Dementie de Baas
An e-health intervention to prevent depression among informal caregivers of people with dementia: randomized trial and cost utility analysis

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AIM - The aim of the proposed study is to evaluate the (cost)effectiveness of *Dementie de Baas*. Research questions are: 1. a. Will the intervention generate superior health gains over care-as-usual in terms of a clinically significant change in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33462

Source
ToetsingOnline

Brief title
RCT Mastery over Dementia

Condition

- Other condition

Synonym
depression, psychological symptoms

Health condition

depressieve klachten en gevoelens van belasting

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: Stichting Geriant;Alzheimer Nederland en VU-FPP

Intervention

Keyword: burden, caregivers, dementia, depression

Outcome measures

Primary outcome

OUTCOMES -The primary outcome is depressive symptoms.

Secondary outcome

Secondary outcomes are symptoms of anxiety, feelings of burden, self-perceived

pressure from informal care, feelings of competence, (health-related) quality

of life and costs (direct medical and non-medical costs and indirect costs).

Study description

Background summary

INTRODUCTION - *Dementie de Baas* (or in English *Mastery over Dementia*) is a recently developed internet course for family caregivers of people with dementia under the guidance of a health care psychologist. The intervention is focused on the empowerment of family caregivers with the aim to improve their psychological well-being in general and reduce their depressive symptoms in particular. Family caregivers were closely involved in the development.

Study objective

AIM - The aim of the proposed study is to evaluate the (cost)effectiveness of *Dementie de Baas*. Research questions are: 1. a. Will the intervention generate superior health gains over care-as-usual in terms of a clinically significant change in depressive symptoms, symptoms of anxiety and feelings of

burden? 1b. And will these effects be maintained up to 12 months? 2. Will the intervention be cost-effective in comparison with *care-as-usual* for QALYs gained?

Study design

DESIGN - The study is a pragmatic randomized controlled trial with two parallel groups. Measurements will be conducted in the experimental condition at baseline, after 4 lessons (1,5-2 months after start) and after all 9 lessons (4-6 months after start) and 3 and 6 months after finishing the course to measure effect maintenace over time. The controlgroup (information condition) will receive measurements at baseline and 2 and 6 months after baseline.

Intervention

INTERVENTION - Dementie de Baas (indicated prevention) focuses on helping caregivers to help themselves in preventing depressive symptoms as much as possible under the guidance of counselor. After a course consisting of 8 sessions and a booster session, ongoing forum participation is offered. Caregivers can be reached in an early stage of the caregiving process, including those who have not sought help for the person with dementia yet.

Study burden and risks

Filling out the questionnaires online will take no longer than one hour.

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:
- informal caregivers of people with dementia (partners, children (in law), other family members, friends)
- A score on the CES-D between 12 and 26
- having a pc with internet access and being able to use it
- informed consent

Exclusion criteria

Exclusion criteria:
- severe mental health problems (e.g. suicidal problems or high scores on the CES-D) warranting immediate medical attention or likely to interfere with participation in the preventive course;
- current treatment for mental disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-05-2009
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	11-05-2009
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20265
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL27434.097.09
OMON	NL-OMON20265