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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21507

Bron
Nationaal Trial Register

Verkorte titel
COGRAT

Aandoening

Post-stroke fatigue
Cognitive Rehabilitation
graded activity

CVA
vermoeidheid
cognitieve revalidatie

Ondersteuning

Primaire 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
Overige ondersteuning: ZonMW: The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-05-2007
Aantal proefpersonen:	96
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2579
NTR-old	NTR2704
Ander register	ZonMw / CMO-approved file number : 14350053 / 2007/139 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

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