Behavioral Intervention Research: 
Designing, Evaluating, and Implementing
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She is a well-funded researcher, having received continuous research and training grants from federal agencies and private foundations for close to 28 years. A theme throughout her research is applying a social ecological perspective and a person-directed approach as well as collaborating with community organizations and health professionals to maximize the relevance and impact of intervention strategies. She is also involved in translating and implementing her team’s proven interventions for delivery in different practice settings globally and in the United States.

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Dr. Czaja has extensive experience in aging research and a long commitment to developing intervention strategies to improve the quality of life for older adults and their families. She has been an active researcher in this area for more than 25 years. Her specific areas of research include aging and cognition; aging and health care informatics; family caregiving; older workers; training; and functional assessment. She brings a unique focus to these issues with her combined background in engineering and the behavioral sciences. She has broad experience with research methodologies in both laboratory and field settings and with translational research. She has received extensive funding from the National Institutes of Health as well as other federal agencies and foundations for her research. Dr. Czaja is very well published in the field of aging, and has written numerous book chapters and scientific articles. She has also collaborated with community organizations, health care providers, and with industry. She recently coauthored a book with other members of the CREATE team concerning the design of technology systems for older adult populations, and a book on training older adults. She is a fellow of the American Psychological Association, the Human Factors and Ergonomics Society, and the Gerontological Society of America. In addition, she is the current president of Division 20 (Adult Development and Aging) of the American Psychological Association. She is also a member of the National Academy of Science/National Research Council Board on Human Systems Integration.
Behavioral Intervention Research: Designing, Evaluating, and Implementing

Laura N. Gitlin, PhD
Sara J. Czaja, PhD

With Contributors

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To Eduardo, Eric, Keith, and my family:
Como siempre. With love, gratitude, and honor—LNG

To my family, friends, and colleagues: Thank you for your continued support and inspiration—SJC

To our collaborators who share our passion;
To our study participants who drive our mission to find better ways.
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Behavioral intervention research is coming of age, as evidenced by Gitlin and Czaja’s book *Behavioral Intervention Research: Designing, Evaluating, and Implementing*. I applaud the book for providing a much needed overview of the entire “behavioral intervention pipeline.” It fills a unique niche in its coverage of key theoretical and methodological aspects as well as its case examples and professional development considerations, which makes the content accessible and practical for a broad audience. The book reflects the current thinking that behavioral intervention research represents a growing science base whose history has unfolded over the past several decades based on the contributions of many researchers, practitioners, and consumers alike.

The importance of behavioral intervention research for improving the health and well-being of individuals, families, and communities cannot be overstated. There is a growing recognition that the application of evidence-based research can make a difference in health promotion and disease prevention efforts across the life course. The book’s contributors recognize the challenges and complexities of behavioral intervention research, but also its many potential benefits. Behavioral intervention research is viewed comprehensively within a socioecological framework that values community-based participatory research perspectives and engagement of stakeholders in the construction of an intervention. The growing appreciation of the interplay between environmental, technological, and economic influences in designing and evaluating and then implementing interventions advances the frontiers of behavioral intervention research. Reflecting the long history of behavioral intervention research, the book appropriately sets its content alongside of and within the emerging field of implementation science, explaining the similarities and differences across these different but highly related fields of study.

I am most pleased to be asked to contribute an independent reflection on this book through its Foreword. It allows me to reflect on the activities that have helped spawn this growing field as well as my own small role in its development. Starting in the 1980s as a program director at the National Institute of Aging’s Social Science Research on Aging Program, I had the distinct pleasure of helping to promote an aging, health, and behavior research agenda, and seeding the development of generations of stellar investigators who are now leaders in the behavioral intervention research field. This volume further emphasizes the importance of understanding
and promoting translational research. Along with other colleagues, I am gratified to have been part of national research initiatives at the Robert Wood Johnson Foundation and federal agencies such as the Centers for Disease Control and Prevention and the Administration for Community Living that have pushed the application of research to practice into the forefront. This area is growing in practical importance, as new federal policies are tying reimbursement to evidence-based practices.

The lessons I learned resonate with those highlighted in the book. Our society faces complex public health problems calling for complex multilevel solutions. Behavioral intervention research as broadly viewed in this book offers one such promising solution. To meet the nation’s public health goals, it is critical to have a better understanding of the design, evaluation, and implementation of a wide range of behavioral health interventions for addressing the multitude of health-related problems across diverse populations and settings. This book is a most welcome addition to helping us meet these research and public health goals, and offers us a much needed comprehensive framework for meeting these challenges and improving population health.

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PREFACE

Behavioral interventions matter! Over the past 50 years, a wide range of novel and important behavioral (psychosocial, environmental, technology-based) or nonpharmacological interventions have been developed, evaluated, translated, and implemented in community and clinical settings. We have proven effective behavioral interventions that address a broad range of behavioral, physical, emotional, and cognitive health, as well as social issues across the life span. Exemplars include but are not limited to: reducing behavioral disturbances in young children (Chicago Parent Program, Gross et al., 2009); enhancing dementia caregiver well-being (REACH II, Belle et al., 2006; Skills2Care®, Gitlin, Jacobs, & Earland, 2010); reducing depression in older adults in primary care (IMPACT, Stewart, Perkins, & Callahan, 2014; Unützer et al., 2002) and the community (Get Busy Get Better: Helping Older Adults Beat the Blues, Gitlin et al., 2012); improving chronic disease self-management (CDSMP, Lorig et al., 1999) and its variants such as Harvest Health (Gitlin et al., 2008); reducing functional decline (ABLE, Gitlin et al., 2006), fall risk and fear of falling (LiFe Program, Clemson et al., 2012; Matter of Balance, Tennstedt et al., 1998); addressing delirium in hospital settings (HELP, Inouye et al., 1999); enhancing social connectedness (PRISM, Czaja et al., 2015); improving well-being through physical exercise (Fit and Strong, Hughes et al., 2004); addressing substance abuse in adolescence through the multidimensional family therapy intervention (MDFT, Liddle, Rowe, Dakoff, Ungaro, & Henderson, 2004); and enhancing cognitive status (ACTIVE, Rebok et al., 2014). These reflect only a very small fraction of the well-designed interventions that have been well tested using rigorous methodologies and that, in turn, have been shown to substantially improve the quality of life and health and well-being of the targeted individuals, families, and communities.

This book is intended to introduce the exciting, challenging, stimulating, and inspiring world of behavioral intervention research. It is about the science and state-of-the-art practices in designing, evaluating, and then translating, implementing, and disseminating novel behavioral interventions for maximum impact on the health and well-being of individuals, families, and their communities. Each chapter tackles critical considerations in behavioral intervention research. Our approach is to be as broad and inclusive as possible of the many nuances, intricacies, and issues in this form of inquiry. We cover a wide range of topics including examining the
heart of the matter (Part I) or strategies for developing behavioral interventions including the pipeline for advancing interventions, the role of theory, intervention delivery characteristics, standardizing treatments, and use of technology. This is followed by evaluative considerations (Part II) including selecting control groups; identifying recruitment, retention, and fidelity strategies; using mixed methodologies; and ethical challenges. Then we examine outcome measures and analytic considerations (Part III) including economic evaluations for maximizing the yield of trial data, and, in Part IV, how implementation science can inform the development and advancement of behavioral interventions. Finally, in Part V, we explore a host of professional issues unique to this form of inquiry including challenges in staffing behavioral interventionist studies, how to obtain funding for developing and evaluating an intervention, and what, when, and where to publish.

Case examples from successful behavioral intervention trials are used throughout each chapter to illustrate key concepts. The primary goal of each chapter is to examine the science and best practices as well as to facilitate decision making related to the fundamental issues in conducting behavioral intervention research. The chapters also identify critical knowledge gaps in an effort to enhance scientific practices in each of the facets of behavioral intervention research.

Despite over 50 years of promising behavioral intervention research, the science of and best practices for behavioral intervention research are not well explained, and common know-how remains largely undocumented or not systematically shared within the research community, especially across disciplines. Thus, there are lost opportunities for advancing the skills and abilities of the current and next generation of researchers in the state of the science (and art) of this form of inquiry. This book is intended to fill this gap. Whereas classical clinical trial texts provide foundational knowledge important to the conduct of behavioral intervention research, they favor methodologies specific to pharmacological and medical device development and testing. These sources tend to ignore fundamental considerations and challenges specific to behavioral intervention work such as fidelity monitoring, the role and important contributions of mixed methodologies, strategies for recruiting and retaining diverse populations, or approaches for embedding and evaluating interventions under field conditions such as in community and clinical settings. Thus, it is critical that the specifics related to behavioral intervention research be documented, discussed, and advanced.

We aspire to have this book positively impact the work of researchers interested in or actively engaged in behavioral intervention research. We also hope this book helps to advance a rich dialogue and to stimulate further research directed specifically at developing best practices in behavioral intervention research. Behavioral intervention research is a complex and challenging form of inquiry that takes time, occurs over many years, and can be daunting at times. Nevertheless, its potential for yielding evidence-based programs, protocols, strategies, and models of care that can make a real difference to real people in real settings makes it a most commendable scientific enterprise that is worthy of our careful attention and elevation.

Please join us in the conversation and the journey of designing, evaluating, translating, implementing, and disseminating novel, health-promoting, and valuable behavioral interventions that can make a difference in the lives of people, their families, and communities.
REFERENCES


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Although we did not have a grant to write this book, we would like to extend our gratefulness to the many federal and foundation sponsors who have supported and continue to support our behavioral intervention research. These include the National Institutes of Health, the Alzheimer's Association, the Retirement Research Foundation, the Hartford Foundation, the Administration on Aging, Langeloth Foundation, AT&T, and Cisco.

Finally, we are most grateful for the thoughtful and significant contributions of our colleagues who participated as authors or coauthors on select chapters in this book.
The heart of the matter in behavioral intervention research is, obviously, the intervention. All other research-related considerations, such as the selection of outcome measures, study design, sampling, and recruitment processes, emanate from the purpose/goals of the intervention and the behavior, policy, and/or health care protocol that the intervention is intended to address.

Therefore, in Part I, we begin with a focus on the important and interrelated considerations in developing a behavioral intervention. This includes an examination of the: promises, challenges, and contexts of behavioral interventions (Chapter 1); pipelines for intervention advancement (Chapter 2); discovery period in which the anatomy of an intervention is developed (Chapter 3); role of theory as a driver of intervention development (and testing) (Chapter 4); selection of delivery characteristics of interventions (Chapter 5); ways to standardize protocols and practices (Chapter 6); and use of technology as a mechanism for delivering, monitoring, and analyzing interventions (Chapter 7).

The key “take home” points of Part I include the following:

- Interventions occur in a broad social ecological context that needs to be understood.
- A systems and user-centered design approach is essential for advancing novel interventions that are responsive to real-world contexts and needs of targeted populations.
- The evidence base for interventions is advanced through a series of iterative steps or phases.
- Interventions have a common etiology, referred to as “a period of discovery” in which the problem area, ways to ameliorate it, and targeted populations at risk are carefully identified.
- Theories or conceptual frameworks to understand why and how interventions work can maximize impact.
- Delivery characteristics of interventions need to be carefully chosen on the basis of theory; empirical evidence; and the specific goals, problem area, target population, context for delivery, and available resources.
- Standardization is critical to ensure treatment fidelity and internal validity, and to enable replication and wide-scale implementation.
- Technologies have an important role in the delivery, monitoring, and evaluation of interventions.
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ONE

PROMISES AND CHALLENGES OF BEHAVIORAL INTERVENTION RESEARCH

An epidemiologist conducts a study showing a strong empirical link between caregiver physical strain and nursing home placement of frail older adults. He now wants to develop an intervention to help minimize the caregiver's physical strain and prevent residential relocation of the older adult.

A clinician scientist observes that her cancer survivor patients tend to have cognitive and functional complaints that are stressful to them. The literature provides evidence for these relationships and factors that contribute to them, but no interventions that address this distressful phenomenon. She seeks to develop an intervention that would help this growing clinical population.

A family member of a behavioral researcher has a life-altering health care event and experiences significant gaps when transitioning among care contexts, highlighting the critical need to develop and test strategies to improve care continuity.

A team consisting of academic and senior center directors implemented an evidence-based program in the senior center to improve chronic disease management. They find that it is less acceptable to and effective for their African American members and that it needs modification to improve its reach to and adoption by diverse groups.

A health care system seeks to adopt a proven health promotion intervention, but it is too costly to deliver to rural populations as originally designed. They partner with researchers to examine the effectiveness of using technology for its delivery.

These are real examples of the common pathways that lead practitioners, health and human service professionals, and novice and experienced researchers to embrace the need for and engage in behavioral intervention research. Behavioral interventions start with a specified problem and are designed to address pressing identifiable and documented public health issues or policy gaps, service delivery snafus, health disparities, or the need for better, more cost-efficient care approaches. Such interventions encompass a wide range of strategies that can involve manipulating cognitive, behavioral, physical, environmental, and/or psychosocial processes to improve outcomes for a targeted population or community. Interventions may be directed at individuals, families, communities, or organizations or their combination, and...
target cognitions (e.g., coping mechanisms, cognitive framing, problem solving), behaviors (e.g., communications, lifestyle choices, medication adherence), emotional or affective well-being, physical health and functioning, physical or social environments, policies, health care practices, or service delivery mechanisms and training. Behavioral interventions are relevant to and important for individuals of any age group, race or ethnicity, socioeconomic status, or culture, as well as families, communities, organizations, and societies at large.

WHY BEHAVIORAL INTERVENTION RESEARCH IS IMPORTANT

The growing recognition and increased acknowledgment of the value and importance of behavioral intervention research for improving the health and well-being of the public can be attributed to several critical trends. The first is the growing recognition that the most pressing contemporary health issues that impose high societal and individual costs primarily involve lifestyle and behavioral factors, such as obesity, smoking, addictions, chronic disease, comorbidities, and functional consequences of diseases, social isolation, depression, delirium, mental illness, family caregiving, and health disparities. Developing and testing behavioral, nonpharmacological interventions that tackle these serious, persistent public health challenges is a widely recognized imperative (Lovasi, Hutson, Guerra, & Neckerman, 2009; Milstein, Homer, Briss, Burton, & Pechacek, 2011; Jackson, Knight, & Rafferty, 2010).

Second, the existing research evidence consistently suggests that behavioral and environmental factors exert a powerful and large influence on health and well-being. This is particularly the case for aging-related processes in which social and environmental factors are intertwined with the medical care of older adults. Take, for example, functional decline associated with growing older. Microenvironmental (individual) and macroenvironmental (family and cultural) effects have been found to contribute to age-related changes in functioning and to account for increasing heterogeneity in abilities even more than genetic factors (Finkel, Ernsth-Bravell, & Pedersen, 2015). The contribution of genetics to the rate of change in functional abilities among older adults >75 years of age is estimated to be only about 16% for women and 9% for men (Christensen, Gaist, Vaupel, & McGue, 2002; Christensen, Holm, McGue, Corder, & Vaupel, 1999). Even for dementia, the genetic heritability is small, with most causes due to age itself and possibly environmental factors, although these are poorly understood (Gatz et al., 1997). Furthermore, although genetics may contribute in part to early onset of chronic diseases, environmental factors and behaviors overwhelmingly account for the wide variation in outcomes after age 75 (Svedberg, Lichtenstein, & Pedersen, 2001). Thus, enhancing health and well-being through behavioral, lifestyle, and environmental modifications is critical to improving the health of the public overall, and the promotion of “successful aging,” in particular. The latter, in particular, is an issue of growing importance given the aging of the population, especially the increase in the “oldest old” cohort (85+ years.).

Third, despite an abundance of proven behavioral interventions, a gap of more than 17 years persists between the conduct of research and the production of evidence and the implementation of its yield. (Institute of Medicine [IOM], 2001). Only about 14% of evidence, including evidence-based intervention programs, is
implemented in clinical and community settings, with Americans receiving only 50% of recommended preventive, acute, and long-term health care (McGlynn et al., 2003). Minority populations are at particular risk, receiving recommended evidence-informed programs less than an estimated 35% of the time (Balas & Boren, 2000; Brownson, Colditz, & Proctor, 2012; McGlynn et al., 2003; Riley, Glasgow, Etheredge, & Abernethy, 2013). This large gap appears to be due to system-level factors (e.g., policies that do not structurally and financially support the delivery of evidence-based programs), workforce-level factors (e.g., the lack of adequate preparation of health and human service professionals or others in using evidence-based programs), individual factors (e.g., the lack of awareness of available programs or inability to access programs), or mismatches between the needs of individuals, resources (financial and expertise) of service organizations, existing policies and practices, and the characteristics of tested and proven interventions.

It is unclear how to close the “chasm” between “knowing” versus “doing” that continues to haunt every part of health and human services for every age group and population. This chasm has led to the growing recognition of the need to reconsider traditional approaches to designing and testing behavioral interventions and to seek alternative approaches for developing interventions that have greater potentiality for being implemented more rapidly and sustained.

A fourth trend that heightens the importance of behavioral intervention research is the paradigm shift occurring in health care today. New approaches and expectations are emerging in health care to view patients and their families as active participants in the management of their own health (Bodenheimer, Lorig, Holman, & Grumbach, 2002). Health self-management may involve adherence to a diet, exercise or medication regimen, coordination of a care network, and use of medical technologies (e.g., activity monitor, blood glucose meter, blood pressure monitor). Self-management can be complex and involve the need for personal oversight of multiple wellness goals, chronic conditions, and medication regimes. Thus, there is growing recognition of the importance of behavioral interventions that can effectively instruct and support patients and their families in the practical skills for self-management. Furthermore, there is an increased awareness of the need for evidence-based approaches to foster adherence; promote engagement in wellness activities; facilitate care coordination, communications, and interactions with health care professionals; and manage transitions between health care practices, facilities, and professionals.

Finally, there is a societal push for the adoption of evidence-based practices in health service delivery settings and community agencies. Evidence-based practices are interventions that have been tested in high-quality research and that are unbiased, have strong internal validity, and in which the results are generalizable with a firm level of confidence in linking outcomes to interventions (Guyatt et al., 2000). Thus, behavioral intervention research is needed to uncover what treatment practices work best, for whom, and under what circumstances. At the same time, there is an emphasis on what is referred to as “translational research” or harnessing knowledge from science to inform treatments and ensure that evidence reaches the intended populations (Woolf, 2008). As a critical goal is to impact practice and health care, it has become imperative to understand how best to design interventions so that they can eventually be successfully applied to and adopted by individuals, clinical practices, services, organizations, and communities.
ADVANCEMENTS IN BEHAVIORAL INTERVENTION RESEARCH

Over the past 50 years, there has been a growing corpus of behavioral intervention research that has yielded well-tested programs and important advancements in the conduct of this form of inquiry. As in any research tradition, behavioral intervention research has an evolving language and specific techniques, methods, rules, and standards that are unique to this particular endeavor. Although it overlaps other forms of inquiry such as classic clinical trial methodologies, behavioral intervention research also has its own distinctive challenges and foci. In the chapters that follow, to the extent possible and where appropriate, we draw upon the most important lessons garnered from classic methodologies and approaches, but also discuss considerations specific to this type of inquiry.

Historically and broadly speaking, the initial wave of behavioral interventions had significant limitations. These included: misalignments between study samples, intervention intent, and measured outcomes; lack of theory-driven approaches and an understanding of underlying mechanism(s) of treatment effects; lack of inclusion of diverse populations; and simplistic approaches such as expecting and measuring behavioral change as an outcome from an intervention that provided only education materials and enhanced knowledge. Take, for example, initial caregiver intervention studies that sought to reduce depressive symptoms although study inclusion criteria did not specifically target depressed caregivers (Knight, Lutzky, & Macofsky-Urban, 1993). Not surprisingly, an initial wave of caregiver studies showed minimal to no treatment effects for depressive symptoms, as there was little to no room for improvement on this outcome (Callahan, Kales, Gitlin, & Lyketsos, 2013). Furthermore, many interventions were designed with little understanding of the context in which they might ultimately be implemented if they were proven to be effective. These missteps have led to a greater understanding and awareness that a translational phase is typically necessary to take an intervention and adapt it for delivery in specific service contexts (Gitlin, Marx, Stanley, & Hodgson, 2015).

Today, we have a much better understanding of best practices in the conduct of behavioral intervention research. Although there is no universal or agreed upon set of approaches, practices, designs, or strategies, the collective knowledge, experience, and empirical evidence as to what works and what does not work in conducting behavioral intervention research is being amassed. For example, we know how to align theory with intervention development, use epidemiologic findings to identify intervention targets, involve communities and stakeholders in developing and implementing interventions, evaluate who benefits the most from interventions, embed interventions in practice settings and evaluate effectiveness using sophisticated adaptive designs and analytic techniques, and monitor and measure the impact of treatment adherence on treatment outcomes. Further, we now have experience standardizing intervention protocols, developing treatment manuals and training protocols, and conducting multisite and pragmatic trial designs that can potentially accelerate knowledge generation and its transfer to broad real-world settings.
CASE EXEMPLARS

Currently, thousands of behavioral interventions have been developed, evaluated, and found to be effective for a very wide range of populations, purposes, public health issues, and outcomes. It is impossible to summarize this vast body of promising and proven behavioral interventions. Nevertheless, considered collectively, common characteristics can be discerned of effective interventions that are designed to address behavior change and complex health and social issues. These are shown in Table 1.1, although this list should not be construed as exhaustive. Effective approaches may differ by the specific purpose or intent of an intervention, its mode, and context of delivery.

However, one apparent shared characteristic of effective interventions for behavioral change is that most tend to involve multiple components each of which targets a different aspect of a presenting problem and pathway for effecting positive change. This is not surprising as most issues targeted by behavioral interventions are complex and multidimensional. For example, an intervention designed to prevent and treat delirium in hospital settings targets factors intrinsic to the person such as medication profile and pain, and extrinsic factors such as staff training and the physical environment (e.g., noise, lighting, cues for orientation) (Inouye et al., 1999). The Get Busy Get Better program to help African Americans address depressive symptoms seeks to improve mood by impacting various potential contributory factors including a person's anxiety, knowledge of depression, and ability to detect his/her symptoms; reducing stressors in the external environment including financial strain and unmet social, housing, and medical needs; and by helping people re-engage in activities that are meaningful to them (Gitlin, Roth, & Huang, 2014).

Effective interventions also appear to tailor or customize content and strategies to key risks, needs, or specific profiles of target populations and contexts (Richards et al., 2007). For example, the REACH II intervention for families caring for persons with dementia modified the intensity (time spent) and amount of exposure (dose) to each of its five treatment components based upon a caregiver's initial (baseline) risk profile (Belle et al., 2006; Czaja et al., 2009). More time was spent on one component versus the other, depending on the risk profile of the individual caregiver; a caregiver with a home safety risk received greater attention in this area than a caregiver without this risk, although both received a minimal dose of this treatment component. The Get Busy Get Better program for depressive symptoms included five treatment components (care management, referral and linkages, stress reduction, depression education and symptom recognition, and behavioral activation). Although all participants received all five treatment components at equivalent dosage and intensity, the content covered in each component was tailored to the participant’s specific care needs; the person’s preferred stress reduction techniques; housing, financial, and unmet medical needs; and self-identified preferred activity and behavioral goals (Gitlin et al., 2013).

Another shared element of many effective interventions is their flexible delivery schedule. Interventions that do not have rigid dosing requirements have a greater likelihood of being adopted by, and integrated into, clinical settings and by end users...
I. Developing Interventions: Heart of the Matter

Table 1.1 Characteristics of Effective and Ineffective Intervention Approaches

<table>
<thead>
<tr>
<th>Effective Approaches</th>
<th>Ineffective Approaches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention and its characteristics are grounded in theory</td>
<td>No theoretical basis for the design of the intervention</td>
</tr>
<tr>
<td>Multicomponent such that different strategies are used to address distinct factors contributing to the identified problem area</td>
<td>Focus on a singular aspect of a complex set of factors contributing to a particular problem area</td>
</tr>
<tr>
<td>Multimodal such that different pathways (e.g., physical exercise, cognitive stimulation) are targeted to impact the identified problem area</td>
<td>One pathway is targeted although multiple factors contribute to the identified problem area</td>
</tr>
<tr>
<td>Strategies are tailored to participant needs, characteristics, cultural preferences</td>
<td>Use of a “one size fits all” approach</td>
</tr>
<tr>
<td>Participant-centered in that it integrates the client perspective</td>
<td>Prescriptive, didactic, standard approach regardless of participant perspective</td>
</tr>
<tr>
<td>Participant-directed in that intervention addresses self-identified needs</td>
<td>Participant needs are assumed a priori</td>
</tr>
<tr>
<td>Use of active engagement of participants and/or problem solving</td>
<td>Use of didactic, prescriptive approach</td>
</tr>
<tr>
<td>Flexible delivery characteristics to accommodate differences in practice settings</td>
<td>Fixed dose and intensity</td>
</tr>
<tr>
<td>Outcomes are closely aligned with and reflect intervention intent</td>
<td>Outcomes are too distal from content or focus of intervention</td>
</tr>
<tr>
<td>Oriented toward building skills and problem solving to bring about behavior change</td>
<td>Providing education to enhance knowledge when goal is to change behavior</td>
</tr>
<tr>
<td>Criteria for participant inclusion reflect intent of intervention</td>
<td>Mismatch between intervention intent and participant inclusion criteria</td>
</tr>
<tr>
<td>Involving end users (participants) and/or stakeholders in the development of the intervention</td>
<td>Not considering the participant or stakeholder perspectives early on in designing an intervention</td>
</tr>
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</table>

(e.g., interventionists and participants who may benefit). For example, the Adult Day Plus intervention provides care management, education, support, and skill building on an “as needed” basis for family caregivers who use adult day services for a relative for whom they provide care. Sessions initially occur biweekly for 3 months and at the time when a family member drops off or picks up their relative at the adult day service. Following this initial phase, ongoing contact is periodic and can be initiated by the service provider or family member (Reever, Mathieu, Dennis, & Gitlin, 2004).

In addition, repeated exposures to an intervention appear to yield better outcomes such as reducing nursing home placement or maintaining independence at
home. For example, the Maximizing Independence at Home for persons with cognitive impairment provides ongoing care management for 18 months; pilot data with over 300 persons showed that this approach resulted in the reduction of some home safety risks and more days at home (versus nursing home placement or death) (Samus et al., 2014).

Finally, interventions that actively involve participants in the treatment process and the learning of new skills may be more effective than prescriptive, didactic approaches (Belle et al., 2003) when the intent is to change behavior and redesign lifestyles for healthier living. Self-paced programs, approaches in which participants have opportunity to practice and integrate behavioral change strategies, afford more positive outcomes than approaches that do not provide such opportunities. Similarly, if the goal is to improve self-management, certain strategies appear to be more effective than others. For example, using behavioral activation techniques (Hopko, Lejuez, Ruggiero, & Eifert, 2003) that involve individuals self-selecting personal life, health, or daily goals, or providing control-oriented strategies to help people achieve their daily activity goals, afford increased control over daily life events and result in better health outcomes (Heckhausen, Wrosch, & Schulz, 2010). Correspondingly, having participants codesign their own action plans for achieving healthier lifestyles (Lorig et al., 1999) are all strategies rooted in complementary theoretical frameworks that result in enhanced self-efficacy and health-related benefits. This is not to say that behavioral interventions must embrace each or all of these treatment elements to be effective. However, it does suggest that consideration be given to these characteristics in order to maximize the impact on certain types of behavioral change outcomes (Zarit & Femia, 2008). Each of these characteristics is rooted in various theories, best practices such as adult learning principles, and research evidence concerning what works and what does not in changing behavior and personal health practices.

We also have fairly good knowledge of what is ineffective when the goal is to change behavior and health care practices through an intervention. Although an implicit goal of an intervention is to have the biggest impact on the largest number of persons as possible, given the heterogeneity and diversity of populations, a “one size” approach typically does not work. For example, the REACH II intervention, overall, was more effective for Hispanic and White/Caucasian caregivers than for African Americans. However, further analyses showed that, within the African American sample, it was more effective for caregivers who were spouses and older. Devising ways of introducing choice and tailoring an intervention to preferences or situations is, in general, preferred (Belle et al., 2006).

Using prescriptive approaches or providing education alone when the goal is behavioral change has also been shown to be mostly ineffective. Fixed dosing requirements may be important, but this also limits the translation and implementation potential as clinical settings and other end users of an intervention may need greater flexibility in the delivery of such a program. Finally, developing interventions without fully understanding the context in which they will be implemented (see discussion below and Figure 1.2) limits its ultimate usability and acceptability. Involving immediate end users and stakeholders (e.g., interventionists, administrators, payors, participants themselves) early on in the intervention development process is emerging as a best practice. This systems-oriented approach integrates a
usability testing and iterative process for developing interventions from the start, to optimize the fit between the intervention and the context in which it is designed for implementation if it is proven to be effective (see Chapter 2).

RELATIONSHIP OF BEHAVIORAL INTERVENTION RESEARCH TO IMPLEMENTATION SCIENCE

An emerging exciting, important, and unique area of inquiry is implementation science. As a complementary and synergistic relationship exists between behavioral intervention research and implementation science, it is important to clarify the scope and processes of each and their relationship to each other. Figure 1.1 maps this relationship and the connections to changing health, education, and/or human service practices, the ultimate goal of both of these domains of science.

Behavioral intervention research is directed at generating evidence in the form of tested and proven programs, protocols, interventions, and strategies. In contrast, implementation science has been variably defined, but basically examines the best strategies for implementing proven programs or evidence in specific practice and/or service contexts (Brownson et al., 2012). It also aims to identify roadblocks (e.g., social, economic, organizational) that impede the implementation of a proven program or evidence base into practice. Specifically, implementation science represents an emerging, important, and dynamic field of inquiry that systematically examines how programs or interventions can be embedded or implemented and sustained in real-world settings and conditions.

Implementation science starts where behavioral intervention research has traditionally ended. It is based on the premise that there is a well-developed, tested, and proven program or intervention, and its goal is to systematically move “it” into community and/or clinical settings. In contrast, behavioral intervention research, and the focus of this book, is about the “it”—designing, evaluating, and building the evidence base for intervention protocols that have the potential for implementation in real-world settings.

Figure 1.1 also suggests that, to optimize the impact of behavioral intervention research on health and health care outcomes, we must begin with the end in mind or some idea of where our interventions will reside if effective. By understanding the downstream challenges and complexities of implementing evidence into a practice environment, we may be able to design and evaluate interventions upfront in more thoughtful, systematic ways that enhance their implementation and scalability potential once they are proven to be beneficial. In this way, knowledge gleaned from implementation science can help guide behavioral intervention research from the inception of an intervention idea through to its evaluation and translation for a practice setting. Starting with the end in mind requires a firm understanding of the characteristics of target populations, communities, organizations, work flow, and systems of care. For example, designing and implementing an Internet-based intervention requires some degree of technology literacy and computer/Internet access among the intervention recipients as well as broadband connectivity in the neighborhood/community. Understanding these challenges upfront is essential for
1. Promises and Challenges of Behavioral Intervention Research

Designing an intervention protocol, selecting the technology, identifying training requirements, and evaluating costs. Designing an intervention for delivery in a social service agency requires an understanding of the agency and, in particular, its staffing and work flow patterns to ensure compatibility with the delivery characteristics of the intervention.

In line with this way of thinking, many of the chapters in this book promote a new and necessary synergy between implementation science and the design and evaluation of behavioral intervention research. We discuss downstream challenges of implementation (e.g., readiness of individuals or organizations to change; workforce considerations for delivering an intervention) when appropriate to help inform the upstream work of behavioral intervention design and evaluation.

Our message is that changing behaviors and health and human service practices is complex. If we seek to have our interventions integrated in and used in real practice settings by health and human service professionals, and individuals and their families, then our interventions must be informed in part by implementation considerations and this emerging science.

CHALLENGES OF BEHAVIORAL INTERVENTION RESEARCH

There are numerous challenges in the conduct of behavioral intervention research. Foremost among them is that behavioral and health problems are complex and changing behaviors is tough; thus, this form of research can be as well. Advancing an intervention can be costly, recruitment is effortful and time consuming, the conduct of interventions (treatment and control groups) requires adequate staffing and standardization, follow-up assessments necessitate resources, and testing of protocols evolves over time. As grant dollars in most countries, including the National Institutes of Health in the United States, favor basic research and then moving findings to clinical applications (referred to as T2 research), behavioral intervention...
research does not currently command a significant proportion of the research dollars of its respective institutes and centers. Furthermore, budget limitations often prohibit researchers from addressing some of the most important issues concerning a behavioral intervention such as determining whether outcomes are maintained over time, whether booster sessions are required to enhance treatment receipt, its cost and cost benefit, or the relationship between subjective and objective outcome measurement points such as biomarkers.

A second challenge is related to the time scale for behavioral intervention research. Designing, evaluating, and then implementing an intervention in a practice setting can take a long time from inception of an initial intervention idea to the demonstration of its efficacy, effectiveness, and evaluation of its implementation potential (discussed in further detail in Chapter 2). Many doctoral and postdoctoral students are dissuaded from pursuing behavioral intervention research because of this complexity, the perception that it delays professional advancement, and that testing may need to evolve over a relatively long time frame, preventing productivity.

A third challenge is that owing to the complexity and multifaceted aspects of behavioral intervention research, developing effective intervention approaches typically requires multidisciplinary research teams in order to enable a complete understanding of the issues at hand. Such collaborations add another layer of complexity to this form of research as researchers from diverse disciplines typically have distinct languages, methodological approaches, and unique perspectives that may initially be challenging to understand and integrate. For example, the development of a technology-based intervention for family caregivers requires combining the expertise of scientists in behavioral sciences and family caregiving with the expertise in engineering and computer science. A team science approach still remains elusive to most researchers and is not fully celebrated and appropriately rewarded in academic institutions in the form of promotions, recognition, and time and space. This prevents moving forward with behavioral intervention work in novel and potentially more effective directions. This, combined with the need to involve end users and stakeholders, adds more complexities to the research endeavor and can also tax the expertise of the originator(s) of the intervention.

A related point is the need to bring individuals from diverse backgrounds together to derive a shared language and understanding of the issues and participate in joint problem solving in advancing a particular approach. Although this can be challenging, involvement of diverse disciplines and backgrounds is also exciting and can yield breakthroughs in approaches.

Another challenge is that the field is often stymied by the lack of adequate outlets for reporting the nuances of behavioral intervention studies. For example, the CONSORT guideline that is widely used in the reporting of trials does not address certain elements of high relevance to behavioral intervention research such as the theory base and fidelity plan used and how adherence affects outcomes (Schulz, Altman, & Moher, 2010). Many medical journals have significant word limitations and are typically uninterested in how theory drives the intervention and links to the outcomes. Few journals allow space for articles to fully detail an intervention and its delivery characteristics so that it can be adequately replicated. Similarly, access to treatment manuals may not be readily available or granted by investigators, and
there are no agreed upon sets of criteria for developing such manuals. The focus on reporting positive outcomes in peer-reviewed journals is upheld to the exclusion of understanding why and how a particular outcome may or may not have been achieved. Knowing that an intervention is not effective for a targeted population can be as informative as understanding what does work, and can prevent the duplication of such unsuccessful intervention approaches.

One more challenge is that little is known about some of the fundamental practices of this form of research. There is limited empirical evidence, for example, as to: which blinding or masking techniques of research staff and study participants are most effective and for which types of interventions; what types of control groups are appropriate and when; what the best practices are for ethically consenting vulnerable populations; which recruitment/retention strategies and types of interventions work best for diverse populations; and which fidelity measures are most useful across different interventions. Documentation and evaluation of specific methodologies for use in each aspect of the conduct of behavioral intervention research is very much needed. Furthermore, there is significant conceptual confusion as to the steps or processes for advancing interventions. Funders, researchers, journals, editors, and reviewers all employ different terminology, definitions, and usages for concepts such as the pipeline, translation, implementation, diffusion, dissemination, fidelity, and so forth. Conceptual misuses and confusion cloud or muddy efforts and impede working toward general consensus as to key terms and methodologies for evaluating and advancing interventions.

Furthermore, the health care landscape and population demographics are changing dramatically. There is an unprecedented need for new research designs, methodologies, procedures, and intervention approaches. Treatments that work today may not be as effective in the future for aging cohorts. For example, the delivery of health care for many conditions is moving away from traditional clinical settings to nontraditional settings such as the home. Patients and caregivers are being asked to perform complex care tasks (e.g., attending to wound care or tube feeding) and use more medical technologies (e.g., infusion systems or blood pressure and heart rate monitoring devices) (Reinhard, Samis, & Levine, 2014). This, in turn, requires the development of intervention strategies to help ensure that patients and caregivers are able to deliver care protocols as intended and that are adhered to over time. Further, the increase in populations with special needs, such as the “oldest old,” individuals aging with developmental and other forms of disability, long-distance caregivers, and individuals without family support, to name only a few, requires understanding the types of interventions that may benefit distinct and highly diverse groups and the approaches that are optimal.

CONCEPTUAL FRAMEWORK

This book is developed with these complexities and challenges in mind. It seeks to sort out and provide best practices and guide a thoughtful approach to designing, evaluating, and implementing behavioral interventions when the goal is to change current practices or address newly emerging problems or health care challenges with real-world solutions.

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Our approach to understanding behavioral intervention research is guided by a socioecological systems framework. This framework, shown in Figure 1.2, conceptualizes interventions as being embedded within a complex system involving multiple and interacting components or levels of influence that also change over time. These interconnected levels include the personal or individual level (e.g., end user of an intervention), the physical environment or setting, the formal and informal social network, the community, neighborhood, organization, and the policy environment.

Consider a drug abuse prevention program whose overall objective is to reduce or prevent the use of illegal substances among high school students. The intervention includes video skill-building sessions that are delivered to both students and parents in the school and overseen by a trained facilitator. In this case, the personal and social levels include the students, teachers/school principal, and parents. The setting and community include the school and classroom where the sessions will be delivered and the surrounding neighborhood. The organizational and policy levels include the school district and school board as well as policies regarding training by outside sources, availability of classrooms for after-hours training, and so forth. Each level has varying and dynamic characteristics, and the interactions among the levels, in turn, can have a significant influence on the degree to which the goals and objectives of an intervention can be achieved and what its delivery characteristics ought to be to maximize benefits. For example, if most of the parents work, it would be difficult to schedule group sessions during the day; if the school policy is to forbid classroom use in the evening, then location could be an issue. Furthermore, the content of each session may need to be carefully reviewed and approved by the full school board prior to its implementation. Knowledge of the characteristics of these levels directly informs construction of an impactful intervention.

By means of our social ecological framework, several guiding principles for behavioral intervention research can be derived.

First, interventions must be understood as occurring within a context that includes multiple levels—the individual, the setting in which the intervention will be delivered (e.g., home, school, clinic, workplace), formal and informal networks and social support systems, the community, and the policy environment (Figure 1.2). Health and behavior, and hence intervention delivery characteristics, may be shaped by influences at each of these levels.

Second, as there are significant interactions among these levels, interventions are more likely to be successful and sustainable if they consider the characteristics of each level and the interactions among them. In other words, interventions cannot be designed in isolation or in a vacuum and focus solely on individual-level determinants of health and behaviors, as has typically been the practice. Rather, interventions must consider the independent and joint influences of determinants at all of the specified levels. Levels will be proximal and distal to the immediate outcomes sought (e.g., increasing physical activity among minority populations); however, at some point in the process of developing the intervention, each level will need to be actively considered.

Third, the levels and the interactions among them are dynamic, and determinants may change with time. Therefore, for interventions to be sustainable, their characteristics must be adaptable to potential changes and dynamic relationships over time.
These principles are interwoven throughout this book and, taken as a whole, suggest that we need new ways of thinking about and acting upon the design, evaluation, and implementation of interventions.

**ROADMAP**

As we have suggested, behavioral intervention research can be exciting, yet it is complex and involves more than the simple design or singular test of an intervention. It requires consideration and understanding of a broad range of issues that may impact an intervention and its delivery (Figure 1.2). Thus, in this book, we cover a broad array of topics of high relevance to, and that impact on, the conduct of behavioral intervention research. We consider the entire “behavioral intervention pipeline” from conceptualization of an intervention through its implementation and sustainability in a practice setting, and examine how the context in which interventions are embedded affects their development and advancement. While our focus is not on implementation science directly, we draw upon it in terms of how it can help to inform the development and evaluation of an intervention. We emphasize the need for behavioral intervention researchers to consider the entire pipeline in their endeavors.
We start with what we consider to be the “heart of the matter” in Part I, by examining recommended pipelines for developing and constructing an intervention, specific considerations and steps that inform what we refer to as “a period of discovery,” how theory informs intervention development, the selection of delivery characteristics, ways to standardize an intervention, and the potential of delivering interventions through technology. Next, in Part II, we tackle considerations related to evaluating interventions, including selecting control groups and identifying samples; recruiting and retaining study participants; using mixed methods to evaluate different aspects of intervention development; determining whether treatment effects are real by attending to fidelity; and the critical ethical considerations that underlie all study-design decision making. In Part III, we move on to look at outcomes measures and analytic considerations, linking both to intervention intent. We also explore analytic considerations such as clinical significance and economic evaluations. Part IV examines implementation science and, in particular, how its theories can inform ways to advance an intervention. We also examine what it takes to disseminate an intervention if the evidence supports its use. Finally, in Part V, we delve into professional issues such as developing and maintaining a cohesive staff, grant writing, and publishing. Throughout, we provide practical guidance and offer real exemplars. We also identify gray areas that need further understanding through research.

Implicitly, this book grapples with and raises big and critical queries:

■ How do we move seamlessly from intervention design to full implementation?
■ How do we design interventions so that they are more market ready if effective?
■ How can we better identify, define, and standardize actions related to each phase of intervention development to enable the current and next generation of behavioral intervention researchers to succeed?

We seek to motivate the reader to participate in the behavioral intervention research arena, be more informed and better prepared to take on the exciting challenges that it presents, and enter into a dialogue about this form of research to derive consensus and empirically based answers to these big questions.

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