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.

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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1525-8610/$ - see front matter Copyright © 2013 - American Medical Directors Association, Inc.
http://dx.doi.org/10.1016/j.jamda.2013.05.017

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]

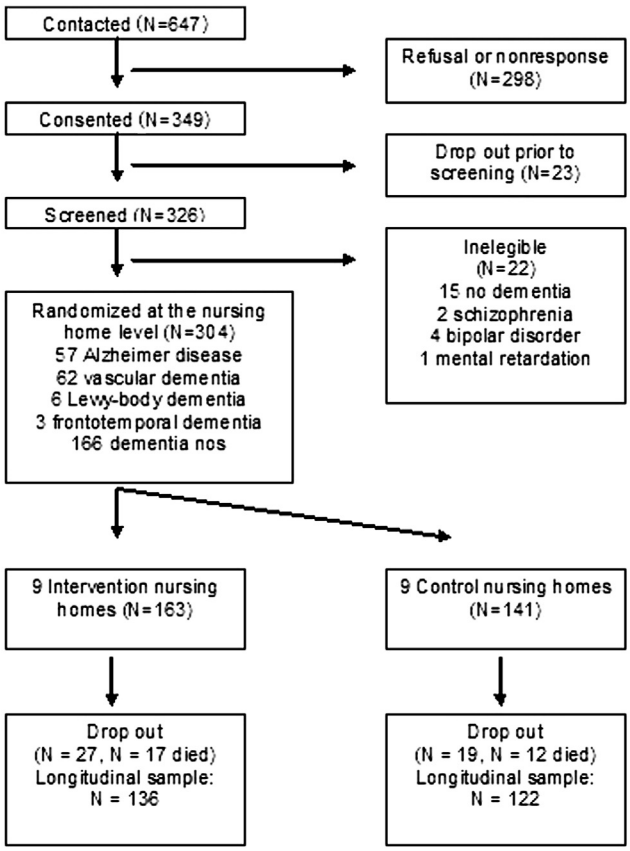

Fig. 1. Flow of participants. Dementia nos denotes dementia not otherwise specified.

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