JAMDA 14 (2013) 690–695

JAMDA

journal homepage: www.jamda.com

Original Study

Agitation in Nursing Home Residents With Dementia (VIDEANT Trial): Effects of a Cluster-Randomized, Controlled, Guideline Implementation Trial

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Keywords:
Dementia
agitation
nursing home
guideline
trial

A B S T R A C T

Objective: To test the effect of a complex guideline-based intervention on agitation and psychotropic prescriptions.
Design, Setting, Participants: Cluster randomized controlled trial (VIDEANT) with blinded assessment of outcome in 18 nursing homes in Berlin, Germany, comprising 304 dementia patients.
Intervention: Training, support, and activity therapy intervention, delivered at the level of each nursing home, focusing on the management of agitation in dementia. Control group nursing homes received treatment as usual.
Measurements: Levels of agitated and disruptive behavior (Cohen-Mansfield agitation inventory [CMAI]) as the primary outcome. Number of neuroleptics, antidepressants, and cholinesterase inhibitors (ChEIs) prescribed in defined daily dosages (DDDs).
Results: Of 326 patients screened, 304 (93.3%) were eligible and cluster-randomized to 9 intervention (n = 163) and 9 control (n = 141) nursing homes. Data were collected from 287 (94.4%) patients at 10 months. At 10 months, compared with controls, nursing home residents with dementia in the intervention group exhibited significantly less agitation as measured with the CMAI (adjusted mean difference, 6.24; 95% CI 2.03–14.14; $P = .009$; Cohen's d = 0.43), received fewer neuroleptics ($P < .05$), more ChEIs ($P < .05$), and more antidepressants ($P < .05$).
Conclusion: Complex guideline-based interventions are effective in reducing agitated and disruptive behavior in nursing home residents with dementia. At the same time, increased prescription of ChEIs and antidepressants together with decreased neuroleptic prescription suggests an effect toward guideline-based pharmacotherapy.

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There is a growing focus on the implementation of guidelines to optimize treatment for nursing home residents suffering from dementia[1–4]; however, the effect of a complex guideline-based intervention has not yet been studied systematically. The proportion of nursing home residents suffering from dementia has constantly been growing throughout the past years,[5] and aggressive behavior and agitation are common behavioral symptoms in moderate and severe stages of dementia.[6] In late stages of the disease, behavioral symptoms occur in more than 75% of all nursing home residents suffering from dementia.[5–9]

Behavioral symptoms in dementia have been shown to have critical negative effects on professional caregivers, causing increased stress and "burn-out" syndromes.[10–12] Moreover, behavioral symptoms result in elevated care costs.[13] Pharmacological as well as non-pharmacological interventions have been applied to treat behavioral symptoms. Up to 75% of nursing home residents suffering from

This study was supported by grant LT 44-076 (Beacon [Leuchtturm] Project Dementia) from the German Federal Ministry for Health. All authors contributed to study design, the carrying out of the study, and writing the manuscript. The study was approved by the local ethics committee.
Trial Registration: Identifier: ISRCTN43578978.
The authors declare no conflicts of interest.
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http://dx.doi.org/10.1016/j.jamda.2013.05.017

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dementia are treated with psychotropic medication, and more than 25% receive neuroleptics.[5,8,9,14] With regard to nonpharmacological interventions, activity therapy,[15] enhanced psychosocial care,[1–3] validation,[16,17] pain treatment,[4] and training interventions for nursing staff[18] have all shown promising effects, but the effect of implementing several intervention modules from a complex guideline has not yet been studied.[19,20]

In this study, we applied the guidelines of the American Geriatrics Society and American Association of Geriatric Psychiatry[21] to study improvement of the treatment of behavioral symptoms in patients suffering from dementia in nursing homes in Berlin, Germany. The main goal of this study was to evaluate the implementation of guidelines in a prospective controlled evaluation study. To investigate this effect, we compared the severity of agitation, and amount and dosage of prescribed psychopharmacological medication in 9 nursing homes receiving a guideline implementation program and 9 nursing homes receiving treatment as usual. We hypothesized that the severity of agitation in moderate and severe dementia would be reduced in nursing homes receiving guideline implementation compared with controls. Furthermore, we tested whether the implementation of guidelines altered the prescription of psychotropics. Specifically, we hypothesized a decrease in neuroleptics and an increase in cholinesterase inhibitors (ChEIs) and antidepressant medication as treatment alternatives for agitation in dementia.

Methods

We designed a cluster-randomized controlled trial to avoid confounds, and our unit of randomization was each nursing home. The study was approved by the local ethics committee.

Participants

We recruited residents from 18 nursing homes in Berlin, Germany, 3 each from the boroughs of Mitte, Treptow, and Koepenick. Nursing homes were enrolled by the trial manager, and had to meet the following criteria to ascertain comparability at the level of each nursing home: being in good standing with local nursing home authorities (thus ensuring comparable nursing staff–to-resident ratios and provision of social workers, physical therapists, and occupational therapists on site), overall nursing home size between 100 and 200 residents, and a ratio of 50% to 70% of residents suffering from dementia.[14] Randomization was then conducted at the nursing home level based on a simple random number walk assignment.

Informed consent was obtained both from the nursing home manager and each resident if he or she had capacity to consent (n = 12), or a family or other caregiver holding power of attorney in case residents lacked capacity to give informed consent (n = 337). Initially, a total of 647 residents were contacted, and 349 consented to participate. Of these, 23 dropped out of the study during the 3-month waiting period before trial initiation (because of death, moving out of the nursing home, or withdrawal of consent), and another 22 proved ineligible during screening because they did not meet diagnostic inclusion criteria. After study initiation, a total of 46 patients dropped out of the study, 27 in the intervention and 19 in the control group, a difference that proved not to be statistically significant ($\chi^2 = .21$, df = 1, $P = .210$). Of these, 17 in the intervention group and 12 in the control group died during the course of the study; again, a difference that proved not to be statistically significant ($\chi^2 = .32$, df = 1, $P = .570$). The flow of recruitment is shown in Figure 1.

Intervention

The guidelines of the American Geriatrics Society and American Association of Geriatric Psychiatry[21] comprise the training of nursing home staff, including the implementation of structured clinical assessments, the implementation of nonpharmacological interventions, and the optimization of pharmacological interventions aimed at reducing behavioral symptoms in patients with dementia living in nursing homes. We implemented these 3 domains in a continuous intervention design, as published previously.[22]

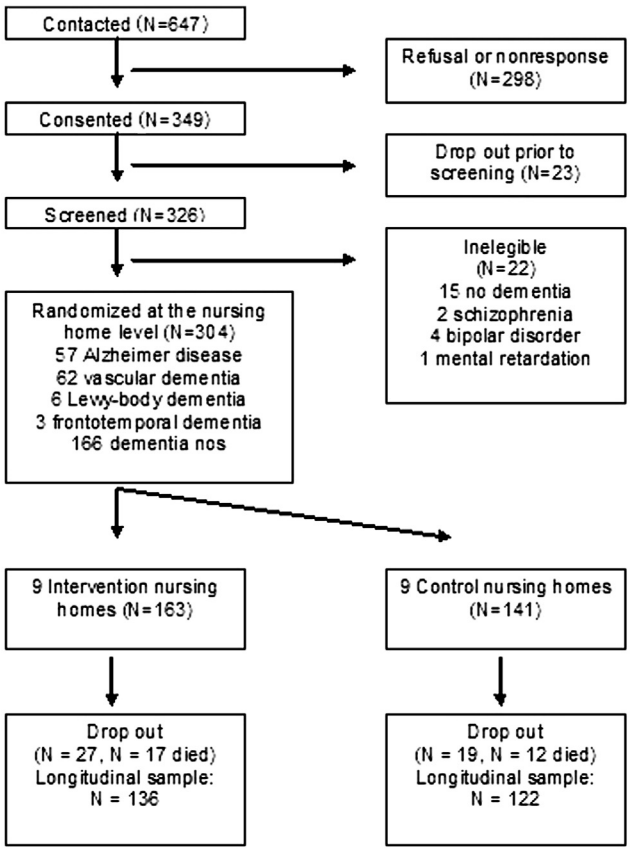

Fig. 1. Flow of participants. Dementia nos denotes dementia not otherwise specified.

Training of Nursing Home Staff

Based on established collaborations in 2 local service collaborations, nursing home staff were trained in groups of up to 8 nursing home staff members by a physician and a nurse specialized in geriatric psychiatry. Training consisted of two 4-hour blocks during a single day and took place at the site of the nursing home. Training included sessions on the symptomatology and causes of behavioral symptoms in dementia, the use of standardized assessments, nonpharmacological and pharmacological interventions, and concluded with case conferences using standardized case vignettes.

Nonpharmacological Interventions

For reasons of practicability and sustainability, we focused on the implementation of physical and activity therapy interventions, which are reimbursable by the German public health system and can be implemented in the routines of nursing homes. There is some evidence for the efficacy of activity therapy[15]; however, in focus groups carried out with nursing home staff and management before the implementation, it emerged that patients with dementia and behavioral symptoms rarely participate in these therapies when offered as group interventions. Specifically, as part of treatment as usual, 13 nursing homes (7 in the control and 6 in the intervention group) provided group activity twice a week for 45 minutes, and 5

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homes (2 in the control and 3 in the intervention group) provided activity sessions once a week for 45 minutes. However, at baseline, only 29.78% of the residents in the control group (n = 42) and 32.51% of residents in the intervention group (n = 53) participated in these group sessions. Therefore, we implemented individual treatment sessions provided by activity and occupational therapists, twice a week for 45 minutes. These sessions were guided by biographical information available on each resident, and consisted of individually tailored activity treatments, such as drawing; use of basic instruments, including cutlery, scissors, knitting, and writing material; use of kitchen utensils and therapy dough; and musical instruments. In the intervention group, a total of 74 residents participated in these individual sessions such that post intervention, the number of residents receiving activity therapy increased to 128, whereas only 49 residents received activity therapy in the control group, a difference that was statistically significant ($\chi^2 = 59.56$, df = 1, $P = .001$).

Optimization of Pharmacological Interventions

To optimize pharmacological interventions toward a guideline-based pharmacotherapy, prescribing primary care psychiatrists were trained in individual session for 4 hours each. Training included basic assessment and causes of behavioral symptoms, the identification of target symptoms for the treatment of behavioral symptoms, the implementation of nonpharmacological interventions before pharmacological interventions, and a specific guideline for pharmacological interventions. To that end, we updated the guidelines of the American Geriatrics Society and American Association of Geriatric Psychiatry,[21] which recommend the use of neuroleptics, ChEIs, and antidepressant agents, using more recent evidence on the risks and benefits of pharmacological interventions in dementia[19,23] that were presented in addition to the 2006 guidelines of the National Institute for Health and Clinical Excellence.[24]

Assessment

Baseline Data

Clinical and demographic data were assessed from December 2008 until February 2009 by specifically trained raters. Raters were postgraduate students in medicine and psychology, and were trained to use these instruments for 2 days in group teaching settings and during individual assessments of inpatients from the local geriatric psychiatry units. For the assessment of cognitive symptoms, the Mini Mental State Examination (MMSE)[25] was used, together with the Functional Assessment Staging (FAST)[26] to estimate the degree of functional impairment. The FAST is a 7-staged scale designed for assessing impaired abilities of daily living. Stages 1 to 5 include no to moderate functional impairment.

Primary Outcome

Agitation symptoms were assessed by the standardized 29-item version of the Cohen-Mansfield Agitation Inventory (CMAI),[27] which consists of 29 items, each rated on a 7-point scale of frequency (1 = never; 7 = several times an hour).

Secondary Outcomes

The number of neuroleptics, ChEIs, and antidepressants prescribed, including as-needed medication, was recorded as defined daily dosages (DDDs) from the medical records for each resident and averaged for the period of 2 weeks before assessment. For the assessment of DDDs, we used the German version of the standard algorithm anatomic therapeutic chemicals (ATC) provided by the World Health Organization.[28] In principle, DDD reflects the percentage of the maximum recommended daily dose on a given day, which can then be averaged across classes of drugs to obtain individual measures of psychotropic load in a given patient.

Ratings on the MMSE, FAST, and recording of prescribed medication were performed by raters blinded to the intervention. The CMAI rating requires an observation period of 2 weeks, and hence raters interviewed nursing staff at each site following the description and sample questions provided in the CMAI manual.[27]

Statistical Analyses

Based on previous research,[3] we estimated an attrition rate of 25% over 10 months, and the main outcome variable hypothesis to be tested with 85% power to detect moderate effect sizes (Cohen's d = 0.45). Significance levels were set to alpha = .05 (2-sided), resulting in a minimum sample size of n = 79 per arm. Furthermore, we expected intracluster correlation coefficients (ICC) to be 0.05, and expected an average of 15 residents in each cluster from individual assessments given by nursing home managers. Using the adjustment formula provided by Donner[29]:

$$\mathrm{mf} = 1 + ([\mathrm{m} - 1] \times \mathrm{r1}), \quad (1)$$

where *mf* denotes the multiplication factor for sample size based on randomization of individual subjects, *m* denotes the mean number of subjects in each cluster, and *r1* the ICC. We estimated overall sample size to be $79 \times (1 + [15 - 1] \times 0.05) = 79 \times 1.7 = 135$ per arm.

Raw scores were used for all baseline analyses. These analyses were performed using SPSS 17.0 (SPSS Inc, Chicago, IL). Between-group *t* tests and χ^2 tests were used to assess group differences on attrition rates, age, gender, education, and cognitive status as assessed by the MMSE, and dementia severity as measured with the FAST. Given the absence of differential attrition between groups, we did not adjust for attrition in our analyses. All tests of significance were 2-tailed with α set at 0.05. The normality assumption for the dependent variables (CMAI, DDD for neuroleptics, ChEIs, and antidepressants, respectively) was tested by examining individual-level distributions.

For the main treatment effect, the outcome measure was the 10-month CMAI score with age, gender, and baseline dementia severity, as measured by the FAST, entered as covariates. Mean adjusted differences and Cohen's d were calculated to measure treatment effect size.[30] For post hoc analyses on CMAI subscores, we computed repeated measures multivariate analyses of variance, controlling for age, gender, and dementia severity. For secondary analyses, we used DDDs for neuroleptics, ChEIs, and antidepressants, respectively, and adjusted for covariates as described previously. Effect sizes are expressed as the difference between the treatment groups, along with 95% confidence intervals (CIs), *P* values, and ICCs. These analyses were carried out using SPSS 17.0 using Huber-Weiss estimates. In post hoc analyses, we tested whether the number of residents receiving psychotropics differed between control and intervention homes, and whether there were significant changes in each group over time.

Results

Demographic and Clinical Characteristics

The overall study group at baseline (n = 304) comprised 83 men (27.3%) and 221 women (72.7%), with a mean age of 81.56 years (SD = 10.52), a mean MMSE of 8.89 (SD = 7.99), and a mean FAST score at baseline of 5.47 (SD = 3.52). CMAI mean score was 53.15 (SD = 20.41), and mean DDD was 0.26 (SD = 0.07) for neuroleptics, 0.18 (SD = 0.03) for antidepressants, and 0.08 (SD = 0.02) for ChEIs, respectively. After

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randomization, the intervention group (9 nursing homes) comprised 163 residents, and the control group (9 nursing homes) comprised 141 residents suffering from dementia.

There were no statistically significant differences between treatment and control groups at the individual level with respect to age, gender, MMSE, and FAST scores (all *P*s > .25), or in the DDDs of neuroleptics, antidepressants, or ChEIs (all *P*s > .46). Characteristics of the sample are listed in Table 1.

Agitation

At the 10-month follow-up, mean CMAI scores were 46.24 (SD = 16.27) in the intervention homes, and in 56.38 (SD = 17.23) in the control groups, respectively (mean difference 10.14, ICC = .11). Adjusting for age, gender, and baseline dementia severity, this difference remained significant (adjusted mean difference, 6.24; 95% CI 2.03–14.14; $P = .009$; Cohen's d = 0.43; see Table 2).

We also conducted post hoc within-subjects analyses of variance on subscores of the CMAI, controlling for age, gender, and baseline dementia severity to localize the nature of our effect on a syndromal level. Specifically, we used the subscores aggressive behavior, physically nonaggressive behavior, and verbally agitated behavior for these analyses.[27] Results showed that aggressive behavior increased in the control group (mean subscore at baseline 14.53, SD = 6.94; at follow-up 17.12, SD = 11.07) and decreased in the intervention group (mean subscore at baseline 14.03, SD = 5.82; at follow up 11.75, SD = 4.32), a difference that proved to be statistically significant (for the time by intervention interaction effect; $F_{4,190} = 6.442$, $P = .012$). The 2 other subscores did not show significant differences between control and intervention groups over time (for physically nonaggressive behavior, $F_{4,188} = 0.001$, $P = .977$; for verbally agitated behavior $F_{4,190} = 0.853$, $P = .357$).

Neuroleptics, Antidepressants, and ChEI Prescriptions

At the 10-month follow-up, mean DDDs in neuroleptics were 0.23 (SD = 0.06) in the intervention homes, and 0.26 (SD = 0.05) in the control groups, respectively (mean difference 0.03, ICC = 0.08). Adjusting for age, gender, and baseline dementia severity, this difference remained significant (adjusted mean difference, 0.03; 95% CI 0.01–0.05; $P = .04$; Cohen's d = 0.13). Mean DDDs in antidepressants were 0.22 (SD = 0.02) in the intervention homes, and 0.18 (SD = 0.04) in the control groups, respectively (mean difference 0.04, ICC = 0.12). Adjusting for age, gender, and baseline dementia severity, this difference remained significant (adjusted mean difference, 0.03; 95% CI 0.01–0.04; $P = .04$; Cohen's d = 0.14). Mean DDDs in ChEIs were 0.19 (SD = 0.06) in the intervention homes, and 0.08 (SD = 0.05) in the control groups, respectively (mean difference 0.11, ICC = 0.12). Adjusting for baseline dementia severity, this difference remained significant (adjusted mean difference, 0.09; 95% CI 0.05–0.11; $P = .01$; Cohen's d = 0.29). Mean DDDs for neuroleptics, antidepressants, and ChEIs in the intervention and control groups at baseline and 10 months are shown in Table 2.

Table 1
Baseline Characteristics of the Sample

	Intervention (n = 163)	Controls (n = 141)
Age	81.34 (11.29)	81.91 (9.12)
Female gender	123	98
MMSE	9.22 (7.95)	8.56 (8.47)
FAST	5.42 (3.67)	5.54 (3.28)
CMAI	52.94 (22.97)	53.86 (16.64)
Neuroleptics	0.263 (0.052)	0.264 (0.091)
Antidepressants	0.184 (0.041)	0.187 (0.032)
ChEI	0.084 (0.022)	0.086 (0.024)

ChEI, cholinesterase-inhibitor; CMAI, Cohen-Mansfield Agitation Inventory; FAST, Functional Assessment Staging; MMSE, Mini-Mental State Examination.

Table 2
Change in Agitation and Psychotropic Prescriptions From Baseline

	10 mo	Adjusted Mean Difference	95% CI	*P*	d
CMAI					
Intervention	46.24 (16.27)				
Control	56.38 (17.23)				
		6.24	2.03–14.14	.009	0.43
Psychotropics					
Neuroleptics					
Intervention	0.23 (0.06)				
Control	0.26 (0.05)				
		0.03	0.01–0.05	.04	0.13
Antidepressants					
Intervention	0.22 (0.02)				
Control	0.18 (0.04)				
		0.03	0.01–0.04	.04	0.14
ChEI					
Intervention	0.19 (0.06)				
Control	0.08 (0.05)				
		0.09	0.05–0.11	.01	0.29

ChEI, cholinesterase-inhibitor; CI, confidence interval; CMAI, Cohen-Mansfield Agitation Inventory; mo, months.
Values in parentheses denote SDs. Adjusted for age, gender, and baseline dementia severity.

Post hoc analyses revealed no statistically significant differences between the control and intervention groups at baseline in the number of residents receiving neuroleptics (n = 71 in the control group, and n = 88 in the intervention group; $\chi^2 = 0.40$, df = 1, $P = .527$), antidepressants (n = 47 in the control group, and n = 53 in the intervention group; $\chi^2 = 0.02$, df = 1, $P = .879$), or ChEIs (n = 24 in the control group, and n = 29 in the intervention group; $\chi^2 = 0.03$, df = 1, $P = .860$). During the intervention, the number of patients receiving neuroleptics did not change significantly in the intervention group (n = 69; $\chi^2 = 2.29$, df = 1, $P = .129$) or in the control group (n = 78; $\chi^2 = 0.32$, df = 1, $P = .566$). The number of patients receiving ChEIs did not increase significantly in the intervention (n = 41; $\chi^2 = 2.62$, df = 1, $P = .104$) or the control group (n = 26; $\chi^2 = 0.32$, df = 1, $P = .571$). For antidepressants, a similar pattern was observed post intervention (n = 63 in the intervention group; $\chi^2 = 0.85$, df = 1, $P = .357$; n = 45 in the control group; $\chi^2 = 0.05$, df = 1, $P = .832$).

Adverse Events

Seventeen residents in the intervention group and 12 residents in the control group died during the course of the study, a difference that proved not to be statistically significant ($\chi^2 = .32$, df = 1, $P = .570$). Overall, 45 patients were hospitalized during the 10 months of the study. Four patients were hospitalized 4 times or more (2 in control and 2 in intervention homes), 6 patients were hospitalized 3 times (4 in control and 3 in intervention homes), 12 patients were hospitalized twice (6 each in control and intervention homes, respectively), and 23 patients were hospitalized once (10 in control and 13 in interventions homes). The pattern of hospitalizations (including the absence of hospitalizations) did not differ between the 2 groups ($\chi^2 = 0.49$, df = 4, $P = .974$).

Discussion

In line with our hypotheses, we found a significant reduction in agitation and disruptive behavior in nursing home residents suffering

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from dementia who were treated with a complex, guideline-based intervention at the nursing home level. This effect was of moderate effect size in the terminology of Cohen[30] and amounted to about a third of a standard deviation of agitation as measured with the CMAI at baseline, suggesting relevant clinical significance. The analysis of subscores of the CMAI indicated that these changes were mainly driven by changes in physically aggressive behavior, which increased in control nursing homes and decreased in the intervention group.

Furthermore, we found a statistically significant reduction in neuroleptic dosage in the intervention nursing homes, together with a sizeable increase in antidepressant and ChEI prescriptions in the treatment group. In Cohen's[30] terminology, this effect was small to moderate. In clinical terms, especially the increase in ChEIs amounted to almost 1 SD, suggesting relevant clinical change, and the effect on neuroleptics amounted to about one-half of an SD, suggesting clinically relevant change to some degree. However, the number of participants receiving psychotropics did not change in the intervention group. In addition, the effect for neuroleptics has to be qualified to the high level of baseline neuroleptic prescriptions, which suggests that patients with dementia received about one-fourth of the recommended defined daily dosage for young adults suffering from schizophrenia. At the same time, the increase in antidepressants may reflect guideline adherence, but more recent studies have raised some debate on the efficacy[31,32] and risk profile[33] of antidepressants in patients suffering from dementia.

Fossey et al[3] found an average of 19.1% reduction in neuroleptic use in an intervention aimed at enhancing psychosocial care by training nursing home staff only. However, they did not find a significant effect on agitation or disruptive behavior. Chenoweth et al,[2] however, found a decrease in agitation in an intervention implementing person-centered care in urban nursing homes. This effect amounted to a mean difference of about 11 points on the CMAI and is of similar size as the effect found in our trial. Bakker et al[1] implemented a psychotherapeutic approach in nursing homes and found a reduction in the severity of behavioral symptoms of roughly 10 points on the neuropsychiatric inventory, indicating again a similar effect size to that found in our trial.

Our trial has several strengths, but also limitations. The cluster design enabled us to account for differences in nursing home size, and has proven to be a robust measure of complex interventions in nursing home care.[1–3] All sites were accredited by local nursing home supervisory authorities, and our outcome measure is well validated and sensitive to change. Attrition rates were low and did not differ between both groups. Although ratings were performed by raters who did not have knowledge as to the intervention status of each nursing home, the CMAI scores, which require interviewing nurses at the site that we could not blind completely to intervention, may have biased our results.

We restricted our hypotheses a priori to the most distressing behavioral symptom, agitation, thus ensuring both clinical relevance and avoiding multiple testing limitations in our analyses. The complex nature of our interventions precludes us from analyses of efficacy for each of the intervention domains. However, given that prior trials aimed at nursing home staff,[1–3] as well as trials implementing activity therapy,[15] showed predominantly significant reductions in agitation, but except for one trial[3] no effect on psychotropic prescriptions, it seems plausible to speculate that both nursing home staff training and the implementation of activity therapy may have driven the effect on agitation. This interpretation is supported by a significant increase in individual and group activity therapy provided by the study team in the intervention groups. At the same time, although clinically relevant, the overall effect of our intervention on psychotropic prescription was rather small, suggesting that, on the one hand, it may prove difficult to alter physicians' prescription behavior with training interventions only, and, on the other hand, altered pharmacotherapy may not have driven our effect to a larger share. Future trials should aim to disentangle the effects of interventions aimed at nursing home staff and primary care physicians, respectively.

The German public health system may differ from private or private-public insurance systems to a significant degree; nursing homes in Germany are often required to provide activity therapy and other nonpharmacological interventions by contract regulations with public insurance carriers. However, our study clearly revealed that these interventions do not reach a significant number of residents with dementia, and we would propose that added, individualized nonpharmacological interventions, which may have driven the effect found in this study, can be implemented across care systems, irrespective of the respective reimbursement structure.

To conclude, we were able to show a significant reduction in agitation in nursing home residents suffering from dementia using a complex, guideline-based intervention,[20] which comprised training of nursing home staff, the provision of activity therapy, and training of prescribing primary care psychiatrists.

Acknowledgments

We thank the patients, their relatives and professional caregivers, and the nursing home administration for their support, which made this study possible.

References

1. Bakker TJ, Duivenvoorden HJ, van der Lee J, et al. Integrative psychotherapeutic nursing home program to reduce multiple psychiatric symptoms of cognitively impaired patients and caregiver burden:randomized controlled trial. Am J Geriatr Psychiatry 2011;19:507–520.
2. Chenoweth L, King MT, Jeon YH, et al. Caring for Aged Dementia Care Resident Study (CADRES) of person-centred care, dementia-care mapping, and usual care in dementia:a cluster-randomised trial. Lancet Neurol 2009;8:317–325.
3. 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.
4. Leone AF, Standoli F, Hirth V. Implementing a pain management program in a long-term care facility using a quality improvement approach. J Am Med Dir Assoc 2009;10:67–73.
5. Testad I, Aasland AM, Aarsland D. Prevalence and correlates of disruptive behavior in patients in Norwegian nursing homes. Int J Geriatr Psychiatry 2007;22:916–921.
6. Lyketsos CG, Lopez O, Jones B, et al. Prevalence of neuropsychiatric symptoms in dementia and mild cognitive impairment:results from the cardiovascular health study. JAMA 2002;288:1475–1483.
7. Brodaty H, Draper B, Saab D, et al. Psychosis, depression and behavioural disturbances in Sydney nursing home residents:prevalence and predictors. Int J Geriatr Psychiatry 2001;16:504–512.
8. Margallo-Lana M, Swann A, O'Brien J, et al. Prevalence and pharmacological management of behavioural and psychological symptoms amongst dementia sufferers living in care environments. Int J Geriatr Psychiatry 2001;16:39–44.
9. Gruber-Baldini AL, Boustani M, Sloane PD, Zimmerman S. Behavioral symptoms in residential care/assisted living facilities:prevalence, risk factors, and medication management. J Am Geriatr Soc 2004;52:1610–1617.
10. Devanand DP. Behavioral complications and their treatment in Alzheimer's disease. Geriatrics 1997;52:S37–S39.
11. Souder E, O'Sullivan P. Disruptive behaviors of older adults in an institutional setting. Staff time required to manage disruptions. J Gerontol Nurs 2002;29:31–36.
12. Sutor B, Rummans TA, Smith GE. Assessment and management of behavioral disturbances in nursing home patients with dementia. Mayo Clin Proc 2001;76:540–550.
13. Beeri MS, Werner P, Davidson M, Noy S. The cost of behavioral and psychological symptoms of dementia (BPSD) in community dwelling Alzheimer's disease patients. Int J Geriatr Psychiatry 2002;17:403–408.

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14. Majic T, Pluta JP, Mell T, et al. The pharmacotherapy of neuropsychiatric symptoms of dementia: A cross-sectional study in 18 homes for the elderly in Berlin. Dtsch Arztebl Int 2010;107:320–327.
15. Alessi CA, Yoon EJ, Schnelle JF, et al. A randomized trial of a combined physical activity and environmental intervention in nursing home residents: Do sleep and agitation improve? J Am Geriatr Soc 1999;47:784–791.
16. Tondi L, Ribani L, Bottazzi M, et al. Validation therapy (VT) in nursing home: A case-control study. Arch Gerontol Geriatr 2007;44:407–411.
17. Neal M, Briggs M. Validation therapy for dementia. Cochrane Database Syst Rev 2000;2:CD001394.
18. Cohen-Mansfield J, Werner P, Culpepper WJ, Barkley D. Evaluation of an inservice training program on dementia and wandering. J Gerontol Nurs 1997; 23:40–47.
19. Seitz DP, Brisbin S, Herrmann N, et al. Efficacy and feasibility of non-pharmacological interventions for neuropsychiatric symptoms of dementia in long term care:a systematic review. J Am Med Dir Assoc 2012;13: 503–506.
20. Cohen-Mansfield J, Thein K, Marx MS, Dakheel-Ali M. What are the barriers to performing nonpharmacological interventions for behavioral symptoms in the nursing home? J Am Med Dir Assoc 2012;13:400–405.
21. American Geriatrics Society & American Association of Geriatric Psychiatry. Consensus statement on improving the quality of mental health care in U.S. nursing homes: Management of depression and behavioral symptoms associated with dementia. J Am Geriatr Soc 2003;51:1287–1298.
22. Rapp MA, Decker A, Klein U, et al. Verhaltenssymptome bei Demenz in Pflegeeinrichtungen:Evaluation eines Tandemprojekts pflegerischer und ärztlicher Leitlinien (VIDEANT). [Behavioral symptoms in dementia in nursing homes: Evaluation design of a guideline implementation program.]. Zeitschrift für Gerontopsychologie & -psychiatrie 2010;21:205–214.
23. Ballard C, Hanney ML, Theodoulou M, et al. The dementia antipsychotic withdrawal trial (DART–AD): Long-term follow-up of a randomised placebo-controlled trial. Lancet Neurol 2009;8:151–157.
24. National Institute for Health and Clinical Excellence guidelines for the treatment of dementia (NICE). Available at: http://publications.nice.org.uk/dementia-cg42. Accessed June 19, 2013.
25. 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.
26. Reisberg B. Functional assessment staging (FAST). Psychopharmacol Bull 1988; 24:653–659.
27. Cohen-Mansfield J. Measurement of inappropriate behavior associated with dementia. J Gerontol Nurs 1999;25:42–51.
28. WHO Collaborating Centre for Drug Statistics Methodology, Guidelines for ATC classification and DDD assignment, 2013. Oslo: 2012.
29. Donner A. Some aspects of the design and analysis of cluster randomization trials. J R Stat Soc Ser C Appl Stat 2002;47:95–113.
30. Cohen J. Statistical Power Analysis for the Behavioral Sciences. 2nd ed. Hillsdale: Lawrence Erlbaum Associates; 1988.
31. Banerjee S, Hellier J, Dewey M, et al. Sertraline or mirtazapine for depression in dementia (HTA-SADD): A randomised, multicentre, double-blind, placebo-controlled trial. Lancet 2011;378:403–411.
32. Bergh S, Selbæk G, Engedal K. Discontinuation of antidepressants in people with dementia and neuropsychiatric symptoms (DESEP study): Double blind, randomised, parallel group, placebo controlled trial. BMJ 2012;344:e1566.
33. Bakken MS, Engeland A, Engesæter LB, et al. Increased risk of hip fracture among older people using antidepressant drugs: Data from the Norwegian Prescription Database and the Norwegian Hip Fracture Registry. Age Ageing 2013;42:514–520.

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