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

Submission date	Recruitment status
30/06/2009	No longer recruiting
Registration date	**Overall study status**
27/08/2009	Completed
Last Edited	**Condition category**
27/08/2009	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 emoion-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 assitants) 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: frequence 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?
Results article	family member opinion results	01/09/2001		Yes	No
Results article	RCT results	01/04/2005		Yes	No