# 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

#### Contact name

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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

#### **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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes