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Original Research Article

The Effect of Person-Centred Dementia Care to Prevent Agitation and Other Neuropsychiatric Symptoms and Enhance Quality of Life in Nursing Home Patients: A 10-Month Randomized Controlled Trial

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Key Words
Dementia · Agitation · Neuropsychiatric symptoms · Person-centred care · Quality of life

Abstract
Aims: We examined whether Dementia Care Mapping (DCM) or the VIPS practice model (VPM) is more effective than education of the nursing home staff about dementia (control group) in reducing agitation and other neuropsychiatric symptoms as well as in enhancing the quality of life among nursing home patients. ***Methods:*** A 10-month three-armed cluster-randomized controlled trial compared DCM and VPM with control. Of 624 nursing home patients with dementia, 446 completed follow-up assessments. The primary outcome was the change on the Brief Agitation Rating Scale (BARS). Secondary outcomes were changes on the 10-item version of the Neuropsychiatric Inventory Questionnaire (NPI-Q), the Cornell Scale for Depression in Dementia (CSDD) and the Quality of Life in Late-Stage Dementia (QUALID) scale. ***Results:*** Changes in the BARS score did not differ significantly between the DCM and the control group or between the VPM and the control group after 10 months. Positive differences were found for changes in the secondary outcomes: the NPI-Q sum score as well as the subscales NPI-Q agitation and NPI-Q psychosis were in favour of both interventions versus control, the QUALID score was in favour of DCM versus control and the CSDD score was in favour of VPM versus control. ***Conclusions:*** This study failed to find a significant effect of both interventions on the primary outcome. Positive effects on the secondary outcomes indicate that the methods merit further investigation.
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Introduction

The worldwide prevalence of dementia is rising and will reach 81.1 million by 2040 [1]. In addition to a decline in cognition that influences the patients' performance of their activities of daily living, neuropsychiatric symptoms (NPS) such as agitation, psychosis, depression and anxiety are common in patients with all types of dementia disorders. Studies have demonstrated that about 70–80% of individuals with dementia in nursing homes have at least one clinically significant NPS [2–5]. Based on the Neuropsychiatric Inventory (NPI) [6], symptom clusters such as agitation/aggression, psychosis and affective symptoms have been identified in nursing home patients with dementia [7, 8]. Agitated behaviour seems to be the most persistent NPS, while affective symptoms tend to decrease during the course of the dementia disease [9]. Agitation and other NPS are often treated with psychotropic drugs, even though the evidence for an effect is modest and this mode of treatment might cause severe side effects [10]. Non-pharmacological interventions are, therefore, recommended as the initial treatment approach [11, 12]. However, Cochrane reviews conclude that there is either a lack of evidence of effect or methodological limitations to studies of non-pharmacological interventions such as music therapy [13], massage and touch [14], validation [15], bright light therapy [16], Snoezelen [17] and aroma therapy [10, 18]. Psychosocial interventions to treat agitation seem to work best when they are tailored to people's backgrounds, interests and capacity [19–21].

Quality of life (QoL) has been increasingly recognized as an important dimension in dementia research to help determine the effect of a particular treatment or intervention [22–24]. As several studies have revealed a correlation between the occurrence of NPS and impaired QoL [25–28], the treatment of these symptoms is important to enhance QoL in nursing home patients. Courtney et al. [29] states that improving the quality of care will improve the QoL for the residents.

In recent decades, person-centred dementia care (PCC) [30–32] has been suggested as an intervention to develop quality of dementia care and further prevent or mitigate NPS. A main focus in PCC is the need to preserve the patient's personhood through the course of the disease [30]. Using the PCC approach, the impact of the social environment is considered important for the well-being of the patient. Additionally, understanding the perspective of the person with dementia and considering agitation as a way for the patient to communicate unmet needs [33] might contribute to tailored interventions suitable to prevent and treat agitation. The basic psychological needs for comfort, identity, occupation, attachment and inclusion need to be met in all stages of dementia [30]. According to Brooker [34], PCC is the sum of the four essential elements described as the 'VIPS' framework: valuing people with dementia (V), individualized care (I), understanding the world from the patient's perspective (P) and providing a social environment that supports the needs of the patient (S), i.e. PCC = V + I + P + S [34].

To implement PCC in nursing homes, Dementia Care Mapping (DCM) was developed as an observational and developmental tool [35, 36]. It has been reported that DCM plays a role in practice development within the broad aim of improving QoL in persons with dementia [37]. DCM is a standardized [38], internationally used and quality-controlled method [37]. A model for systematic use of the VIPS framework in nursing home wards, the VIPS practice model (VPM), has recently been developed and tested for use in nursing homes [39, 40].

A few previous randomized controlled trials (RCTs) have evaluated the effect of staff training on the implementation of PCC in residential homes. One RCT comparing PCC and 'care as usual' showed that the use of antipsychotic drugs was reduced among the patients in the PCC group compared to the control group, but no significant change in NPS or QoL was reported [41]. In an Australian study, the use of both DCM and a training program in PCC

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resulted in decreased agitation in patients from the intervention groups compared to patients from the control group [42].

As non-pharmacological interventions are the recommended initial treatments for NPS, we designed a study aiming to investigate the effect of implementing PCC using DCM and the recently developed VPM. We hypothesized that both DCM and the VPM would be more effective than giving the staff DVDs with lectures about dementia for free use in reducing agitation and other NPS in nursing home patients. Furthermore, we hypothesized that the interventions would result in a better QoL for the patients.

Methods

Study Design

This was an RCT conducted in nursing homes in Oslo, Norway, in the period from January to December 2011. All 51 nursing homes located in the city of Oslo were invited to participate in the study. The 15 nursing homes that accepted the invitation were randomized into three groups. One group of nursing homes received intervention with DCM, one group received intervention with the VPM and the last group constituted a common control group for both intervention groups (fig. 1).

Nursing Homes and Patients

The nursing home population in Oslo mainly comprises people of Nordic ethnic origin. Before randomization, the 15 nursing homes were divided into three blocks according to their size defined as small (30–49 patients; 6 nursing homes), medium (50–69 patients; 6 nursing homes) or large (70–95 patients; 3 nursing homes). This classification was used because most nursing homes in Oslo fall into one of these groups. Block randomization was done by drawing lots, and each of the three intervention groups then consisted of two small, two medium and one large nursing home.

One nursing home withdrew after randomization, thus 14 nursing homes with a total of 40 wards and 624 patients with dementia were included in the study (fig. 2). All patients at all stages of dementia in the participating wards were invited to take part in the study. If competent, the patients gave informed written consent. For patients lacking the capacity to give informed consent, their relatives were given the opportunity to decline participation on behalf of the patients based on written information.

The trial was registered at ClinicalTrial.gov in January 2011 (study ID number: NCT 01280890) and approved by the Regional Ethics Committee for Medical Research in eastern Norway.

Data Collection

Assessments were made at baseline before randomization and after 10 months. The data were collected by 13 (baseline) and 10 (follow-up) research assistants. They received a 1-day training course in the use of the questionnaires in groups of 5–10 persons conducted by the researchers. Most of those collecting the data had participated in similar studies earlier and knew the instruments well. They collected data from the patients' records and interviewed the patients' primary nurse, who was either a registered nurse or an auxiliary nurse. The project leaders were available during the data collection and could be consulted at any time. Those collecting the data were not part of the research group and were not given information on the group an individual patient belonged to.

Interventions

DCM

DCM can be described as both a tool and a process. As a tool, DCM consists of in-depth observations (mappings) over 4–6 h of persons with dementia made in formal care settings. The process is the use of DCM as a driver for the implementation of PCC in practice, including preparations, mapping, feedback on the observations to care staff, action planning, monitoring progress over time and re-mappings [36, 38]. In this study, DCM was used as a process to develop the care staff's skills in delivering PCC to the patients. The DCM intervention consisted of the following elements: 2 care staff members from each ward attended a basic DCM course certifying them to use DCM in their own nursing homes. The rest of the care staff were introduced to PCC and DCM as they received a 3-hour lecture on these topics from the researchers. Subsequently, the DCM observations were carried out by the researchers in collaboration with the internal DCM-certified staff. DCM

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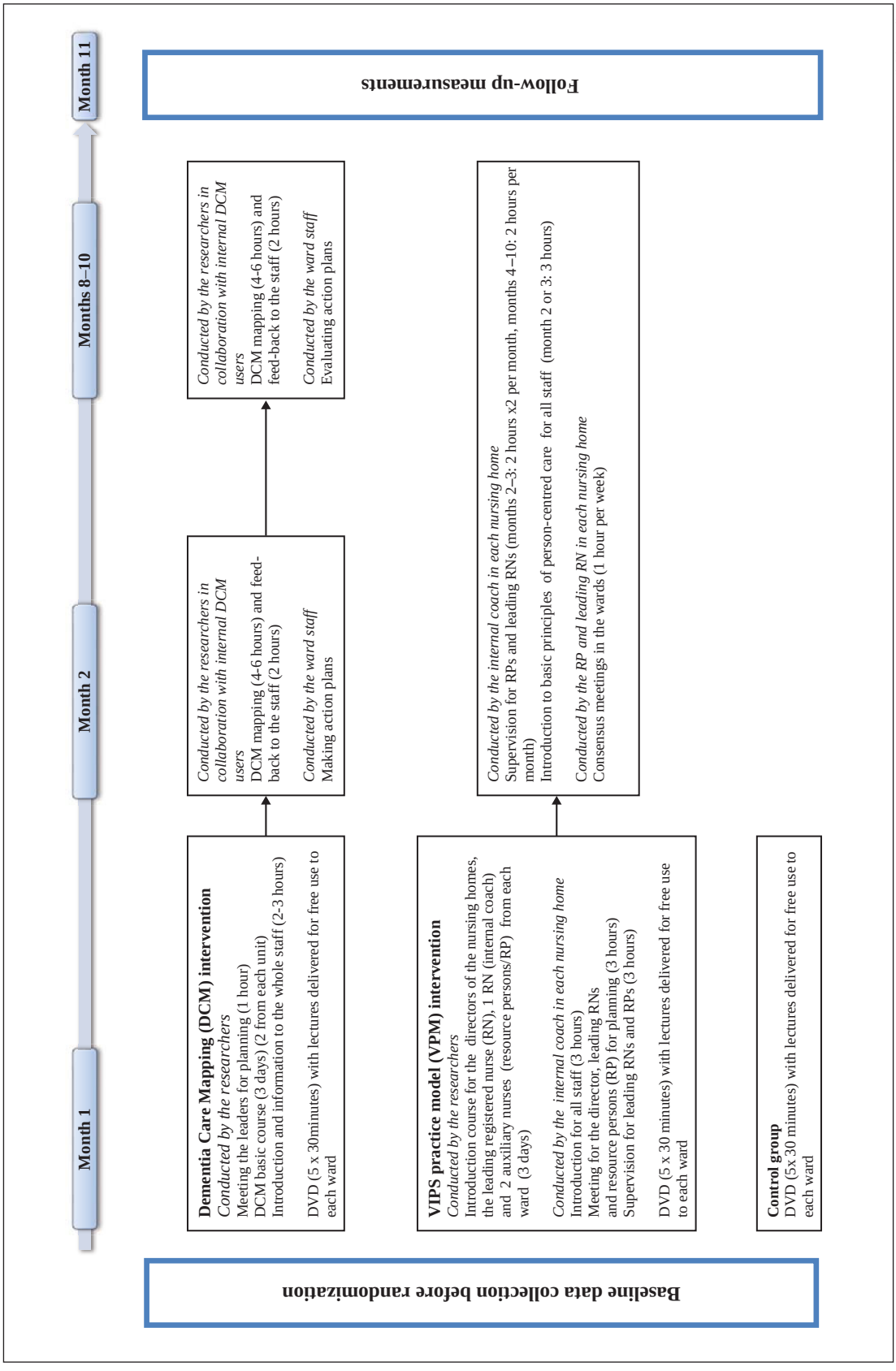

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Fig. 1. Study design.

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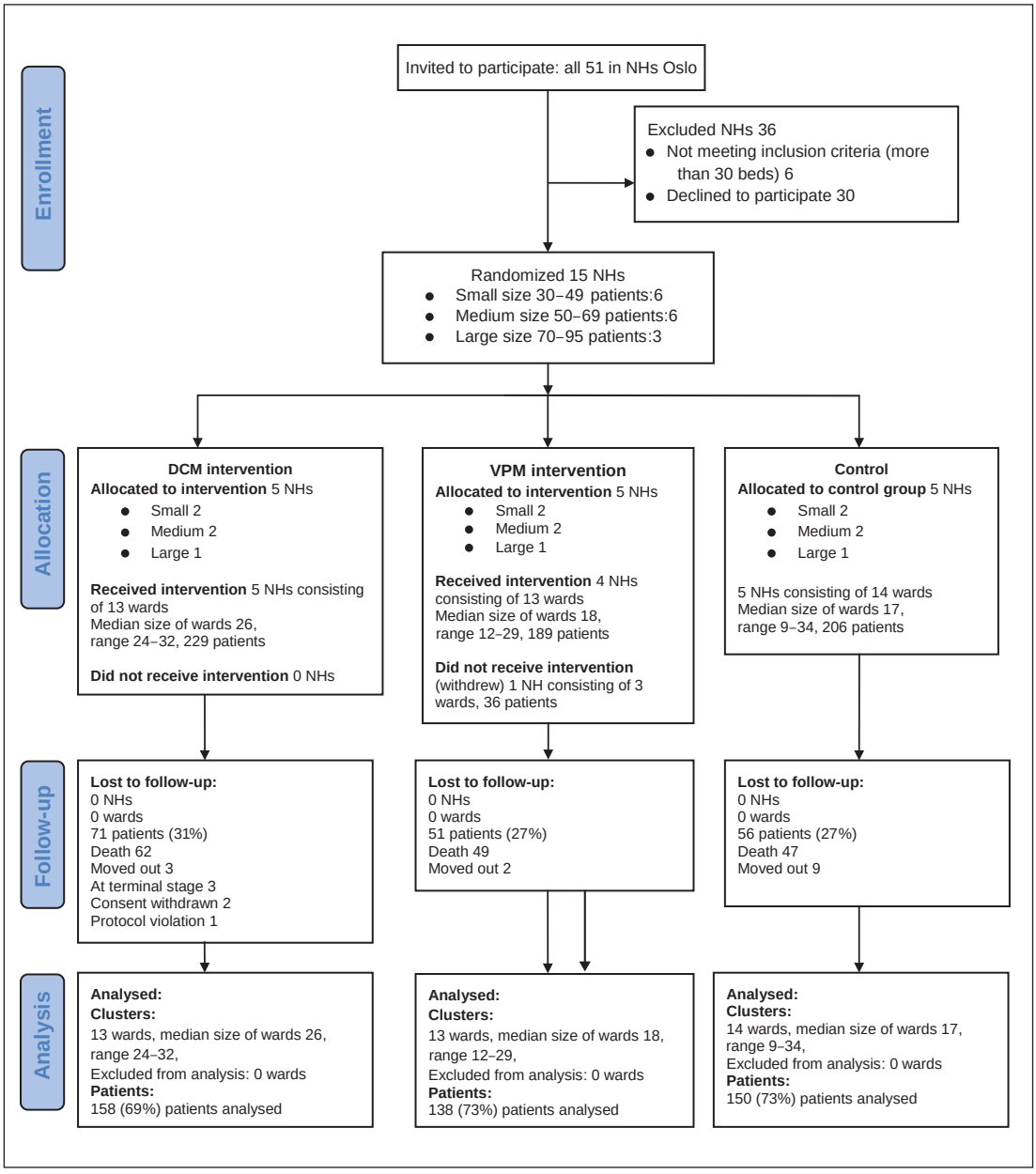

Fig. 2. Flow of participants. NHs = Nursing homes.

observations consisted of the standardized coding of the patients' well-being and behaviour. Additionally, descriptions of interaction between staff and patients were recorded. The observations were followed by a feedback session within 1 week in which the care staff was invited to reflect upon the findings and to plan future actions to improve care. The care staff and their leaders then implemented the action plans in the nursing home units without any further involvement of the researchers. After 6 months, the DCM observations and feedback were repeated.

VPM

The VPM [40] used the VIPS framework, which has 24 indicators [34], to ensure that the care provided was person-centred. The main element was a weekly consensus meeting in the nursing home ward of 45–60 min using the indicators in the VIPS framework to analyse a challenging patient-nurse interaction. The

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analysis emphasized how the patient might experience the situation and how his/her neurological impairment, physical health, personality, life history and psychosocial needs might impact on his/her reactions [30]. One of the nurses chaired the meeting, the patient's primary nurse represented the patient and the staff contributed with their observations and relevant knowledge. The leader provided supervision and support. The aim of this process was to make the staff aligned in a person-centred view of the situation and take part in the decision on how to proceed to prevent agitation or other NPS in the patient [39, 40]. To learn the VPM, the leading registered ward nurse, an auxiliary nurse from each ward and a registered nurse appointed as the VPM coach in each nursing home attended a 3-day basic course before implementing the VPM in each ward. The course, conducted by the researchers, focused on PCC and the VPM's structure for analysis of challenging situations. The directors of the nursing homes were also invited. The VPM coach conducted a 3-hour introduction to PCC and the VPM for the rest of the staff in their nursing home. All staff also received the VPM manual with stories from everyday care situations with emphasis on the perspective of the person with dementia for each indicator in the VIPS framework. Each story included suggested interventions with explanations of why they were appropriate in the actual situation.

The main difference between the two PCC methods was the use of external involvement to implement PCC. DCM used observation of care and feedback to staff by external experts. In the VPM, the staff was given central roles and functions in a decision-making process with sharing of knowledge among peers and no external experts were involved.

Control Group

All three groups received five DVDs with lectures (30 min each) about dementia. Thus, the staff of the control group received only this intervention.

Assessments and Outcomes

The primary end point was the change in the sum score on the Brief Agitation Rating Scale (BARS) [43]. The BARS is a subscale of the Cohen-Mansfield Agitation Inventory (CMAI) [44]. The Norwegian version [45, 46] consists of 9 items: hitting, pushing, grabbing, wandering, restlessness, repetitive sentences, repetitive mannerisms, complaining and making strange noises. The frequencies of these symptoms are rated from 1 (never) to 7 (several times per hour), resulting in a minimum score of 9 and a maximum score of 63. A higher score indicates more agitation.

Secondary end points were changes in scores on scales measuring NPS, depression and QoL. The 10-item version of the Neuropsychiatric Inventory Questionnaire (NPI-Q) [47] was used to assess NPS: delusions, hallucinations, agitation, depression, anxiety, apathy, irritability, euphoria, disinhibition and aberrant motor behaviour. This questionnaire builds on the NPI [6]. The NPI-Q was performed as an interview with the nurse who was closest to the patient. The symptoms were registered as present or not, and, if present, the severity of the symptom ranged from 1 to 3, giving an item score ranging from 0 to 3 and a sum score of the scale ranging from 0 to 30. Both change in the NPI-Q sum score and change in the subscales agitation (agitation + irritability + disinhibition) and psychosis (delusions + hallucinations), based on a factor analysis of a large sample of Norwegian nursing home patients [7], were analysed. Depression was assessed with the Cornell Scale for Depression in Dementia (CSDD) [48], which has a score range of 0–38. A higher score indicates more depressive symptoms. QoL was assessed with the Quality of Life in Late-Stage Dementia (QUALID) scale [49], which records the frequency of 11 observable behaviours in the patients during the previous week (range 11–55). A higher score indicates a poorer QoL. The degree of dementia was assessed by the Clinical Dementia Rating (CDR) scale [50], a 6-item questionnaire. Using an algorithm, the severity of dementia is staged as no, possible, mild, moderate or severe dementia. Adding the scores of each item generates the 'sum of boxes' (0–18), which is highly correlated to the CDR score [51]. The Physical Self-Maintenance Scale (PSMS) proposed by Lawton and Brody [52] was used to assess performance of the activities of daily living. The scale consists of 6 items scored 1–5, ranging from total independence (1) to total dependence (5). A higher score indicates greater impairment (6–30). General physical health was assessed using a modified version of the General Medical Health Rating scale categorizing the patients' physical health as good, fairly good, poor or very poor [53].

Patient characteristics such as age and gender were obtained from the patient records. Information on ward characteristics was obtained by interviewing the registered nurse in charge, using a questionnaire asking for the type of ward unit, number of patients per ward and patient-staff ratio on day shifts.

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Statistical Analysis

Power Calculation

Optimal Design plus Empirical Evidence v 3.01 HML Software, University of Michigan, was used in the power calculation. The calculation gave an average of 10 persons in each cluster (ward) and 150 persons in each intervention group and the control group. Adjusting for a drop-out rate of 20%, we needed 188 persons in each group.

Analyses

The analyses were made by an external statistician with no knowledge about the interventions. All statistical analyses were performed following an analysis plan before the randomization code was known. The graphical inspection of data did not reveal the presence of outliers. The normality of data was assessed by inspecting the histograms, and some degree of skewness was observed in most variables. However, t tests are known to be robust against the violation of normality assumption [54]. Descriptive analyses were used to present patient and ward characteristics, and differences between the intervention and control groups at baseline were assessed by independent t test for continuous and χ^2 test for categorical variables. The difference between baseline and follow-up within each group was assessed by paired-sample t test. The normality of continuous variables was assessed by inspecting the histograms. Data were graphically screened for outliers.

The change in the primary and secondary end points described above was defined as the difference between the follow-up and baseline scores. Most of the scores were skewed at follow-up; however, all differences were close to be symmetrically distributed, a desirable property when using parametric methods. Continuous end points in the intervention and control groups were compared by independent-samples t test. The intra-class correlation coefficient (ICC) defined as the ratio of the intra-individual variation to the total variation (sum of intra- and inter-individual variations) [55] was calculated to assess the degree of clustering within a nursing home ward. As there was a cluster effect in the data, the association between the change in the end points and the type of intervention as main predictor was assessed by regression models for hierarchical data. Such models take possible correlations between members of the same cluster (nursing home ward) into account and might prevent false significant findings. For each continuous outcome, the linear mixed model (SAS MIXED procedure) with random effects for intercepts was estimated. The associations were further controlled for age, gender, the CDR sum of boxes, general physical health, numbers of patients in a ward, type of ward and staff-patient ratio at baseline. Model fit was assessed by examining marginal and conditional residuals. Small deviations from the necessary requirements for a well-fitting model were compensated by a large sample size. The statistical analyses were conducted using SAS version 9.2 and SPSS version 18.0. Findings with $p < 0.05$ were considered significant.

Results

Study Population

As shown in table 1, we found significant differences in the mean scores between DCM and the control group and between the VPM and the control group at baseline with regard to age, gender, NPI-Q sum score, NPI-Q agitation subscore, NPI-Q psychosis subscore, CSDD score, ward type and number of patients per staff on a day shift. In addition, we found significant differences between the VPM and the control group regarding severity of dementia, general physical health, physical function and the QUALID score as well as between DCM and the control group regarding the number of patients per ward. There were no significant differences between the groups in the mean scores on the BARS at baseline.

We included a total of 446 patients in the efficacy analysis as 178 (29%) were lost to follow-up assessments, most of them because of death (fig. 2). There were no significant differences between the groups in neither the number nor the causes of dropouts. The baseline characteristics in the group of patients who dropped out were analysed and compared to those of patients who completed the follow-up. There were no significant differences between these two groups regarding their scores on the BARS and the NPI. Patients who dropped out

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Table 1. Patient and ward characteristics at baseline

Characteristics	Total (n = 624)	DCM intervention (n = 229)	VPM intervention (n = 189)	Control group (n = 206)	p value	
					DCM vs. control	VPM vs. control
Patient characteristics						
Gender						
Women	448 (71.8%)	151 (65.9%)	133 (70.4%)	164 (79.6%)	<0.01[a]	0.03[a]
Men	176 (28.2%)	78 (34.1%)	56 (29.6%)	42 (20.4%)		
Mean age ± SD, years	85.7±8.3	85.1±8.7	85.1±8.5	87.0±8.3	0.02[b]	0.02[b]
General physical health						
Good	123 (19.7%)	42 (18.3%)	50 (26.5%)	31 (15.0%)	0.46[a]	0.01[a]
Fairly good	311 (49.8%)	120 (52.4%)	86 (45.5%)	105 (51.0%)		
Poor	162 (26.0%)	58 (25.3%)	48 (25.4%)	56 (27.2%)		
Very poor	28 (4.5%)	9 (3.9%)	5 (2.6%)	14 (6.8%)		
CDR[1]	12.8±4.1	12.4±4.0	13.5±4.4	12.4±3.9	0.69[b]	<0.01[b]
PSMS[2]	18.2±5.0	18.2±4.9	18.9±5.3	17.5±5.0	0.20[b]	0.01[b]
BARS[2]	19.1±9.3	18.9±8.9	19.9±10.3	18.5±8.6	0.69[b]	0.13[b]
NPI-Q[2]	5.5±4.8	5.4±4.7	6.9±5.3	4.4±4.0	0.01[b]	<0.01[b]
NPI-Q agitation[2]	2.4±2.5	2.3±2.4	3.0±2.8	1.8±2.1	0.02[b]	<0.01[b]
NPI-Q psychosis[2]	0.8±1.3	0.7±1.3	1.1±1.5	0.6±1.2	0.02[b]	<0.01[b]
QUALID[2]	21.3±7.1	21.5±7.0	22.0±7.3	20.8±7.0	0.20[b]	0.04[b]
CSDD[2]	7.3±5.1	7.6±5.3	8.1±5.1	6.3±4.9	<0.01[b]	<0.01[b]
Ward characteristics						
Ward type						
Ordinary unit	371 (59.5%)	139 (60.7%)	104 (55.0%)	128 (62.1%)	<0.01[a]	<0.01[a]
Special care unit	183 (29.3%)	46 (20.1%)	59 (31.2%)	78 (37.9%)		
Strengthened special care unit	57 (9.1%)	31 (13.5%)	26 (13.8%)	0 (0.0%)		
Other	13 (2.1%)	13 (5.7%)	0 (0.0%)	0 (0.0%)		
Mean number of patients per ward ± SD	24.1±6.4	28.0±3.3	21.4±5.8	22.2±7.4	<0.01[b]	0.21[b]
Mean number of patients per staff on day shift ± SD	3.6±0.7	3.6±0.7	3.5±0.7	3.7±0.5	0.02[b]	<0.02[b]

[a] p value for χ^2 test; [b] p value for independent t test.
[1] Values are given as mean sum of boxes ± SD. [2] Values are given as mean sum ± SD.

were significantly older, had more severe dementia and worse general physical health compared with those who completed the follow-up assessments.

Interventions

The DCM and VPM interventions were conducted according to the plan. The DVDs were reported to be used by 62% of the wards in the DCM group and by 69% in the VPM group. Only 31% of the wards in the control group stated that they used the DVDs for staff training.

Efficacy Analysis

The unadjusted changes in the mean scores of the BARS, the NPI-Q, NPI-Q agitation and psychosis subscores, the CSDD and the QUALID scale in each group are shown in table 2.

The changes in the continuous outcomes controlled for age, gender and other explanatory variables are shown in table 3. Since changes in scale scores were calculated as the difference between the follow-up scores and the baseline scores, a negative value represents a decline in the score from baseline to follow-up assessments. Thus, a negative coefficient in

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Table 2. Baseline and follow-up data of patients who completed the study (n = 446)

	DCM intervention (n = 158)	VPM intervention (n = 138)	Control group (n = 150)	p value	
				DCM vs. control[b]	VPM vs. control[b]
BARS					
Baseline	18.8±9.2	19.7±9.8	17.6±8.4		
Follow-up	17.2±9.0	18.5±8.6	17.8±8.0		
Diff: Follow-up vs. baseline (p value[a])	–1.5 (0.02)	–1.2 (0.12)	0.2 (0.75)	0.06	0.17
NPI-Q agitation					
Baseline	2.2±2.4	3.0±2.8	1.6±2.1		
Follow-up	1.9±2.5	2.6±2.5	2.1±2.2		
Diff: follow-up vs. baseline (p value[a])	–0.3 (0.11)	–0.5 (0.05)	0.5 (0.02)	<0.01	<0.01
NPI-Q psychosis					
Baseline	0.7±1.2	1.1±1.5	0.6±1.2		
Follow-up	0.8±1.6	1.0±1.6	0.9±1.5		
Diff: follow-up vs. baseline (p value[a])	0.1 (0.40)	0.01 (0.97)	0.4 (<0.01)	0.16	0.08
NPI-Q					
Baseline	5.2±4.7	6.9±5.1	4.1±3.9		
Follow-up	5.3±5.5	6.2±5.6	5.5±4.5		
Diff: follow-up vs. baseline (p value[a])	0.2 (0.67)	–0.7 (0.18)	1.4 (<0.01)	0.04	<0.01
QUALID					
Baseline	20.4±6.8	21.5±7.0	20.0±6.6		
Follow-up	21.4±7.2	23.1±7.5	22.8±7.4		
Diff: follow-up vs. baseline (p value[a])	1.0 (0.09)	1.6 (0.02)	2.9 (<0.01)	0.03	0.18
CSDD					
Baseline	7.0±5.2	7.9±5.2	6.1±4.9		
Follow-up	8.5±5.6	7.0±5.0	7.4±5.7		
Diff: follow-up vs. baseline (p value[a])	1.7 (<0.01)	–0.9 (0.12)	1.2 (0.02)	0.46	<0.01

Values are given as mean sum ± SD.

[a] p value within groups based on paired-sample t test; [b] p value between groups based on independent-samples t test.

Table 3. Multivariate regression analysis (SAS MIXED procedure) for continuous variables (n = 446)

Variable	n	ICC, %	Total variance explained, %	DCM intervention vs. control		VPM intervention vs. control	
				Crude coefficient (95% CI); p value	Adjusted coefficient[1] (95% CI); p value	Crude coefficient (95% CI); p value	Adjusted coefficient[1] (95% CI); p value
BARS sum	443	11.4	8.6	–1.9 (–4.8; 1.00); 0.19	–2.0 (–5.1; 1.1); 0.19	–1.5 (–4.4; 1.5); 0.31	–1.1 (–3.8; 1.6); 0.42
NPI-Q agitation	436	10.6	7.7	– 0.7 (–1.5; 0.1); 0.07	–0.9 (–1.7; –0.04); 0.04	–0.9 (–1.7; –0.1); 0.04	–0.9 (–1.6; –0.1); 0.02
NPI-Q psychosis	433	11.8	8.3	– 0.3 (–0.9; 0.4); 0.37	–0.9 (–1.4; –0.3); <0.01	–0.4 (–1.0; 0.2); 0.19	–0.6 (–1.1; –0.04); 0.04
NPI-Q	440	16.1	11.0	–1.1 (–3.1; 0.9); 0.25	–2.7 (–4.6; –0.7); 0.01	–2.1 (–4.1; –0.1); 0.04	–2.4 (–4.1; –0.6); 0.01
QUALID	443	6.3	5.1	–2.0 (–4.2; 0.3); 0.08	–3.0 (–5.5; –0.6); 0.02	–1.5 (–3.7; 0.8); 0.21	–1.3 (–3.4; 0.9); 0.26
CSDD	395	15.8	8.9	0.4 (–1.7; 2.6); 0.69	–0.4 (–2.8; 2.0); 0.75	–2.3 (–4.5; –0.1); 0.04	–2.6 (–4.8; –0.4);0.02

[1] Adjusted for age, gender, CDR sum of boxes, general physical health, number of patients per ward, ward type and number of patients per staff on a day shift. CI: maximum of 30 patients per ward in all models.

the hierarchical linear regression analysis (table 3) means that the intervention group had a larger reduction in the score than the control group.

Regarding agitation, there were no significant differences in the change in the BARS sum score with the corresponding 95% confidence interval (CI) in either of the intervention groups as compared to the control group. There were, however, significant differences in

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agitation for both intervention groups as compared to the control group measured by the NPI-Q agitation subscale: DCM versus control –0.9 (–1.7; –0.04) and VPM versus control –0.9 (–1.6; –0.1). We also found significant differences in the change in the total amount of NPS for both groups measured by the NPI-Q sum score: DCM versus control –2.7 (–4.6; –0.7) and VPM versus control –2.4 (–4.1; –0.6). Significant differences in the change in scores were found for psychotic symptoms for both intervention groups measured by the NPI-Q psychosis subscale: DCM versus control –0.9 (–1.4; –0.3) and VPM versus control –0.6 (–1.1; –0.04). Furthermore, there was a significant difference in QoL for DCM measured by the QUALID scale [DCM vs. control –3.0 (–5.5; –0.6)] and in depression for the VPM measured by the CSDD [VPM vs. control –2.6 (–4.8; –0.4)].

Discussion

Main Findings

We found no significant differences between the intervention groups and the control group regarding the change in the primary efficacy measure (the BARS sum score). However, the NPI-Q sum score, the NPI agitation subscore and the NPI psychosis subscore for the patients of both intervention groups were reduced compared with the patients of the control group. The CSDD sum score for the VPM intervention was also significantly reduced compared with the control group, and there was a significant difference in the QUALID scores between the DCM group and the control group showing a positive effect of the DCM intervention on the patients' QoL. To our knowledge, only two other RCTs of a similar size have been published that could show the effect of implementing PCC models for persons with dementia in nursing homes [41, 42].

The BARS, which was used as a primary outcome measure in our study, includes a selection of items from the CMAI [44]. There are divergent findings in the two previous studies regarding agitation measured by the CMAI. Fossey et al. [41], using staff training of PCC, failed to obtain any difference in effect on levels of agitation between the intervention group and the control group using this scale. Chenoweth et al. [42], using a PCC staff training program or the DCM method as two alternative interventions, found significantly lower agitation measured by the CMAI in the patients of both intervention groups than in the patients of a common control group. The study population in the study of Chenoweth et al. [42] was selected on a criterion of persistent need-driven behaviour, and the participating nursing homes were screened before the start of the study using the Therapeutic Environment Screening Survey for Nursing Homes (TESS-NH) [56] to be able to select nursing homes characterized as having a task-focused, not person-centred care system. In our study, there was no screening of the nursing homes' care system or the patients' behaviour after they met the inclusion criterion of dementia in all stages. In our opinion, the aim of PCC is both to prevent situations that can lead to agitation and to treat these symptoms. Based on this consideration, we chose to also include patients with no observed agitation or other NPS at baseline. Thus, our population was more heterogeneous and had a more uncertain improvement potential regarding agitation and other NPS. Chenoweth et al. [42] did not find statistically significant group differences as measured with the NPI sum score. The suggested reason was that 'the NPS measured by the NPI are less likely to be affected by psychosocial approaches than is need-driven dementia-compromised agitation' [42]. Our findings contest this assumption as both intervention groups in our study differed from the control group on the NPI-Q sum score and the NPI-Q subscales agitation and psychosis. The effects were controlled for patient characteristics as well as ward characteristics.

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In the present study, a significant difference between the VPM intervention group and the control group regarding the change in depressive symptoms measured by the CSDD could be observed. To our knowledge, this is the first positive finding of an influence of PCC on depression in a controlled study [41, 42]. A central feature in the VPM is the presentation of challenging situations from the patients' perspective. This focus might have made the nurses more observant of mood symptoms such as anxiety, sadness or irritability and further influenced their actions to prevent or treat depressive symptoms. In light of recent studies indicating that antidepressants may have minimal benefit regarding depression in dementia [57], this finding is encouraging.

In contrast to the results from the study of Chenoweth et al. [42], in our study, significant differences between the DCM group and the control group in QoL, measured by the QUALID scale, were found. During the 10 months from baseline to follow-up, the QoL measured in the control group deteriorated significantly more than in the DCM intervention group. QoL is considered an important dimension to determine the effect of quality of care improvements [29], and more controlled studies are needed to confirm the findings from this study.

The two methods used in the present study were shown to empower nursing homes' staff to act in the best interests of the patients and to facilitate the physical and social environments according to the patients' basic needs [30, 34]. The results of our study were obtained by interventions targeting the regular care staff for them to be able to implement PCC in their daily care. As Cohen-Mansfield et al. [21] suggest in their recent study on the efficacy of non-pharmacological individualized interventions in decreasing agitation in dementia, PCC can address some of the hurdles involved in the prevailing structure in many nursing homes that make the use of psychosocial interventions difficult.

In the two comparable previous studies by Fossey et al. [41] and Chenoweth et al. [42], the intervention groups received substantially more supervision (weekly supervision or regular telephone contact) than any of the intervention groups in our study. However, with the available resources, we consider the methods used in the present study to implement PCC as more realistic in daily practice. In contrast to the interventions called 'PCC' in the previous studies [41, 42], the VPM, like DCM, is standardized and replicable. The duration of the study (10 months) strengthens the probability that, in most nursing homes, the effects can be obtained by implementing the models. In our view, both methods are feasible methods to implement PCC in nursing homes.

Strength and Weakness of the Study

The strength of our study was the cluster-randomized placebo-controlled design. The study had an educator-alone type of comparator (DVDs with lectures on dementia delivered to all three groups) and not 'usual care' alone, which has been pointed out as a weakness in previous studies [58]. This reduces the Hawthorne effect, a phenomenon describing changes in the behaviour of persons taking part in a study as 'related only to the special social situation and social treatment they received' [59]. On the other hand, the brief education program given to all groups may in part explain the modest impact of the interventions on agitation, and it should be added that the use of the DVDs in the control nursing homes was rather modest.

The assessment tools employed are internationally recommended and have been used in previous studies in the field. As this was a complex intervention involving the whole staff, blinding of participants was not an option. However, the assessors did not know to which group the assessed participants belonged.

Some baseline differences in the variables showing effects in the analyses are potential confounders that needed consideration. To adjust for this, baseline scores were subtracted from the follow-up scores in the efficacy analyses. In the regression analysis (table 3), the

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results were adjusted for age, severity of dementia and general physical health – variables that were significantly different between the groups at baseline. The ICC, showing evidence for differences in the conditions of the wards, was higher than stipulated. Additionally, the attrition rate, which was higher than expected (29%), weakens the power of the study.

Conclusions

Even though the study failed to find a significant effect of PCC on the primary outcome, it adds to the growing but not conclusive evidence that PCC may reduce and prevent agitation and other NPS in nursing home patients with dementia. The positive finding that DCM demonstrated an effect on the patients' QoL has not been shown in previous studies and needs to be further investigated. Similarly, the impact of the VPM on depression is important, particularly in the context of recent studies indicating that antidepressants may offer limited benefit in treating depression in patients with Alzheimer's disease. In our view, both methods are feasible tools to implement PCC in most nursing homes.

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Disclosure Statement

G.S. has given lectures on meetings sponsored by the pharmaceutical industry. The authors have no other conflicts of interest to declare.

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