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

Submission date	Recruitment status	[ ] Prospectively registered
29/04/2010	No longer recruiting	[ ] 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 Ietje de Rooij

Contact details
Care Centre De Kievitshorst
Beneluxlaan 101
Tilburg
Netherlands
5042WN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/06/2007

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

Age group
Senior

Sex
Both

Target number of participants
180

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

Sponsor details
Faculty of Social and Behavioral Sciences
Po box 90153
Tilburg
Netherlands
5000 LE
+ 31 (0)13 466 2969
tranzo@uvt.nl

Sponsor type
University/education

Website
http://www.tilburguniversity.nl/faculties/fsw/departments/tranzo/

ROR
https://ror.org/04b8v1s79

Funder(s)

Funder type
University/education

Funder Name
University of Tilburg (Netherlands) - Department Tranzo

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	caregivers' questionnaire results results	01/06/2012		Yes	No

Results article	01/11/2012	Yes	No