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Family meetings in Memory clinics

Submission date	Recruitment status	[X] Prospectively registered
23/08/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2013	Mental and Behavioural Disorders	

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
Family Meetings in Memory clinics: indicated prevention of developing anxiety and depressive disorders in primary informal caregivers of demented patients

Acronym
FaMe

Study objectives
Affective disorders (i.e., depressive or anxiety disorders) of dementia caregivers are largely preventable.

Summary of Family Meetings in memory clinics (FaMe):
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. These effects were not replicated in other countries yet. We perform the first trial comparing only structured family meetings with significant others versus usual care among primary family caregivers of community dwelling demented patients and measure the effectiveness on both depression and anxiety, both on disorder and symptom levels.

Four family meetings will be organised with the primary family caregiver of a community dwelling patient with a clinical diagnosis of dementia, family and close friends. Dyads of patients and their primary caregiver are followed up to two years after baseline assessment. The main outcome measure of the effect evaluation is the incidence of anxiety and depressive disorders assessed with the Mini-International Neuropsychiatric Interview (MINI) added with the time of onset in case of a disorder. The severity of anxiety and depressive symptoms is measured by validated self report instruments: the Centre for Epidemiologic Studies Depression Scale (CES-D) and Geriatric Depression Scale (GDS-5) for depression and the anxiety scales of the Hospital Anxiety and Depression scales (HADS) for anxiety. The economic evaluation is performed from a societal perspective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Committee of the VU University medical centre in Amsterdam has approved the study on July 18, 2007 (ref: 2007/83)

Study design
Multicentre, randomised, single-blinded, active controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Affective disorders (i.e., depressive or anxiety disorders) of dementia caregivers

Interventions
Intervention group:
Primary caregivers of a community dwelling dementia patient and their family and close friends will receive four family meetings during a year. A trained counsellor will run the meetings according to a manual. The aim is to offer psycho-education, increase problem-solving skills and mobilise the naturally existing social network of patient by sharing support tasks of network members.

Usual care group:
Patients and their caregiver will receive the usual care given by the participating memory clinic.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Incidence of major depression and anxiety disorders (i.e. generalised anxiety and panic) as defined according to DSM-IV criteria
2. Dimension/severity of anxiety and depression symptoms

Both primary and secondary outcome measures will be measured at baseline and at 6, 12, 18 and 24 months after baseline

Secondary outcome measures
Caregiver:
1. Caregiver Burden
2. Quality of life

Additional psychological questionnaires are used to explore profiles of caregivers who are best helped by the intervention.

Patients:
1. Depressive symptoms in patients (Neuropsychiatric Inventory [NPI])
2. Quality of life

Other:
1. (In)-direct costs caregiver and patient
2. Time until institutionalisation

Both primary and secondary outcome measures will be measured at baseline and at 6, 12, 18 and 24 months after baseline

Overall study start date
01/09/2007

Completion date
01/03/2012

Eligibility

Key inclusion criteria
1. Family caregiver who takes primary responsibility for the informal care of a community dwelling patient with a clinical diagnosis of dementia and who lives in the same region as the patient. We only include spouses, children (in-law), brothers and sisters of the patient
2. In each family, at least one other family member lives in the same region of the patient and caregiver
3. Both caregiver and patient have sufficient language proficiency in Dutch for adequate participation in meetings, interviews and tests
4. 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

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
172

Key exclusion criteria
1. Severe somatic or psychiatric co-morbidity of either caregiver or patient, which will significantly impair cooperation to the program
2. Either caregiver or patient participates in other intervention studies at inclusion or during the study
3. Scheduled to move a patient to a nursing home

Date of first enrolment
01/09/2007

Date of final enrolment
01/03/2012

Locations

Countries of recruitment

Netherlands

Study participating centre
Vrije University Medical Centre Amsterdam
Amsterdam
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Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

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Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The 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?
Protocol article	protocol	21/01/2008		Yes	No
Results article	anxiety and depression results	01/01/2012		Yes	No
Results article	time to nursing home results	01/01/2012		Yes	No
Results article	cost-effectiveness results	22/09/2013		Yes	No