Quality of Life and Rehabilitation Care in Amyotrofic Lateral Sclerosis.

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(1) To study the efficacy of AET for improving activities and QoL in patients with ALS. (2) To identify generic and disease-specific determinants of effects. (3) To obtain insight into patients* , partners* and professionals' expectations of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON39262

Source
ToetsingOnline

Brief title
FACTS-2-ALS

Condition

- Neuromuscular disorders

Synonym
Amyotrophic Lateral Sclerosis, muscular disease, neuromuscular disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW en Prinses Beatrix Fonds

Intervention

Keyword: Aerobic Exercise Therapy, Amyotrophic Lateral Sclerosis, Quality of Life

Outcome measures

Primary outcome

Quality of life (ALSAQ-40, SF-36), activities (LAPAQ, IPA)

Secondary outcome

Functional capacity.

Patients*, partners* and professionals* expectations of and experiences with

the AET intervention.

Study description

Background summary

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 and consequently in decline of Quality of Life (QoL). 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, a therapeutic intervention can be executed: aerobic exercise therapy (AET) to maintain/enhance functional capacity in ALS-patients. However, evidence to support this approach is still insufficient and understanding of the underlying mechanisms of the approache is unclear. There is preliminary evidence for the effectiveness of exercise in ALS. There is need for rigorous, appropriately controlled assessment of the efficacy of this intervention for ALS patients.

Study objective

(1) To study the efficacy of AET for improving activities and QoL in patients with ALS. (2) To identify generic and disease-specific determinants of effects.

(3) To obtain insight into patients* , partners* and professionals' expectations of and experiences with the AET intervention.

Study design

A multicentre, single-blinded, randomized controlled clinical trial. A *post-poned* information model randomisation will be used.

Intervention

The 80 patients will be randomized to one of two groups i.e. (1) aerobe exercise therapy (AET) + usual care. AET consist 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 (2) Usual care.

Study burden and risks

All patients will be asked to visit the university hospital / rehabilitation centre 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 a pilot study, the aerobe exercise program is feasible and safe.
Considering the positive effects of AET known from preliminary pilot study it can be concluded that the benefits outweigh the burden and minimal risk associated with this study.
In order to obtain insight into patients*, partners* and professionals* expectations of and experiences with the AET intervention, individual interviews and focus groups will be organised, with a duration of a maximum of 2 and 3 hours, respectively. There are no risks associated with this responsive research methodology.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age between 18 and 80 years
2. A life-expectancy longer than one year
3. Forced Vital Capacity at least 80%
4. Diagnosis of "Probable" or "definite" ALS according to the "revised El Escorial WFN criteria"
5. At least 1 month 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2010
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	21-07-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-07-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-04-2013
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	ID
CCMO	NL26331.041.08

Study results

Date completed: 21-02-2016

Actual enrolment: 72

Summary results
Trial is onging in other countries