Effectiveness of cognitive and graded activity training (COGRAT) on post stroke fatigue. A multi-center study.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON30647

Source
ToetsingOnline

Brief title
Effectiveness of COGRAT on PSF.

Condition

- Structural brain disorders
- Lifestyle issues

Synonym
fatigue after stroke, PSF

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Subsidie door ZonMw

Intervention

Keyword: cognitive rehabilitation, graded activity, Post Stroke Fatigue, stroke

Outcome measures

Primary outcome

The assessment comprise fatigue complaint lists, registrations of physical activity (with actometers) and neuropsychological tests to assess memory and attention.

Intervention effects will be examined with multivariate repeated measures analysis of variance (MANOVA) and multiple regression analysis.

Secondary outcome

Psychosocial questionnaires willl be used to assess coping, attributions, self-efficacy and social support.

Study description

Background summary

Stroke patients frequently complain of excessive fatigue, both in post-acute and in the chronic stage of their illness. This complaint is one of the major problems encountered in clinical practice and recent studies have confirmed thes clinical impressions: Post Stroke Fatigue (PSF) is ferquently reported after stroke, even by patients who seem to recover well, and it may lead to several impairments in daily functioning. Although clinicians are aware that a treament for PSF is urgently needed, there are almost no standardized treatmenst available, neither in Dutch hospitals, nor in rehabilitation centers. An exception is the Day Clinic for Brain Injury of the Sint Maartenskliniek in Nijmegen.
In this group intervention (6 to 7 patients per group), cognitive strategy trainig is combined with an individual graded activity program.
In a recent pilot-study the effectiveness of this combined approach has been investigated in 23 trained stroke patients, with effects beyound expectation. However, a well designed, prospective study of COGRAT is still lacking.

Study objective

Therefore the present study is aimed at answering the following question: does cognitive and graded activity training (COGRAT) lead to a clinically significant reduction of subjective fatigue complaints in stroke patients, when compared with cognitive training alone and with a no-treatment condition? Is this effect still present 6 months after training?
Secondary questions are:
1. is the reduction of fatigue complaints coupled to an improvement of physical activity in the trained group?
2. Is the reduction of fatigue complaints accompanied by a decrease of cognitive impairments in the fields of attention and memory, as measured by neuropsychological tests and as experienced by the patients?
3. Can (a) the level of initial physical activity, (b) the severity of the initial cognitive impairments, and (c) post onset time, significantly predict the effects of COGRAT treatment?

Study design

In a multi-center trial 96 stroke patients will participate in this study. Each patient will be submitted to a first measurement at admission. Then, every patient will be placed on a waiting list for three months (the so-called qualification period)and a second measurement will take place, just before random assignment to one out of two treatment conditions: (a) the full COGRAT training, (b) the cognitive part of COGRAT only. At the end of treatment, and 6 months after the end of treatment (follow-up) every participant will be assessed again.

Intervention

In this study patients will be given Cognitive trategy training for 12 weeks, depdending on the treatment condition accompanied by the Graded Activity training.

Compared withe the original treatment, COGRAT will be modified on the following points:
A. The cognitive strategy intervention will be extended with cognitive and behavioral strategies aimed at dealing more effectively with present fatigue, instead of offering only fatigue avoidance strategies.
B. Graded Acitvity will be better structured, by describing it in a protocol and basing it on the Exercise Programming Recommentdations for Stroke Survivors of the American Heart Association.
C. Based on the experience gathered in the pilot study, in which patients with information processing deficiencies derived less benefit from COGRAT, group size in the cognitive intervention will be limited to 4.

Study burden and risks

Patients will be asked to be placed on a waiting list for 3 months. They are tested on 4 different moments. The tests will consist of: walking with an acotmeter for a time period of one week, to establish actual taken steps per minute; questionnaires on social functioning and attributions, and neuropsychological tests to measure attention, concentration and memory. We do not expect any risks in involving this project.

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

- age between 18 and 70 years

- post onset at least 4 months
- Checklist Individual Strengt (CIS) fatigue-score of 40 or more
- Patient must be able to walk independently (as measured with the Rivermead Mobility Index > 11/15) and must be able to turn around an pick something up from the floor without losing balance (as measured with the Berg balance Scale > 48/56)

Exclusion criteria

- Be free from severe neglect symptoms (cut-off scores Bahevioral Inattention Test) , severe memory problems (Rivermead Behavioural Memory test screening score> 8), severe planning problems (Behavioural Assessment of Dysexecutive Syndrome score> borderline), severe denial of illness (clinical interview and questionnaire on denial), severe psychopathology and (premorbid) psychiatric problems, particularly depression (Beck Depression Inventory)
- be free from severe cardial problems (angina pectoralis or pacemaker/ventricular impairments)
- be free from severe pulmonal disease (severe dispnoe d'effort or severe pulmonal emphysema)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-05-2007
Enrollment:	96
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL15117.091.07