A Randomized Trial of Dementia Care in Nursing Homes

Barry W. Rovner, MD, Cynthia D. Steele, RN, MPH,† Yochi Shmuely, DSW,* and Marshal F. Folstein, MD‡*

OBJECTIVE: To evaluate the efficacy of a dementia care program to reduce behavior disorders in nursing home patients with dementia.

DESIGN: Randomized controlled clinical trial with 6-month follow-up.

SETTING: A 250-bed community nursing home.

PATIENTS: The nursing home was screened to identify patients with dementia and behavior disorders. A total of 118 patients were eligible for randomization. Of these, 89 (75.4%) were randomized, and 81 of these (91.0%) completed the trial.

INTERVENTION: The A.G.E. dementia care program consisted of Activities, Guidelines for psychotropic medications, and Educational rounds. The control treatment was usual nursing home care.

MEASUREMENTS: Behavior disorders, antipsychotic drug and physical restraint use, patient activity levels, and cognitive and functional status.

RESULTS: After 6 months, 12 of 42 (28.6%) intervention patients exhibited behavior disorders compared with 20 of 39 (51.3%) controls (OR = 0.38; 95% CI [0.15, 0.95]; P = .037). Controls were more than twice as likely to receive antipsychotics (OR = 2.55, 95% CI [0.96,6.76]; $P < .056$), to be restrained during activity times (OR = 2.98, 95% CI [1.10, 8.04]; $P < .028$), and to be restrained on nursing units (OR = 2.14, 95% CI [0.9,5.3]; $P < .10$). Intervention patients were much more likely to participate in activities (OR = 13.71; 95% CI [4.51,41.73]; P = .001).

CONCLUSIONS: The A.G.E. program reduces the prevalence of behavior disorders and the use of antipsychotic drugs and restraints. It is practical, feasible, and appears to improve the lives of patients with dementia in nursing homes. **J Am Geriatr Soc 44:7–13, 1996.**

From the *Department of Psychiatry and Human Behavior, Jefferson Medical College, Philadelphia, Pennsylvania; † Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine, Baltimore, Maryland; and ‡ Department of Psychiatry, New England Medical Center, Boston, Massachusetts.

This study was supported by a grant from the National Institute of Mental Health (RO1 MH45293).

Presented at the Gerontological Society of American Meeting, November 1993, New Orleans, Louisiana.

Address correspondence to Barry W. Rovner, MD, 900 Walnut Street, 8th Floor, Philadelphia, PA. 19107.

More than 80% of nursing home patients experience dementia, behavior disorders, psychosis, or depression, but fewer than 5% receive mental health care.[1–3] Instead, many are uncritically prescribed psychotropic medications or are physically restrained.[4] The high frequency of these psychiatric symptoms and the use of psychotropic drugs and restraints suggest that nursing homes serve as de facto mental institutions for older people in the United States.

In spite of these epidemiological and clinical realities, nursing homes continue to model themselves after general medical hospitals and fail to meet current standards of psychiatric care.[5] An Institute of Medicine report reached similar conclusions, which led to the Nursing Home Reform Act of 1987.[6,7] This federal legislation describes specific indications for psychotropic drug and restraint use and requires the development of psychosocial programs to improve patients' level of functioning.

For editorial comment, see p. 91

Although the mandate to transform nursing homes from restrictive to rehabilitative environments is clear, the means to achieve this are not. For example, no new funding is available to create psychosocial programs, and little research exists to guide them. Clinical experience, anecdotal reports, and studies with limited research designs have suggested the value of various behavioral techniques, medications, and special care units, but to our knowledge no randomized controlled clinical trials have been conducted.[8–15]

This study reports the improvements associated with the A.G.E. program of dementia care (Activities, Guidelines for psychotropic medications, and Education) in a randomized controlled clinical trial. We tested the hypothesis that structured activity, along with pharmacologic treatment of depression, delusions, and hallucinations, would reduce behavior disorders to a greater extent than usual nursing home care.

METHODS

Setting

The study was conducted in a 250-bed intermediate level-of-care nursing home in Baltimore, Maryland, from 1989 to 1991. The facility was divided into three floors comprising six nursing units ranging in size from 30 to 56 beds. It was owned by a private corporation that operated 13 other nursing homes in Maryland and 32 nationwide and was the largest nursing home chain in Maryland. The corporation and the Dementia Research Clinic of the Johns Hopkins Hospital established a collaborative relationship in 1983 to

0002-8614/96/$3.50

conduct epidemiological studies and to develop new approaches to psychiatric care.

Design

A two-stage sampling procedure was used to identify patients eligible for the study. First, the presence of a behavior disorder was determined by a research nurse who screened all patients by interviewing nursing staff most familiar with each patient. The Psychogeriatric Dependency Rating Scale (PGDRS),[16] a reliable and valid standardized observer rating scale for older institutionalized patients that assesses dependency attributable to behavior disorders, disorientation, and functional impairment, was used to determine eligiblity. A behavior disorder was "present" if a patient exhibited two of the following eight behaviors more than twice a week: disrupts nursing routines, wanders and requires redirection, demands attention, makes intolerable noises, is physically combative, refuses directions, is verbally abusive, or paces restlessly. We had used the PGDRS previously in a 1-year longitudinal study of 454 nursing home patients and had demonstrated its reliability and validity.[17]

Second, cases who screened positive for behavior disorder were examined by a research psychiatrist to diagnose primary degenerative dementia and multi-infarct dementia according to DSM-III-R criteria using the modified Present State and the Mini-Mental State Examinations (MMSE).[18,19] There was no MMSE cut-off score for eligibility. In addition, physician and family consent and patient assent were required. The Johns Hopkins Institutional Review Board and the nursing home corporation approved the treatment protocol and consent procedures.

The trial was conducted in two planned replications to achieve an adequate sample size. The sample size was based on an anticipated 25% difference in the prevalence of behavior disorders after 6 months. The total target sample size was 80 cases, error protection was 0.05 (1-sided), and power .76. In the first replication, 46 patients were randomized and studied for 6 months. Two months later, a second replication enrolled patients following the same procedures. Data from both replications were combined because no significant differences were found between them (data available upon request).

One hundred eighteen patients met both the behavior and dementia criteria and were eligible for randomization. The allocation procedure was a fixed, uniform randomization scheme by computer algorithm. Twenty-nine patients were not randomized because families (n = 24) or physicians (n = 5), refused, but these cases did not differ from randomized patients in their demographic characteristics nor number of behavior disorders. Eighty-nine patients were randomized, and 81 (91%) completed the trial. Eight patients dropped out before the trial began: three had died, three refused participation, and two were transferred. One intervention and one control patient died during the trial and 3-month data were used. After the first replication, controls who continued to meet entry criteria were eligible for the second replication. Fourteen of 20 (70%) controls were subsequently randomized. Intervention patients from the first replication were excluded because they no longer represented usual nursing home patients.

Experimental Treatment

Patients participating in the A.G.E. program received usual nursing and medical care as well as the experimental intervention, which was made up of three components.

Activity Program

The activity program functioned as a day program (weekdays 10 AM to 3 PM) within the nursing home. It provided activities to the intervention patients, who continued to reside in their usual rooms but who were assembled in an activities room each morning. The 20′x 40′ room had been used for nursing reports, and its existing design was not modified. A creative arts therapist and two nursing aides, who were not employed by the nursing home, developed and implemented the program. The activities included music, exercise, crafts, relaxation, reminiscences, word games, and food preparation and were based on activities described by Zgola in *Doing Things*.[20] Its goals were to provide structure and mental and physical stimulation and to reinforce social skills. A part-time research nurse assisted in the activities and assessed patients' clinical symptoms (13.5 hours/week).

Guidelines for Psychotropic Drug Management

Psychotropic drugs used before the study were considered possibly unnecessary, and attempts were made to taper or discontinue them. Primary care physicians turned over psychotropic drug prescribing to the psychiatrist. After a 2-week period of adjustment to the activity program, if patients met DSM-III-R criteria for major depression, based on a study psychiatrist's examination, nortriptyline was prescribed according to the protocol (Appendix). If delusions or hallucinations were present and were associated with restlessness or combativeness, thioridazine was prescribed (Appendix).

Educational Rounds

The study psychiatrist met with the A.G.E. activities staff weekly for 1 hour to discuss each patient's behavioral, functional, and medical status. Discussions focused on patients' predisposing features to behavior disorders (e.g., depression, delusions, hallucinations, delirium) or any precipitants (e.g., incident medical symptoms, medication changes, sleep disorders, or notable environmental changes).

Control Treatment

Usual nursing home care was modified by the experimental intervention. Because intervention patients were removed from the units during the day, the nurse-to-patient ratio was increased. The nursing home's activity program was staffed by an activities director, two assistants, and two volunteers. It included discussion groups, arts and crafts, special programs with outside entertainers, and bedside sensory stimulation. There was no specific group activity for demented patients. On average, approximately 3 to 6 hours per week of activities were provided for each resident. A community psychiatrist was consulted by primary care physicians for 13 of 39 (33.3%) of controls.

Outcome Measures

Primary outcome

The primary outcome was a composite behavior disorder measure assessed as "present" or "absent" at 6 months. A

behavior disorder was present if (1) a research psychiatrist (blind to treatment assignment) directly observed a behavior disorder. If no behavior disorder were observed, then a behavior disorder was present if (2) nursing staff (nonblind) reported two or more behaviors on the PGDRS that were severe enough to require restraints on the nursing unit.

For criterion #1, a research psychiatrist observed patients directly for 5 minutes on two occasions for 1 week between 3 and 5 PM when no activities were in progress. This time was chosen because demented patients tend to exhibit more behavior disorders in late afternoon. The PGDRS Behavior Subscale and the Cohen-Mansfield Agitation Scale were used to record behaviors.[21] For criterion #2, a research nurse not involved in the intervention interviewed nursing staff at 6 months using the PGDRS to determine the frequency of behaviors during the preceeding week. Nursing home staff determined the use of restraints on the units independent of the A.G.E. program and without knowledge of the A.G.E. restraint protocol.

Secondary Outcomes

Antipsychotic drug and restraint use: The proportion of patients receiving antipsychotics or being restrained was determined from medical records and direct observations at baseline and at 6 months. Restraint use was assessed during activity times and on the nursing units.

Cognition and levels of nursing care: Cognition was assessed using the Mini-Mental State Examination. The RUGS-II (Resource Utilization Groups) was used to indicate level of nursing services provided to patients.[22] It is a case-mix reimbursement system consisting of 16 categories ranging from physical dependence in activities of daily living (ADLs) to physical rehabilitation, with scores ranging from 0.55 to 1.74. A typical patient with a RUGS score of 0.9 (approximate median for all patients in the study) would be dependent in four ADLs. A research nurse not involved in the intervention interviewed nursing staff to determine RUGS levels.

Patient activity level: Participation rates in the intervention activities were recorded by daily census; in nursing home-provided activities recording was done by direct observation at months 2, 3, 5, and 6. Engaged in activity (yes/no) meant that the patient was participating in a group activity, reading, or talking with another patient. Not active meant the patient was sleeping or not engaged in any activity.

Patient care reimbursement/costs: Monthly billing records were used to compare patient charges at baseline and 6 months. These included Maryland case-mix rates based on ADLs plus special services such as decubitus ulcer care, tube feeding, peripheral or central IV care, and isolation precautions. Additional costs included prescription and nonprescription medications, personal care supplies, restraints, injections, ostomy, oxygen, suction/tracheostomy care, and turning/positioning. The intervention costs included the salaries and benefits of the activities director, two nursing aides, and the research nurse, as well as supplies. The cost per hour of the study psychiatrist and the community psychiatrist was estimated at $150.00/hour. The study psychiatrist spent 1 hour per week for 26 weeks. The community psychiatrist's time was estimated at 1 hour per initial consultation and 15 minutes for two follow-up visits.

Statistical Analysis

SPSS Version 4.0 was used for statistical procedures. *t* tests, Mann-Whitney U, and chi-square tests were used for comparison of baseline data. The primary statistical hypothesis was that the the proportion of patients with behavior disorder would be lower in the intervention compared with the control group after 6 months. Behavior disorder was designated as "present" or "absent" according to the definition outlined above. Chi-square tests were used for this and other comparisons of proportions at 6 months, and results were reported with odds ratios and confidence intervals. McNemar's test was used to compare change in proportions, and paired *t* tests and median tests were used for changes in continuous measures within treatment groups over time.[23] Attributable differences in the prevalence of behavior disorders, restraint, and antipsychotic use were calculated as prevalence at baseline minus prevalence at 6 months for intervention patients, minus the same difference for controls. Confidence intervals were calculated to assess the magnitude of these changes. Intention-to-treat (n = 89) and active-treatment (n = 81) analyses were performed for the primary outcome measure. Because the two yielded essentially identical results, only the active-treatment analysis is presented. Logistic regression with behavior status as the dependent variable was used to determine whether age, sex, severity of baseline cognitive impairment (MMSE score), functional capacity (RUGS level), number of behavior disorders, medical problems, or medications were associated with behavior disorder.

RESULTS

Patient Characteristics

The demographic and medical characteristics and payment sources (65% Medical Assistance) of the sample resembled other nursing home patients in the United States.[17] Table 1 compares the two treatment groups and shows there were no baseline demographic or clinical differences except for the greater number of females in the intervention group (86% vs 67%, $X^2 = 4.08$, $df = 1$; $P < .043$).

Table 1. Patient Characteristics at Baseline by Treatment Group

	Intervention n = 42	Control n = 39	*P*
Sex (% female)	86	67	.043
Race (% white)	79	87	.331
Age*	82.0 (8.0)	81.2 (7.2)	.666
Behavior disorders*	3.7 (1.4)	3.6 (1.6)	.829
Cognition MMSE* (0–30)	9.1 (7.4)	8.9 (6.1)	.861
Function RUGS† (0.55–1.74)	.89 (.69–1.64)	.94 (.69–1.74)	.459
Medical diagnoses*	3.5 (5.0)	2.9 (4.4)	.561
Restraints (%)	40.5	43.6	.105
Antipsychotics (%)	42.9	53.8	.161

*Mean (SD).
†Median (Range).
MMSE = Mini-Mental Status Exam.
RUGS = Resource Utilization Group.

Behavior Disorder

Twelve of 42 intervention patients (28.6%) had behavior disorders at 6 months, six of whom had behavior disorders observed by the blinded psychiatrist and six of whom had nurse-reported behavior disorders. Twenty of 39 control patients (51.3%) had behavior disorders; 11 of these were observed by the psychiatrist, and nine were nurse-reported. All patients with psychiatrist-observed behavior disorders had a nurse-reported behavior disorder. At 6 months intervention, patients were less likely to have behavior disorders compared with controls (odds ratio = 0.38, 95% CI [0.15, 0.95]; $P = .037$). Table 2 shows the attributable difference was 22.7%; 95% CI [1.9, 43.5].

The logistic regression revealed that no demographic or clinical characteristics were associated with behavior at 6 months (data not shown). The proportion of patients who received any psychotropic medications who improved (e.g., no behavior disorder at 6 months) was similar in both groups (intervention 14/30 (46.7%) vs controls 9/20 (45.0%); $X^2 = .13$, $df = 1$; $P < .91$). For controls, those seen by the community psychiatrist were as likely to improve as those who were not 8/13 (61.5%) vs 13/23 (56.5%); $X^2 = .86$, $df = 1$, $P < .38$).

Restraint and Psychotropic Drug Use

Restraint use was examined both in activities and on the nursing units. Table 2 shows that during activities, restraint use was reduced by 17.4% for intervention patients and increased by 3.6% for controls. The attributable difference was 21.0%; 95% CI [14.9, 27.1]. Controls were almost three times more likely to be restrained at this time (OR = 2.98%; 95% CI [1.10, 8.04]; $P < .028$). On the nursing units, restraint use was reduced by 6.4% for intervention patients and increased by 9.0% for controls. The attributable difference was 15.4%; 95% CI [3.8, 27.0]. Controls were over twice as likely to be restrained on the units (OR = 2.14; 95% CI [0.9, 5.3] $P < .10$.

Antipsychotic drugs were discontinued for 12 of 18 (66.7%) intervention patients and were initiated for three of 24 (12.5%) over 6 months. Table 2 shows their use was reduced by 21.5%. For controls, antipsychotics were discontinued for six of 21 (28.6%) and initiated for one of 18 (5.6%). Overall, their use was reduced by 12.8%. The attributable difference was 8.7%; 95% CI [-7.6, 25.0]. Controls were over twice as likely to receive antipsychotics as intervention patients at 6 months (OR = 2.55, 95% CI [0.96, 6.76] $P = .056$). There were no significant differences in antipsychotic drug dosages over time in controls ($X^2 = .15$, $P < .697$) or intervention patients ($X^2 = 1.56$, $P < .892$).

Treatment for depression was initiated for six intervention patients and no controls over the study period. No intervention patients on nortriptyline had side effects requiring discontinuation. Benzodiazepines were discontinued in two intervention patients and one control, and none were started in either group. Table 2 shows that there were no significant changes over time in the total number of medications ($t = 1.12$, $df = 32$, $P < .270$) for controls or intervention patients ($t = .81$, $df = 30$, $P < .423$).

Table 2. Change in Outcome Measures over 6 Months for Intervention and Control Patients

		BL	6 Months	Change (BL − 6 MO)	[CI]
Behavior disorder	I	42/42 (100 %)	12/42 (28.6%)	71.4%	[55.4, 87.4]
	C	39/39 (100 %)	20/39 (51.3%)	48.7%	[30.5, 66.9]
			Attributable difference	22.7%	[1.9, 43.5]
Restraints (activities)	I	17/42 (40.5%)	9/39 (23.1%)	17.4%	[−1.6, 36.4]
	C	17/39 (43.6%)	17/36 (47.2%)	−3.6%	[−21.5, 14.3]
			Attributable difference	21.0%	[14.9, 27.1]
Restraints (nursing units)	I	17/42 (40.5%)	14/41 (34.1%)	6.4%	[−8.0, 21.1]
	C	17/39 (43.6%)	20/38 (52.6%)	−9.0%	[−16.7, 1.30]
			Attributable difference	15.4%	[3.8, 27.0]
Antipsychotic drug use	I	18/42 (42.9%)	9/42 (21.4%)	21.5%	[6.0, 36.9]
	C	21/39 (53.8%)	16/39 (41.0%)	12.8%	[−6.4, 32.0]
			Attributable difference	8.7%	[−7.6, 25.0]
Antipsychotic dose (CPZ eq)*	I	50 mg (20–750)	35 mg (10–500)	$P < .692$	
	C	50 mg (20–1375)	75 mg (10–1500)	$P < .697$	
Number of medications†	I	7.6 (6.8)	6.6 (4.0)	$P < .423$	
	C	6.4 (2.5)	6.0 (2.8)	$P < .270$	
MMSE† (0–30)	I	9.1 (7.6)	8.8 (7.7)	$P < .723$	
	C	9.1 (6.2)	8.5 (6.0)	$P < .453$	
RUGS† (0.55–1.74)	I	0.89 (.23)	0.89 (.23)	$P < .989$	
	C	0.94 (.30)	0.95 (.28)	$P < .810$	

*Median and Range/Chlorpromazine Equivalents.
†Mean (SD).

Activity Participation

Thirty-eight of 42 (92.8%) intervention patients attended the activity program daily. Three patients and one patient's family refused participation. On average, intervention patients spent 17.0 (5.9) hours per week in the activity program. Activity levels for controls were observed four times during the 6-month period (months 2, 3, 5, 6) and revealed that an average of 23.4% (5.1) participated in nursing home-provided activities. At 6 months, intervention patients were more than 10 times more likely to participate in activities than were controls (OR = 13.71; 95% CI [4.50, 41.73]; $P < .001$).

Cognition, Function and Costs

Table 2 shows there were no significant changes, over time, in MMSE scores for either intervention patients ($t = .36$, $df = 38$; $P < .723$) or controls ($t = .76$, $df = 36$, $P < .453$) or in RUGS levels for intervention patients ($t = -.01$, $df = 41$, $P < .989$) or controls ($t = -.24$, $df = 38$, $P < 0.810$).

Average monthly costs/patient were distributed normally and compared on a group level. No significant differences were found from baseline to 6 months (controls: $2336.6 (497.0)/month to $2290.6 (488.0)/month; intervention: $2214.7 (414.1)/month to $2203.0 (381.6)/month). The total 6-month cost of the intervention for 20 patients was $41,300 (Activities Director ($13,200), Part-time Nurse ($7700), two Nursing Aides ($18,200), and supplies ($2200). This cost was weighed against the potential cost savings to the nursing home achieved by transferring care for intervention patients during the day to the activities program. We estimated conservatively that at least one floor nursing aide position could be saved ($9100) and subtracted this from the intervention cost. The daily cost per patient for the intervention was $8.94. The 6-month cost for the nursing home-provided activity program was $48,873 (Activities Director ($14,560), two Part-time activity assistants ($22,425), two lay staff ($8000), and supplies ($3888). The daily activity cost per patient was $1.13.

The intervention psychiatrist's cost was $3900, based on 1 hour per week at $150/hour x 26 wks. The community psychiatrist's cost was $2925, based on a 1-hour initial evaluation and two 15-minute follow-up visits at $150/hour for the 13 controls for whom he was consulted. There was no significant difference in hospitalization rates between groups intervention (21.4%) versus control (20.3%); $X^2 = 1.87$, $df = 1$, $P < .18$). One control hospitalization was a psychiatric admission.

DISCUSSION

This trial demonstrates the efficacy of a program to reduce behavior disorders, antipsychotic drug use, and physical restraints in nursing home patients with dementia. It is the first study, to our knowledge, to use systematic sampling, randomization, adequate controls, a statistically meaningful sample size, psychiatric diagnoses according to DSM-III-R criteria, instruments of known reliability and validity, and multiple relevant outcome measures. While it shows that this kind of behavioral research is feasible in nursing homes, the results must be interpreted with caution. The single setting facilitated standardized sampling, data collection, and protocol adherence, but it also restricted the sample size, introduced confounding variables, and limited the study's generalizability. Moreover, several interventions occurred during this study. First, the nursing home was made the focus of an academic research program, which brought new enthusiasm and increased attention to the care of patients. This might be subsumed under the Hawthorne effect and may explain some of the results. Second, although originally planned as a strict randomized controlled study, the design actually compared two levels of intervention, one formal with structured components and the other indirect and less structured. For the controls, it consisted of the nonspecific effects above plus the increased staff available when intervention patients were off the units.

A number of other factors were also operative: the OBRA-1987 drug and restraint regulations were implemented, a community psychiatrist treated a large number of controls, and a nursing home-wide educational program was initiated. These internal and external factors likely reduced the difference between the test and control treatments. However, for both groups, the reductions in behavior disorders contrasted with their natural tendency to increase over time without treatment, making regression to the mean a less likely explanation.[17]

Another difficulty was rating behavior disorders free of measurement bias. We recognized that behavior disorders frequently emerged during bathing and dressing. It was difficult to record them objectively because the observer influenced both the nurses' and patients' behavior. As a result, the blinded observations were usually made when patients were alone. This approach was insensitive to behavior disorders that occurred during nurse-patient interactions or that occurred episodically. We approached this problem by developing a composite measure that combined blinded behavioral assessments with unblinded nursing staff reports to balance issues of sensitivity, observer reactivity, and bias. To reduce the bias, restraint use on the nursing units was added to provide an objective indicator of a behavior disorder that required them. The decision to use restraints on the unit was made by nursing home staff independent of the A.G.E. staff and without knowledge of the A.G.E. restraint protocol. The need to develop such a composite measure reflects the conceptual and measurement difficulties in the field. Future studies might consider behavioral mapping over longer periods of time or might videotape observations.

In spite of its limitations, this study helps to answer relevant questions about nursing home care: What are the primary needs of patients with dementia? In addition to assistance in bathing and dressing, these patients require a safe environment that provides active routines to minimize their exposure to unstructured circumstances that can overwhelm them and lead to behavior disorders. Because behavior disorders are expected in these patients, environmental factors are often overlooked as their causes.[24] Such factors may include the admission process itself, uninformed approaches to care, limited availability of staff, restraint use, unidentified medical problems, excessive stimulation, and inactivity.[25–31] We previously have shown that most activity programs in nursing homes exclude patients with dementia.[32]

Can an activities program under psychiatric supervision reduce behavior disorders? We found that it can and that antipsychotic drugs and restraints could be reduced in the very patients for whom they are most often prescribed. Both the psychosocial and medical aspects of the intervention made this possible. The former provided predictable sched-

ules removed from the random activity of busy nursing units or the isolation of one's room. The latter treated conditions such as depression, delusions, or hallucinations if these symptoms were unresponsive to the psychosocial component. Moreover, the multidisciplinary team conveyed optimism and affection for patients, sustained by the view that demented patients are treatable rather than incurable and that they retain the capacity to benefit from meaningful activity. Could other physicians or clinical nurse specialists achieve similar results? We suspect that they could if they were sensitive to environmental influences on behavior, able to recognize and treat depression, delusions, and hallucinations, and able to work effectively as part of a multidisciplinary team.

How did the nursing home respond to the A.G.E. program? We had the impression that nursing staff held divergent views. Most valued the program because they saw new life emerge in patients they once regarded as incapable of meaningful activity. However, a few resented the intrusion of "experts" who altered their usual care routines. Physicians welcomed the additional care and fully supported psychotropic drug modifications. Families were enthusiastic about the increased attention their relatives received. The patients clearly enjoyed the human contact and activities. However, when the program ended, some patients again became anxious, restless, and disruptive. The recurrence of these behaviors suggests that activity programs must be ongoing to sustain their beneficial effects.

Previous studies have suggested the value of reality orientation, reminiscence groups, validation therapy, and cognitive-behavioral group therapy for these patients.[8–15] However, these studies have been limited by small samples, lack of randomization, and lack of standardized clinical assessments. Special care units have also been developed to care for patients with dementia, although what constitutes "special care" is unclear. An Office of Technology Assessment report found that such units "vary in virtually every respect," making their effectiveness difficult to determine.[33] They are also costly to develop because they require modifications of existing designs or creation of new ones and often charge higher rates than most patients can afford.

Does the A.G.E. program reduce costs? We found no reductions in costs for intervention patients to offset the additional costs of the intervention. However, we examined costs over a relatively short time period in a relatively crude way. For example, we likely underestimated the savings to the nursing home that was associated with transferring the care of severely behaviorally disturbed patients from the nursing units to the activity program. Moreover, although no significant changes were noted in functional levels over 6 months, had function been assessed over longer periods of time, prevention of functional decline may have been observed. We previously reported stability in functional levels over 1 year among patients cared for on a dementia unit in which activity programs and psychotropic drug management were central treatment components.[34] Our current calculations indicate, however, that the A.G.E. program required more resources and, therefore, cost more than usual nursing home care.

The 1987 Nursing Home Reform Act now requires nursing homes to develop psychosocial rehabilitation programs and to follow guidelines for antipsychotic drug and restraint use. Although reductions in the latter have occurred, there have been no systematic attempts to develop psychosocial programs.[35] Thus far, the Act institutes a correctional reform that sets minimum standards for drug and restraint use but does little to change what might be an inappropriate institutional model. In light of this, and in the absence of a federal policy on mental health care in nursing homes, this study has important clinical and policy implications. It demonstrates the efficacy of a new approach to delivering psychiatric services to nursing home patients with dementia who might otherwise not receive them. It expands our knowledge about what can be implemented in nursing homes and shows that the necessary expertise is currently available.

Additional research is needed to replicate these findings and to address whether activity participation should be part of quality improvement plans or be reimbursed through special mental health benefits. In the meantime, this study indicates that activity programs and psychiatric care can reduce distressing behavioral symptoms, antipsychotic medications, and restraints and can increase the activity of nursing home patients with dementia.

ACKNOWLEDGMENT

The authors thank Ms. Oneita M. Harmon and Ms. Kate Kelly for preparation of the manuscript, and Ms. Kimberly Stanley and Ms. Mary Wimmer for their devotion to the patients and to the program.

REFERENCES

1. Rovner BW, German PS, Broadhead J et al. The prevalence and management of dementia and other psychiatric disorders in nursing homes. Int Psychogeriatr 1990;2:13–24.
2. Tariot PN, Podgorski CA, Blazina L et al. Mental disorders in the nursing home: Another perspective. Am J Psychiatry 1993;150:1063–1069.
3. Burns BJ, Wagner HR, Taube JE et al. Mental health service use by the elderly in nursing homes. Am J Public Health 1993;83:331–337.
4. Ray WA, Federspiel CF, Schaffner W. A study of antipsychotic drug use in nursing homes: Epidemiologic evidence suggesting misuse. Am J Public Health. 1980;70:485–491.
5. Rovner BW, Katz IR. Psychiatric disorders in the nursing home: A selective review of studies related to clinical care. Int J Geriatr Psychiatry 1993;8:75–87.
6. Institute of Medicine. Improving the Quality of Care in Nursing Homes. Washington, DC: National Academy Press, 1986.
7. Department of Health and Human Services: Medicare and Medicaid: Requirements for long-term care facilities final rule with request for comments. Federal Register. 1989:54:5322.
8. Kane RA, Kane RL. Long-Term Care: Principles, Programs, and Policies, New York: Springer Publishing Company, 1987.
9. Morton I, Bleathman C. The effectiveness of validation therapy in dementia - A pilot study. Int J Geriatr Psychiatry 1991;6:327–330.
10. Diesfeldt HFA, Diesfeldt-Groenendijk H. Improving cognitive performance in psychogeriatric patients: The influence of physical exercise. Age Ageing. 1977;6:58–64.
11. Abraham IL, Neundorfer MM, Currie LJ. Effects of group interventions on cognition and depression in nursing home residents. Nurs Res 1992;41:196–202.
12. McGrowder-Lin R, Bhatta A. A wanderer's lounge program for nursing home residents with Alzheimer's disease. Gerontologist 1988;28:607–609.
13. Cleary TA, Clamond C, Price M, Shullawg. A reduced stimulation unit: Effects on patients with Alzheimer's disease and related disorders. Gerontologist 1988;28:511–514.
14. Petrie WM, Ban TA, Berney S et al. Loxapine and psychogeriatrics: A placebo and standard controlled clinical investigation. J Clin Psychopharmacol 1982;2:122–126.
15. Barnes RF, Veith R, Okimogo J et al. Efficacy of antipsychotic medications and behaviorally disturbed dementia patients. Am J Psychiatry 1982;9:1170–1174.
16. Wilkinson IM, Graham-White J. Psychogeriatric dependency rating scale: A method of assessment for use by nurses. Br J Psychiatry 1980;137:558–565.
17. German PS, Rovner BW, Burton LC et al. The role of mental morbidity in the nursing home experience. Gerontologist 1992;32:152–158.

18. Robinson RG, Kubos KL, Starr LB. Mood changes in stroke patients: Relationship to lesion locations. Compr Psychiatry 1983;24:555–566.
19. 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.
20. Zgola JM. Doing Things: A Guide To Programming Activities For Persons With Alzheimer's Disease and Related Disorders. Baltimore: Johns Hopkins Univ. Press, 1987.
21. Cohen-Mansfield J, Marx MS, Rosenthal AS. A description of agitation in a nursing home. J Gerontol 1989;44:M77–84.
22. Foley WJ. Dementia among nursing home patients: Defining the conditions, characteristics of the demented, and dementia on the RUGS-II classification system. Troy, NY: Rensselaer Polytechnic Institute, 1986.
23. McNemar Q. Psychological Statistics. New York: Wiley, 1969, pp. 260–262.
24. Evans JG. Prevention of age-associated loss of autonomy: Epidemiological approaches. J Chronic Dis 1984;37:357–363.
25. Bridges-Parlet S, Knopman D, Thompson T. A descriptive of study of physically aggressive behavior in dementia by direct observation. J Am Geriatr Soc 1994;42:192–197.
26. Morriss RK, Rovner BW, Folstein MF, German PS. Delusions in newly admitted residents of nursing homes. Am J Psychiatry 1990;147:299–302.
27. Werner P, Cohen-Mansfield J, Braun J et al. Physical restraints and agitation in nursing home residents. J Am Geriatr Soc 1989;37:1122–1126.
28. Burgener S, Jirovec M, Murrell L et al. Caregiver and environmental variables related to difficult behaviors in institutionalized demented elderly persons. J Gerontol Psychiatry Sci 1992;47:242–249.
29. Schnelle JF, Simmons SF, Ory MG. Risk factors that predict staff failure to release nursing home residents from restraints. he Gerontologist. 1992;32:767–770.
30. Svarstad BL, Mount JK. Nursing home resources and tranquilizer use among the institutionalized elderly. J Am Geriatr Soc 1991;39:869–875.
31. Sporl DL, Smyer MA, Cohn MD. Assessing nursing assistants' knowledge of behavioral approaches to mental health problems. Gerontologist 1991;31:309–317.
32. Rovner BW, German PS, Burton LC et al. A longitudinal study of participation in nursing home activity programs. Am J Geriatr Psychiatry 1994;2:169–174.
33. Office of Technology Assessment. Special care units for people with Alzheimer's and other dementias: Consumer education, research, regulatory, and reimbursement issues. Washington, DC: US Government Printing Office, 1992.
34. Rovner BW, Smith S, Blaustein J, Folstein MF. Stability over one year in patients admitted to a nursing home dementia unit. Int J Geriatr Psychiatry 1990;5:77–82.
35. Shorr I, Fought RL, Ray WA. Changes in antipsychotic drug use in nursing homes during implementation of OBRA-87 regulations. JAMA. 1994;271:358–362.

Appendix I

Antipsychotic Drug Protocol for Delusions/Hallucinations

1. Thioridazine 10 mg qhs × 1 week, then (if no improvement),
2. Thioridazine 10 mg bid × 2 weeks, then (if no improvement),
3. Dosage adjustment according to improvements/side effects with increments of 10 mg/week.

Antidepressant Drug Protocol*

1. Nortriptyline 10 mg qhs × 1 week, then,
2. Nortriptyline 25 mg × 2 weeks;
3. At week 3, check blood levels for therapeutic range (50–140),
4. Dosage adjustment according to drug level, with increasing or decreasing increments of 10 mg/week.

Guidelines for the Use of Restraints

1. Mechanical restraints will be used only in the following situations:
   a. When a patient is unable to walk without falling because of a neurological/medical disorder.
   b. When patients pose an immediate risk to harming themselves or others as a result of combativeness.

*Contraindications would include cardiac conduction delays, severe prostatism, narrow angle glaucoma

Improving Long-Term Care for Persons with Alzheimer's Disease

Alzheimer's disease poses unique behavioral challenges to the families, friends, and professionals who serve as companions and care providers. Whereas research in the biochemistry and genetics of the disease is extremely active, management of Alzheimer's remains almost entirely behavioral. The problems of coping with a demented family member are often compounded with an entire group of people with the disease residing in a long-term care institution.

"Warehousing" is an uncomfortably accurate designation for the traditional management of many institutionalized Alzheimer's patients. The disease itself contributes to the problem. Disruptive behaviors such as wandering, uncooperativeness, and physical abusiveness tend to be very prevalent in demented persons, leading to frequent caregiver distress.[1,2] In response, caregivers have often turned to strategies such as isolation and the use of physical and pharmacologic restraint.[3,4] Compounding the problem is the fact that the disease itself promotes social isolation. Persons with Alzheimer's often have limited verbal skills, do not comprehend such conveniences as call bells, and are unable to learn the names of staff on which they depend; as a result, they are unable to "work" the system effectively. Furthermore, their deficiencies in memory and reasoning make them less likely than their cognitively intact counterparts to suggest or initiate meaningful activities . All this has tended to limit interactions between long-term care staff and demented patients. Consequently, Alzheimer's patients can be spotted dozing restrained in chairs parked in front of the nursing station while crafts and other activities are offered to the few whose cognition supports participation.

The past decade and a half have seen significant improvement in attitudes toward the management of long-term care residents with dementia. Increasingly programs for demented adults have employed the concepts of rehabilitation, postulating that such approaches would improve symptoms and reduce the rate of physical decline.[5] Architects and design experts have recognized that the physical environment can be structured in ways that reduce agitation and disorientation, enhancing communication, self-esteem, and independence.[6,7] Activity programs have been developed that are designed specifically for persons with dementia, promoting exercise, sensory stimulation, reminiscence, socialization, nutrition, and self-esteem.[8,9] Specialized settings, such as dedicated dementia units (Special Care Units) and day programs, have been at the forefront of many of these innovations.[10] Anyone who has visited a vibrant, activity-rich Alzheimer's unit can attest to the fact that the patients there seem to interact more often, to smile more frequently, and to be happier.

But, as we all know, appearances do not always tell the entire story. The history of medicine is replete with therapies whose effectiveness was supported by multitudinous testimonials and anecdotes but which, under the scrutiny of rigorous science, were proven ineffective either because their effect represented a placebo response or because some inadvertant side effect cancelled out their apparent benefit. Thus, behavioral interventions to improve the management of Alzheimer's disease must be subjected to scientific scrutiny.

In this issue of the *Journal*, Rovner et al. report the results of one such study: a randomized trial of an in-house day program for persons with dementia.[11] Their study provides one of the most rigorous examinations to date of the impact of specialized dementia programming on the residents of a nursing facility. It is encouraging that positive outcomes were demonstrated: residents in the experimental group were more active, use of physical and pharmacologic restraint was reduced, and disruptive behaviors were reported less frequently.

See also p 7

The methodological challenges to such research are manifold. Thus, it is not surprising that some aspects of the study's design raise concerns. In spite of their attempt to describe it in some detail, the intervention of Rovner et al. involved a blend of strategies, a therapeutic "black box" that would be extremely difficult to replicate in a consistent manner.[12] The intervention had three separate components — an activity program, a drug reduction program, and educational rounds for staff; it is quite possible that one or more components was ineffective or that the entire effect was caused by increased attention to dementia (expectancy bias or the Hawthorne effect).[13] On the other hand, the study intervention's interdisciplinary combination of medical, activity, and educational programs may exemplify the type of approach, albeit a methodologically untidy one, that will prove most effective in practice.

While Rovner, et al. are to be commended for their use of a randomized trial, the adequacy of controls could be, as is true for many studies of this type, debated. Guidelines for placebo treatments suggest that those who administer them should believe in their efficacy.[14] Use of controls from the same facility is problematic inasmuch as it is impossible to avoid interactions among subjects and treatment providers.[15] Indeed, Rovner et al. acknowledge these issues and note that the control group was probably managed differently by virtue of having members of the experimental group removed from their ward for much of the day.

Measurement is probably the thorniest methodological issue confronting such studies.[16] Not only are the target outcomes subject to debate,[17] but important outcomes such

JAGS 44:91–92, 1996

0002-8614/96/$3.50

as agitation, participation, and a sense of well-being are difficult to measure with precision and reliability. Rovner et al. used a combination of staff report and direct observation to monitor these outcomes, a laudable approach. Blinding of data collectors as to treatment status may have been incomplete, however, leading to the possibility that some measures may have been reported in a biased fashion, and multiple observers of behavior —a strategy that increases reliability— were not used.[18] Greater use of objective measures, such as quantifying decibel levels on the unit or blinded ratings of videotapes, could have reduced the potential for measurement bias. Finally, the study would have been improved by use of a global measure of well-being, but no valid measure of well-being in dementia is available as a gold standard.

In spite of its limitations, the study by Rovner et al. is an important contribution to the slowly emerging body of data linking specialized management of Alzheimer's disease with improved outcomes. It verifies what many have observed but which has proven difficult to demonstrate scientifically: the notion that dementia-specific programming can make a difference. Families certainly believe this; by the thousands they not only willingly pay higher rates for dementia Special Care Units, but they also express higher satisfaction than families of persons with dementia who receive traditional care.[19,20] Thus, the study by Rovner et al. should spur additional investigations, in which various components of the "black box" are examined alone and in combination.

In this era of cost containment, however, we need to ask not only if an intervention leads to better outcomes but whether the result is worth the expense. Rovner, et al. again should be commended for attempting to quantify what they have done, and here the results are even more daunting: a total daily cost of $8.94 per subject.

In many respects nursing home care is like cafeteria food. One can purchase a reasonably healthy lunch for less than $2.00 in some institutional cafeterias, but the taste and preparation may leave much to be desired. We prefer a better cafeteria, where the food is fresh, appealing, and tasty, the atmosphere pleasant, and the average cost around $6.00 – so much so that our meetings to plan this editorial took place in such a location. Because the benefits of specialized dementia programming seem to be largely the "soft" outcome areas such as socialization and satisfaction, one must ask how much value the public is willing to assign to these gains. Will public support for Alzheimer's care provide the equivalent of the $2.00 meal, the $6.00 meal, or something in between? Perhaps it is the role of researchers to identify which components of the $6.00 meal are most effective and least wasteful so that long-term care will be better if not ideal.

Philip D. Sloane, MD, MPH
University of North Carolina at Chapel Hill

Ann Louise Barrick, PhD
University of North Carolina at Chapel Hill and
John Umstead Hospital, Butner, North Carolina

REFERENCES

1. Rabins PV. Noncognitive symptoms in Alzheimer disease. In: Terry RD, Katzman R, Bick KL, eds. Alzheimer's Disease. New York: Raven Press, 1994, pp 419–429.
2. Rovner BW, Steele CD, German P et al. Psychiatric diagnosis and uncooperative behavior in nursing homes. J Geriatr Psychiatry Neurol 5:102–105.
3. Everitt DE, Fields DR, Soumerai SS, Avorn J. Resident behavior and staff distress in the nursing home. J Am Geriatr Soc 1991;39:792–798.
4. Sloane PD, Mathew L, Scarborough M et al. Physical and chemical restraint of dementia patients in nursing homes: Impact of specialized units. JAMA 1991;265:1278–1282.
5. Hall GR, Buckwalter KC. From almshouse to dedicated unit: Care of institutionalized elderly with behavioral problems. Arch Psychiatr Nurs 1990;4:3–11.
6. Calkins MP. Design for Dementia. Owings Mills, MD: National Health Publishing, 1988.
7. Cohen U, Day K. Contemporary Environments for People with Dementia. Baltimore MD: Johns Hopkins University Press, 1993.
8. Ritter L. Developing a therapeutic activities program. In: Sloane PD, Mathew LJ, eds. Dementia Units in Long-Term Care. Baltimore: Johns Hopkins University Press, 1991.
9. Zgola JM. Doing Things. A Guide to Programming Activities for Persons with Alzheimer's Disease and Related Disorders.
10. Mace N. Programs and services that specialize in the care of persons with dementia. In: US Congress, Office of Technology Assessment. Losing a Million Minds: Confronting the Tragedy of Alzheimer's Disease and Other Dementias. OTA-BA-323. Washington, DC: US Government Printing Office, 1987, pp 239–270.
11. Rovner BW, Steele CD, Shmuely Y, Folstein MF. A randomized trial of dementia care in nursing homes. J Am Geriatr Soc 1996;44:0000–0000.
12. Mahoney M. Experimental methods and outcome evaluation. J Consult Clin Psychol 1978;46:660–672.
13. Rosenthal R, Rosnow R. Essentials of Behavioral Research: Methods and Data Analysis. New York: McGraw-Hill, 1984.
14. Parloff M. Placebo controls in psychotherapy research: A sine qua non or a placebo for research problems?
15. Kramer M, Shapiro S. Scientific challenges in the application of randomized trials. JAMA 252:2739–2745.
16. Teresi J. Overview of methodological issues in the study of chronic care populations. Alzheimer Dis Assoc Disord 1994;8(suppl 1):S247–273.
17. Advisory Panel on Alzheimer's Disease. Third Report of the Advisory Panel on Alzheimer's Disease, 1991. DHHS Pub. No. (ADM)-92–1917. Washington, DC: US Goverment Printing Office, 1992.
18. Wilkinson I, Graham-White J. Psychogeriatric dependency rating scales: A method of assessment for use by nurses. Br J Psychiatry 1980;137:558–565.
19. Cleary TA, Clamon C, Price M, Shullaw G. A reduced stimulation unit: Effects on patients with Alzheimer's disease and related disorders. Gerontologist 1988;28:511–514.
20. Mathew LJ, Sloane P, Kilby M, Flood R. What's different about a special care unit for dementia patients? A comparative study. Am J Alzheimer's Care Rel Disord Res 1988;3:16–23.