

# Nonpharmacological Treatment of Agitation: A Controlled Trial of Systematic Individualized Intervention

Jiska Cohen-Mansfield,<sup>1,2,3</sup> Alexander Libin,<sup>4</sup> and Marcia S. Marx<sup>1</sup>

<sup>1</sup>Research Institute on Aging, Charles E. Smith Life Communities, Rockville, Maryland.

<sup>2</sup>Herczeg Center on Aging and Department of Health Promotion, Sackler Faculty of Medicine, Tel Aviv University.

<sup>3</sup>George Washington University Medical Center, Washington, DC.

<sup>4</sup>Georgetown University Department of Psychology, Washington, DC.

**Objective.** The objective of this study was to examine the efficacy of a systematic algorithm for providing individualized, nonpharmacological interventions for reducing agitated behaviors in nursing home residents with dementia.

**Methods.** This placebo-controlled study combined nomothetic and ideographic methodologies. The study was conducted in 12 nursing home buildings in Maryland; 6 were used as treatment facilities, and 6 as control facilities. Participants were 167 elderly nursing home residents with dementia. Interventions were tailored to the individual profiles of agitated participants using a systematic algorithm that considered type of agitation and unmet needs. Interventions were then designed to fulfill the need in a manner that matched the person's cognitive, physical, and sensory abilities, and their lifelong habits and roles. Interventions were provided for 10 days during the 4 hours of greatest agitation. Direct observations of agitation were recorded by trained research assistants via the Agitated Behavior Mapping Instrument (ABMI). Evaluation of positive and negative affect was also based on direct observation and assessed via Lawton's Modified Behavior Stream. Data analysis was performed via SPSS software.

**Results.** The implementation of personalized, nonpharmacological interventions resulted in statistically significant decreases in overall agitation in the intervention group relative to the control group from baseline to treatment ( $F_{1,164} = 10.22, p = .002$ ). In addition, implementation of individualized interventions for agitation resulted in statistically significant increases in pleasure and interest ( $F_{1,164} = 24.22, p < .001$ ;  $F_{1,164} = 20.66, p < .001$ ).

**Conclusions.** The findings support the use of individualized nonpharmacological interventions to treat agitation in persons with dementia and underscore the importance for clinicians of searching for underlying reasons for agitated behaviors.

AGITATION has been 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 (1). The key phrase in that definition is "not judged . . . to result directly from apparent needs or confusion," as the underlying cause of the agitation is often a mystery to the observer. The term "agitation," which is at times used interchangeably with labels such as "problem behaviors" and "disruptive behaviors," encompasses a variety of inappropriate behaviors, including repetitive acts, behaviors that deviate from social norms, and aggressive behaviors that are directed toward oneself or others. Factors found to be linked with manifestations of agitated behaviors in elderly persons with dementia include cognitive impairment (2), the physical and social environment (3,4), individual past experiences (5), medical conditions (4), and depression and social isolation (6,7).

Traditionally, methods utilized to deal with agitation have been the use of physical restraints (8) and/or pharmacological management (9). However, there is growing dissatisfaction with these interventions due to the inhumane consequences of physical restraints and the ongoing concern about adverse side effects and drug interactions resulting from pharmacological interventions (10–12). Moreover,

neither method addresses the underlying reasons for agitation, such as social isolation or pain.

To target unmet needs at the root of agitated behaviors [e.g., pain (13), feelings of loneliness or isolation (14), boredom (15), or sensory deprivation (16)], nonpharmacological interventions (i.e., interventions based on specific needs rather than psychoactive medication) for problem behaviors have been conducted with persons with dementia (17–19). These interventions include modifications of the physical or social environment to decrease agitation or trigger positive behaviors (17,20,21), removal of physical restraints (22), provision of individualized music or other sensory stimulation (14,23,24), real or simulated social contact [e.g., family videotapes and one-on-one social interactions (14), family audiotapes in simulated presence therapy (25)], art activities (26), hand massage (27), and real, toy, or robotic animal-assisted therapy (28,29). Combination interventions have also been successful, as exemplified in the A.G.E. program, which included Activities, Guidelines for psychotropic medications, and Educational rounds (30). Despite the substantial amount of research on nonpharmacological interventions for managing agitated behaviors in cognitively impaired elderly persons, the results of the majority of these studies are ambiguous

Approaches to Management of Verbal Agitation

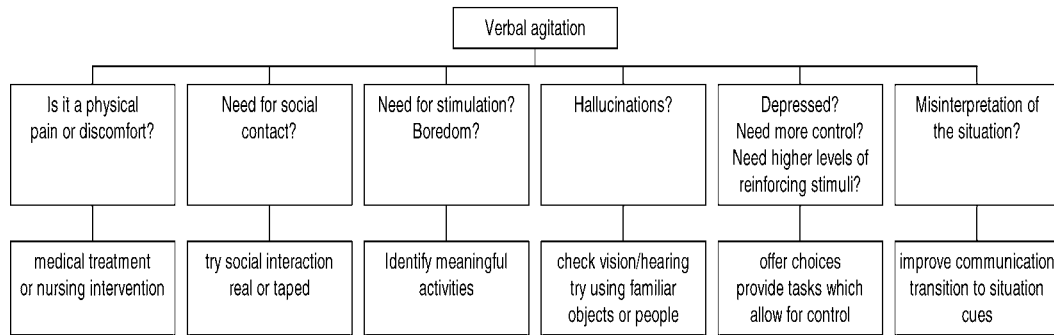


Figure 1. Protocol for assessing reasons for verbal agitated behavior. [Modified from Cohen-Mansfield (31,33).]

due to small sample sizes (which rarely have the statistical power to yield significant findings), diversity of approaches to measurement, and an absence of control conditions (17). Moreover, most studies were based on a solitary intervention, and thus neither matched the intervention to a specific need underlying the agitation nor tailored it to the person’s abilities and background.

In this study we tested a new approach for providing interventions for agitation, which is named Treatment Routes for Exploring Agitation (TREA; 31). TREA is based on a theoretical framework that provides a systematic methodology for individualizing nonpharmacological interventions to the unmet needs of agitated persons (16). Using TREA, needs and preferences of agitated persons are identified through data collection from both formal (nursing staff members) and informal (family members) caregivers, and through observation of the agitated person’s behavior and environment. This information is then used in systematic algorithms to suggest personalized interventions for decreasing agitation. The TREA approach can be viewed as a decision tree that guides caregivers through the necessary steps for exploring and identifying underlying unmet needs that contribute to agitated behaviors (16,17,31). For example,

in the case of a resident who manifests verbal agitation, we know from previous research (4) that the main etiologies of this syndrome are physical pain, lack of social contacts, boredom/inactivity, hallucinations, and depression, all of which form the top row of the decision tree (Figure 1). Because correlates of the different syndromes vary (33), different decision trees are used for the different syndromes of agitated behaviors (Figure 2). In the present study we excluded residents who manifested aggressive behaviors, as these often have a different etiology than do verbal agitation or physically nonaggressive agitation and would require a different research and intervention approach. (A chart of interventions by needs and abilities along with case study examples are available elsewhere) (31).

The following assumptions form the basis of the TREA approach:

- The first step toward developing an individualized treatment plan is to attempt to understand the etiology of the agitated behavior based on individual examination.
- Different types of agitated behaviors have different etiologies; therefore, they require different approaches to treatment.

Approaches to management of physically nonaggressive behaviors

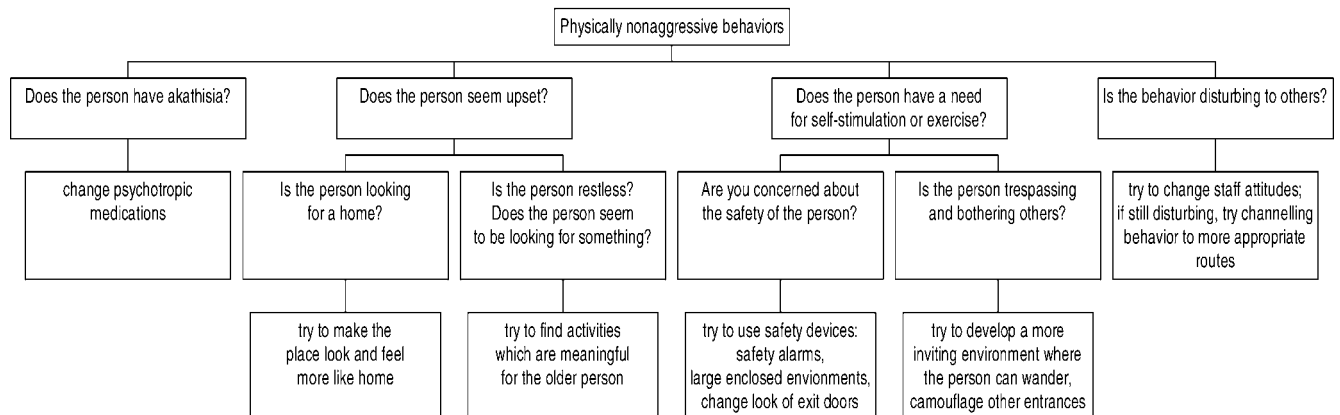


Figure 2. Protocol for assessing reasons for physical nonaggressive behavior. [Modified from Cohen-Mansfield (31,33).]

- In developing a treatment plan, one should capitalize on the remaining abilities and strengths of the individual while recognizing current deficits, especially those related to sensory perception, cognition, and mobility.
- The unique characteristics of the individual, such as past work, hobbies, important relationships, and sense of identity, need to be explored to match the treatment to the past and current preferences of the person.
- Prevention, accommodation, and flexibility are essential elements of intervention

This study was conducted to determine the utility of combining a quantitative aggregate (nomothetic) methodology summarizing results across individuals with an approach that stresses the need to individualize the nonpharmacological treatment of agitation and recognize the unique individuality of each person (idiographic methodology). We used a structured (universal) decision tree protocol to methodically uncover what agitated behaviors were present in each individual participant and the possible reasons for these behaviors. This information was then used to choose which interventions might be appropriate for each participant. In this article, we present the first large placebo-controlled evaluation of systematic individualized nonpharmacological interventions for reducing agitated behaviors in nursing home residents with dementia.

## METHODS

### *Sample and Settings*

The study was conducted in 11 suburban nursing home facilities totaling 12 buildings, as one facility housed two buildings. This project received Institutional Review Board approval.

In this article we present findings from 89 participants from 6 nursing home buildings in the intervention group and 78 participants from 6 nursing home buildings in the control group (see Figure 3 for participant flow). To limit contamination of the interventions' effectiveness, buildings were assigned either control or intervention status (rather than having both within each building). We were unable at times to assign buildings randomly to either intervention or control groups because the administrators of two facilities insisted on making the decision as a condition of participation. Other facilities without such stipulations were randomly assigned to the treatment or control group while balancing the number of facilities in each group. As to the one facility that contained two buildings, one served as an intervention and the other as a control.

Eighty percent of the participants were women, and the average age was 86 years with a range of 59–103 years (Table 1). Statistically significant differences were not found between the intervention and control groups with regard to demographic variables, diagnoses, and current medication, with the exception that participants in the control group were significantly younger than those in the intervention group (means = 85 and 88 years, respectively; Mann-Whitney  $U$  test = 2832,  $p = .04$ ). Moreover, staffing patterns and medical indicators in the intervention and control facilities did not differ significantly based on data obtained

from the National Nursing Home Watch List (34) for the State of Maryland (see Table 2).

### *Assessment*

Background data regarding age, gender, ethnicity, education, and marital status were collected from each resident's chart at the nursing home. Data regarding ADL (activities of daily living) performance, pain, vision, hearing, and speech were obtained via the Minimum Data Set (MDS) (35,36). Information from medical records included current medication lists (including pain relievers and psychotropic drugs) and confirmation of the diagnosis of dementia, as well as other medical diagnoses.

Cognitive functioning of the participants was assessed in two ways: through a modified version of the Brief Cognitive Rating Scale (BCRS) (37,38), and via the Mini-Mental State Examination (MMSE) (32). The BCRS asked nursing staff to rate participants on a 7-point scale ranging from 1 (normal functioning) to 7 (complete inability to function). The MMSE was administered to participants and has possible scores ranging from 0 (severe cognitive impairment) to 30 (normal cognitive functioning).

Depressed affect was rated via the Raskin Depression Scale (RDS) (39) during a structured interview with each participant's immediate nursing staff caregiver. The scale assesses three domains: verbal depression, behavioral manifestations of depression, and manifestations of depression through secondary symptoms. Each area was rated on a 5-point scale from 1 (not at all depressed) to 5 (very much depressed). An overall RDS score was calculated as an average of the separate ratings. Inter-rater agreement averaged 81% (40).

### *Outcome Variables*

*Primary outcome: observed agitation.*—Direct observations of agitation were recorded by trained research assistants via the Agitation Behavior Mapping Instrument (ABMI) (41). Direct observations were chosen because these are more objective and more accurate than other forms of assessment. The ABMI includes 14 items that describe physically agitated (e.g., pacing, repetitive movements) and verbally agitated (e.g., screaming, complaining) behaviors. Inter-rater reliabilities regarding agitated behaviors for this instrument previously averaged 93% (41) and averaged 95.2% during the present study with intra-class correlation (ICC) of .92. Another measure of reliability examined the possible effect of the nonblindness of the observations. For this measure, 10 study participants were videotaped, and inter-rater reliability was obtained from a research assistant who was blinded both to the background characteristics of the observed residents and to the raters themselves. The average agreement between observed agitation recorded from videotape and direct observations of agitated behaviors was 95%, with an ICC of .97. The measure used in the final analysis was an overall agitation score of all observed verbal and physically nonaggressive behaviors.

*Secondary outcome: affect.*—Evaluation of positive and negative affect was based on direct observation and assessed via Lawton's Modified Behavior Stream (42). Five different

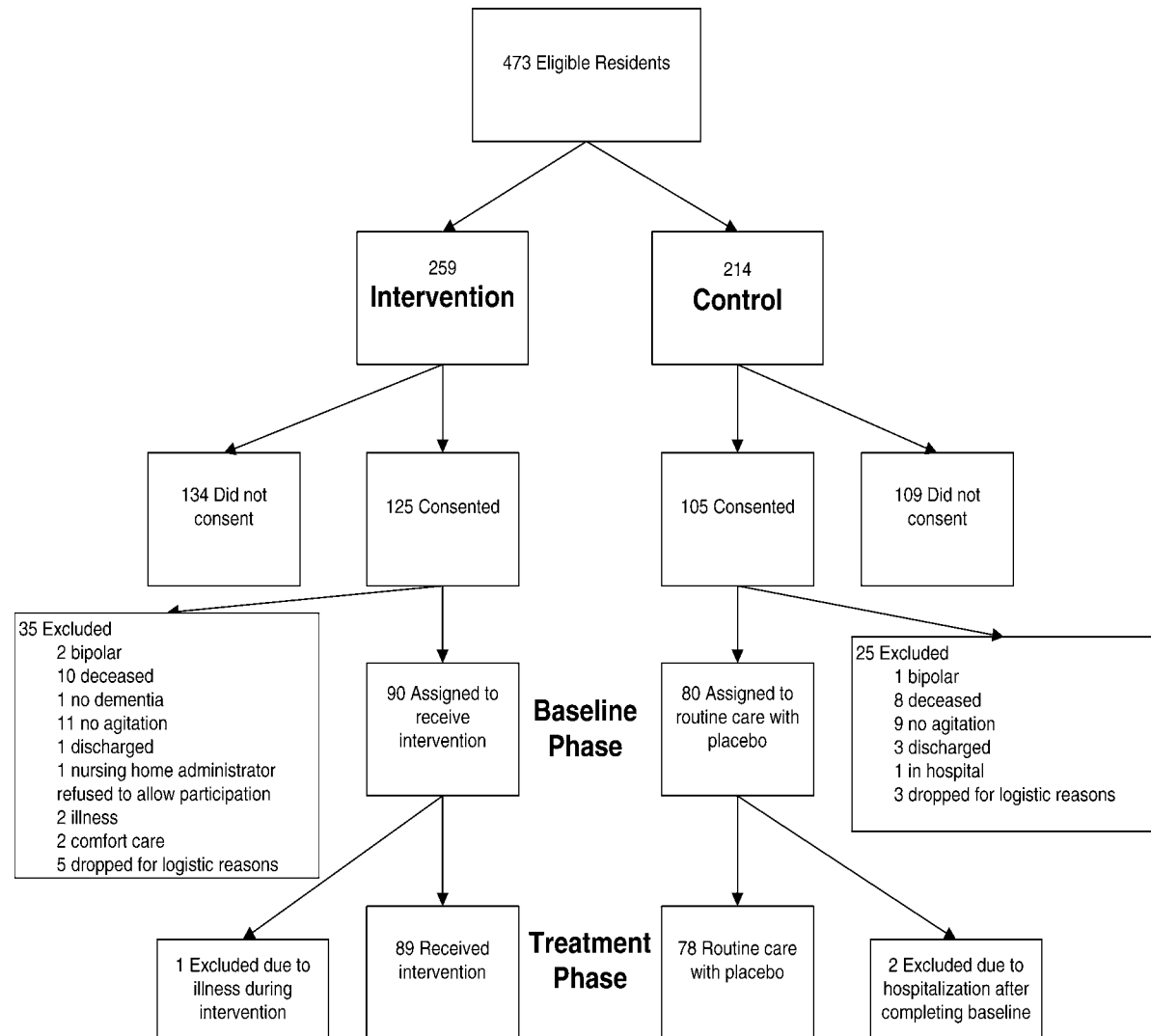


Figure 3. Flow of study participants. Participants were not included if they were expected to die in the next few months, on comfort or hospice care, or if they had an acute illness that excluded them from normal activities.

modes of affect were evaluated: pleasure, interest, anger, anxiety, and sadness. Inter-rater agreement evaluations were conducted repeatedly throughout the study and averaged 85% per emotional mode, with a range of 67%–100%, and an average ICC of .70.

### Procedure

The criteria for exclusion of participants were:

- The resident had been at the facility for < 3 weeks, so nursing staff members would not know the resident well enough to accurately assess him or her.
- The resident exhibited agitation fewer than several times a day.
- There was no dementia diagnosis.
- Nursing staff judged this resident to have a life expectancy of < 3 months due to obvious causes.
- The resident had an accompanying diagnosis of bipolar disorder or schizophrenia.

Informed consent was obtained in written form directly from 2.4% of participants ( $n = 4$ ). These participants were responsible for making their own decisions as listed in the medical chart, and were found to be sufficiently capable of understanding and giving their own consent. For the remaining 97.5%, informed consent was provided by a guardian or the closest family member (43).

After demographics and medical data were obtained, a trained research assistant recorded baseline observations of agitation and affect onto a Palm Pilot m100 handheld computer (Palm, Inc., Sunnyvale, CA). Each participant was observed for 3 consecutive days. Each observation lasted 3 minutes. Each participant was observed once every half hour from 8:00 AM to 9:00 PM over the 3-day period. Research assistants observed one resident at a time, and three to five residents during every half-hour period. On average, 72 baseline observations were recorded for each resident (on a few occasions the research assistants were not

Table 1. Background Characteristics of Participants

Characteristics	% Present		
	Overall <i>N</i> = 167	Control <i>N</i> = 78	Intervention <i>N</i> = 89
<b>Demographic</b>			
Age, mean years*	86.0 (7.6)	85.0 (8.6)	88.0 (6.4)
Gender			
Female	80.2	75.6	84.3
Male	19.8	24.4	15.7
Ethnicity			
Minority	16.8	19.2	14.6
Caucasian	83.2	80.8	85.4
Marital status			
Never married	6.7	9.1	4.5
Married	18.8	20.8	17.0
Widowed	66.1	59.7	71.6
Separated/Divorced	8.5	10.4	6.8
Dementia diagnosis			
Alzheimer's	39.5	41	38.2
Parkinson's	3	3.8	2.2
Multi-infarct/vascular dementia	13.8	12.8	14.6
Other (mainly senile dementia and unspecified)	40.1	39.7	40.4
With two diagnoses (mainly of Alzheimer's, Parkinson's, multi-infarct/vascular dementia, and one Lewy body dementia)	3.6	2.6	4.5
Education ( <i>n</i> = 86; control = 43; intervention = 43)			
High school or less	62.8	58.1	67.4
College/Technical school	31.4	32.6	30.2
Graduate degree	5.8	9.3	2.3
<b>Functional</b>			
		Mean ( <i>SD</i> )	
<b>Cognitive status</b>			
MMSE	7.08 (6.2)	6.88 (6.5)	7.26 (6.0)
BCRS	5.43 (1.1)	5.52 (1.0)	5.36 (1.2)
<b>Diagnoses and prescribed medication</b>			
Total No. of diagnoses per person	5.12 (2.3)	4.91 (2.3)	5.30 (2.4)
Total No. of medications per person	3.55 (1.6)	3.58 (1.5)	3.52 (1.6)
% Administered sedatives	13.3	16.9	10.1
% Administered antipsychotics	56	58.4	53.9
% Administered antidepressants	43.4	45.5	41.6
% Administered antianxiety	34.9	37.7	32.6
% Administered analgesics	72.3	68.8	75.3
ADL, mean	2.46 (1.02)	2.42 (1.03)	2.49 (1.01)
Depression (Raskin depression scale)	1.45 (0.7)	1.52 (0.8)	1.39 (0.6)
Vision (index based on MDS)	0.62 (1.0)	0.67 (1.1)	0.57 (1.0)
Hearing (index based on MDS)	0.47 (0.8)	0.49 (0.9)	0.46 (0.7)
Speech (index based on MDS)	0.93 (0.3)	0.89 (0.3)	0.96 (0.2)
Pain frequency (index based on MDS)	1.32 (0.6)	1.29 (0.6)	1.35 (0.7)
Overall agitation (ABMI)	5.11 (3.6)	5.05 (3.4)	5.17 (3.8)
Pleasure <sup>†</sup>	1.25 (0.3)	1.20 (0.2)	1.30 (0.3)
Interest	2.59 (0.7)	2.56 (0.7)	2.61 (0.7)
Negative affect	1.12 (0.2)	1.12 (0.2)	1.12 (0.2)

Notes: Numbers are either percent or mean (standard deviation). Ranges for scales are as follows: Activities of Daily Living (ADL), from 0 (independent) to 4 (total dependence); Raskin, from 1 (not at all depressed) to 5 (very much depressed); Vision, 0 (adequate) to 4 (severely impaired); Hearing, 0 (hears adequately) to 3 (highly impaired); Speech, 0 (clear speech) to 2 (no speech); Pain frequency, 1 (no pain) to 3 (pain daily).

\*Mann-Whitney *U* test = 2832, *p* = .04.

<sup>†</sup>Mann-Whitney *U* test = 2746, *p* = .019.

MMSE = Mini-Mental State Examination; BCRS = Brief Cognitive Rating Scale; MDS = Minimum Data Set; ABMI = Agitated Behavior Mapping Instrument.

able to observe the resident because the door was closed, the resident was asleep, or the resident needed privacy to complete an ADL). Based on these data, a 4-hour peak period of agitation was identified for each resident.

Relatives of participants in the intervention group responded to a questionnaire that included items concerning

participants' medical history (44), self-identity (45), and social functioning (46). Medical history was provided to a consulting geriatrician who then performed physical evaluations to determine presence of pain, delirium, and infection.

For the intervention group, we used the TREA decision tree protocol (31) to uncover possible reasons for each



participant's manifestations of agitated behaviors, and we paid close attention to data derived from consultant geriatricians' evaluations, direct observations, psychosocial assessments, and interviews with the nursing staff. Using TREA, a cause was hypothesized, a corresponding treatment category was identified, and the specifics of the treatment were chosen to fit the person's past identity, preferences, and abilities. Some of the interventions used were individualized music, family videotapes and pictures, illustrated magazines and large print books, board games and puzzles, plush toys, sorting cards with pictures and words, stress balls, baby dolls, electronic massagers, pain treatment, outdoor trips to the nursing home garden, perfume, a "busy apron," building blocks, and Play-Doh. Interventions were individualized and administered to each participant based on the peak periods of agitation determined during baseline. The exact time of the interventions varied depending on the resident's medical and psychological condition (e.g., whether the resident was awake, ill, willing). One research assistant was responsible for conducting the interventions and a second research assistant recorded the observations.

A placebo intervention was provided for the control buildings. Staff members on the control units attended an in-service presentation that described the different syndromes of agitation, their etiologies, and possible nonpharmacological treatments. 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 (47), yet does provide the staff with information and with a sense of having received an intervention. We considered and rejected several other types of controls: no intervention—usual care group (we felt our in-service placebo condition was superior to this as it controls for the impression that an intervention has taken place), a placebo tablet group (clearly inappropriate for a nonpharmacological study), and a group that received the same amount of social contact as the intervention group (rejected because social contact is a crucial ingredient of the intervention and part of the effect being evaluated).

The intervention period for the treatment group lasted 10 consecutive days, and observations were recorded during the four designated hours of the first and last 3 days of the intervention. The same days of observation were used for residents in the control group, that is, days 1–3 and days 8–10 of the designated corresponding period.

#### 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 control) was the between-subjects factor, and MMSE score was used as a covariate. The primary dependent measure was the overall agitation score. Secondary measures were those of observed affect: pleasure, interest, and a composite score of negative affect based on anger, anxiety, and sadness which was developed because of the low occurrence of these three variables. All statistical analyses were performed using SPSS software (SPSS Inc., Chicago, IL).

Table 2. Characteristics and Means of Intervention and Control Facilities Compared via *t* Tests

	Intervention Facilities ( <i>N</i> = 6 Buildings)	Control Facilities ( <i>N</i> = 6 Buildings)
Nursing Home Indicator		
Average number of beds in each building	195	150
Religious affiliation	33%	33%
Specialized dementia unit	83%	50%
Registered Nurse hours per resident per day	0.55 (.13)	0.54 (.16)
Licensed Practical Nurse/Licensed Vocational Nurse hours per resident per day	0.58 (.21)	0.74 (.20)
Certified Nursing Assistant hours per resident	2.67 (.38)	2.44 (.36)
Total number of nursing staff hours per resident per day	3.80 (.37)	3.72 (.42)
Percentage of residents . . .		
Who need more help doing daily activities	15.17 (4.55)	18.33 (3.88)
With pressure (bed) sores—measures	7.17 (3.31)	8.33 (3.08)
Who lost too much weight	11.60 (8.79)	12.50 (3.21)
With pain	12.83 (6.91)	7.67 (4.13)
In physical restraints	2.83 (2.64)	2.00 (3.46)
With infections	16.67 (5.32)	15.83 (8.45)
With delirium	7.80 (12.54)	8.50 (10.65)
Percentage of short stay residents with pain	27.00 (5.46)	19.50 (7.77)
Percentage of residents who improved in walking	33.80 (11.03)	32.00 (14.10)

Note: Data taken from: <http://www.medicare.gov>. None of the differences were statistically significant.

## RESULTS

### Primary Outcome

There was a significant interaction between the time factor and the group factor for overall agitation, demonstrating a greater decrease in agitation for the intervention group as compared to the control group ( $F_{1,164} = 10.22, p = .002$ ) (see Table 3 and Figure 4).

### Secondary Outcomes: Affect

Significantly greater increases in pleasure from baseline as well as increased interest were observed in the intervention group as compared to the control group ( $F_{1,164} = 24.22, p < .001$ ;  $F_{1,164} = 20.66, p < .001$ ; respectively) (see Table 3 and Figures 5 and 6). Significant changes did not occur for negative affect.

We also examined the number of sedatives, antipsychotics, and antianxiety and antidepressant medications administered to participants in the intervention and control groups to rule out the possibility that these medications could account for differences in agitation. No differences were found between the groups at baseline or from baseline to treatment within each group. The only significant difference between the intervention group and control group was in number of antidepressant medications during the treatment phase, when participants in the control group received more antidepressant medication

Table 3. Changes in Outcome Variables by Time and by Group: Results of Two-Way Repeated-Measures ANCOVAs

Dependent Variable	Control Group Mean ( <i>SD</i> )		Intervention Group Mean ( <i>SD</i> )		Interaction F Value
	Baseline	Treatment	Baseline	Treatment	
Primary outcome—observed agitation					
Overall agitation (ABMI)	5.05 (3.36)	4.10 (3.47)	5.17 (3.75)	3.23 (3.16)	10.223*
Secondary outcome—affect					
Pleasure	1.20 (.24)	1.28 (.34)	1.30 (.30)	1.65 (.49)	24.216**
Interest	2.56 (.66)	2.41 (.75)	2.61 (.68)	2.89 (.70)	20.662**
Negative affect	1.12 (.16)	1.11 (.19)	1.12 (.17)	1.08 (.10)	2.173

Notes: \* $p \leq .01$ ; \*\* $p \leq .001$ .

ANCOVA = analysis of covariance; ABMI = Agitation Behavior Mapping Instrument; *SD* = standard deviation.

than did those in the intervention group (means: control = 0.69, intervention = 0.45;  $t_{(161)} = 2.587$ ,  $p = .011$ ).

## DISCUSSION

This is the first large study to demonstrate the efficacy of the systematic use of individualized nonpharmacological interventions for agitation. The study has several strengths: it utilized a placebo control which offered an intervention to the control group; it used comparable control and placebo nursing facilities and residents; there were no significant differences in the use of psychotropic medications between the facilities; and the sample size was large relative to those in most nonpharmacological studies (19), although not in comparison to those in pharmacological studies (48,49). As has been seen in other studies, a strong placebo effect was found, yet the intervention had an even stronger impact.

The individualized interventions used in this study are anchored in “person-centered care” (50) and involve a systematic analysis of the needs underlying agitated behaviors, the person’s past role-identity, personal past and/or present preferences, and cognitive, mobility, and sensory abilities and limitations. As “person” information is matched to an assortment of available interventions, it is easy to see how

we came to use a wide range of interventions throughout the study—from family videos and puzzles to outdoor walks and electric massage devices. Such interventions need not be expensive, but well thought out so as to be relevant to the needs, abilities, and willingness of the agitated individuals. Many of the interventions involved engaging residents in an activity that was meaningful to them, which is one reason for the increase in interest and pleasure found in the treatment group. Although the required time of intervention delivery varied, all interventions were designed with the idea that they could be easily administered and matched the participant’s level of functioning. The study’s findings are considered an underestimate of the potential effects of non-pharmacological interventions because: (i) the period for preparing the interventions was too short in some cases, such as when environmental modifications or unique materials for interventions were indicated; and (ii) staff cooperation varied greatly across the different nursing homes, such that when staff intervention was needed it was not always available. For instance, in some cases we thought the resident suffered from pain, but the physician disagreed with us. In one case, when we suggested scheduled toileting for a resident who urinated on the radiators, the nursing staff member refused, saying that the

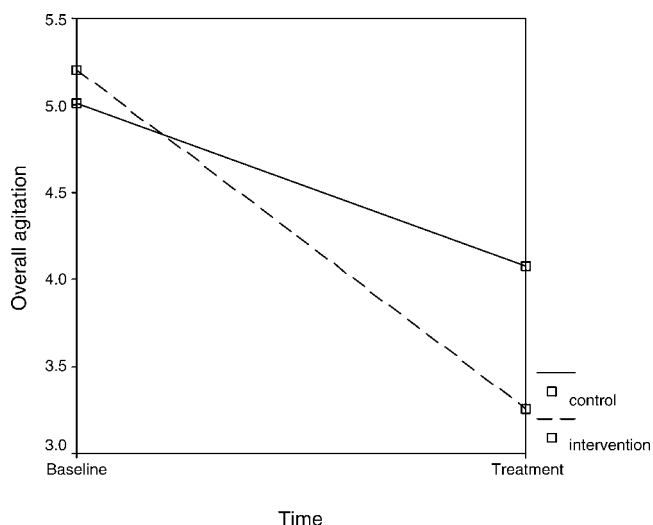


Figure 4. Change in overall agitation from baseline phase to the treatment phase for the intervention and control groups.

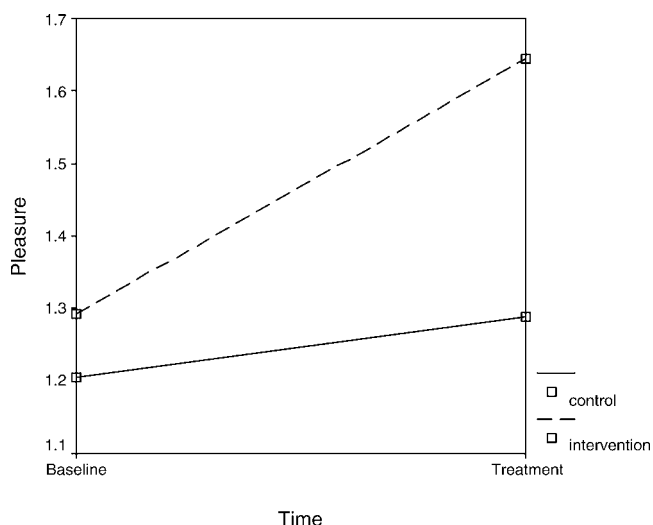


Figure 5. Change in pleasure from baseline to treatment for the intervention and control groups.

resident had an MMSE score of 0 and therefore could not benefit from a schedule. Removal of physical restraints was also an intervention that sometimes met with staff resistance.

It was challenging to apply rigorous methodological design to intervention research conducted in nursing homes, and we acknowledge that we fell short of the gold standard with respect to randomization of participants into intervention and control groups, as it was necessary to leave the decision to receive interventions to the facility administrators. Yet, we did include a placebo-controlled control group with demographic and medical attributes comparable to the intervention group. Along these lines, it was impossible to conduct “pure” nonpharmacological interventions in the nursing home setting, as our nonpharmacological interventions were often superimposed on pharmacological treatment. However, we were able to control for this by using intervention and control groups that received comparable amounts of sedatives and psychotropic drugs.

Our findings suggest that nonpharmacological interventions decrease agitation. The importance of the findings regarding the efficacy of an individualized nonpharmacological intervention is bolstered by the ongoing controversy regarding the use of antipsychotic drugs for treatment of these behaviors, especially in view of both general side effects and cerebrovascular adverse events (51). Additionally, by addressing underlying needs, the interventions provide an improved quality of life for persons who are compromised in their ability to care for their needs, in their health status, in their physical and cognitive functioning, or in other aspects of life. This basic tenet is expressed in the enhanced sense of interest and pleasure that accompanied the decrease in agitation. The clinical significance of using a TREA intervention was also demonstrated by comments from many staff members on the noticeable reduction of these behaviors in participants following treatment. This effect is often limited to the time of intervention. However, it may have an ongoing impact when implemented by staff members, as illustrated by Fossey and colleagues (20), whose staff training and support intervention enabled the continued reduction in the number of neuroleptic drugs taken by intervention participants in comparison to controls, despite the absence of a significant reduction in the number of agitated behaviors.

Such findings have implications for the nursing home system in terms of medical and nursing care, reimbursement, and research. From the point of view of medical and nursing care, there is a need to educate nursing home personnel that nonpharmacological interventions can be a valuable option. In our contact with both physicians and administrators, we were surprised to find that some had little understanding of nonpharmacological interventions, whereas others did not believe that nonpharmacological treatments could have any effect. To implement such interventions, staff members must receive training and mentoring in implementation and be given sufficient time and resources to ascertain each resident's past preferences to match these to the resident's current needs. The methodology required for such training and mentoring and its cost need to be studied in future

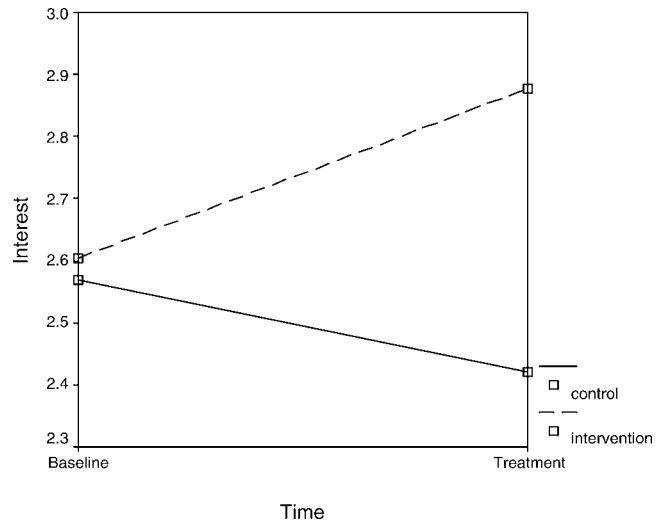


Figure 6. Change in interest from baseline phase to the treatment phase for the intervention and control groups.

research. In addition to staff preparation, other resources may be necessary, such as purchasing objects with which residents can safely engage, or adapting the environment to allow residents to walk around in a comfortable and pleasant environment. In this study, we did not collect cost data. Whereas an intervention can sometimes be costly in terms of both money and time (e.g., making a video with a family member), many of the interventions used in the present study were inexpensive. Furthermore, it is important to keep in mind that the use of psychotropic drugs can also be costly. To increase the systematic use of nonpharmacological interventions, reimbursement will need to address their costs. A limitation of the present study was the use of research staff to conduct interventions rather than training nursing home staff. This procedure was used to assure adherence to treatment protocol. Future studies are needed to translate our findings for use with nursing home staff. Another limitation of the present study is that our intervention phase lasted only 10 days. With the assistance of nursing home staff, this time could be extended in future studies. Finally, future research needs to clarify additional issues, such as which residents are more likely to benefit from nonpharmacological approaches, what system and training modifications are needed to embrace this approach as part of nursing home care, and the associated cost.

#### ACKNOWLEDGMENTS

This study was supported by National Institutes of Health grant AG 10172.

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

#### CORRESPONDENCE

Address correspondence to Jiska Cohen-Mansfield, PhD, Research Institute on Aging of the Charles E. Smith Life Communities, 6121 Montrose Road, Rockville, MD 20852. E-mail: cohen-mansfield@hebrew-home.org



## REFERENCES

- Cohen-Mansfield J, Billig N. Agitated behaviors in the elderly: a conceptual review. *J Am Geriatr Soc.* 1986;34:711–721.
- Cohen-Mansfield J, Culppepper W, Werner P. The relationship between cognitive function and agitation in senior day care participants. *Int J Geriatr Psychiatry.* 1995;10:585–595.
- Cohen-Mansfield J, Werner P. Environmental influences on agitation: an integrative summary of an observational study. *Am J Alzheimers Dis Other Dement.* 1995;10(1):32–39.
- Cohen-Mansfield J, Marx MS, Werner P. Agitation in elderly persons: an integrative report of findings in a nursing home. *Int Psychogeriatr.* 1992;4(Suppl 2):221–240.
- Cohen-Mansfield J, Marx M. Do past experiences predict agitation in nursing home residents? *Int J Aging Hum Dev.* 1989;28:285–294.
- Cohen-Mansfield J, Marx MS. The relationship between depression and agitation in nursing home residents. *Compr Gerontol B.* 1988;2:141–146.
- Cohen-Mansfield J, Werner P, Marx MS. The social environment of the agitated nursing home resident. *Int J Geriatr Psychiatry.* 1992;7:789–798.
- Burton LC, German PS, Rovner BW, et al. Mental illness and the use of restraints in nursing homes. *Gerontologist.* 1992;32:164–170.
- Bronskill SE, Anderson GM, Sykora K, et al. Neuroleptic drug therapy in older adults newly admitted to nursing homes: incidence, dose, and specialist contact. *J Am Geriatr Soc.* 2004;52:749–755
- Herrmann N, Lanctot KL. Do atypical antipsychotics cause stroke? *CNS Drugs.* 2005;19:91–103.
- Pacher P, Kecskemeti V. Cardiovascular side effects of new antidepressants and antipsychotics: new drugs, old concerns? *Curr Pharm Des.* 2004;10:2463–2475.
- Katona CL. Psychotropics and drug interactions in the elderly patient. *Int J Geriatr Psychiatry.* 2001;16(Suppl 1):S86–S90.
- 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. *Ann Long-Term Care.* 1998;6:174–179.
- Cohen-Mansfield J, Werner P. Management of verbally disruptive behaviors in the nursing home. *J Gerontol Med Sci.* 1997;52A:M369–M377.
- Buettner L, Kolanowski A. Practice guidelines for recreation therapy in the care of people with dementia. *Geriatr Nurs.* 2003;24:18–25.
- Cohen-Mansfield J. Theoretical frameworks for behavioral problems in dementia. *Alz Care Quart.* 2000;1:8–21.
- Cohen-Mansfield J. Non-pharmacological interventions for inappropriate behaviors in dementia: a review, summary, and critique. *Am J Geriatr Psychiatry.* 2001;9:361–381.
- Opie J, Rosewarne R, O'Connor D. The efficacy of psychosocial approaches to behaviour disorders in dementia: a systematic literature review. *Aust N Z J Psychiatry.* 1999;33:789–799.
- Snowden M, Sato K, Roy-Byrne P. Assessment and treatment of nursing home residents with depression or behavioral symptoms associated with dementia: a review of the literature. *J Am Geriatr Soc.* 2003;51:1305–1317.
- 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;332:756–761.
- Day K, Carreon D, Stump C. The therapeutic design of environments for people with dementia: a review of the empirical research. *Gerontologist.* 2000;40:397–416.
- Evans D, Wood J, Lambert L. A review of physical restraint minimization in the acute and residential care settings. *J Adv Nurs.* 2002;40:616–625.
- Gerdner LA, Swanson EA. Effects of individualized music on confused and agitated elderly patients. *Arch Psychiatr Nurs.* 1993;7:284–291.
- Burns A, Byrne J, Ballard C, Holmes C. Sensory stimulation in dementia. *BMJ.* 2002;325:1312–1313.
- 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;47:446–452.
- 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.* 1994;15:155–159.
- Remington R. Calming music and hand massage with agitated elderly. *Nurs Res.* 2002;51:317–323.
- Zisselman MH, Rovner BW, Shmuelly Y, Ferrie P. A pet therapy intervention with geriatric psychiatry inpatients. *Am J Occup Ther.* 1996;50:47–51.
- Libin A, Cohen-Mansfield J. Therapeutic robot for nursing home residents with dementia: a comparative study. *Am J Alzheimers Dis Other Dement.* 2004;19:111–116.
- Rovner BW, Steele CD, Shmuelly Y, Folstein MF. A randomized trial of dementia care in nursing homes. *J Am Geriatr Soc.* 1996;44:7–13.
- Cohen-Mansfield J. Non-pharmacological management of behavioral problems in persons with dementia: the TREA model. *Alz Care Quart.* 2000;1:22–34.
- 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;12:189–198.
- 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: Springer; 2000:39–65.
- Nursing Home Compare—Centers for Medicare & Medicaid Services. Available at <http://www.medicare.gov/NHCompare>. Last accessed February 17, 2005.
- Morris J, Fries B, Morris S. Scaling ADLs within the MDS. *J Gerontol Med Sci.* 1999;54A:M546–M553.
- Morris J, Hawes C, Murphy K, et al. *MDS Resident Assessment.* Natick, MA: Eliot Press; 1991.
- Reisberg B, Schneck MK, Ferris SH, et al. The Brief Cognitive Rating Scale (BCRS): findings in Primary Degenerative Dementia (PDD). *Psychopharmacol Bull.* 1983;19:47–50.
- Cohen-Mansfield J, Marx MS, Rosenthal AS. Dementia and agitation in nursing home residents: how are they related? *Psychol Aging.* 1990;5:3–8.
- Raskin A. Three area severity of depression scales. In Bellack AS, Herson M, eds. *Dictionary of Behavioral Assessment Techniques.* New York: Pergamon Press; 1988:476–477.
- Cohen-Mansfield J, Werner P. Depression in senior day care participants: ratings by different informants. *Depression.* 1995;2:272–277.
- Cohen-Mansfield J, Werner P, Marx MS. An observational study of agitation in agitated nursing home residents. *Int Psychogeriatr.* 1989;1:153–165.
- Lawton MP, Van Haitsma K, Klapper J. Observed affect in nursing home residents with Alzheimer's disease. *J Gerontol Psychol Sci.* 1996;51B:P3–P14.
- Cohen-Mansfield J, Kerin P, Pawlson LG, et al. Informed consent for research in the nursing home: processes and issues. *Gerontologist.* 1988;28:355–359.
- Cohen-Mansfield J. Relatives' assessment of pain in cognitively impaired nursing home residents. *J Pain Symptom Manage.* 2002;24:562–571.
- Cohen-Mansfield J, Golander H, Arnheim G. Self-identity in older persons suffering from dementia: preliminary results. *Soc Sci Med.* 2000;51:381–394.
- Cohen-Mansfield J, Marx MS. The social network of the agitated nursing home resident. *Res Aging.* 1992;14:110–123.
- Cohen-Mansfield J, Werner P, Culppepper WJ, Barkley D. Evaluation of an in-service training program on dementia and wandering. *J Gerontol Nurs.* 1997;23:40–47.
- Brodady H, Ames D, Snowdon J, et al. A randomized placebo-controlled trial of risperidone for the treatment of aggression, agitation, and psychosis of dementia. *J Clin Psychiatr.* 2003;64:134–143.
- DeDeyn PP, Carrasco MM, Deberdt W, et al. Olanzapine versus placebo in the treatment of psychosis with or without associated behavioral disturbances in patients with Alzheimer's disease. *Int J Geriatr Psychiatry.* 2004;19:115–126.
- Zeman S. Person-centered care for the patient with mid- and late stage dementia. *Am J Alz Dis.* 1999;14:308–310.
- Ballard C, Cream J. Drugs used to relieve behavioral symptoms in people with dementia or an unacceptable chemical cost? Argument. *Int Psychogeriatr.* 2005;17:4–12; discussion 22–29.

Received March 1, 2006

Accepted October 17, 2006

Decision Editor: Darryl Wieland, PhD, MPH