

Practice Concepts

The Gerontologist
Vol. 46, No. 6, 827-832

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Project CARE: A Randomized Controlled Trial of a Behavioral Intervention Group for Alzheimer's Disease Caregivers

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Purpose: The neuropsychiatric symptoms associated with Alzheimer's disease are a major contributor to caregiver distress and burden. Despite recent efforts to teach caregivers skills to manage neuropsychiatric symptoms and reduce burden, there continues to be limited evidence that these strategies have helped caregivers of individuals with Alzheimer's disease to effectively manage neuropsychiatric symptoms. We report here on Project CARE, a randomized controlled trial designed to test the effectiveness of a caregiver-based multicomponent behavioral intervention aimed to reduce caregiver distress related to neuropsychiatric symptoms, as well as general caregiver burden, and to decrease neuropsychiatric symptom severity among individuals with Alzheimer's disease. **Design and Methods:** The behavioral intervention involved five weekly sessions designed to teach caregivers specific techniques for managing patient neuropsychiatric symptoms in the home environment. Through the use of a randomized control trial, 80 caregivers were assigned to either the behavioral intervention group or a psycho-

educational control group and were assessed both before and after the intervention. **Results:** Compared with caregivers in the control group, caregivers in the behavioral intervention group displayed significantly greater reductions in caregiver distress related to neuropsychiatric symptoms ($p = .005$). Global caregiver burden, however, did not decrease significantly for caregivers in either group ($p > .05$). Although it was not statistically significant, there was a trend toward greater reductions in care recipients' neuropsychiatric symptom severity in the intervention group ($p = .10$). **Implications:** The current findings suggest that targeted, group-based behavioral interventions are effective for reducing distress related to neuropsychiatric symptoms among caregivers of individuals with Alzheimer's disease and for reducing care recipients' neuropsychiatric symptoms.

Key Words: *Alzheimer's disease, Burden, Caregiver interventions, Neuropsychiatric symptoms*

This research was funded by grants from the Alzheimer's Association of America and the John A. Hartford Foundation. We especially thank all the caregivers who participated in this project.

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Neuropsychiatric symptoms occur in more than 80% of individuals with Alzheimer's disease (Teri, Borson, Kiyak, & Yamagishi, 1989) and are major contributors to distress among family caregivers (Cohen et al., 1993; Rymer et al., 2002; Teri, 1997; Victoroff, Mack, & Nielson, 1998). Neuropsychiatric symptoms include apathy, irritability or agitation, anxiety, and depression, among others (Cohen et al.; Cummings &

Victoroff, 1990; Teri, Larson, & Reifler, 1988). Previous research has shown that neuropsychiatric symptoms of individuals with Alzheimer's disease are associated with a decrease in caregivers' psychological well-being and an increase in caregiver distress and burden (Markowitz, Gotterman, Sadik, & Papadopoulos, 2003; Pinquart & Sorensen, 2003); these symptoms also are a leading precipitant to nursing home placement of care recipients (de Vugt et al., 2005; Steele, Rovner, Chase, & Folstein, 1990).

Awareness of the many negative consequences that neuropsychiatric symptoms have on the well-being of individuals with dementia and their caregivers has prompted intervention studies designed to reduce neuropsychiatric symptoms and the burden they produce for caregivers. Most of the early interventions designed for Alzheimer's caregivers were broad in nature and scope, typically providing general information about the disease process, stress-management skills, some access to community resources, and, perhaps most notably, peer support. However, the results of studies evaluating the effectiveness of such interventions generally indicated only modest, if any, beneficial effects on specific outcomes (Brodsky, Green, & Koschera, 2003; Schulz et al., 2002). A number of methodological issues, including the lack of focused interventions, the absence of random assignment to treatment condition or control groups, and the use of nonequivalent treatment populations across studies, make it difficult to draw conclusions about treatment effectiveness.

The Resources for Enhancing Alzheimer's Caregiver Health or REACH I and II initiatives of the National Institutes of Health have been important catalysts in advancing caregiver intervention research. Although different intervention strategies were tested at the six REACH sites (Boston, Birmingham, Memphis, Miami, Palo Alto, and Philadelphia), they shared a common goal of seeking to change specific caregiving stressors, caregivers' appraisals, or caregivers' responses to the stressors (Schulz et al., 2003). Together, the findings from REACH's multisite studies offer evidence that targeted, multicomponent interventions may be more effective than broader psychoeducational interventions, and thus they are contributing to a new generation of caregiver interventions. Of particular relevance is the Palo Alto site study assessing the benefits of Coping With Caregiving (CWC), a psychoeducational, skill-building group approach for reducing caregivers' psychological distress (Gallagher-Thompson et al., 2003). Participants in the CWC intervention, which was based on principles of cognitive behavioral therapy, reported significant declines in depressive symptoms and an increase use of adaptive coping strategies. However, the intensity of the CWC intervention—10 weekly session followed by 8 monthly sessions—may exceed the resources of some agencies and caregivers and suggests a need to also test shorter term interventions.

In order to examine the potential utility of a brief, targeted, multicomponent group intervention for Alzheimer's caregivers, we conducted Project CARE, a randomized controlled trial designed to examine the

effectiveness of a 5-week behavioral intervention aimed to reduce caregiver distress related to neuropsychiatric symptoms of patients with Alzheimer's disease, as well as general caregiver burden, and to decrease neuropsychiatric symptoms among individuals with dementia. The behavioral intervention utilizes three primary behavioral components including behavioral management training, pleasant events training, and relaxation training. We chose to test the effectiveness of this intervention through the use of a group format, as it allowed us the opportunity to offer peer support and reach a greater number of caregivers.

The current study focuses on outcomes after completion of the intervention (6 weeks after baseline assessment) and compares the effectiveness of the intervention group with a standard psychoeducational control group. Specifically, we tested three hypotheses:

1. Caregivers in the intervention group would show significantly greater post-treatment reductions in distress related to patients' neuropsychiatric symptoms than would caregivers in the control group.
2. Caregivers in the intervention group would show significantly greater reductions in global burden than would caregivers in the control group.
3. Care recipients in the intervention group would show significantly greater reductions in neuropsychiatric symptom severity than would care recipients in the control group.

Methods

Recruitment and Participant Eligibility

We recruited Project Care participants from the greater Boston metropolitan area by means of newspaper advertisements, flyers, community-based lectures, and referrals from elder day programs. Criteria for study inclusion were as follows: (a) the caregiver provides a weekly minimum of 4 hours of caregiving; (b) the care recipient carries a physician-confirmed diagnosis of Alzheimer's disease; (c) the care recipient's level of dementia severity falls in the mild to moderate range, as determined by a Mini-Mental State Examination (Folstein, Folstein, & McHugh, 1975) score of 10 or higher; (d) the care recipient is reported to have at least one neuropsychiatric symptom at the time of enrollment; and (e) the caregiver is willing to accept random assignment to the behavioral experimental approach or the psychoeducation usual care control approach.

Research Design and Timeline

We conducted a randomized, controlled clinical trial with preintervention and postintervention assessments. First, after reviewing the potential benefits and risks associated with study participation with the eligible caregivers and gathering their informed consent, a trained interviewer met with the caregivers

Table 1. Behavioral Intervention Group: Session Topics and Description

1. Introduction: Overview of Group Goals and Guidelines

Caregivers introduce themselves to begin to foster group rapport. Therapists give overview of Alzheimer's disease and caregiver burden. They describe the neuropsychiatric symptoms associated with Alzheimer's disease; explain that they, like memory loss, are symptoms of the disease; and describe the importance of increasing pleasant activities as one method for improving care recipients' behavior the caregiver-care recipient relationship. Therapists present the Pleasant Activity Log. Caregiver homework: record daily pleasant activities; generate three ideas for future pleasant events.

2. Increasing Pleasant Events and Improving Communication

Therapists review homework; discuss the importance of engaging in pleasant events as a method for improving care recipients' behavior; suggest possible pleasant events and strategies for generating personal ideas of pleasant activities; and provide education about how to increase pleasant activities. They discuss strategies to improve communication. Caregiver homework: engage in one new pleasant activity daily and record in log; generate additional ideas for pleasant events; compliment the individual with dementia at least one time every day.

3. Increasing Pleasant Events and Understanding Behavior

Therapists review homework; discuss strategies for increasing pleasant events; and problem solve around difficulties that may have occurred as caregivers attempted to engage in pleasant activities. They introduce behavioral management theory: they teach how to identify and define problem behaviors, and their antecedents, and consequences. They discuss triggers for problem behaviors and how they can be avoided. Caregiver homework: engage in one pleasant activity daily; identify and record three patient problem behaviors, when they occur, why they are upsetting, and how they have to be changed.

4. Understanding and Changing Difficult Behaviors

Therapists review homework; review definition of problem behaviors, their antecedents, and consequences; and present the ABC behavioral chain and teach behavior modification techniques. They help caregivers practice goal setting and methods for changing problem behaviors in the home. Caregiver homework: Add one more pleasant event every day; choose one difficult behavior and attempt to modify it on the basis of the presented and practiced strategies.

5. Final Review: Where Do We Go From Here?

Therapists review homework; review lessons on understanding behavior, behavior modification techniques, and the ABCs of behavior; problem solve difficulties caregivers had in modifying behaviors at home; and provide guidance on how to continue using these new skills in the future. With the caregivers, they discuss and explore plans for and thoughts about the future. They recognize the completion of the group, participant contributions, personal growth, challenges, and willingness to participate and share.

to administer the baseline interview. We then assigned participants by block randomization to one of the two conditions: the behavioral intervention group (experimental group) or the psychoeducational group (control group). Group interventions began within 1 week of the baseline assessment. Post-treatment assessment was conducted within 1 week after the completion of the intervention.

Intervention Descriptions

Both the intervention and control groups were run over the course of 5 weeks, with each group meeting once a week for 90 minutes. Only caregivers participated in the groups; care recipients did not. Groups were highly structured and typically were conducted with 5 to 10 members; over the course of the study, we ran a total of 10 groups. When necessary, we provided caregivers with transportation vouchers to assist with the cost of attending groups. In most cases, when caregivers required respite care, we were also able to make these arrangements if the individual with Alzheimer's disease could come to the group site.

The therapists conducting the interventions participated in 16 to 20 hours of training in the intervention protocols, which included both didactic and experiential training. To monitor treatment fidelity throughout the study, the principal investigator consulted with the

therapists on a regular basis to review the group session experience and assess group progress. The content of the intervention and control groups is described in more detail in the paragraphs that follow and in Table 1. Caregivers in both conditions received equal contact time with group leaders.

We based the behavioral intervention on the principles of behavior therapy and behavioral activation, and we designed it to teach caregivers specific behavioral techniques for managing care recipients' neuropsychiatric symptoms in the home environment. For example, caregivers were taught to identify problem behaviors, determine their antecedents and consequences, set reasonable goals regarding behavior change, practice behavior modification and behavioral activation techniques, and make successive approximations toward reaching larger goals. Increasing caregivers' and care recipients' involvement in pleasant activities also was an important component of the intervention. Finally, caregivers were offered guidance regarding other techniques (e.g., relaxation) to manage their own levels of distress. Caregivers also were given approximately 15 minutes each session to discuss personal challenges, share their experiences doing the homework, and receive peer support. Table 1 further summarizes the content and objectives of the intervention.

The control group was similarly structured, but its content consisted of only general information on aging and Alzheimer's disease (e.g., its causes, course, and

Table 2. Means and Standard Deviations for Outcome Measures

Measures	Behavioral Intervention M (SD)	Psychoeducational Intervention M (SD)
NPI distress		
Preintervention	11.18 (6.61)	11.45 (7.46)
Postintervention	7.23 (3.97)	10.00 (6.22)
ZBI		
Preintervention	17.38 (8.33)	18.62 (7.53)
Postintervention	16.55 (7.39)	18.77 (7.94)
NPI severity		
Preintervention	22.85 (12.99)	21.73 (12.85)
Postintervention	16.38 (10.12)	19.40 (12.33)

Notes: SD = standard deviation; NPI = Neuropsychiatric Inventory (Cummings et al., 1994); ZBI = Zarit Burden Inventory (O'Rourke & Tuokko, 2003); for both the behavioral and psychoeducational interventions, $n = 40$.

treatment), home safety tips, techniques for improved communication, and support.

Primary Outcome Measures

We assessed care recipients' neuropsychiatric symptoms by using the Neuropsychiatric Inventory (Cummings et al., 1994). This clinician-administered interview was designed to assess the frequency and severity of neuropsychiatric symptoms of individuals with Alzheimer's disease. Ten symptoms are assessed: delusions, hallucinations, agitation or aggression, depression or dysphoria, anxiety, elation or euphoria, apathy or indifference, disinhibition, irritability or lability, and aberrant motor behavior. Symptom presence or absence is assessed first. If a symptom is present, its frequency is rated on a scale of 1 (occasionally, less than once per week) to 4 (very frequently, once or more per day). Scores are summed to provide a total symptom-frequency rating. Symptom severity is rated on a scale of 1 (mild) to 3 (marked). Frequency and severity scores are multiplied to provide a total score, with higher scores reflecting greater neuropsychiatric impairment. The Neuropsychiatric Inventory also provides a measure of caregiver distress as it relates to neuropsychiatric symptoms. Caregivers are asked to provide a rating from 0 (not at all distressed) to 5 (very distressed) indicating how distressed they are by each of the 10 problems areas assessed. Scores are then summed to provide a total distress score ranging from 0 to 50, with higher scores reflecting greater distress.

We measured caregiver burden by using an abridged version of the Zarit Burden Interview (ZBI; O'Rourke & Tuokko, 2003). This 12-item interview assesses those aspects of caregiving most frequently described as burdensome, including patient needs, patient-caregiver interactions, caregiver well-being, and social functioning. Individual items are rated on a 5-point scale ranging from 0 (never) to 4 (nearly always). The Zarit Burden Interview yields a total score ranging

from 0 to 48, with higher scores reflecting greater burden.

Analysis

Our first analytic step was to examine the baseline characteristics of the caregivers on demographic and outcome variables by using chi-square and analysis of variance tests, as appropriate, to identify possible differences between the intervention group and the control group participants at baseline. Second, we assessed intervention effects on the outcome measures by using an analysis of covariance. In these analyses, the outcome variable was the post-treatment 6-week score; the independent variable was the intervention condition; and the covariate was the baseline or pretreatment value of the outcome variable. We conducted all analyses by using SPSS Version 13. We chose a two-tailed value of $p < .05$ as the cutoff for statistical significance.

Results

We recruited and randomized 91 caregivers into the project, and we achieved high participant retention in both groups over time. Eighty participants completed the intervention (with approximately 88% of these individuals attending at least 4 of 5 weekly sessions) as well as the postintervention assessment. The 11 caregivers who discontinued participation in the study or did not complete a minimum of two sessions are not included in our analysis; these individuals did not differ significantly in terms of the baseline rating on the three outcome measures ($p > .05$).

Our final sample of 80 caregivers included mostly spouses (59%) or adult children (32%) of individuals with Alzheimer's disease. The majority of caregivers were female (67%) and Caucasian (94%), and their average age was 64.4 years ($SD = 13.8$ years). The vast majority of caregivers (87%) lived with the individual for whom they were caring, and the average length of caregiving was 3.5 years ($SD = 2.5$ years). The care recipients had a mean age of 77 years ($SD = 6.9$ years) and typically had moderate levels of functional impairment as measured by the Lawton and Brody Activities of Daily Living Questionnaire ($M = 10.9$, $SD = 5.1$). There were no statistically significant differences at baseline between the 40 participants in the intervention group and the 40 participants in the control group on any of the caregiver or care recipient demographic and outcome measures ($p > .05$).

Table 2 presents pretreatment and post-treatment means and standard deviations for the intervention group and the control group on the three outcome measures: caregiver distress related to neuropsychiatric symptoms, overall caregiver burden, and patient neuropsychiatric symptom severity.

Our first hypothesis was that the intervention group would experience a decline in neuropsychiatric symptom-related distress, and this was supported. Caregivers in the intervention group reported a significantly greater post-treatment reduction in caregiver

distress related to neuropsychiatric symptoms than did caregivers in the control group: $F(1, 78) = 8.28, p = .005$. As shown in Table 2, the trajectories for the intervention and control groups differed dramatically. Our second hypothesis was that the intervention group would experience greater post-treatment declines in global caregiver burden. Contrary to our expectation, we did not find a significant difference between groups: $F(1, 77) = 1.32, p = .26$. As Table 2 shows, caregivers' overall level of burden did not decline in either group. Thus, although the intervention effectively reduced caregiver distress related to the neuropsychiatric symptoms of care recipients, it did not diminish the overall level of burden perceived by caregivers. Our third hypothesis was that the intervention group would experience a greater post-treatment reduction in neuropsychiatric symptom severity. Although the difference was not statistically significant, our analysis did reveal a trend in the predicted direction: $F(1, 78) = 3.48, p = .10$. Intratreatment-group analyses found that the neuropsychiatric symptoms tended to decrease for intervention group participants ($p = .01$) but not for the control group participants ($p = .21$).

Discussion

Project Care was initiated to examine the effectiveness of a focused, behavioral intervention group designed to teach caregivers of individuals with Alzheimer's disease behavioral modification techniques for managing neuropsychiatric symptoms in the home environment. Our primary goals were to reduce caregiver distress related to neuropsychiatric symptoms, reduce overall caregiver burden, and decrease neuropsychiatric symptom severity among care recipients. The behavioral intervention was effective in reducing caregiver distress related specifically to neuropsychiatric symptoms as compared with the control group, but neither the intervention nor the control group was successful in reducing overall caregiver burden. The intervention also effectively reduced the severity of care recipients' neuropsychiatric symptoms from preintervention to postintervention.

Findings from the present study suggest that targeted caregiver interventions may be beneficial for specific purposes. Most previous caregiver interventions have been broad in nature, and such interventions appear to have modest, if any, beneficial effects. Our intervention was highly specific in nature and aimed to teach caregivers behavioral techniques for managing neuropsychiatric symptoms in the home environment. Our findings suggest that this intervention was successful in this regard.

Although we hypothesized that caregivers in the intervention group would show significant reductions in their overall levels of caregiver burden, contrary to our expectation, the overall level of burden was not significantly reduced in either group. There are a few potential reasons for the lack of effect; perhaps most notably, caregiver burden is a general construct that is impacted by many factors, including financial, emotional, and social stressors. A targeted interven-

tion such as ours may not be sufficient to effectively impact enough of these factors to influence overall burden. Another possible reason for the lack of a reduction in overall burden is that the experience of burden may be related to internal caregiver attributes that are not easily amenable to change. Similar to the theory of a biological *set point* for the experience of positive and negative affect (Rowe, 2001), individual caregivers may possess a set point for experiencing feelings of burden. If this is the case, then burden may be only partially determined by situational factors. Given the numerous contributors to burden and the complexity of caregiver burden as a measurable construct, we may expect that targeted interventions would be relatively unsuccessful in changing the level of overall burden perceived by caregivers.

This study makes two important contributions to the field. First, the study adds to the growing body of literature that suggests that targeted interventions based on the principles of behavioral therapy are effective in helping families cope with stresses of caregiving. Second, it provides evidence of the effectiveness of a brief intervention; this reduced time commitment may be of particular importance to already busy caregivers of individuals with Alzheimer's disease, many of whom have limited respite care options.

There are, however, several limitations to our research. We relied on caregivers' self-report of neuropsychiatric symptom severity; therefore, future research should be undertaken to validate our findings with an objective measure. It was also not possible to blind all interviewers to the caregiver's treatment condition at the postintervention assessment. Furthermore, although we routinely asked for copies of caregivers' homework, thereby having a sense that the majority of the caregivers were using the therapeutic techniques in their home environments, not all caregivers chose to submit their work. Finally, it is important to note the low rate of participation by ethnically and racially diverse individuals, which limits the generalizability of our findings to diverse populations. Minority groups are unstudied in Alzheimer's disease research, and the importance of tailoring treatments to an ethnically diverse audience is increasingly being recognized (Aranda & Knight, 1997; Austrom et al., 2004).

Although our findings suggest that targeted group-based multicomponent interventions may be effective for use with caregivers of individuals with Alzheimer's disease, we recognize that caregivers are often challenged to find the time and resources needed to attend such groups outside the home. Future studies should attempt to develop and test targeted interventions that use new technologies to capitalize on the advantages they offer. For example, Internet-based interventions may have great potential to reach homebound caregivers or caregivers who live in areas where resources are not available (Eisdorfer et al., 2003; Klemm & Wheeler, 2005). Burgio, Stevens, Guy, Roth, and Haley (2003) reported on an intervention designed to reduce neuropsychiatric symptoms and related caregiver distress that utilized a one-time group workshop in combination with follow-up home-based training.

Adapting some or all of our behavioral intervention by using such technology, perhaps to include a home-based component, may also represent an area for future investigation.

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Received November 15, 2005

Accepted March 10, 2006

Decision Editor: Nancy Morrow-Howell, PhD