Cost effectiveness of augmented cognitive behavioural therapy for post stroke depression and anxiety

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON36300

Source
ToetsingOnline

Brief title
Restore - CBT study

Condition

- Mood disorders and disturbances NEC
- Vascular haemorrhagic disorders

Synonym
post stroke depression and anxiety. emotional complaints after stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: VSB-fonds via ZonMW

Intervention

Keyword: cognitive behavioural therapy, cost effectiveness, poststroke depression and anxiety, stroke

Outcome measures

Primary outcome

The main study parameter will be the HADS

Secondary outcome

Secondary parameters will be cost effectiveness, participation, quality of

life, goal attainment, and rehabilitation/treatment participation.

Study description

Background summary

Not only does stroke cause physical disability, it also has severe emotional consequences (e.g., anxiety and depression symptoms). Depression is a commonly reported neuropsychiatric complication of stroke. Most studies on treatment of Post Stroke Depression (PSD) have focused on medical interventions (e.g., antidepressants). In studies on treatment effects in depression Cognitive Behavioural Therapy (CBT) has been shown to decrease depressive symptoms and improve quality of life. Since there is a lack of research studying psychological interventions in PSD, and positive CBT treatment effects have been found in a pilot study, we will perform a randomised controlled trial on the treatment effects of an augmented CBT intervention in patients with post stroke depression and anxiety (PSDA). We expect this treatment to decrease patients* depression and anxiety symptoms and to increase the level of social activities and life satisfaction. In addition, the cost effectiveness of the intervention will be studied from a societal perspective.

Study objective

Our main objective is to investigate whether an augmented CBT leads to the reduction of depression and anxiety symptoms in stroke patients. We will compare the outcomes of this experimental treatment with a control intervention (i.e., computerized cognitive training) in which the elements that are hypothesized to be essential and effective in the augmented CBT intervention will not be offered. A secondary objective is to determine the costs of both

interventions in relation to the outcomes. Furthermore, we will investigate whether the experimental treatment will lead to higher levels of social activities, attainment of individual goals, life satisfaction and quality of life, compared to control treatment.

Study design

The present study will be a double blind randomised controlled trial. Post stroke patients and their significant others will be assessed at T0, pre-treatment; T1, post treatment; T2, 6 months post treatment; and T3, 12 months post treatment.

Intervention

The intervention consists of augmented cognitive behavioural therapy. CBT treatment will focus on registering, challenging and altering of negative thoughts, concomitant mood states, , cognitions and emotional symptoms, which comprise depression as well as anxiety. The CBT intervention is an individually administered psychological therapy. Treatment sessions will be given within a time span of 4 months (minimum 13, maximum of 16 sessions)

Study burden and risks

Subjects will have to meet their rehabilitation specialist (e.g., psychologist) for regular CBT treatment sessions, augmented with additional occupational or movement therapy. Next to that, they will have to keep up their homework in a workbook and possibly make use of a diary. There will be four measurements where subjects have to fill in multiple questionnaires, significant others will be assessed at the same moments in time, yet with a shortened set of questionnaires.

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

Subjects have suffered from symptomatic stroke (ischaemic, subarachnoid or intracerebral haemorrhagic lesion), first or recurrent, verified by CT and/or MRI scan.
- Subjects experience depression and/or anxiety symptoms, according to scores >=7 on the depression subscale of the Hospital Anxiety and Depression Scale (HADS).
- Subjects are >3 months post stroke.
- Subjects are at least 18 years of age or older.
- Subjects have sufficient communication and cognitive skills to engage in treatment (MMSE and NIHSS-item).
- Written informed consent.
- Subjects have sufficient knowledge of the Dutch language to speak and understand in Dutch. ;Significant Others
- Significant others are able to read and write in Dutch.
- Significant others are >18 years of age.

Exclusion criteria

Subjects* pre-existing impairment or history that might influence cognitive or functional outcome (pre-existent dependence in activities of daily living as defined by an estimated pre-morbid Barthel Index of 18).
- subjects staying in inpatient settings.
- subjects* co-morbidity that might affect outcome like cancer or psychiatric illnesses for which treatment is given at the moment of inclusion in the study, pre-existent cognitive decline as defined by a s score of 3.6 or higher on the IQCODE.
- Major Depression diagnosis in subjects that requires medication therapy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2011
Enrollment:	106
Type:	Actual

Ethics review

Approved WMO Date:	01-06-2011
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

ID: 21664

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL35333.091.11
OMON	NL-OMON21664