ISRCTN56768265 https://doi.org/10.1186/ISRCTN56768265

Does implementing need-based care in nursing homes impact formal caregivers' well-being?

Submission date
07/08/2023

Recruitment status
No longer recruiting

Registration date
10/08/2023

Overall study status
Completed

Last Edited
18/12/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Need-based care is a structured and standardized model that supports formal caregivers in nursing homes (NHs) in delivering person-centred care by responding with tailored non-pharmacological interventions on residents' unmet needs as well as having positive effects on behavioral and psychological symptoms on residents with dementia (BPSD). However, limited resources as well as the shortage of caregivers in NHs make the implementation of need-based care challenging, especially when it comes to finding ways to spend more time with residents. The aim of this study is to evaluate the impact of the implementation of need-based care in nursing homes on formal caregivers' well-being.

Who can participate?
Adult professional caregivers in the participating nursing homes

What does the study involve?
This study is part of a larger intervention design study with a need-based group (intervention), time group (placebo) and standard care group (control). This study will be set up in 24 Belgian nursing homes. The overall objective of the study was to decrease behavioral and psychological symptoms among residents with mild to moderate dementia in NHs.In the need-based care group and the time group, formal caregivers are asked to spend time twice a week with residents who have dementia and who show signs of agitation or aggression as determined on the Neuropsychiatric Inventory. To identify these residents two NH staff per resident are designated as observers throughout the entire study. For every resident with symptoms of agitation or aggression, "time moments" (duration and content decided by staff members) are prescribed over an eight-week period. The intervention consists of three cycles of eight weeks with one week in between wherein no time moments are provided during which a re-evaluation of residents' BPSD is undertaken (measurement and evaluation week).

What are the possible benefits and risks of participating?
Healthcare professionals may experience an increase or decrease in their sense of competence in dementia care, level of burnout and level of engagement

Where is the study run from?
University College Odisee (Belgium)

When is the study started and how long is it expected to run for?
September 2019 to December 2022

Who is funding the study?
Odisee University College (Belgium)

Who is the main contact?
Katrin Gillis, katrin.gillis@uantwerpen.be

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The impact on formal caregivers' well-being of the implementation of need-based care in nursing homes: a three-arm cluster randomized controlled trial

Study objectives
The study hypothesis is that the implementation of need-based care will have an inverse effect on formal caregivers' well-being.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/11/2019, Committee of Ethics Antwerp University Hospital (Wilrijkstraat 10, Edegem, 2650, Belgium; +3238213000; ethisch.comite@uza.be), ref: B300201942084

Study design
Three-arm cluster randomized clinical trial

Primary study design
Interventional

Secondary study design

Cluster randomised trial

Study setting(s)
Care home

Study type(s)
Quality of life

Participant information sheet
Not available in web format. Please use contact details to requenst a participant information sheet

Health condition(s) or problem(s) studied
Professional well-being

Interventions
The study is being performed in the wards where residents with dementia live. As well as direct formal caregivers (e.g., nurses, therapists, nurse assistants), indirect formal caregivers like logistic staff, kitchen staff, and cleaning staff are included in the study. Only students are excluded.

In the need-based care group and the time group, formal caregivers are asked to spend time twice a week with residents who have dementia and who show signs of agitation or aggression as determined on the Neuropsychiatric Inventory. To identify these residents, two NH staff per resident are designated as observers throughout the entire study. For every resident with symptoms of agitation or aggression, “time moments” (duration and content decided by staff members) are prescribed over an eight-week period. The intervention started in January 2022 and consists of three cycles of eight weeks with one week in between wherein no time moments are provided during which a re-evaluation of residents’ BPSD is undertaken (measurement and evaluation week).

The way formal caregivers spend time with residents differs between the two groups. In the need-based care group, the “time moments” are tailored to the resident’s identity and unmet needs, based on the framework of Nolan and refined in Gillis et al. The content of the moments is prescribed during an interdisciplinary meeting and can be one of the following non-pharmacological treatments: aromatherapy, massage, multisensory stimulation, reminiscence, attachment, music, moments of movement, or creative moments. In the time group, formal caregivers are individually free to fill in how they spend extra time with residents. The minimum amount of time is 10 minutes (recommended time between 15 minutes and 40 minutes). In the standard care group, formal caregivers are not asked to spend extra time with residents.

A total of 481 residents with mild to moderate dementia participate in this study: 142 in the need-based care group, 169 in the time group, and 170 in the standard care group. Forty-four percent of the participating residents have symptoms of agitation or aggression, without any significant difference in prevalence between the three groups.

Before investigating the impact of the implementation of need-based care, it is necessary to monitor the fidelity of the intervention. To know whether formal caregivers in the need-based care and time group really spend extra time twice a week with residents with BPSD, a pre-printed registration booklet (tick-box style to reduce time spent filling it in) is offered for every participating resident per cycle. Furthermore, staff are only asked to briefly describe how they

fill the time with a resident or, in case of a lack of time, to describe the reason (i.e., illness of a colleague).

An implementation strategy (looking at needs, resources, and fit) is set up based on the four phases of the Quality Implementation Framework. Ten focus groups are held with 60 formal caregivers from 10 different teams from eight NHs between October 2019 and January 2020. To reduce bias in the trial, none of these NHs are involved as participating NHs in the implementation study; however, four teams have had experience with the method of 'need-based care' since they participated in a pilot study back in 2016. Eighty-seven percent of the participants are female, 38% are nurse assistants, 22% are nurses, 19% are therapists, 15% are ward managers, 3% are logistic staff, and 3% are NH managers. All participants recognize that the current person-centred practice in NHs is not optimal. They express hope for alternative effective strategies and readiness for innovation when the following conditions can be fulfilled: guarantee of continuity of care, a sense of competence in 'need-based care,' and a sense of motivation and perspective on the sustainability of the implementation of 'need-based care.' Based on these findings, an implementation strategy is built with five components: 1) an educational strategy to enhance a sense of competence, 2) a leadership trajectory for ward managers to enhance facilitating leadership and ensuring continuity of care and motivation, 3) ongoing recognition of ward champion(s) to strengthen clinical leadership with a focus on sustainability and motivation, 4) supervision sessions on perceived problems and challenging situations to develop problem-solving competences and create an open culture of trust, and 5) support of an expert in need-based care.

Adaptation of the intervention is not permitted. However, adaptation of the implementation strategy is possible for the educational aspect and the supervision sessions: the e-learning is recommended but not obligated, and ward managers can either choose the full package of workshops for all formal caregivers or the more comprehensive package that includes the wider supportive workforce. In some NHs, the general practitioner attends the workshops. Supervisory sessions are recommended "every month" but can differ depending on capacity.

To assess the capacity and readiness, the intervention and the accompanying implementation strategy are presented to the ward managers of all participating facilities. Their affirmation implies that they have obtained explicit support from critical stakeholders and that a supportive organizational climate is fostered.

After agreeing to take part, the randomization of the NHs to the different groups (need-based care, time group, and standard care group) is performed by computer randomization on the permuted block design, using an Excel sheet system at the NH level. The rank of the random number defines the allocation of the NHs to the need-based care group block, the time group block, or the control group block. One of the research teams (experienced in need-based care) is allocated to the need-based care teams as an expert. The ward managers and the expert form the implementation team. The expert provides educational workshops, guides the analysis of residents' behavior, and holds supervision sessions. The expert's role is expected to change depending on the level of leadership from the ward manager and the ward champion(s). Ward managers attend a leadership course one day every month for three months and build a supportive feedback mechanism for the team of formal caregivers. All teams in the intervention group undergo the implementation strategy. All formal caregivers in the need-based care group start the e-learning (2h), and 18% of them also complete the digital course with a certificate. Afterwards, three educational sessions (total of 9h) are conducted on-site for all formal caregivers of the participating teams between November 1 and December 31, 2021. A written toolkit is developed to lead the teams through all the steps of need-based care. To optimize the analysis of residents' behavior, caregivers use the tools to collect information about the life,

identity, wishes, and preferences of residents with agitated or aggressive behavior between December 1, 2021, and January 10, 2022.

Intervention Type
Behavioural

Primary outcome measure
1. Attitudes to dementia among care staff measured using the Sense of Competence in Dementia Care Staff (SCIDS) scale in October 2021 (T0), January 2022 (T1), March 2022 (T2), May 2022 (T3) and July 2022 (T4)
2. Burnout measured using the Utrecht Burnout Scale (UBOS) in October 2021 (T0), January 2022 (T1), March 2022 (T2), May 2022 (T3) and July 2022 (T4)
3. Engagement measured using the Utrecht Work Engagement Scale (UWES) in October 2021 (T0), January 2022 (T1), March 2022 (T2), May 2022 (T3) and July 2022 (T4)

Secondary outcome measures
Perception of the level of person-centred care measured using the Person-centred care Assessment tool (P-CAT) in October 2021 (T0), January 2022 (T1), March 2022 (T2), May 2022 (T3) and July 2022 (T4)

Overall study start date
01/09/2019

Completion date
31/12/2022

Eligibility

Key inclusion criteria
All caregivers involved in the direct care of residents with dementia in nursing homes

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Upper age limit
67 Years

Sex
Both

Target number of participants
750

Total final enrolment

747

Key exclusion criteria
There are no secondary outcome measures

Date of first enrolment
01/10/2021

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
Belgium

Study participating centre
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Molenstraat 32
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9130

Study participating centre
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8551

Study participating centre
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Beernem
Belgium
8730

Study participating centre
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Study participating centre
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Belgium
9100

Study participating centre
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Waasmunster
Belgium
9250

Study participating centre
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Schakelstraat 43
Waregem
Belgium
8790

Study participating centre
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Study participating centre
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Sponsor type
University/education

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ROR

https://ror.org/02c89h825

Funder(s)

Funder type
University/education

Funder Name
University College Odisee

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact and peer-reviewed journal, including BMJ Geriatrics and other peer-reviewed journals with a similar scope

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during the study will be available upon request from katrin.gillis@uantwerpen.be.

All of the individual participant data collected during the trial, after identification, is available with no end date to availability. Consent from participants was required and obtained at every timepoint before caregivers started to fill in the questionnaires.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/11/2023	18/12/2023	Yes	No