# The pros and cons of small-scale living for elderly people suffering from dementia in the Netherlands and Belgium

| Submission date   | Recruitment status No longer recruiting | <ul><li>Prospectively registered</li></ul> |  |  |
|-------------------|---|--|--|--|
| 29/04/2010        |   | ☐ Protocol                                 |  |  |
| Registration date | Overall study status                    | Statistical analysis plan                  |  |  |
| 12/05/2010        | Completed                               | [X] Results                                |  |  |
| Last Edited       | Condition category                      | Individual participant data                |  |  |
| 03/04/2013        | Mental and Behavioural Disorders        |  |  |  |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Ms letje de Rooij

#### Contact details

Care Centre De Kievitshorst Beneluxlaan 101 Tilburg Netherlands 5042WN

## Additional identifiers

**Protocol serial number** N/A

# Study information

#### Scientific Title

Perspectives on the results of small-scale living facilities in the Netherlands and Belgium

## Study objectives

What is the effect of living in a small-scale facility compared to living in a traditional care ward on patient outcomes, including quality of life, for elderly people suffering from dementia?

## Ethics approval required

Old ethics approval format

#### Ethics approval(s)

- 1. Ethics committee of the University of Tilburg approved in April 2007
- 2. Ethics committee of De Wever approved in April 2007

#### Study design

Multicentre cross-national longitudinal qualitative study

#### Primary study design

Observational

#### Study type(s)

Quality of life

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

Severe dementia

#### Interventions

Participants will be followed for a year during their stay at a closed-environment dementia care ward. They were not assigned a kind of ward by the researchers. At three points during the study (the beginning, after six months, after a year) participants will fill out the Standardized Mini Mental State Examination with the help of a psychologist, care givers will provide information on quality of life measures, activities of daily living, depression, neuropsychatric symptoms and social engagement. The family will provide information about the quality of the care received at the start and end of the study. The participating care giving staff will provide information about their workload and work experiences at the start and the end of the study.

## Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

- 1. Quality of life, assessed by Quality of Life in Dementia (QUALIDEM)
- 2. Activities of daily living (ADL), assessed by Barthel Index
- 3. Depression, assessed by Cornell Scale for Depression in Dementia (CSDD)
- 4. Neuropsychiatric symptoms, assessed by Neuropsychiatric Inventory, Nursing Home Version (NPI-NH)
- 5. Social engagement, assessed by Revised Index of Social Engagement (RISE) taken from the Resident Assessment Instrument (RAI 2.0)

All outcomes were measured at baseline (i.e. start of study), 6 months and one year. All questionnaires used were in the Dutch language.

## Key secondary outcome(s))

- 1. Control measures:
- 1.1. Severity of dementia, assessed by Standardized Mini Mental State Examination (S-MMSE)
- 1.2. Medications falling in the category antipsychotics, antidepressants and sedatives were
- 1.3. Restriction measures, kind of measure and number of measures were noted
- 1.4. Visitors, a single question was answered how many times a month the patient gets a visit from family or friends
- 1.5. Weight, registered fully clothed and with shoes on
- 2. Family:
- 2.1. Quality of care
- 2.2. Interactive activities with their loved one

The questionnaire they received was designed by the researchers themselves. A copy can be requested through the contact details below.

- 3. Staff:
- 3.1. Work load and work experience

The questionnaire they received was designed by the researchers themselves. A copy can be requested through the contact details below.

Additionally, staff filled out the Utrecht Burnout Scale (Utrechtse Burnout Schaal) (UBOS-C), a questionnaire for professions in which physical contact is present

All patient and family outcomes will be measured at baseline (i.e. start of study), 6 months and one year. Staff outcomes will be measured at the beginning and end of the study. All questionnaires used were in the Dutch language.

#### Completion date

01/06/2010

## Eligibility

#### Key inclusion criteria

Care centres were selected based on the kind of wards existing contacts and willingness to participate. Traditional and Small-scale closed-environment wards were selected with a policy indicating that a patient can stay there till the end of their life. From those care centres participants were selected who were patients suffering from dementia, over the age of 70, of either sex. Also, information from family and direct care-givers of the participants were included in the study.

For every participant a compliance form was filled out and returned by the family to the researchers

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Senior

#### Sex

All

## Key exclusion criteria

- 1. Patients did not fit the inclusion criteria
- 2. Patients did not finish the study. This could happen for example by a death or by moving to another institution.

#### Date of first enrolment

01/06/2007

#### Date of final enrolment

01/06/2010

## Locations

## Countries of recruitment

Belgium

Netherlands

## Study participating centre Care Centre De Kievitshorst

Tilburg Netherlands 5042WN

# Sponsor information

## Organisation

University of Tilburg (Netherlands) - Department Tranzo

#### **ROR**

https://ror.org/04b8v1s79

# Funder(s)

## Funder type

University/education

#### **Funder Name**

University of Tilburg (Netherlands) - Department Tranzo

## **Results and Publications**

# Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                   | Details                              | Date<br>created | Date<br>added  | Peer<br>reviewed? | Patient-<br>facing? |
|-------------------------------|--------------------------------------|-----------------|----------------|-------------------|---------------------|
| Results article               | caregivers' questionnaire<br>results | 01/06/2012      |                | Yes               | No                  |
| Results article               | results                              | 01/11/2012      |                | Yes               | No                  |
| Participant information sheet | Participant information sheet        | 11/11/2025      | 11/11<br>/2025 | No                | Yes                 |