Targeting and Managing Behavioral Symptoms in Individuals with Dementia: A Randomized Trial of a Nonpharmacologic Intervention Neha Shah, Trisha Parekh

Laura Gitlin, PhD, Laraine Winter, PhD, Marie Dennis, PhD, EdM, Nancy Hodgson, PhD, RN, Walter Hauck, Phd. JAGS 58:1465-1474, 2010.

Clinical Bottom Line: Targeting problematic behaviors in patients with dementia and teaching caregivers skills to modifying triggers promotes caregiver well-being and improve patient's symptoms.

Introduction: Neuropsychiatric behaviors can be very challenging for caregivers of individuals with dementia. Behavioral symptoms greatly affect family members, and leads to increased cost of care, greater risk of nursing home placement, and greater mortality. Frequently to manage behavioral problems individuals are given atypical antipsychotic drugs. However, this off label use comes with its own risks and does not address behaviors like refusal of care, repetitive vocalizations, and argumentation. Thus, it is important to try nonpharmacological treatment modalities first.

Objectives: To test the effects of an intervention that helps families manage difficult and distressing behaviors in other family members with dementia.

Source of Funding: National Institute on Aging and National Institute on Nursing Research Grant RO1 AG22254.

Study Design: This is a two-group randomized trial with follow up at 16 and 24 weeks. Participants were recruited from media announcements and mailings by social agencies. The respondents were called and screened for eligibility. Written informed consent for the caregiver and proxy patient was obtained at the beginning. After the patient was assessed using an institutional approved form they were randomized to Advancing Caregiving Training (ACT) or no treatment group. Caregivers were interviewed at 16 and 24 weeks in which the interviewers were no aware of which group participants were in. Participants were separated based on whether or not they were the spouse. Randomization was based on permuted blocks and assigning blocking numbers unknown to others.

Interventions: Patient behavioral problems were conceptualized in ACT by breaking them down into 3 causing categories. The first was patient based such as unmet needs, pain, or medical conditions. The second was caregiver based such as stress, communication style. The third was environmental based like hazards and clutter. ACT hoped to reduce caregiver upset by giving them the proper tools to deal with problem behaviors. ACT includes up to 9 OT sessions and 2 nursing sessions (one home and one telephone) within the first 16 weeks. Between weeks 16 and 24 there was 3 OT phone sessions for reinforcement. Occupational therapists used standardized checklists to

identify caregiver communication styles, went over home safety, and reviewed behavior problems. Caregivers were taught self care and stress reducing techniques. Assistive devices like grab bars and monitors were given to reduce burden. The nurse met with caregivers to education on medical problems that can exacerbate behavioral problems. Labs were ordered to reveal any other underlying illnesses. The workup included a BMP, thyroid studies, and culture and sensitivity on urine samples.

Participants: 272 caregivers and people with dementia. 137 in the Advancing Caregiver Training group and 135 in the control group

Inclusion Criteria: Caregivers living with individuals with a Mini-Mental State Exam score less than 24 and were over the age of 21. Spoke English, planned on living in the area for 6 months, not actively searching for nursing home placement, and reports a >5 score out of 10 for caregiver upset.

Exclusion Criteria: Individuals with a terminal illness with less than 6 months to live, undergoing cancer treatments, has had more than 3 acute hospitalizations in the past year, enrolled in another trial for problem behaviors, schizophrenia, bipolar disorder, dementia secondary to head trauma, MMSE score of 0 and are bed bound, and those that are nonresponsive were excluded.

Primary Outcome Measures: Primary outcome for the patient was the frequency of the targeted problem behaviors. At baseline caregivers chose which of the 23 behaviors were most present in the past month and how often it occurred. Caregivers also chose which one behavior they found to be the most distressing. The problem behavior picked at baseline was reassessed at 16 weeks for its frequency. Primary caregiver outcomes are caregiver upset on a scale of 1 to 10 and caregiver confidence in managing problematic behavior on a scale of 1 to 4.

Secondary Outcome Measures: Outcomes for caregiver well-being, skill enhancement, and perceived study benefits.

Well-being: measure burden (Zarit Burden 12-item measure), upset with problem behaviors, depression (10-item Center for Epidemiologic Studies Depression Scale), and perceived changes in well-being (13- item Perceived Change Index).

Skill Enhancement: measure use of strategies like cueing and simplifying routines (19 item Task Management Strategy Index), and use of communication forms like yelling, threatening, criticizing, withdrawal, harsh tone, and screaming **Perceived Benefits:** measure participant satisfaction with the study (11-item investigator developed survey), types of caregiver and patient benefits (3-point scale)

Statistical Analysis: To calculate sample size, the study assumed a medium effect size (0.4 standard deviation), less than 26% attrition rate, and a study hypothesis with 0.5

statistical significance with 80% power to detect a medium effect for improvement in targeted problem behavior. To compare baseline characteristics of patients, Chi-square and Wilcoxon rank-sum tests were used. Primary and secondary outcome measures were computed by means, standard deviations, and ranges. The Mantel-Haenszel chi-square analysis was used to analyze the main treatment effect for patient targeted problem behavior at 16 weeks. Analysis of covariance (ANCOVA) was used to analyze the treatment effects on caregiver upset and their confidence managing targeting problems. Longterm treatment effects (24 weeks) were also analyzed using ANCOVA. Mantel-Haenszel chi square analysis was used to assess effects on depressive symptoms and perceived study benefits; caregiver relationship and sex were controlled variables.

Results: 374 caregivers were screened, of which 79.9% (299) were eligible and of which 91% (272) of those eligible were willing to participate. Studies showed that there was no statistical significant demographic differences between those eligible and those not; however there were differences between those who completed treatment and those who were lost to follow-up. Those who completed treated were caregivers who had a higher baseline upset and a lower baseline confidence level for managing difficult behaviors. The attrition rate at 16 and 24 weeks was 12.1% and 19.1%, respectively. At the end of a 6 month analysis, the intervention group with follow-up was 106 patients; the control group with follow-up was 114 patients.

Background Characteristics: Caregivers were primarily white, female, spouses who were well educated. Average age was 66.3 +/- 12.2 years and average length of care was 3.7 +/- 3.0 years. Patients with dementia were primarily female, white, older (mean 82.1 =/- 8.4) with an average MMSE of 13.0. Caregivers reported 9.6 +/- 3.9 problem behaviors that would occur approximately 13 times per month.

Treatment Implementation: During the active phase, 8.6 +/- 2.1 occupational therapy (OT) sessions were completed. Each OT session had a mean length of 1 hour and 25 minutes for in home and 21 minutes for telephone. Assistive devices issued included those for monitoring, bathing, toileting, and leisure, with average cost per dyad of \$152.52 +/- \$102.7.

Medical Test Results: Blood and urine samples were obtained for 117/131 active intervention patients. Undiagnosed illnesses were detected in 40 (34.1%) of patients, with most prevalent conditions including bacteriuria (14.5%), hyperglycemia (5.9%), and anemia (5.1%). 37 of these 40 patients followed up with a physician.

Primary Outcome (16 weeks): Through the study, caregivers rated problem behaviors that were most bothersome. These included resistance to care (15.4%), repetitive questioning (10.5%), and argumentativeness (8.4%). Other problems included waking up at night, toileting problems, verbal aggression, and trying to leave the home. There was a significant improvement in the ACT group (67.5%) vs. control group (45.8%) for targeted behavioral problems. Also, fewer ACT caregivers reported a worsening of

symptoms (31.7%) or no improvement (22.5%) than the control group caregivers (18.4%, 14% respectively). The ACT caregivers also had a statistically significant improvement in confidence in managing the problem behaviors than in the control group caregivers.

Secondary Caregiver Outcomes (16 and 24 weeks): At 16 weeks, ACT caregivers reported using less negative communication than the control group. The greatest differences favoring ACT over control group were in the areas of well being, including burden, upset with problem behaviors overall, and perceived change. There was an improvement in simplification strategy use, but it was not significant until 24 weeks. The perceived change index was significant for ACT participants, including an improvement in affect, somatic symptoms and managing daily care. Caregivers with depression had improved symptoms in the ACT group vs. the control group (67.8% vs. 53.0%). For long-term outcomes (24 weeks), the caregiver areas assessed, including skill-building and well-being, favored intervention. However, negative communications did not improve at 24 weeks, although there was a prior trend that favored intervention.

Perceived Benefits: Each area of the perceived change index favored intervention. Both ACT group and control participants found the study to be not very time consuming, felt they were treated with respect and felt that the study was explained clearly. Among many improvements, 69% of the ACT caregivers reported an increased understanding of the disease vs 25.2% of the control group (P = .001).

	ACT	Control
Understanding disease	69.0%	25.2%
Confidence managing	71.9%	29.1%
behaviors		
Making life easier	46.0%	9.7%
Ability to provide care	58.0%	16.7%
Ability to keep patients at	46.5%	17.6%
home		
Overall benefit in caregiving	79%	36.9%
Overall benefit in daily life	46.1%	9.7%

Discussion: Trials with Advanced Caregiver Training focused on families who experience behavior problems and caregiver distress. The ACT sought to reduce symtomatology in patients through non-pharmacological methods as well as ease the stressors experienced by the caregivers. The study showed that it was efficacious in areas of improving problematic behaviors while increasing the confidence in caretakers' ability to care for their family member.

 Most of the patient behaviors that were ranked highest as problematic could not be alleviated through pharmacological means. Less than 5% of caregivers reported the

- psychiatric conditions that are pharmacologically treatable as problematic. This study displays that although there are many conditions which can be treated with drugs, these are not the behaviors that are of highest burden to the caretaker.
- The results from the ACT trials focused on three main areas: symptom improvement, quality of life, and social acceptability (caregiver impressions of study benefit). At 16 weeks, improvements were found in all areas. However, at 24 weeks, there was a lack of improvement in negative communications. This shows us that over time, it was harder for caregivers to maintain the skills of positive communication. They may require a longer training in areas of constructive communication.
- The ACT trials also showed benefit in reducing depressive symptoms experienced by the caretaker. At 16 and 24 weeks, caretakers felt less upset at the same behavioral problems, had enhanced caretaking skills, and a better well-being overall. However, results were only statistically significant at 16 weeks. This also shows that there is a need for longer or more effective training in managing depressive symptoms.
- 37% of patients had an undiagnosed medical illness that could be treated. Because of their dementia, it may be harder for patients to express their symptoms; therefore patients should receive more frequent physical exams.
- The ACT trials showed that a targeted approach to intervention will prove successful.
 Rather than choosing among the many problematic behaviors that could potentially bother caregivers, it is best to target one's approach to those that cause the most upset.

Limitations: As with any trial, the ACT trial also had its limitations.

- The most problematic and the most frequent behavior may not always match. Safety concern such as leaving the stove on or wandering out of the house may not be a very frequent occurrence; however, it is dangerous. Repetitive questioning is a frequent occurrence and was ranked 2nd as most problematic, but may not necessarily pose a threat or cause harm. The ACT trial assesses specifically the problems that stand out relative to other problems in the eyes of the caregiver.
- Problems that are identified as most problematic at baseline (0 weeks) may not be
 the greatest problem at 16 weeks or 24 weeks. During the OT, if another more
 pressing problem was identified, the focus would go to that problem. At the 16 and
 24 week check points, the study focuses on those problems that were present at
 baseline only. Therefore, results of the study can underestimate the full effect that
 it may have had.
- Control group participants showed benefit in areas throughout the ACT trial. The
 reason is unknown, but it could be attributed to increased attention and the chance
 for caregivers to discuss their feelings and express frustrations. Also, because
 behaviors fluctuate over time, at 16 weeks the behaviors may not have been as
 frequent or bothersome.
- The effects of treatment components cannot adequately be assessed. It cannot be determined whether either the nurse visits or the OT provided the most benefit.

 This study was voluntary. Therefore, the sample of caretakers may have been more ready to learn and implement new strategies in patient care. Also, this group only involved families who experienced severe distress and caretaker upset. ACT therefore may not be as effective in patients who are not fully willing to participate, and in those who are minimally upset.

Overall, it is clear through the significantly statistical results that the Advance Caregiver Training provides a therapeutic, nonpharmacologic approach to improving symptomatic behaviors in patients and improving depressive symptoms in caretakers while training caretakers in strategies to manage problematic behaviors effectively. Implementing intervention as part of standard dementia care should be considered, provided the positive impact that it can have on a patient and their family.