Effectiveness of an e-Mental Health intervention for family caregivers of people with dementia

No registrations found.

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

Summary

ID

NL-OMON20265

Source
Nationaal Trial Register

Brief title
RCT-DDB

Health condition

Depression, depressive symptoms, family caregivers, caregiver burden, dementia, psychological intervention, e-Mental Health.

Depressie, depressieve klachten, mantelzorg, familieleden, belasting, dementie, psychologische behandeling, e-Mental Health.

Sponsors and support

Primary sponsor: VU University Amsterdam, Department of Clinical Psychology in colloboration with Netherlands Institute of Mental Health and Addiction.
Source(s) of monetary or material Support: Univé (Health Insurance), Geriant, Alzheimer Nederland, VU University. the Netherlands Institute of Mental health and Addiction

Intervention

Outcome measures

Primary outcome

Depressive symtoms as measured by the CES-D.

Secondary outcome

Symptoms of anxiety (HADS), caregiver stress (RPBMC) and feelings of burden (SPICC). Other measures are self-perceived competence , subjective health, quality of life, use of care services and time spent on care.

Study description

Background summary

INTRODUCTION

'Dementiedebaas.nl' (or in English 'Mastery over Dementia') is a recently developed internet course for family caregivers of people with dementia under the guidance of a 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.

AIM

The aim of the proposed study is to evaluate the (cost)effectiveness of 'Dementiedebaas.nl'. Research questions are: 1a. 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 6 months after the intervention? 2. Will the intervention be cost-effective in comparison with "care-as-usual" for QALYs gained?

INTERVENTION

Mastery over Dementia focuses on assisting caregivers to help themselves in preventing depressive symptoms as much as possible under the guidance of a coach. After a course consisting of 8 sessions and a booster session, ongoing forum participation and free access to the course and their file is offered. Caregivers can be reached in an early stage of the care giving process, including those who have not sought help for the person with dementia yet.

The intervention incorporates elements of psycho-education, cognitive behavioral therapy, problem solving therapy, relaxation therapy and assertiveness training. Interactive feedback is given by a coach.

DESIGN

The study is a pragmatic randomized controlled trial with two parallel groups. The control group will receive bulletins with practical information via mail at regular intervals. Measurements will be conducted in both conditions at baseline (T=0), after the fourth lesson or bulletin (T=1) and after the ninth lesson or bulletin (T=2). Maximum time interval between T0 and T2 is set at 26 weeks. The intervention group will receive prolonged measurements at 3 and 6 months after T2 to monitor effect maintenance over time.

OUTCOMES

The primary outcome is depressive symptoms. Secondary outcomes are symptoms of anxiety, feelings of competencies, self-perceived pressure from informal care and health-related quality of life.

ANALYSES

Analysis will be conducted following the intention-to-treat principle. Missing values on T1 and T2 because of drop-out will be imputed on the basis of regression analysis. Multivariate linear regression analysis will be used to answer research question 1a. Generalized estimated equations (GEE) analysis will be conducted to answer research question 1b. Research question 2 will be answered by using costs utility analysis for a period of six months.

Study objective

The e-Mental Health intervention has a positive effect on psychological well-being, feelings of burden and perceived health of family caregivers of people with dementia. This effect will last for several months after finishing the intervention.

Study design

Baseline, after 4 lessons/bulletins, after finishing the intervention (both experimental and control group). Experimental group again 3 months and 6 months after finishing the intervention.

Intervention

The experimental group receives an innovative e-Mental Health intervention, called ‘Dementie de Baas’ (‘Mastery over Dementia’). The intervention consist of 8 lessons and a booster session (follow-up). Working principles are psycho education, cognitive behavioral therapy, problem solving behavior, assertiveness training and relaxation therapy. Participants are in contact with a professional counselor (digital coach) who gives them feedback. The control group receives a minimal intervention. The participants will receive a serie of information bulletins sent every two weeks by e-mail. There is no contact with a professional counsellor.

Contacts

Public
Trimbos-institute, Netherlands Institute of Mental Health and Addiction,
P.O. Box 725

A.M. Pot
Utrecht 3500 AS
The Netherlands
Scientific
Trimbos-institute, Netherlands Institute of Mental Health and Addiction,
P.O. Box 725

A.M. Pot
Utrecht 3500 AS
The Netherlands

Eligibility criteria

Inclusion criteria

(1) informed consent given; (2) insufficient knowledge or computer skills; (3) depressive symptoms in specific range (CES-D score: 12-26).

Exclusion criteria

(1) severe psychiatric problems for which immediate treatment or referral is needed; (2) current treatment for psychiatric problems; (3) suidical thoughts.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-05-2009
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-10-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33462
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1934
NTR-old	NTR2051
CCMO	NL27434.097.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33462

Study results