Restore4Stroke: Angst en depressie.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21664

Source
Nationaal Trial Register

Health condition

post stroke depression anxiety, depressie en angst na een CVA, beroerte

Sponsors and support

Primary sponsor: Nijmegen Medical Centre UMC St Radboud
Source(s) of monetary or material Support: VSB-fonds, ZonMw

Intervention

Outcome measures

Primary outcome

Hospital Anxiety and Depression Scale (HADS).

Secondary outcome

1. Utrechtse Schaal voor Evaluatie van Revalidatie-Participatie (USER-P), Utrecht Scale for Evaluation of Rehabilitation Participation;

2. The Stroke Specific Quality of Life (SSQoL);

3. The six-Dimensional EuroQuality of Life (EQ6D);

4. The post stroke depression rating scale (PSDRS);

5. Goal Attainment Scale (GAS);

6. The Pittsbugh Rehabilitation Participation Scale (PRPS);

7. Cost questionnaire.

Study description

Background summary

Rationale:
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.

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 an assessor blind randomised controlled trial. Post stroke patients and
their significant others will be assessed at T0, pre-treatment; T1, post treatment; T2, 4 months
post treatment; and T3, 8 months post treatment.

Study population:

This study will include 53 stroke patients (>3 months post stroke, living independently) with depression and anxiety problems measured with the Hospital Anxiety and Depression Scale (HADS Depression subscale score ≥ 7). Subjects will be included on the basis of case-finding in
participating hospitals and rehabilitation centres. Significant others will be included in the study as well.

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).

Main study parameters/endpoints:
The main study parameter will be the HADS.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
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.

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

T0: Pre intervention;
T1: Post intervention (4 months post TO);
T2: 4 months post intervention;
T3: 8 months post intervention.

Intervention

In this study, subjects in the experimental (PSDA) group will receive augmented CBT. The

CBT treatment will focus on registering, recognising and altering mood, negative thoughts, cognitions and emotional symptoms, which comprise depressive problems as well as anxiety.

The intervention protocol of this study has been discussed thoroughly with a group of clinical psychologists and senior health care psychologists, both experienced in stroke rehabilitation. This discussion led to a tailored CBT intervention for PSDA patients. The present study will use the augmented CBT intervention as an individual therapy. All treatment sessions will be given within a time span of 4 months, with a minimum of 13, and a maximum of 16 sessions. Each session will last 1 hour, excluding a 15 minutes break. However, the health care psychologist will determine the sequence of the various sessions and the individual (sub) goals and thereby tailors the intervention to the individual needs of the patient. Each treatment consists of 10 to 12 CBT sessions by an experienced health care psychologist, augmented with 3 or 4 sessions of occupational therapy or movement therapy. Each patient receives his own module booklet, which will facilitate the homework and give a summary and additional information about the sessions.

The CBT treatment will start with two introduction sessions together with the significant other and will be devoted to detailed problem analysis, including psychological, social and somatic factors possibly contributing to the depression and anxiety symptoms. Subsequently, in 3 sessions, patient and therapist will assess the current situation and possibilities of the patient, define current problems, explore and describe ideal situations. Accordingly the therapist will assist patients with restructuring their goals, consistent with their altered possibilities. After this restructuring phase, subject and therapist will develop and formulate specific goals they want to achieve by the program. In the third and final goal setting session the occupational or movement therapist will be present, in order to adjust the goals if necessary and plan the content of the occupational or movement therapy sessions. These sessions will serve as an optimal translation of therapeutic advice into practice and to resolve practical obstacles. The additional (3 to 4) sessions of occupational or movement therapy will be executed/carried out under supervision of the patients' health care psychologist. The following 5 sessions will focus on recognizing and challenging negative thoughts, and on increasing and incorporating pleasurable activities in daily life adjusted to the individual's physical and social constraints and to his/her previous leisure activities The last 2 sessions will be specifically directed at prevention of relapse by (self-) identification and acknowledgement of risk factors.

An extra occupational or movement therapy session is optional if high anxiety levels are present (HADS anxiety subscale >7). In this case we advise therapists to adjust the CBT protocol with additional relaxation session provided by the occupational or movement therapist. A relaxation tape with specific instructions will be provided by the investigator.

Treatment goals:

1. Reducing depressive and anxiety symptoms;

2. Increasing pleasurable activities;

3. Preventing relapse of anxiety and depressive symptoms after treatment;

4. Acceptance of current limitations.

The CBT intervention will be offered by a health care psychologist (GZ-psychologist) working in the participating institution, who has sufficient experience with the basic principles of CBT. In addition, occupational therapists and/or movement therapists will be enrolled in the intervention as co-therapists. Extensive training of the psychologists as well as the occupational and movement therapists will be provided by the research team. For evaluation and control of the CBT protocol regular follow-up meetings will be held in all participating institutions during the study. Patient satisfaction of the treatment will be registered.

Contacts

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Eligibility criteria

Inclusion criteria

Subjects:

1. Subjects have suffered a symptomatic stroke (ischaemic, subarachnoid or intracerebral haemorrhagic lesion), first or recurrent, verified by CT and/or MRI scan;

2. Subjects experience depression and/or anxiety symptoms, according to scores >7 on the depression subscale of the Hospital Anxiety and Depression Scale (HADS);

3. Subjects are at least >3 months post stroke;

4. Subjects are at least 18 years of age or older;

5. Subjects have sufficient communication and cognitive skills to engage in treatment (MMSE>27 and NIHSS-item);

6. Written informed consent;

7. Subjects have sufficient knowledge of the Dutch language to speak and understand in Dutch.

Significant Others:

1. Significant others are able to read and write in Dutch;

2. Significant others are >18 years of age;

3. Written informed consent.

Exclusion criteria

1. 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);

2. Subjects staying in inpatient settings;

3. 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. The referring MD will check and provide this information in advance;

4. 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:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	53
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-07-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36300
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2857
NTR-old	NTR2999
CCMO	NL35333.091.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36300

Study results

Summary results
N/A