

# Case management in patients with Amyotrophic Lateral Sclerosis and their caregivers

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21038

### Source

NTR

### Brief title

ALS-case management

### Health condition

Amyotrophic Lateral Sclerosis, ALS

## Sponsors and support

**Primary sponsor:** Netherlands ALS Centre Amsterdam, Utrecht, and Nijmegen

**Source(s) of monetary or material Support:** ZonMW (Palliative Care, 11500008)

## Intervention

## Outcome measures

### Primary outcome

Quality of life (ALSAQ-40)

### Secondary outcome

Patient:

- ALS specific symptomatology (e.g. fatigue, stiffness/spasticity, pain, breathing difficulty, cramps, sialorrhea: ordinal scale score)
- Delivery time of aids and adaptations (recording time procedure request-delivery).
- Actualisation of a PEG catheter and a meeting at the CTB (recording of the duration of the procedure issue-actualisation).
- Restrictions in activities (ALSFRS-R)
- Restrictions in autonomy and participation (IPA)

Caregiver:

- Caregiver burden (CSI).

Patient and caregiver:

- Quality of care (Quality of care questionnaire MITTZ)
- Depression and Anxiety (HADS)

## Study description

### Background summary

Previous research has shown that the quality of care for patients with ALS is insufficient, especially the collaboration of the various disciplines, timely delivery of the necessary aids and adaptations, the high frequency of unsatisfactorily treated, but well treatable symptoms and that the caregivers' total burden is high.

Case management appears to be the organisational solution. The case manager may provide a better symptom control since the coordinating and steering function leads to early interventions and early solutions to problems. In a randomized controlled trial the effectiveness of case management during 1 year on the quality of life of ALS-patients and the caregiver burden will be investigated.

### Study objective

Case-management in ALS improves quality of life of ALS-patients and reduces the caregiver burden.

## **Study design**

baseline (T0)

4 months (T1)

8 months (T2)

12 months (T3)

## **Intervention**

For 1 year a case manager maintains contact with ALS patients and their informal caregiver through home visits, telephone calls and e-mail designed to provide information regarding symptoms, aids and adaptations and interventions, to control disease symptoms, and to coordinate care with the person's specialized ALS care teams.

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

1. Diagnosed as clinically definite, clinically probable, clinically probable lab-supported or clinically possible Amyotrophic Lateral Sclerosis according to the El Escorial criteria.
2. Age > 18 years.

## Exclusion criteria

1. Insufficient proficiency in the Dutch language.
2. Cognitive impairment (diagnosed through the cognitive screening test: Mini Mental State Examination < 20).
3. Residence in a hospice/terminal care unit.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2008
Enrollment:	195
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	NL1225
NTR-old	NTR1270
Other	MEC AMC : 08/083
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A