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Targeting and Managing Behavioral Symptoms in Individuals with Dementia: A Randomized Trial of a Nonpharmacologic Intervention

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Abstract

Objectives—Test effects of an intervention that helps families manage distressful behaviors.

Design—Two-group randomized trial

Setting—In-home

Participants—272 caregivers and dementia patients

Intervention—Up to 11 home/telephone contacts over 16-weeks by health professionals who identified potential triggers of patient behaviors including communication, environment, patient undiagnosed medical conditions (by obtaining blood/urine samples), and trained caregivers in strategies to modify triggers and reduce caregiver upset. Between 16–24 weeks, 3 telephone contacts reinforced strategy use.

Measurements—Primary outcomes included frequency of targeted problem behavior, and caregiver upset with and confidence managing it at 16-weeks. Secondary outcomes included caregiver well-being and management skills at 16 and 24 weeks, and caregiver perceived benefits. Prevalence of medical conditions for intervention patients were also examined.

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Results—At 16 weeks, 67.5% of intervention caregivers reported patient improvement in targeted problem behavior compared to 45.8% of caregivers in a no-treatment control group ($p=.002$), reduced upset with ($p=.028$) and enhanced confidence managing ($p=.011$) the behavior. Additionally, compared to controls, intervention caregivers reported less upset with all problem behaviors ($p=.001$), negative communication ($p=.017$), burden ($p=.051$), and improved well-being ($p=.001$). Fewer intervention caregivers had depressive symptoms (53.0%) than control group caregivers (67.8%, $p=.020$). Similar caregiver outcomes occurred at 24-weeks. Compared to controls, intervention caregivers perceived more study benefits (p values $<.05$) including ability to keep patients home. Blood/urine samples of intervention patients showed 40 (34.1%) had undiagnosed illnesses requiring physician follow-up.

Conclusion—Targeting behaviors upsetting to caregivers and modifying potential triggers improves patient symptomatology and caregiver well-being and skills.

Keywords

Quality of life; neuropsychiatric behaviors; dementia; caregiving; environmental modification

INTRODUCTION

Managing neuropsychiatric behaviors is one of the most challenging aspects of caring for individuals with dementia. Behavioral symptoms are common, occur throughout the course of the disease, have a profound effect on families, and are associated with increased time spent caregiving, higher care costs, heightened risk for nursing home placement, and mortality.^{1–5} Caregivers managing behavioral symptoms report high levels of distress and depressive symptoms. This is particularly the case for caregivers who perceive that they have inadequate skills to manage behaviors.^{6,7}

Efforts to manage problem behaviors have typically involved pharmacologic treatments, especially the off-label use of atypical antipsychotic drugs.^{8,9} However, pharmacologic approaches yield modest to no benefits, and at considerable risk.^{8–11} Additionally, common troublesome behaviors for families (refusal of care, repetitive vocalizations, argumentation), do not respond to pharmacological treatments. For these reasons, recent consensus reports recommend nonpharmacologic approaches as the initial treatment modality.^{12–14}

However, it is unclear which nonpharmacologic approaches are effective.^{15,16} With few exceptions, nonpharmacologic research is characterized by small sample and effect sizes, lack of methodological rigor, foci on nursing home or assisted living residents, or need for replication.^{17–19} The few methodologically rigorous trials of nonpharmacologic interventions for community-dwelling patients examine one type or cluster of problem behaviors (depression,²⁰ agitation,²¹), or show reductions in caregiver upset but not behavioral symptoms.²² Also, few studies evaluate intervention effects on caregiver management skills.

One exception is the Environmental Skill-building Program (ESP), tested with 255 dyads in a randomized trial. Part of the NIH Resources for Enhancing Alzheimer's Caregiver Health (REACH I) initiative,²³ ESP instructs caregivers in problem-solving, modifying home environments and simplifying daily tasks to address caregiver concerns including but not limited to patient problem behaviors. The ESP trial revealed reductions in caregiver upset among spouses at 6 months, and frequency of problem behaviors at 12 months.^{23,24} While ESP improved patient and caregiver outcomes, symptom reduction did not occur immediately, effect sizes were small, reduced upset occurred for spouses only, and there was only a trend toward skill enhancement. ESP also did not exclusively target problem behaviors.

Building on ESP, best clinical practices, and research on neuropsychiatric behaviors and caregiver distress, we designed Advancing Caregiver Training (ACT) to target problem behaviors identified by caregivers as most troublesome and provide strategies to effectively manage them. We hypothesized that caregiver-patient dyads in ACT, compared to those in the no-treatment control group, would experience a reduction in frequency of the targeted problem behavior and associated caregiver upset, and improved caregiver confidence, and secondarily enhanced caregiver well-being and skills at 16 weeks. We also examined caregiver benefits at 24 weeks and compared impressions of perceived benefits. As ACT included a brief medical screen to rule out undiagnosed medical conditions possibly contributing to behavioral symptoms, we also report prevalence of conditions for intervention patients.

METHODS

Study Sample and Procedures

Participants were recruited between December 2003 and March 2007 from media announcements and mailings by social agencies. Interested caregivers contacting the research team (telephone or return postcard), were explained study procedures and administered a telephone screen for eligibility. Eligible caregivers were living with individuals with a physician diagnosis of dementia or a Mini-mental State Examination (MMSE) score <24 ; ²⁵ at least >21 years; English speaking; planning to live in area for 6 months, not actively seeking nursing home placement; managing problem behaviors; and reporting upset (>5 on 10 point scale). Dyads were excluded if either had terminal illness with life expectancy <6 months; active treatments for cancer; >3 acute hospitalizations in past year; or involvement in another trial concerning problem behaviors. They were also excluded if patients had schizophrenia or bi-polar disorder, dementia secondary to probable head trauma, or an MMSE=0 and bed-bound. The last criterion excluded patients who were either non-responsive to their environment and thus would not benefit from ACT, or were non-testable.

Written informed caregiver consent and proxy patient consent were obtained at baseline, with patient assent obtained for each patient-related assessment using institutional approved forms. Following baseline assessment, caregivers were randomized to ACT or a no-treatment control group and reassessed at 16 and 24 weeks from baseline by interviewers masked to participants' treatment assignment. Control group participants did not receive any intervention contact. Following completion of all study assessments for the trial at 24 weeks, control group participants were offered a 2 hour in-home workshop involving education and tips for managing problem behaviors.

Randomization

Study participants were stratified by relationship (spouse/non-spouse) and randomized within each of two strata using random permuted blocks to control for possible changes in subject mix over time. The blocking number was developed by the project statistician and unknown to others. Randomization lists and two sets of randomization forms were prepared using opaque envelopes. The project director randomized each participant within 48 hours of baseline interview.

Intervention—ACT conceptualized problem behaviors as a consequence of interacting factors reflecting three domains:^{17,26} patient-based (unmet needs, discomfort/pain, incipient medical condition); caregiver-based (stress, communication style); and environment-based (clutter, hazards). ACT sought to identify and then modify potential triggers in each of these domains to help caregivers eliminate, reduce or prevent the targeted problem behavior.

To understand relationships between problem behaviors and caregiver distress, we used the stress health process model.²⁷ The model suggests that problem behaviors are a primary stressor. Caregivers who perceive managing problem behaviors as threatening and their coping resources inadequate are at heightened risk for distress. ACT sought to reduce caregiver upset by providing skills to effectively manage problem behaviors.

ACT involved a 16-week active phase of up to 9 occupational therapy (OT) sessions and 2 nursing sessions (one home/one telephone), and a maintenance phase (16–24 weeks) of 3 brief OT telephone contacts to reinforce strategy use.

OTs met with caregivers to introduce intervention goals, review targeted problem behaviors identified at baseline (described under primary outcome), and observe home environment for patient way-finding and potential hazards (e.g., placement of medications), and caregiver-patient interactions (e.g., communication style) using standardized checklists.^{28,29} In subsequent sessions, OTs used the NIH REACH II problem-solving approach,³⁰ to help caregivers identify antecedents and consequences or potential modifiable triggers of the target problem behavior. OTs brainstormed with caregivers to identify acceptable management strategies. A typed “action plan” was provided stating targeted behavior, treatment goal, potential triggers, and four management strategies (adapting physical environment, assistive devices, simplifying communication and tasks, engaging patients in activity). Caregivers were also instructed in stress reduction and self-care techniques. Skills were built by having caregivers practice with OTs problem-solving, strategy identification and use, and then independently between scheduled sessions. Low-cost assistive devices (e.g., monitors, grab bars) were paid for through grant funds at no cost to families.

An advanced practice nurse met with caregivers to provide education on common medical conditions that may exacerbate problem behaviors (pain, dehydration, constipation). To uncover possible undiagnosed illness, serum and urine samples were collected from patients. Laboratory evaluations included SMA 12 blood chemistry and thyroid testing of serum samples, and culture and sensitivity of urine samples. Patient medications were reviewed for appropriateness, polypharmacy and dosing using published guidelines.³¹ The nurse contacted caregivers by telephone to review laboratory results and mailed two copies (for caregiver and physician). For positive results, the nurse coordinated physician contact if needed.

During weeks 16–24, 3 OT telephone sessions reinforced and validated problem-solving and strategy use.

Treatment Implementation

Ten licensed OTs and one nurse with at least one year homecare experience received 35 training hours (readings, didactic instruction, practice, calibration in clinical interview). Treatment fidelity was monitored and maintained through twice-monthly meetings involving case presentations. Interventionists submitted audiotapes of 10.0% of home sessions randomly selected by investigators for review and feedback. For each contact, documentation concerning time spent and content covered was completed and reviewed for delivery adherence.

Outcomes

Primary Patient Outcome—Primary patient outcome was frequency of the problem behavior targeted by caregivers as most distressful to them. To identify the problem behavior, we used a standard method employed in medical, pharmacologic, psychotherapeutic, and behavior management trials.^{32–34} At baseline, caregivers indicated

whether each of 23 behaviors occurred (yes/no) in the past month using standardized scales.^{23,35, 36} For each problem behavior that occurred, caregivers indicated frequency of occurrence in the past month and then the one behavior most distressful to them which they sought to manage better. The problem behavior selected at baseline and its frequency of occurrence were then reassessed at 16 (main endpoint) weeks.

Primary Caregiver Outcomes—Primary caregiver outcomes included caregiver upset with (0=no upset to 10=extreme upset with midpoint labeled “fairly upset”) and confidence in managing (0=not confident to 4=extremely confident) the target problem behavior.²³

Secondary Outcomes—Other outcomes for caregivers included measures of well-being, skill enhancement, and perceived study benefits.

Well-being

Four psychometrically sound measures were used to assess caregiver well-being; burden, upset with problem behaviors overall, depression, and perceived changes in well-being. To assess caregiver burden, we used the Zarit Burden 12-item measure which assesses burden items on a 5-point scale (0=“Never to 4=“Nearly always”).³⁷ Scores represented caregivers' summed responses across 12 items with higher total scores indicating greater burden ($\alpha=.88$ for sample).

To measure caregiver upset with problem behaviors overall, we derived a mean score by averaging caregiver responses across all occurring behaviors as described above with higher scores indicating greater upset ($\alpha=.78$ for sample).

To assess depressive symptoms, we used the 10-item Center for Epidemiology Studies Depression Scale (CES-D)^{38,39} in which caregivers indicated extent of symptomatology in the past week (0=rarely/never to 3=most or all of time). Scores were summed across items with higher total scores indicating greater depressive symptomatology ($\alpha=.81$ for sample). Scores >8 represent clinical symptomatology.

Finally, to evaluate change (improvement/worsening) in well-being, we used the 13-item Perceived Change Index⁴⁰ for which caregivers rated change (1=“got much worse” to 5=“improved a lot”) over the past month in three domains: managing care challenges (5 items, $\alpha=.77$); affect including anger, stress (4 items, $\alpha=.85$), and somatic symptoms including energy, sleep quality (4 items, $\alpha=.82$). We computed mean scores representing an average response across the 13 items and for each domain with higher scores indicating improvement ($\alpha=.88$). To evaluate clinically significant changes, we recoded (0=no change; >0=improvement; <0=worsening) and graphed domain scores.

Management Skills

As evidence of skill enhancement, we used the 19-item Task Management Strategy Index²⁸ in which caregivers indicated extent of use (1=never to 5=always) of strategies (cueing, simplifying routines). A mean score was calculated with high scores indicating greater positive strategy use ($\alpha=.77$ for sample).

To evaluate communication, caregivers rated frequency of use (1=“never” to 5=“always”) of 6 communication forms derived from standardized scales (yelling, threatening, criticizing, withdrawing from patient,⁴¹ using harsh tone and screaming).⁴² An index representing mean responses across the six items was derived. Higher scores indicated greater negative communication ($\alpha=.80$ for sample).

Perceived Benefits

An 11-item investigator-developed survey was used to assess caregiver perceptions of study benefits. Items concerned satisfaction with study participation (study clearly explained, treated with respect, level of effort required, willingness to recommend study to others); types of benefit (overall, dementia understanding, confidence managing daily care, enhanced skills, life easier) and patient benefits (improved daily life, helped keep patient home). Caregivers responded on 3-point scales (“not at all,” “some,” or “a great deal.”).

Statistical Analysis

We based sample size calculation on assumptions of a medium effect size (0.4 standard deviation), < 26.0% attrition rate (based on previous research), study hypothesis tested at .05 level with 80.0% power to detect a medium effect for improvement in targeted problem behavior. Given our expected attrition rate, we planned to randomize 272 dyads.

Descriptive data included caregiver socio-demographic characteristics (age, gender, race, education, relation to patient, living arrangement, years caregiving, financial difficulty) and patient characteristics (age, gender, race, number and frequency of problem behaviors, and MMSE). Chi-square and Wilcoxon rank-sum tests were used to compare intervention and control participants on baseline characteristics and detect differences between participants with and without 16-week data. These procedures were also used to examine potential differences at screening between eligible participants willing to participate and those who were not. Means, standard deviations and ranges for primary and secondary outcome measures were computed. The normality assumption for each dependent measure was tested by examining the distribution of residuals.

The main treatment effect for patient targeted problem behavior at 16-weeks was examined using Mantel-Haenszel Chi Square analyses controlling for the design variable, relationship to patient (spouse/non-spouse), and caregiver gender based on previous research showing differential responses to caregiving and treatment.

For main treatment effects on caregiver upset with and confidence managing targeted problem behavior we examined adjusted mean differences from baseline to 16-weeks using analysis of covariance (ANCOVA). The outcome measure was 16-week score with the design variable (relationship) and gender entered as covariates.

To evaluate long-term treatment effects (baseline to 24-weeks) for secondary caregiver outcomes, we used the same statistical procedures: baseline value, the design variable and gender entered as covariates in ANCOVA models. To evaluate secondary treatment effects on depressive symptoms (16 and 24-weeks), and perceived study benefits (24-weeks), we used Mantel-Haenszel Chi Square analyses, again controlling for caregiver relationship and gender.

SPSS 17.0 was used with significance level of .05. All analyses were two-sided. Analyses followed intention-to-treat such that all participants providing data were included in analyses regardless of level of participation.

RESULTS

Of 374 caregivers screened, 299 (79.9%) were eligible, of whom 272 (91.0%) were willing to participate. There were no large or statistically significant demographic differences between 272 eligible and willing participants and 27 (7.2%) caregivers eligible but unwilling to participate. (Figure 1) There was a statistically significant difference between study completers and those lost to follow-up Study completers had higher baseline upset ($M=7.7$

vs. $M = 6.8$; $Z = -1.96$, $p = .050$) and lower baseline confidence managing target behaviors ($M = 2.0$ vs. $M = 2.5$; $Z = -2.19$, $p = .029$).

At 16-weeks, 239 caregivers (87.9%), and at 24 weeks, 220 caregivers (81.0%) were available for follow-up, representing 12.1% and 19.1% attrition respectively, below expected level (26.0%). While more were lost to follow-up in intervention (16-weeks=20; 24-weeks=13) than control group (16-weeks=13; 24-weeks=9), the difference was not statistically significant ($p > .10$).

Background Characteristics

Caregivers were primarily female (82.0%), white (69.9%), spouses (51.0%), and well-educated (66.9% > high school). On average, they provided care for 3.7 years ($SD = 3.0$, range = <1 yr. to 20 years) and were 66.4 years old ($SD = 12.2$; range = 33 to 93 years). Dementia patients were primarily female (52.7%), white (69.9%) and older ($M = 82.1$ years, $SD = 8.4$) with an average MMSE of 13.0 (range = 0.0–29.0). On average, caregivers reported 9.6 ($SD = 3.9$) problem behaviors occurring an average of 3.2 ($SD = 3.2$) times weekly in the month prior to study entry (Table 1). Most patients were taking medications: 38.6% on antidepressants, 33.5% on medications for problem behaviors, 36.0% on pain medications, and 71.7% on memory enhancement medications.

Treatment Implementation

Of 136 caregivers in intervention, 5 participants (3.6%) did not complete any sessions. In active phase, an average of 8.6 ($SD = 2.1$) OT sessions were completed with mean length being 1 hour, 25 minutes for in-home and 21 minutes for telephone. The mean number of nurse contacts was 2.0 (1 in-home; 1 telephone) with a mean of 1 hour and 20 minutes spent. In maintenance, a mean of 2.7 ($SD = 0.6$) OT telephone sessions were completed. Assistive device costs ranged from \$4.80 to \$282.93 with average cost per dyad being \$152.52 ($SD = \102.7). Most frequently issued devices were for monitoring, bathing, toileting, and leisure (videos, music).

Medical Test Results

Of 131 active intervention participants, blood or urine samples were obtained for 117 (89.3%) patients. Of these, undiagnosed illnesses were detected in 40 (34.1%) with physician follow-up recommended. Six subjects (5.1%) had 2 or more coexisting, undiagnosed medical illnesses. Most prevalent conditions were bacteriuria (14.5%), hyperglycemia (5.9%), and anemia (5.1%). Of these 40 patients, 37 (92.5%) caregivers followed up with a doctor; one caregiver (patient with hyperglycemia) dropped out and two caregivers did not follow-up. Of 37 with physician follow-up, only one chose not to treat as patient had asymptomatic bacteriuria.

Primary Outcomes (16-Weeks)—A wide range of problem behaviors were targeted by caregivers with the most common being resistance to care (15.4% caregivers), repetitive questioning (10.5%) and argumentativeness (8.4%) (Table 2). We observed significantly greater improvement in occurrence of the primary targeted problem behavior for ACT (67.5%) versus the control group (45.8%; Chi Square=8.7, $p = .002$). Also, a higher percentage of control group caregivers reported that symptoms worsened (31.7%) or stayed the same (22.5%) compared to ACT caregivers (18.4% and 14%, respectively), although the difference was not statistically significant.

We also observed a statistically significant reduction in upset with the target problem behavior among ACT caregivers from baseline ($M = 7.8$, $SD = 2.3$) to 16-weeks ($M = 5.5$, $SD = 3.3$) compared to control group caregivers from baseline ($M = 7.6$, $SD = 2.6$) to 16-weeks

($M=6.4$, $SD=3.1$), $F=4.88$ (1, 180); adjusted mean difference $=-0.93$; $CI=1.76, -0.10$, $p=.028$; Cohen's $d=.30$). Similarly, we found a statistically significant improvement in confidence managing the target problem behavior among ACT caregivers from baseline ($M=2.1$, $SD=1.1$) to 16 weeks ($M=2.5$, $SD=.92$) compared to control group caregivers from baseline ($M=2.0$, ($SD=1.1$) to 16-weeks ($M=2.2$, $SD=1.0$), $F=6.61$ [1, 196]; adjusted mean difference $=.33$; $CI=0.08, 0.58$; $p=.011$; Cohen's $d=.30$), representing small effect sizes.

Secondary Caregiver Outcomes (16 and 24c-Weeks)—For improvements in skills at 16-weeks, ACT caregivers reported using less negative communication than the control group; however, use of simplification strategies did not improve significantly. We found statistically significant treatment differences favoring ACT caregivers for well-being (burden, upset with problem behaviors overall, perceived change). (Table 3)

At 16-weeks we also found statistically significant benefit for ACT participants for each domain of perceived change: affect (F [1, 233] $=22.4$, adjusted mean difference $=0.46$, $CI=0.27, 0.65$, $p=.001$, Cohen's $d=.58$), somatic symptoms (F [1, 233] $=21.0$, adjusted mean difference $=.41$, $CI=0.24, 0.59$, $p=.001$; Cohen's $d=.55$) and managing daily care (F [1, 233] $=25.7$, adjusted mean difference $=0.49$, $CI=0.30, 0.68$, $p=.001$; Cohen's $d=.64$), representing moderate to large effect sizes. (Figure 2)

As to caregiver depression at 16-weeks, we found significantly greater symptomatology ($CES-D>8$) among control group than ACT caregivers (67.8% vs. 53.0%, Chi Square $=5.4$, $p=.020$).

For long-term outcomes (baseline to 24-weeks), we found that all assessed caregiver outcomes including simplification strategy use were statistically significant favoring intervention except for negative communication, which showed a trend favoring intervention (Table 3). Similarly, each domain of the Perceived Change Index was statistically significant favoring intervention at 24-weeks (Figure 2). There was a higher prevalence of depressive symptoms among controls than intervention caregivers (61.4% vs. 56.2%), and more intervention caregivers did not have clinical symptoms (43.8%) compared to controls (38.6%), although differences were not statistically significant.

Perceived Benefit—At completion of the study at 24-weeks, both intervention and control group caregivers perceived participation as not too time consuming, felt they were treated with respect, and reported the study was clearly explained. Compared to control group caregivers, however, ACT caregivers reported a “great deal” of improvement in understanding the disease (69.0% vs. 25.2%, Chi Square $=46.2$, $p=.001$), confidence managing behaviors 71.9% vs. 29.1%, Chi Square $=41.1$, $p=.001$), making life easier (46.0% vs. 9.7%, Chi Square $=60.6$, $p=.001$), enhancing ability to provide care (58.0% vs. 16.7%, Chi Square $=55.5$, $p=.001$), improving patient's daily life (36.4% vs. 7.8%, Chi Square $=43.8$, $p=.001$), and keeping patients at home (46.5% vs. 17.6%, Chi Square $=22.0$, $p=.001$), over benefit in caregiving (79% vs. 36.9%, Chi Square, 39.7, $p=.001$), daily life (46.1% vs. 9.7%, Chi Square $=58.2$, $p=.001$). Finally, 99% of ACT caregivers would have recommended study participation, compared to 83.3% of control group caregivers (Chi Square, 15.3, $p=.001$).

DISCUSSION

The ACT trial targeted families experiencing frequent behavioral symptoms and caregiver distress. ACT sought to reduce symptomatology of the most pressing behavioral disturbance and provide caregivers with skills to manage problem behaviors overall.

We show that an intervention that identifies and modifies three sources of potential triggers of problem behaviors has immediate positive effects on the most problematic behavior identified by caregivers, and caregiver upset with and confidence managing that behavior. These proximal outcomes included alleviating the presenting behavioral symptomatology, offering caregivers relief by 16-weeks. Noteworthy is that the problem behaviors caregivers identified as distressful (e.g., refusal of care) are not amenable to pharmacologic treatments. Also, most patients were on memory enhancement medications but still experienced problem behaviors. Of the psychiatric symptoms typically treated by medications (delusions, hallucinations), few caregivers (<5%) identified these as troublesome. Thus, while medications may be helpful for some behaviors (depression, agitation, delusions), these were not the ones endorsed by caregivers as most upsetting or for which they sought management skills.

We also found generalized benefits for caregivers including decreased depressive symptomatology, burden, upset with problem behaviors overall, and improved well-being, and enhanced skills. Subscales of the Perceived Change Index further showed that ACT caregivers improved in affect and management abilities whereas control group caregivers had worsening scores. For somatic symptoms, we showed less worsening for ACT caregivers. Treatment effects across all outcomes ranged from small to moderate, comparing favorably to other nonpharmacologic and pharmacologic interventions, which most report small to no effects.^{44,45}

ACT showed immediate and long-term benefits in three areas of clinical significance:⁴³ symptom reduction (targeted problem behaviors, caregiver upset), life quality (caregiver burden, well-being), and social acceptability (caregiver impressions of study benefit). Caregiver benefits found at 16-weeks were also found at 24-weeks except for negative communications, in which there was a trend favoring intervention. It appears that both ACT and control group caregivers used more negative communications by 24-weeks although ACT caregivers still reported a slightly lower frequency of use of poor communication approaches. As communication is key to managing problem behaviors, it may be that caregivers need more and continuous reinforcement of positive communication strategies. Similarly, we found that a fewer proportion of ACT caregivers reported depressive symptoms at both 16 and 24-weeks, but the difference was statistically significant only at 16-weeks. This suggests that a more sustained intervention to manage depressive symptoms may be necessary for a longer-term effect. Also, at 16-weeks, ACT caregivers in comparison to control group caregivers showed improvement in simplification strategy use, but this was not statistically significant until 24-weeks. This suggests that to master skill in simplifying environments, tasks and everyday communications requires a longer time frame.

Of importance is that more than one third of ACT patients with specimens had an undiagnosed but treatable medical condition. This suggests that more frequent medical examinations may be warranted as dementia patients may not adequately report symptomatology.

The trial also demonstrated the value of a targeted problem behavior measurement approach. There is no single, universally accepted approach for operationalizing dementia behaviors.⁴⁶ Commonly used behavioral inventories yield a global score across diverse problem behaviors most of which are not endorsed by caregivers at any one time. A global score may mask important clinical treatment effects occurring for some behaviors but not others.^{47,48} Moreover, although a problem behavior may occur frequently, it may not be distressing to families or warrant intervention.

A particular strength of a targeted approach is that it facilitates identification of the problem behavior most salient to families, resonating with client-centered geriatric care and enhancing intervention efficiency.⁴⁹ Pinpointing problem behaviors causing the most upset from among the many behaviors that occur, avoids reliance on surveying a broad range of behavioral symptoms, most of which caregivers may not identify as problematic. Thus, a targeted measurement and intervention approach provides a systematic yet customized strategy with high clinical relevance. It is particularly applicable in dementia care because the universe of possible problem behaviors, although theoretically unlimited, is in practice finite and definable.

One limitation of this approach may be that problem behaviors selected by caregivers are not necessarily comparable regarding their frequency of occurrence or the safety concern they may pose. For example, repetitive vocalizations may occur constantly but not pose a threat whereas wandering outside the home or physical aggressiveness are infrequent but potentially dangerous. Nevertheless, selected problem behaviors are of immediate salience to caregivers.

Another point is that the problem behaviors identified as distressing at baseline, may not be the most distressing a few weeks later. Some caregivers identified a different problem behavior to target with the OT than the one identified at baseline. While the behavior targeted at baseline was consistently measured at 16 and 24 weeks, this may not have been the actual behavior targeted during intervention. Thus, the study may underestimate the impact of the intervention, because at 16 weeks caregivers may be responding to questions about a behavior that was not addressed in the intervention.

As in other trials, control group participants showed benefit, and it is unclear why this occurred. One reason may be that caregivers may benefit from discussing their experiences and feelings. Secondly, behaviors fluctuate over time, and thus we may be detecting regression to the mean at 16 weeks.

This study adds to the growing evidentiary base supporting nonpharmacologic interventions. We show that an in-home 16-week program focusing on caregiver skill-enhancement has the predicted effect of improving skills and well-being, achieving positive results in 16 weeks, with most benefits extending to 24 weeks. This compares favorably with more diffused and longer-term caregiver supportive programs. ACT combines known treatment modalities (nurse examination) with behavioral and environmental approaches in a coordinated, novel fashion. This bio-behavioral approach has translation potential; the nurse component could be conducted in a physician's office with referral to an OT trained in ACT for the home skill-building sessions. The in-home portion may be Medicare reimbursed as caregiver training is directed at improving patient functioning. Results also suggest ACT is well-received and effective across a wider range of outcomes (skills, caregiver somatic symptoms) than considered previously in other caregiver trials. Finally, the trial shows that distressed, overwhelmed caregivers can learn simple strategies to manage effectively.

Several study limitations should be noted. Use of a no-treatment control group leaves open the possibility that attention may account for observed benefits. However, it is unlikely that reported improvements in skills and the range of benefits found can be attributed to attention from health professionals alone.

Another potential limitation is the inability to disentangle effects of any one treatment component. We can not suggest whether the nurse component or OT caregiver training was most critical. ACT assumed both components critical to address dementia-related behaviors.

Yet another concern is generalizability. Study participation was voluntary. This sample may have been more motivated to learn new strategies than non-volunteers.⁵⁰

We purposely targeted caregivers exposed to problem behaviors and reporting high upset; ACT may not be beneficial to those with minimal distress. As shown, study dropouts reported less upset and behavioral symptoms than study completers.

A related point is that control group participants show improvements in target behaviors despite the absence of intervention. As we did not track participation in non-study activities (e.g. adult day care, caregiver support groups), it is possible that both groups participated in and benefited from other services.

As most dementia patients live at home and exhibit problem behaviors that are distressing to families, an intervention that instructs caregivers in behavioral management skills should be considered part of standard dementia care. Future research is necessary to determine the relationship between problem behaviors and underlying medical conditions, whether intervention benefits persist, and the translational potential of ACT in practice settings.

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Figure 1.
Flow Chart of Study Design
Note: *Includes 2 study participants who missed T2 follow-up
**Includes 1 study participant who missed T2 follow-up

Figure 2a,b,c.

Perceived Change Index: Improvement or Worsening in Caregiver Affect, Managing Daily Care, and Somatic Symptoms from Baseline to Weeks 16 (N = 239) and 24 (N = 220)

Figure 2a–2c Note: Perceived Change Index was recoded such that 0=no change; >0=improvement; <0=worsening)

Table 1

Characteristics of Caregivers and Individuals with Dementia by Treatment Group*

Characteristic	Usual Care (n =122)		Experimental (n =117)		Total (N = 239)	
	χ^2	Z	χ^2	Z	p	p
Caregiver						
Mean Age (SD)	65.7 (12.2)		67.1 (12.3)		66.3 (12.2)	.353
Race (%)					1.8 ^b	.180
White	73.8		65.8		69.9	
Non-white	26.2		34.2		30.1	
Gender (%)						
Male	17.2		18.8		18.0	.749
Female	82.8		81.2		82.0	
Relationship to individual with dementia (%)					0.1 ^b	.943
Spouse	50.8		51.3		51.0	
Non-spouse	49.2		48.7		49.0	
Education (%)					2.4 ^c	.294
< High School	7.4		7.7		7.5	
High School	21.3		29.9		25.5	
> High School	71.3		62.4		67.0	
Mean Years Caregiving (SD)	3.6 (3.0)		3.9 (3.1)		3.7 (3.1)	.387
Mean Financial Difficulty Level (SD) ^a	2.0		2.0		2.0	.728
Mean Simplification Strategies (SD) (TMSI)	2.9 (0.6)		2.9 (0.5)		2.9 (0.6)	
Mean Negative communications (SD)	14.0 (4.0)		14.2 (4.2)		14.2 (4.0)	
Mean Burden (SD)	22.0 (9.6)		21.2 (9.5)		21.6 (9.4)	
Mean Behavior upset overall (SD)	5.6 (2.0)		5.8 (2.1)		5.7 (2.0)	
Mean Perceived change index (SD)	2.8 (0.6)		2.8 (0.6)		2.8 (0.6)	
Individual with Dementia						
Mean Age (SD)	81.9 (8.3)		82.3 (8.5)		82.1 (8.4)	.783
Gender (%)					0.0 ^b	.934
Male	47.5		53.0		52.7	

Characteristic	Usual Care (n =122)		Experimental (n =117)		Total (N = 239)		χ^2	Z	p
Female		52.5		47.0		47.3			
Race (%)							1.8 ^b		.180
White		73.8		65.8		69.9			
Non-white		26.2		34.2		30.1			
Mean Number of Behaviors (SD)		9.9 (4.0)		9.4 (3.7)		9.6 (3.9)		-1.0	.337
Mean Frequency of Behavioral Occurrences (SD)		13.5 (11.7)		12.1 (13.4)		12.8 (12.6)		-1.3	.206
Mean MMSE (SD)		12.8 (8.1)		13.1 (8.2)		13.0 (8.2)		-0.3	.773

Note: ADL = activities of daily living; IADL = instrumental activities of living; MMSE = Mini Mental Status Examination; χ^2 = Chi square; Z = Wilcoxon Rank Sum Test.
* Limited to those included in outcome analyses at 16 weeks.

^aValue represents median response category with 2 = “not very difficult paying for basics like food, housing, medical care.”

^b $df = 1$.

^c $df = 2$

Table 2

Problem Behaviors and Prevalence of Caregivers Targeting as Most Upsetting (N=239)

Problem Behavior	Number (%) of Caregivers
Refusing help/resisting care	35 (15.4)
Repetitive questioning	25 (10.5)
Argumentative	20 (8.4)
Wakes up at night	19 (7.9)
Toileting issues	19 (7.9)
Aggressive verbally	19 (7.9)
Wandering/tries to leave home	17 (7.1)
Inappropriate behaviors (destroys property, loud in public, blames others)	14 (5.9)
Upset/agitated	12 (5.0)
Safety concerns (leaves stove on, unlocks doors, overdoses on medications)	12 (5.0)
Delusions	12 (5.0)
Screaming/crying	10 (4.2)
Shadowing	10 (4.2)
Harmful to self	9 (3.8)
Worry, anxious, fearful	9 (3.8)
Other (inability to communicate, affective stance, non-responsive)	8 (3.3)
Aggressive physically	7 (2.9)
Hallucinations	7 (2.9)
Rummaging/hoarding	6 (2.5)
Restlessness	5 (2.1)

Table 3

Comparison of Experimental and Control Group Caregivers at 16 Weeks (N = 239) and 24 Weeks (N= 220) on Secondary Outcome Measures

Dependent Variable	16-Week Follow-up					24-Week Follow-up				
	Usual Care (N=122)	ACT (N=117)	Difference of Adjusted Mean ^c	95% CI	p	Usual Care (N=114)	ACT (N=106)	Difference of Adjusted Mean ^c	95% CI	p
<u>Skill-building</u>										
Simplification (TMSI) ^b	3.0 (0.5)	3.1 (0.6)	0.06	-0.03 0.15	.212	3.0 (0.6)	3.1 (0.6)	0.14	0.04 0.24	.005
Negative communications	12.5 (5.1)	11.3 (4.9)	-0.93	-1.69 -0.17	.017	13.5 (4.6)	12.4 (4.2)	-0.89	-1.81 0.03	.058
<u>Well-being</u>										
Burden ^a	21.0 (9.3)	19.0 (8.5)	-1.37	-2.75 0.01	.051	21.3 (9.8)	19.1 (9.0)	-1.61	-3.13 -0.09	.039
Behavior upset overall	5.4 (2.3)	4.6 (2.4)	-1.07	-1.57 -0.56	.001	5.3 (2.4)	4.6 (2.4)	-0.82	-1.34 -0.29	.002
Perceived Change Index ^a	2.8 (0.7)	3.3 (0.7)	0.45	0.29 .62	.001	2.8 (0.6)	3.1 (0.7)	0.29	0.14 0.44	.001

Note: TMSI = Task Management Strategy Index

^a 16-week data unavailable for 1 caregiver (N=238); 24-week data unavailable for 4 caregivers (N=216)

^b 16-week data unavailable for 14 caregivers (N=225); 24-week data unavailable for 1 caregiver (N=219).

^c Adjusted for baseline value, caregiver gender and relationship to patient.