

E-care 4 caregivers

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24595

Source

Nationaal Trial Register

Brief title

Not applicable

Health condition

subjective experienced caregiver burden and psychological symptoms (depression, anxiety and stress).

Sponsors and support

Primary sponsor: Primary: VU University of Amsterdam (VU Amsterdam), department of Clinical Psychology. Secondary: Depression Association (Depressie Vereniging).

Source(s) of monetary or material Support: Mental Health fund (Fonds Psychische Gezondheid) ID20146819, VSB fund ID20141096, NutsOhra fund ID1303065.

Intervention

Outcome measures

Primary outcome

Psychological stress as measured by the Kessler-10

Secondary outcome

Subjective experienced burden as measured by ZARIT-12. Depressive symptoms, measured by Kessler-10. Anxiety symptoms as measured by GAD-7. Quality of life, measured by EuroQol. Experienced control over the situation, measured by the Dutch version of the Mastery Questionnaire. User-friendliness of the online intervention, measured by the System Usability Scale. Evaluation of the online intervention, its applicability and its user-friendliness as assessed by participants in a qualitative telephone interview.

Study description

Background summary

Background: Informal caregivers are highly important in everyday life for depressed patients. Yet, informal caregivers experience more overburdening, stress- and anxiety symptoms. **Methods and design:** An online self-management intervention will be developed and studied in a pilot-RCT (N=40). In stage one, the intervention will be developed using results from a literature study and two focus groups (professionals and 'experts by experience'). In stage two, participants will be recruited and randomly assigned to one of two conditions: experimental and waitlist control group. Participants will be assessed at baseline and post-test. Primary outcome measure is subjective experienced burden. Secondary outcome measures are psychological stress, depression, anxiety and quality of life. A qualitative analysis will be performed post-intervention assessing user-friendliness and feasibility satisfaction. **Discussion:** This intervention could potentially benefit informal caregivers as well as patients and professionals indirectly. It could also lead to a more comprehensive healthcare structure around depressed people.

Study objective

This pilot intervention has two main hypotheses: 1) The online self-management course for the non-professional caregiver of a depressive patient is accessible and feasible; and 2), The online self-management course will increase mental resilience and self-reliance, improve quality of life, prevents and/or decreases subjective experienced burden and psychological symptoms in the non-professional caregiver (depression, anxiety and stress).

Study design

There will be a pre-and a post-test measurement, using the following questionnaires: Kessler-10, Generalized Anxiety Disorder scale, EUROQOL, Pearlin Mastery Scale, Zarit Burden Interview and the System Usability Scale. There will also be a qualitative semi-structured telephone interview post-intervention.

Intervention

Intervention group: online intervention based on CBT principles and psychoeducation, waitlist control group.

Contacts

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Eligibility criteria

Inclusion criteria

Being an informal (not necessarily the principal) caregiver for a person with depressive symptoms, minimum age of 18 years, Dutch' proficiency, access to the internet and providing informed consent.

Exclusion criteria

Professional caregivers

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	70
Type:	Actual

Ethics review

Positive opinion	
Date:	30-06-2015
Application type:	First submission

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	NL5128
NTR-old	NTR5268
Other	EMGO+ institute : WC2015-028

Study results

Summary results

Not applicable