Design, Evaluation, and Translation of Nursing Interventions

Nurse-led intervention research is a core component of the global initiative to improve quality of care. Though research in this area has already contributed much to the advancement of patient care, future strides depend on the dissemination of practical, how-to instruction on this important area of research. Design, Evaluation, and Translation of Nursing Interventions aids in this endeavor by presenting both general approaches and specific methods for developing nursing interventions.

Logically organized to facilitate ease of use, the book is divided into four sections. The introduction provides a firm grounding in intervention science by situating it within the broader topics of evidence-based practice, client-centered care, and quality of care redefined. Section Two describes each step of intervention design, including correct identification of the health issue or problem, clarification of the elements comprising an intervention, and application of theory. Section Three centers on implementation, highlighting such topics as development of the intervention manual, training interventionists, and intervention fidelity. The book concludes with methods to evaluate interventions enacted and suggestions for their translation into practice.

Design, Evaluation, and Translation of Nursing Interventions distills the authors’ years of expertise in intervention research into comprehensive, easy-to-follow chapters. It is a must-have resource for students, researchers, and healthcare professionals wishing to impact the future of patient care.

Key Features:
- Provides a thorough foundation in nursing intervention research and its impact on improving standards of care
- Segments the multifaceted process of intervention development into easy-to-follow, step-by-step chapters
- Presents methods for the evaluation of interventions developed
- Written by experts in the field

About the Authors:
Souraya Sidani, Ph.D. is Professor and Canada Research Chair at the School of Nursing, Ryerson University. She has served as an investigator on over 20 funded grants and has numerous publications in peer-reviewed journals and books. Dr. Sidani’s research focuses on evaluating interventions and advanced practice roles, examining patient preferences for treatments, and refining research methods and measures for determining the clinical effectiveness of interventions.

Carrie Jo Braden, Ph.D. is Associate Dean for Research and Hugh Roy Cullen Professor of Nursing at the University of Texas Health Sciences Center at San Antonio. Dr. Braden is a Fellow of both the American Academy of Nursing and the Western Academy of Nursing. Her research focuses on learned response to chronic illness, mechanisms enhancing scholarly achievement (interprofessional research mentoring), and support resources for health disparities research. She has served as an investigator on 23 funded grants. She is a recipient of the Nurse of the Year Award for Excellence in Nursing Research and has authored or co-authored three books and numerous articles for refereed journals.

Also of interest:
Improving Health through Nursing Research
William L. Holzemer
ISBN: 978-1-4051-3411-8
Design, Evaluation, and Translation of Nursing Interventions
Design, Evaluation, and Translation of Nursing Interventions

Souraya Sidani, PhD
Professor and Canada Research Chair
Health Intervention: Design and Evaluation
School of Nursing
Ryerson University
Toronto, Ontario, Canada

Carrie Jo Braden, PhD, RN, FAAN
Professor and Associate Dean for Research
Hugh Roy Cullen Professor of Nursing
School of Nursing
The University of Texas Health Science Center at San Antonio
San Antonio, Texas, US
Contents

Preface xi
Acknowledgment xiii

SECTION 1 INTRODUCTION

1 Introduction to Intervention Research 3
  1.1 Overview of paradigm shift 4
    1.1.1 Evidence-based practice: a review 5
    1.1.2 Client-centered care 7
    1.1.3 High-quality care redefined 9
  1.2 Process for designing, evaluating, and translating interventions 11
    1.2.1 Design of interventions 11
    1.2.2 Evaluation of interventions 12
    1.2.3 Translation of interventions 13
  1.3 Overview of the book 14

SECTION 2 DESIGNING INTERVENTIONS

2 Overview of Designing Interventions 17
  2.1 Nursing interventions defined 17
    2.1.1 Definition of interventions 17
    2.1.2 Characteristics of interventions 19
  2.2 Presenting problems 21
    2.2.1 Definition of problem 21
    2.2.2 Characteristics of problems 21
  2.3 Design of interventions 23

3 Understanding the Problem 27
  3.1 Theoretical approach for understanding the problem 27
  3.2 Empirical approach for understanding the problem 31
  3.3 Experiential approach for understanding the problem 35
  3.4 Combined approach for understanding the problem 40
  3.5 Theory of the problem 42
Contents

4 Clarifying Elements of the Intervention 43
  4.1 Theory-based approach for designing interventions 43
  4.2 Empirical approach for designing interventions 49
  4.3 Experiential approach for designing interventions 53
    4.3.1 Focus group 53
    4.3.2 Concept mapping 54
    4.3.3 Assessment of treatment preferences 54
  4.4 Specification of interventions 56
    4.4.1 Intervention goals 56
    4.4.2 Intervention components and activities 56
    4.4.3 Intervention mode of delivery 57
    4.4.4 Intervention dose 59

5 Intervention Theory 61
  5.1 Delineation of intervention outcomes 61
  5.2 Intervention theory 64
    5.2.1 Structure 64
    5.2.2 Process 68
    5.2.3 Outcome 68
  5.3 Utility of intervention theory 71

6 Tailored Intervention 73
  6.1 Design of tailored interventions 74
    6.1.1 Intervention theory 74
    6.1.2 Identification of client characteristics for tailoring 75
    6.1.3 Assessment of client characteristics 76
    6.1.4 Construction of a list of intervention strategies 76
    6.1.5 Development of algorithm 78
  6.2 Effectiveness of tailored interventions 81
  6.3 Mechanisms underlying effects of tailored interventions 82

SECTION 3 IMPLEMENTATION OF INTERVENTIONS

7 Overview of Implementation of Interventions 85
  7.1 Variations in intervention implementation 85
  7.2 Consequences of variations in intervention implementation 90
  7.3 Strategies to enhance intervention implementation 91

8 Development of Intervention Manual 93
  8.1 Procedure for developing the intervention manual 93
    8.1.1 Contextual characteristics 94
    8.1.2 Process 94
Contents

8.2 Content of the intervention manual
  8.2.1 Section 1: overview of the intervention 95
  8.2.2 Section 2: human and material resources 97
  8.2.3 Section 3: procedure 100
8.3 Use of the intervention manual 108

9 Selecting, Training, and Addressing the Influence of Interventionists
  9.1 Traditional perspective on interventionist influence 112
  9.2 Interventionist influence: the evidence 113
  9.3 Selection of interventionists 116
  9.4 Training of interventionists 119
  9.5 Methodological features of studies aimed at investigating interventionist effects 123

10 Intervention Fidelity
  10.1 Definition of fidelity 125
  10.2 Methods for monitoring fidelity
    10.2.1 Theoretical fidelity 130
    10.2.2 Operational fidelity 133
  10.3 Importance of monitoring fidelity of intervention implementation 143

SECTION 4 EVALUATION OF INTERVENTIONS

11 Overview of Evaluation of Interventions
  11.1 Criteria for inferring causality 149
  11.2 Phases for intervention evaluation
    11.2.1 Phase 1 154
    11.2.2 Phase 2 155
    11.2.3 Phase 3 158
    11.2.4 Phase 4 160
  11.3 Role of intervention theory 161

12 Testing the Acceptability and Feasibility of Interventions
  12.1 Acceptability of interventions
    12.1.1 Conceptualization of intervention acceptability 165
    12.1.2 Operationalization of intervention acceptability 167
  12.2 Feasibility of interventions
    12.2.1 Definition of feasibility 180
    12.2.2 Indicators of feasibility 181
  12.3 Feasibility of research methods
    12.3.1 Recruitment procedures 186
    12.3.2 Screening 188
### Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.3.3</td>
<td>Randomization</td>
<td>189</td>
</tr>
<tr>
<td>12.3.4</td>
<td>Retention</td>
<td>191</td>
</tr>
<tr>
<td>12.3.5</td>
<td>Data collection</td>
<td>192</td>
</tr>
<tr>
<td>12.4</td>
<td>Design of pilot study</td>
<td>193</td>
</tr>
</tbody>
</table>

#### 13 Examining the Efficacy of Interventions

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.1</td>
<td>Factors affecting the causal relationship between intervention and outcomes</td>
<td>198</td>
</tr>
<tr>
<td>13.1.1</td>
<td>Conceptual factors</td>
<td>198</td>
</tr>
<tr>
<td>13.1.2</td>
<td>Methodological factors</td>
<td>200</td>
</tr>
<tr>
<td>13.1.3</td>
<td>Addressing conceptual and methodological factors</td>
<td>201</td>
</tr>
<tr>
<td>13.2</td>
<td>Design features of an efficacy study</td>
<td>201</td>
</tr>
<tr>
<td>13.2.1</td>
<td>Careful selection of participants</td>
<td>219</td>
</tr>
<tr>
<td>13.2.2</td>
<td>Control of experimental condition</td>
<td>222</td>
</tr>
<tr>
<td>13.2.3</td>
<td>Selection of comparison group</td>
<td>223</td>
</tr>
<tr>
<td>13.2.4</td>
<td>Allocation of participants to groups</td>
<td>228</td>
</tr>
<tr>
<td>13.2.5</td>
<td>Standardized treatment implementation</td>
<td>230</td>
</tr>
<tr>
<td>13.2.6</td>
<td>Outcome measurement</td>
<td>231</td>
</tr>
<tr>
<td>13.2.7</td>
<td>Outcome data analysis</td>
<td>231</td>
</tr>
</tbody>
</table>

#### 14 Determining the Effectiveness of Interventions

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1</td>
<td>Efficacy versus effectiveness: A brief review</td>
<td>234</td>
</tr>
<tr>
<td>14.2</td>
<td>Limitations of the RCT design in effectiveness research</td>
<td>235</td>
</tr>
<tr>
<td>14.2.1</td>
<td>Unrepresentativeness of the sample</td>
<td>235</td>
</tr>
<tr>
<td>14.2.2</td>
<td>Highly select setting</td>
<td>236</td>
</tr>
<tr>
<td>14.2.3</td>
<td>Limited applicability of interventions</td>
<td>237</td>
</tr>
<tr>
<td>14.2.4</td>
<td>Irrelevance of comparison treatment</td>
<td>238</td>
</tr>
<tr>
<td>14.2.5</td>
<td>Limited utility of randomization</td>
<td>239</td>
</tr>
<tr>
<td>14.2.6</td>
<td>Limited relevance of findings</td>
<td>240</td>
</tr>
<tr>
<td>14.3</td>
<td>Alternative designs for evaluating effectiveness</td>
<td>241</td>
</tr>
<tr>
<td>14.3.1</td>
<td>Overall function or goal</td>
<td>241</td>
</tr>
<tr>
<td>14.3.2</td>
<td>Broad representative sample</td>
<td>241</td>
</tr>
<tr>
<td>14.3.3</td>
<td>Selection of different settings</td>
<td>242</td>
</tr>
<tr>
<td>14.3.4</td>
<td>Comparison of clinically relevant alternative treatments</td>
<td>242</td>
</tr>
<tr>
<td>14.3.5</td>
<td>Assessment of relevant health outcomes at follow-up</td>
<td>243</td>
</tr>
<tr>
<td>14.3.6</td>
<td>Allocation to treatment</td>
<td>243</td>
</tr>
<tr>
<td>14.3.7</td>
<td>Additional features</td>
<td>245</td>
</tr>
</tbody>
</table>

#### 15 Preferences for Treatment

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.1</td>
<td>Conceptualization of treatment preferences</td>
<td>251</td>
</tr>
<tr>
<td>15.1.1</td>
<td>Factors influencing treatment preferences</td>
<td>252</td>
</tr>
<tr>
<td>15.1.2</td>
<td>Consequences of treatment preferences</td>
<td>253</td>
</tr>
</tbody>
</table>
15.2 Mechanisms underlying influence of treatment preferences in intervention research
  15.2.1 Influence of treatment preferences on external validity 254
  15.2.2 Influence of treatment preferences on internal validity 256
  15.2.3 Research designs accounting for treatment preferences 258

SECTION 5 TRANSLATION OF INTERVENTIONS

16 Translation of Interventions 263
  16.1 Systematic review of evidence 264
  16.2 Translation of evidence 265
  16.3 Transfer of guideline to practice 268
    16.3.1 Adaptation of guideline 268
    16.3.2 Dissemination and implementation of guideline 270

References 271
Index 295
Preface

Provision of high-quality care to persons with different health problems rests on the delivery of interventions that are appropriate and effective in addressing the presenting problem. Interventions are subjected to a systematic process consisting of four phases, before making them available for use in the context of day-to-day practice.

The first phase relates to the careful design of interventions, which is based on a comprehensive understanding of the presenting problem and the development of interventions that target the problem. The acquired knowledge is synthesized into an intervention theory that clarifies the nature of the targeted problem; identifies the active ingredients, mode of delivery, and dose of the intervention; and explains the mechanisms underlying the intervention’s effects on the intended outcomes. The second phase focuses on the operationalization of the intervention into an intervention manual. The manual details the human and material resources required to deliver the intervention, as well as the specific actions or steps undertaken to carry out the intervention. The manual directs the actual implementation and assessment of the fidelity of the intervention implementation. The third phase consists of a series of consecutive studies for investigating the acceptability, feasibility, efficacy, and effectiveness of the intervention. To be relevant to practice, the studies’ results should indicate which clients, presenting with which personal and health or clinical characteristics, benefit, to what extent, from the intervention delivered in what mode and at what dose, under what context. The fourth phase involves the translation of the intervention. Translation entails the transformation of the studies’ results into meaningful guidelines and the transfer of the guidelines to healthcare professionals who are ultimately responsible for providing the intervention in their day-to-day practice.

Although the systematic process has been delineated, there are limited resources available to inform nurses and other healthcare professionals of the general approaches and specific methods for designing, evaluating, and translating interventions. This book is concerned with describing the phases of the systematic process and clarifying what is to be achieved, and how, in each phase. It is intended to serve as a helpful “one-step” reference for healthcare professionals planning to engage in this process. The content of the book covers conceptual, methodological, and practical knowledge needed to carry out each phase. The conceptual knowledge clarifies the aspects of the problem that should be understood to guide the development of interventions; the active ingredients of the intervention that are responsible for inducing
Preface

The desired changes in the presenting problem; the mechanisms underpinning the intervention effects on the intended outcomes; and the definition and indicators of the acceptability, feasibility, efficacy, and effectiveness of the intervention. The methodological knowledge presents different but complementary approaches for designing and evaluating interventions. The principles underlying each approach are explained and its strengths and limitations are discussed. The practical knowledge entails detailed description of the methods and procedures for carrying out the approaches in each phase of the process. The goal is to support students, researchers, and healthcare professionals in the careful design, systematic evaluation, and meaningful translation of interventions, and, consequently, in the provision of high-quality care.
Acknowledgment

The authors gratefully acknowledge the informal feedback from colleagues, the constant challenge of students, and the instrumental support of staff (at the Health Intervention Research Center and the Office of Nursing Research and Scholarship), which contributed to the refinement of our thinking and continuous expansion and evaluation of our conceptual and methodological knowledge.

This work could not be accomplished without the love, encouragement, and unlimited support of our family (in particular Leila Sidani).
Section 1

Introduction
Chapter 1
Introduction to Intervention Research

In many countries around the world, nursing has achieved recognition as a scientific discipline (Lutzen, 2000). Nursing research is developing rapidly (Hallberg, 2009), evidenced by the quantity and quality of nurse-led studies reported in regional and international journals describing the health and/or illness experience and response to interventions of individuals residing in countries that vary in cultural beliefs and values, and in healthcare systems. To preserve recognition as a scientific discipline, nurses need to generate, expand, and refine the knowledge base that demonstrates the unique contribution of the discipline to meet the needs of individuals, families, groups, and society at large. Nursing’s contribution is reflected in the provision of high-quality care that successfully promotes health, addresses clinical problems, and produces beneficial outcomes. Therefore, it is imperative to prioritize efforts to advance nursing science so that it supplies the theoretical and practical knowledge required for the provision of high-quality care (Evers, 2003; Hallberg, 2009).

The nursing process forms the foundation of high-quality nursing care. The nursing process consists of four steps: (1) assessment, (2) diagnosis, (3) intervention, and (4) evaluation, which nurses implement when caring for individuals, families, or communities (thereafter referred to as clients). Nurses assess the biophysiological, physical, psycho-behavioral, and sociocultural conditions of clients in order to identify their health needs, values, and preferences, and to formulate a diagnosis. A nursing diagnosis clearly delineates the nature of the actual or potential health-related problem with which clients present and requiring remediation. An in-depth and lucid understanding of the clients’ condition and presenting problem is necessary for selecting appropriate and effective interventions to be implemented for, on behalf, or with the clients, with the goals of promoting and restoring health through resolution of the presenting problem. Evaluation refers to monitoring clients’ status on a regular basis to determine the extent to which the interventions were successful in achieving the intended goals. This description of the nursing process
4 Introduction

highlights the centrality of interventions. Interventions constitute the essential element that characterizes nursing care (Tripp-Reimer et al., 1996). Carrying out the nursing process in the context of day-to-day practice requires a sound knowledge base that informs nurses of interventions that are effective in addressing the clients’ presenting problem and in promoting their health (Evers, 2003; Kim, 2002). Nursing interventions that are effective in producing the intended beneficial outcomes are carefully designed, systematically evaluated, and successfully translated into the day-to-day practice setting. The process of designing, evaluating, and translating interventions is conducted in a way that maintains rigor within a context characterized by evolving perspectives or paradigms underlying science and practice. This chapter begins with an overview of the paradigm shift, then highlights the steps of the process for designing and evaluating interventions prior to translating and using them in the day-to-day practice setting.

1.1 Overview of paradigm shift

The new millennium is witnessing a shift in paradigm of what constitutes high-quality care and of what comprises acceptable evidence to guide provision of high-quality care. Although evidence-based practice was introduced as an approach for delivering high-quality care (Guyatt et al., 2002), efforts to implement it in the day-to-day practice setting is raising many questions about the utility of available knowledge in guiding practice. For example, while evidence is becoming available about the effects of interventions on specific outcomes, there is much less evidence about the specific mechanisms underlying the intervention effects. There is even less evidence to guide intervention translation within specific practice settings. Insufficient evidence about mechanisms linking interventions to outcomes for specific clients, coupled with a growing demand of enlightened clients for a participatory role in health-related decision-making, is bringing the person or client-centered approach to the forefront of what defines high-quality care (American Nurses Association, 2003; Institute of Medicine, 2001; McCormack & McCance, 2006). Person- or client-centered care is congruent with the philosophical orientation underpinning nursing practice. In addition, it complements evidence-based practice in defining high-quality care (Sidani et al., 2006). The emergence of this conceptualization of high-quality care led some scholars in various disciplines, including nursing, to reflect on the methods used throughout the process of designing, evaluating, and translating interventions. There is a growing request to embrace alternative methods that have the potential to generate theoretical and practical knowledge to inform delivery of care (e.g., Gross & Fogg, 2001; Nallamothu et al., 2008; Sidani et al., 2003) and to plan effective knowledge translation and implementation strategies (Eccles et al., 2005) that are relevant to a variety of practice settings within and across countries (Hallberg, 2009).
1.1.1 Evidence-based practice: a review

Evidence-based practice was introduced as an approach for delivering high-quality care (Guyatt et al., 2002; Jennings & Loan, 2001). It is broadly defined as “the conscientious, explicit, and judicious use of current, best evidence in making decisions about the care of individual patients” (Sackett et al., 1997, p. 2). Proponents of evidence-based practice believe that interventions found effective and safe on the basis of best available evidence can be delivered in a consistent manner to produce the same effects in clients presenting with the same problem, under the conditions of day-to-day practice (Victora et al., 2004). They advocate the development of guidelines to inform practice. Guidelines are systematically developed statements of recommendations to assist health professionals in decision-making about client care (Lugtenberg et al., 2009). The guidelines specify the target population in terms of experience of the presenting problem, the intervention(s) to be used to address the problem, and the procedures for monitoring the intervention outcomes (Titler et al., 1999). The guidelines are disseminated to health professionals who are expected to implement them as recommended. The end results are provision of best available care and improvements in clients’ condition.

The above definition of evidence-based practice underscores the importance of best evidence in guiding practice. Proponents of this approach to care place high value on research as compared to other sources of evidence. In particular, they consider most appropriate evidence derived from primary or meta-analytic studies that used the randomized controlled or clinical trial (RCT) design to investigate the effects of interventions. The RCT is deemed the gold standard for intervention evaluation research (Richardson, 2000). The features that characterize the RCT design include careful selection of participants on the basis of stringent eligibility criteria; random assignment of participants to the experimental and comparison groups; concealment of treatment allocation; manipulation and standardization of intervention delivery; blinding of research staff and participants to allocated treatment; and control of contextual factors. These features are believed to minimize the influence of potentially confounding factors, which is required for demonstrating the causal effects of the intervention on outcomes.

To date, experience with evidence-based practice raises concerns with the nature of the evidence forming the basis for developing guidelines for practice, with the emphasis on using and/or adhering to these guidelines in practice, and with the strategies for transferring the guidelines into the practice setting. The relevance of empirical evidence on intervention effects derived from RCT studies to the practice setting has been questioned. Recent critique of the RCT design highlights its limitations in maintaining internal and external validity. The limitations stem from the features of the RCT. The application of strictly defined inclusion and exclusion criteria confines the accrued sample to a very selective and homogeneous subgroup of the target population seen in the practice setting. Random assignment does not reflect the process of selecting and providing interventions within the context of practice. This method
of treatment allocation is often not well received by clients participating in an RCT and the health professionals responsible for their care. It may contribute to self-selection into the trial, to attrition, and to dissatisfaction and nonadherence of participants with the allocated treatment and subsequent poor outcome achievement; these, in turn, result in inaccurate estimates of the intervention effects that may not be replicable in the practice setting. Manipulation and standardization of the intervention are not congruent with day-to-day practice, where treatment is not withheld from needy clients, and interventions are modified to fit the needs and values of clients, and/or given sequentially in response to changes in clients’ condition. Therefore, interventions validated in RCT studies may not be transferable to and easily incorporated in the practice setting. The experimental control that characterizes the RCT is unrepresentative of the complexity of the practice context; thus, the intervention effects may not be reproduced in practice (Grapow et al., 2006; Huibers et al., 2004; Lindsay, 2004; Richardson, 2000; Robitaille et al., 2005; Valentine & McHugh, 2007).

The emphasis on using and/or adhering to guidelines has been criticized for reducing practice to a mechanistic application of empirically supported interventions that is informed by generic algorithms (Sehon & Stanley, 2003). The algorithms instruct health professionals which interventions to select and implement to address the clients’ presenting problem. This mechanistic application of generic algorithms does not take into consideration the clients’ experiences, needs, beliefs, and perceived acceptability of the intervention. Also, it disregards the health professionals’ skills at critical thinking, and obligations to respond flexibly to the clients’ needs. Further, the guidelines’ recommendations are often stated in general terms that simply identify the interventions to be given. They do not clearly specify the conditions under which the interventions are most effective, and do not explain how the intervention effects are produced. Yet, knowledge of who benefit the most from the intervention given at what dose and in what mode is essential for guiding practice (Brown, 2002; Sidani & Braden, 1998).

Numerous projects have been undertaken to transfer, translate, and implement evidence into practice. Various strategies have been utilized in these endeavors, of which education is the most common. Typically, educational strategies are didactic, involving passive learning, where health professionals are informed of the evidence and expected to apply the intervention in their day-to-day practice. However, recent literature on knowledge translation indicates that overall, attempts to implement evidence-based practice in particular settings were not successful at sustaining changes in health professionals’ practice and hence in improving the quality of client care (Sales et al., 2006). Considerable variation in success rate was observed within an individual intervention and across interventions (Eccles et al., 2005; Lugtenberg et al., 2009). Findings of relevant studies consistently pointed that health professionals, including nurses, do not depend on research as a source of evidence to guide practice. Rather, they rely on other sources, primarily clinical knowledge either gained personally or
shared by colleagues, as well as patient experience (French, 2005; Spenceley et al., 2008).

This state of affairs has contributed to reconsideration of different sources of evidence as acceptable for generating the knowledge needed to guide practice, and the client-centered as an approach to provide high-quality care (see Section 1.1.2). Acceptable sources of evidence include local knowledge and client experience, as well as research. Local knowledge is embedded within particular practice settings and is accumulated in two ways. First, local knowledge is obtained through performance evaluation and/or quality improvement initiatives undertaken in the setting. The results of these initiatives represent valuable information about the practice area requiring change; unmet needs of clients and of health professionals working in the setting; and the type and impact of interventions delivered to address the health problems of the locally served population (Rycroft-Malone et al., 2004). Second, local knowledge is gained through health professionals’ experience and is embedded in the human capital, that is, expert professionals available in the setting. Local knowledge is critical for translating evidence. It directs efforts at adapting guidelines to fit the contextual characteristics of a particular setting. Client experience is emerging as a useful source of evidence to guide the process of making decisions about care of individuals, families, and communities. Patient experience is not clearly defined in the literature on evidence-based practice; however, it appears to connote attendance to the clients’ characteristics, needs, and preferences (Mykhalovskiy & Weir, 2004), as advocated in the implementation of client-centered care. Research evidence has been expanded to include quantitative and qualitative studies. Accumulating results suggested that non-RCT designs (e.g., quasi-experimental and cohort) provide meaningful evidence supporting the effectiveness of interventions delivered under usual conditions of day-to-day practice (Concato & Horwitz, 2004; Nallamothu et al., 2008; Vandenbroucke, 2004). Findings of non-RCT designs, in combination with those of studies investigating factors that moderate and/or mediate intervention effects, address questions of concern to health professionals. In other words, they enhance the clinical relevance of research findings, which can promote uptake and application of interventions in the practice setting.

1.1.2 Client-centered care

Client-centered care has been, and still is, highly valued in nursing (Lauver et al., 2002). It is resurging as an approach aimed to provide high-quality care (Naylor, 2003). Client-centered care is congruent with the philosophical orientation of nursing practice (Rolfe, 2009). Nurses are instructed, socialized, and expected to deliver client-centered care. Nurses recognize the multidimensionality of clients’ experience, acknowledging the biophysiological, physical, psycho-behavioral, and sociocultural domains of health; respect the uniqueness of clients’ needs; and individualize care to be consistent with the clients’ needs. The description of client-centered care, available in the literature, has
focused on characterizing this approach to care at the individual client level. The features that distinguish client-centered care are: (1) acknowledging the client as a unique person; (2) understanding the individual characteristics, needs, beliefs, values, and preferences of the person; and (3) responding flexibly to the persons’ characteristics, needs, and preferences (McCormack, 2003; Radwin, 2003). Responding flexibly, also termed responsiveness (Radwin et al., 2009), involves participation of persons in decision-making and individualization of care (McCormack & McCance, 2006; Sidani, 2008). Participation of persons in the process of decision-making consists of a joint effort between the health professionals and the person to identify his or her needs and preferences, and to select the intervention that will address the person’s needs and that the person views as acceptable (Sidani et al., 2006). Individualization of care involves customization of the intervention activities, dose, and/or mode of delivery so that they are mindful of the person’s characteristics, resources, and/or context. The client-centered approach has also been applied to the care of families. Family-centered care encompasses similar features; however, the focus is on the family as a unit. The application of the client-centered approach to the care of communities is reflected in the collaborative participation of community members in identifying health needs and in developing, adapting, or selecting relevant interventions.

The implementation of client-centered care is expected to benefit the individuals, families, and communities. It is proposed that this approach promotes clients’ sense of independence and control through their participation in treatment-related decisions (Reid Ponte et al., 2003); increases satisfaction with care related to the receipt of the intervention of choice; enhances adherence to treatment; and, subsequently, achievement of intended outcomes (Sidani et al., 2010). The limited number of studies that investigated the benefits of the client-centered approach to care have focused on either participation of clients in decision-making or individualization of educational interventions. The results of these studies were promising, showing improvement in health outcomes for clients who participated in decision-making and/or received client-centered care or individualized interventions (e.g., Fremont et al., 2001; Lauver et al., 2002; Sidani, 2008; Wensig & Grol, 2000).

Responding flexibly to clients’ characteristics, needs, and preferences raised the issue of discrepancy between the selected intervention and the intervention considered most effective on the basis of the best available evidence. That is, clients may find acceptable, express a preference for, and choose interventions which may not be effective or may have been minimally effective in managing the presenting problem or producing the desired outcomes (Wensig & Grol, 2000). To address this issue, Coyler and Kamath (1999) proposed an integrated “patient-centered evidence-based” approach to care. Briefly, this approach entails identifying evidence-based interventions, incorporating only those interventions as alternatives from which clients can choose and/or nurses can individualize to be consistent with clients’ characteristics and preferences (Sidani et al., 2006). The integrated client-centered evidence-based approach has implications for the definition of high-quality care.
1.1.3 High-quality care redefined

High-quality care refers to the delivery of interventions that are appropriate, acceptable, effective, safe, and efficient. Appropriate interventions are logical, reasonable, and sound treatments that specifically address the health problem with which clients present. This implies that the nature of such interventions is consistent with the nature of the presenting problem, where activities comprising the interventions should fit with the defining characteristics and/or the determinants of the presenting problem, and the dose with which the interventions are given is compatible with the severity with which the problem is experienced. For instance, educational interventions involving the provision of information about a chronic illness and its management is appropriate for increasing clients’ knowledge but may not be adequate for changing their self-management behaviors. In the latter case, behavioral interventions focused on facilitating the initiation and maintenance of self-management behaviors are more appropriate.

Acceptable interventions are agreeable to clients expected to receive the interventions. Agreeable interventions are perceived favorably; that is, they are consistent with the clients’ beliefs about health in general, about the presenting problem, and about treatment. They are deemed suitable to their lifestyle, convenient, and easy to apply in their daily life (Sidani et al., 2009). For instance, persons who ascribe to a holistic perspective to health that admits a strong body-mind connection find complementary and alternative interventions (e.g., meditation) more acceptable treatments than conventional medical treatments; the former interventions are congruent with their beliefs about health and treatments (Tataryn, 2002). Related to acceptability is the notion of cultural relevance of interventions. Within and across countries, clients identify with different ethnic or cultural groups who share common experience and hold particular beliefs, values, and norms. Cultural relevance refers to the extent to which the content and/or activities of the intervention, the format for delivering the intervention, and the outcomes expected of the intervention are consistent with the ethnic and cultural experiences, values, and beliefs of the group or community (Resnicow et al., 1999). For example, intervention targeting dietary habits are acceptable to clients of diverse cultural backgrounds if they take into account the typical dishes and way of cooking adopted by respective groups, and/or the food items available within a particular context and affordable by clients residing in that context.

Effective interventions produce the best outcomes for clients. When carefully implemented, effective interventions are successful in addressing the presenting problem, reducing its severity, and/or in improving the physical, psychological, and/or social domains of health. For instance, behavioral interventions are considered effective in managing insomnia if they assist individuals sleep efficiently, reduce daytime fatigue, improve cognitive performance related to poor sleep, and ultimately enhance physical and psychosocial functioning.
Introduction

Safe interventions are associated with no or minimal negative consequences. Negative consequences encompass physical and/or psychological discomfort, as well as side effects or untoward reactions experienced with or as a result of the interventions. For example, adherence to behavioral interventions for managing insomnia may result in increased daytime fatigue within the first 2 weeks of treatment; however, the experience of this discomfort does not exceed that suffered following a “bad night” sleep, is temporary, and is outweighed by the long-term benefit of the intervention manifested in adequate sleep quantity and quality.

Efficient interventions are those worth their cost. They produce the intended beneficial outcomes within the context of human and financial resources used to implement them. For instance, the costs of cognitive behavioral interventions for managing insomnia relates to those incurred by therapist and persons for delivering the sessions over a specified time period, whereas the costs of pharmacological treatment to address the same problem encompass the purchase of the pills over an extended period of time. The cost-efficiency of the cognitive behavioral interventions stems from their long-term improvement in sleep and daytime functions (Jacobs et al., 2004).

The provision of high-quality, client-centered evidence-based care consists of delivering appropriate, acceptable, effective, safe, and efficient interventions. Whereas evidence-based practice is concerned with identifying effective, safe, and efficient interventions, client-centered care focuses on the appropriateness and acceptability of interventions to clients. Implementation of client-centered evidence-based care requires a sound knowledge base that informs health professionals of the following:

(1) The nature, severity, and determinants of the health problem with which clients present.
(2) The nature, dose, and mode of delivering interventions that are appropriate for addressing the presenting problem and that are acceptable to clients holding different personal and cultural beliefs, values, and attitudes toward health and healthcare.
(3) The effectiveness, safety, and cost-efficiency of the interventions, as compared to no-treatment or to other available interventions for the same presenting problem.
(4) The personal and clinical profile of clients who benefit from the interventions to varying degree.
(5) The contextual factors that may interfere with the implementation and/or effectiveness of the interventions.
(6) The mechanisms through which the interventions produce their effects on the desired outcomes and/or side effects.

This type of knowledge is generated through the application of a process for designing and evaluating interventions. It forms the basis for developing guidelines that present specific recommendations for delivering the intervention in a manner that is responsive to clients’ characteristics and preferences.
and that is mindful of the clients' resources and context, with the ultimate goal of producing the desired short- and long-term outcomes. The guidelines are then translated to fit the context of particular settings.

1.2 Process for designing, evaluating, and translating interventions

The process for designing, evaluating, and translating interventions is systematic, rigorous, yet flexible. It involves phases that are logically sequenced; however, the results of each phase drive the work forward toward the next phase or backward toward earlier phases. In the former case, appropriate interventions found acceptable to different subgroups of the target population are tested for efficacy; in the latter case, interventions that are not well received or deemed unacceptable to clients or health professionals should be reconceptualized (i.e., going back to the drawing board!) or refined. For example, initial evaluation of the Pro-Self Program revealed that patients with cancer were overwhelmed with its content that covered multiple symptoms and proposed to have different modules, each focusing on one symptom, provided on an as-needed basis (Dodd & Miaskowski, 2000; Larson et al., 1998). Each phase is carried out using research methods that are most pertinent to achieve the stated goals and objectives and to maintain the validity of findings. The phases of the process are consistent with those described by Whittmore and Grey (2002), Campbell et al. (2000), and the National Institutes of Health. The phases are briefly reviewed in the following sections relative to the design, evaluation, and translation of interventions.

1.2.1 Design of interventions

The first phase in the design of interventions focuses on gaining a clear and thorough understanding of the presenting problem requiring remediation. This understanding should clarify the nature of the problem, the specific indicators with which it is manifested, the range of severity with which it can present or be experienced, the determinants or factors that contribute to the problem, and possible consequences of the problem. Understanding of the problem is derived deductively from relevant middle range theory, and/or inductively from a systematic exploration of the problem as experienced by the target population. Knowledge about the presenting problem is critical as it points to the aspect(s) of the problem amenable to change or remediation; this, in turn, indicates the nature of the intervention activities that are most appropriate to address the presenting problem.

The second phase in the design of interventions is concerned with elaborating the intervention. This work is guided by relevant middle range and practice theories. The aim is to elucidate the essential, specific elements or active ingredients and the nonspecific elements of the intervention. These
intervention elements are necessary to specify the components and activities comprising the intervention, the mode or format for delivering the intervention, and the dose with which the intervention should be given to attain the preset outcomes. This information then guides the development of the intervention protocol required for proper implementation of the intervention.

The third phase is the development of the intervention theory. The theory describes the conditions that influence the implementation of the interventions and the achievement of outcomes; it also clarifies the mechanisms responsible for its effects. The conditions relate to the characteristics of the clients receiving the intervention, the interventionist delivering the intervention, and the setting or environment in which the intervention is given. The mechanisms represent the changes that should take place in order to achieve the desired outcomes. The intervention theory guides the evaluation of the intervention.

Although the three phases rely on theoretical and empirical knowledge to design appropriate interventions, members of the target client population and health professionals (who will ultimately be involved in its implementation in practice) are invited to participate in these phases. These individuals help clarify the presenting problem and the activities and mode for delivering the interventions. Their involvement is crucial for enhancing the acceptability of interventions.

1.2.2 Evaluation of interventions

In general, evaluation of interventions proceeds in three consecutive phases. The first phase consists of a pilot test. The primary focus is on examining the acceptability and feasibility of the intervention. Acceptability refers to the clients’ perception of the intervention in terms of its appropriateness, effectiveness, severity of side effects, and convenience of implementation (Sidani et al., 2009). Feasibility relates to the ease with which the intervention is delivered and the factors that facilitate or hinder its implementation. In addition, the pilot test explores the extent to which changes in the hypothesized mechanisms underlying its effects and outcomes occur following implementation of the intervention. The results of the pilot test guide the refinement of the intervention theory and/or any aspect of the intervention delivery, such as its elements or activities, mode of delivery, and dose. The refinement can be done in collaboration with the research staff (in particular, the interventionists) and the clients who participated in the pilot test. The revised intervention is then subjected to further evaluation.

The purpose of the second evaluation phase is to determine the efficacy of the intervention. Efficacy refers to the extent to which the intervention causes the intended effects. The focus is on examining the extent to which the intervention produces its effects under ideal conditions. The ideal conditions are those that minimize the potential influence of any factors, other than the intervention, that could contribute to the outcomes, and that maximize the power to detect the hypothesized effects. The features of the RCT design
allow control for potential confounds. This experimental control is necessary to attribute, with confidence, the observed outcomes to the intervention, that is, to demonstrate the causal relationship between the intervention and the outcomes (Sidani & Braden, 1998; Victora et al., 2004). Results of the efficacy study inform the next step to be undertaken in the process of intervention evaluation. For interventions that do not show the expected effects, the next step entails exploratory work to identify what contributed to the unanticipated findings. The search is for conceptual and/or methodological factors that could account for the findings. Conceptual factors are illustrated with inadequate specification of the severity of the problem amenable to treatment by the intervention under evaluation, influence of a confounding client characteristic (e.g., age), and low intervention dose that did not induce the anticipated mechanisms responsible for producing the anticipated changes in the outcomes. Methodological factors are illustrated with issues with fidelity of intervention delivery and nonadherence to the intervention. For interventions that demonstrate the hypothesized causal effects, the next step is an evaluation of their effectiveness.

The main concern of the third evaluation phase is to investigate the effectiveness of interventions. Effectiveness refers to the extent to which the intervention produces the intended beneficial outcomes when delivered under the real world, or usual conditions of day-to-day practice. Under the latter conditions, the intervention is implemented (1) by health professionals with different levels of theoretical knowledge, practical experience, and skills in delivering the intervention; (2) to clients presenting with a range of personal and clinical characteristics representing different subgroups of the target population, and with varying levels of perceived acceptability of and/or motivation to apply the intervention; and (3) in practice settings with different contextual features that may affect the implementation of the intervention (Sidani & Braden, 1998; Tunis et al., 2003). Practical or pragmatic clinical trials are considered appropriate for evaluating the effectiveness of interventions (Thorpe et al., 2009). The results point to the characteristics of clients who benefit to different degrees from the intervention implemented in what format and at what dose; by health professionals with personal characteristics and professional qualifications; and in with what type of context. In other words, the findings of effectiveness studies provide the knowledge health professionals need to properly deliver the intervention in the context of day-to-day practice.

1.2.3 Translation of interventions

Translation involves the development of guidelines for implementing the intervention in day-to-day practice and the incorporation of the guidelines as part of usual practice. To be useful in informing practice, the guidelines should be specific, describing (1) the presenting problem amenable to treatment by the intervention, with a particular emphasis on the aspects of the problem targeted; (2) the active ingredients of the intervention and their operationalization in relevant components and actions that should be carried out to claim
14  Introduction

that the intervention is delivered, (3) the range of nonessential elements of the intervention and their operationalization in mode or format for delivering the intervention in a flexible way that is responsive to clients’ preferences; and (4) the minimal and optimal dose associated with the beneficial outcomes and side effects. The guidelines should also explain the mechanisms underlying the intervention effects. Different strategies are used to assist healthcare professionals incorporate the guidelines in their practice.

1.3  Overview of the book

The development of the knowledge base needed to inform nurses of interventions deemed appropriate, acceptable, effective, and safe, and to direct the selection and implementation of interventions that are responsive to clients’ characteristics and preferences, should rely on a combination of research methods. The different methods that can be used in the phases of the process for designing, evaluating, and translating interventions are the focus of this book. The methods are discussed relative to each step of the process for designing, evaluating, and translating interventions. The second section of the book (Designing Interventions) concentrates on the design of interventions. The content of this section is consistent with the perspective that interventions are rational, designed in response to a health problem and to achieve desired outcomes. Deductive and inductive strategies are presented to generate a thorough understanding of the problem amenable to intervention, to clarify elements of the intervention (i.e., active ingredients, components, activities, mode of delivery, dose), to develop an intervention theory that explains how the intervention produces the intended outcomes, in what groups of persons, and to design tailored interventions that are responsive to clients’ characteristics. The third section of the book (Implementation of Interventions) addresses issues pertaining to the implementation of the intervention. The issues relate to the development of an intervention protocol that directs the delivery of the intervention; training of interventionists in providing the intervention; and the assessment of fidelity with which the intervention is implemented. In the fourth section (Evaluation of Interventions), conventional and alternative research designs and methods are presented for examining the feasibility, acceptability, efficacy, and effectiveness of interventions. The role of preferences for treatment and methods for examining their influence within a research context are discussed. The fifth and last section of the book (Translation of Interventions) covers issues and strategies for translating interventions into the day-to-day practice setting.