7

Identifying Mechanisms of Action: Why and How Does Intervention Work?

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INTRODUCTION

An important new direction in clinical trial research with AD family caregivers is the systematic documentation and evaluation of intervention processes. This approach to caregiver intervention research is critical for several compelling reasons. First, whereas a range of service programs for AD family caregivers has been tested (see chapter 2), our understanding of why and how interventions work is limited. Second, previous reports have found variable results among intervention studies (Bourgois, Schulz, & Burgio, 1996; Knight, Lutzky, & Macofsky-Urban, 1993). Some research has also shown that family caregivers tend to underutilize available formal services (Gill, Hinrichsen, & diGiuseppe, 1998; Hamilton, 1996). Finally, a lack of accepted and standard methods for documenting intervention characteristics and processes has made it difficult to generalize study findings and implement interventions in different service settings (Bala, Austin, Ewigman, Borwn, & Mitchell, 1995). These limitations have intensified the importance of identifying specific intervention features and caregiver characteristics that are associated with treatment outcomes. An understanding of intervention processes may suggest new approaches to support family members. Moreover, it may enhance knowledge of which strategies work best and for whom and at which caregiving stage interventions are most beneficial.

Of particular importance to the study of intervention processes is identifying the underlying *mechanism(s) of action* of an intervention. Mechanism of action refers to the theoretical and empirical accounting of why and how a particular change in a caregiver or care recipient occurs as a consequence of participating in an intervention. A mechanism of action seeks to elucidate underlying associations or pathways through which desired changes in behavior, cognition, or affect are achieved through intervention. Mechanisms also delineate how change proceeds, the particular conditions under which an intervention achieves beneficial results, and why a change may occur for certain groups of participants and not others.

Caregiver intervention studies are implicitly grounded in a particular understanding of how a behavioral or cognitive change may take place or the mechanism of action. Unfortunately, to date, few clinical trials with AD family caregivers have included adequate design features and measures to adequately explain the underlying mechanisms for the effect of an intervention. Thus, little is presently known about the psychological, social, and physiological mechanisms that predispose caregivers to achieve or not achieve positive outcomes from interventions. To advance this area of research, clinical trials must consider mechanisms as a specific research query and include the evaluation of intervention effects as specific design and measurement goals.

Mechanisms have traditionally been examined in the biological and pharmocologic sciences. However, identifying mechanisms of behavioral change may require a different approach due to the complexity and multifactorial nature of caregiver interventions. This chapter provides an overview of the mechanisms of action concept and its application to the study of interventions for AD family caregivers. First, the significance of the study of mechanisms of action is discussed. Next, we identify three recent developments in research that may advance this form of inquiry. Following this, we delineate and discuss two interrelated considerations in examining mechanisms as shown in Table 7.1. Foremost in the study of mechanisms is the requirement to pose relevant theoretical frameworks which underpin the intervention and from which to generate specific hypotheses and testable causal pathways. In this chapter we discuss select theoretical frameworks to illustrate different causal pathways through which interventions may work. Another important consideration in the study of mechanisms is clearly specifying the structural elements and processes of delivering an intervention. Accordingly, we identify key dimensions of caregiver interventions such as dose, intensity, methods of delivery, and discuss approaches to their measurement. These dimensions describe the conditions of treatment and how change may proceed. It may be that only one dimension or a combination of factors produce an intervention effect. Thus, in this chapter, we suggest that the study of mechanisms of caregiver interventions requires the integration of a theoretical model with the measurement of its treatment components. To illustrate each of these points, we draw on the experiences of the REACH study group.

SIGNIFICANCE OF MECHANISMS OF ACTION

The concept, *mechanism of action*, is relatively new to social and behavioral clinical trial research, and virtually absent in the study of caregiver interventions. By contrast, identifying mechanisms of action

TABLE 7.1 Components to the Study of Mechanisms of Action

1. Why intervention works	2. How intervention works
• Theory to explain caregiver change • Theory to explain care recipient change • Causal pathways (direct, mediation, moderation)	• Structural elements • Entity and targeted domains • Fidelity components —Delivery —Receipt —Enactment

has been a fundamental aspect of inquiry in the physiologic basis of aging. For instance, specifying the mechanisms by which aging occurs at the cellular level remains a primary focus of biologic research and is central to the understanding of age-related disease processes and physical frailty (Morrison, Katz, Parmelee, Boyce, & Ten Have, 1998).

The significance of understanding mechanisms of action is best illustrated by clinical trial research in pharmacology. The centrality of this concept to this field is reflected in the more than 3,234 citations found in a Medline database search conducted from 1990 to April, 1998. Searches on this topic in Psychlit, Health Star, and CINHAL databases yielded similar results with all citations referring to pharmacological studies. Mechanisms of action in pharmacology include two components: (1) identifying the physiologic or biologic actions that occur, and (2) specifying the drug regimen such as the strength of dose, time of dose, and form of dose (e.g., liquid, tablet). Thus, identifying mechanisms, or how a particular drug activates physiologic or biologic change, is critical in that it informs dosing decisions and the conditions for its administration. Examining mechanisms of action in caregiver intervention studies include parallel components: (1) identifying relevant theoretical models, and (2) specifying the treatment dosage such as the number of contacts or type of contacts (e.g., face-to-face, telephone, computer).

It is important to recognize that identifying mechanisms of action represents an ongoing research process in which knowledge is gained incrementally through repeated research endeavors. The ongoing efforts of scientists to discern the effects of cholinergic agents on memory functioning in dementia patients illustrates this knowledge-building process. At present, cholinergic agents are considered one of the most promising pharmacological treatments for cognitive impairment. In research on the first generation of cholinergic agents, the proposed mechanism of action was described as the "cholinergic hypothesis." This hypothesis suggested an association between cognitive decline and cholinergic cell loss in areas of the brain. Currently, with the second generation of cholinergic agents, investigators are suggesting that cognitive symptoms improve through synaptic effects. Still other researchers are suggesting that these agents provide neuroprotective effects through activating nicotinic receptors (Schneider, 1996). Thus, the mechanisms by which these agents function have not been fully disclosed and competing hypotheses continue to be tested.

RESEARCH DEVELOPMENTS TO ADVANCE THE STUDY OF MECHANISMS

Several recent developments in social science and behavioral research significantly advance the study of the mechanisms of action in caregiver interventions. First, well-developed theories and models of behavior change have been proposed and tested in other fields. These theories and models provide useful frameworks for developing hypotheses and identifying specific factors and pathways by which caregiver interventions may function.

Another factor facilitating the study of mechanisms is a growing literature on methodological issues in clinical trial research (Egan, Snyder, & Burns, 1992; Spilker, 1996; Teri & Logsdon, 1996; Weissert & Hedrick, 1994). This literature has identified specific factors that may confound treatment effects and which must be controlled or tested in clinical trials. For example, research on psychotherapeutic interventions has shown that therapist attributes may influence the treatment process and its outcomes (Crits-Christoph & Mintz, 1991; O'Leary & Borkovec, 1978). Studies suggest that information about the characteristics of those who provide intervention should be collected. Statistical analyses can be performed to examine differences in outcomes between interventionists and the relationship between therapist factors and treatment outcomes.

Recent advances in statistical modeling techniques also permit a more focused examination of mechanisms. Mechanisms of action are conceptually linked to the statistical ideas of mediation and moderation. The distinction between mediators and moderators has been carefully explicated in the experimental psychology literature, most notably by Baron and Kenney (1986). Mediation refers to the generative mechanism through which an independent variable influences an outcome. A mediator is a third variable that affects the relation between an independent or predictor variable and a dependent variable or outcome.

A variable functions as a mediator to the extent that it accounts for the relationship between a predictor and an outcome. Mediation is especially important in the context of intervention research since variables identified as such may be likely candidates for the foci of interventions, assuming, of course, that the identified factors are amenable to change. For instance, if psychosocial resources such as self-efficacy and social support emerge as mediators of well-being, interventions may be designed to enhance these resources.

In contrast, a moderator considers the subgroups of a particular independent variable to determine which group or level leads to maximal effectiveness in a designated dependent variable. Examples of typical moderating variables in caregiving research include gender, ethnicity, and spousal relationships. Independent variables may have differential effects on intervention outcomes as a function of these variables. While direct, mediation, and moderation models have been used to predict change in caregiver well-being in prospective studies (Haley, Roth, Coleton, Ford, West, Collins, & Isobe, 1996), these models have not been applied to intervention research but may be useful for describing mechanisms of action.

Unquestionably, providing care to a family member with dementia represents a complex activity that potentially may have multiple consequences for caregiver health and well-being. Consequently, interventions for caregivers are generally multifaceted and are designed to effect multiple caregiver and care recipient outcomes, such as behaviors, cognition, and emotional responses. Thus, a given intervention may have more than one mechanism through which it operates. A combination of theoretical frameworks may be necessary to explain the role and impact of various intervention components. Likewise, statistical modeling techniques will be required to account for mechanisms by which change is evinced in the different domains that are targeted by an intervention.

UNDERSTANDING WHY CHANGE OCCURS

One of the first set of tasks in the study of mechanisms is articulating a relevant theoretical framework or the underpinning of an intervention, developing appropriate hypotheses, and testing a causal pathway by which change in the targeted area may occur. For this effort, a vast array of theories from related fields of inquiry are available. Here we highlight select theories that may be particularly useful to the study of why interventions do or do not work with AD family caregivers.

Stress Process Models

Stress process models have been used extensively in prospective studies to examine the mechanisms by which psychosocial factors influence caregiver well-being (Goode, Haley, Roth, & Ford, 1998; Schulz, Visintainer, & Williamson, 1990; Schulz, O'Brien, Bookwala, & Fleissner, 1995). Briefly stated, this vast body of research has shown that psychosocial resources such as caregiver appraisals, coping responses, and level of social support mediate the effect of caregiving stressors on caregiver well-being. As described in detail in chapter 2, a broad stress-process health model is used by the REACH study group as a basis for understanding the outcomes and underlying mechanisms of its diverse interventions. The model is useful in this context because it accounts for the environment, physical health, and psychosocial influences on caregiver well-being. Also, the model considers the impact of various interventions on each of these factors. For example, an intervention may provide education to enhance a caregiver's understanding of and ability to cope with the demands of caregiving. Alternately, an intervention may be directed at changing the caregiver's physical and social environment to reduce the impact of problem behaviors. Thus, the model provides the framework for testing caregiver interventions and elucidating the specific pathways by which burden is reduced or other behavioral and cognitive changes occur.

Motivational Theories

Motivation is an important concept in the study of mechanisms of interventions that involve behavioral change. Motivation refers to the notion that human activity is grounded in or stems from goals. Goals orient people to particular interpretations of events, organize behavior, and guide actions which result in the pursuit of desired outcomes (Gollwitzer & Bargh, 1996). There are numerous theories of motivation, but each attempts to link cognitive processes to actual behaviors.

As applied to caregiving, these theories suggest that caregivers have implicit ideas about best care practices with dementia patients (e.g., keep routines normal and unchanged). As suggested in Figure 7.1, a theory of best care may lead to the formation of specific goals, and subsequently, to behavioral actions that caregivers wish to accomplish (e.g., bathe family member daily as he used to do). However, as the disease progresses, goals may become difficult to achieve. Caregivers may become motivated to learn new strategies that will enable them to either achieve their implicit or stated goals or to reframe these goals. One mechanism suggested by motivational theory is that tailoring an intervention to individual goals, as opposed to using a structured group intervention, may elicit desired outcomes by tapping into the specific goals and personal motivational frameworks of caregiver participants.

Caregiver theory of best care ⇒ Formation of specific caregiving goals ⇒ Actions

FIGURE 7.1 Application of motivational theory to caregiving.

Behavior Change Theories

Behavior change theories provide a framework for understanding mechanisms of changing lifestyle-type behaviors (Meillier, Lund, & Kok, 1997). The transtheoretical model of behavioral change, developed by Prochaska and colleagues (Prochaska & DiClemente, 1983; Prochaska, Redding, & Evers, 1997) may be helpful in understanding mechanisms of action of caregiver interventions. The transtheoretical model views behavior change as occurring incrementally, through a series of well-defined stages. These stages may be used to classify individuals so that intervention approaches can be tailored to a specific level of readiness for modifying actions. Levels of readiness also may be used to explain why some intervention participants achieve behavior gains while others do not. The stages of readiness have been used extensively to examine the effects of varied interventions that are designed to alter health-related behaviors such as tobacco use and weight loss.

With regard to caregiving, the acquisition of new skills that allow a caregiver to manage daily care problems requires a sequence of behavioral changes. A caregiver may need to have a certain level of readiness before being able to modify or change what may be long-standing care routines. In this way, readiness for behavior change may mediate caregiver outcomes. This behavior staging framework is currently used by the Memphis and Philadelphia REACH study sites to understand which caregiver participants may benefit most from intervention. Memphis REACH modified Prochaska's four basic stages of change to fit the caregiving situation. This is illustrated in Figure 7.2. At each of the two sites, interventionists classify caregivers according to four levels of readiness to accept intervention strategies. By cross-tabulating readiness data with components of treatment implementation such as dose and intensity rates, investigators hope to discern patterns of treatment effects. Additionally, the moderating

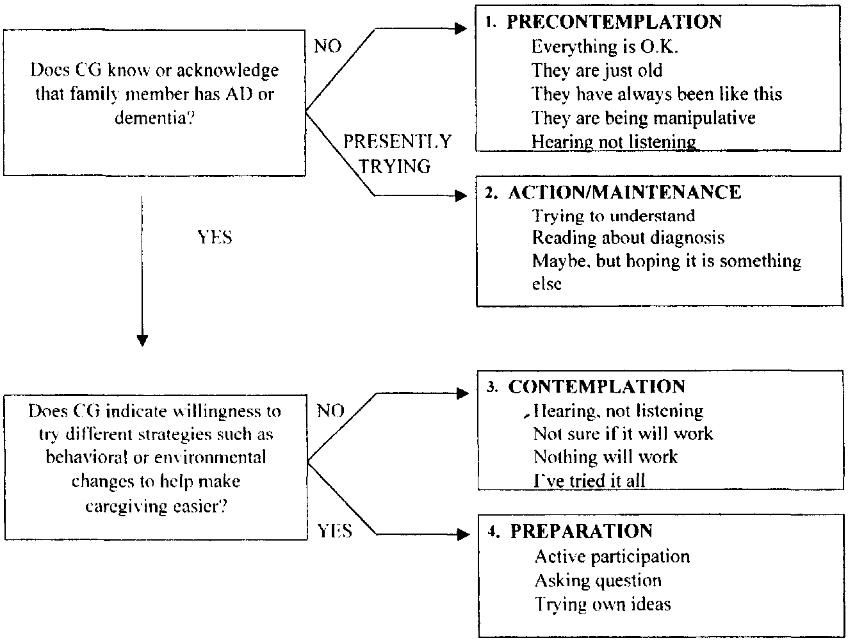

FIGURE 7.2 Readiness form.

role of factors, such as gender and ethnicity, can be evaluated. For example, analyses will be conducted to determine if gender moderates treatment effects at each stage of readiness. This theory offers a useful framework from which to refine our understanding of mechanisms of action and how interventions operate for different ethnic and gender groups.

Personal Control Theory

Another useful framework for the study of mechanisms is the construct of self-efficacy. Bandura (1997) has suggested that self-efficacy beliefs influence the initiation of actions, and therefore, serve as important mediators of behavior in different domains of daily life. A substantial body of research supports this theory and indicates that strong self-efficacy beliefs are related to positive health outcomes and the adaptation of health promoting behaviors (McAvay, Seeman, & Rodin, 1996). Caregiver studies also have shown that strong self-efficacy beliefs and a personal sense of control are important psychological resources that have a negative relationship with depression (Intrieri & Rapp, 1994; Miller, Campbell, Farran, Kaufman, & Davis, 1995).

Schulz, Heckhausen, and O'Brien (1994) have applied the concept of personal control to the study of disability. These researchers have advanced a theory of personal control which suggests that as people are threatened with loss in their ability to control daily life outcomes, they seek adaptive strategies to compensate for this threat. If adaptive strategies cannot be used or do not adequately compensate for the threat of loss of control, then the result may be heightened anxiety and depression.

Applied to caregiving, personal control theory suggests caregivers may be motivated to learn and use new care techniques in order to maintain direct personal control over important life domains. The successful use of strategies to manage new problems may provide caregivers with a sense of mastery or self-efficacy. Theoretically, enhanced feelings of self-efficacy will, in turn, result in less caregiver depression, upset and burden. As shown in Figure 7.3, personal control theory offers a testable pathway as to the mechanism by

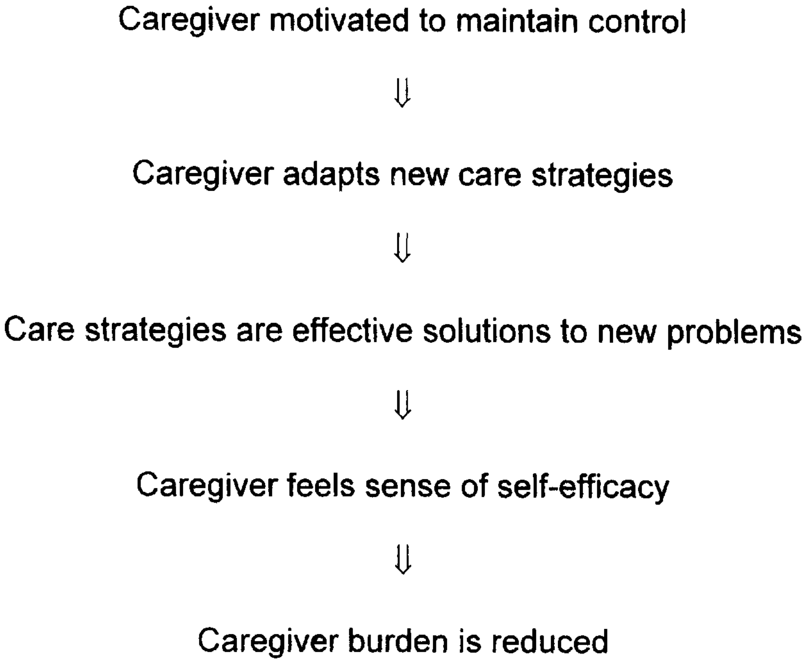

FIGURE 7.3 Application of personal control theory to caregiving.

which caregivers may benefit from an intervention involving skills training or behavioral management techniques.

Table 7.2 summarizes these and other theoretical approaches that may be useful in explaining the mechanisms through which different caregiver interventions result in reduced burden, just one of the potential outcomes of a caregiver intervention.

IDENTIFYING STRUCTURAL AND PROCESS DIMENSIONS OF INTERVENTIONS

Another component in the study of mechanisms of action (see Table 7.1) is determining the way in which change occurs. This involves identifying the structural dimensions of an intervention and the process of its implementation. Examining structural and process

TABLE 7.2 Common Caregiver Interventions, Possible Theoretical Frameworks and Hypothetical Mechanisms of Action to Explain Reduced Burden

Intervention	Theoretical framework	Implied mechanism of action
Family therapy	Social exchange theory/equity theory	Individuals use exchanges to maximize rewards and minimize costs. Reciprocation of exchanges need to be perceived as equal or fair to maintain stable family relationships and caregiver well-being. Caregivers benefit from family therapy because it equalizes exchanges and enhances social support. Increased social support that is perceived as beneficial reduces burden.
Individualized skills training	Motivational theories	Personal goals provide a framework for initiating behaviors. Caregivers become motivated to adapt new skills and change behaviors to address self-identified goals of caregiving. Attainment of personal goals to achieve desired outcomes leads to reduction of burden.
Behavior management techniques	Self-efficacy/ personal control theory	Individuals need to control daily life events to maintain positive affect and well-being. When faced with loss of control, caregivers are motivated to adapt new care strategies that enhance their control and improve self-efficacy. Improved self-efficacy leads to reduced burden.
Home environmental modifications	Competence-environmental press framework	Competence-environmental press framework emphasizes a just right fit between the individual and environment to optimize behavior. This suggests that a change in the environment to decrease its press will enhance abilities of the dementia patient to carry out tasks and reduce excess behaviors associated with the disease. Maintenance of function and control of difficult behaviors reduces objective caregiver burden.

elements allows researchers to discern the optimal conditions under which an intervention is effective. For instance, some evidence suggests that psychoeducational counseling enhances psychological resources and feelings of self-efficacy among caregivers (Mittleman, Ferris, Shulman, Steinberg, Ambinder, Mackell, & Cohen, 1995). However, it is unclear which delivery format (standard group or individualized session) and for which group of caregivers this intervention is most beneficial (Brodaty, Gresham, & Luscombe, 1997). Describing, manipulating, and testing conditions of delivery enable researchers to determine how changes in behavior, cognition, and/or affect occur. Developing an understanding of the basic elements of an intervention is necessary before service efficiency and effectiveness can be maximized (Basler, 1995).

Structural Dimensions of Interventions

To categorize the structural dimensions of interventions, REACH has developed two matrices from which to map and compare interventions (see chapter 2 for a complete description of the conceptual underpinning of this approach and definitions of the components of the matrices).

Attributes of Service Delivery. Briefly, one matrix characterizes 19 attributes of service delivery. Examples of these attributes include the frequency and duration of contacts, location of intervention (e.g., home versus clinic), and whether delivery is standardized (e.g., group-end goals), tailored (e.g., individualized goals), or involves others (e.g., care recipient, other family members). These dimensions represent the pragmatics of implementing an intervention, but are rarely described comprehensively in caregiver intervention studies. Nevertheless, these attributes may either hinder or enhance the enactment of treatment strategies by caregivers, and thus, are important to understanding mechanisms of action.

For example, each REACH intervention introduces behavior management strategies in some form to improve caregiver skills. However, the method of delivery and the care setting in which strategies are introduced vary across sites. Memphis REACH implements its interventions in a primary care setting; Palo Alto provides interventions in clinical settings, and Miami, Philadelphia, and Birmingham implement interventions in caregiver homes. REACH will be able to examine whether an attribute such as the setting of service delivery enhances or hinders caregiver acceptance and use of new skills. Investigators also will be able to discern the extent to which the setting of service delivery is a condition of an intervention that either enhances or hinders its effectiveness.

Domains Targeted for Change. The second matrix developed by REACH characterizes interventions in terms of two domains or aspects that an intervention targets for change. The first aspect concerns the primary entity that an intervention targets. Although the caregiver is the point of implementation of an intervention, the content of the intervention may target issues that are related to either caregivers, care recipient behaviors, and/or to the social (e.g., family, social supports) and/or physical environment (use of objects). Each intervention may be directed at any one or a combination of these three primary entities.

The second aspect of the matrix concerns the primary domain within each entity that is the focus or content of the intervention. Four domains have been identified. The intervention may seek to (1) build knowledge, (2) address cognitions, (3) change behaviors, or (4) improve affect. Again, any one intervention may target multiple areas. In summary, the primary entity and the domain of interventions represent two orthogonal dimensions which result in a 3 (entity) by 4 (domain) or 12 component matrix by which all caregiver interventions can be mapped (see chapter 2 to examine the matrix). For instance, a common intervention is to enhance caregiver understanding of the disease process using education materials. In this case, the primary entity that is the target of intervention is the care recipient and the disease process, and the primary domain or content is knowledge-building. Another common intervention is to enhance a caregiver's sense of mastery and well-being through support group programs. In this case, the primary entity that is the target of the intervention is the caregiver, and the domain or content of the intervention is cognitions. Thus, the mechanisms underlying a change in knowledge level via an education-based intervention may differ from the mechanisms underlying a change in cognitive processes that occur in a support group intervention.

This point is illustrated by a recent intervention study of women with breast cancer. This study compared an education-based intervention to a peer discussion group (Helgeson, Cohen, Schulz, & Yasko, in press) and evaluated mechanisms for the interventions' effects. Clear benefits were derived only in the education group and participants in the peer group demonstrated negative psychological outcomes. The primary mechanism by which patients benefitted from the education intervention centered on self-image. The authors showed that the educational materials normalized the experience of having breast cancer. In contrast, women in the peer group demonstrated negative effects because they increased their rate of negative downward comparisons. That is, they experienced greater anxiety by interacting with women who were worse off.

To further illustrate the utility of this approach, consider the three interventions that are being tested at Memphis REACH. Each intervention builds on the other so that there are incremental increases in duration, dose, and intensity from one group to the next. The most basic intervention is the Information and Referral group which has the lowest levels of duration, dose, and intensity. This intervention provides information about the disease process and referral to local resources for family caregivers. Thus, the intervention targets the domain of knowledge-building for two entities, the caregiver and care recipient. This is considered a minimal treatment group. Conversely, the Memphis Behavioral Care intervention provides information. Additionally, it introduces caregivers to behavior management techniques, presents coping strategies, and ways of modifying the social and physical environment. The intervention targets three entities: caregiver, care recipient, and the social/physical environment. The content of the intervention is directed at three domains improving knowledge building, behaviors, and affect. The third intervention, the Memphis Enhanced Care group, has the highest levels of duration, dose, and intensity. This intervention provides information about and referral to local resources, introduces and has caregivers practice behavior management techniques, presents coping strategies, and provides suggestions for modifying the social and physical environment. It not only targets the caregiver's and care recipient's cognition-knowledge, the care recipient's behavior and affect, but also the caregiver's cognition-skills, behavior, and affect. As in the second intervention group, this level of intervention also targets the caregiver's cognition-knowledge of the social and physical environment. Each of these interventions occur on-site at a primary care physician's office and involves repeated contacts with caregivers over two years.

The intervention tested by Philadelphia REACH provides a different set of contrasts along the 3 by 4 matrix. The Philadelphia intervention involves home visits during which multifaceted strategies are introduced to address specific caregiver-identified difficulties in managing dementia. Strategies include knowledge building about the progression of the disease, management techniques such as task breakdown and effective communication, and modifying the social and physical environment, including the use of adaptive equipment. The intervention is individualized and specific strategies are tailored to fit the particular concerns that are identified by the caregiver, the characteristics of the physical and social environment, and the level of function of the care recipient. Therefore, the intervention is directed at three primary entities: the caregiver, care recipient, and social/physical environment. The domains that are targeted include knowledge building and behavior change.

The two REACH matrices provide a categorical approach from which to analyze and contrast interventions along key elements of delivery and the specific target areas. For each cell of the matrix (e.g., care recipient by behavior), a different mechanism of action may be posed. REACH investigators will be able to use hierarchical analytic models to investigate the relationship between components of various interventions and treatment outcomes. Also, with this approach, REACH will be able to derive expanded measures for comparing and contrasting interventions. For example, dose, duration, and intensity measures (e.g., frequency and duration of contacts, and number of strategies introduced) can be combined with other dimensions such as method of contact, environmental setting, and/or the number of domains and entities that the intervention targets.

Process Dimensions of Interventions

To understand process dimensions of interventions, it is helpful to apply the concept of treatment fidelity. Typically, treatment fidelity refers to a set of measures that document treatment implementation. Measures serve two purposes. The first purpose is to examine the extent to which independent variables are manipulated (Moncher & Prinz, 1991). That is, fidelity assessments enable investigators to systematically analyze the relationship between process and treatment outcomes. The second purpose of fidelity assessment is to monitor the actions of interventionists to ensure consistency and adherence to study protocols. Since measures of treatment fidelity provide invaluable detail of content and procedures, the data informs the mechanisms by which the intervention achieves its effectiveness. Thus, treatment fidelity measures serve the dual purposes of determining the relationship between degree of implementation and treatment effects and monitoring the integrity and consistency of intervention implementation.

Lichstein, Riedel, and Grieve (1994) have recommended the systematic evaluation of three elements of treatment fidelity: treatment delivery, receipt, and enactment. These researchers also have recommended a number of strategies to enhance and measure each element. Although strategies must be customized to specific interventions, those developed by the REACH study group and summarized in Table 7.3, exemplify this approach.

Lichstein, Riedel, and Grieve (1994) describe treatment delivery as the degree to which an interventionist presents the treatment to participants as intended. Treatment delivery addresses basic questions such as whether interventionists are adequately trained and render the intervention consistently and accurately. Obviously, if an intervention is not delivered in the intended manner, it is not possible to interpret findings. A number of factors potentially threaten the ability to deliver an intervention according to protocol and thereby impede the mechanisms that lead to direct actions. These threats include, but are not limited to, the following conditions: a) the intervention is long-term, b) there are multiple components to its implementation, c) multiple experimental groups are being tested simultaneously, d) more than one interventionist is involved, and e) there is attrition of interventionists. Common strategies to enhance treatment delivery include development and use of a treatment manual, systematic training and a certification process for interventionists, and developing a mechanism for ongoing monitoring and feedback.

TABLE 7.3 Treatment Fidelity Enhancement Strategies and Measures

Fidelity component	Enhancement strategies	Measures
Delivery	• Manual guidance • Standard scripts • Protocol monitoring • Training interventionists	• Intended/actual dose • Intended/actual intensity • Characteristics of interventionists
Receipt	• Client-centered approach • Active therapeutic techniques (role play) • Use of visual-auditory aids	• Number and type of intervention strategies introduced • Record of who (CG or therapist) suggests strategy • Number and type of techniques used (role play, demonstration, video, etc.) • Knowledge gains
Enactment	• Provide opportunities to practice strategies • Provide intervention over long time frame	• Number and type of strategies in use (observation and self-report) • Reasons for nonuse/ abandonment • Caregiver report of effectiveness of each strategy

Treatment receipt refers to the extent to which study participants receive the treatment as intended. Potential threats to receipt include use of only one teaching method, a lack of sufficient opportunity to practice new strategies, and communication difficulties or cultural differences between interventionist and study participant (e.g., use of technical or medical terms, differences in value systems). Common strategies to enhance treatment receipt include the use of multiple active therapeutic techniques (e.g., role play, demonstration), use of multimedia (e.g., video, written materials), and an approach that is either client-centered or collaborative.

Treatment enactment refers to the extent to which study participants actually enact or apply the knowledge and skills learned in treatment. If participants do not use the knowledge and skills transmitted in intervention, then little benefit will likely be derived. Enactment then is an important component of treatment fidelity and represents a measure of intervention utilization.

MEASUREMENT CONSIDERATIONS

Thus far we have defined fidelity components and discussed methods to strengthen the mechanisms of delivery, receipt, and enactment of an intervention. The measurement of each of these components also is an important aspect in studying mechanisms of action. In developing measures of delivery, receipt, and enactment, several methodological issues must be considered. These are listed in Table 7.4.

To date, an accepted and standard set of measures to assess the components of treatment fidelity has not been developed. Consequently, investigators must develop their own assessments and test their psychometric properties. One recommended strategy to accomplish this task is to triangulate data by combining different data types and sources from which information is gathered. For example, to examine the receipt and enactment of intervention strategies, a rating scale can be devised by the investigator and completed by the interventionist, caregiver, another family member, and/or an independent, objective evaluator. Also, data can be collected using a range of methodologies including videotape or audiotape of inter-

TABLE 7.4 Measurement Considerations

- Source of ratings:
  - —Caregiver
  - —Observation
  - —Audio/videotape
  - —Interventionist
- Inter-rater reliability
- Validity
- Level of measurement
- Type of expected change:
  - —Change from absence to presence of a particular behavior
  - —Change from low to high occurrence of a particular behavior

vention sessions, fieldnotes/progress notes written by interventionists at each caregiver contact, caregiver narratives and personal journals, and/or behavioral logs that track the occurrence of targeted problem areas. These documents can then be coded and analyzed for evidence of delivery, receipt, and enactment. The data can also be triangulated to obtain validity or convergence of emerging themes and other findings.

The specific measures developed by the REACH study group and summarized in Table 7.3 illustrate the use of a range of effective strategies. To examine treatment delivery across study sites, REACH uses a standard form to document the dose, intensity, and other elements of delivery. This form records several aspects of each caregiver contact including its length, the setting, the presence of others, and who initiated contact. Summary scores can be derived to describe dose and intensity rates, variation in delivery settings, and the number of occasions in which others are involved in any one particular intervention. Another important measure of delivery assesses the personal characteristics of interventionists. REACH uses a simple demographic form that is completed for each interventionist at each site. Attributes such as race, age, years of experience, and gender will be examined in relation to treatment outcomes.

To measure treatment receipt, a variety of measures are being used by REACH sites. For example, some sites have developed forms that are completed by interventionists at each contact. These forms record detailed information such as the specific recommendation or strategy provided to a caregiver and at which contact the recommendation is offered, who initiates the strategy (e.g., caregiver, interventionist, both or other), and whether the strategy is attempted and ultimately enacted. These data will yield frequency distributions as to the number and type of recommended strategies offered for each caregiver problem area, the number and type of strategies that caregivers themselves derive during intervention, and the number and type of strategies successfully used.

Several REACH sites also measure caregiver knowledge to determine level of treatment receipt. Varied methodologies are used including audiotaping intervention contacts, having an objective evaluator randomly observe the interventionist and study participant, and, in two sites, using computer technology to record the number of times caregivers access the technology.

Finally, to measure treatment enactment, REACH sites have developed specific approaches tailored to the contours of their individual interventions. Direct observation of whether a caregiver uses recommended intervention techniques is perhaps the most reliable method for evaluating enactment. However, this approach may not always be feasible and may be augmented by self-report. Several REACH sites collect information from caregivers about the frequency with which they use each recommended strategy, reasons for abandoning a strategy or its nonuse, the length of time a particular strategy is used, and the perceived effectiveness of the strategy in addressing a problem area.

SUMMARY

Mechanisms of action have been inadequately addressed in AD family caregiver intervention research. To date, we can only speculate about the particular pathways through which behavioral, cognitive, or emotional changes occur in caregivers and/or care recipients as a consequence of intervention participation. In this chapter we have argued that future studies must not only test treatment effectiveness, but must also systematically identify the mechanisms through which interventions achieve or fail to achieve desired outcomes among diverse caregiving groups. To advance this new direction in caregiver research, a more rigorous approach to theory formulation and measurement of treatment implementation is necessary.

Recent progress in theory development, clinical trial methodology, and statistical techniques may contribute to advancing the study of mechanisms. Specifically, stress process models, motivational theories, and behavior change models are being used to predict a range of health-related behaviors, and may be particularly helpful in articulating the pathways through which treatment effects are achieved in caregiver interventions. Furthermore, to expand our understanding of mechanisms, intervention studies must include the systematic assessment of treatment processes as a measurement goal. To this end, the REACH study group has developed an effective categorization scheme for comparing interventions along 19 service delivery components and have devised a 3 by 4 matrix that summarizes the primary entities and domains that reflect the specific target areas of interventions. These matrices are useful in deriving summary scores and creating delivery indices from which to examine which elements contribute to and strengthen mechanisms of action. Additionally, the tripartite concept of treatment fidelity facilitates a methodical evaluation of treatment components from which to disentangle process from outcomes and discern the optimal conditions for delivering interventions.

Knowledge about why and how families derive benefit from formal intervention has immense clinical and theoretical import. The search for explanations as to why and how interventions work promises to yield significant knowledge about regulatory systems that guide caregiving activity and the conditions under which desired behavioral, cognitive, and/or affective change occurs. From such knowledge, interventions can be more effectively developed to meet the multiple needs of caregivers at each stage of caregiving and as the disease progresses.

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8

From Intervention Studies to Public Policy: Translating Research into Practice

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OVERVIEW

In the research arena, we can no longer be satisfied with conducting research and reporting scholarly findings. Rather, the scientific community, funding agencies, and the public increasingly expect researchers to report their findings in a manner that informs public policymakers' initiatives. Although researchers universally report the direct outcomes from their intervention studies, policy implications and outcomes are not necessarily discussed. In this chapter our intentions are to provide a background on the rationale for addressing policy issues in caregiving studies, to describe common cost analysis methodologies used in policy analyses, and to integrate examples that illustrate the linkage between research findings and public policy.