothers may have been using effective coping strategies, such as distraction, humour, or non-procedural talk, with greater frequency. Since families self-selected who would accompany the child in the procedure room, a second possibility for this difference in distress is that fathers chose to accompany "difficult" or expressive children more frequently than mothers alone did. Without collecting more data from parents regarding their relationship with the child, or their preferred method of coping, it is hard to draw conclusions with respect to this difference in distress. A secondary analysis of the videotapes would allow us to determine the frequency and type of coping strategies used by family members, and to validate the hypothesis that different family members use alternative coping strategies.

One study has suggested that distraction loses efficacy in reducing distress if the painful or unpleasant stimulus is prolonged (McCaul & Malott, 1984). Laceration repair in our study took several minutes to complete ($M$ = 328 seconds), in stark contrast to immunization, heel sticks, or blood sampling, which may take only seconds. The degree to which a child is distracted may be further influenced by their degree of stimulation. As our intervention was fairly passive, it may not have provided a sufficiently strong stimulus to overcome the unpleasantness of the laceration repair.

The present study had several limitations. A non-randomized design was chosen for the study, because there were no differences expected in children presenting to the ED during the 2-week study blocks. Despite this expectation, groups differed on gender, family member present during the procedure, and type of laceration repair. A single-blind RCT may have prevented the skewing of groups and increased the generalizability of our results. We cannot conclude that the gender composition among groups affected our results, as the literature on gender differences

and distress in children is inconclusive (e.g., Carr et al., 1998; Goodenough et al., 1999).

Because audio was recorded and required for proper scoring of the videotapes, the objective scorers were not blind to group assignment. However, the scorers remained blind to study purpose throughout the study, which reduced the risk of bias in video scoring. In any future research it may be useful to apply a measure that does not require audio cues, such as the Child Facial Coding System (CFCS) (Breau et al., 2001), to reduce the risk of bias introduced by scorers who are not blind to group assignment.

The small sample size ($N = 57$) may be a further limitation. A larger sample size would have increased the power of the study and allowed us to detect a smaller clinical effect. Further, no qualitative data were collected from participating families and staff. Data such as satisfaction with the intervention, likelihood of adopting the intervention for future procedures, and parents' and staff members' perceptions of the effectiveness of the treatment might have allowed us to infer the clinical usefulness of the intervention.

### *Practice Implications*

Our findings suggest that significant predictors of higher levels of distress during laceration repair are younger age and paternal accompaniment in the procedure room. This information could influence unit managers/team leaders to more effectively allocate available resources, such as CLSs, to families where there is greater need. Older children may require less attention by auxiliary staff. This finding suggests that auxiliary staff can spend more time attending to the needs of other patients on the unit. Further, the data suggest that the younger population may require more attention from support staff than they are currently receiving, to lower the increased level of distress experienced by these patients.

## Conclusion

Although the provision of music and pre-procedural teaching did not increase the proportion of parental participation, the study did find that children are more distressed in the presence of fathers — an important finding not described in other studies. This finding will help inform future studies where parent gender may be an important covariate.

## References

Babl, F., Mandrawa, C., O'Sullivan, R., & Crellin, D. (2008). Procedural pain and distress in young children as perceived by medical and nursing staff. *Pediatric Anesthesia, 18*(5), 412–419.

Bhatt, M., Sobieraj, G. S., & Johnston, C. C. (2009, May 5). *Improving emergency department treatment of pediatric lacerations with the use of children's songs as a distraction technique.* Poster presentation at meeting of Pediatric Academic Societies, Baltimore, Maryland.

Blount, R. L., Corbin, S. M., Sturges, J. W., Wolfe, V. V., Prater, J. M., & James, L. D. (1989). The relationship between adults' behavior and child coping and distress during BMA/LP procedures: A sequential analysis. *Behavior Therapy, 20*(4), 585–601.

Breau, L., McGrath, P. J., Craig, K. D., Santor, D., Cassidy, K. L., & Reid, G. J. (2001). Facial expression of children receiving immunizations: A principal components analysis of the child facial coding system. *Clinical Journal of Pain, 17*(2), 178–186.

Carr, T. D., Lemanek, K. L., & Armstrong, F. D. (1998). Pain and fear ratings: Clinical implications of age and gender differences. *Journal of Pain and Symptom Management, 15*(5), 305–316.

Cavender, K., Goff, M. D., Hollon, E. C., & Guzzetta, C. E. (2004). Parents' positioning and distracting children during venipuncture: Effects on children's pain, fear, and distress. *Journal of Holistic Nursing, 22*(1), 32–56.

Cepeda, M. S., Carr, D. B., Lau, J., & Alvarez, H. (2006). Music for pain relief. *Cochrane Database of Systematic Reviews, 2,* CD004843.

Claar, L. R., Walker, L. S., & Barnard, J. A. (2002). Children's knowledge, anticipatory anxiety, procedural distress, and recall of esophagogastroduodenoscopy. *Journal of Pediatric Gastroenterology and Nutrition, 34*(1), 68–72.

Cohen, L. L. (2002). Reducing infant immunization distress through distraction. *Health Psychology, 21*(2), 207–211.

Fradet, C., McGrath, P. J., Kay, J., Adams, S., & Luke, B. (1990). A prospective survey of reactions to blood tests by children and adolescents. *Pain, 40*(1), 53–60.

Frank, N. C., Blount, R. L., Smith, A. J., Manimala, M. R., & Martin, J. K. (1995). Parent and staff behavior, previous child medical experience, and maternal anxiety as they relate to child procedural distress and coping. *Journal of Pediatric Psychology, 20*(3), 277–289.

Goodenough, B., Thomas, W., Champion, G. D., Perrott, D., Taplin, J. E., von Baeyer, C. L., et al. (1999). Unravelling age effects and sex differences in needle pain: Ratings of sensory intensity and unpleasantness of venipuncture pain by children and their parents. *Pain, 80,* 179–190.

Langer, D. A., Chen, E., & Luhmann, J. D. (2005). Attributions and coping in children's pain experiences. *Journal of Pediatric Psychology, 30*(7), 615–622.

LeBaron, S., & Zeltzer, L. (1984). Assessment of acute pain and anxiety in children and adolescents by self-reports, observer reports, and a behavior checklist. *Journal of Consulting and Clinical Psychology, 52*(5), 729–738.

Luhmann, J. D., Kennedy, R. M., Porter, F. L., Miller, J. P., & Jaffe, D. M. (2001). A randomized clinical trial of continuous-flow nitrous oxide and midazolam for sedation of young children during laceration repair. *Annals of Emergency Medicine, 37*(1), 20–27.

Luhmann, J. D., Schootman, M., Luhmann, S. J., & Kennedy, R. M. (2006). A randomized comparison of nitrous oxide plus hematoma block versus keta-

mine plus midazolam for emergency department forearm fracture reduction in children. *Pediatrics, 118*(4), e1078–e1086.

Magaret, N. D., Clark, T. A., Warden, C. R., Magnusson, A. R., & Hedges, J. R. (2002). Patient satisfaction in the emergency department – a survey of pediatric patients and their parents. *Academic Emergency Medicine, 9*(12), 1379–1388.

Manimala, M. R., Blount, R. L., & Cohen, L. L. (2000). The effects of parental reassurance versus distraction on child distress and coping during immunizations. *Children's Health Care, 29*(3), 161–177.

McCaul, K. D., & Malott, J. M. (1984). Distraction and coping with pain. *Psychological Bulletin, 95*(3), 516–533.

McMurtry, C. M., McGrath, P. J., & Chambers, C. T. (2006). Reassurance can hurt: Parental behavior and painful medical procedures. *Journal of Pediatrics, 148*(4), 560–561.

Piira, T., Sugiura, T., Champion, G. D., Donnelly, N., & Cole, A. S. J. (2005). The role of parental presence in the context of children's medical procedures: A systematic review. *Child: Care, Health and Development, 31*(2), 233–243.

Public Health Agency of Canada. (2002a). *Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP) report: Age and sex distribution of injured persons.* Retrieved September 4, 2009, from http://dsol-smed.phac-aspc.gc.ca/dsol-smed/is-sb/c_chrp-eng.phtml.

Public Health Agency of Canada. (2002b). *Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP) report: Indication of the type of injury suffered by the injured person.* Retrieved September 4, 2009, from http://dsol-smed.phac-aspc.gc.ca/dsol-smed/is-sb/c_chrp-eng.phtml.

Sinha, M., Christopher, N. C., Fenn, R., & Reeves, L. (2006). Evaluation of nonpharmacologic methods of pain and anxiety management for laceration repair in the pediatric emergency department. [Comment.] *Pediatrics, 117*(4), 1162–1168.

Spafford, P. A., von Baeyer, C. L., & Hicks, C. L. (2002). Expected and reported pain in children undergoing ear piercing: A randomized trial of preparation by parents. *Behaviour Research and Therapy, 40*(3), 253–266.

Taddio, A., Katz, J., Ilersich, A. L., & Koren, G. (1997). Effect of neonatal circumcision on pain response during subsequent routine vaccination. *Lancet, 349*(9052), 599–603.

Uman, L. S., Chambers, C. T., McGrath, P. J., & Kisely, S. (2006). Psychological interventions for needle-related procedural pain and distress in children and adolescents. *Cochrane Database of Systematic Reviews, 4,* CD005179.

von Baeyer, C. L., & Spagrud, L. J. (2007). Systematic review of observational (behavioral) measures of pain for children and adolescents aged 3 to 18 years. *Pain, 127*(1–2), 140–150.

Walco, G. A., Conte, P. M., Labay, L. E., Engel, R., & Zeltzer, L. K. (2005). Procedural distress in children with cancer: Self-report, behavioral observations, and physiological parameters. *Clinical Journal of Pain, 21*(6), 484–490.

Wolfram, R. W., & Turner, E. D. (1996). Effects of parental presence during children's venipuncture. *Academic Emergency Medicine, 3*(1), 58–64.

Young, K. (2005). Pediatric procedural pain. *Annals of Emergency Medicine, 45*(2), 160–171.

**Acknowledgements**

The authors would like to acknowledge the funding support of Groupe de recherche interuniversitaire en interventions en sciences infirmières du Québec (GRIISIQ) and the Montreal Children's Hospital Research Institute; the Emergency Department staff and the Child Life Services Department of the Montreal Children's Hospital; Fonds de la recherche en santé du Québec (FRSQ); and their research assistants, Sushmita Shivkumar and Kamy Apkarian.

Disclosure: There is no conflict of interest.

---

*Gregory Sobieraj, RN, BN, is a PhD student at the School of Nursing, McGill University, Montreal, Quebec, Canada. Maala Bhatt, MD, MSc, is Attending Physician, Division of Pediatric Emergency Medicine, Montreal Children's Hospital. Sylvie LeMay, RN, PhD, is Associate Professor, Faculty of Nursing, Université de Montréal. Janet Rennick, RN, PhD, is Nurse Scientist, Montreal Children's Hospital. Celeste Johnston, RN, DEd, FCAHS, is Professor and Associate Director of Research, School of Nursing, McGill University.*

*CJNR 2009, Vol. 41 Nº 4, 83–89*

# *Knowledge Translation*

# Getting Efficacious Interventions Incorporated Into Practice: Lessons Learned

**Gina Browne**

The knowledge translation movement emphasizes implementing efficacious interventions in practice or using practice guidelines. However, a goal stated this way is demeaning of "usual care," has a flavour of superiority, and fails to acknowledge the value of "the way we do it now" for some people with particular characteristics. There is little wonder why some approaches to the implementation of efficacious interventions are met with resistance by frontline providers. I would like to offer some lessons learned from implementing random controlled trials of new practices compared to following usual or current care practices.

## Approach

*Approach* refers to the style with which an investigator or clinician scientist goes about implementing or testing a new or best practice in a clinical setting. One successful approach to improving practice is to begin by having conversations with providers and managers in order to establish

- their most pressing issues related to practice
- what they believe they do well
- what they think they could or should improve, for whom, and in what circumstances
- what individual, team, management, and organizational issues act as barriers to the implementation of their ideas
- what is needed to address these barriers
- what should be done to move forward

There is a large literature in cognitive and social psychology on individual trials associated with the propensity to try out and use innovations (e.g., tolerance for ambiguity, learning style, motivations). This literature is for the most part ignored by researchers studying the implementation of best practices (Rogers, 1995).

Sometimes there are divergent ideas about what, in combination or alone, would improve outcomes. Comparing one's ideas with those currently being implemented in practice, or subjecting one's ideas to trial, presents an opportunity to study the impact of alternative interventions (effective for whom, and at what price?). This is sometimes called "trialability" or "reinvention," especially if best practices are modified to fit the context.

## Appropriateness and Applicability

A best practice can be inappropriate or inapplicable in certain situations. Using a best practice inappropriately might include counselling people with a chronic illness when they are well adjusted (Roberts et al., 1995), or providing empowerment training to long-term-care residents with a serious mental illness (Byrne et al., 1999), or deploying emergency department quick response teams for the elderly (Weir et al., 1999). This is sometimes called "incompatibility." At times the so-called best practice is aimed at a person's deficit when opportunities to strengthen their competencies may be more effective and less expensive (Browne, 2003; Browne, Gafni, Roberts, Byrne, & Majumdar, 2004).

Preliminary information about who is and is not eligible for the best practice is necessary, to establish the appropriateness and applicability of the new intervention. Researchers might also learn of any systemic barriers, motives, or areas of resistance, and generally get a sense of the appropriateness of a particular best practice *at this time* and *in this setting,* with its culture and its nuances.

Before embarking on the implementation phase, do clinicians need to carry out other work, such as address their other priorities or transform the organizational culture into a "learning" culture at all levels? Different courses of action may have a "relative advantage." For example, we found that nurses working in critical-care burn units were not interested in a study to promote adjustment of burn survivors until they could find out why people with burn injuries were dying after the insertion of a Swan-Ganz catheter during the acute phase. It turned out that the correct procedure for inserting the catheter was not being followed. Further, the nurses thought we should study the adjustment of burn survivors after 1 to 12 years before embarking on a study to promote their adjustment following the burn injury. It transpired that the prevalence of poor adjustment among burn survivors was the same as that for the general population and was unrelated to the severity of the burn (Browne et al., 1985). In another trial, efforts to promote adjustment to chronic illness at three specialty outpatient clinics were shown to have no effect because 64% of the patients were well adjusted to begin with (Arpin, Fitch, Browne, & Corey, 1990). This is another example of incompatibility.

### Accessibility

Accessibility is related to both users and providers of services. Do poor and vulnerable clients have geographic and cultural access to a service, or are they incapable of reaching out, because they are depressed or for other reasons, and taking advantage of the service (Browne, Roberts, et al., 2001; Byrne et al., 1998)?

Do frontline providers have access to the investigative resources necessary to pursue their initial interests? Nothing can happen without a relationship, and relationships require the exchange of goods or some knowledge about the costs and benefits of adopting a new approach. We researchers solicit clinicians' ideas and want their help with the logistics of implementing a new practice. Can they have our service in conducting their research, our respect for their question, and a real sense of collegiality and collaboration by offering the currency of co-authorship (Pringle, 2008)?

### Acceptability

Acceptability refers to the willingness of practitioners and patients to accept new practices that are adopted (Markle-Reid & Browne, 2001). In order to have efficacious interventions put into practice, practitioners must be full participants both in addressing the nuances and logistics of the desired changes and in interpreting the findings. Often, the current practice is beneficial for some patients in particular circumstances (Roberts et al., 1995). In a trial of a counselling intervention for family caregivers of people with dementia, we found that counselling was beneficial only for those caregivers who had problem-solving difficulties at the outset (Markle-Reid & Browne, 2001). When we tried to counsel caregivers with good problem-solving skills, we merely increased their uncertainty about their relative's illness. Good practices are not necessarily useful in every context.

There are usually good reasons why practice patterns evolve as they do, although these may not always be expressed. As a clinician scientist, I wondered why the first thing hospital staff did after morning report was distribute the linen. As it happens, they were doing several things at once: providing an overview of patients' status, checking intravenous medications, and distributing the linen.

### Adequacy and Appropriateness of Resources for Practice

Too often, best practices address only "slivers" of a client's situation, and in so doing can fail to produce the intended outcome (Roberts et al., 1999), as in the provision of social assistance without help for their mental health problems (Browne, Byrne, Roberts, Gafni, & Whittaker,

2001). For example, the homemaker services for which a client is eligible may be insufficient to address the person's underlying problems with depression (Markle-Reid et al., 2008). Parents of disabled children with complex needs receive instructions in best practices and activities to do with their child from physiotherapists, speech therapists, and occupational therapists. For an already overwhelmed mother of three, these additional expectations of her can be "the straw that breaks the camel's back." In the Canadian province of Ontario, mental health services for mothers are provided by agencies funded by the Ministry of Health and Long-Term Care, while services for children with complex needs are funded by the Ministry of Children and Youth; policies and funding serve to further fragment services for households and families.

## Effectiveness of Behavioural Change Strategies

The implementation of best or effective practices requires changes in provider behaviour, organizational behaviour and policy (Browne, 1999), and client behaviour (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004). Yet the best practice guideline literature rarely addresses these fundamental issues. Other disciplines have processes for promoting behavioural change, such as cognitive behavioural therapy and strength-based, motivational, or problem-solving counselling. However, this expertise is rarely incorporated into the dissemination and uptake of medical or nursing practice guidelines or quality-assurance practices. Finally, the vast knowledge on the diffusion of innovations would be useful for guiding the implementation of new practices. This situation highlights the multiple levels of influence entailed in the adoption of a new practice (Greenhalgh et al., 2004).

## Efficiency or Return on Investment

In our 18 years of economically evaluating the randomized trialling of new versus existing practices (Browne et al., 1999), we have learned several lessons about how to get efficacious interventions put into practice:

- Principles of community development, behavioural change, and diffusion of innovations must guide every step, by means of "learningful" conversations.
- A service agency can be said to have adopted a culture of learning when it compares its actual practices with its ideas about innovation in order to address its greatest challenges. Our "learnings" are "beyond main effects." There is usually an interaction between an alternative

intervention and the characteristics of the clients served. People and agencies with particular characteristics will benefit from the new service.

- "Usual care" is adequate for some patients.
- A uniform best practice is inappropriate, as no best practice is suitable in every context.
- No one service agency is mandated to address the needs of all clients. Strategic alliances between agencies can lead to proactive, integrated, comprehensive, and stepped care for people with complex conditions and circumstances. A system of national health insurance can realize savings in the same year by reducing its use of expensive crisis services.

## Coverage

A "whole-of-government" approach is necessary (Proctor et al., 2006) because the efficiencies produced by strategic alliances between service agencies result in reduced expenditures for health care. These allied social care services funded by different parts of government should be rewarded for the savings they generate for ministries of health (Browne et al., 2001). This could serve as an incentive for the adoption of best practices, especially if the savings were to be pooled and retained at the local level.

## References

Arpin, K., Fitch, M., Browne, G., & Corey, P. (1990). Prevalence and correlates of family dysfunction and poor adjustment to chronic illness in specialty clinics. *Journal of Clinical Epidemiology, 43*(4), 373–383.

Browne, G. (1999). Evidence that informs practice and policy: The role of strategic alliances at the municipal, provincial, and federal levels. *Canadian Journal of Nursing Research, 31*(1), 79–94.

Browne, G. (2003). Making the case for youth recreation: Integrated service delivery – more effective and less expensive. *Ideas That Matter,* 2(3), 3–8.

Browne, G., Byrne, C., Brown, B., Streiner, D., Roberts, R., Dabbs, R., et al. (1985). Psychosocial adjustment of burn survivors. *Burns, 12*(1), 28–35.

Browne, G., Byrne, C., Roberts, J., Gafni, A., & Whittaker, S. (2001). When the bough breaks: Provider-initiated comprehensive care is more effective and less expensive for sole-support parents on social assistance. *Social Science and Medicine, 53,* 1697–1710.

Browne, G., Gafni, A., Roberts, J., Byrne, C., & Majumdar, B. (2004). Effective/efficient mental health programs for school-age children: A synthesis of reviews. *Social Science and Medicine, 58,* 1367–1384.

Browne, G., Roberts, J., Byrne, C., Gafni, A., Weir, R., & Majumdar, B. (2001). The costs and effects of addressing the needs of vulnerable populations:

Results of 10 years of research. *Canadian Journal of Nursing Research, 33*(1), 65–76.

Browne, G., Roberts, J., Gafni, A., Byrne, C., Weir, R., Majumdar, B., et al. (1999). Economic evaluations of community-based care: Lessons from twelve studies in Ontario. *Journal of Evaluation in Clinical Practice, 5*(3), 191–209.

Byrne, C., Brown, B., Voorberg, N., Schofield, R., Browne, G., Gafni, A., et al. (1999). Health education or empowerment education with individuals with a serious persistent psychiatric disability. *Psychiatric Rehabilitation Journal, 22,* 4, 368–380.

Byrne, C., Browne, G., Roberts, J., Ewart, B., Schuster, M., Underwood, J., et al. (1998). Surviving social assistance: 12-month prevalence of depression in sole-support parents receiving social assistance. *Canadian Medical Association Journal, 158*(7), 881–888.

Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., & Kyriakidou, O. (2004). Diffusion of innovations in service organizations: Systematic review and recommendations. *Milbank Quarterly: A Multidisciplinary Journal of Population Health and Health Policy, 82*.

Markle-Reid, M., & Browne, G. (2001). Explaining the use and non-use of community-based long-term care services by caregivers of persons with dementia. *Journal of Evaluation in Clinical Practice,* 7(3), 271–287.

Markle-Reid, M., Browne, G., Weir, R., Gafni, A., Roberts, J., & Henderson, S. (2008). Seniors at risk: The association between the six-month use of publicly funded home support services and quality of life and use of health services for older people. *Canadian Journal on Aging, 27*(2), 207–224.

Pringle, D. (2008). Fostering research partnerships: Interview with Dr. Gina Browne. *Nursing Leadership, 21*(4), 16–23.

Proctor, S., Watson, B., Byrne, C., Bremner, J., van Zwanenberg, T., Browne, G., et al. (2006). The development of an applied whole-systems research methodology in health and social service research: A Canadian and United Kingdom collaboration. In J. Winterdyk, L. Coates, & S. Brodie (Eds.), *Qualitative and quantitative research methods reader: A Canadian orientation*. Toronto: Pearson Education.

Roberts, J., Browne, G., Milne, C., Spooner, L., Gafni, A., Drummond-Young, M., et al. (1999). Problem-solving counseling for caregivers of the cognitively impaired: Effective for whom? *Nursing Research, 48*(3), 162–172.

Roberts, J., Browne, G., Streiner, D., Gafni, A., Pallister, R., Hoxby, H., et al. (1995). Problem-solving counselling or phone-call support for outpatients with chronic illness: Effective for whom? *Canadian Journal of Nursing Research, 27*(3), 111–137.

Rogers, E. M. (1995). *Diffusion of innovations.* New York: Free Press.

Weir, R., Browne, G., Byrne, C., Roberts, J., Gafni, A., Thompson, A., et al. (1999). The quick response initiative in the emergency department: Who benefits? *Health Care Management Science, 2,* 137–148.

*Gina Browne, MEd, PhD, Hon. LLD, is Professor, School of Nursing; Founder and Director, Health and Social Service Utilization Research Unit; Ministry of Health and Long-Term Care Theme Lead – Research on Innovative and Integrated Systems of Prevention and Care; and Member, Department of Clinical Epidemiology and Biostatics, McMaster University, Hamilton, Ontario, Canada.*

*CJNR 2009, Vol. 41 Nº 4, 91–99*

*Knowledge Translation*

# Reflections From a Research Program on Nursing Interventions for Family Caregivers of Seniors

**Francine Ducharme**

## Background

In the past decade, the development of research infrastructure in the field of nursing science has been marked by the creation of research chairs. The Desjardins Research Chair in Nursing Care for Seniors and Their Families is one of these, having been founded in the wake of two major social transformations in the Western world: the aging of the population and the shifting configuration of the family. One consequence of these phenomena is that the type of assistance and care provided to aging and increasingly dependent parents has undergone many changes. Family caregivers are growing in number and the care they are called upon to deliver is becoming more and more complex. Empirical research has shown that these changes can have a significant impact on the lives of family caregivers, whose health is often undermined by stress, physical and psychological exhaustion, and a sense of being overwhelmed (Schulz & Martire, 2004). As a result, family caregivers are being considered more and more as an at-risk group within the health-care system. Their quality of life has come to depend in large part on nursing care. However, given that caregivers are reluctant to use services (Ducharme et al., 2007), and given that outcome studies have generally concluded that selected services and interventions have a marginal or modest impact on caregiver well-being (Brodaty, Franzep, Green, & Koschera, 2003), innovative nursing interventions to support families need to be developed and tested.

The Desjardins Research Chair has, over the past decade, contributed to knowledge development by carrying out evaluative studies of innovative nursing interventions for family caregivers of seniors living at home or in health-care institutions. It engages in four interrelated activities: knowledge development (evaluative studies of individual, group, and online nursing interventions); research training for graduate students;

knowledge translation for clinicians and decision-makers, with a view to improving nursing practices; and recommendations for improving policies around seniors and their families (www.chairedesjardins.umontreal.ca). The purpose of this article is to reflect upon the issues and challenges that we have identified within the framework of our research program concerning knowledge translation activities. Our reflections on these issues and challenges were guided by the following question: *What are the conditions that favour the utilization of research-based evidence and that foster changes both in the practice and management of nursing care and in health-care policies?*

Though the models and approaches underlying research translation are numerous (Grol & Grimshaw, 2003), our reflection emerges above all from the efforts of our research team in fostering the application of our findings. Our studies, based on a variety of theoretical models (i.e., stress-coping, self-efficacy, transition) and mixed methodological approaches, have focused on the development and evaluation of various psycho-educational interventions. The primary purpose of these interventions has been to provide family caregivers with strategies for coping with the health-illness transitions they encounter daily in their informal caregiver role. Three of the key strategies we have evaluated are social-support-seeking, problem-solving, and cognitive reframing. The issues discussed in this article derive from our experiences in translating our own research results.

## Partnership: A *sine qua non* for Success in Knowledge Application

At the start of the 2000s, our team was confronted with what might be referred to as a "partnership obligation" — that is, interdisciplinary and intersectoral alliances stipulated by various funding agencies. Nearly a decade later, we have come to recognize this imposition as a condition for success in bringing about changes in practice and policy. In short, it has now been acknowledged that research projects conducted in partnership yield better results (Godin & Gingras, 1999). In the context of our research program, partnership constituted a *sine qua non* of the impact of our work on practice, management, and political decision-making. Partnership accelerates the application of new knowledge by contributing to the decentralization of knowledge bases and destabilization of the dominant thought processes among stakeholders (researchers, clinicians, managers, and decision-makers) (Ducharme, 2003).

A harmonious partnership, however, calls for a strategic approach. In the course of our work in conceptualizing and evaluating nursing inter-

ventions, we sought to respect the conditions for a successful strategic alliance such as those put forth by Austin (2000):

- Our studies had to be realistic and had to address important clinical and social problems about which little or nothing is known. The caregiving studies in our program were not yet producing hard "evidence" to shape nursing practices in home support services and in health-care institutions. Moreover, families wanted us to address their concerns regarding the quality of the care offered to their relatives and their own health needs.
- The partners selected had to be passionate and highly motivated with respect to the goals of the studies undertaken. Given that managers had too often been excluded from research partnership models — despite their critical contribution as agents of change — from the outset our projects included decision-makers from the Quebec Association of Health Establishments and managers from local community service centres and long-term-care facilities, in addition to practising nurses, members of advocacy groups, family caregivers (as principal stakeholders), and competent researchers from various disciplines.
- It was essential for us to learn one another's culture within the team, especially the culture of decision-makers, with which we were not well acquainted.
- Other winning conditions included flexibility of partners, transparency with regard to the research process, and, to be sure, sufficient funding.

However, there is a downside to partnerships. The drawbacks include time- and energy-intensiveness, the need to make compromises and choices, the need to understand partners' culture, and the need to share power. Partnership also calls for a complex process that entails agreement on a number of points: the composition of the team and its values, beliefs, and objectives; availability of resources; the role of each partner; a conflict-resolution mechanism; and intellectual proprietorship. Owing to these multiple conditions, our research projects have taken much longer to operationalize and complete, but, paradoxically, the transfer of their results to users has taken much less time.

### Once Trained, Each Graduate Student Becomes a Multiplier

As stated above, one of the missions of a research chair is to train graduate students. In this regard, numerous graduate students in master's and doctoral nursing programs, as well as others pursuing postdoctoral training within our team, have greatly contributed to the application of our

results in nursing practice and management. These nurses now hold key positions in the health and social services network and are driving forces within their care teams; they have the power to bring about changes in practice. We strive to maintain close ties with these practitioners so that our results can be "translated." For instance, we have worked closely with nurses who today hold positions in the home support departments of Quebec's health and social service centres. A stress-management intervention evaluated in one of our studies (Ducharme, Lebel, Lachance, & Trudeau, 2006), intended for family caregivers of physically or cognitively impaired persons living at home, is currently being applied by nurse case managers in eight of these centres. We have also worked with clinical nurse specialists in long-term-care facilities to promote the Taking Care of Myself program (Ducharme, Lévesque, Lachance, Legault, & Préville, 2005), which we conceptualized and evaluated in 26 nursing homes; this program, which is intended for family caregivers who place a cognitively impaired person in a residence, is used in various settings either as originally designed or in an adapted version.

Another important factor that can greatly affect the application of research results is how they are communicated.

## Communicating Our Research Results: A Process That Must Be Learned

The type of communication still favoured by nurse researchers is the scientific article in a peer-reviewed journal that only the chosen few can access and appreciate. This type of communication, however essential for empirical knowledge, is often at a remove from the direct application of knowledge. Whereas hard evidence from research seems to be not yet part of the decision-making process of clinicians, managers, and political authorities, and whereas tacit informal knowledge, organizational memory, and experience are preferred over explicit scientific knowledge (Thompson, McCaughan, Cullum, Sheldon, & Raynor, 2005), our team has sought to examine the various modalities for communicating research results that might foster change in practice.

One of the issues appears to be translation. It is crucial that the results of our research be properly translated by researchers and be understood by clinicians and decision-makers. What this entails is not only giving results visibility but also rendering them digestible and comprehensible. Practising nurses, unit managers, and health-care decision-makers all need to be able to quickly grasp the meaning of hard research results, as these data can influence their decisions and actions. A major obstacle, at times, is the researcher's lack of skill in conveying a key message to those who have the power to change usual care practices: It is a matter of matching the

message with the needs, culture, experience, and knowledge of the target audience. In this respect, we were inspired by several questions: *How do we get people to rapidly understand a key message? How do we prepare an executive summary of a study's results?* And, at a more general level, *How do we demonstrate the power of research?* These considerations are addressed below.

## A Matter of Monumental Import: Communicating With Political Authorities

Evidence obtained through research provides decision-makers with an invaluable tool for offering the population care and services that are both effective and efficient. This, in turn, can help to rationalize costs, which is a constant concern in times of strained budgets. Though decisions to change not only care practices but also service supply are ultimately political, nurse researchers have not yet made politics a prerogative. Yet politics is a major factor in the potential impact of research findings on practice changes (Choi et al., 2004). It has become clear to us that researchers must either develop political skills or, at the very least, surround themselves with qualified resource persons who possess these skills. Research training and success with grant applications are no guarantee that one has the skills needed to write concise texts conveying the salient results of a study or, for that matter, to persuade decision-makers of the authenticity of their findings. Consequently, believing they lack the expertise required for these tasks, many nurse researchers simply ignore them. This too is a "cultural" issue. What it concerns is the link between the world of research and the world of politics.

In the case of our research program, some members of the team are field researchers who have experience with political influence or who come from disciplines where this type of activity is more recognized and exercised (e.g., sociology). What this means for us is being heard and understood by the provincial ministries responsible for health and social services and for families and seniors, or even by the Canadian Caregivers Coalition, so that policies and concrete actions (e.g., work-family reconciliation measures and innovative health-promotional services) can be developed for families of seniors, who constitute an at-risk clientele for the health-care system.

It is only after learning different modalities of political participation, thanks to a team with multiple competencies, that we were able to contribute, however little, to Quebec's home support policy, released in 2003 as *Chez soi : le premier choix* (Home: The first option; Ministère de la Santé et des Services sociaux, 2003). This policy clearly stipulates the importance of supporting the family caregivers of seniors in their daily lives, offering services adapted to their needs, and considering these caregivers as health and social service clients rather than merely as resources for caregiving.

This is one example of the influence that our research can have on health policy. There are others. In 2008 a province-wide public consultation was undertaken on the living conditions of seniors. Briefs were solicited from different bodies and groups. This was a golden opportunity to demonstrate the reach and impact of research. The Desjardins Chair presented a brief (Ducharme, 2007), and when the ministerial report was published we noticed that many of our points about family caregivers and their support needs had made it into the document (Ministère de la Famille et des Aînés, 2008). Then the provincial government tabled a bill (Bill 6) for the creation of a fund to provide support to the family caregivers of seniors for the next 10 years. In a parliamentary commission, the ministry solicited our team's opinion on best practices regarding care for families of seniors in support of this investment (Ducharme, 2009). The bill was passed in October 2009. One last example of ties with decision-makers concerns the recent publication of the Quebec plan regarding Alzheimer's disease and related dementias (Bergman et al., 2009). Our team was mandated to make specific recommendations about issues worth pursuing in order to improve support to the family caregivers of persons afflicted with this cognitive degenerative disease. Based on practice in other countries, such as the United Kingdom and Sweden, we suggested the systematic use by nurses of a caregiver support needs assessment tool. The instrument is the *Carers Outcome Agreement Tool,* validated in an international study (Ducharme et al., 2009).

Of course not all research has such implications in terms of health and social policy. The social significance of a project is a major factor in this respect, as is momentum. Still, politics comes into play at all levels. Very often, matters of a more micro-systemic dimension but of no less importance must be considered at the regional or local level. For example, the translation of research findings can serve to sway members of the nursing board or the board of directors of a health-care institution.

## A Point Often Neglected: Communicating With the Media and the Public

From the viewpoint of research translation, two other interlocutors must be taken into account, namely the media and the general public. The nature of the messages conveyed by nurse researchers continues to pose challenges. The popularization of scientific knowledge by researchers has long been belittled, considered no more than a hobby, particularly within universities. Today, the rendering of specialized knowledge more accessible to the layperson is being viewed more and more as essential for the application of knowledge. It is recognized that knowledge, if it is to be applied in practice, must be disseminated to different audiences in differ-

ent forms. Learning how to make science and research results accessible is a challenge, then, that must be met. Experience has taught us that the value of media contacts should not be underestimated when an important finding needs to be publicized. Disseminating messages through the broadcast and print media, in collaboration with journalists, is a strategy that has enabled us to acquaint families with the interventions we have developed. Obviously, not all researchers are interested in this type of communication. However, as with politics, the availability of people who are capable of such translation is key to making the greatest possible impact. In our case, the research centre's communication department was of enormous help.

Regarding other strategies for targeting the general public, collecting the findings of several studies and publishing them in a book (Ducharme, 2006) allowed us to reach a much larger audience. Moreover, we have produced brochures that summarize particular results in a reader-friendly manner and have allied ourselves with partners for their mass distribution. For example, VON Canada helps distribute our brochure titled *A Five-Step Approach to Reducing Your Stress*. We have also created a Web site (www.aidant.ca) and have participated in public events such as Science on Tap, a monthly café sponsored by the Canadian Institutes of Health Research. Admittedly, these strategies are time-, energy-, and resource-intensive. However, there is no doubt that they have allowed us to speed up the research-translation process. These strategies must be supported by solid infrastructure, and that is where research chairs come in.

## Conclusion

In these times of instantaneous knowledge, a paradigm shift is called for. Opening up to a multiplicity of modes of exchange, conducting research within interdisciplinary and intersectoral partnerships, training graduate students who will later become ambassadors and multipliers, and appreciating the power of politics at the macro and micro levels, as well as the power of the media and mass communication — these are but some of the strategies that enable the translation of research findings for the purpose of promoting best practices in nursing. Experience has taught us that a single approach is not enough, that we must develop a mix of approaches, each tailored to specific situations and directed at different audiences: decision-makers, consumers of care, advocacy groups, and journalists, as well as practising nurses. This is an undertaking that is relatively costly in terms of resources. However, it is necessary, to ensure that our studies have the utmost impact on quality of care. The ultimate goal is to shorten the lag that persists between the end of our research projects and the application of their results.

## References

Austin, J. (2000). *The collaborative challenge.* San Francisco: Jossey-Bass.

Bergman, H., Arcand, M., Bureau, C., Chertkow, H., Ducharme, F., Joanette, Y., et al. (2009). *Relever le défi de la maladie d'Alzheimer et des maladies apparentées : une vision centrée sur l'humanisme, la personne et l'excellence* [Meeting the challenge of Alzheimer's disease and related dementias: A vision centred on humanism, the individual, and excellence]. Report of the Expert Committee to Develop a National Plan for Alzheimer's Disease. Quebec: Ministère de la Santé et des Services sociaux.

Brodaty, H., Franzep, F., Green, A., & Koschera, A. (2003). Meta-analysis of psychosocial interventions for caregivers of people with dementia. *Journal of the American Geriatrics Society, 51,* 657–664.

Choi, B., Pang, T., Lin, V., Puska, P., Sherman, G., Goddard, M., et al. (2004). Evidence-based public health policy and practice: Can scientists and policy makers work together? *Journal of Epidemiology and Community Health, 59,* 632–637.

Ducharme, F. (2003). Partnership in research: A tandem of opportunities and constraints. *Canadian Journal of Nursing Leadership, 16,* 61–72.

Ducharme, F. (2006). *Famille et soins aux personnes âgées : enjeux, défis et stratégies* [The family and eldercare: Issues, challenges, and strategies]. Montreal: Beauchemin.

Ducharme, F. (2007). *Parce que nous sommes tous concernés… Mémoire présenté dans le cadre de la consultation publique sur les conditions de vie des aînés* [Because we are all concerned… Brief presented to the public consultation on the living conditions of seniors]. Quebec: Ministère de la Famille et des Aînés.

Ducharme, F. (2009). *Mémoire présenté à la Commission parlementaire portant sur le projet de loi no 6, loi instituant le Fonds de soutien aux proches-aidants de personnes âgées* [Brief presented to the Parliamentary Commission on Bill 6, an Act respecting the creation of a fund to provide support to the family caregivers of seniors]. Montreal: Chaire Desjardins en soins infirmier à la personne âgée et à la famille.

Ducharme, F., Lebel, P., Lachance, L., & Trudeau, D. (2006). Implementation and effects of an individual stress management intervention for family caregivers of an elderly relative living at home: A mixed research design. *Research in Nursing and Health, 29,* 427–441.

Ducharme, F., Lévesque, L., Caron, C. Hanson, E., Magnusson, L., Nolan, J., et al. (2009). Validation transculturelle d'un outil d'évaluation des besoins de soutien des proches-aidants de personnes âgées à domicile [Transcultural validation of an instrument for assessing the support needs of family caregivers of seniors living at home]. *Recherches en soins infirmiers,* (97), 63–73.

Ducharme, F., Lévesque, L., Lachance, L., Legault, A., & Préville, M. (2005). Taking care of myself: Efficacy of an intervention program for caregivers of a relative suffering from dementia living in a long-term-care setting. *Dementia: International Journal of Social Research and Practice, 4,* 23–47.

Ducharme, F., Lévesque, L., Lachance, L., Zarit, S., Gangbè, M., Vézina, J., et al. (2007). Older husbands as caregivers: Factors associated with health and the intention to end home caregiving. *Research on Aging, 29,* 3–31.

Godin, B., & Gingras, Y. (1999). The impact of collaborative research on scientific production. *Research Files of the Association of Universities and Colleges of Canada, 3,* 1–8.

Grol, R., & Grimshaw, J. (2003). From best evidence to best practice: Effective implementation of change in patients' care. *Lancet, 362,* 1225–1230.

Ministère de la Famille et des Aînés. (2008). *Public consultation report on the living conditions of Quebec seniors: Preparing the future with our seniors*. Quebec: Author.

Ministère de la Santé et des Services sociaux. (2003). *Chez soi : le premier choix. La politique de soutien à domicile* [Home: The first option. The home support policy]. Quebec: Author.

Schulz, R., & Martire, L. (2004). Family caregiving of persons with dementia: Prevalence, health effects, and support strategies. *American Journal of Geriatric Psychiatry, 12,* 240–249.

Thompson, C., McCaughan, D., Cullum, N., Sheldon, T., & Raynor, P. (2005). Barriers to evidence-based practice in primary care nursing — why viewing decision-making as context is helpful. *Journal of Advanced Nursing, 52,* 432–444.

---

*Francine Ducharme, PhD, is Professor, Faculté des sciences infirmières, Université de Montréal, Quebec, Canada; Chair, Nursing Care for Seniors and Their Families, Centre de recherche, Institut universitaire de gériatrie de Montréal; and a member of Groupe de recherche interuniversitaire en interventions en sciences infirmières du Québec (GRIISIQ).*

*CJNR 2009, Vol. 41 N° 4, 101–108*

*Knowledge Translation*

# Challenges in Translating an Evidence-Based Home Visitation Program Into Public Health Practice

**Ruth A. O'Brien**

Increasingly, organizations such as the Coalition for Evidence-Based Policy, the Brookings Institution, the Rand Corporation, and the Canadian Task Force on Preventive Health Care are advocating that interventions show strong evidence of effectiveness before they are included in public policy initiatives involving large expenditures of public funds. While such efforts have focused attention on the importance of adopting evidence-based health practices, the translation of research interventions into mainstream practice is fraught with challenges. This article describes experiences over the past 12 years in translating the Nurse-Family Partnership (NFP), an evidence-based home visitation program for low-income, first-time parents, into public health practice. To provide context for discussion of the challenges encountered, a brief description of the key components of an NFP intervention and evidence for its implementation is presented, followed by an overview of dissemination of the program to communities.

## The Nurse-Family Partnership

The NFP program targets low-income first-time parents and their families during pregnancy and through the first 2 years of the child's life. It has three goals: improve pregnancy outcomes by helping women to alter their health-related behaviours, including reducing use of cigarettes, alcohol, and illegal drugs; improve child health and development by helping parents to provide more responsible and competent care for their children; and improve families' economic self-sufficiency by helping parents to develop a vision for their own future, plan subsequent pregnancies, continue their education, and find work.

Each full-time nurse carries a caseload of 25 families. Although nurses have a structured set of visit-by-visit guidelines, they adapt these to the individual needs of families. On average, nurses visit weekly for the first

month in order to establish a relationship, then every other week throughout the pregnancy. Following the birth of the infant, weekly visits are resumed for the first 6 weeks postpartum and then decrease to every other week until the child is 21 months old. To facilitate termination of the relationship, nurses visit monthly until the child's second birthday.

Evidence for the effectiveness of the intervention has been established through three randomized clinical trials conducted with culturally diverse populations over a 20-year span. Key findings for nurse-visited women in at least two of three trials, compared to their counterparts in the control group, are:

- improvement in women's prenatal health — for example, reduction in prenatal cigarette smoking and reduction in hypertensive disorders
- reduction in children's health-care encounters for injuries
- reduction in unintended subsequent pregnancies
- longer intervals between first and second births
- improvement in children's school readiness — for example, in language skills, cognitive abilities, and behavioural regulation
- increased maternal employment, with accompanying reductions in families' use of welfare and food stamps
- increased father involvement

(Kitzman et al., 1997, 2000; Olds et al., 1997, 2002, 2007; Olds, Henderson, & Kitzman, 1994; Olds, Kitzman, et al., 2004; Olds, Robinson, et al., 2004)

The cost-benefits of the program also have been established. An early economic evaluation conducted by Olds and colleagues demonstrated that the savings to government, especially with respect to low-income unmarried women and their children, exceeded the cost of the program by the time children were 4 years of age (Olds, Henderson, Phelps, Kitzman, & Hanks, 1993). Evaluations by two external groups provide more recent data on the potential long-term cost-benefits of the program. The Rand Corporation estimates that for every dollar invested in providing the intervention to families at greatest risk, there is a return of $5.70, with most of the savings in reduced government expenditures on health care, education, social services, and criminal justice (Karoly, Kilburn, & Cannon, 2005), while an analysis by the Washington State Institute for Public Policy found that the program produced $18,000 in net benefits per family served (Lee, Aos, & Miller, 2008).

## Dissemination of the NFP to Communities

As evidence from the trials has come to the attention of local and state policy-makers, communities have shown more and more interest in adopting the NFP. Between 1996 and 1999, small-scale dissemination of

the program was undertaken with a number of communities through grants from the US Department of Justice and the US Department of Health and Human Services. In November 1999, the National Center for Children, Families and Communities was established at the University of Colorado School of Nursing (since renamed College of Nursing) to provide the infrastructure for a scale-up of the program with funding from the Robert Wood Johnson Foundation. As the number of new communities running the program approached 200, it became apparent that continued scale-up through the university would be difficult to manage in light of state rules and regulations. Thus in 2003 the Nurse-Family Partnership National Service Office (NFP NSO) was established as a separate not-for-profit organization to continue the work of disseminating the program. In October 2009 the program was operational in 28 states, serving families in approximately 323 cities or counties (www.nursefamilypartnership.org). Although the program is implemented in these new settings by a variety of community-based organizations, the most common implementing entity is a city/county public health department.

## Challenges in Translating the NFP Into Public Health Practice

### *Measuring the Readiness of Practitioners and Communities to Adopt an Evidence-Based Program*

The extent to which an organization establishes administrative structures for the selection and performance evaluation of key personnel and to ensure ongoing resources and support for evidence-based programs has been identified as a critical factor in implementation effectiveness (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005). The utility of existing scales or tools for assessing organizational influences on implementation in public health and community settings, however, appears to be limited (O'Brien, Racine, & Vojir, 2009; Schoenwald, Sheidow, Letourneau, & Liao, 2003). Such assessment may require the investment of considerable personnel resources for gathering initial data to determine site readiness to adopt an evidence-based program and monitoring once the program is in place. A further challenge is that many community-based organizations do not have well-developed quality-improvement processes to handle issues that are identified.

### *Selecting and Recruiting Home Visitors to Deliver the Program*

Due to limited financial resources and nursing shortages in some regions, it is not uncommon for administrators and policy-makers to question whether the NFP program really needs to be implemented by nurses. This issue is most prevalent in communities that have other established

home visitation programs that use paraprofessionals. Because of the consistency of significant effects for nurse-visited women compared to controls across randomized clinical trials (Korfmacher, O'Brien, Hiatt, & Olds, 1999; Olds et al., 2002), the NFP is being disseminated only to communities that agree to use nurses as home visitors. Yet many sites, particularly in rural areas, have to rely on nurses without baccalaureate preparation to implement the program. Lack of formal public health training for professionals working in state and city/county health departments has resulted in the establishment of competency-based performance standards by the NFP NSO, rather than a specific degree requirement. This reliance on competency-based standards adds to the importance of having nurse supervisors make regular home visits with staff, to identify areas where they are not meeting competency expectations and to provide ongoing in-services and skill-building activities. As will be discussed below, observational home visiting by supervisors poses its own set of challenges.

### *Training Nurses in the Implementation of an Innovative Evidence-Based Intervention*

Implementation research has found that the successful translation of a research intervention into practice rests on three factors: timely training, skilful supervision, and coaching of those involved in adopting the new program or practice model (Fixsen et al., 2005). The NFP NSO requires that all nurse home visitors and their supervisors complete a series of training sessions to acquire the knowledge and skills needed to deliver the program to families. Although this requirement is included in the contract with implementing organizations, the timely training of new program staff is not easy to ensure. In the early years of program dissemination, training involved three face-to-face sessions (approximately 9 days) over the course of 12 to 15 months. As new programs faced restrictions on funding for travel, the NFP NSO developed written materials to orient staff to key components of the program and reduced the number of face-to-face sessions from three to two. As of September 2009, new program staff are required to attend one face-to-face session prior to program implementation, with follow-up training provided through online modules facilitated by the nursing supervisor at the local site. While distance-learning strategies have been shown to be efficacious in formal settings such as colleges and universities, they do require considerable infrastructure support. A study conducted by the author found that the use of distance learning to deliver additional content, to help nurses improve their knowledge and skills related to child development and parenting, is not always supported by the local implementing organization; a number of nurse home visitors reported that they had to complete the

online modules at home on their own time, due to administrative pressures to maintain service delivery levels.

***Acknowledging the Importance of Clinical Supervision***

The ZERO TO THREE National Center for Infants, Toddlers and Families believes that reflective supervision fosters an interpersonal environment conducive to self-reflection on one's practice, resulting in experiential learning — a process that enables professionals to help parents nurture the development of their young children (Eggbeer, Mann, & Seibel, 2007). The NFP NSO has embraced reflective supervision as a key component of program implementation, with the expectation that nursing supervisors at program sites will hold weekly one-on-one supervisory meetings with nurses, hold bi-weekly case conferences with the team of nurse home visitors, and make quarterly observational home visits with nurses. As budgets in community-based organizations have shrunk, administrative and supervisory staffs have invested more time in management functions and less time in clinical supervision. Thus many new NFP nursing supervisors lack the skills needed to promote and facilitate reflective practice. To fill this gap, the NFP NSO has increased the education and consultation required to help nursing supervisors become comfortable with reflective supervision. However, a large proportion of NFP nursing supervisors still struggle to find the time for observational home visiting with staff nurses in order to appraise their competence in working with families and to identify areas for ongoing clinical development. And while most programs do hold team meetings on a regular basis, the time allotted for reflection on practice issues encountered in working with families may be subsumed by the need to update staff on organizational policies and requirements.

***Maintaining Fidelity to the Program Model***

It is not unusual for tensions to arise around the importance of implementing the NFP program as it was designed and tested versus adapting it to the cultural values and beliefs of the populations served. There is a growing body of evidence that the intended outcomes documented through research are unlikely to be achieved unless the practices associated with the original model are fully adopted (Committee on Quality of Health Care in America, Institute of Medicine, 2001; Washington State Institute for Public Policy, 2002). Some of the tensions that arise over this issue reflect misunderstandings about what "fidelity" comprises. There is no prohibition against individualizing care when using an evidence-based approach. For example, an important component of the NFP model is a strength-based approach directed towards optimizing the family's sense of efficacy. Four strategies intrinsic to a strength-based approach are: lis-

tening to what families want and starting there; believing that families are the experts on their own lives and are capable of making choices to achieve desired goals; supporting families' view of options available to them; and helping families to set modest and reasonable goals that, when achieved, will contribute to their growing sense of efficacy (O'Brien & Baca, 1997). Adherence to these strategies is consistent with respect for the cultural values and beliefs of diverse populations. Therefore, the extent to which evidence-based programs can explicate the components and activities needed to reach the desired goals is crucial to the achievement of effective program implementation on a wider scale.

### *Valuing Prevention as an Essential Strategy for Improving Population Health*

As public health resources become increasingly constrained, primary prevention programs are confronted with a number of challenges. For instance, services rarely show an immediate effect at the population level, yet their cost is immediate. The NFP, which targets an essentially well population of low-income pregnant women and their children, is an easy target for budget cuts when fiscal resources are in decline. Major national threats, such as flu pandemics or large-scale environmental destruction due to catastrophic weather events, may drive state and local public policy in ways that would not apply in normal circumstances. Thus cities, counties, or states may abruptly withdraw their support from an NFP program, resulting in sudden closures.

Moreover, evidence-based programs often focus on a segment of the population for whom the intervention has demonstrated effectiveness, rather than on the entire population. The segment of the population for whom the NFP is known to be effective is first-time mothers. This has raised issues in some communities about the need to balance spending on preventive services with spending on treatment services for families with known risks such as child abuse or with special-needs children. A related issue may be the place of direct-care services in public health agencies, as in the United States there has been a strong national and state emphasis on core public health functions related to community assessment, policy development, and assurance (e.g., linking individuals to needed personal health services). Where policy development has embraced evidence-based programs as a means of improving population health, agencies have been more willing to consider the NFP model.

In summary, the various challenges confronting the NFP, an exemplar of the dissemination of an evidence-based program intervention, include both programmatic and policy issues. In managing these issues, the NFP NSO has had to build a substantial infrastructure to assess the readiness of new communities to adopt the program and to provide services, guid-

ance, and support on a number of fronts: education for new staff on how to effectively deliver the intervention; ongoing nursing consultation and oversight of program implementation; quality improvement monitoring and guidance; and advocacy at state and national levels to facilitate the development of policies that are supportive of the program. As public health practice is increasingly being treated with the same rigour as acute and primary practice, we need further research on how to effectively scale up evidence-based programs and address the many challenges.

## References

Committee on Quality of Health Care in America, Institute of Medicine. (2001). *Crossing the quality chasm: A new health system for the 21st century.* Washington: National Academy Press.

Eggbeer, L., Mann, T. L., & Seibel, N. L. (2007). Reflective supervision: Past, present and future. *Zero to Three, 38*(2), 5–9.

Fixsen, D. L., Naoom, S. F., Blase, K. A., Friedman, R. M., & Wallace, F. (2005). *Implementation research: A synthesis of the literature*. FMHI publication #231. Tampa, FL: University of South Florida, Louis de la Parte Florida Mental Health Institute, National Implementation Research Network.

Karoly, L. A., Kilburn, M. R., & Cannon, J. S. (2005). *Early childhood interventions: Proven results, future promise.* Santa Monica, CA: Rand Corporation.

Kitzman, H., Olds, D. L., Henderson, C. R. Jr., Hanks, C., Cole, R., Tatelbaum, R., et al. (1997). Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childrearing: A randomized controlled trial. *Journal of the American Medical Association, 278*(8), 644–652.

Kitzman, H., Olds, D. L., Sidora, K., Henderson, C. R. Jr., Hanks, C., Cole, R., et al. (2000). Enduring effects of nurse home visitation on maternal life course: A 3-year follow-up of a randomized trial. *Journal of the American Medical Association, 283*(13), 1983–1989.

Korfmacher, J., O'Brien, R., Hiatt, S., & Olds, D. (1999). Differences in program implementation between nurses and paraprofessionals providing home visits during pregnancy and infancy: A randomized trial. *American Journal of Public Health, 89,* 1847–1851.

Lee, S., Aos, S., & Miller, M. (2008). *Evidence-based programs to prevent children from entering and remaining in the child welfare system: Benefits and costs for Washington*. Olympia: Washington State Institute for Public Policy.

O'Brien, R. A., & Baca, R. P. (1997). Application of solution-focused interventions to nurse home visitation for pregnant women and parents of young children. *Journal of Community Psychology, 25*(1), 47–57.

O'Brien, R. A., Racine, D. P., & Vojir, C. P. (2009). *Organizational context, clinical learning of an innovation, and program fidelity.* Unpublished report.

Olds, D. L., Eckenrode, J., Henderson, C. R. Jr., Kitzman, H., Powers, J., Cole, R., et al. (1997). Long-term effects of home visitation on maternal life course

and child abuse and neglect: Fifteen-year follow-up of a randomized trial. *Journal of the American Medical Association, 278*(8), 637–643.

Olds, D. L., Henderson, C. R. Jr., & Kitzman, H. (1994). Does prenatal and infancy nurse home visitation have enduring effects on qualities of parental care giving and child health at 25 to 50 months of life? *Pediatrics, 93*(1), 89–98.

Olds, D. L., Henderson, C. R. Jr., Phelps, C., Kitzman, H., & Hanks, C. (1993). Effect of prenatal and infancy nurse home visitation on government spending. *Medical Care, 31*(2), 155–174.

Olds, D. L., Kitzman, H., Cole, R., Robinson, J. A., Sidora, K., Luckey, D. W., et al. (2004). Effects of nurse home-visiting on maternal life course and child development: Age 6 follow-up results of a randomized trial. *Pediatrics 114*(6), 1550–1559.

Olds, D. L., Kitzman, H., Hanks, C., Cole, R., Anson, E., Sidora-Arcoleo, K., et al. (2007). Effects of nurse home visiting on maternal and child functioning: Age 9 follow-up of a randomized trial. *Pediatrics, 120,* e832–e845.

Olds, D. L., Robinson, J., O'Brien, R., Luckey, D. W., Pettitt, L. M., Henderson, C. R. Jr., et al. (2002). Home visiting by paraprofessionals and by nurses: A randomized, controlled trial. *Pediatrics, 110,* 486–496.

Olds, D. A., Robinson, J. A., Pettitt, L. M., Luckey, D. W., Holmberg, J., Ng, R. K., et al. (2004). Effects of home visits by paraprofessionals and by nurses: Age 4 follow-up results of a randomized trial. *Pediatrics, 114*(6), 1560–1566.

Schoenwald, S. K., Sheidow, A. J., Letourneau, E. J., & Liao, J. G. (2003). Transportability of multisystemic therapy: Evidence for multilevel influences. *Mental Health Services Research, 5*(4), 223–249.

Washington State Institute for Public Policy. (2002). *Washington State's implementation of functional family therapy for juvenile offenders: Preliminary findings* (#02-08-1201). Olympia: Author.

---

*Ruth A. O'Brien, PhD, RN, FAAN, is Professor, College of Nursing, University of Colorado, Denver, United States.*

*CJNR 2009, Vol. 41 N° 4, 109–114*

# *Knowledge Translation*

# Challenges in Knowledge Translation: Integrating Evidence on Pain in Children Into Practice

**Bonnie Stevens**

Hospitalized children undergo multiple painful procedures daily. There is compelling evidence that well-managed procedural pain is associated with faster recovery, fewer complications, and decreased use of health-care resources. Also, the need for evidence-based acute pain management has been acknowledged by professional, quality care, patient safety, political, and policy initiatives. Furthermore, acute pediatric pain research has expanded exponentially. Yet acute procedural pain management in pediatric clinical settings is frequently inadequate. This situation, although distressing for both clinicians and researchers, is consistent with the significant delay in effective research-endorsed clinical strategies making their way into clinical practice.

Kitson stated a decade ago that research utilization is a social process involving the integration of scientifically derived knowledge within personal experience, patient preferences, and the complexities of the broader context (Kitson, 1999). This theoretical stance is congruent with the dilemmas encountered in translating knowledge on pain in children into clinical practice — a process that requires dialogue, interaction, and social exchange between researchers, clinicians, administrators, and policy-makers.

## CIHR Team in Children's Pain

The goal of a program of research funded by the Canadian Institutes of Health Research (CIHR) is to determine the effectiveness of an interactive system-based knowledge translation (KT) intervention, Evidence-Based Practice for Improving Quality (EPIQ; Lee et al., 2009), in narrowing the gap between clinical practice and improved process and clinical outcomes. The program comprises two projects: CIHR Team in Children's Pain (Stevens et al., 2006–11), and Translating Research on Pain in Children (Stevens et al., 2008–12).

We have used the PARiHS framework (Rycroft-Malone, 2004), which integrates the quality of *evidence* with *context* of care and *facilitation* approaches as a model for integrating three projects in the CIHR Team in Children's Pain research as it resonates theoretically and clinically with the proposed research. In project 1, we developed a standardized database to capture (a) local evidence on current pain practices in all children admitted to 32 research units (in eight pediatric health-care centres across Canada), and (b) contextual data on all research units participating in the study. In project 2, we delineated data on unit context where acute pain is experienced and interventions are tested. In project 3, we are evaluating the EPIQ intervention while simultaneously considering the existing evidence and the unit context. The three key elements of the PARiHS framework will serve as a guide to highlight some of the KT challenges encountered in this program of research and the strategies employed to address them.

## Evidence

The consequences of unrelieved pain and its associated human suffering provide a compelling argument for utilizing evidence in practice. Rycroft-Malone (2004) describes evidence as knowledge that is derived from a variety of sources, has been tested, and is credible. Knowledge, however, is more than research. It includes clinical experience, patient experience, and local contextual information; evidence-based practice is facilitated by the interplay between all forms of knowledge. Over the past two decades there has been exponential growth in the generation of research evidence with respect to pain-relieving strategies. Yet suboptimal pain management can be attributed to both inadequate knowledge of the evidence and inability to use available evidence in practice (Scott-Findlay & Estabrooks, 2004). Thus generation of new knowledge is not the primary solution; this knowledge must be translated for frontline health professionals in an understandable and usable way (Kavanagh, Stevens, Seers, Sidani, & Watt-Watson, 2008; Scott-Findlay & Estabrooks, 2004).

In our pediatric pain research, we encountered two key challenges in relation to evidence: determining comprehensive and accurate data on local pain practices, and evaluating and synthesizing key research evidence in a user-friendly format for practitioners. To address these challenges, we developed a centralized Web-based database (Canadian Pediatric Pain Research [CPPR]; www.childrenspainstudy.ca) to record data on child sociodemographic factors; pain assessment; painful procedures; and pharmacological, physical, and psychological interventions by the participating research units. We also collected data on the hospital unit, including patient census data, staff composition and complement, and whether the

unit included a pain management team. Although these data enriched our knowledge of the local context, construction of the CPPR was expensive, time-consuming, and resource-intensive. Also, the collection of patient data from approximately 4,000 patient charts over a 6-month period required heavy investment in the training, supporting, and monitoring of research personnel. Therefore, finding a rigorous yet efficient and comprehensive way of capturing clinical, patient, and local contextual information remains a priority for effective KT.

## Context

We also conducted a comprehensive assessment of the context in which acute pediatric pain is experienced, with the ultimate goal of determining how context influences the KT process, pain processes (e.g., pain assessment and management), and pain outcomes (e.g., pain intensity). In the PARiHS framework, context reflects the environment or setting in which the proposed change is implemented (Rycroft-Malone, 2004) and includes organizational culture, leadership, and evaluation. Our goal was to determine evidence use, within an organizational context, by the 32 participating units from the perspective of interprofessional health-care practitioners. We struggled with two challenges. The first was how to achieve an interprofessional perspective on context, as most theory-driven KT research has been nursing-focused. Therefore, the applicability of existing nursing KT models to behavioural change in other professions has yet to be determined. The second challenge was how to adequately and accurately measure evidence use (e.g., research utilization) at the unit/organizational level in a climate where most research is focused on the individual. Estabrooks has made strides in deepening our understanding of research utilization within the organizational context and in developing a valid and feasible measure to capture the key components of organizational context and research utilization behaviour. The Alberta Context Tool (ACT; Estabrooks, Squires, Adachi, Kong, & Norton, 2008), which was developed and validated with nurses working in adult settings, has been used in our present CIHR-funded research to assess context within pediatric settings. This was also an opportunity to adapt and validate the measure for use with a wider interdisciplinary group. As such work had not been done previously, there was no existing response rate from professional groups; a response rate of 43% within five groups (nurses, physicians, allied health-care providers, managers, and advanced practice nurses) was achieved at baseline in project 2, with rigorous and assiduous follow-up, and was considered satisfactory. Analyses will include assessment of the influence of organizational context and related factors on research use in the different professional groups.

## Facilitation

Facilitation enables the implementation of evidence in practice (Rycroft-Malone, 2004) and is enhanced by innovative interventions that use the best evidence and that take context and the complexities of the KT process into account. EPIQ is an interactive, multifaceted continuous quality improvement (CQI) strategy that merges *evidence* (i.e., systematic reviews, reviews of systematic reviews), identifies potential practice changes using local contextual information (i.e., baseline data in the CPPR database), and involves collaboration by interdisciplinary health professionals who *facilitate* the implementation of tailored KT strategies using CQI techniques (Lee et al., 2009). EPIQ allows for customization of a strategy to improve clinical care (e.g., introducing a new pain assessment tool on a unit where none exists), based on local data (e.g., audit of patient charts), evidence (e.g., systematic review of all existing pediatric pain measures), and involving a small group of local champions (e.g., nurse educator, quality improvement officer, and staff pediatrician) implementing strategies such as interactive education sessions, reminders, and outreach. In our program of research, we are evaluating the effects of EPIQ on acute pain practices in children and clinical outcomes, as well as examining the intervention fidelity (i.e., the degree to which the intervention is implemented as planned) and the effectiveness of KT strategies in different contexts (e.g., type of unit, age of children, and type of painful procedures).

A key challenge in facilitation is the engagement of individual unit-based health professionals in uptake and implementation of the selected clinical practice. This process requires cooperation between clinicians and researchers in terms of communication; mutual respect for roles, values, and beliefs; and appreciation of the intricacies of a complex, multifaceted KT strategy (EPIQ) and organizational context. We have attempted to meet this challenge through a comprehensive approach, one that (a) supports the unit and the organizational context (by recruiting unit leadership for research practice councils and engaging research nurses who employ enabling facilitation strategies), (b) communicates existing local information, (c) synthesizes research evidence (in the form of evidence summaries), and (d) tailors KT strategies and outcomes to the unit context. Determining the efficacy of such a tailored intervention also poses a research design dilemma. The ideal design for determining intervention efficacy would be a cluster randomized controlled trial (RCT). However, standardization of a complex customized KT intervention is problematic because of contextual factors, the potential threats (e.g., contamination) to internal validity, and the limited number of pediatric hospitals available to participate in such a study. We used a

non-RCT comprehensive allocation schema (taking into account baseline data on pain practices, geographic location, and size of hospital unit) and took advantage of the opportunity to test the acceptability and viability of the intervention prior to moving to the cluster RCT. We considered this an ethically responsible way to refine designs and methodologies prior to moving ahead. Adequate sampling for RCTs requires large sample sizes, considerable resources, and outcomes that can be clearly defined and measured. Also, just as practice change usually occurs following several trials (or a meta-analysis of pooled data) supporting the efficacy of a new intervention, standards for changing practice based on the efficacy of KT strategies will need to be carefully considered.

## Conclusion

The translation of knowledge into practice is wrought with challenges. We have developed and are implementing a theoretically derived program of research to address some of these challenges. Along the way, we are discovering and evaluating unique strategies that will be the basis for future refinement and expansion of KT research.

## References

Estabrooks, C. A., Squires, J. E., Adachi, A. M., Kong, L., & Norton, P. G. (2008). *Utilization of health research in acute care settings in Alberta*. Technical report 08-01-TR. Edmonton: Faculty of Nursing, University of Alberta.

Kavanagh, T., Stevens, B., Sears, K., Sidani, S., & Watt-Watson, J. (2008). Examining appreciative inquiry as a knowledge translation intervention in pain management. *CJNR, 40*(2), 40–56.

Kitson, A. (1999). Research utilization: Current issues, questions, and debates. *Canadian Journal of Nursing Research, 31*(1), 13–22.

Lee, S. K., Aziz, K., Singhal, N., Cronin, C. M., James, A., Lee, D. S. C., et al. (2009). Improving the quality of care for infants: A cluster randomized controlled trial. *Canadian Medical Association Journal, 181*(8), 469–476.

Rycroft-Malone, J. (2004). The PARiHS framework: A framework for guiding the implementation of evidence-based practice. *Journal of Nursing Care Quality, 19*(4), 297–304.

Scott-Findlay, S., & Estabrooks, C. A. (2004). Knowledge translation and pain management. In G. A. Finley, P. J. McGrath, & C. T. Chambers (Eds.), *Bringing pain relief to children* (pp. 199–228). Totowa, NJ: Humana Press.

## Acknowledgements

I would like to acknowledge the financial support of the Canadian Institutes of Health Research for this work: the CIHR Team in Children's Pain, CIHR Team Grant 79854 (2006–11); and the Translating

Research on Pain in Children (TROPIC) study, CIHR Operating Grant 86605 (2008–12); as well as the 27 co-investigators who participate in the program of research that is covered by the grants — M. Barwick, F. Campbell, C. Chambers, J. Cohen, G. Cummings, C. Estabrooks, A. Finley, C. Johnston, P. Kavanagh, M. Latimer, S. Lee, S. LeMay, P. J. McGrath, J. Rashotte, C. Rosmus, D. Sawatsky-Dickson, S. Scott, S. Sidani, J. Stinson, R. Stremler, A. Synnes, A. Taddio, E. Villeneuve, F. Warnock, A. Willan, and J. Yamada.

---

*Bonnie Stevens, RN, PhD, is Professor, Lawrence S. Bloomberg Faculty of Nursing and Faculty of Medicine, University of Toronto; and Signy Hildur Eaton Chair of Paediatric Nursing Research, Associate Chief, Nursing Research, and Senior Scientist, Research Institute, Hospital for Sick Children, Toronto, Ontario, Canada.*

*CJNR 2009, Vol. 41 Nº 4, 115–121*

# *Happenings*

# Developing Synergy to Enhance the Impact of Nursing Intervention Research on Patient Health

**Celeste Johnston, Sylvie Cossette, Julie Archer, Manon Ranger, Georgette Nahas-Chebli**

## Introduction

The challenge of nursing intervention research is to conduct studies that are both methodologically sound and clinically relevant. A forum where nurse researchers, students, and clinicians can gain knowledge and network around this goal is crucial to research success. The Quebec Interuniversity Nursing Intervention Research Group/Groupe de recherche interuniversitaire en interventions en sciences infirmières du Québec (GRIISIQ; www.griisiq.ca) is a unique Canadian entity in this regard. Founded in 2003, GRIISIQ is involved exclusively in developing and evaluating nursing interventions and measuring their patient outcomes. It is funded principally by Fonds de recherche en santé du Québec (FRSQ), with additional contributions by the participating universities. It serves as an infrastructure to bring together nurses, researchers, students, and clinicians from Université de Montréal, McGill University, Université de Sherbrooke, and Université Laval.

The purpose of this article is to describe the GRIISIQ nursing intervention research group — its goals, strategies, research productivity, and role in knowledge exchange.

## History of GRIISIQ

The seeds of GRIISIQ were planted in 2002, with the impetus of a group of Quebec nurses to advance the field of nursing research beyond description and fact-finding, to interventions with a direct impact on patient health. While there were other areas of excellent nursing research, such as health services research, there were no groups focused specifically on interventions with patient outcomes.

A letter submitted to FRSQ pointed out the need for the development and evaluation of such interventions, for the training of researchers in this field, and for a focus on life transitions as an important point of intervention. A life transition can be any of a variety of changes in the life of a person or a family, including a change in the site or the level of care, a developmental transition such as a birth or death, or a change in health status such as the worsening of a condition or the need for intensified treatment.

In 2003, by virtue of a partnership between Université de Montréal and McGill University, Quebec's first nursing research group was formed, with support from FRSQ and the Newton Foundation. For its first 2 years, the group, initially known as GRISIM (Groupe de recherche interuniversitaire en sciences infirmières de Montréal), focused on fostering alliance between the two academic sites — each with its own research culture, expertise, and linguistic traditions. With time, it began to function as a whole, with trainees benefiting from balanced and complementary input from the two sites.

In 2007 the group expanded to include the other Quebec universities with doctoral programs in nursing — Université de Sherbrooke and Université Laval — and underwent a name change. Currently its membership comprises 21 regular researchers, eight emerging researchers, four associate researchers, seven adjunct researchers, 24 funded students, 20 clinicians, and six clinical decision-makers.

## A Unique Approach to Nursing Intervention Research and Its Patient Outcomes

GRIISIQ's mission is to develop cutting-edge research on nursing interventions and their patient outcomes. Overall, the group's objectives are to (a) create and consolidate a critical mass of nurse scientists with an interest in intervention research, (b) develop and evaluate innovative nursing interventions in the context of today's health-care system, (c) generate evidence-based knowledge and promote a culture of evidence-based nursing practice, and (d) facilitate the exchange of knowledge between clinicians and researchers. In the long term, GRIISIQ is intended to serve as an international authority on nursing intervention research, through collaborative efforts and the creation of a bank of tested interventions.

### *Multiple Approaches to Research*

GRIISIQ's research encompasses a wide range of clinical populations, and it uses theoretical frameworks that are drawn mostly from the nursing sciences but also from related disciplines such as psychology, edu-

cation, and epidemiology. For every study, interuniversity collaboration and/or collaboration with health-care agencies is emphasized. Studies focus on the development of innovative interventions, refinement of existing interventions, or adaptation of interventions to other clinical populations or health-care settings. GRIISIQ members also conduct qualitative studies aimed at intervention development — for example, the exploration of needs. There is also a strong emphasis on randomized controlled trials, feasibility studies, pilot studies, and the development of indicators that are sensitive to nursing interventions. The following are but a few examples of such studies: a sensory minimization intervention to promote physiological stability and minimize the pain response of preterm infants; a psycho-educational intervention for caregivers of individuals with early-stage Alzheimer's disease; a computer tailored intervention to optimize adherence to antiretroviral treatment in people with HIV; and validation of a pain-assessment measure in critically ill or unconscious patients.

### *Creating Synergy for More Comprehensive Research*

While nursing researchers tend to focus narrowly on the specific populations and issues of interest, GRIISIQ strives for collaboration across a diverse range of expertise and experience. To facilitate collaborative opportunities between members, the group functions in four research teams comprising a mix of researchers, clinicians, and graduate students from the four participating universities. The resulting heterogeneity serves to strengthen the scientific foundation that is relevant to all nursing intervention research. The generic results can then be applied to specific clinical issues or populations.

The four teams explore different but complementary themes. Team 1 focuses on the development of nursing interventions, Team 2 on the evaluation of interventions, Team 3 on knowledge exchange throughout the research process, with appropriate knowledge uptake as the final step. Team 4 is dedicated to research design and the delivery of complex nursing interventions in clinical environments. Each team strives to meet annual scientific productivity goals through the publication of educational and research materials, the organization of internal scientific activities, participation in knowledge-exchange activities, and applications for research grants.

## Strategies to Enhance Research-Driven Nursing Practice

GRIISIQ uses many approaches to advance its research agenda and strategically direct nursing practice towards improved patient care. Both

within and beyond their team work, GRIISIQ researchers continue to develop comprehensive and innovative research intervention programs aimed at making an impact on patient health. Investments in infrastructure, student training, partnership collaboration, continuing education for clinicians, and public awareness all contribute to new knowledge that advances clinical practice.

### *Providing Infrastructure Support*

GRIISIQ offers multiple sources of support to researchers, enabling them to become competitive and to undertake complex research studies. Financial support comes from a comprehensive grant and fellowship program that, in addition to funding research, enables members to attend continuing education seminars or present their findings in the international arena. Statistical/methodological consultants help members to select appropriate study designs, determine optimal sample sizes, plan data analyses, and interpret results. Professional writing consultations with a medical journalist, a translator, and an editor allow members to target their manuscripts for the appropriate journals. The provision of office space, computers, and Web-conferencing facilities allows for efficient meetings. In addition, GRIISIQ hosts its own workshops and seminars, to enable its members to interact with other experts in the field of nursing intervention research.

### *Training the Next Generation of Academic and Clinical Scientists*

Today's students are tomorrow's leaders. Therefore, in response to the enormous need for highly educated nurses, GRIISIQ has invested much of its resources in fostering the careers of young researchers, training them to use research as a basis for influencing future practice and policies. By offering a competitive grant and fellowship program, GRIISIQ attracts the brightest students from the province of Quebec and elsewhere and helps them to move forward in their careers. Within GRIISIQ these students have an opportunity to bolster their network, implement their findings in a clinical setting, submit grant proposals that prepare them for the reality of high academic expectations, and publish early in their career. In terms of their contribution to nursing knowledge, GRIISIQ trainees are well schooled in various methods of intervention research so that they will be generators of knowledge as well as consumers of knowledge.

To date, GRIISIQ has provided funding for a host of student studies at the graduate level, including 14 doctoral, two postdoctoral, and six master's level studies, and has awarded 16 doctoral, eight master's, and two postdoctoral fellowships. It has awarded seven undergraduate fellow-

ships to fast-track students towards a research career, as well as 13 travel grants to enable students to present their work to national or international audiences or to obtain specialized training in their field.

### *Consolidating Key Partnerships*

When the group was formed, it consisted almost exclusively of nurse researchers from Université de Montréal and McGill. By evolving from GRISIM to GRIISIQ and adding Sherbrooke and Laval, the group has increased its academic partnerships, and its membership count and financial capacity have also grown significantly. In addition to its ongoing collaboration with the Canadian Nursing Foundation, GRIISIQ has recently diversified its research partnerships, securing a partnership with the Quebec Nursing Research Foundation (FRESIQ) for the funding of pilot studies and clinical research studies. GRIISIQ is in the process of forming partnerships with other research groups, with a view to broadening the spectrum for research outcomes and diversifying future audiences. Particularly important — and unusual for a nursing research group — is the inclusion of clinical partners. Since its founding, GRIISIQ has more than doubled its clinician membership and has increased the number of clinical decision-makers on its Scientific Evaluation Committee and its Board of Directors. This participation is central to the development of GRIISIQ, as these partners are both liaisons for knowledge about current health issues that can be addressed in GRIISIQ's research and facilitators for the implementation of GRIISIQ-funded studies in their institutions.

### *Fostering the Emergence of Studies by Clinicians*

GRIISIQ was created in response to an obvious need for the fostering of evidence-based practice in nursing. In this regard, the development of a research-based culture in clinical arenas and consultation with clinical experts with respect to research orientation remain its top priorities.

Clinicians play an active role in bridging the research and clinical communities. Therefore, GRIISIQ has responded to the needs of its clinician membership by facilitating the active involvement of clinicians in research activities in their clinical milieus. While clinicians are ultimately involved in the implementation of nursing intervention research, many would like to be more actively involved in intervention research. To this end, GRIISIQ has developed a special program to enable clinicians to reconnect with research and to become familiar with the research process. The program consists of a series of four half-day workshops hosted by a nurse scientist and using GRIISIQ research studies as examples. The purpose is to enable clinicians to "touch base" with research

and gain experience with various research tools — the ultimate goal being generation of their own studies. This approach also facilitates the integration of research-related knowledge in their day-to-day professional activities. Themes in this program include: learning how to formulate a clear and pertinent research question from a clinical issue that the clinician has experienced; identifying the facilitating factors and potential obstacles in launching a research study; locating the scientific literature pertinent to the research question or a particular clinical issue; becoming knowledgeable about the different types of studies and their associated research methodologies in order to judiciously choose the appropriate method; and learning about the different elements involved in writing a clear and articulate grant proposal.

GRIISIQ encourages clinicians to team up with other group members to take advantage of its new clinical research grant competition. The program targets clinical nurses who wish to work with GRIISIQ researchers, either as principal investigators or as collaborators on a specific project. A nurse clinician has already teamed up with two GRIISIQ researchers from Université de Montréal and the McGill University Health Centre to act as the principal investigator on a GRIISIQ-FRESIQ study evaluating an educational intervention on women's self-efficacy and anxiety before surgery for breast cancer.

## Conclusion

In conclusion, GRIISIQ's collective efforts by nursing intervention researchers are greater than the sum of its parts. The group's international symposium, to be held in Montreal in 2011, is expected to attract the most visionary and talented minds. These research scholars will come to exchange innovative ideas in a forum that will vector nursing intervention research to the next level, making it an important resource for all clinical practice and patient-centred care initiatives. A future goal is to increase public awareness about nursing intervention research and how the public might ultimately benefit from it.

## Acknowledgements

The authors would like to acknowledge the editing and writing assistance of Kate Johnson.

---

*Celeste Johnston, RN, DEd, FCAHS, is Professor and Associate Director of Research, School of Nursing, McGill University, Montreal, Quebec, Canada; and Co-director, GRIISIQ. Sylvie Cossette, RN, PhD, is Associate Professor, Faculty*

*of Nursing, Université de Montreal; Researcher, Montreal Heart Institute Research Centre; and Co-director, GRIISIQ. Julie Archer, MPs, is Coordinator and Research Professional, GRIISIQ. Manon Ranger, RN, is a doctoral candidate at the School of Nursing, McGill University, and a GRIISIQ fellowship and grant recipient. Georgette Nahas-Chebli, RN, MSc, is a doctoral student at the Faculty of Nursing, Université de Montréal, and a GRIISIQ fellowship recipient.*

# INDEXES

## Authors / *Auteures* — Volume 41: 2009

**Titles / *Titres*** Volume 41: 2009

*CJNR* is indebted to the persons below, who served as reviewers for Volume 41. They gave generously of their time and shared their knowledge, and in so doing have contributed greatly to the editorial process and to the development of nursing knowledge.

CJNR *est reconnaissante envers les personnes ci-dessous nommées pour leur participation en tant qu'examinatrices des articles publiés dans le volume 41. Ces personnes ont généreusement donné de leur temps et ont partagé leur savoir. Ce faisant, elles ont largement contribué au processus éditorial et au développement des connaissances en sciences infirmières.*

Marilyn Aita
Université de Montréal

Jan Angus
University of Toronto

Sanchia Aranda
University of Melbourne

Ruth Babcock
Palliser Health Authority

Marianne Baernholdt
University of Virginia

Andrea Baumann
McMaster University

Esther Bay
Michigan State University

Karen Benzies
University of Calgary

Helene Berman
University of Western Ontario

Marilyn Bookbinder
Beth Israel Medical Center

Margaret Boone
Lakehead University

Anne Bourbonnais
Université de Montréal

Michael Buzzelli
University of Western Ontario

Mariette Chartier
Government of Manitoba

Jeannie Cimiotti
University of Pennsylvania

Benita Esther Cohen
University of Manitoba

Sylvie Cossette
Université de Montréal

Ginette Coutu-Wakulczyk
Université d'Ottawa

Jeni Cross
Colorado State University

Natasha Demidenko
Ottawa Hospital

Barbara Downe-Wamboldt
Dalhousie University

Vicki Blair Drury
National University of Singapore

Diane Lynn Duff
York University

Dana Edge
Queen's University

Dana R. Epstein
Phoenix Veterans Affairs
Health Care System

Carol Ewashen
University of Calgary

Marcia Facey
University of Toronto

Karen Francis
Monash University

Kim Fraser
University of Alberta

Elaine Gallagher
University of Victoria

Carolyne Gorlick
King's College

Sigrun Gunnarsdottir
University of Iceland

Nancy Hanrahan
University of Pennsylvania

David Hartley
University of Southern Maine

Jean Hughes
Dalhousie University

Cynthia Jacelon
University of Massachusetts

Sonya Lee Jakubec
Mount Royal College

Patricia Jamerson
University of Kansas

Elsabeth Jensen
York University

Ann Kutney
University of Pennsylvania

Bonnie Lee
University of Lethbridge

Helen Lee
Montana State University

Susan Lehmann
University of Iowa

Mark Linden
Queen's University Belfast

Robert Lucero
Columbia University

Mary R. Lynn
University of North Carolina

Heather MacDonald
University of New Brunswick

Jody MacDonald
University of Toronto

Edward Makwarimba
University of Alberta

Ruth Martin-Misener
Dalhousie University

Carol L. McWilliam
University of Western Ontario

Jennifer Medves
Queen's University

Pertice Marie Moffitt
Aurora College

Phyllis Montgomery
Laurentian University

Nuelle Novik
University of Regina

Orawan Nukaew
University of Missouri

Karin Olson
University of Alberta

Abram Oudshoorn
University of Western Ontario

Monica Parry
University of Toronto

Pauline Paul
University of Alberta

Cindy Peternelj-Taylor
University of Saskatchewan

Jessica Peterson
University of Toronto

Myra Piat
McGill University

Roger Pitblado
Laurentian University

Jenny Ploeg
McMaster University

Kathy Reavy
Boise State University

Magdalena Sophia Richter
University of Alberta

Rose Roberts
University of Saskatchewan

Don Rose
Ryerson University

Jean Ross
Otago Polytechnic

Abraham Rudnick
University of Western Ontario

Jane Rysberg
California State University

Karen G. Schepp
University of Washington

Margaret Ann Schneider
Wilfrid Laurier University

Ruth Schofield
McMaster University

Patricia Sealy
University of Western Ontario

Leah Shever
University of Iowa

Souraya Sidani
Ryerson University

Laura Simich
University of Toronto

Hans Skott-Myhre
Brock University

Anne Snowdon
University of Windsor

Janet Storch
University of Victoria

Robyn Stremler
University of Toronto

Marilyn Stringer
University of Pennsylvania

Christine Struthers
University of Ottawa
Heart Institute

Nancy C. Tkacs
University of Pennsylvania

Lorraine Tulman
University of Pennsylvania

Gerry Veenstra
University of British Columbia

Ellen Olive Wahoush
McMaster University

John Welton
University of South Carolina