#### Background

The personal, social, and health impacts of caregiving have been well documented in recent years (Ory, Hoffman, Yee, Tennstedt, & Schulz, 1999; Schulz & Beach, 1999; Schulz, 2000; Schulz, O'Brien, Bookwala, & Fleissner, 1995). These findings in turn have generated intervention studies aimed at addressing the burden, distress, and health-related morbidity associated with caregiving. The majority of intervention studies have focused on caregivers of persons with progressively dementing illnesses such as Alzheimer's disease (AD). Using a wide variety of intervention approaches, researchers have been able to achieve small to moderate decreases in burden and depression and, in a few cases, impressive clinically meaningful outcomes (Schulz, 2000; Schulz et al., under review). Similar results have been reported for the intervention literature overall. A recent meta-analysis of the caregiver intervention literature reports that interventions produced significant improvement of .14 to .41 standard deviation units, on average, for caregiver burden, depression, and subjective well-being (Sorensen, Pinquart, & Duberstein, in press). However, these conclusions need to be qualified by a host of methodological problems that still characterize much of this literature. First, sample sizes are often too small to detect even large effects (Cooke et al., 2001), and minority populations are not well represented in intervention trials. Second, randomized controlled trial methods have been used infrequently and are often implemented incompletely. Third, interventions are not well described, and treatment implementation data are infrequently collected or reported (Burgio et al., 2001). Finally, the proportion of studies reporting clinically significant outcomes for important public health indicators is relatively small (Schulz et al., under review).

REACH I addressed several of these shortcomings by implementing six different randomized clinical trials at six different sites using identical measurement intervals and common outcome measures. Studies included relatively large sample sizes (N =1222 total) with significant numbers of African American and Hispanic caregivers. Interventions were carefully described and implemented. Meta-analysis was used to examine pooled parameter estimates of 9 active compared to 6 control group conditions of REACH at 6-months on burden and depressive symptoms in family caregivers (Gitlin et al., submitted). Associations of caregiver relationship, gender, education, racial/ethnic identity and treatment outcomes were examined. For burden, active interventions were superior to control conditions. Also, active interventions were superior to control conditions for women but not for men, and for caregivers with < high school education but not for those with higher education. For depressive symptoms, a statistically significant association of group assignment was found for Miami's combined family therapy and computer technology intervention. Also, active interventions were superior to control conditions for caregivers who were Hispanic, non-spouses or of lower education. Analyses based on a conceptual framework developed by REACH investigators showed that interventions using hands-on training modalities such as role play, modeling, demonstration and practice were most effective in reducing depressive symptomatology (Czaja et al., submitted; Belle et al., submitted). Finally, the data suggest that caregivers are receptive to and benefit from new technology (the CTIS system) that facilitates communication and information access. Overall, these findings suggest that interventions need to be responsive to important variations in need among caregivers and should therefore have some degree of tailoring to the individual, and that there are specific components and delivery methods likely to enhance the effectiveness of an intervention.

#### Rationale for REACH II Intervention

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 is no single, easily implemented, and consistently effective method for achieving clinically significant effects among caregivers or care recipients.

One of the disappointments in the caregiving intervention research literature has been the relative lack of success in achieving clinically significant outcomes. Researchers have achieved small to moderate statistically significant outcomes on a wide variety of indicators such as depressive symptoms, burden, and other indicators of psychological well-being. The lack of strong findings is in part due to the misapplication of intervention approaches borrowed from medical and psychotherapeutic approaches. With rare exception, caregivers typically do not fall into single syndromal clinical categories that lend themselves to a clearly targeted intervention. For example, although most caregivers have elevated levels of depressive symptoms they do not meet criteria for clinical depression. Thus, unless one targets specific subgroups of caregivers who are clinically depressed, the ability to demonstrate large effects is constrained by the moderate level of the problem being addressed and the limited range of improvement possible. In general, caregivers can be characterized as having problems in multiple interrelated domains which exist at varying, but typically not extreme, levels of intensity. The intervention approach selected for this study is based on this assumption and is designed to maximize outcomes in multiple different domains by tailoring the intervention to respond to individual variation in risk.

Virtually all caregiving interventions involve several treatment elements aimed at simultaneously addressing multiple problems. Multi-component interventions delivered in high doses are generally more effective than more narrowly targeted interventions (Schulz, 2000; Sorensen et al., in press). Although we subscribe to the multi-component approach to caregiver interventions, we diverge from the existing literature in an important way. Based on our assessment of the existing literature and the experience of REACH I, we believe a 'one size fits all' approach to caregiver interventions is likely to be ineffective. Because of the diversity of challenges inherent in the caregiving situation, interventions need to allow for some degree of tailoring of intervention components to meet the specific needs of the individual. Thus, we subscribe to a structured – but at the same time, tailored – approach to delivering interventions that are responsive to individual risk profiles.

Figure 1 illustrates the stress-health process, the overarching framework we use in REACH. Figure 2 shows how various components of the intervention we plan to test might impact on each element of the stress-health process. The goal of a multi-component intervention is to reduce stressors, enhance the individual's capacity to deal with stressors, and change negative emotional and behavioral responses of the caregiver and care recipient. This, in turn, should decrease the risk for mental and physical health problems. Our 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/care recipients, we use a risk appraisal approach to determine how much emphasis we place on each of the treatment components. Thus, the intervention is standardized with respect to the treatment components available, but varies with respect to the dosing or depth of treatment delivered for each of the available treatment components. The tailoring of the intervention will be guided by the individual profiles of the Risk Appraisal For example, persons in active treatment who have minimal problems with depression will receive only a small dose of the intervention component designed to enhance emotional well-being. This will enable the interventionist to concentrate on those areas where risk factors are higher.

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 outcomes assessment approach is consistent with the multiple risk factors intervention approach described above in that our primary outcome is a multivariate measure comprised of indicators in five domains: depressive symptoms, burden, self care, social support, and change in problem behaviors. Thus, we predict that overall, individuals assigned to active treatment will demonstrate better outcomes on our composite multivariate measure than individuals assigned to the control condition.

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# Figure 1 REACH Stress-health Process Model



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Figure 2. Hypothesized impact of various intervention components on the stress-health process applied to caregivers.



## **Flowchart of REACH II Intervention Protocol**

