# Efficacy of Nonpharmacologic Interventions for Agitation in Advanced Dementia: A Randomized, Placebo-Controlled Trial

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## ABSTRACT

**Background:** A randomized, placebo-controlled clinical trial was undertaken to determine the efficacy of nonpharmacologic individualized interventions (individualized to address unmet needs such as boredom or pain) in decreasing agitation in persons with dementia.

Method: Agitated nursing home residents with advanced dementia (from 9 nursing homes in 5 locations in Maryland, United States) were randomized into an intervention group (n = 89) and a placebo control group (n = 36). On the basis of data from baseline assessment, a systematic methodology for individualizing nonpharmacologic interventions, Treatment Routes for Exploring Agitation (TREA), was used with the intervention group: an unmet need was hypothesized, a corresponding treatment category was identified, and specifics of the treatment were chosen to fit the person's need, past identity, preferences, and abilities. (Unmet needs were hypothesized based on physician evaluations, structured staff interviews, relative questionnaires, direct observations of agitation with the Agitation Behavior Mapping Instrument [the primary outcome measure] and affect with Lawton's Modified Behavior Stream [the secondary outcome measure], and resident assessments.) TREA interventions were implemented for 2 weeks, and observations of agitation and affect were recorded. The study was conducted from June 2006 until December 2011.

**Results:** Relative to a control group, TREA interventions for unmet needs produced statistically significant declines in total (P < .001), physical nonaggressive (P < .001), and verbal agitation (P = .004) and significant increases in pleasure (P < .001) and interest (P < .05).

**Conclusions:** This is the first large randomized controlled trial to demonstrate the efficacy of TREA and one of only a few such trials of nonpharmacologic interventions for agitation in persons with dementia. The translation of these findings into practice is sorely needed and would require structural changes dedicating staff time to observing each agitated resident, determining unmet needs, obtaining appropriate intervention materials, conducting the individualized nonpharmacologic interventions, and evaluating results.

Trial Registration: ClinicalTrials.gov identifier: NCT00820859

J Clin Psychiatry 2012;73(9):1255–1261 © Copyright 2012 Physicians Postgraduate Press, Inc.

Submitted: May 31, 2012; accepted July 6, 2012 (doi:10.4088/JCP.12m07918). A gitation, defined as inappropriate verbal, vocal, or motor activity that is not judged by an outside observer to result directly from apparent needs or confusion of the agitated individual,<sup>1</sup> can pose a major problem for persons with dementia and their caregivers. The syndromes of agitation, also termed behavior problems, include aggressive behaviors, physical nonaggressive behaviors, and verbal agitation.<sup>2,3</sup> The presence of these behaviors in persons with dementia can result in institutionalization, where agitated behaviors can remain challenging even for professional caregivers in nursing homes. Consequently, research has examined effective ways to deal with, minimize, and prevent agitation in persons with dementia.

Nonpharmacologic interventions have emerged as useful in managing agitated behaviors, and have been heralded as alternatives to pharmacologic treatments due to the latter's potential for adverse side effects.<sup>4,5</sup> The theory behind the utility of nonpharmacologic interventions is that these target the underlying unmet needs of persons with dementia such as pain,<sup>6</sup> feelings of loneliness or isolation,<sup>7</sup> boredom,<sup>8</sup> or sensory deprivation,<sup>9</sup> which are not addressed with medication. Nonpharmacologic interventions that have been tested include modifications of the individual's physical or social environment to elicit calming effects,<sup>10,11</sup> removal of physical restraints,<sup>12</sup> presentation of individualized music,<sup>13</sup> real or simulated social contacts such as respite videos, oneon-one socialization,<sup>7,14,15</sup> art therapy,<sup>16</sup> and animal-assisted therapy.<sup>17</sup>

Previously, we pioneered an approach for providing interventions for agitation, termed Treatment Routes for Exploring Agitation (TREA).<sup>18,19</sup> Based on a theoretical framework that utilizes a systematic methodology for individualizing nonpharmacologic interventions to agitated persons' unmet needs,9 TREA identifies needs and preferences through data collection from both formal (ie, nursing home staff) and informal (ie, family) caregivers, and through observations of the agitated person's behavior and environment. Collected information regarding needs and preferences is then used in systematic algorithms (ie, decision trees) to suggest personalized interventions for lowering agitation. As correlates for the different syndromes of agitation vary,<sup>20</sup> separate decision trees are followed to formulate interventions for persons with syndromes such as physical nonaggressive or verbal agitation. Driving the TREA concept is the assumption that various types of agitation have varying etiologies, and the first step toward developing an individualized treatment plan is to understand the etiology of each individual's agitated behaviors. Furthermore, interventions should consider

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each individual's remaining abilities (eg, mobility), level of cognitive functioning, and past/present interests.

In a previous study of the TREA approach,<sup>19</sup> we found a significantly greater decrease in agitation and increase in pleasure for agitated nursing home residents in the individualized intervention group versus the control group. However, this study was limited due to time and randomization restrictions. The results, though, demonstrated the benefits of individualizing interventions, showing that each agitated person with dementia should be approached in a unique way to maximize treatment effectiveness.

The present study addresses the limitations of our previous study,<sup>19</sup> using randomization to eliminate bias in treatment assignment and is designed to provide a more systematic approach to choice of intervention. In this article, we further examine the efficacy of individualized interventions for total agitation, and extend our research to include physical and verbal syndromes. Our hypothesis was that utilization of individualized nonpharmacologic interventions would yield significant decreases in both physical nonaggressive and verbal agitation relative to a placebo control condition.

## METHOD

# **Participants and Settings**

Participants were 89 residents from 6 nursing home buildings in the intervention group and 36 participants from 5 nursing home buildings in the control group, all in Rockville, Silver Spring, Takoma Park, Chevy Chase, and Gaithersburg, Maryland, United States. The study was conducted from June 2006 until December 2011; data collection ended in June 2011. The study was registered at ClinicalTrials.gov (identifier NCT00820859). Because of the possibility of contamination between intervention and placebo procedures, we randomized participants either by units (for larger nursing homes with many eligible participants) or by nursing homes (when there were fewer eligible participants). Participants' demographic characteristics are listed in Table 1. Statistically significant differences were not found between treatment and control groups with regard to demographics, diagnoses, and levels of agitation and affect at baseline; however, participants in the treatment group received significantly more antidepressant (P < .01) and antianxiety (P < .05) medications than the control group. Treatment and control groups were also comparable with regard to nursing home characteristics. Using data obtained from http://www.medicare.gov/default. aspx, treatment and control facilities were compared using t tests for a variety of facility items (eg, total number of beds per facility) as well as care items (eg, percentage of residents whose need for help with daily activities had increased). None of the differences were statistically significant. (Further information is available from the authors.)

# Assessment

Background data were collected from nursing home charts. Data regarding activities of daily living, pain, vision,

- The study is the first large randomized, placebocontrolled clinical trial to show the impact on agitation of individualized nonpharmacologic interventions based on the unmet need model.
- The effect size of the intervention was larger than in a previous study, probably due to (1) a rigorous methodology of ascertaining the optimal nonpharmacologic intervention, (2) greater experience in discerning and delivering the interventions, and (3) the accumulation of a wide variety of materials that could be matched to individual backgrounds and needs.
- Nonpharmacologic interventions not only decreased agitation but also increased pleasure and interest, suggesting that these interventions contribute to improved quality of life for persons with dementia.

hearing, and speech were obtained from the Minimum Data Set (MDS).<sup>21,22</sup> Information from medical records included current medication lists (including pain relievers and psychotropic drugs) and medical diagnoses. Cognitive functioning was assessed by a trained research assistant via the Mini-Mental State Examination (MMSE)<sup>23</sup> (range, 0-30; 0 = severe cognitive impairment).

# **Outcome Variables**

Primary outcome: observed agitation. Direct observations of agitation were recorded by trained research assistants (additional information is available on request) via the Agitation Behavior Mapping Instrument (ABMI).<sup>2</sup> Direct observations were chosen for their increased accuracy and objectivity. The ABMI includes 14 items that describe physically and verbally agitated behaviors. The mean interrater reliability of behaviors was 93% in a previous study<sup>2</sup> and 96% in the present study with an intraclass correlation (ICC) of 0.90. Another measure of reliability examined the possible effect of the nonblindedness of the observations. For this measure, 25 residents were videotaped, and interrater reliability was obtained from a research assistant blinded both to the background characteristics of the observed residents and to the original ratings. The ICC between videotaped and direct observations in the current study was 0.94 for verbal agitation, 0.93 for physical agitation, and 0.94 for total agitated behaviors (0.97 in the previous study).

**Secondary outcome: observed affect.** Evaluation of positive and negative affect was based on direct observation and assessed via Lawton's Modified Behavior Stream.<sup>24</sup> Five different modes of affect were evaluated: pleasure, interest, anger, anxiety, and sadness. Due to low frequencies of negative affect, the measures of anger, anxiety, and sadness were combined to yield a mean score of negative affect. The

#### Table 1. Background Characteristics of Control and Intervention Group Participants With Dementia

	Intervention	Control	Total
Characteristic	(n = 89)	(n = 36)	(N = 125)
Demographic			
Age, mean (SD), y	85.9 (8.62)	85.3 (9.62)	85.7 (8.89)
Sex, %			
Female	73.0	77.8	74.4
Ethnicity, %			
White	80.9	66.7	76.8
Marital status, %			
Widowed	60.7	55.9	59.3
Married	28.1	14.7	24.4
Separated/divorced	9.0	17.6	11.4
Never married	2.2	11.8	4.9
Education, %			
High school or less	57.3	70.6	61.2
College/technical school	23.2	17.6	21.6
Graduate degree	19.5	11.8	17.2
Functional, mean (SD)			
Cognitive status (MMSE) <sup>a</sup>	7.62 (6.33)	9.38 (6.76)	8.12 (6.48)
ADL <sup>b</sup>	2.72 (0.84)	2.75 (0.98)	2.73 (0.88)
Vision (based on MDS) <sup>c</sup>	0.64 (1.07)	0.81 (1.35)	0.69 (1.15)
Hearing (based on MDS) <sup>d</sup>	0.40 (0.72)	0.33 (0.72)	0.38 (0.72)
Speech (based on MDS) <sup>e</sup>	0.17 (0.41)	0.25 (0.44)	0.19 (0.42)
Pain frequency (based on MDS) <sup>f</sup>	1.12 (0.36)	1.08 (0.37)	1.11 (0.36)
Diagnoses and medication			
Diagnosis index, mean (SD)	5.3 (1.47)	5.3 (1.07)	5.3 (1.36)
Total medications per person, mean (SD), no. <sup>g</sup>	8.8 (2.11)	7.5 (2.41)	8.4 (2.27)**
Administered sedatives, %	9.0	16.7	11.2
Administered antipsychotics, %	60.7	41.7	55.2
Administered antidepressants, % <sup>h</sup>	70.8	41.7	62.4**
Administered antianxiety, % <sup>i</sup>	42.7	19.4	36.0*
Administered analgesics, %	100	100	100
Baseline value of outcome variables, mean (SD)			
Total agitation (ABMI)	8.76 (5.61)	7.16 (7.61)	8.30 (6.26)
Pleasure	1.06 (0.13)	1.07 (0.10)	1.06 (0.12)
Interest	3.20 (0.78)	2.98 (0.71)	3.14 (0.76)
Negative affect	1.06 (0.10)	1.06 (0.08)	1.06 (0.09)

<sup>a</sup>Higher scores indicate higher cognitive function. <sup>b</sup>Range from 0 (independent) to 4 (total dependence). <sup>c</sup>Range from 0 (adequate) to 4 (severely impaired). <sup>d</sup>Range from 0 (hears adequately) to 3 (highly impaired). <sup>e</sup>Range from 0 (clear speech) to 2 (no speech). <sup>i</sup>Range from 1 (no pain) to 3 (pain daily). <sup>g</sup>Mann-Whitney *U* test: z = -2.92, P = .003. <sup>h</sup>Mann-Whitney *U* test: z = -2.48, P = .013. <sup>\*</sup> $P \le .05$ . <sup>\*\*</sup> $P \le .01$ .

Abbreviations: ABMI = Agitation Behavior Mapping Instrument, ADL = activities of daily living, MDS = Minimum Data Set, MMSE = Mini-Mental State Examination.

mean interrater agreement evaluation was 88% per emotional mode, with a range of 70%–99%, and the mean ICC was 0.91.

#### Procedure

The study protocol was approved by the Institutional Review Board of the Hebrew Home of Greater Washington (Washington, DC). Inclusion criteria were that the resident (1) had been at the nursing home  $\geq 3$  weeks, (2) had been identified by nursing staff as agitated at least several times a day, (3) was aged  $\geq 60$  years, and (4) had a diagnosis of dementia. Exclusion criteria were that the resident (1) had a life expectancy < 3 months; (2) had a diagnosis of bipolar disorder, schizophrenia, or mental retardation; (3) was expected to leave the nursing home within 4 months; (4) had an MMSE score  $\geq 25$ , or (5) had participated in a previous TREA trial.

Written informed consent was obtained directly from 7 residents (3% of the 231 consenting participants). These

participants were responsible for making their own decisions as listed in their medical charts and were found to be sufficiently capable of understanding and giving consent. The remaining 97% of the informed consents were provided by a family member or guardian.<sup>25</sup>

As nursing homes were recruited, randomization to intervention or placebo control protocols was performed using random numbers via a ratio of 1.5:1, with the intent of having more intervention than control participants in order to investigate process issues. Recruiting and randomization of nursing homes/units were done by 2 separate people. With this protocol, the research assistants who gathered initial baseline data were blind to the group allocation of residents; of course, once treatment started, research assistants were no longer blinded to group assignment. As research assistants could not be blinded once interventions began, we took measures to assess the impact of nonblindness, as described earlier. Study participants were blinded as to their group assignment.

After background data were obtained, a trained research assistant recorded baseline observations of agitation and affect onto a personal digital assistant. Each participant was observed every half hour from 8 AM to 9 PM for 3 consecutive days. Each observation lasted 3 minutes. Research assistants observed 1 resident at a time and 3–5 residents during every half-hour period. A mean of 69 baseline

observations was recorded per resident and a 4-hour peak period of agitation for each resident was identified.

For those in the intervention group, relatives completed a questionnaire containing items concerning participants' medical history,<sup>26</sup> self-identity,<sup>27</sup> and social functioning.<sup>28</sup> The physician responsible for treating a specific participant was asked to complete a short form confirming that participant's dementia diagnosis and identifying the presence of akathisia, delirium, pain, and/or depression.

The TREA decision tree protocol<sup>18</sup> was used with each intervention group participant to uncover possible reasons for agitated behaviors, relying on data derived from physicians, nursing home staff, relatives, direct observations, and psychosocial assessments. Using TREA, an unmet need was hypothesized, a corresponding treatment category was identified, and specifics of the treatment were chosen to fit the person's past identity, preferences, and abilities. When TREA treatments involved intervention, these were piloted for each participant over the 3 weeks prior to the actual treatment

Table 2. Treatment Routes for Exploring Agitation	
Interventions Provided to Residents With Dementia	

Type of Intervention	Sessions, %	
Simulated social <sup>a</sup>	27.2	
One-on-one interaction	16.4	
Magazine/reading/book on tape	12.7	
Music	10.3	
Videos and television	6.3	
Physical activity	4.9	
Arts and crafts	4.6	
Worklike activities	4.3	
Sensory stimulation	2.7	
Care <sup>b</sup>	2.6	
Puzzles and games	2.3	
Food or drink	1.8	
Sorting	1.6	
Group activity	1.5	
Other	0.7	

<sup>a</sup>Simulated social includes a robotic animal, lifelike baby doll, baby video, respite video, stuffed animal, family pictures, and family video. <sup>b</sup>Care includes taking person to bathroom, bringing a sweater or blanket, getting nursing staff, discussing medical condition with physician, repositioning person, taking person to his/her room, bringing eyeglasses, and other care activities.

phase. The trial involved a short presentation of the intervention or a request to staff for a care activity and observation as to whether that presentation resulted in a change in agitation, interest, or pleasure. Those activities with the most beneficial effect during the trials were subsequently used during the 2-week treatment phase during the 4 hours identified as having the highest levels of agitation.

When the hypothesized unmet need was loneliness or depression, standardized interventions in the trial phase included (1) simulated animal-assisted therapy (robotic animal), (2) one-on-one interaction with a research assistant, (3) simulated interaction (eg, family videos), (4) a lifelike baby doll, (5) group activities with individuals with similar MMSE scores, and (6) a respite video in the participant's native language.

When the hypothesized unmet need was boredom, standardized interventions were of 2 categories: activities and stimulation. Activities included (1) arts and crafts (eg, coloring); (2) physical activities such as going outdoors, a seated exercise video, a squeeze ball, or ball-tossing; (3) games appropriate for the participant's level of functioning; (4) large-print magazines; and (5) "work" activities (eg, sorting envelopes, folding towels). Types of stimulation were (1) massage (hand or foot), (2) music based on participant preference, and (3) movies (eg, a period film, animal movies, or baby videos).

The final unmet need explored was discomfort. For medical issues (eg, pain, constipation, rashes, drug interactions), the research assistants approached the physician and discussed possible remedies. With difficulty hearing or seeing, research assistants made appropriate adjustments, such as using an amplifier or locating an individual's eyeglasses. If physical restraints were being used, research assistants spoke with the nurse manager and director of therapy to recommend removal. If hunger or thirst was causing discomfort, food or drink would be provided if possible. When it appeared a participant was not taken to the bathroom often enough, research assistants asked the certified nursing assistants to take the resident when the resident requested or was agitated. When wheelchairs or walker/chair combinations were causing discomfort, research assistants e-mailed the director of therapy about a possible seat adjustment. If a participant was feeling excessively hot or cold, appropriate adjustments were made.

Interventions used during the treatment phase are described in Table 2. The treatment phase lasted 2 weeks, with observations recorded during the first and last 3 days of this period. One research assistant conducted interventions while another research assistant recorded observations. In order to assure adherence to the protocol, 2 senior research staff members performed random checks to observe intervention administration.

For those in the placebo group, the same days of observation were used (ie, days 1–3 and 8–10 of the 2 week period). A placebo intervention was provided for staff on the control units, who attended an in-service presentation describing the syndromes of agitation, their etiologies, and possible nonpharmacologic interventions. The rationale for using an educational presentation as a placebo stems from an earlier study that showed that such an in-service does not affect practice<sup>29</sup> yet provides staff with information and with a sense of having received an intervention.

#### **Analytic Approach**

The results were analyzed via repeated-measures analyses of covariance (ANCOVAs) in which time (baseline vs treatment phase) was the within-subjects factor. Group (intervention vs placebo control) was the between-subjects factor, and MMSE score was used as a covariate. The analysis was intent-to-treat, as observations were included regardless of whether or not the intervention was actually provided at the time of observation (information concerning additional intent-to-treat analysis is available upon request). The primary dependent measures were the total agitation score, physical nonaggressive agitation, and verbal agitation. Secondary measures were pleasure, interest, and negative affect. Effect size was calculated as

 $\frac{(IG_t - IG_b) - (CG_t - CG_b)}{\text{Standard deviation of } (CG_t - CG_b)}$ 

in which IG = intervention group, CG = control group, t = treatment assessment, and b = baseline assessment. Confidence intervals for effect sizes were calculated using a method by Kelley<sup>30</sup> that requires computing the percentiles of the noncentral *t* distribution. We implemented this calculation by use of a program on the Web (http://keisan. casio.com/).

Statistical analyses were performed using SPSS software (IBM, Armonk, New York). (Information regarding the original power calculations and issues of units of analysis is available on request.)

## RESULTS

#### Figure 1. Flow of Study Participants

A flow diagram that presents exclusions of participants after randomization can be found in Figure 1.

#### **Primary Outcome**

The intervention group showed a significant decline in total, physical nonaggressive, and verbal agitation during treatment (Figure 2, Table 3). This difference yielded a significant interaction term in all 3 ANCOVAs (P<.01, Table 3). The effect size was -0.451 for verbal, with a 95% confidence interval of -0.05 to -0.85; -0.896 for physical nonaggressive, with a 95% confidence interval of -0.45 to -1.33; and -0.913 for total agitation, with a 95% confidence interval of -0.45 to -1.35. We revisited the data set from our previous study<sup>19</sup> for the purpose of comparison and found effect sizes to be -0.240 for verbal, -0.410 for physical nonaggressive, and -0.493 for total agitation.

#### Secondary Outcomes

The intervention group showed significant increases in pleasure and interest from baseline to the treatment condition, whereas the control

group remained constant (Table 3, Figure 2). This difference between groups is manifested by significant interaction terms (P<.001 for pleasure, P<.05 for interest). The relationship with negative affect was not statistically significant (P=.092).

No important adverse events or side effects were noted for participants in either the intervention or placebo groups.

### DISCUSSION

The main contribution of this study is finding significant effects of nonpharmacologic interventions based on the unmet needs of agitated nursing home residents with dementia within a randomized, placebo-controlled clinical trial, contributing to the evidence supporting nonpharmacologic interventions for behavior problems in persons with dementia. The effect size of TREA intervention is larger in this trial than in the previous  $one^{19}$  which we stipulate is due to (1) a more systematic approach to the trials preceding intervention in the current protocol, (2) greater availability of appropriate stimuli, (3) cumulative experience of providing a variety of stimuli and multiple interventions to this population in various studies, and (4) our use of a systematic rating to assess the efficacy of the intervention trials in order to determine the final set of interventions for the treatment condition. We must also note a larger placebo effect in the previous study as compared to this one, the reason for which is unclear.

Our intervention and control groups were similar in both nursing home and resident characteristics. Significant



<sup>a</sup>Resident gave consent but could not be included before the data collection phase ended. <sup>b</sup>Resident's life expectancy < 3 months.

Abbreviations: MMSE = Mini-Mental State Examination, TREA = Treatment Routes for Exploring Agitation.

differences were found only with regard to medication prescription, with those in the intervention group receiving more antidepressant (P = .003) and antianxiety (P = .013) medication during baseline (further analyses showed no significant differences between the intervention and the placebo groups in the change in medication administered between the baseline and treatment phases-total medications [P=.70], antipsychotic medications [P=.28], antidepressant medications [P=.82], and antianxiety medication [P=.12]). While these prescribing differences may reflect that participants in the intervention group had more agitation, more depressed affect, and lower cognitive function, this does not weaken the significant demonstration of the TREA intervention. As shown in Figure 2, the impact of the TREA intervention was not merely a return to the mean, but also a significant decrease in agitation, far beyond that of the control group. While a reduction in psychoactive medication is an important goal, this was not the objective of this study.

The fact that the interventions increased pleasure and interest significantly is compatible with our theoretical framework that TREA interventions address unmet needs and in turn improve quality of life. Interestingly, levels of pleasure as well as levels of negative affect are low. Even after a statistically significant increase in pleasure, the level of pleasure is low, albeit higher, reflecting the fact that good quality of life for persons with dementia involves moments of pleasure and the reduction of suffering. While a person unfamiliar with nursing homes may scorn such minimal success, daily contact

Table 3. Changes in Outcome Variables by Time (Baseline, Treatment) and by Group (Control, Intervention) in Residents With Dementia: Results of 2-Way Repeated-Measures ANCOVAs

	Interventi Mean	on Group, (SD)	Contro Mear	l Group, n (SD)	$F_{1122}$				
Dependent Variable	Baseline	Treatment	Baseline	Treatment	Value	P Value			
Primary outcome: agitation (ABMI)									
Total agitation	8.76 (5.61)	2.08 (2.68)	7.16 (7.61)	7.92 (9.09)	37.954	<.001			
Verbal agitation	2.74 (3.91)	0.96 (1.97)	2.41 (6.26)	2.84 (6.57)	8.604	.004			
Physical nonaggressive agitation	6.02 (5.02)	1.12 (1.80)	4.74 (3.03)	5.08 (6.23)	29.472	<.001			
Secondary outcome: affect (LMBS)									
Pleasure	1.06 (0.13)	1.27 (0.28)	1.07 (0.10)	1.04 (0.06)	30.271	<.001			
Interest	3.20 (0.78)	3.54 (0.81)	2.99 (0.71)	2.92 (0.83)	5.257	.024			
Negative affect	1.06 (0.10)	1.03 (0.05)	1.06 (0.08)	1.05 (0.07)	2.875	.092			
Abbreviations: ABMI = Agitation Behavior Mapping Instrument, ANCOVA = analysis of covariance, LMBS = Lawton's									

Modified Behavior Stream.

Figure 2. Change in (A) Total Agitation,<sup>a</sup> (B) Verbal Agitation,<sup>a</sup> (C) Physical Agitation,<sup>a</sup> (D) Pleasure,<sup>b</sup> and (E) Interest<sup>b</sup> in Control and Intervention Groups of Patients With Dementia at Baseline and During the Treatment Condition



with residents highlights the meaning of such pleasure, as those emotions define their quality of life.

A limitation of this study is that it was not possible for research assistants to be blinded to group assignment, as they were the ones to administer the nonpharmacologic interventions. For this reason, we took measures to ensure that nonblindness did not affect observations by having an independent observer, blinded both to the background characteristics of the observed residents and to the original ratings, analyze videotapes of agitated study participants and found acceptable interrater agreement of the independent observer's ratings with those of the originally collected direct observations. Given the success of TREA intervention, we believe the results provide convincing evidence that our approach to treatment is indeed solid. However, our interventions were provided by trained research assistants who ascertained the unmet need, obtained materials or referrals needed for intervention, and provided the intervention in a responsible and humane manner. The prevailing structure of most nursing homes is such that there is no one person on the unit responsible for understanding, observing, and determining the unmet needs of the persons with dementia, and current staff members rarely have time to prepare appropriate materials. Moreover, many staff members are overburdened and stressed and not practicing the therapeutic communication style that is necessary for interventions to be effective.<sup>31</sup> Some of these hurdles could be addressed in interventions that train staff members in person-centered care. However, translation of our findings into practice would require a realignment of resources in the nursing homes to hire appropriate staff to meet the needs of residents.

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**Potential conflicts of interest:** The authors report no financial or other relationship relevant to the subject of this article.

*Funding/support:* This study was supported by the National Institutes of Health grant 2 R01 AG010172-10A2.

*Acknowledgments:* We thank the nursing home residents, their relatives, and nursing home staff members and administration for all of their help, without which this study would not have been possible.

## REFERENCES

- 1. Cohen-Mansfield J, Billig N. Agitated behaviors in the elderly, 1: a conceptual review. *J Am Geriatr Soc.* 1986;34(10):711–721.
- Cohen-Mansfield J, Werner P, Marx MS. An observational study of agitation in agitated nursing home residents. *Int Psychogeriatr.* 1989; 1(2):153–165.
- Rabinowitz J, Davidson M, De Deyn PP, et al. Factor analysis of the Cohen-Mansfield Agitation Inventory in three large samples of nursing home patients with dementia and behavioral disturbance. *Am J Geriatr Psychiatry*. 2005;13(11):991–998.
- Jeste DV, Blazer D, Casey D, et al. ACNP White Paper: update on use of antipsychotic drugs in elderly persons with dementia. *Neuropsychopharmacology*. 2008;33(5):957–970.
- Pacher P, Kecskemeti V. Cardiovascular side effects of new antidepressants and antipsychotics: new drugs, old concerns? *Curr Pharm Des.* 2004;10(20):2463–2475.
- Douzjian M, Wilson C, Shultz M, et al. A program to use pain control medication to reduce psychotropic drug use in residents with difficult behavior. *Annals of Long-Term Care*. 1998;6:174–179.
- Cohen-Mansfield J, Werner P. Management of verbally disruptive behaviors in nursing home residents. J Gerontol A Biol Sci Med Sci. 1997;52(6):M369–M377.
- Buettner L, Kolanowski A. Practice guidelines for recreation therapy in the care of people with dementia (CE). *Geriatr Nurs (Minneap)*. 2003; 24(1):18–25.
- Cohen-Mansfield J. Theoretical frameworks for behavioral problems in dementia. Alzheimer's Care Quarterly. 2000;1(4):8–21.
- Day K, Carreon D, Stump C. The therapeutic design of environments for people with dementia: a review of the empirical research. *Gerontologist*. 2000;40(4):397-416.
- Fossey J, Ballard C, Juszczak E, et al. Effect of enhanced psychosocial care on antipsychotic use in nursing home residents with severe dementia: cluster randomised trial. *BMJ*. 2006;332(7544):756–761.
- Evans D, Wood J, Lambert L. A review of physical restraint minimization in the acute and residential care settings. J Adv Nurs. 2002;40(6): 616–625.

- Gerdner LA, Swanson EA. Effects of individualized music on confused and agitated elderly patients. Arch Psychiatr Nurs. 1993;7(5):284–291.
- 14. Camberg L, Woods P, Ooi WL, et al. Evaluation of Simulated Presence: a personalized approach to enhance well-being in persons with Alzheimer's disease. *J Am Geriatr Soc.* 1999;47(4):446–452.
- Lund DA, Hill RD, Caserta MS, et al. Video Respite: an innovative resource for family, professional caregivers, and persons with dementia. *Gerontologist*. 1995;35(5):683–687.
- Sterritt PF, Pokorny ME. Art activities for patients with Alzheimer's and related disorders: working with art may help a client get back in touch with the outside world. *Geriatr Nurs (Minneap)*. 1994;15(3):155–159.
- Kramer SC, Friedmann E, Bernstein PL. Comparison of the effect of human interaction, animal-assisted therapy, and AIBO-assisted therapy on long-term care residents with dementia. *Anthrozoos: A Multidisciplinary Journal of The Interactions of People & Animals.* 2009;22(1):43–57.
- Cohen-Mansfield J. Non-pharmacological management of behavioral problems in persons with dementia: the TREA model. *Alzheimer's Care Quarterly*. 2000;1:22–34.
- Cohen-Mansfield J, Libin A, Marx MS. Nonpharmacological treatment of agitation: a controlled trial of systematic individualized intervention. *J Gerontol A Biol Sci Med Sci.*2007;62(8):908–916.
- Cohen-Mansfield J. Approaches to the management of disruptive behaviors. In: Rubinstein R, Lawton MP, eds. Alzheimer's Disease and Related Dementias: Strategies in Care and Research. New York, NY: Springer; 2000:39–65.
- Morris J, Hawes C, Murphy K, et al. MDS Resident Assessment. Natick, MA: Eliot Press; 1991.
- 22. Morris JN, Fries BE, Morris SA. Scaling ADLs within the MDS. J Gerontol A Biol Sci Med Sci. 1999;54(11):M546–M553.
- Folstein MF, Folstein SE, McHugh PR. "Mini-mental state": a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res.* 1975;12(3):189–198.
- Lawton MP, Van Haitsma K, Klapper J. Observed affect in nursing home residents with Alzheimer's Disease. J Gerontol Psychol Sci Soc Sci. 1996; 51B(1):P3–P14.
- Cohen-Mansfield J, Kerin P, Pawlson G, et al. Informed consent for research in a nursing home: processes and issues. *Gerontologist*. 1988.28(3):355–360.
- Cohen-Mansfield J. Relatives' assessment of pain in cognitively impaired nursing home residents. J Pain Symptom Manage. 2002;24(6):562–571.
- Cohen-Mansfield J, Golander H, Arnheim G. Self-identity in older persons suffering from dementia: preliminary results. *Soc Sci Med.* 2000;51(3):381–394.
- Cohen-Mansfield J, Marx MS. The social network of the agitated nursing home resident. *Research on Aging*. 1992;14(1):110–123.
- Cohen-Mansfield J, Werner P, Culpepper WJ 2nd, et al. Evaluation of an inservice training program on dementia and wandering. *J Gerontol Nurs*. 1997;23(10):40–47.
- Kelley K. Confidence intervals for standardized effect sizes: theory, application and implementation. J Stat Softw. 2007;20(8):1–24.
- Cohen-Mansfield J, Parpura-Gill A. Practice style in the nursing home: dimensions for assessment and quality improvement. *Int J Geriatr Psychiatry*. 2008;23(4):376–386.

Editor's Note: We encourage authors to submit papers for consideration as a part of our Focus on Alzheimer's Disease and Related Disorders section. Please contact Eric M. Reiman, MD, at ereiman@psychiatrist.com.