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

Gepubliceerd: 31-05-2005 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26504

Bron
Nationaal Trial Register

Verkorte titel
PIKOM (in Dutch: Preventive Intervention among cognitively frail elderly and their caregiver)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1. Usual care;

2. Care programme by district nurses.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-07-2002
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	31-05-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A