# Effects of small scaled special care units for patients with dementia

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

## 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)

# **Contact information**

# Type(s)

Scientific

#### Contact name

Mr Jeroen Kok

#### **ORCID ID**

https://orcid.org/0000-0003-3969-572X

#### Contact details

Dignis|Lentis PO Box 128 9470AC Zuidlaren Netherlands 9470AC

# 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 adde	d 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 07/03/201	9 Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	5 No	Yes