

# Evaluation of emotion-oriented care versus usual care for elderly persons with dementia in the nursing home

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| <b>Submission date</b><br>30/06/2009   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>27/08/2009 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>27/08/2009       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Integrated emotion-oriented care versus usual care for elderly persons with dementia in the nursing home: a clinical experimental study into the effects and costs

## Study objectives

1. Integrated emotion-oriented care in nursing homes has as compared to usual care more positive effect on:
  - 1.1. The adaptation of demented elderly to their disabilities and to the nursing home
  - 1.2. The general health of the nursing assistants
  - 1.3. The satisfaction of relatives of residents with dementia
2. Integrated emotion-oriented care is more cost-effective than usual care

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Medical Ethical Commission of the VU University Medical Centre approved in 1995

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Dementia, psychogeriatrics

## Interventions

Intervention:

Dutch Model Care plan and integrated emotion-oriented care, partly based on the validation approach, partly based on elements of other psychosocial care strategies/approaches in dementia care such as the reality orientation approach, reminiscence and sensory stimulation. The starting point of the application of the integrated emotion-oriented care strategy/approach are the individual emotional and social needs of the residents as well as their physical and mental (dis)abilities.

Control:  
Dutch Model Care plan only.

We investigated if professional caregivers (most nurses and nurse assistants) applied the emotion-oriented care method as trained. The caregivers (n = 61) in the experimental wards were trained to work according to the principles of the Dutch Model Care plan as well as an integrated emotion-oriented care for people with dementia, while the caregivers (n = 63) in the control wards were trained in working according to the Dutch Model Care plan only.

In the pre-experimental period the caregivers of both the experimental group and the control group received 6 days of training (course and supervision/training on the job) on the Dutch Model Care plan to make the groups comparable on basic care quality. During the intervention period the training on the job and supervision on how to work according to the Dutch Model Care plan proceeded in both research arms, while in the experimental group a selection of caregivers were trained (10 days) as consultants in integrated emotion-oriented care and the other caregivers received a basic course in integrated emotion-oriented care (2 days; n = 32 caregivers per ward of 30 residents) and some of them also an advanced course (7 days; one out of 4 caregivers who passed the basic course).

The pre-experimental period was 6 months, the intervention period (actual implementation of integrated emotion-oriented care) was 7 months. Pre- and post-tests measurements in the experimental group took place directly before the start of the courses in emotion-oriented care and after 7 months, and in the control group after the training in the Dutch Model Care plan and 7 months later. At 7 months in both arms a retrospective baseline measurement was executed as well. Qualitative observation data were gathered by participant observation during 9 days at 8 of the 15 ward units at baseline and after 7 months.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

1. Behaviour and mood problems as symptoms of difficulties with the cognitive, emotional and social adaptation to the consequences of the disease and nursing home admittance
2. Positive behaviour, affect and institutionalisation

All measurements of this implementation effectiveness study took place at baseline and after 7 months.

### **Secondary outcome measures**

General health of professional caregivers:

1. Stress experience
2. Stress reactions
3. Illness
4. Sense of competence

All measurements of this implementation effectiveness study took place at baseline and after 7 months.

**Overall study start date**

01/04/1996

**Completion date**

31/03/1999

## **Eligibility**

**Key inclusion criteria****1. Patients:**

- 1.1. Persons older than 65 years of age, either sex
- 1.2. Probable diagnosis of dementia of the alzheimer-type (DAT), mixed diagnosis of DAT and vascular dementia, amnestic syndrome and dementia syndrome not otherwise specified
- 1.3. In need of assistance or care
- 1.4. Living in nursing homes for at least one month before the start of the baseline measurement

**2. Professional caregivers in the experimental group:**

- 2.1. Certified nursing assistants that followed the course Validation-worker
- 2.2. First responsible nurse assistants

**3. Professional caregivers in the control group:**

- 3.1. Nurse assistants that were matched with the experimental group on education, age and work experience
- 3.2. Did not participate in any course of Validation-worker

**4. Relatives: frequency of visiting the resident with dementia at least ones a month****Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

146 people with dementia and 125 professional carers

**Key exclusion criteria**

- 1. Patients: refusal to participate in the study
- 2. People who did not fullfil the inclusion criteria
- 3. People with severe physical disabilities (such as total blindness or muteness), that made adequate data collection for the effect study impossible
- 4. Professional caregivers:
  - 4.1. Did not fulfil the inclusion criteria
  - 4.2. Were not prepared to participate in the study

**Date of first enrolment**

01/04/1996

**Date of final enrolment**

31/03/1999

# Locations

## Countries of recruitment

Netherlands

## Study participating centre

Valeriusplein 9

Amsterdam

Netherlands

1075 BG

# Sponsor information

## Organisation

The Dutch Health Care Insurance Board (CVZ) (Netherlands)

## Sponsor details

Eekholt 4

Diemen

Netherlands

1112 XH

## Sponsor type

Government

## Website

<http://www.cvz.nl/>

# Funder(s)

## Funder type

Government

## Funder Name

The Dutch Health Care Insurance Board (CVZ) (Netherlands)

# 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? |
|---------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | family member opinion results | 01/09/2001   |            | Yes            | No              |
| <a href="#">Results article</a> | RCT results                   | 01/04/2005   |            | Yes            | No              |