

Effectiveness of the web-based self-management intervention 'Partner in Balance' for family caregivers of people with early-stage dementia

No registrations found.

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

Summary

ID

NL-OMON24958

Source

NTR

Brief title

PrepAD

Health condition

Intervention, e-health, self-management, family/informal caregivers, dementia, MCI (Mild Cognitive Impairment), online, computer, prevention

Interventie, e-health, zelfmanagement, mantelzorgers, dementia, MCI (milde geheugenproblemen), online, computer, preventie

Sponsors and support

Primary sponsor: Maastricht University Medical Center (MUMC+)

P. Debyelaan 25

6229 HX

Maastricht

The Netherlands

Source(s) of monetary or material Support: Maastricht University Medical Center (MUMC+)

P. Debyelaan 25
6229 HX
Maastricht
The Netherlands

Intervention

Outcome measures

Primary outcome

The effect evaluation of the online self-management program will be based on the Stress and Coping Model (Lazarus & Folkman, 1984) and the Social Learning theory (Bandura, 1977). The underlying assumption of these models and the findings from previously executed studies in the line of the current research (systematic review (Boots, de Vugt et al. 2013) and focus group study (Boots et al., in preparation)) has resulted in an ambitious set of measures aimed at self-care and goal achievement to promote more healthy behavior. The self-management programme aims to strengthen caregivers in the early stages and increase their confidence level. Therefore, our primary proximal outcomes will be feelings of self-confidence in spouses. The primary distal outcome will be depressive complaints in the spouse.

Secondary outcome

Secondary proximal outcome is experienced control and goal attainment. Secondary distal outcome is psychological complaints. Possible mediating factors of the online self-management program on the primary outcome measures (e.g. coping style, emotional instability and quality of the relationship with the patient) will also be evaluated.

Study description

Background summary

N/A

Study objective

The null-hypothesis states that there is no difference before and after participating in the self-management intervention 'Partner in Balans' and that there is no difference between the intervention group and the waitlist-control group in participant's subjective well-being. The alternative hypothesis states that there is a difference within and between groups after participating in the self-management program. We expect the alternative hypothesis to be true, with an improved subjective self-confidence (increased self-efficacy) and a decreased or

constant level of depressive complaints after participation in the self-management intervention.

Study design

Data will be collected pre- and post-intervention/control period and at 3, 6 and 12 months follow-up.

Intervention

Participants will be asked to participate in an online self-management program called "Partner in Balans" over an 8-week period. In addition, they will meet twice with a personal coach. The online program will make use of a self-management program, aimed at learning skills and taking the personal needs of the caregivers as starting point. Online self-management programs have already been used to support patients and caregivers and show promising results. The Stress and Coping model by Lazarus and Folkman (1984) and the Social Learning theory by Bandura (1977) also served as the theoretical framework for the development and evaluation of the program. In addition, the program was based on the knowledge and experience of the target group (by means of focus group interviews) and professionals (individual interviews) who deal with MCI/dementia caregivers on a daily basis.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- Family caregiver of people with Mild Cognitive Impairment (MCI) or mild dementia of all subtypes as described in the Diagnostic and Statistical Manual of Mental Disorders
- Caregiver has access to the Internet at home and already masters basic skills in the use of computers.
- Written informed consent is obtained.

Exclusion criteria

- Caregivers who have insufficient cognitive abilities to engage in the online self-management program (based on clinical judgment of knowledgeable practitioner, based on his/her experience with the target group).
- Caregivers who are overburdened or have severe health problems (based on clinical judgment of knowledgeable practitioner, based on his/her experience with the target group).
- Caregivers who's current or near-future situation demands acute, intensive counselling (based on clinical judgment of knowledgeable practitioner, based on his/her experience with the target group).
- Caregivers of people with dementia caused by human immunodeficiency virus (HIV), acquired brain impairment, Down syndrome, chorea of Huntington or alcohol abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	08-08-2014
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 20-08-2014

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42080

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4589
NTR-old	NTR4748
CCMO	NL48760.068.14
OMON	NL-OMON42080

Study results

Summary results

N/A