

# Family meetings in Memory clinics

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| <b>Submission date</b><br>23/08/2007   | <b>Recruitment status</b><br>No longer recruiting             | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>23/08/2007 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>25/09/2013       | <b>Condition category</b><br>Mental and Behavioural Disorders | <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

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  
Netherlands  
1081 BT

## **Sponsor information**

**Organisation**

Vrije University Medical Centre (VUMC) (The Netherlands)

**Sponsor details**

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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? |
|----------------------------------|--------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol                       | 21/01/2008   |            | Yes            | No              |
| <a href="#">Results article</a>  | anxiety and depression results | 01/01/2012   |            | Yes            | No              |
| <a href="#">Results article</a>  | time to nursing home results   | 01/01/2012   |            | Yes            | No              |
| <a href="#">Results article</a>  | cost-effectiveness results     | 22/09/2013   |            | Yes            | No              |