Effectiveness of iSupport for unpaid carers of people with dementia: a randomised controlled trial.

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28037

Bron
Nationaal Trial Register

Verkorte titel
iSupportNL

Aandoening

dementia, informal caregivers intervention, online support programme, e-health intervention

Ondersteuning

Primaire sponsor: Faculty of Behavioural and Movement Sciences, VU University
Overige ondersteuning: This project is part of a European Marie Curie Innovative Training Network (ITN) action, H2020-MSCA-ITN-2015, under grant agreement number 676265 funded by the European Commission.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter will be caregivers’ stress at post-intervention. This will be measured with the Perceived Stress Scale (PSS14).

Toelichting onderzoek

Achtergrond van het onderzoek

This project aims to determine the effectiveness of an online intervention (iSupport) for dementia carers to decrease carers' stress, burden, and symptoms of depression and anxiety. This online support programme includes several CBT techniques like problem-solving, relaxation and cognitive reframing as well as psycho-education. The content of the intervention consists of 23 lessons organized around 5 modules: What is Dementia?, Being a caregiver, Caring for Me, Providing everyday care, and Dealing with Challenging Behaviour. All the lessons are personalized and include small exercises with instant feedback.

A superiority two-arm randomized controlled trial comparing the effects of the online support programme with a waitinglist control group will be carried out from 2019 to 2020 in The Netherlands. Unpaid carers (n=200), experiencing at least some stress or burden, will be recruited through websites, national caregivers associations, and advertisements in newspapers, magazines, etc. The experimental group (n=100) will be provided access to the intervention for three months while those in the waiting-list group (n=100) will be granted access to the intervention after three months. Assessments will be done at baseline (t0), 3 months after baseline (post-intervention, t1), and 6 months after baseline (follow-up, t2). Comparison between groups and the size of the intervention effect at post-test and follow-up will be analysed.

Doel van het onderzoek

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Onderzoeksopzet

Data will be collected via internet at baseline (T0), 3 months after baseline (T1) and 6 months after baseline (T2)

Onderzoeksproduct en/of interventie

The trial contains two arms: (1) iSupport and (2) a comparison group which will receive a minimal intervention which consists of psycho-education about dementia.

-iSupport:

iSupport is an online support programme to enhance self-help, skills, and support for caregivers of people with dementia. The iSupport online intervention is based on the principles of Cognitive Behavioral Therapy (CBT), and includes techniques like problem solving, relaxation, and cognitive reframing.

iSupport consists of twenty-three lessons, distributed over five modules: What is Dementia? (1 lesson); Being a caregiver (4 lessons); Caring for Me (3 lessons); Providing everyday care (5 lessons), and; Dealing with Challenging Behaviour (10 lessons). Each caregiver can choose which lessons they like to do, depending on their needs, and when they like to complete them. The program will be available via personal computers and tablets.

-Minimal intervention (Comparison condition):

Participants assigned to comparison group will receive psycho-education about dementia and caregiver stress. This is based on information provided by Alzheimer Nederland. This information will be made avalaible online (eBook) and in printed format. Caregivers can choose which format they prefer. Next to this psycho-education caregiver are allowed to receive care-as-usual. They can search for other information or seek help from other providers. After the last assessment, 6 months after baseline, the caregivers in this group will be offered to access to iSupport.

Contactpersonen

Publiek

Faculty of Behavioural and Movement Sciences (VU Amsterdam)
Ángel C. Pinto Bruno
van der Boechorststraat 1

Amsterdam 1081 BT
The Netherlands
+31205986727

Wetenschappelijk

Faculty of Behavioural and Movement Sciences (VU Amsterdam)
Ángel C. Pinto Bruno
van der Boechorststraat 1

Amsterdam 1081 BT

The Netherlands
+31205986727

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1) Be aged 18 years or older;

2) Be an unpaid carer (partners, children, friends, etc) of a person with dementia for at least 6 months and experience at least some caregiver burden. This is assessed with one item on which the person can score the burden between 1 (no burden) and 10 (extreme burden). People with a score of 4 or higher will be included;

3) Well-being needs to be affected and might be expressed as stress, depressive symptoms or anxiety. This mean that people need to have a score of > 13 on the Perceived Stress Scale (PSS14) or a score ≥4 on the Hospital Anxiety and Depression Scale, anxiety subscale (HADS-A)), or a score ≥4 on the Centre for Epidemiological Studies Depression scale (CES-D);

4) The care recipient has to have a confirmed diagnosis of dementia (through self-report of the caregiver) or a score ≥2 on the Ascertain Dementia 8-item Informant Questionnaire (AD8).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1) Those receiving psychological treatment from a mental health specialist at the time of recruitment;

2) Being unable to comprehend written Dutch;

3) No access to internet.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-01-2019
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6417
NTR-old	NTR6593
Ander register	METC / EMGO scientific committee / VCWE scientific and ethical committee : 2017.331 / WC2017-044 /

Resultaten