

Original Article

Staff Distress Improves by Treating Pain in Nursing Home Patients With Dementia: Results From a Cluster-Randomized Controlled Trial



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Abstract

Context. Most people with dementia develop neuropsychiatric symptoms (NPSs), which are distressing for their carers. Untreated pain may increase the prevalence and severity of NPSs and thereby staff burden.

Objectives. We investigated the association between NPSs and the impact of individual pain treatment on distress in nursing home staff.

Methods. Nursing home (NH) units were cluster-randomized to an intervention group (33 NH units; $n = 175$) or control group (27 NH units; $n = 177$). Patients in the intervention group received individual pain treatment for eight weeks, followed by a four-week washout period; control groups received care as usual. Staff informants ($n = 138$) used the Neuropsychiatric Inventory–NH version (including caregiver distress) as primary outcome to assess their own distress. Other outcomes were pain (Mobilization-Observation-Behavior-Intensity-Dementia-2 Pain Scale) and cognitive functioning (Mini–Mental State Examination).

Results. Using hierarchical regression analysis, all NPS items at baseline were associated with staff distress ($P < 0.01$) apart from euphoria; agitation had the largest contribution ($\beta = 0.24$). Using mixed models, we found significantly lower staff distress in the intervention group compared to the control group. Moreover, we also found significantly reduced distress in the control group, and there were still effects in both groups throughout the washout period.

Conclusion. Individual pain treatment reduced staff distress in the intervention group compared to control group especially in regard to agitation-related symptoms and apathy. Furthermore, our results indicated a multifactorial model of staff distress, in which enhanced knowledge and understanding of NPSs and pain in people with advanced dementia may play an important role. *J Pain Symptom Manage* 2016;52:795–805. © 2016 The Authors. Published by Elsevier Inc. on behalf of American Academy of Hospice and Palliative Medicine. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Key Words

Staff distress, staff education, nursing home, dementia, neuropsychiatric symptoms, pain

Introduction

Approximately 35 million people worldwide and 10 million people in Europe suffer from dementia, a progressive and terminal condition.¹ During the first years

of the disease, the majority of patients live at home with their family; consequently, a vast number of people with informal caregiving responsibilities are indirectly affected by the condition.² As the dementia progresses, people lose their independence and 90%

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develop neuropsychiatric symptoms (NPSs) such as agitation, psychosis, and sleep disturbances.^{2,3} These symptoms are distressing, not only for the patients but also for the carers, and lead to institutionalization as reflected in the nursing home (NH) population, 80% of whom have dementia.⁴

Distressing symptoms do not recede with NH admission, and the care for these patients is found to affect formal carers, both emotionally and physically, leading to depression, anxiety, and sleep problems.⁵ The societal consequences are significant: burnout, sick leave, turnover, and increased economic costs.^{2,6,7} Interestingly, only a few and mostly cross-sectional studies specifically investigate the differential effect of discrete NPSs on distress in NH staff.^{2,6,8,9} Interviews with licensed nurses and certified nursing aides ($n = 24$) demonstrated that aggression and agitation were more distressing than other NPSs such as euphoria and nonaggressive behaviors.² Results are supported by 445 formal caregivers in Japan who experienced the presence of disruptive behaviors such as aggression and screaming as most burdensome.⁶ To handle NPSs, psychotropic drugs are often used as a first-line therapy and are prescribed to approximately 75% of people with dementia in NHs.⁴ A placebo-controlled trial with risperidone in older people with dementia ($N = 279$) demonstrated a significant reduction in NH staff distress.¹⁰ Another intervention study using the cognitive enhancer memantine in people with dementia and behavioral disturbances also found supplementary amelioration of staff distress.¹¹

Although the etiology of NPSs is largely unknown, undiagnosed, and untreated, pain may be an important trigger for the increased prevalence of NPSs^{12–14} and is thereby, indirectly, an important concern for staff distress. Recently, our research group completed a cluster-randomized controlled trial (RCT) that included people with advanced dementia and agitation who received either individual pain treatment (intervention) or care as usual (control). Beneficial effects were found in relation to several NPSs.^{15–17} Study results also suggested that a Hawthorne effect can be of matter because NPSs improved in both intervention and control groups, possibly related to training and staff support. Increased knowledge may empower staff to cope with difficult symptoms in contrast to being helpless witnesses of the suffering with untreated pain in patients.^{7,18} These complex issues have not yet been addressed.

In the present study, the objectives may be divided into three stages: 1) a prestage investigating the nature of staff distress and patient symptoms, 2) the main objectives as a second stage, 3) and a third stage investigating secondary effects of the study protocol.

- 1) We aimed to investigate the association between different NPSs and level of staff distress at baseline as we hypothesized that different NPSs would not all be equally distressing to staff.
- 2) We have already shown that pain treatment reduces NPSs in NH patients and that this effect was reverted during washout.^{15,17} Thus, the main aim of this study was to investigate if the introduction of a systematic pain treatment also had an effect on staff distress. In particular, we wished to investigate 1) whether the level of distress was reduced in the intervention as compared to control group after eight weeks of systematic pain treatment and 2) whether staff distress increased after the analgesic washout period in intervention group vs. control group. We hypothesized that introducing individual pain treatment would reduce staff distress but did not have any scientific grounds to suggest if the effect was large enough to detect change after washout.
- 3) Because both the intervention and control groups received education regarding pain, neuropsychiatric symptoms, and received training in several assessment tools, we also aimed to investigate the effect of the study intervention within both the intervention and control groups. We hypothesized that the mere participation in a study would entail positive effects also for the control group.

Methods

This study is based on secondary data analyses from a cluster-RCT including 352 long-term care patients from 18 NHs in Western Norway. The study was conducted between October 2009 and June 2010. Participants were included from 60 NH units (1 NH unit = 1 cluster), randomized to control (27 NH units; $n = 177$) or intervention (33 NH units; $n = 175$). Inclusion criteria were as follows: age 65 years or more, expected survival of more than six months, advanced dementia (Mini-Mental State Examination [MMSE], score <20), and high levels of agitation (Cohen-Mansfield Agitation Inventory score ≥ 39).

NH Staff Participation

Primary caregivers ($n = 138$) who knew the patient and had direct patient contact for at least four weeks participated as proxy raters (informants). The informants in both the intervention and control groups received a half-day specific training in clinical

assessment of pain, cognition, NPSs, activities of daily living, and functional assessment staging. They were later interviewed by research assistants in connection with data collection. Research assistants and caregivers were blinded to allocation of treatment and control groups during the clinical assessments. Those who were responsible for delivering the intervention, including the medication, did not participate in the data collection. To further ensure blinding, the staff was encouraged not to talk about management procedures during the study period.

Study Intervention

Patients in the intervention group received pain treatment according to a Systematic Pain Treatment Protocol (SPTP) adhering to the American Geriatric Society's recommendations for pharmacological pain management.¹⁹ Patients receiving treatment were individually assessed by the responsible team including the NH physician, primary patient caregiver, and a pain therapist (B. S. H.). The team discussed and agreed on the appropriate pain medication and dosage according to the standardized SPTP.²⁰ The intervention lasted eight weeks, followed by a four-week washout period. The control group received care as usual. The inclusion, design, and study intervention (SPTP) have been described in detail in previous publications.^{15–17,20}

Outcome Measures

The main outcome measure in this study was staff distress, as measured by the Neuropsychiatric Inventory–NH (NPI-NH) version. The inventory is a 12-item proxy-rated instrument addressing different NPSs in the patient, and self-reported distress of these symptoms for the staff.²¹ Both the international^{21–23} and Norwegian²⁴ versions of the inventory have shown satisfactory validity and reliability. Each symptom is rated both according to its severity/intensity (0–3) and frequency (0–4) often expressed as a product (frequency score \times severity score, $F \times S$) ranging from 0 to 12. The staff distress scale, also known as occupational disruptiveness scale for the NPI-NH, consists of six levels: “not at all distressing” (0), “minimally distressing” (1), “mildly distressing” (2), “moderately distressing” (3), “severely distressing” (4), and “extremely distressing” (5). This means that NH staff assesses how emotional distressing the patient's behavior is for them and if it entails more occupational burden. In previous studies, the NPSs in patients have been collated into symptom clusters: mood (depression, apathy, anxiety, night-time behaviors, and appetite/eating disorders), agitation (agitation/aggression, disinhibition, irritability, and aberrant motor behavior), and psychosis

(delusions and hallucinations) with euphoria as a single item.²⁵

Pain was assessed using the Mobilization-Observation-Behavior-Intensity-Dementia-2 (MOBID-2) Pain Scale, developed and validated for use in NH patients with advanced dementia.²⁶ MOBID-2 is an instrument in which pain behavior, such as vocalization, facial expression, and defensive body movements are observed to ascertain pain presence and intensity using a 10-point numerical rating scale (range 0–10). MOBID-2 has demonstrated good reliability and validity²⁷ as well as responsiveness.²⁸

We used the MMSE to ascertain the patients' cognitive functioning. It produces a sum score ranging from 0 to 30 that can be used to follow the course of patients or for case detection using cutoff scores. It has been used extensively in clinical and research settings and has high test-retest reliability, internal consistency, and interrater reliability.^{29,30}

Statistical Analyses

All analyses were performed using IBM SPSS statistics version 23 and Stata/IC version 14 (StataCorp LP, College Station, TX, USA). Descriptive data including demographic data of the NH staff were calculated showing means and percentages.

According to the main Objective 1, the differential associations between each NPS and total staff distress were analyzed at baseline using a hierarchical linear regression analysis, and we used the robust estimator of variance, allowing for intragroup correlation. Total staff distress was entered as the dependent variable. The patients' age, gender, pain (MOBID-2 total score), cognitive functioning (MMSE), and all 12 NPI-NH item scores were entered as predictors. In this analysis, age, gender, and MMSE were entered in the first step, pain was entered in the second step, and all NPI items were entered in the third and final step. Before performing regression analysis, the data were checked for multicollinearity, normality, linearity, homoscedasticity, independence of residuals, and outliers.

The second objective for the study was to examine whether the level of staff distress was reduced after implementing individual pain treatment and whether staff distress increased after the analgesic washout period in control group versus intervention group. Although the third aim was to investigate the effect of the study intervention within both the intervention and control groups, the change of NPI-NH staff distress scores from baseline to eight and 12 weeks were estimated by linear mixed-effect models, using maximum likelihood estimation. The analyses were conducted separately for each of the following outcome variables: total staff distress; the 12 distinct NPI-NH staff distress items; and the three combined items mood, agitation, and psychosis, in total 16

analyses. We treated time as a categorical variable and included fixed effects for time, intervention, and their interaction in the models. To account for clustering, patients were nested within NH-units and NPI-NH scores within patients, and the models were fitted with random intercepts and slopes for both NH-units effects and for patient-level effects. The covariance structures were specified using an unstructured model within individuals and identity model within NH units. The model selections were based on best fit according to likelihood ratio tests, AIC, and BIC.

The regression coefficients for time indicates the within-group change of the NPI-NH score from baseline to Week 8 and Week 12 in the intervention and the control groups, and the corresponding CIs indicate the within-group change statistical significance. The regression coefficient for the interaction term shows the difference in within-group change at eight weeks and 12 weeks between the intervention group and the control group and is thus interpreted as the effect of the intervention. The corresponding CIs were used as a measure of statistical significance. The significance levels were set to 0.05. *P* for interaction was obtained by likelihood ratio tests comparing the models with interaction to the models without interaction. Significant *P*-values indicate an overall difference in within-group change over time between the intervention group and the control group. The

intracluster correlation (ICC) coefficients were reported at the NH unit level and at the patient level. The ICC at NH-unit level is the correlation between the responses in the same NH-unit but for different patients, whereas the ICC at the patient level is the correlation between responses for the same patient at different time points.

Ethics

The NH staff gave informed consent to participate as informants. Informed consent was also obtained from all patients who had sufficient capacity. If patients did not have the capability, written consent was provided by the next of kin or the authorized legal representative. The study was approved by the Regional Committee for Medical Ethics, Western Norway (REK-Vest 248.08).

Results

Baseline Characteristics of NH Patients and Staff Informants

At baseline, the included NH patients ($n = 341$) had a mean age of 86 years, and mean MMSE of 8. Patients' demographics and symptoms are presented in Table 1. The attrition rate of 17.6% did not cause significant differences between the intervention and control groups.¹⁵

Table 1
Patient Characteristics and Neuropsychiatric Symptoms and NH Staff Distress at Baseline

Characteristics and Symptoms	NH Patient Characteristics		Staff Distress	
	Intervention Text	Control	Intervention	Control
Age (SD)	84.9 (7.0)	86.5 (6.8)		
Women%	74.9	74		
Cognitive function/MMSE (SD)	7.51 (6.5)	8.40 (6.7)		
Pain/MOBID-2 (SD)	3.70 (2.7)	3.67 (2.5)		
NPI-NH	NH Patient Neuropsychiatric Symptoms		NPI-NH Distress Score	
Total NPI-NH score (SD)	35.42 (21.7)	31.35 (20.8)	15.06 (9.6)	13.10 (9.2)
Symptom clusters				
Mood (SD)	6.0 (4.4)	5.1 (4.4)	5.98 (4.4)	5.08 (4.4)
Agitation (SD)	6.5 (4.7)	5.9 (4.7)	6.53 (4.7)	5.88 (4.7)
Psychosis (SD)	2.3 (2.6)	1.9 (2.4)	2.28 (2.6)	1.89 (2.4)
Single items				
Delusions (SD)	3.52 (4.3)	2.60 (3.8)	1.50 (1.7)	1.21 (1.6)
Hallucinations (SD)	1.67 (3.1)	1.48 (2.9)	0.78 (1.4)	0.68 (1.3)
Agitation (SD)	4.19 (4.2)	3.66 (4.0)	2.09 (1.9)	1.81 (1.7)
Depression (SD)	2.80 (3.5)	2.86 (3.7)	1.42 (1.5)	1.31 (1.5)
Anxiety (SD)	3.58 (4.3)	3.09 (4.0)	1.55 (1.7)	1.31 (1.6)
Euphoria (SD)	0.57 (1.9)	0.71 (2.1)	0.26 (0.9)	0.24 (0.8)
Apathy (SD)	3.80 (4.3)	2.56 (3.7)	1.19 (1.4)	0.68 (1.1)
Disinhibition (SD)	2.92 (3.9)	2.98 (4.0)	1.33 (1.6)	1.33 (1.6)
Irritability (SD)	4.35 (4.1)	3.72 (3.7)	1.96 (1.7)	1.71 (1.6)
Aberrant motor behavior (SD)	3.44 (4.6)	3.04 (4.5)	1.18 (1.6)	1.02 (1.5)
Sleep disturbance (SD)	2.02 (3.4)	2.17 (3.2)	0.92 (1.5)	1.02 (1.5)
Appetite/eating disorder (SD)	2.61 (4.2)	2.48 (4.1)	0.90 (1.5)	0.76 (1.4)

NH = nursing home; MMSE = Mini-Mental State Examination; MOBID-2 = Mobilization-Observation-Behavior-Intensity-Dementia-2; NPI-NH = Neuropsychiatric Inventory-Nursing Home; n = number of patients.

Intervention group = NH units: 33, $n = 177$; control group = NH units: 27, $n = 175$. Numbers represent mean (SD). Numbers of women are expressed in percentage.

The primary caregivers ($n = 138$) had a mean age of 43 years; 136 were women. Their average professional experience was 17 years, with nine years of work experience in their current institution. Most of the included informants were of Norwegian national origin (93.3%) and educated health workers, of which 44% were registered nurses and 49% assistant nurses, whereas the remaining 7% were unskilled workers. Staff distress was assessed in relation to 341 patients at baseline.

The Relationship Between Different Neuropsychiatric Symptoms and Staff Distress

As summarized in Table 2, the full hierarchical linear regression model including the NPI-NH scores entered at Step 3 explained 81% of the total staff distress variance. At Step 1, higher cognitive functioning assessed by MMSE was related to lower total staff distress. This association persisted when pain was entered at Step 2. At Step 2, pain was also significantly related to staff distress. In essence, staff experienced less distress related to patients with higher cognitive functioning and less pain compared to patients with lower cognitive functioning and more reported pain. When NPI items were entered at Step 3, cognitive functioning and pain were no longer related to total staff distress. Thus, the effects of pain and reduced cognitive functioning were precluded when controlling for NPSs.

All NPI-NH items, except for euphoria, were significantly related to a higher risk of total staff distress at baseline. The individual effect of NPI-NH items on staff distress varied, with standardized coefficients ranging from 0.048 (small effect) to 0.235 (moderate effect). Agitation ($\beta = 0.235$), disinhibition ($\beta = 0.201$), and delusions ($\beta = 0.202$) were the only items showing coefficients over 0.20, closely followed by sleep ($\beta = 0.185$).

Effect on Staff Distress During the Treatment Period

Within-group comparisons (Table 3) showed a significant decrease in total staff distress from baseline to Week 8, in both the intervention group ($B -6.51$, 95% CI -7.88 to -5.14) and control group ($B -2.98$, 95% CI -4.38 to -1.59). As seen in Table 3, the majority of the staff distress items, including NPI-NH symptom clusters, showed a significant decrease in both the intervention and control groups, but with larger effect in the intervention group (Table 3).

In terms of between-group comparisons at Week 8, there were significantly lower staff distress in the intervention group compared to control group in relation to single items such as agitation, anxiety, apathy, aberrant motor behavior, and appetite/eating disorder (Fig. 1). There was also less staff distress in the intervention group compared to control group in relation

Table 2
Multiple Hierarchical Linear Regression Analysis ($n = 341$) for the Baseline Associations Between Patient Characteristics and Neuropsychiatric Symptoms and the Dependent Variable Total Staff Distress as Measured by the Neuropsychiatric Inventory—Nursing Home Version

Distress Associated to	R^2	Δr^2	B	SE	β
Step 1	0.017	0.008			
Age			0.019	0.082	0.014
Female			1.051	1.176	0.049
MMSE			-0.176	0.080	-0.123 ^a
Step 2	0.04	0.025 ^a			
Age			0.050	0.086	0.037
Female			0.969	1.220	0.045
MMSE			-0.180	0.082	-0.125 ^a
MOBID-2 total score			0.491	0.194	0.134 ^a
Step 3	0.810	0.800 ^b			
Age			0.047	0.042	0.034
Female			-0.278	0.515	-0.013
MMSE			0.002	0.041	0.002
MOBID-2 total score			0.078	0.080	0.021
Neuropsychiatric symptoms					
Delusions			0.467	0.069	0.202 ^b
Hallucinations			0.507	0.099	0.164 ^b
Agitation			0.542	0.064	0.235 ^b
Depression			0.356	0.073	0.136 ^b
Anxiety			0.401	0.061	0.178 ^b
Euphoria			0.230	0.218	0.048
Apathy			0.283	0.085	0.120 ^b
Disinhibitions			0.480	0.065	0.201 ^b
Irritability			0.266	0.072	0.109 ^b
Aberrant motor behavior			0.271	0.056	0.128 ^b
Sleep			0.535	0.096	0.185 ^b
Appetite/eating disorder			0.278	0.083	0.122 ^b

n = number of patients; B = coefficient; β = standardized coefficient; SE = standard error; MMSE = Mini-Mental State Examination; MOBID-2 = Mobilization-Observation-Behavior-Intensity-Dementia-2.

^a $P < 0.05$.

^b $P < 0.001$.

to total distress ($B -3.53$, 95% CI -5.47 to -1.58) and symptom cluster: mood ($B -1.74$, 95% CI -2.66 to -0.83) and agitation ($B -1.62$, 95% CI -2.60 to -0.65) (Fig. 2).

Effect on Staff Distress After the Washout Period

Neither the intervention group nor the control group showed significant within-group changes in total staff distress during the washout period, from Week 8 to Week 12. However, the intervention group demonstrated a significant increase in distress scores for aberrant motor behavior ($P < 0.05$), whereas staff in the control group felt more stressed by patients' irritability ($P < 0.05$).

Between-group comparisons at Week 12 showed significantly less total distress in the intervention group in relation to total staff distress, to the mood ($B -2.13$, 95% CI -3.28 to -0.98) and agitation ($B -1.69$, 95% CI -2.93 to -0.45) symptom cluster, and to the following single items: agitation, depression, anxiety, apathy, irritability, and appetite/eating disorder (Table 3).

Table 3
Changes in Staff Distress^a Within Groups From Baseline to Week 8 and From Baseline to 12 Weeks, and Estimated Intervention Effects Between Groups at Week 8 and Week 12^b

Symptoms	Change From Baseline to Eight Weeks			Change From Baseline to 12 Weeks			P-Int.	ICC NH-Units	ICC Pat.
	Intervention Group	Control Group	B-Interaction (95% CI)	Intervention Group	Control Group	B-Interaction (95% CI)			
	B (95% CI)	B (95% CI)		B (95% CI)	B (95% CI)				
Total staff distress	-6.51 (-7.88, -5.14)	-2.98 (-4.38, -1.59)	-3.53 (-5.47, -1.58)	-6.24 (-8.01, -4.48)	-2.53 (-4.34, -0.71)	-3.72 (-6.24, -1.20)	0.003	0.15	0.78
Symptom cluster									
Mood	-2.57 (-3.21, -1.94)	-0.84 (-1.47, -0.20)	-1.74 (-2.66, -0.83)	-2.80 (-3.59, -2.00)	-0.68 (-1.48, 0.12)	-2.13 (-3.28, -0.98)	<0.001	0.16	0.75
Agitation	-2.96 (-3.64, -2.29)	-1.34 (-2.02, -0.66)	-1.62 (-2.60, -0.65)	-2.54 (-3.39, -1.70)	-0.86 (-1.71, -0.003)	-1.69 (-2.93, -0.45)	0.005	0.10	0.75
Psychosis	-0.87 (-1.25, -0.49)	-0.71 (-1.07, -0.35)	-0.15 (-0.70, 0.39)	-0.86 (-1.34, -0.37)	-0.80 (-1.25, -0.35)	-0.05 (-0.74, 0.65)	0.758	0.01	0.75
Single items									
Delusions	-0.61 (-0.86, -0.36)	-0.46 (-0.71, -0.20)	-0.15 (-0.54, 0.23)	-0.59 (-0.90, -0.29)	-0.54 (-0.85, -0.22)	-0.05 (-0.55, 0.44)	0.597	0.03	0.70
Hallucinations	-0.25 (-0.43, -0.08)	-0.24 (-0.41, -0.07)	-0.01 (-0.26, 0.23)	-0.26 (-0.46, -0.05)	-0.24 (-0.44, -0.04)	-0.01 (-0.30, 0.28)	0.995	0.03	0.73
Agitation	-1.01 (-1.28, -0.74)	-0.39 (-0.65, 0.13)	-0.62 (-0.99, -0.25)	-0.87 (-1.19, -0.56)	-0.29 (-0.61, 0.02)	-0.58 (-0.03, -0.14)	0.006	0.04	0.69
Depression	-0.60 (-0.84, -0.36)	-0.31 (-0.55, -0.07)	-0.29 (-0.63, 0.05)	-0.66 (-0.96, -0.36)	-0.22 (-0.52, 0.08)	-0.45 (-0.87, -0.02)	0.128	0.04	0.71
Anxiety	-0.79 (-1.00, -0.57)	-0.32 (-0.53, -0.11)	-0.47 (-0.77, -0.17)	-0.85 (-1.10, -0.59)	-0.36 (-0.61, -0.11)	-0.49 (-0.85, -0.13)	0.008	0.04	0.76
Euphoria	-0.11 (-0.24, 0.03)	-0.03 (-0.17, 0.10)	-0.07 (-0.26, 0.11)	-0.04 (-0.21, 0.12)	-0.08 (-0.24, 0.09)	0.03 (-0.18, 0.26)	0.373	0.04	0.64
Apathy	-0.67 (-0.86, -0.49)	0.13 (-0.06, 0.31)	-0.80 (-1.06, -0.54)	-0.63 (-0.85, -0.42)	0.07 (-0.14, 0.28)	-0.70 (-1.00, -0.40)	<0.001	0.14	0.65
Disinhibitions	-0.61 (-0.85, -0.37)	-0.33 (-0.57, -0.10)	-0.28 (-0.61, 0.06)	-0.51 (-0.78, -0.23)	-0.23 (-0.50, 0.04)	-0.27 (-0.66, 0.11)	0.249	0.07	0.65
Irritability	-0.74 (-1.00, -0.47)	-0.40 (-0.66, -0.14)	-0.34 (-0.71, 0.03)	-0.78 (-1.09, -0.46)	-0.15 (-0.47, 0.17)	-0.63 (-1.08, -0.17)	0.029	0.03	0.65
Aberrant motor behavior	-0.65 (-0.89, -0.41)	-0.20 (-0.43, 0.04)	-0.45 (-0.79, -0.12)	-0.43 (-0.72, -0.13)	-0.15 (-0.45, 0.15)	-0.28 (-0.69, 0.14)	0.017	0.08	0.73
Sleep disturbance	-0.20 (-0.40, -0.004)	-0.31 (-0.50, -0.12)	0.11 (-0.17, 0.38)	-0.28 (-0.52, -0.04)	-0.16 (-0.39, 0.08)	-0.12 (-0.56, 0.22)	0.146	0.08	0.77
Appetite disorder	-0.31 (-0.54, -0.08)	0.04 (-0.19, 0.27)	-0.35 (-0.67, -0.03)	-0.37 (-0.65, -0.10)	0.07 (-0.20, 0.35)	-0.45 (-0.83, -0.06)	0.069	0.07	0.66

P-Int = interaction was obtained by likelihood ratio test; ICC NH-units = intraclass correlation on NH-units level meaning correlation between the responses in the same NH-unit but for different patients; ICC Pat. = intraclass correlation on patient level meaning the correlation between responses for the same patient at different time points.

^aMeasured by Neuropsychiatric Inventory–Nursing Home version.

^bMixed-model analyses.

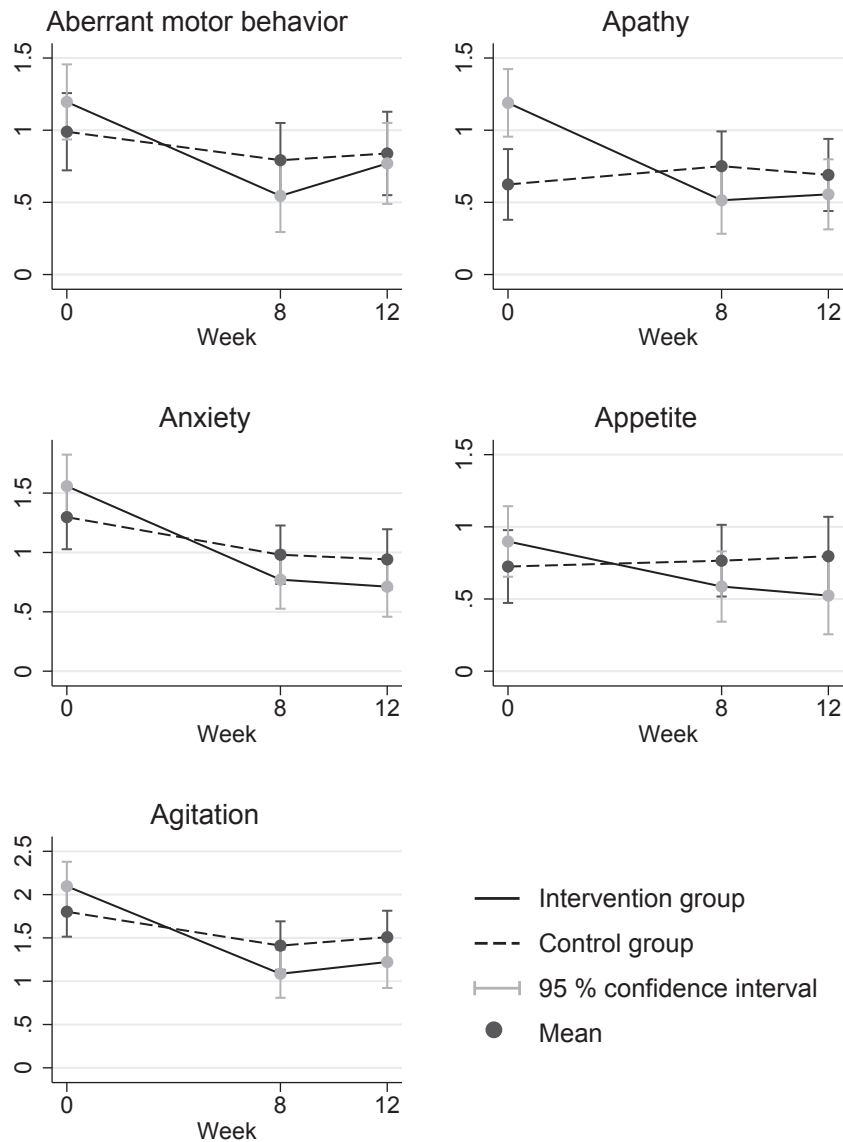


Fig. 1. Staff distress in relation to single items (agitation, anxiety, apathy, aberrant motor behavior, and appetite) in the Neuropsychiatric Inventory–Nursing Home version at baseline, Week 8, and Week 12.

Discussion

This present study suggests that individual pain treatment in people with advanced dementia and NPSs may improve staff distress as a secondary effect of the treatment. Staff distress was especially provoked by agitation and disinhibition, whereas euphoria was least distressing for the carers. These findings confirm our hypotheses and highlight that pain treatment, and thereby ameliorated NPSs, may additionally improve staff distress as a valuable secondary effect. Our results also highlighted the potential value of education and enhanced knowledge of NH staff because the changes in total staff distress from baseline to Week 8 persisted throughout the washout period. In addition, we also saw beneficial effects of the trial in the control groups.

The Relationship Between Different Neuropsychiatric Symptoms and Staff Distress

The higher risk of staff distress related to agitation, disinhibition, delusions, and disturbed sleep may be explained by the disruptive nature of these symptoms, both for other patients in the NH unit and the staff. This may have some unfortunate clinical results, as Zwijsen et al.⁸ points out, if for example apathy causes little disruption, staff may not feel the same urgency to address this symptom. Indeed, the finding is in line with previous studies where the highest caregiver distress scores were related to externalized and disruptive behavior such as agitation, aggression, and disinhibition.^{2,6,8} In addition, although disturbed sleep has not been previously highlighted in studies on staff

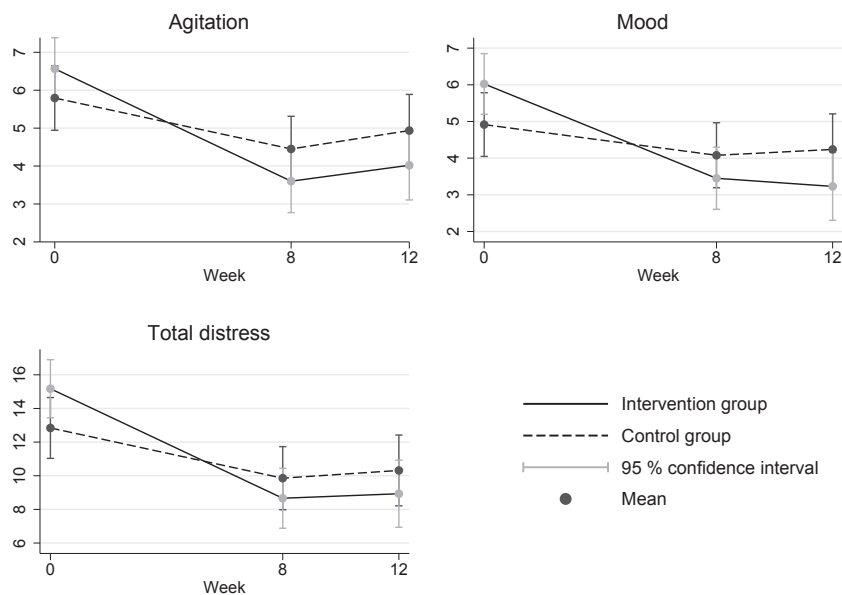


Fig. 2. Total staff distress and symptom clusters of mood (depression, anxiety, apathy, sleep disturbance, and appetite) and agitation (agitation, disinhibitions, irritability, aberrant motor behavior) in the intervention group compared to the control group at baseline, Week 8, and Week 12.

distress, it has been identified as one of the most frequent symptoms to negatively impact in-formal caregivers and thus increase the risk of institutionalization.³¹

Furthermore, none of the other variables (age, gender, cognitive functioning, and pain) included in the full hierarchical regression model were related to staff distress. Meanwhile, we did find effect of both cognition and pain before the model accounted for NPSs. The association we found between severe dementia and staff distress before the NPSs were entered may be an effect of low MMSE representing an added burden when a patient additionally had demanding NPSs. Likewise, the fact that the total pain intensity score was only associated with staff distress at Step 2 may imply that a patients' pain is distressing for caregivers largely due to the behavior triggered by the pain.⁷ Indeed, studies that previously have investigated pain as distressing for carers have focused on the agitated pain behavior.^{7,13,32} This supports results from previous studies suggesting untreated pain is difficult to identify and is primarily distressing for the staff when expressed as NPSs.^{7,8,33}

Effect on Staff Distress During the Treatment Period

Several of the distress scores were significantly reduced in the intervention group at Week 8 confirming our second hypothesis that pain treatment would reduce staff distress. Although staff distress was reduced in the control group as well, the effect was substantially higher in the intervention group. Importantly, comparison of groups showed significantly less total staff distress in the intervention group as well

as single NPI-NH items. It is a peculiar contradiction that staff in our study did not experience significant distress related to pain, yet individual pain treatment ameliorated staff distress. Because typical pain behavior may be similar to behavioral disturbances related to dementia, we suggest that symptoms related to pain and discomfort are incorrectly labeled as behavioral problems related to dementia.¹³

This reduction in staff distress after eight weeks' systematic pain treatment is in line with our previous studies where individual pain treatment significantly reduced several NPSs.¹⁵⁻¹⁷ Taken together, the better effect in the intervention group and our previous findings are suggestive of an indirect link between pain treatment and reduced staff distress via reductions in behavioral problems. This is also in line with the study by Norton et al.⁷ relating pain to staff distress associated with behavioral problems. However, the results are not unequivocally indicative of this reasoning. Although the effects of pain treatment on NPSs in people with dementia receded during the washout period described in previous publications,^{15,16,20} most staff distress differences between the intervention and control groups persisted throughout the washout period.

Impact of Clinical Studies

The subjective experience of distress is affected by phenomena such as coping and appraisal.³⁴ Agitation and NPSs may, in general, interfere and create insecurity in the NH setting, especially if the staff have not received training in dealing, that is coping, with such symptoms.⁷ The importance of staff

understanding and appraisal of symptoms were highlighted in a study by Rodney³³ where the appraisal of aggressiveness as threatening was significantly related to staff stress.³³ Participation in research projects may lead to higher staff competence, consequently expanding their understanding of symptoms.³⁴ The use of systematic assessment of NPSs and pain by NPI and MOBID-2, respectively, directs the NH staff to see symptoms as a part of the patients' clinical condition rather than a malevolent threat. In addition, training in symptoms assessment allows the staff to describe the patient's condition more competently with evidence-based knowledge. This training is needed; previous studies have highlighted a lack of knowledge around persons with dementia- and cancer-related pain in NH.³⁵ Meanwhile, our findings do not imply a model where pain management and staff training are the sole factors necessary to reduce staff distress. As illustrated by Testad et al.,³⁶ psychosocial factors such as feelings of proficiency and control at work as well as leadership and organizational culture also affect staff stress.

Although this study was double-blinded, the staff knew that they were part of a study. In previous publications, from this RCT, we have observed effects in the intervention and control groups which may indicate a Hawthorn effect.³⁷ The finding may be of particular interest for the clinician and can be connected to the Rosenthal's Pygmalion effect,³⁸ the phenomenon where high expectations improve performance due to more attention and positive reinforcement. Such improvements in trial control conditions are common in studies investigating treatments of NPSs and are consistent with potential benefits of participating in a trial such as social interaction.^{39,40} The presence of researchers provided recognition of the staff's daily work in the NH, which may additionally have had a positive effect for the staff.

Strengths and Limitations

This is the first well-powered RCT that investigates the link between different NPSs and staff distress in NH patients with severe dementia. This represents a strength due to the interrelated and often cooccurring nature of NPSs.⁴¹ Thus, controlling for other NPSs, age, gender, cognitive functioning, and pain allows us to rule out distress related to a total symptom burden. Although some of the informants were without formal competence, they were selected because of their skills and knowledge of the clinical condition to the participating NH patients. In addition, a research assistant was present and provided guidance throughout the whole assessment procedure. As such, this represents a strength and ensures high data quality.

Unfortunately, our data do not fully link proxy rater or workplace characteristics to the staff distress scores because we lack elements such as sick leave, staff attitude, or details about organizational issues that might impact staff distress. We did not assess the effect of staff education in either the control or the intervention group. Organizational and psychosocial aspects (personality) to identify risk factors for staff distress should be addressed in future studies. To focus on education of staff and implementation is a prerequisite to better understand these effects and should be taken into consideration in complex intervention studies.

Although it is common to collate NPSs in NPI-NH version into symptom clusters,²⁵ symptom clustering of the NPI-NH distress scale has not been validated. In practice, it can be difficult to distinguish the NPSs, which also often cooccur.⁴¹ It is thus reasonable to collate staff distress in the same symptom clusters used to describe NPSs.

We reported staff distress and NPSs as measured with the NPI-NH scale. Hence, the informants who reported the patients' NPSs also reported the staff distress in relation to these symptoms. This represents a potential source of common method bias. Partly addressing this issue, statistical analyses excluded concerns of multicollinearity. Although precautions were taken to blind research assistants and NH staff to group allocation, the efforts to fully blind staff will always be difficult in these studies due to the requirements in an NH setting. In addition, this study only included patients with severe dementia and clinically significant agitation. When including a patient group with high symptoms burden (i.e., agitation), there is always a possibility that some of the improvement may be attributed to a mere regression toward the mean. We cannot exclude this effect in our study. Although our patient sample is not representative for the general NH population, this sample was relevant for our study focus.

Conclusions

This study shows that individual pain treatment in people with advanced dementia indirectly reduced staff distress by improved NPSs. The lasting positive effect on staff distress after the washout period may suggest that introducing clinical tools and training is of key importance not only for the well-being of patients but also for the NH staff participating in a relevant research project for the NH setting. Participation in research projects may lead to higher staff competence, consequently expanding their understanding of symptoms. This effect signals the manifold importance of enabling proper medical patient follow-up in NHs.

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References

1. Ferri CP, Prince M, Brayne C, et al. Global prevalence of dementia: a Delphi consensus study. *Lancet* 2005;366:2112–2117.
2. Wood SA, Cummings JL, Barclay T, et al. Assessing the impact of neuropsychiatric symptoms on distress in professional caregivers. *Aging Ment Health* 1999;3:241–245.
3. Selbaek G, Engedal K, Benth JS, Bergh S. The course of neuropsychiatric symptoms in nursing-home patients with dementia over a 53-month follow-up period. *Int Psychogeriatr* 2014;26:81–91.
4. Selbaek G, Kirkevold O, Engedal K. The prevalence of psychiatric symptoms and behavioural disturbances and the use of psychotropic drugs in Norwegian nursing homes. *Int J Geriatr Psychiatry* 2007;22:843–849.
5. McPherson S, Hiskey S, Alderson Z. Distress in working on dementia wards - a threat to compassionate care: a grounded theory study. *Int J Nurs Stud* 2016;53:95–104.
6. Miyamoto Y, Tachimori H, Ito H. Formal caregiver burden in dementia: impact of behavioral and psychological symptoms of dementia and activities of daily living. *Geriatr Nurs* 2010;31:246–253.
7. Norton MJ, Allen RS, Snow AL, Hardin JM, Burgio LD. Predictors of need-driven behaviors in nursing home residents with dementia and associated certified nursing assistant burden. *Aging Ment Health* 2010;14:303–309.
8. Zwijsen SA, Kabboord A, Eefsting JA, et al. Nurses in distress? An explorative study into the relation between distress and individual neuropsychiatric symptoms of people with dementia in nursing homes. *Int J Geriatr Psychiatry* 2014;29:384–391.
9. Voyer P, Verreault R, Azizah GM, et al. Prevalence of physical and verbal aggressive behaviours and associated factors among older adults in long-term care facilities. *BMC Geriatr* 2005;5:13.
10. Frank L, Kleinman L, Ciesla G, Rupnow MF, Brodaty H. The effect of risperidone on nursing burden associated with caring for patients with dementia. *J Am Geriatr Soc* 2004;52:1449–1455.
11. Herrmann N, Cappell J, Eryavec GM, Lanctot KL. Changes in nursing burden following memantine for agitation and aggression in long-term care residents with moderate to severe Alzheimer's disease: an open-label pilot study. *CNS Drugs* 2011;25:425–433.
12. Achterberg WP, Pieper MJ, van Dalen-Kok AH, et al. Pain management in patients with dementia. *Clin Interv Aging* 2013;8:1471–1482.
13. Flo E, Gulla C, Husebo BS. Effective pain management in patients with dementia: benefits beyond pain? *Drugs Aging* 2014;31:863–871.
14. Ahn H, Horgas A. The relationship between pain and disruptive behaviors in nursing home residents with dementia. *BMC Geriatr* 2013;13:14.
15. Husebo BS, Ballard C, Sandvik R, Nilssen OB, Aarsland D. Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial. *BMJ* 2011;343:d4065.
16. Husebo BS, Ballard C, Cohen-Mansfield J, Seifert R, Aarsland D. The response of agitated behavior to pain management in persons with dementia. *Am J Geriatr Psychiatry* 2014;22:708–717.
17. Husebo BS, Ballard C, Fritze F, Sandvik RK, Aarsland D. Efficacy of pain treatment on mood syndrome in patients with dementia: a randomized clinical trial. *Int J Geriatr Psychiatry* 2014;29:828–836.
18. Monin JK, Schulz R. Interpersonal effects of suffering in older adult caregiving relationships. *Psychol Aging* 2009;24:681–695.
19. American Geriatrics Society Panel on Pharmacological Management of Persistent Pain in Older Persons. Pharmacological management of persistent pain in older persons. *J Am Geriatr Soc* 2009;57:1331–1346.
20. Sandvik RK, Selbaek G, Seifert R, et al. Impact of a stepwise protocol for treating pain on pain intensity in nursing home patients with dementia: a cluster randomized trial. *Eur J Pain* 2014;18:1490–1500.
21. Cummings JL, Mega M, Gray K, et al. The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. *Neurology* 1994;44:2308–2314.
22. Kaufer DI, Cummings JL, Christine D, et al. Assessing the impact of neuropsychiatric symptoms in Alzheimer's disease: the Neuropsychiatric Inventory Caregiver Distress Scale. *J Am Geriatr Soc* 1998;46:210–215.
23. Wood S, Cummings JL, Hsu MA, et al. The use of the neuropsychiatric inventory in nursing home residents. Characterization and measurement. *Am J Geriatr Psychiatry* 2000;8:75–83.
24. Selbaek G, Kirkevold O, Sommer OH, Engedal K. The reliability and validity of the Norwegian version of the Neuropsychiatric Inventory, nursing home version (NPI-NH). *Int Psychogeriatr* 2008;20:375–382.
25. Cheng ST, Kwok T, Lam LC. Neuropsychiatric symptom clusters of Alzheimer's disease in Hong Kong Chinese: prevalence and confirmatory factor analysis of the Neuropsychiatric Inventory. *Int Psychogeriatr* 2012;24:1465–1473.
26. Husebo BS, Strand LI, Moe-Nilssen R, Husebo SB, Ljunggren AE. Pain in older persons with severe dementia. Psychometric properties of the Mobilization-Observation-Behaviour-Intensity-Dementia (MOBID-2) Pain Scale in a clinical setting. *Scand J Caring Sci* 2010;24:380–391.
27. Husebo BS, Strand LI, Moe-Nilssen R, et al. Mobilization-Observation-Behavior-Intensity-Dementia Pain Scale

- (MOBID): development and validation of a nurse-administered pain assessment tool for use in dementia. *J Pain Symptom Manage* 2007;34:67–80.
28. Husebo BS, Ostelo R, Strand LI. The MOBID-2 pain scale: reliability and responsiveness to pain in patients with dementia. *Eur J Pain* 2014;18:1419–1430.
29. 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.
30. Velayudhan L, Ryu SH, Raczek M, et al. Review of brief cognitive tests for patients with suspected dementia. *Int Psychogeriatr* 2014;26:1247–1262.
31. Ornstein K, Gaugler JE. The problem with “problem behaviors”: a systematic review of the association between individual patient behavioral and psychological symptoms and caregiver depression and burden within the dementia patient-caregiver dyad. *Int Psychogeriatr* 2012;24:1536–1552.
32. Husebo BS, Strand LI, Moe-Nilssen R, et al. Who suffers most? Dementia and pain in nursing home patients: a cross-sectional study. *J Am Med Dir Assoc* 2008;9:427–433.
33. Rodney V. Nurse stress associated with aggression in people with dementia: its relationship to hardiness, cognitive appraisal and coping. *J Adv Nurs* 2000;31:172–180.
34. Lazarus RS, Folkman S. *Stress, appraisal, and coping*. New York: Springer, 1984. XIII, 445 s.
35. Drageset J, Corbett A, Selbaek G, Husebo BS. Cancer-related pain and symptoms among nursing home residents: a systematic review. *J Pain Symptom Manage* 2014;48:699–710.e1.
36. Testad I, Mikkelsen A, Ballard C, Aarsland D. Health and well-being in care staff and their relations to organizational and psychosocial factors, care staff and resident factors in nursing homes. *Int J Geriatr Psychiatry* 2010;25:789–797.
37. Merrett F. Reflections on the Hawthorne effect. *Educ Psychol* 2006;26:143–146.
38. Learman LA, Avorn J, Everitt DE, Rosenthal R. Pygmalion in the nursing home. The effects of caregiver expectations on patient outcomes. *J Am Geriatr Soc* 1990;38:797–803.
39. Craig D, Mirakhor A, Hart DJ, McIlroy SP, Passmore AP. A cross-sectional study of neuropsychiatric symptoms in 435 patients with Alzheimer’s disease. *Am J Geriatr Psychiatry* 2005;13:460–468.
40. Livingston G, Johnston K, Katona C, et al. Systematic review of psychological approaches to the management of neuropsychiatric symptoms of dementia. *Am J Psychiatry* 2005;162:1996–2021.
41. Selbaek G, Engedal K. Stability of the factor structure of the Neuropsychiatric Inventory in a 31-month follow-up study of a large sample of nursing-home patients with dementia. *Int Psychogeriatr* 2012;24:62–73.