The Effect of Staff Training on Agitation and Use of Restraint in Nursing Home Residents With Dementia: A Single-Blind, Randomized Controlled Trial

Ingelin Testad, RN, MS; Clive Ballard, MD, PhD; Kolbjørn Brønnick, PhD; and Dag Aarsland, MD, PhD

Introduction: Agitation is common in dementia and is associated with use of restraints and use of psychotropic drugs. The aim of this study was to determine whether an education and supervision intervention could reduce agitation and the use of restraints and antipsychotic drugs in nursing homes.

Method: Four Norwegian nursing homes were randomly allocated to receive either treatment as usual or an intervention consisting of a 2-day educational seminar and monthly group guidance for 6 months. One hundred forty-five residents with dementia (based on medical records and corroborated with a Functional Assessment Staging score ≥ 4) completed baseline and 6-month intervention assessments and were included in the analyses. The co–primary outcome measures were the proportion of residents subject to interactional restraint and the severity of agitation using the Cohen-Mansfield Agitation Inventory (CMAI). Patients were assessed at baseline, immediately after completion of the intervention at 6 months, and 12 months after baseline. Comparison of change in the 2 groups was made using repeated-measures analysis of variance (CMAI) and Mann-Whitney test (restraints). The study was conducted from 2003 to 2004.

Results: The proportion of residents starting new restraint was lower in the intervention than in the control group at 6-month evaluation ($P = .02$), but no statistically significant differences were found at 12-month assessment ($P = .57$). The total CMAI score declined from baseline to 6 and 12 months' follow-up in the intervention homes compared to a small increase in the control homes ($F_{2,176} = 3.46$, $P = .034$). There were no statistically significant differences in use of antipsychotic drugs.

Conclusions: A brief 2-day staff education program followed by continued monthly guidance was able both to improve quality of care by reducing the frequency of interactional restraints and to reduce severity of agitation.

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Corresponding author: *Ingelin Testad, RN, Psychiatric Clinic, Stavanger University Hospital, PO Box 8100, 4068 Stavanger, Norway (itestad@gmail.com).*

Dementia is a growing public health problem. Almost 25 million people worldwide have dementia now, with 4.6 million new cases every year, and the financial costs to society are €55 billion per annum in Europe. The number of people with dementia along with the associated cost are expected to increase dramatically as the population ages.[1,2] Dementia is the most common reason for nursing home placement,[3] and approximately 50% of people with dementia live in nursing homes in Norway.[4] Eighty percent of residents in nursing homes have dementia, the majority of whom have severe functional impairments and complex needs, including associated behavioral changes, with severe consequences for their functioning and quality of life.[5]

Behavioral and psychological symptoms of dementia (BPSD) are commonly observed in most dementia syndromes and are an important predictor of nursing home placement.[3] Agitation is one of the most common clusters of BPSD,[6] defined as inappropriate verbal, vocal, or motor activity that may be abusive or aggressive toward self or others and is performed with inappropriate frequency, or is inappropriate according to social standards for the specific situation.[7]

Agitation has a massive impact on the lives of people with dementia and family caregivers[8] and causes excess disability, including reduced activities of daily living (ADL) function.[9] In addition, agitation is associated with more frequent use of physical restraints. In a systematic review on reasons for restraining residents, agitation-related reasons for restraint use were reported in 90% of the studies,[10] and the most frequent use of restraint was related to ADL (61.3%) and medical treatment (49.8%).

Another consequence of agitation is the frequent use of sedating and potentially harmful psychotropic drugs such as antipsychotics. There is accumulating evidence of harm associated with antipsychotic drugs, including increased mortality[11] and stroke,[12] particularly over a more sustained period of time.[12]

Thus, it is mandatory to identify effective nonpharmacologic strategies to increase quality of life and care in nursing home residents with dementia. Caring for people with dementia requires specific skills and knowledge of the cognitive, functional, and emotional changes accompanying dementia, and care-staff training has become an important element of nursing home care.

Two systematic reviews[13,14] concluded that there is little scientific evidence as to the effectiveness of education and training for nursing home staff, with methodological limitations such as nonrandomized studies, small sample sizes, and high attrition rates. Most notably, few studies employed long-term follow-up evaluation to ensure whether any effect is sustained beyond the intervention period, and many studies reported staff outcomes only. However, several recent studies of person-centered staff training have demonstrated that the use of antipsychotic drugs[15] and agitation[16,17] can be significantly reduced using care staff training.

Few studies, usually small or nonrandomized, have demonstrated reduction in the use of restraint after staff education.[18–20] Two randomized trials[21,22] found no change in the use of restraint after an educational program for nurses was performed, but they did find an increase in the control group, indicating that the use of restraint can be prevented, although this was not confirmed in a recent study.[23]

The aim of this rater-blinded, randomized controlled trial (RCT) was, therefore, to determine whether an education and supervision intervention could reduce agitation and the use of restraints and antipsychotic drugs among people with dementia in nursing homes.

METHOD

Participants

The study was conducted from 2003 to 2004 in Rogaland County, Norway. Of the 7 nursing homes invited, 4 agreed to participate: 2 small homes with 17 and 21 residents, and 2 larger homes with 92 and 81 residents. A diagnosis of dementia was based on medical records and corroborated with a Functional Assessment Staging (FAST)[24] score ≥ 4. Severity of dementia was rated using the FAST[24] by a specially trained research nurse, who also recorded demographics and drug dosages. All care-staff members at the participating nursing homes were invited to participate. Although the design of the study did not involve the residents directly, the residents and/or their family were informed about the study and that they could refuse participation at any stage of it. The study was approved by the Regional Committee for Ethics in Medical Research, Western Norway.

Randomization

Because the intervention was based on models of care, we randomly assigned subjects at home level. One small and one larger home were randomly allocated to either intervention or the control condition (treatment as usual).

Outcome Measures

Outcome measures of care staff and residents were administered at baseline and immediately after completion of the 6-month intervention period. In addition, a long-term follow-up was performed 6 months after end of the intervention, ie, 12 months after study start. The administration of the outcome measures and drug recording were done by a trained research nurse who was uninformed as to the objective and design of the study and the treatment allocation.

Co–Primary Outcome Measures

Restraints. *Restraint* was defined as any limitation on a person's freedom of movement,[25] including physical restraint, electronic surveillance, force or pressure in medical examination or treatment, or any force or pressure in ADL.[26] Use of restraints was determined by a standardized interview in which all use of restraint during the last 7 days was recorded.[26] The interview consists of 25 items within 4 domains: physical restraint (belts or other fixing to bed, belts or other fixing to chair, locked in a room), electronic surveillance (devices on patients that automatically lock the door, devices on patients that alarm the staff, devices to track patients, devices that sound when a patient leaves the bed), force or pressure in medical examination or treatment (mixing drugs in food or beverages, use of force to perform examination or treatment), and any force or pressure in ADL (holding of hands, legs, or head for washing or dressing/undressing, showering or bathing against the patient's verbal or physical resistance, forcing the patient to the bathroom, feeding a patient against his/her will). Restraints were classified as either structural or interactional. *Structural restraints* are measures of restraint aiming at protecting the resident through structural measures. Structural restraints are outside the treatment and caregiving activity, such as locked doors on the ward, electronic surveillance, and bedrails. *Interactional restraints* are measures of restraint aiming at treatment and care for the resident through caregiving activity. Interactional restraints are within the care staff–resident relation, and the treatment and caregiving activity, such as force or pressure in medical examination or treatment, force, or pressure, in ADL. For the current study, restraints were coded as "present" or "not present," and interactional restraints were considered the primary outcome for this study.

Agitation. Agitation was rated using the Norwegian version of the Cohen-Mansfield Agitation Inventory (CMAI),[27] a structured interview that uses an informant to assess the frequency of 29 agitated behaviors in the patient. Each behavior is rated on a 7-point frequency rating scale (1 [never] to 7 [several times per hour]). The CMAI was validated by the Alzheimer's Disease Cooperative Study instrumentation protocol[28] and shows sensitivity to treatment

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effects and course of illness. The test-retest reliability of the CMAI over 1 month was good ($r = .74$ to 0.92).[28]

As a secondary outcome measure, use of antipsychotics was registered, and doses were transformed to chlorpromazine equivalents.[29]

Intervention

The education and training program Relation-Related Care provides a practical framework for staff to reduce agitation and use of restraint in the interaction with residents with dementia. It has been developed through clinical practice since 1999 and is structured into 3 main factors: predisposing factors (dissemination of information; ie, lectures, written), enabling factors (resources to implement new skills; ie, treatment guidelines), and reinforcing factors (reinforcing new skills; ie, feedback, peer support). This classification system was originally developed by Green et al[14,30] to examine educational interventions, sorted by factors relevant to behavior change in health promotion,[14] and a combination of these 3 factors is necessary to change the knowledge, attitudes, and practices of care staff on a long-term basis.[14] Relation-Related Care consists of 2 major elements: a 2-day seminar and monthly group guidance for 6 months. The guidance group includes tools to implement and reinforce new skills.

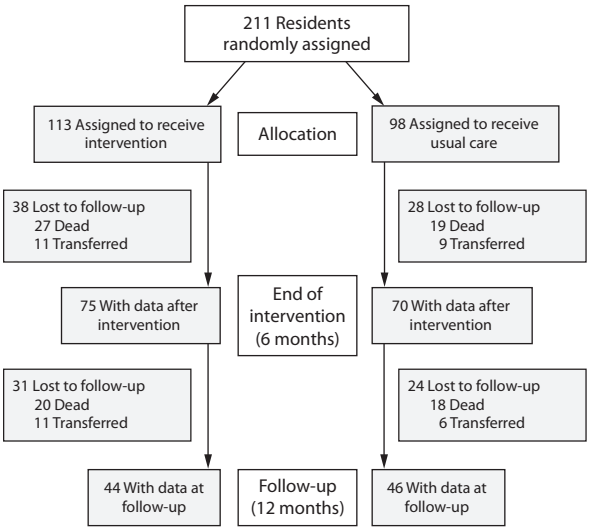
The same educators lectured at the 2-day seminar using a specifically developed manual and were also leaders for the guidance groups.

All care staff with and without formal education, including leaders and domestic staff, participated in both the seminar and group guidance.

Statistics

The primary efficacy population consisted of the residents who remained in the study for the 6-month follow-up assessment, the observed cases. Baseline comparisons between groups were made using parametric (Student *t*) and nonparametric (Mann-Whitney and χ^2) tests as appropriate. The primary efficacy analysis consisted of a repeated-measures analysis of variance (ANOVA), with group as between-subject factor and baseline, follow-up, and second follow-up as within-subjects factor (the time factor), using the CMAI sum as dependent variable. The Greenhouse-Geisser correction for violation of the assumption of sphericity inherent in repeated measurement was used to correct the degrees of freedom. Statistically significant results were followed up with separate ANOVAs for the control group and the intervention group. Comparison of change in interactional restraint (ie, proportion of residents who started, remained unchanged, or stopped, coded as 1, 2, and 3, respectively) in the categorical outcome measures (restraints and antipsychotic drugs) between the 2 groups was made using Mann-Whitney test, whereas repeated-measures ANOVA was used for analyzing change in antipsychotic drug dosage at the 6- and 12-month assessments.

Figure 1. Flowchart of Nursing Home Residents With Dementia Randomly Assigned to Receive Treatment as Usual or Intervention Consisting of Care by Staff Trained to Reduce Agitation and Use of Restraint in Dementia Patients



RESULTS

The 197 care staff (95.4% female and 4.6% male) consisted of 66 (33.5%) registered nurses, 108 (54.8%) licensed practical nurses, and 23 (11.7%) certified nurse assistants. The mean (SD) age of the care staff was 43.1 (12.9) years, working experience was 11.1 (9.1) years, and working experience in the nursing homes included in this study was 6.7 (7.8) years. During the study period, there was considerable turnover of staff, and at study end there were 56 (53.8%) remaining in the intervention and 53 (57.0%) in the control group. Reasons for leaving the job position included retirement, pregnancy, long-term sick leave, and moving or changing job to another home.

There were 211 residents at baseline evaluation: 113 in the intervention and 98 in the control homes. Staff-resident ratio was 0.7–0.8 in both treatment groups. During the study period, there was attrition mainly due to death, and the observed population consisted of 145 participants (81.4% with dementia): 75 in the intervention group and 70 in the control group (Figure 1).

At baseline, the residents in the intervention and control homes were similar with regard to age, gender distribution, and stage number of FAST, but there were statistically significant differences in the proportions of residents using antipsychotics and restraints as well as total CMAI score between the groups (Table 1).

Use of Restraints

The proportions of residents who were subject to use of restraints during the study period are shown in Table 2.

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Table 1. Baseline Characteristics of Nursing Home Residents in the Intervention and Control Conditions

Characteristic	Intervention Group (n = 75)	Control Group (n = 70)	*P*
Age, median (IQR), y	86.0 (9)	86.0 (11.25)	.38
Men/women, n	19/56	19/51	.80
FAST stage, median (IQR)	6 (1)	6 (3.25)	.17
CMAI total score, median (IQR)	38 (17)	33 (14.5)	.002
Use of restraints, n (%)	49 (65)	25 (36)	.000
Antipsychotic, n (%)	21 (28)	6 (9)	.003

Abbreviations: FAST = Functional Assessment Staging, CMAI = Cohen-Mansfield Agitation Inventory, IQR = interquartile range.

Table 2. Use of Structural and Interactional Restraints

	Control Group (n = 70)		Intervention (n = 75)	
Restraint	n	%	n	%
Structural				
Baseline	9	13	45	60
6 mo	23	33	48	64
12 mo[a]	6	13	8	18
Interactional				
Baseline	19	27	34	45
6 mo	32	46	36	48
12 mo[a]	9	20	23	53

[a]In the control group, n = 46; in the intervention group, n = 44.

In the intervention period, 15 residents (21.4%) were started on interactional restraint in the control group, compared to only 6 (8%) in the intervention group, and use of restraints was stopped in 2.9% and 5.3%, respectively (Table 2). The change in interactional restraint use over time (ie, proportion who started, remained unchanged, and stopped) differed significantly between groups (Mann-Whitney test, $P = .021$) (Figure 2).

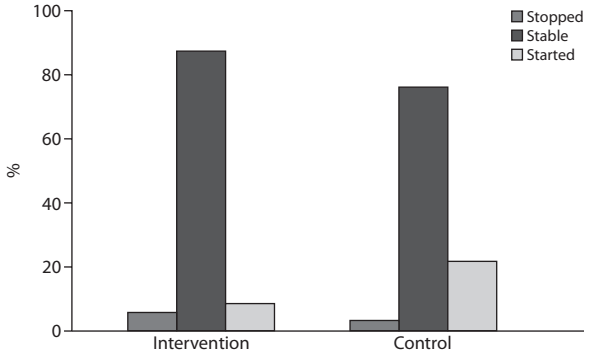
At the 12-month assessment, however, the proportion of residents subject to restraints was reduced in the control but not further reduced in the intervention group, and the difference between the groups in change between baseline and 12 months was not significant ($P = .57$). This suggests that the beneficial effect on restraint use was not sustained beyond the intervention period.

Agitation

The total CMAI score declined from baseline to 6-month follow-up in the intervention homes and was further reduced at the 12-month follow-up.

In contrast, in the control homes, there was no change in total CMAI score from baseline to 6- and 12-month follow-up (Table 3) (Figure 3). A significant interaction effect between time and group was found in the repeated-measures ANOVA ($F_{2,176} = 3.46$, $\varepsilon = .98$, $P = .034$), indicating that the difference in change between the groups was significant. Follow-up analyses of the significant interaction with separate repeated-measures ANOVAs for the control and intervention group, indicated that there was a significant reduction in CMAI score in the intervention group ($F_{2,86} = 4.55$, $\varepsilon = .88$, $P = .017$) but no difference in the control group ($F_{2,90} = .31$, $\varepsilon = .78$, $P = .675$). The changes in agitation and restraint use were similar in both small and large homes, although they did not reach significance due to the smaller numbers (data not shown).

Figure 2. Change (%) in Interactional Restraints During the 6-Month Intervention Period



Use of Antipsychotic Drugs

The proportion of residents taking antipsychotic drugs was low, particularly in the control group, and remained essentially unchanged in both groups at 6- and 12-month observation period (Table 4), with no statistically significant differences between groups ($P = .7$ and $P = .8$, respectively). There was a numerically larger dose increase in the control group than in the intervention group during the 12 months, but this difference was not statistically significant (repeated-measures ANOVA, $F_{2,176} = 1.4$, $P = .25$).

DISCUSSION

The main findings of this study are that a brief 2-day staff education program focusing on handling agitation and other challenging behaviors followed by continued monthly group guidance was able both to improve quality of care by preventing the frequency of interactional restraints and to reduce severity of agitation. The improvement of agitation continued 6 months after the completion of the intervention, indicating that sustained improvement of agitation can be achieved by means of a brief and cost-effective model of staff training. In contrast, the effect on restraints, which was evident by a much smaller proportion of residents starting new restraints in the intervention group compared to the control group, seemed to be short lived, suggesting that continuous supervision is needed to achieve sustained reduction of the use of restraints. These findings are encouraging because they demonstrate that improved quality of life and quality of care can be achieved for nursing home

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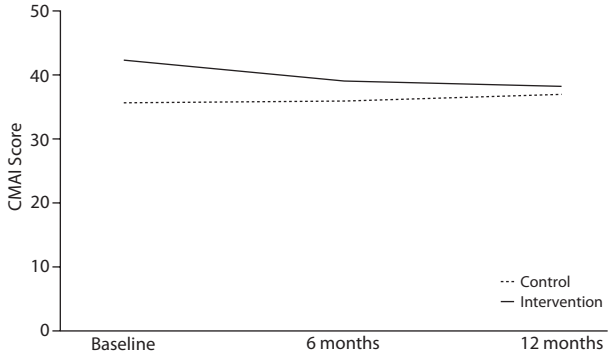
Table 3. Change in Total Cohen-Mansfield Agitation Inventory Score 6 and 12 Months After Baseline

Variable	n	Baseline Score	Follow-Up Score	Change	Between-Group Difference, Change (95% CI)[a]
6-Month follow-up					
Intervention	75	42.3 (13.9)	39.3 (12.1)	3.0 (12.4)	
Control	70	35.7 (8.2)	36.1 (8.5)	−0.4 (7.3)	−3.4 (−6.8 to −0.06)
12-Month follow-up					
Intervention	44	42.6 (13.7)	38.3 (10.4)	4.3 (11.6)	
Control	46	35.6 (7.3)	37.0 (10.4)	−1.3 (10.3)	−5.6 (−10.2 to −1.0)

[a]The difference between the groups was statistically significant ($P < .05$) using repeated-measures analysis of variance.

Figure 3. Change in Agitation During the Study Period



Abbreviation: CMAI = Cohen-Mansfield Agitation Inventory.

Table 4. Proportion of Residents Taking Antipsychotic Drugs and Dose Levels During the Study Period

	Intervention Group			Control Group		
Time point	n	%	Dose, mg[a]	n	%	Dose, mg[a]
Baseline	21	28.0	58 (125)	6	8.6	52.5 (130)
6 mo	22	29.3	63 (92)	10	14.3	62.5 (179)
12 mo[b]	14	31.8	50 (103)	4	8.7	255 (413)

[a]Median (IQR) dose chlorpromazine equivalent among those taking antipsychotics.
[b]In the control group, n = 46; in the intervention group, n = 44.

residents by means of simple tools that are relatively easy to implement compared to the cost of care and reduced quality of life related to agitation and use of restraint in nursing home residents.

Our findings are consistent with some recent studies demonstrating reduction of agitation[16] and prevention of restraints after staff training,[21,22] although a recent study did not show prevention of restraints.[23] This latter finding, and the short-lived effect on restraints in our study, raises the question as to whether the intervention period was too short or whether it is possible for care staff to meet the challenging and complex situations in their relations to residents with agitation without guidance in the group process. When the intervention of this study ended, it is possible that the care staff were about to integrate the new tools and routines into practice but needed more time and support to fully integrate these new tools and routines. On the other hand, the convincing results immediately after the intervention raise the suggestion that all care staff should have continuous and ongoing guidance of their group process.

The biomedical model of acute care, the focus of nursing on physical conditions and ADL, has been the traditional way of caring in nursing homes, resulting in neglect of psychosocial and emotional needs and inappropriate use of psychotropic medication and restraints in agitated residents.[17] However, over the last decade, the concept of agitation has become more nuanced, with researchers acknowledging several causal factors, including interpersonal interaction and psychosocial and emotional needs,[31] and that the behavior can provide valuable information about the patient condition.[32]

Person-centered care, the concept of the person being central to deliver high-quality care, is increasingly advocated in clinical practice and academia,[33] even though more clinical trials are needed.[33] The change from the biomedical model toward person-centered care in the complex situation of caring may need ongoing education and group guidance with emphasis on the care-staff resident interaction over a longer period of time to be fully integrated.

There are most likely structural and cultural differences that may contribute to different findings in clinical trials to reduce the use of restraints. For example, different attitudes and options regarding the use of physical restraints among nursing staff in European countries have been found.[34] These might contribute to different response in patients to staff intervention programs and suggest that staff training programs should acknowledge nation-specific issues related to nursing home structure and staff culture.

Among the methodological limitations, one difficulty in interpreting the findings was the baseline differences in agitation and use of restraints in the intervention and control homes, which might introduce a confounding effect. The more severe agitation and more frequent use of restraints in the intervention homes might have contributed to the differences between the 2 groups by unspecific factors such as regression to the mean or differential effect depending on severity of agitation. Although attempts to control statistically for such baseline differences are frequently reported, for example, by means of analysis of covariance, this is considered inappropriate.[35]

A cluster design, ie, randomizing nursing homes rather than individual patients, is needed to address the effect of staff training and most other psychosocial interventions to control conditions to avoid spillover of the effect of the intervention. However, the small number of participating homes precluded the use of standard cluster analysis in the statistical analyses, and, thus, comparing individual

patients might have introduced a bias. Basing the analyses on individual patients without adjusting for the cluster randomization may have increased the risk for false-positive findings.

The control condition was usual care, and, thus, nonspecific benefits due to increased attention and activity in the intervention homes might have contributed to the observed differences in agitation. The study design did not allow us to estimate to what degree the staff had actually changed their behavior as an effect of the intervention, and, thus, we cannot entirely exclude the possibility that residents changed their behavior without any change in staff support. However, we experienced that changes in care staff's attitude and behavior did occur in the group guidance, and this needs to be addressed in future studies. Key outcome measures, such as quality of life and psychiatric symptoms other than agitation, were not assessed. Only 50% of the invited homes agreed to participate, and a selection bias cannot be ruled out. For example, administrators who felt vulnerable might have been less motivated to participate. Finally, the relatively low proportion of residents taking antipsychotic drugs limited the possibility of demonstrating statistically significant reduction and made it difficult to interpret the findings of this outcome measure.

The strengths of the study include the use of patient-centered and clinically meaningful outcome measures, the long-term follow-up to address sustainability of any effects, the randomized allocation to intervention or control condition and the blinded assessment procedures, and the participation of all care staff. The relatively long study duration is a strength in terms of generalizability of the findings over a long duration of time, but it also inevitably leads to a high attrition rate due to the high mortality in this frail population. This, in addition to the fact that nearly 50% of the nursing homes contacted refused to participate, resulted in a relatively low number of participants for the outcome analyses. However, the attrition rate was similar in the 2 groups, without any evidence of selective attrition.

We demonstrated that education and group guidance lead to prevention in the use of restraints and induced sustainable reduction of agitation. Given the frequency and clinical impact of agitation and the need to reduce use of restraints, these findings suggest that such programs should be implemented in order to improve quality of care and well-being of residents with dementia. More studies are needed to explore this further, using larger cohorts, with a combination of elements from different approaches that might obtain the greatest and broadest benefit, and employing additional outcome measures, such as cost-effectiveness, quality of life, and biomedical markers, and more detailed assessment of how the resident-staff interaction can be positively altered. Finally, whether the cost effectiveness of sustaining education and guidance for care staff compares positively to the cost of care related to resident agitation remains to be studied.

Author affiliations: Psychiatric Clinic, Stavanger University Hospital, Stavanger, and School of Medicine, University of Bergen (Ms Testad and Dr Aarsland); The Norwegian Centre for Movement Disorders, Stavanger University Hospital (Dr Brønnick), Norway; and The Wolfson Centre for Age-Related Diseases, King's College London, United Kingdom (Dr Ballard).

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