

ALS caregivers

No registrations found.

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

Summary

ID

NL-OMON28612

Source

NTR

Health condition

The emotional functioning of caregivers of people with Amyotrophic Lateral Sclerosis (ALS).

Sponsors and support

Primary sponsor: University Medical Center Utrecht

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

Intervention

Outcome measures

Primary outcome

The emotional functioning of the caregiver measured with the Hospital Anxiety and Depression Scale (HADS).

Secondary outcome

Secondary outcomes are the feelings of caregiver burden (Zarit Burden Scale) and quality of life of the caregiver (Care Related- Quality of Life) and the quality of life (McGill Quality of Life Questionnaire- Single Item Scale) and emotional functioning of the patient (Hospital Anxiety and Depression Scale).

Study description

Background summary

Caregivers are key figures in ALS care as patients become increasingly dependent of their care during the disease course. ALS 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. In this study we will investigate the effects of a psychosocial support program based on Acceptance and Commitment Therapy in a randomized waitlist controlled trial. Caregiver-patient dyads will be asked to fill in questionnaires on 3 occasions during the study: baseline, 3 months and 6 months. The main study outcome is the emotional functioning of the caregiver assessed with the Hospital Anxiety and Depression Scale. Secondary outcomes are the caregiver burden, caregiver quality of life, quality of life of the patient and emotional functioning of the patient. Group differences in primary and secondary outcomes will be compared with linear mixed model analysis.

Study objective

A psychological supportprogram based on Acceptance and Commitment Therapy improves the emotional functioning of caregivers of people with Amyotrophic Lateral Sclerosis(ALS).

Study design

Baseline, 3 months and 6 months after baseline.

Intervention

A psychological supportprogram based on Acceptance and Commitment Therapy.

Contacts

Public

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, caregiver-patient dyads must meet all of the following criteria:

1. The informal caregiver is the partner of an ALS patient
2. The informal caregiver is 18 years or older
3. The informal caregiver and the patient have access to the Internet

Exclusion criteria

Caregiver-patient dyads who meet any of the following criteria will be excluded from participation in this study:

1. The caregiver or patient is unable to complete questionnaires due to insufficient mastery of the Dutch language
2. The caregiver is diagnosed with a severe psychiatric disorder or physical disorder
3. The patient is diagnosed less than 3 months ago
4. The patient has a life expectancy of less than six months

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	16-06-2016
Enrollment:	140
Type:	Anticipated

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	NL5627
NTR-old	NTR5734
Other	METC UMC Utrecht : 16/273

Study results