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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28037

Source
Nationaal Trial Register

Brief title
iSupportNL

Health condition

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

Sponsors and support

Primary sponsor: Faculty of Behavioural and Movement Sciences, VU University
Source(s) of monetary or material Support: 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.

Intervention

Outcome measures

Primary outcome

The main study parameter will be caregivers’ stress at post-intervention. This will be

measured with the Perceived Stress Scale (PSS14).

Secondary outcome

The secondary study parameters can be grouped into three categories. First, mental health outcomes. This includes: symptoms of depression (Centre for Epidemiological Studies Depression scale (CES-D)), symptoms of anxiety (Hospital anxiety and depression scale, anxiety sub-scale (HADS-A)), and caregiver burden (Zarit Burden Scale (ZBS). The second category of outcomes relate to the way caregivers perceive that they can cope with the situation and the person with dementia. It includes: general sense of mastery (Pearlin Mastery Scale), self-efficacy (RIS) which relate to the feeling that one can perform a certain task in a given situation competently and capably, sense of competence (Short Sense of Competence Questionnaire (SSCQ)) of the caregiver to care for the person with dementia, and the way the caregiver approaches the person with dementia (ADQ) which measures specifically if the caregiver can see the person with dementia as a unique and valuable person. The third category consists of usability (System usability scale (SUS)) which evaluates the satisfaction about the intervention as a whole. Next to this we will measure satisfaction with every lesson but this is incorporated into the intervention itself. Finally, we will gather data about the number of logins and the time spend on the intervention as indicators of intervention adherence.

Study description

Background summary

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.

Study objective

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Study design

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

Intervention

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.

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

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):	22-01-2019
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6417
NTR-old	NTR6593
Other	METC / EMGO scientific committee / VCWE scientific and ethical committee : 2017.331 / WC2017-044 /

Study results