Aerobic Exercise Therapy and Cognitive Behavioural Therapy in Amyotrophic Lateral Sclerosis: effects on activities and quality of life.

No registrations found.

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

Summary

ID

NL-OMON20642

Source
NTR

Brief title
FACTS-2-ALS

Health condition

Amyotrophic Lateral Sclerosis, Quality of life, Cognitive Behavioural Therapy, Aerobic Exercise therapy, Neuromuscular diseases.

Amyotrofische Lateraal Sclerose (ALS), Kwaliteit van Leven, Cognitieve GedragsTherapie, Aerobe Fysieke Training, NeuroMusculaire Ziektes

Sponsors and support

Primary sponsor: University Medical Centre Utrecht, Department of Rehabilitation
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development, Prinses Beatrix Fonds

Intervention

Outcome measures

Primary outcome

Quality of Life and activities.

Secondary outcome

1. Functional capacity of the patient: cardiorespiratory fitness, strength endurance of the quadriceps, isokinetic muscle strength of the quadriceps, lung function, functional tests, fatigue and pain;

2. Cognitive behavioural aspects of the patient: coping, illness cogitions, personality, mood, impact of event, competences, social suppport;

3. Partner of the patient: quality of life, coping, mood, caregiver strain.

Study description

Background summary

Rationale:

Amyotrophic lateral sclerosis (ALS) is a progressive, fatal disease, characterised by loss of motor neurons in the cortex, brainstem, and spinal cord. Patients have progressive wasting and weakness of limb, bulbar, and respiratory muscles, and die on average within 3 years of symptom onset, usually because of respiratory failure. Muscle weakness may result in the avoidance of physical activity, which consequently enhance the disuse weakness and cardiovascular deconditioning. The impact of the infaust prognosis may also result in depressive symptoms and hopelessness. Since ALS is not considered curable, rehabilitation management is the mainstay of treatment. We hypothesize that to preserve daily activity and Quality of Life on the highest achievable level, two distinctly different therapeutic interventions may be added to the current multidisciplinary treatment program: aerobic exercise therapy (AET) to maintain or enhance functional capacity and cognitive behavioural therapy (CBT) to improve coping style and cognitions in ALS-patients and/or partners. However, evidence to support either approach is still insufficient and understanding of the underlying mechanisms of the approaches is unclear. There is preliminary evidence for the effectiveness of exercise in ALS. CBT has been proven effective in a.o. patients with Multiple Sclerosis and patients with fatigue after cancer. There is need for rigorous, appropriately controlled assessment of the efficacy of these interventions for ALS patients.

Objectives:

1. To study the efficacy of AET and CBT for improving activities and QoL in patients with ALS;

2. To identify determinants of effectiveness of AET and CBT;

3. To obtain insight into patients' and partners' expectations of and experiences with both interventions.

Study design:

A multicentre, single-blinded, randomized controlled clinical trial. A Zelen design randomisation will be used.

Study population:

A sample of 75 patients with ALS (3 months post-diagnosis), aged 18-70 years recruited from 3 different university hospitals.

Intervention: The 75 patients will be randomized to one of three groups i.e.
1. AET + usual care. AET consists of aerobic exercises for a period of 16 weeks, 3 days a week, twice at home and once a week in an individually guided group session in a hospital or rehabilitation centre;

2. CBT + usual care. CBT consist of 5 to 10 sessions with a psychologist in a period of 16 weeks;

3. Usual care.

Main study parameter:

At baseline, completion of the intervention and at 3- and 6-months follow-up, quality of life (ALSAQ-40, SF-36), activities (LAPAQ, IPA) and secondary outcome measures will be assessed.

Nature and extent of the burden and risks associated with participation and benefits:
All patients will be asked to visit the university hospital 4 times over the study period of 10 months to participate in a physical examination. The duration of these examinations will be

less than 2 hours. Additionally, patients receive questionnaires to fill out at home. The duration for completing the questionnaires is approximately 1 hour. There are no costs related to the interventions for the patients.
Possible medical risks related to the aerobe exercise therapy tests are considered low. All participating centres are well experienced in providing exercise therapy in patients with different neuromuscular diseases. Therefore, the occurrence of medical events is considered minimal. Patients allocated to the AET intervention group are supposed to participate in a 16 – week group and home aerobe exercise program of 2 hours a week. According to results of pilot studies, the aerobe exercise program is feasible and safe. The CBT intervention, 5 to 10 hours in 16 weeks, is provided by experienced psychologists.

Considering the positive effects of both the AET as well as CBT known from preliminary pilot studies it can be concluded that the benefits outweigh the burden and minimal risk associated with this study.

Study objective

It is hypothesized that aerobic exercise therapy (AET) and cognitive behavioural therapy (CBT) are both effective in improving activities and QoL in patients with Amyotrophic Lateral Sclerosis (ALS) compared to the usual care.

Study design

1. At baseline t=0;

2. after the treatment period t = 4 months;

3. after three motnhs follow-up t = 7 months;

4. aftre 6 months follow-up t = 10 months.

Intervention

(Exp. group 1) AET + usual care. AET consists of aerobic exercises for a period of 16 weeks, 3 days a week, twice at home and once a week in an individually guided group session in a hospital or rehabilitation centre.

(Exp. group 2) CBT + usual care. CBT consist of 5 to 10 sessions with a psychologist in a period of 16 weeks in a hospital.

(Control group 3) Usual care.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 18 and 70 years;

2. A life-expectancy longer than one year;

3. Forced Vital Capacity at least 80%;

4. Diagnosis of "Probable" of "definite" ALS according to the "revised El Escorial WFN criteria";

5. At least 3 months post-diagnosis ALS;

6. Being in the rehabilitation phase; diagnotic phase is completed;

7. Walking-ability with or without a ankle-foot orthotic or stick and cycling-ability on a bicycle ergometer, in that capacity that the intervention is expected to be completed.

Exclusion criteria

1. Cognitive impairment;

2. Insufficient mastery of the Dutch language;

3. Disabling co-morbidity interfering with the intervention programs or influencing outcome parameters (including severe cardiopulmonair disease, like chest pain, arrhytmia, pacemaker, cardiac surgery, sever dyspnoea d'effort or emphysema, epileptic seizures, poorly regulted diabetes mellitus or hypertension;

4. Psychological disorder, in that capacity that the intervention could not be completed.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	75
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	NL1545
NTR-old	NTR1616
Other	ZonMW : 89000003
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A