Family Meetings in Memory Clinics: Indicated Prevention of developing Anxiety and Depressive Disorders in primary informal caregivers of demented patients

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To investigate the effectiveness of family meetings on indicated prevention of anxiety and depressive disorders (DSM IV) and symptom levels of primary family caregivers of patients with dementia. To perform an economic evaluation alongside the trial...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33647

Source
ToetsingOnline

Brief title
FAME

Condition

- Other condition
- Psychiatric disorders
- Family issues

Synonym
anxiety and depressive disorders

Health condition

psychische stoornissen: angststoornissen- en symptomen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: dementia caregivers, family meetings, psychosocial intervention

Outcome measures

Primary outcome

- Incidence of major depression and anxiety disorders (i.e. generalised anxiety and panic) as defined according to DSM-IV criteria (APA 1994) and assessed with the Mini International Neuropsychiatric Interview (MINI) (Sheehan 1998). The MINI is used as 6 month prevalence measure.

- The dimensional or severity measure of anxiety and depression symptoms is derived by validated self report instruments: the Centre for Epidemiologic Studies Depression Scale (CES-D) and Geriatric Depression Scale (GDS-5) for depression, the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS) for anxiety.

Secondary outcome

Caregiver

- Caregiver Burden with the Caregiver Reaction Assessment (CRA) (Given 1992)

- Sense of competence with the SSCQ (Vernooij-Dassen 2000)

- Quality of Life with the Short Form 12 item version (Ware 1995)

- 'Quality adjusted life years' with the SF6D (SF-12)

Patienten

- Depressive symptoms in patients (NPI)

- Quality of Life (SF-12)

Other

- Time until institutionalization

- Costs

Resource utilization of patient and carer will be measured from a societal perspective with cost diaries (filled out by the carer) which include both direct (hospital visits) and indirect costs (travel time) and both within and outside (loss labour days) the health care (RUD, Wimo 1997)

Study description

Background summary

The growing group of family caregivers of dementia patients has a highly increased risk of developing depressive and anxiety disorders. An American landmark study reported substantial beneficial effects of family meetings on depression in family caregivers as well as on delay of institutionalisation of patients. Effects are not replicated in other countries yet. When effective, family meetings can be an important addition to the current care services in the Netherlands.

Study objective

To investigate the effectiveness of family meetings on indicated prevention of anxiety and depressive disorders (DSM IV) and symptom levels of primary family caregivers of patients with dementia. To perform an economic evaluation alongside the trial.

Study design

Randomised controlled clinical trial comparing structured family meetings

versus usual care with significant others of 224 primary family caregivers of community dwelling demented patients recruited in memory clinics with a follow up of 24 months.

Intervention

Four meetings with family and close friends will be organized and run by a trained counsellor according to a manual (Mittelman 2003) . The aim is to offer psycho-education, increase problem-solving skills and mobilize the naturally existing social network of patient by sharing support tasks of network members.

Study burden and risks

The burden of the intervention will be minimal for the dementia patients and their family caregivers. A possible burden can be created by the number of questionnaires which have to be filled in/ will be taken to assess the study parameters. Furthermore, emotional discomfort and family conflicts can exist as a consequence of participation in the intervention. This possible burden will be in proportion to the potential value of the research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- family caregiver takes primary responsibility for the informal care of a patient with a clinical diagnosis of dementia and lives in the same region as the patient.
- In each family, at least one other family member lives in the same region of the patient and caregiver.
- Both caregiver and patient have sufficient language proficiency in Dutch for adequate participation in meetings, interviews and tests.
- Written informed consent from both patient and caregiver is obtained. In case of mental incompetence of a patient the family caregiver will sign the consent for the patient.

Exclusion criteria

1) Severe somatic or psychiatric co-morbidity of either caregiver or patient, which will significantly impair cooperation to the program.
2) Caregiver does have a depressive or anxiety disorder at baseline
3) Either caregiver or patient participates in other intervention studies at inclusion or during the study.
4) Scheduled to move a patient to a nursing home.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	224
Type:	Anticipated

Ethics review

Approved WMO
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL16681.029.07