SECTION 1

BACKGROUND INFORMATION

DESCRIPTION OF PROJECT/STUDY DESIGN

Built upon the findings of REACH I, REACH II was funded in 2001 to design and test a single multi-component intervention among family caregivers of persons with Alzheimer's Disease or related disorders. The overall objectives of REACH II are to 1) identify and reduce modifiable risk factors among diverse family caregivers of patients with Alzheimer's Disease or a related disorder, 2) enhance the quality of care of the care recipients, and 3) enhance the well-being of the caregivers. This competing renewal will build on existing infrastructure and results obtained from its parent multi-site feasibility study, REACH I. REACH I explored the effectiveness of different interventions to reduce burden and distress of family caregivers in six participating sites. Detailed analyses of these data suggest specific components of the REACH I interventions may be efficacious in improving caregiver outcomes.

The design of the REACH II intervention is guided by a careful consideration of the existing literature as well as the experience and findings from REACH I. The overriding message from both of these sources is that caregiving presents multiple challenges that are not easily addressed. As a result, there exists no single, easily implemented, and consistently effective method for achieving clinically significant effects among caregivers or care recipients. The REACH II intervention approach targets multiple components of the stress-health model and focuses on five areas linked to caregiver stress health processes: safety, self-care, social support, emotional well-being; and problem behaviors. Because there is considerable variability in the needs of caregivers, we use a Risk Appraisal Questionnaire to determine how much emphasis we place on each of the treatment components. The tailoring of the intervention will be guided by the individual profiles of the Risk Appraisal. In order to deliver the intervention in a cost-effective manner we use a combination of in-home visits augmented by telephone based technology found to be effective in REACH I.

The study design is a multi-site, two group randomized clinical trial, comparing the active intervention to an information only control. Unlike REACH I, which implemented a variety of active interventions at 6 different sites, this study will implement the same two interventions at each of five participating sites: Birmingham, Memphis, Miami, Palo Alto, and Philadelphia. Across the five sites we expect to enter 600 (120 per site) caregiver-care recipient dyads with a goal of 510 completing the protocol. The 15% missing data rate at six months is based on data from REACH I (5% attrition, 10% missed visits). Differential attrition among race/ethnic groups was not found in REACH I and is not expected in the proposed study. The dyads will be randomized into two equal sized groups, a multi-component core intervention group or a standardized information-only control group. Equal numbers of African Americans/Blacks, Hispanics/Latinos, and Caucasians/Whites will be assigned to the two groups at each site. Thus, each site will enter 120 dyads (40 African Americans/Blacks, 40 Hispanics/Latinos, and 40 Caucasians/Whites) with the goal of completing the six-month assessment.

The study will be conducted in two study Phases. Phase 1 will involve intervention refinement and staff training in how to conduct the new intervention protocol; in Phase 2, the randomized clinical trial will be conducted. A uniform battery of predictor and outcome measures will be collected at baseline and six months. The primary outcome is a multivariate measure comprised of indicators in five domains: depressive symptoms, burden, self-care, social support, and change in problem behaviors. We predict that overall, individuals assigned to active treatment will demonstrate better outcomes on the composite multivariate measure than individuals assigned to the control condition. Cost-effectiveness and clinical significance of the intervention will also be evaluated.

To summarize, this study promises to:

- Test a potent multi-component intervention.
- Assess the intervention's impact on ethnically diverse populations.

- Provide new measurements for assessing the quality of care provided by caregivers and tools for identifying caregivers at risk for adverse outcomes.

- Evaluate the cost effectiveness and public health significance of the intervention.

PROJECT TIMELINE

The REACH II study will extend for three years (see Table below). During the first eight months of the study, the Principal Investigators of the intervention sites and the Coordinating Center as well as the NIA and NINR Program Officers will meet three times to refine the intervention, develop and translate the intervention materials and new/modified measures, and train and certify the interventionists and assessors. A Hispanic/Latino interventionist and assessor will be recruited at each site. Dyads will be recruited and entered into the study starting at Month 9; recruitment will continue until Month 27, and the final six-month assessment will occur at Month 33. The analyses will be conducted and the final report generated during Months 34-36.

	YEAR 1	YEAR 2	YEAR 3
Development (months 1 – 8) • Refinement of Intervention • Development/Translation of Intervention Materials and New/Modified Measures • Training and Certification in Interventionists • Training and Certification of Interviewers	********		
Rolling Recruitment and Baseline Assessment (months 9 – 27)	****	**********	***
Intervention/Assessment (months 9 – 33)	****	**********	*********
Analyses and Final Report (months 34 – 36)			***

* = 1 month

How Will This Study Be Conducted?

Five Universities have been funded by the National Institute on Aging (NIA) and the National Institute of Nursing Research (NINR) components of the National Institutes of Health to carry out the REACH II intervention. A Coordinating Center will perform a variety of administrative and support functions, handle information collected by each team, and contribute study design and statistical expertise

What Happens To the Answers Caregivers Provide?

All information collected is strictly confidential. The identities of participants will never be released. A report of the results will be available to participants after the study is completed.

How Can I Get More Information?

For further information, contact the Coordinating Center:

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Reach II

Resources For Enhancing Alzheimer's Caregiver Health

Sponsored by the

National Institutes of Health
National Institute on Aging
National Institute of Nursing Research

Reach II

Resources For Enhancing Alzheimer's Caregiver Health

6 Million Americans Currently Have Memory Problems: More than Half Are Cared for at Home by Spouses, Relatives, and Friends.

What Is This Study About?

REACH II (Resources for Enhancing Alzheimer's Caregiver Health) is an initiative started in 2001 by the National Institutes of Health. Its primary purpose is to test a multicomponent intervention among family caregivers of persons with Alzheimer's Disease or related disorders. This intervention seeks to increase caregiver knowledge, skills, and well being while enhancing support to the caregiver.

Why Is This Study Being Conducted?

Millions of older Americans are afflicted with Alzheimer's Disease or a related disorder. More than half of those affected are cared for in the community by family members, and the number of these family caregivers is expected to increase significantly as the population ages. Caregivers of people with Alzheimer's Disease or a related disorder often face significant emotional distress, as well as extreme physical and financial difficulties. In some cases, caregivers must also deal with apathy or hostile behavior from the person receiving care. This informal network of family caregivers provides an extremely important and often difficult service to loved ones and to society. The REACH II project hopes to discover new ways of helping these caregivers.

Who Is Asked To Participate?

Caregivers of family members with diagnoses of Alzheimer's Disease or related disorders will be asked to participate in the study. REACH II is particularly interested in learning about the interventions impact on minority populations, such as African-Americans and Hispanics.

What Does Participation In the Study Involve?

During the 6-month ***REACH II*** program, participants are assigned by chance to one of two groups. The groups will be offered the same information but on different time schedules and in different ways. One group will receive the information during home visits by a member of the research team, who will review the material with them. This group will also be given a touch-tone screen/phone system that works like a normal telephone but will also allow them to obtain information from the research team. The other group will receive the information in a caregiving workshop at which time other resources and services will be offered.

Both groups will receive payment for answering a series of questions during two interviews in their home. There is no cost for any part of the program.

The project staff will offer caregivers information about:

- Community resources
- Caregiving and memory loss
- Ways to manage behavior problems
- Coping strategies and ways to handle stress

What Kind of Questions Will Be Asked?

Interview questions will cover a wide range of topics, including the health and functioning of the person with Alzheimer's Disease or a related disorder as well as the well-being, health, responsibilities, and roles of the caregiver.