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Effects of the Namaste Care Family programme on quality of life of nursing home residents with advanced dementia and on family caregiving experiences: study protocol of a cluster-randomised controlled trial

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ABSTRACT

Introduction Quality of life of people with advanced dementia living in nursing homes is often suboptimal. Family caregivers can feel frustrated with limited contact with their relatives, which results in visits that are perceived as stressful and not very meaningful. Few psychosocial interventions are specifically developed for people with advanced dementia, and actively involve family caregivers or volunteers. Also, interventions usually stop when it becomes difficult for people to participate. The Namaste Care Family programme aims to increase the quality of life of people with advanced dementia, and improve family caregiving experiences through connecting to people and making them comfortable.

Methods and analysis Our study will evaluate the effects of the Namaste Care Family programme on quality of life of people with advanced dementia living in nursing homes and family caregiving experiences using a cluster-randomised controlled trial. Longitudinal analyses will be performed taking into account clustering at the nursing home level. Both a cost-effectiveness and a cost-utility analysis from a societal perspective will be performed. We will modify the Namaste Care Family programme to increase family and volunteer involvement in ongoing and end-of-life care. Data collection involves assessments by family caregivers, nursing staff and elderly care physicians using questionnaires, and observations by the researchers at baseline and multiple times over 12 months. The last questionnaire will be sent up to month 24 after the death of the person with dementia. During semistructured interviews, the feasibility, accessibility and sustainability of the Namaste Care Family programme will be assessed.

Ethics and dissemination The study protocol is approved by the Medical Ethics Review Committee of the VU University Medical Center in Amsterdam (protocol no. 2016.399) and registered with the Nederlands Trial Register (NTR5692). The findings will be disseminated via publications in peer-reviewed journals, conference presentations and presentations for healthcare professionals where appropriate.

Strengths and limitations of this study

- ► The Namaste Family Care programme offers a novel approach to involve family caregivers and volunteers in care of nursing home residents with advanced dementia and at the end of life that is subjected to a thorough (cost-)effectiveness and process evaluation during its implementation.
- ► A large sample of at least 192 people with advanced dementia living in at least 16 nursing homes—equally randomised to the intervention group and the usual care group—will be recruited to allow for detection of a possible meaningful difference in change of quality of life and family experiences.
- ► A design with multiple follow-up assessments per resident is used to increase power, to enable longitudinal analyses and to allow for analyses of mediators and moderators.
- ► Nursing staff, elderly care physicians and family caregivers cannot be blinded to the treatment condition due to the nature of the intervention programme, but parts of the observations are blinded.

Trial registration number NTR5692.

INTRODUCTION

Background and rationale

Currently, 47.5 million people are living with dementia worldwide and the prevalence is projected to double every 20 years.[1] Dementia is a progressive, life-limiting disease without an imminent cure or effective drug treatment. Although a number of psychosocial interventions are available for people with dementia, few specifically target people with advanced dementia.[2] Moreover, the end-of-life phase is usually not included. Experts in

dementia and palliative care endorse the benefits of palliative care in advanced dementia.[3] It is therefore of vital importance to identify psychosocial interventions which at least sustain, but preferably improve, the quality of life of people with (advanced) dementia and to develop and provide high-quality end-of-life care.

When people with dementia are admitted to a long-term care facility, most of the care is taken over by professionals. However, previous research has shown that the burden for family caregivers (eg, family, relatives, friends) often remains high,[4] and family caregivers find it difficult to connect meaningfully with people with dementia in the advanced stages. Family caregivers can become frustrated if contact with the person with dementia is limited by aphasia and cognitive impairment, resulting in experiencing their visits as stressful and not very meaningful.[5] Also, most people with dementia manifest neuropsychiatric symptoms such as anxiety, restlessness, agitation and aggression over the course of the disease. The prevalence of neuropsychiatric symptoms increases as the disease progresses,[6 7] and challenging behaviours commonly occur in nursing home residents with advanced dementia and even—although possibly to a lesser extent—at the end of life.[8 9] Neuropsychiatric symptoms are considered the most distressing, difficult and burdensome aspects of caring for people with dementia.[10–12]

With the progression of dementia, difficulties in communication and in performing activities of daily living occur. Therefore, people with advanced dementia become less engaged with their environment and with those around them, and as a result, quality of life may decrease.[13–16] People with advanced dementia may be isolated in their rooms or hallways as they cannot participate anymore in the regular activities that are offered in the nursing home.[17 18] The presence of neuropsychiatric symptoms makes it more difficult to engage people with advanced dementia in meaningful activities and may further increase the risk of isolation. These behaviours may arise from unmet needs.[19–21] Psychosocial needs of people with dementia, such as the need to engage in daily individualised activities and care, should therefore not be ignored in long-term care.[22] Also, evidence supports that psychosocial interventions can improve a number of outcomes in people with dementia, including neuropsychiatric symptoms.[23–25]

Psychosocial interventions for people with dementia living in nursing homes often do not involve family caregivers or lack evaluation of the effects on family caregiving experiences. Ideally, a programme that involves family caregivers should be easy to implement, while it does not require extensive resources and can be tailored to the individual, as personalised interventions have been proven to be the most effective interventions for nursing home residents with more severe dementia, and particularly for people with challenging behaviours.[26]

An intervention which may meet these requirements is a programme called Namaste Care,[27] a daily multidimensional care programme with psychosocial, sensory and spiritual components that incorporates person-centred and palliative care approaches. By respecting each person with dementia as a unique individual, the programme pays attention to the individual's dignity until death.[28] By engaging people with dementia in meaningful activities on a daily basis, the programme attends to their psychological, bodily and spiritual needs.[27 29 30] Namaste Care is designed to reach people with dementia who are socially withdrawn and who no longer benefit from the regular recreational social and group activities, have severe cognitive impairments, require care with all activities of daily living, have limited verbal abilities and spend a lot of time sleeping.[27 29] Namaste Care is also deemed beneficial for people with behavioural symptoms of dementia.[29] It aims to increase the quality of life of people with advanced dementia who live in long-term care facilities. There are indications that the programme successfully improved the lives of people with advanced dementia and their families at no extra healthcare costs.[30–32] For example, in the UK, implementation of the programme was achieved with only modest expenditures and no change in staffing levels.[30] Further, it reduced behavioural symptoms of dementia and the use of psychotropic medication in people with dementia.[29 33 34]

Additional research about the effects of Namaste Care is needed. Although less behavioural symptoms of dementia have been reported and qualitative work indicated improved quality of life of people with advanced dementia,[29 30 34 35] these outcomes have not yet been tested in a large sample with a randomised control group. Furthermore, when effective, we need to identify the effective elements of the programme and whether the programme is more effective in specific subgroups. Also, it is important to assess the impact on family caregiver-related outcomes and evaluate cost-effectiveness from a societal perspective. This study will contribute in fulfilling some of these gaps in the current knowledge about the effects of Namaste Care and helps to further improve and disseminate the programme. This is important as Namaste Care has the potential to positively change how end-of-life care is provided to people with advanced dementia.

Objectives

The primary objective of this cluster-randomised controlled trial will be to examine the effectiveness of the Namaste Care Family programme, an adapted version of the original Namaste Care, on (1) the quality of life of people with advanced dementia living in nursing homes and on (2) caregiving experiences of their family caregiver. The adaptations of Namaste Care include an emphasis on family caregivers and volunteers providing the care in collaboration with nursing staff, and more explicit and elaborate incorporation of end-of-life care. The secondary objects include (3) assessing the cost-effectiveness of the programme compared with usual care; (4) examining the effects of Namaste Care Family programme on discomfort, comfort in dying, behavioural symptoms of dementia, psychotropic medication use and

intercurrent health problems in nursing home residents with dementia; (5) assessing the effects of Namaste Care Family programme on family caregiver burden, guilt and conflict in caregiving, and (anticipatory) grief in family caregivers; (6) examining the effective elements of the programme; (7) defining subgroup(s) in which the intervention or elements are more effective; and (8) conducting a process evaluation to assess feasibility, accessibility and sustainability of the Namaste Care Family programme.

METHODS AND ANALYSIS

We will conduct a cluster-randomised controlled trial. A cluster-randomised design was chosen because the intervention is structured around groups of residents rather than individuals and it requires a different way of working by the nursing staff, and to minimise contamination. The unit of randomisation will be the nursing home or nursing home organisation. Data will be collected between May 2016 and December 2018 in the Netherlands. The study was registerted with the Nederlands Trial Register (NTR5692).

Recruitment of nursing homes

The study will take place in Dutch nursing homes. In the Netherlands, a nursing home is a facility with a domestic-styled environment that provides 24-hour functional support and (medical) care for persons who require assistance with activities of daily living and who often have complex health needs. Although postacute rehabilitation may be provided in the nursing home, care is often long term and often includes palliative care.[36] Dutch nursing homes employ their own multidisciplinary teams, consisting of an elderly care physician (a specialised physician who combines competencies of a general practitioner with those of a geriatrician) and various other professionals (eg, nursing staff (eg, registered nurses and certified nursing assistants), psychologist, physiotherapist, dietician).[37] There are long-stay departments specifically for residents with dementia, so-called psychogeriatric wards. At least 16 nursing homes with a psychogeriatric ward will be recruited for the current study. Nursing homes should be willing to offer the Namaste Care Family programme for at least 2 years.

We will send the manager of the nursing home an email with information about the study and the Namaste Care Family programme, and an invitation to participate in the study. After 2 weeks, a follow-up telephone call will be made to enquire whether there is an interest to participate. Reasons for not wanting to participate will be recorded. If there is interest, a meeting with the manager and/or other staff members will be scheduled to further discuss the aims of the study and the Namaste Care Family programme. When the nursing home decides to participate in the study, the manager will be asked to fill in a short questionnaire to assess the characteristics of the nursing home. Randomisation to the Namaste Care Family programme or the usual care group will be performed (see Randomisation procedure section for more details) and an individualised schedule is discussed to plan the procedural steps of the study (who will do what, when and where). Finally, the research team will organise a meeting in the nursing home to inform all staff about the study and the Namaste Care Family programme. The manager will also receive templates of leaflets and other materials to inform staff about the study.

Randomisation procedure

Included nursing homes will be matched on various criteria that might impact the effects of the programme on outcome measures based on the questionnaire filled in by the manager. We will match nursing homes on volume of psychosocial programmes and programmes involving family caregivers in the care for the person with dementia. We will further take into account whether or not the ward is part of a small-scale living arrangement, and situated in a rural versus urban area as family support is likely to be a greater part of social life in more rural areas of the Netherlands. Furthermore, we will match on the number of residents on a ward and the manager's perceived influence of the nursing home's religious affiliation, as this was found to be independently associated with people with dementia dying more peacefully.[38]

Possible matches will be judged for appropriateness by three researchers (HJAS, KJJ, JTvdS). Successfully matched pairs of nursing homes will be randomised with one nursing home being allocated to the intervention condition and the other to the usual care condition. Randomisation is performed by a statistician who is not involved in recruitment or data collection (PMvdV). Due to the nature of the intervention, the group allocation cannot be masked.

Recruitment of participants

After randomising the nursing home to a treatment condition, the recruitment of participants within the nursing home will start. Within each nursing home, nursing staff will be asked to indicate which residents with advanced dementia and/or their family caregivers may benefit from the Namaste Care Family programme. They are residents with advanced dementia unable to participate in the regular activity programme and residents with moderate dementia with behavioural symptoms of dementia, having family caregivers understanding the Dutch language and who are willing and able to fill in questionnaires.

The family caregivers of eligible residents will be sent an invitation letter from the nursing home, a consent form and a participant information letter. The family caregiver will be asked to sign and return an informed consent form to the research team via a pre-stamped envelope. After 2 weeks, a reminder will be sent. For study participation, written informed consent given by the family caregiver will be required. All nursing homes will be offered a 'family meeting' at their location, organised by the research team, to inform family caregivers and volunteers about the study

and the programme. Participants will have the right to withdraw from participation at any time if they wish so. No financial incentive to participate will be provided.

Intervention

The nursing homes in the intervention group will implement the Namaste Care Family programme, a modified version of the original Namaste Care.[27] The adaptations include an emphasis on family caregivers and volunteers providing the care in cooperation with the nursing staff, and more explicit and elaborate incorporation of end-of-life care. We have developed two manuals about the Namaste Care Family programme, one for management and one for nursing staff, family caregivers and volunteers, based on Simard's book[27] and the British toolkit for implementing Namaste Care.[39] We will make a summary available of the parts that are specific to the adapted Family form of the intervention after completing the study.

Namaste Care Family, similar to the original Namaste Care, is a 7-day-a-week programme, intended to be offered in 2-hour sessions, twice a day. The sessions take place in a calm home-like room, the 'Namaste room', with soft music or nature sounds and pleasant scents, and without external distractions or interruptions. Each session starts with personally greeting each resident when entering the Namaste room. Each resident is comfortably seated and screened for signs of pain. Nutritious, appetising foods and drinks are offered frequently to increase hydration and raise caloric intake. During the sessions, meaningful activities and multisensory stimulation are integrated with person-centred care and reminiscence. Extra personal care (massages; washing the face, hands and feet; grooming; nail care) is offered during the sessions to facilitate an experience of gentle, caring touch. The session ends with thanking each resident for their presence in the Namaste session and a personalised goodbye.[27 30]

Nursing staff and volunteers in the intervention group will receive a 2-hour training from the research team in which they will learn about the principles of the Namaste Care Family programme, the purpose and the benefits of the programme for people with dementia, their families and staff, and will be offered tools to develop a plan to implement, evaluate and sustain the programme in their nursing home. The training will take place after the baseline assessment. One month after the start of the Namaste Care Family programme, the manager or 'Namaste coordinator' (ie, person in charge of all practical aspects of the programme in the nursing home) in each nursing home will be contacted by the research team to evaluate the first month of the programme and, if they prefer, to discuss questions and problems. The primary researcher (HJAS) will participate in or observe at least two Namaste sessions in each nursing home, one in the first 3 months and one after 6 months from the start of the programme, and will evaluate these sessions afterwards with the nursing staff and will provide feedback to improve the implementation of the programme when needed.

Patient and public involvement

Patients (ie, people with advanced dementia) were not involved in the research design. The research protocol was reviewed by family caregivers and people with mild dementia. Family caregivers were consulted to select the best questionnaires for measuring positive caregiving experiences for family caregivers of people with advanced dementia. Family caregivers will be asked to review the participant information letter that will be used for the recruitment. Also, family caregivers and volunteers will be invited to participate in the Namaste sessions. Family caregivers will receive a newsletter every 3 to 4 months with an update of the progress of the study and, in time, the results of the study.

Data collection

Figure 1 outlines the trial recruitment and data collection process. Table 1 shows an overview of the instruments that will be used for assessment. Questionnaires will be made available online or on paper, depending on the preferences of the respondent and the nursing home. If preferred, the research team will assist in filling out the questionnaires.

The manager of the nursing home will assign each resident to a member of the nursing staff who knows the resident well and can fill in the questionnaires about the resident throughout the study. The elderly care physicians will also complete questionnaires about the residents and they may be assisted by a nurse practitioner. All respondents will be asked to fill in the questionnaires within 2 weeks. If needed, a reminder to fill in the questionnaire will be sent after 2 weeks.

Observations will be performed by trained research assistants who are unfamiliar with the residents and the assessments will last approximately 10 min per resident. The primary researcher (HJAS) and the project coordinator will train all research assistants with an instructional video and set of examples. The research assistants will be instructed to plan observations, if possible, at the same time for each assessment during daytime, but not during meals or shortly after burdensome procedures (eg, physiotherapy, toileting or transfers). Each resident will be observed by the same observer at each assessment whenever feasible. For the intervention group, standard observations after the baseline assessment will be conducted during a Namaste session. This does not allow for blinding the research assistants for the treatment group. To minimise bias, the research assistants will not be told any details about the intervention or study goals. We will also plan an additional observational assessment at least 3 months after the start of the Namaste Care Family programme after a Namaste session, performed by a blinded research assistant who is new to the team. To monitor inter-rater reliability, 10% to 20% of the observations will be scored by two research assistants independently.

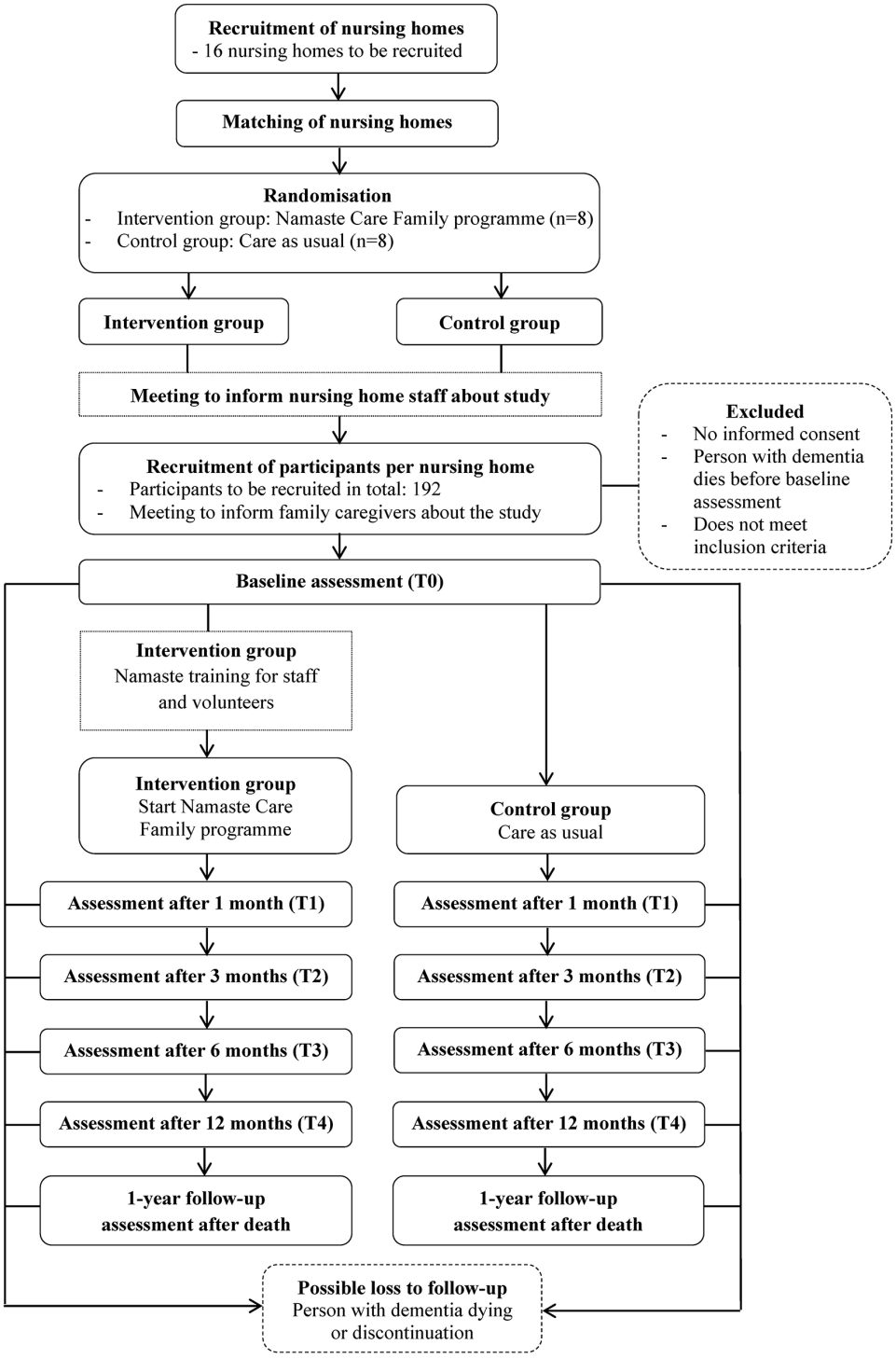

Figure 1 Study flow diagram.

Primary outcome measures

Quality of life

The Quality of Life in Late-Stage Dementia (QUALID)[40 41] will be used to assess quality of life of the person with dementia. The QUALID is a brief, proxy informant-based questionnaire consisting of 11 domain-specific items. Each item has five response options indicating the frequency of concrete and observable mood and performance items, such as smiles, enjoys eating or facial expression of discomfort, over the last week. Summed scores can range from 11 to 55 with lower scores indicating better quality of life. The QUALID, including the Dutch translation, has good psychometric properties.[40 42 43]

Positive caregiving experiences

To better understand the positive aspects of caregiving, we will use two instruments to measure family caregivers' caregiving experiences, one focusing specifically on positive experiences and the other focusing on gains in dementia caregiving.

Table 1 Schematic of concepts, measures and measurements to assess the (cost-)effectiveness of the Namaste Care Family programme in nursing homes

Assessment (*perspective/rater*)	Measurement instrument	Time of measurement (proximate to start programme for intervention group)					
		Baseline	Month 1	Month 3	Month 6	Month 12	After death
Primary outcomes							
Person with dementia							
Quality of life of the person with dementia—change (*nursing staff*)	► Quality of Life in Late-Stage Dementia (QUALID)[40 41]	x	x	x	x	x	x
Family caregiver							
Positive caregiving experiences—change (*family caregiver*)	► Positive Experiences Scale (PES)[44] ► Gain in Alzheimer Care Instrument (GAIN)[45]	x	x	x	x	x	x
Secondary outcomes							
Person with dementia							
Discomfort—change (*research assistant*)	► Discomfort Scale-Dementia of Alzheimer Type (DS-DAT)[46]	x	x	x	x	x	
Comfort (in dying) (*nursing staff*)	► End-of-Life in Dementia (EOLD)—Comfort Assessment in Dying (CAD)[48]						x
(*family caregiver*)	► EOLD—Symptom Management (SM)[48]	x	x				x
Behavioural symptoms of dementia—change (*nursing staff*)	► Neuropsychiatric Inventory Questionnaire (NPI-Q)[52]	x	x	x	x	x	
Medication use (*physician*)	► Psychotropic medication: antipsychotics, antidepressants, anti-anxiety, analgesics	x			x	x	x
(Intercurrent) health problems (*physician*)	► Sentinel events: pneumonia, (other) febrile episode, new eating or drinking problem, other new major medical illness or event[55] ► Health problems (eg, delirium, infections, dehydration, weight loss, comorbid diseases): items from the InterRAI—Minimum DataSet (MDS)[57 58] and Dutch End of Life with Dementia Study (DEOLD) study[55]	x			x	x	x
Family caregiver							
Caregiver burden (*family caregiver*)	► Zarit's caregiver burden scale (ZBI),[59 60] 7-item version ► Self-Rated Burden scale (SRB)[62]	x		x		x	
Guilt and conflict in caregiving (*family caregiver*)	► Family Perceptions of Caregiving Role (FPCR),[63] subscales 'guilt' and 'conflict with staff'	x		x		x	
(Anticipatory) grief (*family caregiver*)	► Prolonged Grief Disorder Scale (PGD),[65 66] pre-death and post-death versions	x					x
Potential mediators of an effect on the primary outcomes							

Continued

Table 1 Continued

Assessment (*perspective/rater*)	Measurement instrument	Time of measurement (proximate to start programme for intervention group)					
		Baseline	Month 1	Month 3	Month 6	Month 12	After death
Person-centredness of caring (*family caregiver*)	► Person-centred Climate Questionnaire (PCQ-F),[73] adapted family version	x	x	x	x	x	x
Family caregiver visit experiences (*family caregiver*)	► Family Visit Scale for Dementia (FAVS-D)[75]	x	x	x	x	x	x
Family caregiver visits (*family caregiver*, *nursing staff*)	► No and estimated duration of visits ► No of Namaste sessions family caregiver attended	x	x	x	x	x	
Engagement (*research assistant*)	► Observed frequency of positive vocalisations	x	x	x	x	x	
Fidelity of implementation (*manager*) (*nursing staff*)	► Implementation checklist Namaste Care Family programme					x	
	► Elements implemented at the individual level ► Time in Namaste session per participant	On a continuous basis through registration forms in the nursing home					
Potential moderators of an effect of the primary outcomes							
Behavioural symptoms of dementia	► NPI-Q: apathy and agitation (*secondary outcome measure*)	x	x	x	x	x	
Caregiver burden	► ZBI (*secondary outcome measure*) ► SRB (*secondary outcome measure*)	x		x		x	
Pain (*research assistant*)	► Pain Assessment in Advanced Dementia (PAINAD)[82]	x	x	x	x	x	
Gender of person with dementia and caregiver (*family caregiver*)	► Informal Caregivers Survey–Minimum Data Set (TOPICS-MDS)[61]	x					
Personality (*family caregiver*)	► Person with dementia's previously expressed preference for touch and being socially engaged	x					
Satisfaction with care (*family caregiver*)	► EOLD—Satisfaction With Care (SWC)[48]	x		x		x	x
Other data							
Demographic information caregiver and person with dementia (*family caregiver*)	► TOPICS-MDS	x					
Mortality risk (*physician*)	► Mitchell's Advanced Dementia Prognostic Tool[86]	x					
Dementia (*physician*)	► Type	x					
Dementia severity (*physician*)	► Bedford Alzheimer Nursing Severity-Scale (BANS-S)[84]	x		x		x	x
Societal cost variables							

Continued

Table 1 Continued

Assessment (*perspective/rater*)	Measurement instrument	Time of measurement (proximate to start programme for intervention group)					
		Baseline	Month 1	Month 3	Month 6	Month 12	After death
Namaste Family Care costs (*manager*, *nursing staff*, *family caregiver*)	► Any supplies purchased, donations, extra or less time of staff and caregiver for the intervention unrelated to the project's research nature	x	x	x	x	x	x
Medication costs (*physician*)	► Medication use, active substance, duration, dose	x			x	x	x
Informal caregiving costs (*family caregiver*)	► Informal caregiving tasks (by family caregiver and others)	x		x		x	
Use of healthcare services (*physician*)	► Hospitalisation, ambulant specialist care	x	x	x	x	x	
Quality of life of the person with dementia—change (*nursing staff*)	► QUALID (*primary outcome measure*) ► EuroQol-5D (EQ-5D)[89]	x	x	x	x	x	x
Positive caregiving experiences—change (*family caregiver*)	► PES (*primary outcome measure*)	x	x	x	x	x	x
Process evaluation							
(*managers*, *nursing staff*, *family caregivers and volunteers*) *(manager)*	► Semistructured qualitative interviews to assess feasibility, accessibility and sustainability					x	
	► Short evaluation about ongoing implementation of Namaste Care Family		x	x	x		

The Positive Experiences Scale (PES)[44] for family caregivers of people with dementia will be used to measure positive experiences by family caregivers. The PES consists of hierarchically ordered items which vary from intrinsic satisfaction ('Caring for my loved one makes me feel good') and relational enhancement ('During the period that I have been providing care, my loved one and I have grown closer (quality of our relationship is better now)') to improvement of competence ('As a result of providing care, I have learnt new things myself') and social enhancement ('As a result of providing care, I have met new people'). Items are scored on a three-point Likert scale (agree, don't agree/don't disagree, disagree). In addition to the six items that have been identified as suitable for caregivers of people with dementia in previous research, we use a seventh PES item 'Helping has made my relationship with my family and friends closer', as we expect that the Namaste Care Family programme might have a positive influence in this regard. The PES has good psychometric properties.[44]

The Gain in Alzheimer Care Instrument[45] will be used for measuring family caregivers' gains in dementia caregiving. The scale has 10 items that make up three components: (1) personal growth, (2) gains in relationships and (3) higher-level gains. Items are scored on a Likert scale from 0 (disagree a lot) to 4 (agree a lot). Summed scores can range from 0 to 40, with higher scores indicating higher gains. The instrument has good psychometric properties.[45]

Secondary outcome measures

Discomfort

The well-tested Discomfort Scale–Dementia of Alzheimer Type (DS-DAT)[46] will be used to observe discomfort in the person with dementia. The scale uses duration and frequency of seven negative (eg, negative vocalisation) and two positive (eg, relaxed body language) behaviours. Each item is scored 0–3 and summed scores range from 0 to 27 with higher scores referring to more discomfort. The Dutch DS-DAT has good psychometric properties.[47]

Comfort (in dying)

The End-of-Life in Dementia—Comfort Assessment in Dying[48] comprises 14 items and consistently refers to the quality of dying.[49] This simple tool, developed for evaluation retrospectively after death, had the best psychometric properties and feasibility to measure quality of dying in long-term care in a combined US–Dutch study.[50] A higher total score indicates a better comfort level.

The nine items of the End of Life in Dementia—Symptom Management (EOLD-SM)[48] quantify the frequency a resident experiences the following nine symptoms and signs: pain, shortness of breath, depression, fear, anxiety, agitation, calm, skin breakdown and resistance to care. Frequency is quantified on a six-point Likert scale ranging from 0 to 5 as follows: daily, several days a week, once a week, 2 or 3 days a month, once a month, never. The original timeline was 'previous 90 days', but we will adapt this timeframe to 'last month'. The scale ranges from 0 to 45 with higher scores indicating better symptom control. The EOLD-SM has moderate to good psychometric properties.[48 51]

Behavioural symptoms of dementia

The Neuropsychiatric Inventory Questionnaire (NPI-Q)[52] will be used to measure 12 behavioural symptoms of dementia over the past month, namely delusions, hallucinations, dysphoria, anxiety, agitation/aggression, euphoria, disinhibition, irritability/lability, apathy, aberrant motor activity, night-time behaviour disturbances and eating abnormalities. Nursing staff are asked to indicate 'yes' or 'no' to each screening question, and to subsequently rate the presence of symptoms in terms of severity on a three-point scale (mild, moderate, severe). The total NPI-Q severity score ranges from 0 to 36 and represents the sum of individual symptom scores. Distress associated with the symptom will be measured for symptoms that are present with the NPI-Distress Scale (NPI-D) with scores ranging from 0 'not emotionally stressful' to 5 'extremely stressful'. The total NPI-D sum score ranges from 0 to 60. We will also include subscales of the behavioural scales as outcome measures. The NPI-Q provides a reliable, valid assessment of neuropsychiatric symptoms.[52 53] However, there is less evidence for validity of subscales compared with total scores.[54]

Medication use and health problems

We will measure intercurrent health problems (sentinel events) in the past 6 months: pneumonia, (other) febrile episode, new eating or drinking problem, and other new major medical illness or event (eg, hip fracture, stroke, gastrointestinal bleed, cancer).[55] The health condition of the resident, including incontinence, comorbid diseases, nutritional and hydration status, and delirium,[55] will also be measured. A clinical judgement of illness severity will be assessed on a scale ranging from 1 ('not ill') to 9 ('moribund').[56] To assess infections, dehydration and weight loss, we will use items from the InterRAI-Minimum DataSet.[57 58] The elderly care physician will be requested to provide a list of all medication used in the week before each assessment.

Caregiver burden

We will use the shortened seven-item version of Zarit's well-tested caregiver burden interview (ZBI).[59 60] Items are scored on a five-point scale, with a cut-off score of ≥13 considered as a clinically significant burden.[59] We will also use a Visual Analogue Scale (VAS)[61] based on the Self-Rated Burden scale (SRB)[62] for assessing the burden of family caregiving. The family caregiver will be asked to indicate on the VAS how burdensome they feel in caring for the person with dementia. The VAS is anchored at 0 'not at all straining' (not hard at all) and 10 'much too straining' (much too hard).

Guilt and conflict in caregiving

The Family Perceptions of Caregiving Role will be used to measure multiple dimensions of family member distress associated with an institutionalised relative with dementia.[63] Response options form a seven-point agreement scale.[63 64] We will only use the subscales 'conflict with

staff over caregiving' (10 items) and 'guilt from perceived failure in caregiving' (5 items), as increased caregiver involvement has been associated with increased feelings of guilt and conflict with staff in an intervention helping family caregivers create meaningful roles for themselves in long-term care settings.[64]

(Anticipatory) grief

Grief will be assessed with the pre-loss and post-loss versions of the Prigerson's Prolonged Grief Disorder (PGD) Scale.[65 66] The post-loss version of the PGD Scale comprises 11 items from the Inventory of Complicated Grief-Revised that were slightly modified to resemble the proposed criteria for PGD.[66] Family caregivers rate the occurrence of symptoms in the past month on a five-point scale ranging from 'never' to 'always'. We modified the Dutch PGD-11[65] to refer to the pre-loss period while retaining the meaning of the items. Two items from the English pre-loss version that were not congruent with the Dutch post-loss items were translated into Dutch and added to the Dutch pre-loss questionnaire. This resulted in a 13-item pre-death grief scale asking family caregivers how often they experience distressing grief symptoms related to yearning, bitterness, interpersonal disengagement and a sense of meaninglessness. The items are summed to result in an overall severity score.

Measures to evaluate mediators

An effect of the intervention on quality of life and family caregiving experiences may be achieved through person-centredness of care, frequency and quality of the family visits, engagement of the person with dementia, received dose of the intervention and level of implementation of the Namaste Care Family programme (see table 1).

Challenging behaviour may be theorised as due to unmet psychosocial needs which may be met by person-centred caregiving. A person-centred caring environment (eg, 'A place that feels homely')[67 68] was found to improve residents' quality of life and increased family involvement while it decreased perceived care burden.[69] The involvement of family caregivers in dementia care was found to reduce residents' challenging behaviour, improve the residents' quality of life as well as the quality of life of their family caregivers.[70–72] Family caregiver perceptions of a better quality of their visits to the person with dementia may mediate the effects on the primary outcomes. Also, engagement with stimuli and structured activities has been found to improve affect and decrease behavioural symptoms of dementia.[17] Finally, the dose of the intervention and the fidelity of implementation may also mediate effects in the intervention group.

Person-centredness

Person-centredness of caring will be assessed using the Person-centred Climate Questionnaire—family version (PCQ-F).[73] The PCQ-F is similar in content to the previously published patient version,[74] but we changed the perspective to a proxy perspective. The 17 items of aspects about care climate are rated on a six-point Likert scale ranging from 0 ('No, I disagree completely') to 5 ('Yes, I agree completely'). The total score ranges from 0 (lowest person-centred care) to 85 (highest score for person-centred care).

Family visits

The frequency and average time of a regular visit by the family caregiver will be measured. In the intervention group, we will also assess if and how often the family caregiver participates in Namaste sessions.

The quality of family visits will be measured with the Family Visit Scale for Dementia (FAVS-D).[75] The FAVS-D comprises 14 items rated on a five-point scale ('strongly disagree', 'disagree', 'neutral', 'agree' and 'strongly agree'). A total score can be calculated with a higher score indicating a higher quality of the visits.

Engagement

We will measure positive vocalisations, an important dimension of engagement.[76] Positive vocalisation has been operationalised after pilot testing observation of positive vocalisation as any verbal, vocal utterance or noise with a positive quality, such as sounds expressing happiness, joy and/or satisfaction, a high-pitched noise with a definite pleasant sound, repeating the same words with a joyful tone, expressing joy, pleasure, happiness or satisfaction (eg, 'I am happy', 'This cake is my favourite', laughing, singing). We will score the presence of positive vocalisations for 7 min. A sum score can be calculated and examples of positive vocalisations will be noted when expressed.

Fidelity of programme implementation

Nursing staff will be asked to register the activities offered during each Namaste session for individual participants and the time each participant spends in the Namaste session, so an overview of elements implemented at an individual level and a Namaste dose per participant can be made. The researchers will visit at least two Namaste sessions in each nursing home, once at the start of the programme and after at least 6 months, during which the quality of the implementation will be monitored. We will also develop a 10-item checklist to score the level of implementation of Namaste components on a three-point scale. An implementation sum score with a possible range from 0 to 20 can be composed by summing the items, with higher scores indicating a better implementation of the Namaste Care Family programme.

Measures to evaluate moderators

Moderators modify the effect of the intervention, indicating subgroups in which it is more or less effective. The baseline levels of agitation and apathy of the person with dementia and initial caregiver burden will be examined as potential moderators for quality of life and positive caregiving experiences, respectively. For example, it may be more difficult to experience satisfaction from caregiving when caregivers perceived their role as a burdensome experience.[77] Agitation and apathy in people with dementia are associated with caregiver frustration and a reduced quality

of life. People with dementia with agitation or apathy may benefit more from the programme, as psychosocial interventions based on person-centred care and with elements of sensory stimulation, offering activities, and teaching the family to connect to the person with dementia are effective in reducing agitation and apathy in people with advanced dementia.[78 79]

Other possible moderators in our study are sociodemographics (eg, gender and personality), pain and satisfaction with care. Gender and personal characteristics impact the caregiving experience.[77 80] Planned reporting of treatment outcomes by specific subgroups, such as gender,[80] is being encouraged to tailor interventions to specific subgroup needs. The Namaste Care Family programme seeks to enrich quality of life through shared activity and increased social interaction. More personal care and touch are used to connect to the person with dementia. The effects of the Namaste Care Family programme on quality of life may therefore differ depending on the previously expressed preferences for touch and whether the person with dementia was socially engaged.[81] One of the UK studies found Namaste Care effective in improving behaviour only in homes with adequate pain control in place, which suggests pain is a moderator of programme effectiveness.[34] Family caregivers who are satisfied with the care may experience more positive experiences. Satisfaction with care may also be a subjective indicator of quality of care and thus impact the quality of life the residents.

The presence and severity of agitation and apathy in the people with dementia will be assessed using the NPI-Q.[52] Caregiver burden is measured using the ZBI[59 60] and SRB.[61] These instruments have been described in more detail under Secondary outcome measures section.

Sociodemographics: gender and personality

Sociodemographic information of the family caregiver and person with dementia will be assessed using items of the Older Persons and Informal Caregivers Survey–Minimum Data Set (TOPICS-MDS).[61] Additionally, we will include the two items for personality indicating the family caregiver's perception of the person with dementia previous preference for touch (ie, whether or not the person liked to be touched) and being socially engaged (ie, whether or not the person liked group activities).

Pain

The five-item Pain Assessment in Advanced Dementia[82] will be used to assess pain in the person with dementia. The items are scored during a direct 2 min observation on a three-point scale. A sum score can be calculated with a higher score indicating higher probability of pain (possible range 0–10). A validated cut-off of 2 indicates probable presence of pain.[83]

Satisfaction with care

The family caregiver's satisfaction with care will be measured with the 10-item End-of-Life in Dementia–Satisfaction With Care (EOLD-SWC).[48] Items are scored on a four-point scale ('strongly disagree' to 'strongly agree'). The EOLD-SWC has the best psychometric properties and feasibility for families to evaluate the quality of end-of-life care[49 50] and can also be used when a person is not at the end-of-life stage. Higher total scores indicate higher levels of satisfaction with care.

Other clinical characteristics

The severity of dementia will be measured with the seven-item Bedford Alzheimer Nursing Severity-Scale (BANS-S).[84] Item scores range from 1 to 4, and total scores range from 7 to 28, with a cut-off of 17 or higher indicating severe dementia.[85] Type of dementia and Mitchell's Advanced Dementia Prognostic Tool[86] will be used to calculated a 12-month mortality risk score.

Cost-effectiveness

Costs will be measured from a societal perspective according to a Dutch standardised data collection tool for older people, the TOPICS-MDS.[61] We will use a bottom-up micro-costing approach to estimate intervention costs which will include costs of supplies for Namaste Care Family programme, any change (increase or decrease) in staff time, and family and volunteer time investments. Healthcare costs will include medication, hospitalisation, and emergency room and specialist visits. For the valuation of healthcare use, standard prices published in the Dutch costing guidelines will be used.[87] Medication will be valued using prices of the Dutch National Healthcare Institute.[88] Informal care spent by family excluding time spent on the Namaste Care Family programme will be assessed and valued using the Dutch standard price. Societal costs will be related to the main effect measures of quality of life as measured by the QUALID,[40 41] quality-adjusted life years (QALY) and positive caregiving experiences measured by the PES[44] in the economic evaluation.

QALYs will be calculated using the Dutch tariff for the EuroQol-5D (EQ-5D).[89] The EQ-5D is a five-item objective measure of health status in which items (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) are described by choosing one out of three possible degrees of impairment/severity (ie, no, some, extreme). The instrument also includes a VAS anchored at 0 'worse imaginable health state' and 100 'best imaginable health state'. The EQ-5D has been shown to be responsive, internally consistent and reliable when used for people with dementia or cognitive impairment.[90 91]

Data management

The questionnaires and observations will be coded with unique identification numbers to guarantee privacy. A unique identifier will be assigned to all participants (eg, people with dementia, family caregivers, nursing staff, elderly care physicians and research assistants) and nursing homes, with linkage keys to be stored separately from the data. Respondents can choose to fill in questionnaires digitally or on paper. The data from the digital questionnaires will be converted into a SPSS data file. The data from any

paper questionnaire will be entered directly into a SPSS database by research assistants. We will subject 10% of the latter data to a random audit by a second researcher to test the accuracy of data entry. We will store all study data on a password-protected drive that is only accessible to members of the research team.

Sample size

The standard power calculations to detect a relevant difference in the primary outcomes—quality of life of the persons with dementia and positive caregiving experiences—indicated sufficient power with eight nursing homes per group (16 in total) and 14 residents per home for QUALID and PES outcomes. We used the mean (M) and SD as calculated in previous work validating the Dutch version of the QUALID in nursing home residents with advanced dementia (M=7.5, SD=4.9).[41] For the PES, it was analysed and provided for the subgroup of family caregivers with dementia (M=2.9, SD=1.9).[92] Clinically relevant differences in means were defined as 1.5 on the PES and 4 on the QUALID.

Simulations were performed considering QUALID as the primary outcome and accounting for a maximum of four assessments per person. Power was based on the test for an interaction between time of measurement and intervention, taking into account the three-level structure with measurements within persons within nursing homes. The SD (total of between subjects and between nursing homes) for QUALID and the within-subject correlation were first estimated using the six consecutive QUALID assessments available from the Dutch End of Life with Dementia Study (DEOLD) dataset,[55] selecting patients with severe dementia (BANS-S score of 17 or higher). Different scenarios were considered where the SD and within-subject correlation were varied around these estimates. Additionally, various scenarios for attrition over time were considered.

Assuming, conservatively, that the full effect of the intervention occurs after 3 months, SDs between 6 and 8, up to four consecutive follow-up assessments with several drop-out scenarios to accommodate mortality differential for initial QUALID score and based on an estimated survival of half of these patients in a year follow-up as in DEOLD, we found that the power to detect a difference of 4 QUALID points change between the intervention and usual care groups was between 83% and 100% for all 32 scenarios for 8 homes per group (16 in total) and an average of 12 residents per home. For 7 homes per group and 10 residents per home, the power varied between 70% and 90.5%, with 28 of 32 of scenarios presenting with over 80% of power.

However, for mediator analyses with an intracluster correlation coefficient of 0.09 for clustering within facilities as observed in DEOLD, we prefer the larger number of 8 nursing homes per group, and 12 residents per facility, totalling 192 residents. These numbers will suffice to test associations with mediators which are at least medium in strength.[93] Our aim of 192 residents will also suffice for subsequent testing of moderators. Finally, as a rule of thumb, with 192 residents, we can test between 12 and 19 covariates per analysis. In all, with these conservative estimates, power is large to very large to detect the expected medium to large effect sizes.

Analysis plan

Analyses of effects on primary outcomes

All analyses will be undertaken by intention to treat at both the nursing home and patient level. Differences between the intervention and control group in characteristics of residents and sites at baseline will be tested with appropriate parametric or non-parametric tests. We will correct for baseline differences between groups in our analyses. We will test if the longitudinal course of quality of life and positive caregiving experiences differs between the intervention and usual care group using mixed linear models that include random effects for nursing home and patients nested within nursing homes. The models will include fixed effects for time and intervention group and their two-way interaction. Confounders will be added as main effects. In particular, we will adjust for baseline mortality risk using Mitchell's 12-month mortality risk score[86] and its two-way interaction with time so that any missing data due to death during follow-up can be considered missing at random. Moderation will be assessed by means of a third-order interaction between time, intervention group and the moderator with models containing all lower-order terms. Mediation will be assessed using Structural Equation Modelling.

Analyses of effects up to in the last phase of life

Because the Namaste Care Family programme includes end-of-life care, we expect that effects persist until death (and afterwards for family caregivers, affecting family grief). For this, we will include specific outcomes, such as comfort in the dying phase. We will follow an estimated proportion of 70% of residents until death, based on survival curves of patients with severe dementia enrolled in the DEOLD study who have resided in the nursing home for some more than a year on average.[55] We will obtain primary and other outcomes after death (referring to the period shortly before death). End-of-life outcomes will be compared between persons who die within 12 months in the intervention and usual care group using a mixed model with random effect for nursing home and a fixed effect for intervention group.

Cost-effectiveness

We will perform an economic evaluation from a societal perspective. Both cost-effectiveness and cost-utility analyses will be performed with a time horizon of 12 months. Discounting of costs and effects is not necessary since follow-up is limited to 12 months.[87] Incremental costs per 1-unit decrement on the QUALID scale, per QALY and per 1-unit increment on the PES scale will be estimated. Sensitivity analyses will assess the robustness of the results using different assumptions regarding costs and effects including different ways to account for family caregiving time. We will assess the level of implementation of the Namaste Care Family programme in relation to outcomes as well as costs.

Multiple imputations techniques will be used to handle missing cost and effect data. Incremental cost-effectiveness ratios (ICERs) will be calculated by dividing the difference in mean total costs between the treatment groups by the difference in mean effects. Bootstrapping with 5000 replications will be used to estimate 95% CIs around cost differences and the uncertainty surrounding the ICERs. Cost-effectiveness planes will graphically present uncertainty surrounding the ICERs. We will estimate cost-effectiveness acceptability curves to show the probability that the intervention is cost-effective in comparison with usual care for a range of different ceiling ratios.[94] If appropriate, analyses will be adjusted for confounders or moderators that modify the effect.

Process evaluation and analyses

A mixed-method approach will be used for the process evaluation. The process evaluation includes qualitative semistructured interviews after 12 months with nursing staff, managers, family caregivers and volunteers focusing on feasibility, accessibility and sustainability. We will analyse interviews by open and selective coding of content, with two researchers, independently. Triangulation of interviews that present different perspectives is used. We will also map barriers and facilitators of implementation.

ETHICS AND DISSEMINATION

Most participants will have advanced dementia, although some can have moderate dementia with challenging behaviour and may therefore respond well to the Namaste Family Care programme (accordingly, behavioural symptoms of dementia are hypothesised as a moderator in table 1). Written consent will therefore be obtained from the primary family caregiver. If judged by the researcher and/or nursing home as being able to understand information about the study and make an informed decision about participation, the person with dementia will be asked to provide written consent as well.

Dissemination

We will publish our findings in peer-reviewed scientific journals and present results at relevant conferences within the field. A symposium for healthcare professionals working in long-term care, policy-makers and health insurers will be organised. The aim will be to inform and motivate attendees to improve the lives of people with advanced dementia and their families in the Netherlands. We will develop an informative short film about the Namaste Care Family programme which includes interviews with nursing staff, family caregivers and volunteers about their experiences with the programme. Based on the results of the process evaluation, an improved version of the Namaste manuals will be developed. We will also offer the homes randomised to the usual care group the opportunity to implement the Namaste Care Family programme at the end of the study. This may serve as a pilot test for rolling out the Namaste Care Family programme more widely in the Netherlands if appropriate. The manuals will be made available to interested healthcare professionals, organisations and individual families and volunteers. The train-the-trainers concept will retain experienced families and volunteers for further implementation.

In the future, more people with dementia will be expected to stay and die at home. Therefore, connecting to people with dementia and managing behavioural symptoms of dementia at home are also very important goals for family caregivers and people with dementia. The application of the Namaste Care Family programme in a home setting might be a useful intervention to provide in this setting. Based on our experiences with Namaste Care Family in nursing homes, we will develop a Namaste Care Family manual and training for use at home and will conduct a pilot study examining the feasibility of the programme for people with dementia living at home and their family caregiver(s). People with advanced dementia may be able to stay at home longer with less challenging behaviour, lower caregiver burden and more positive family caregiving experiences.

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Competing interests JS developed the Namaste Care programme and is the author of The end-of-life Namaste Care programme for people with dementia. LV is married to the developer of Namaste Care.

Patient consent Not required.

Ethics approval The study protocol has been reviewed by the Medical Ethics Review Committee of VU University Medical Center, and they approved of the protocol and declared that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study (protocol no. 2016.399).

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