Effect of a training program on dementia and caregiving.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21009

Source
Nationaal Trial Register

Brief title
Training program for people with dementia and caregivers

Health condition

Dementia
Alzheimer's Disease
Caregiver
Exercise
Training

In Dutch:
Dementie
Mantelzorg
Ziekte van Alzheimer
Beweging
Training
Depressie

Sponsors and support

Primary sponsor: - VU University
- Institute for health and Care Research (EMGO+)
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars

Intervention

Outcome measures

Primary outcome

People with dementia:

1. Physical health (SIP & SF36);

2. Mood (Cornell).

Secondary outcome

People with dementia:

1. Cognition(neurospychological research).

Caregivers:

1. Physical Health (GHQ-12);

2. Mood (CES-D);

3. Stress (SPICC, RMBPC and cortisol).

Study description

Background summary

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.

Study objective

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?

Study design

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

Intervention

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.

Contacts

Public
A-E. Prick
VU University Amsterdam,
Department of Clinical Psychology,
Van der Boechorststraat 1, room 2E-13

Amsterdam 1081 BT
The Netherlands
+31 (0)20 5988757
Scientific
A-E. Prick
VU University Amsterdam,
Department of Clinical Psychology,
Van der Boechorststraat 1, room 2E-13

Amsterdam 1081 BT
The Netherlands
+31 (0)20 5988757

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-06-2009
Enrollment:	312
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-05-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A