

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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20265

Bron

Nationaal Trial Register

Verkorte titel

RCT-DDB

Aandoening

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.

Ondersteuning

Primaire sponsor: VU University Amsterdam, Department of Clinical Psychology in collaboration with Netherlands Institute of Mental Health and Addiction.

Overige ondersteuning: Univé (Health Insurance), Geriant, Alzheimer Nederland, VU University, the Netherlands Institute of Mental health and Addiction

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Depressive symptoms as measured by the CES-D.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	31-05-2009
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	11-10-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33462
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten