# Effect of a training program on dementia and caregiving.

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1. What is the effect of the training program on physical health, depressive symptoms, cognitive and executive functions of people with dementia in comparison with care-as-usual? 2. What is the effect of the training program on physical health,...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON21009

**Bron**
NTR

**Verkorte titel**
Training program for people with dementia and caregivers

**Aandoening**

Dementia
Alzheimer's Disease
Caregiver
Exercise
Training

In Dutch:
Dementie
Mantelzorg
Ziekte van Alzheimer
Beweging
Training
Depressie

## Ondersteuning

**Primaire sponsor:** - VU University
- Institute for health and Care Research (EMGO+)
**Overige ondersteuning:** Innovatiefonds Zorgverzekeraars

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

People with dementia:<br>
1. Physical health (SIP & SF36);<br>
2. Mood (Cornell).

# Toelichting onderzoek

### Achtergrond van het onderzoek

People with dementia and their caregivers can suffer a lot from dementia. Providing care to people with dementia is a heavy responsibility which can affect the health and normal lives of family caregivers. There is no cure for dementia, but prevention and treatment focused on behaviour problems that may result from the dementia and the care situation is feasible. A recent review shows that combined interventions both for people with dementia and their caregivers were most effective to diminish depressive symptoms of people with dementia. One of the promising combined interventions is an intervention developed by Teri and colleagues. People with dementia receive an exercise program together with their caregivers. The caregivers are also trained in behaviour management techniques to deal with behavioural disturbances. People with dementia who participated in the intervention program performed significantly better on physical measures and measures of affective status compared to the usual care group.

In our study we will translate and adapt the intervention program of Teri to the Dutch situation and study whether it is feasible and effective for both people with dementia and their caregivers. We will use the same measures as in the study of Teri and add measures for physical, cognitive and executive functioning to study the effects of the intervention program. In addition we will study the effects of the integrated treatment program on the mood of the family caregivers. The patients-caregivers dyads will be randomly assigned to the training program or care-as-usual after written informed consent. Measurements take place at baseline, at the end of the training program after 3 (posttreatment) and at 6 and 12-months after baseline. Confidential information and patient names are treated according to the medical confidentiality rules.

**Doel van het onderzoek**

1. What is the effect of the training program on physical health, depressive symptoms, cognitive and executive functions of people with dementia in comparison with care-as-usual?

2. What is the effect of the training program on physical health, depressive symptoms and perceived pressure of caregivers in comparison with care-as-usual?

3. Are there prognostic factors (e.g. demographics) that in combination with the training program predict lower or higher effects on the outcomes of people with dementia and their caregivers?

4. Are there different effects between this study and the study of Teri and the Dutch study (by Karin Volkers and Erik Scherder VU University) including exercise for people but no caregiver support?

5. What are the working components of the training program to improve care receivers' and caregivers' functioning according to the participants? And what effects does the training program have on their relationship?

**Onderzoeksopzet**

Measurements take place at baseline, at the end of the training program after 3 (posttreatment) and at 6 and 12-months after baseline.

**Onderzoeksproduct en/of interventie**

The patients-caregivers dyads will be randomly assigned to the training program or care-as-usual after written informed consent.

The goal of the exercise training program is that people with dementia will exercise actively during at least 30 minutes a day. The exercises will include balance, strength training, aerobic/endurance activities and flexibility training.
In addition the caregiver will learn how to cope with the demented person, will be advised in dementia and the consequences and pleasure activities with the patient will be stimulated.

The control group will receive – in line with the experimental group – usual care, e.g. from the geriatric policlinic or the outpatient clinic. Self-evidently, the received care will be registered accurately in this group. Also we will control for the effect of attention. The control group will be phoned by trained people.

# Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria for people with dementia are:

1. People with dementia (Alzheimer Disease, Lewy Bodies, Vascular Dementia, Frontotemporal Dementia etc.);

2. Minimum age 55 years;

3. Living at home and not institutionalized;

4. To have caregivers willing to participate in the training sessions;

5. Written informed consent (caregivers provide consent on behalf of the people with AD);

6. Be able to keep balance and to walk some steps without help.

Inclusion criteria for the caregivers are:

1. To be spouses or adult relatives who live with, or spent a minimum of 4 hours every day with the patient;

2. Minimum age 25 years;

3. Be able to give instructions to the patient;

4. 5 or more points on CES-D;

5. To have enough understanding of the Dutch language;

6. Written informed consent.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for people with dementia are:

1. Use of antidepressants;

2. MMSE < 14;

3. Presence of psychotic symptoms or cerebral trauma;

4. Receive more than two days outpatients' care.

Exclusion criteria for the caregivers are:

1. Physical difficulties (not possible to assist the participant with the exercises);

2. Presence of psychotic symptoms;

3. Use of antidepressants.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 15-06-2009 |
| Aantal proefpersonen: | 312 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 06-05-2009 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL694 |
| NTR-old | NTR1802 |
| Ander register | MEC VUmc : 2008/320 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Resultaten

**Samenvatting resultaten**
N/A