

Family meetings in Memory clinics

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Registration date 23/08/2007	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 25/09/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

Netherlands

1081 BT

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

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

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	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
Protocol article	protocol	21/01/2008		Yes	No