Effectiveness and cost-effectiveness of a care-programme by district nurses among elderly with dementia symptoms and their primary informal caregiver.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26504

Source
Nationaal Trial Register

Brief title
PIKOM (in Dutch: Preventive Intervention among cognitively frail elderly and their caregiver)

Intervention

Outcome measures

Primary outcome

1. Sense of mastery over the caregiver task as measured with the Sense of Competence Questionnaire (SCQ);

2. Quality of life by means of the MOS 36-item short-form health survey (SF-36);

3. Psychological well-being as determined with the Center for Epidemiologic Studies Depression Scale (CES-D).

Secondary outcome

1. Days until institutionalization of the patient as checked with the GPs;

2. Quality of life of the patient as measured with the Dementia Quality of Life Instrument (DQOL);

3. Days until death of the patient as checked with the GPs;

4. Hospital days of the patient by means of cost diaries.

Study description

Background summary

Subject:

Informal caregivers of demented elderly who live at home are often burdened with the caregiver task. Support of caregivers could increase the sense of competence over the caregiver task, increase psychological well-being, decrease medical consumption, and delay nursing home placement. The object of this RCT is to determine effectiveness and cost-effectiveness of an intervention among informal caregivers of elderly with dementia symptoms who live at home.

The main research questions of this RCT are:

1. Is the care-programme more effective than usual care in improving sense of mastery over the caregiver task, quality of life, and psychological well-being of primary informal caregivers?

2. Is the care-programme cost-effective compared to usual care when assessed from a societal perspective?

Design:

The design is a randomized controlled trial with assignment to either usual care or the care-programme among patients with dementia symptoms and their primary informal caregivers. Measurements are at baseline and after 6 and 12 months. Randomization takes place after baseline. The random order is established by an independent person using random number tables. We aspire to include 100 dyads of caregiver and patient.

Study objective

Caregivers' sense of competence will improve significantly more in participants of the intervention group compared to the participants in the usual care group.

Study design

N/A

Intervention

1. Usual care;

2. Care programme by district nurses.

Contacts

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Eligibility criteria

Inclusion criteria

Elderly are eligible for trial entry if they are 65 years or over, live outside of institutional settings, suffer from dementia symptoms, and have a primary informal caregiver. Both caregiver and patient should have a good command of the Dutch language. Patients with

dementia symptoms are persons with multiple cognitive impairments (i.e. memory impairments, aphasia, apraxia, agnosia, and impairment in executive functioning). It is assumed that these dementia symptoms lead to significant limitations in social functioning, progressive decline in general functioning.

Exclusion criteria

The following exclusion criteria are applied at baseline:
assistance by an outpatient geriatric team for cognitive problems, terminal illness, participation in other research projects and institutionalization.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2002
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	31-05-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL39
NTR-old	NTR66
Other	: ZonMw-number: 2200.0114
ISRCTN	ISRCTN83135728

Study results

Summary results
N/A