# Treatment of severe fatigue after stroke. A study of cognitive therapy and physical exercise training in eight rehabilitation centres in the Netherlands.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21507

**Source**
Nationaal Trial Register

**Brief title**
COGRAT

**Health condition**

Post-stroke fatigue
Cognitive Rehabilitation
graded activity

CVA
vermoeidheid
cognitieve revalidatie

### Sponsors and support

**Primary sponsor:** The principal initiator for the study and promotor is:
Prof. dr. L. Fasotti
Donders Insitute for Brain, Cognition and Behaviour.
Radboud University Nijmegen, The Netherlands
**Source(s) of monetary or material Support:** ZonMW: The Netherlands Organization for

Health Research and Development

## Intervention

## Outcome measures

### Primary outcome

Fatigue severity (Checklist Individual Strength, fatigue severity score).

### Secondary outcome

1. Psychosocial well-being (SCL-90 & HADS);

2. Functional impairments (SA-SIP-30);

3. Physical condition (6 minute walking test);

4. Activity (actometers & registration);

5. Attention (SART & ANT);

6. Memory (RMBT & CVWLT);

7. Cognitive complaints (CIS-C, CFQ);

8. Coping (CISS);

9. Attribution (SES & FCS);

10. Social support (SSL).

# Study description

### Background summary

N/A

### Study objective

Stroke patients frequently complain of excessive fatigue, both in post-acute and in the chronic stage of their illness. The prevalence of severe fatigue is estimated between 28-73%, even in patients who seem to recover well. This may lead to impairments in daily functioning.

Although clinicians are aware that a treatmnet for PSF is urgently needed, there are no evidence-based treatments available. On the basis of positive outcomes of a pilot-study of a cognitive and physical treatment in the Maartenskliniek, the protocol was adapted and a multi-center randomised waiting-list controlled study proposed. This cognitive and graded activity training (COGRAT) is offered to stroke patients in the chronic phase (> 4 mnts post stroke), and compared to the Cognitive therapy alone, and waiting list condition.

The hypotheses are: Cognitive and Graded Activity Training (COGRAT) will be helpfull in decreasing chronic fatigue after stroke. Furthermore the addition of a Graded activity programme will enhance the effectiveness of the treatment.

**Study design**

All questionaires and tests are performed at all testing points (T1-T4).
T1: 3 months prior to randomisation and treatment;

T2: Prior to randomisation and treatment;

Randomisation;

Treatment (COGRAT, or Cognitive treatment alone);

T3: After treatment;

T4: 6 months post treatment follow-up.

**Intervention**

COGRAT consist of 2 arms given alongside during 12 weeks.

1. Cognitive strategy training: Frequency; 1x week for 2 hours (& homework) in small groups (max 4 patients). It consists of:

A. Patient education on fatigue after stroke and sleep hygiene;

B. Gaining insight into the individual activity and fatigability pattern by logging activities and fatigue;

C. Cognitive strategy training in order to prevent fatigue and manage existing fatigue. These strategies are: modification of activity patterns, improvement of planning abilities and the use of relaxation and leisure activities;

D. Cognitive behavioural Therapy (CBT) to enhance behavioural change and to assist in

managing existing fatigue.

2. Graded Activity Training: Frequency: 2x week, for 2 hours & homework assignments.

A. Walking on a treadmill (with increasing inclination);

B. Strength training;

C. Stretching;

Maximum heart rate and strength are increased from 40% at the beginning of the training and increased during the treatment to a maximum of 70% at the end of the 12 weeks.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Post-onset of stroke at least 4 months;

2. Age between 18 and 70 years;

3. Checklist Individual Strength (CIS) fatigue severity score of 40 or more;

4. Rivermead Mobility Index > 11/15 (able to walk independently).

### Exclusion criteria

1. Severe cognitive impairments (severe neglect, severe memory problems, severe planning problems, denial of illness);

2. Psychopathology (clinical interview and HADS-depression score >10);

3. Severe cardiac and pulmonary disease.

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 16-05-2007 |
| Enrollment: | 96 |
| Type: | Actual |

## Ethics review

Positive opinion

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|---|---|
| Date: | 20-01-2011 |
| Application type: | First submission |

# 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 | NL2579 |
| NTR-old | NTR2704 |
| Other | ZonMw / CMO-approved file number : 14350053 / 2007/139 ; |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
Cognitive and Graded Activity Training Can Alleviate Persistent Fatigue After Stroke: A Randomized, Controlled Trial.<br>
Aglaia M.E.E. Zedlitz, MSc; Toni C.M. Rietveld, PhD; Alexander C. Geurts, MD, PhD; Luciano Fasotti, PhD<br>
Stroke. 2012; 43: 1046-1051 Published online before print February 2, 2012, doi: 10.1161/STROKEAHA.111.632117