A training program for people with dementia and their family caregivers: A randomized controlled trial

Published: 28-04-2009
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33982

Source
ToetsingOnline

Brief title
Effect of a training program on dementia and caregiving

Condition

- Other condition
- Dementia and amnestic conditions

Synonym
dementia / memory problems

Health condition

depressie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Innovatiefonds zorgverzekeraars

Intervention

Keyword: Alzheimer's Disease, Caregiver, Dementia, Depression, Exercise, Training

Outcome measures

Primary outcome

People with dementia outcome measures:

• Physical health and function (SIP & SF36)

• Mood (Cornell)

We hypothesized that patients receiving the training program would improve on these areas. We believed that these areas will show improvement only in patients whom such problems were evident at baseline.

Secondary outcome

People with dementia outcome measure:

• Cognition (measured by neurpsycholocical research)

Caregivers:

• Physical health and functioning (GHQ-12)

• Mood (CES-D)

• Perceived pressure (SPICC, RMBPC en analyse salivary 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.

Study objective

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 the intervention program of Teri, adapt the program to the Dutch situation and study whether it is feasible and effective. 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.

Study design

A randomized Controlled Trial (RCT) will be conducted. There will be pre-measurement before randomization. The patients-caregivers dyads will be randomly assigned to the training program or care-as-usual with attention. The duration of the exercise training is three months. The intervention effect will be assessed by trained interviewers blind to the treatment assignment. Assessments are conducted at screening baseline, after 3 months (posttreatment)

and at 6, and 12-month follow-up.

Intervention

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 patient-caregiver dyads will be visited in their own homes by trained students for 12 hour-long sessions during a schedule of 2 sessions per week during the first 3 weeks, followed by weekly sessions during 4 weeks, and then biweekly sessions over the next 4 weeks. In these sessions the trained students will explain the exercise program and train the caregivers in behaviour management techniques to deal with behavioural disturbances.

Study burden and risks

All research will be conducted at the residence of the participants

People with dementia:
- Analyse APOE4 via wangslijmvlies: 1 time
- Analyse heart-rate & blood pressure: 3-4 times
- analyse slaap-waakritme middels actiwatches om de pols gedurende 24 uur: 3-4 times
- Neuro Psychological Research: 3-4 times
- Questionnaires (all questionnaires will be completed by the interviewer):
Medical Outcome Study Short Form Health Survey (SF-36)
Sickness Impact Profile (SIP)
Cornell scale for Depression in Dementia
Hamilton Depression Rating Scale

Caregivers:
- Analyse salivary cortisol: 3-4 times (Cortisol will be assessed by sampling saliva at the time of awakening and within the first 30 minutes after awakening)
- Questionnaires:
General Health Question-12 (GHQ-12)
Centre for Epidemiologic Studies-Depression (CES-D)
Perceived Pressure from Informal Care (SPPIC)
RMBPC: perceived stress

Confidential information and patient names are treated according to the medical confidentiality rules.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for people with dementia are:
- people with dementia (Alzheimer Disease, Lewy Bodies, Vascular Dementia, Frontotemporal Dementia etc.)
- minimum age 55 years
- living at home and not institutionalized,
- to have caregivers willing to participate in the training sessions, and
- written informed consent (caregivers provide consent on behalf of the people with AD).
- be able to keep balance and to walk some steps without help;Inclusion criteria for the caregivers are:
- to be spouses or adult relatives who live with, or spent a minimum of 4 hours every day with the patient,
- minimum age 25 years,

- be able to give instructions to the patient,
- 5 or more points on CES-D
- to have enough understanding of the Dutch language,
- written informed consent.

Exclusion criteria

Exclusion criteria for people with dementia are:
- use of antidepressants
- MMSE < 14
- presence of psychotic symptoms or cerebral trauma
- receive more than two days outpatients* care. ;Exclusion criteria for the caregivers are:
- physical difficulties (not possible to assist the participant with the exercises)
- presence of psychotic symptoms
- use of antidepressants.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	312
Type:	Actual

Ethics review

Approved WMO

Date:	28-04-2009

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL26088.029.08