Effects on quality of life and family caregiving experiences by the Namaste Care Family program for advanced dementia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22922

Source
Nationaal Trial Register

Brief title
Namaste Care Family

Health condition

Dementia-related impairments

Sponsors and support

Primary sponsor: VU University Medical Center, EMGO+ Institute for Health and Care Research, Department of Public and Occupational Health, Amsterdam, the Netherlands
Source(s) of monetary or material Support: ZonMw The Netherlands Organisation for Health Research and Development grant number 733050302 and Fonds NutsOhra grant number 1405-181

Intervention

Outcome measures

Primary outcome

Patients’ quality of life and families’ positive caregiving experiences. These are measured with the Dutch translation of the Quality of Life in Late-Stage Dementia (QUALID) scale, the Dutch Positive Experiences Scale (PES) and the Dutch translation of the Gain in Alzheimer care Instrument (GAIN)

Secondary outcome

Secondary patient outcomes are (dis)comfort, behavior, health problems, and psychotropic medications. Secondary family outcomes are caregiver burden, (pre)grief, and perceptions of caregiving role. Finally, costs assessed from a societal perspective

Study description

Background summary

Quality of life of people with advanced dementia in the Netherlands can be improved. People may be isolated as they cannot participate anymore in the activities that are offered. Some present challenging behaviors, and families may be frustrated with limited contact with their loved ones.

A US program called Namaste Care aims to increase quality of life and comfort specifically for these people. It incorporates person-centered and palliative care approaches and includes end-of-life care. Loving touch, presence of others, and engaging people in meaningful activities, such as gentle personal grooming, are central. Evidence accumulates that the program successfully changed the lives of people and their families in US, UK, and Australian nursing homes. In particular, it improved behavior, reduced use of psychotropic medications and did not increase health care costs.

With the committed support of the developers, experts, and an End-user Panel with families and volunteers, we propose to modify the program to sustainably fit it into the Dutch health care landscape. The adapted Namaste Care Family program will emphasize family and volunteer involvement, and end-of-life care.

In 16 nursing homes, a cluster-randomized controlled trial will assess if the Dutch Namaste

Care Family program improves outcomes in a cost-effective manner. We will match pairs of homes on ongoing psychosocial and family programs before we randomize to the intervention or control conditions. The primary outcomes are patients' quality of life and families' positive caregiving experiences. These are measured with the valid Dutch version of the Quality of Life in Late-Stage Dementia (QUALID) scale, and the validated Dutch Positive Experiences Scale (PES) and another instrument because pilot data collected in 2015 indicate psychometric properties are not fully satisfactory. Assessments are at baseline and multiple times over 12 months and also include an after-death assessment up to after 24 months, for efficient longitudinal analyses of data of 192 patients enrolled at baseline. Secondary patient outcomes, all measured with valid Dutch-version instruments, are (dis)comfort, behavior, health problems, and psychotropic medications. Secondary family outcomes are caregiver burden, (pre)grief, and perceptions of caregiving role. Costs from a societal perspective are measured with the Dutch standardized TOPICS-MDS. Semi-structured qualitative interviews with families, volunteers, nurses and managers will assess feasibility, accessibility, and sustainability.

We will adapt and (pilot)test the program also in the community, anticipating more people with advanced dementia staying there and the importance of helping family caregivers to achieve the best possible quality of life and positive caregiving experiences.

To assess effects and the most effective components (elements) of the program, we will perform longitudinal mediation Structural Equation Modeling (SEM) analyses. Based on literature and experiences with Namaste elsewhere, we refine the testing of effects in three ways. First, we test mediation through increased person-centeredness, patient engagement, and family visits. Second, we will test if the degree to which program elements are implemented at the individual level affect outcomes, also separately for touch and non-touch activities. Third, we will test if effects differ for subgroups (moderation) such as male patients, those with agitation or apathy, in pain (for moderating patient outcomes) and by family caregiving burden at baseline (for family outcomes).

An economic evaluation will relate the difference in societal costs to the difference in quality of life and positive caregiving experiences attributed to Namaste Care Family. Both a cost-effectiveness and a cost-utility analysis will be performed. Statistical uncertainty will be estimated using bootstrapping, and results presented using cost-effectiveness planes and cost-effectiveness acceptability curves.

Regarding sustainability, any resources such as supplies lists and an instructional video will be translated or developed, and improved for an accessible toolkit for further implementation. We will train "champion" families and volunteers to become trainers

themselves. Mediation, moderation, and cost effectiveness analyses allow for informed limiting of the future intervention to the most cost-effective elements for patient subgroups (e.g, those with apathy), and activities planning (e.g., if touch approaches were most effective).

Study objective

Implementation of the Namaste Care Family program will improve lives of Dutch nursing home residents with advanced dementia and their families

Study design

The primary outcomes are assessed at baseline, 1, 3, 6, and 12 months after the start of the intervention, and after death if the patient dies within the period of data collection

Intervention

The Namaste Care Family program

Contacts

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Eligibility criteria

Inclusion criteria

Nursing home residents with dementia who cannot initiative meaningful activities themselves. They cannot participate in the activities a nursing home usually offers. People will typically have advanced dementia. Others may have moderate dementia and challenging behaviour or they are particularly responsive to touch, and therefore they are expected to benefit from the program

Exclusion criteria

Family does not give permission for the resident to participate in the program and the research

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	192
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5570
NTR-old	NTR5692
Other	VU University Medical Center, EMGO: WC2014-048 : ZonMw: 733050302

Study results

Summary results
none yet