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Effects of small scaled special care units for patients with dementia

Submission date	Recruitment status	[ ] Prospectively registered
05/06/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/06/2017	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/03/2019	Mental and Behavioural Disorders	

Plain English summary of protocol
Background and study aims
Dementia is a broad category of brain diseases that cause a long-term gradual decrease in the ability to think and remember that affects a person's daily functioning. Evidence shows that treatment in a small scaled home-like Special Care Unit (SCU) can have positive effects on the behavioral and psychological symptoms of patients with dementia. Aspects of cognition (thinking), rest/activity, mood and medication use are scarcely investigated. The aim of this study is to gain more insight into the effects of living in a small-scale home-like SCU compared to a regular traditional SCU for residents with dementia.

Who can participate?
Patients aged 65 – 100 with dementia living in two regular SCUs

What does the study involve?
Participants living in one of the SCUs move to a small scaled home-like SCU (intervention group) and the participants in the other SCU stay at their regular SCU (control group). The participants' cognitive functions, rest/activity, mood and medication use are assessed with tests, observations, questionnaires and information from medical files. All the data are collected 3 months before, 3 months after and 6 months after the relocation of the intervention group.

What are the possible benefits and risks of participating?
No benefits or risks are expected for the participants.

Where is the study run from?
Dignis|Lentis - Nursing home 'De Enk' (Netherlands)

When is the study starting and how long is it expected to run for?
June 2009 to December 2012

Who is funding the study?
Lentis (Netherlands)

Who is the main contact?
Mr Jeroen Kok

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
009-2302

Study information

Scientific Title
A longitudinal controlled trial comparing patients with dementia living in a regular special care unit with patients with dementia living in a small scaled home-like special care unit

Study objectives
The aim of the study is to investigate the possible positive effects on patients with dementia of living in a small scaled homelike special care unit (SCU) on cognition, rest/activity, mood, quality of life and medication use compared to patients with dementia living in a regular special care unit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Committee of the Department of Psychology of the University of Groningen, 03/06/2009, ref: PPO-008-093

Study design
Longitudinal quasi-experimental field study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dementia

Interventions
The patients were living in two different nursing homes before the study started. Patients of the intervention group were relocated from their regular SCU to a small-scale home-like SCU due to organizational reasons (the building no longer met the requirements of the current healthcare standards). The control group stayed in their regular SCU during the study. All measurements were conducted at baseline (3 months before intervention), follow up 1 (3 months after intervention) and follow up 2 (6 months after intervention).

Intervention Type
Other

Primary outcome(s)
All measurements conducted at baseline (3 months before intervention), follow up 1 (3 months after intervention) and follow up 2 (6 months after intervention).

1. Cognition:
1.1. Cognitive status, assessed using the Dutch version of the Standardized Mini-Mental State Examination
1.2. Verbal memory, assessed using the Eight Word Verbal Memory Test of the Amsterdam Dementia Screening Test (ADS)
1.3. Visual memory, recognition of pictures and recognition of faces, assessed using two subtests of the Rivermead Behavioural Memory Test (RBMT)
1.4. Language functioning, assessed using the shortened Boston Naming Test-15 (BNT)
1.5. Different aspects of praxis, assessed using the diagnostic test for apraxia of van Heugten
1.6. Executive control, measured using the Trail Making Test A and B, The Category Fluency Task from the Groningen Intelligence Test (GIT) and a Clock Drawing test
1.7. Figure recognition, assessed using a subtask of the GIT, Incomplete Drawings
1.8. Aspects of cognition, observed by nursing personnel with a behavioural observation scale for intramural psychogeriatry (GIP)
1.9. Cognitive decline, measured using the Information Questionnaire on Cognitive Decline in the Elderly

2. Rest/activity:
2.1. Objective rest-activity variables, measured with an Actiwatch (Cambridge Neurotechnology Ltd, Cambridge, UK)
2.2. Intersubjective activity level, assessed by using two scales of a behavioral observation scale for intramural psychogeriatry (GIP)

3. Quality of life:
3.1. Quality of life, assessed using the QUALIDEM
3.2. Relevant neuropsychiatric symptoms of quality of life, collected with subscales of the GIP

4. Mood, assessed with the Dutch version of the Geriatric Depression Scale-15 (GDS-15)

5. Medication use, assessed using tnformation from medical files

Key secondary outcome(s))
No secondary outcome measures

Completion date
12/12/2012

Eligibility

Key inclusion criteria
1. Age 65 - 100
2. Diagnosis of dementia reported in the medical file

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
No dementia reported in the medical file

Date of first enrolment
01/01/2009

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Dignis|Lentis - Nursing home 'De Enk'
Zuidlaren
Netherlands
9470AC

Sponsor information

Organisation
VU University Amsterdam

ROR
https://ror.org/008xxew50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lentis

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Jeroen Kok

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/02/2016		Yes	No
Results article	results	05/07/2017		Yes	No
Results article	results	27/02/2018		Yes	No
Results article	results	01/04/2020	07/03/2019	Yes	No