

Informal caregivers are key figures in ALS and PMA care, take care of them!

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To investigate the effectiveness of a psychological support program especially designed on the needs of ALS and PMA caregivers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Family issues
Study type	Interventional

Summary

ID

NL-OMON46256

Source

ToetsingOnline

Brief title

ALS and PMA caregivers

Condition

- Family issues

Synonym

distress, Emotional functioning

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Stichting ALS Nederland

Intervention

Keyword: Amyotrophic Lateral Sclerosis, E-mental health, Informal caregivers, Progressive

Outcome measures

Primary outcome

The main study outcome is the emotional functioning of the caregiver assessed with the Hospital Anxiety and Depression Scale.

Secondary outcome

Secondary outcomes are the caregiver burden, caregiver quality of life, quality of life of the patient and emotional functioning of the patient

Study description

Background summary

Caregivers are key figures in ALS and PMA care as patients become increasingly dependent of their care during the disease course. ALS and PMA caregiving is an intensive task and involves stressful demands. Caregivers* emotional functioning deteriorates as the disease progresses. Improving the emotional functioning of caregivers may not only improve the wellbeing of caregivers but also the wellbeing of patients.

Study objective

To investigate the effectiveness of a psychological support program especially designed on the needs of ALS and PMA caregivers.

Study design

We will investigate the effects of the psychosocial support program in a randomized waitlist controlled trial. Caregiver-patient dyads will be asked to fill in questionnaires on 4 occasions during the study: baseline, 3 months, 6 months and 9 months.

Intervention

The psychosocial support program consists of one face-to-face contact, 6 online guided modules and one telephone contact directly after randomization. The

online program entails 6 modules based on Acceptance and Commitment therapy with information, psychological exercises and meditation exercises aimed at Mindfulness. Participants will receive weekly feedback from a psychologist. The program offers the opportunity to get in contact with other informal ALS or PMA caregivers.

Study burden and risks

During 9 months informal caregivers and patients will complete four online assessments in total. The first assessment for the caregivers is more extensive than the other three assessments. For caregivers the time investment for completing the assessment ranges from 25-35 minutes for the first assessment to 20-30 minutes for the follow up assessments. Total time investment for participating patients is limited to 20 minutes (fill in the four questionnaires, which takes 5 minutes per questionnaire). To limit the burden of the intervention for the caregivers, the face-to-face session will take place at the participants* homes and the rest of the supportprogram is offered online. Participants may benefit from the interventions. There are no known risks for participating in this study.

Contacts

Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Scientific

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

The research population consists of informal caregivers and the ALS and PMA patients they provide care for. In order to be eligible to participate in this study, caregiver-patient dyads must meet all of the following criteria:

- * The caregiver is the partner of the ALS or PMA patient
- * The informal caregiver is 18 years or older
- * The informal caregiver and the patient have access to the Internet
- * The patient gives the caregiver permission to answer questions which are related to the patient and the disease of the patient.
- * The caregiver and the patient are able to complete Dutch questionnaires; When patients indicate they do not want to participate in the study, caregivers are allowed to participate without the patient. The inclusion criteria remain in force.

Exclusion criteria

- * The caregiver participates in the ALS-CarE study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2017
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO	
Date:	22-06-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	17-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	14-09-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	29-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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

CCMO

ID

NL56989.041.16