

The evaluation of a group therapy for patients with depressive symptoms after stroke - a pilot study

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The objective of the study is to investigate the effect of the *Coping with depressive symptoms after stroke* course on depressive symptoms and quality of life in a waiting list controlled study.

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|------------------------------|---|
| Ethical review | Approved WMO |
| Status | Pending |
| Health condition type | Central nervous system vascular disorders |
| Study type | Interventional |

Summary

ID

NL-OMON29896

Source

ToetsingOnline

Brief title

Evaluation of a group therapy for depressive symptoms after stroke

Condition

- Central nervous system vascular disorders
- Mood disorders and disturbances NEC

Synonym

Depressive symptoms

Research involving

Human

Sponsors and support

Primary sponsor: iRv, Kenniscentrum voor Revalidatie en Handicap

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognitive behavioral therapy, depressive symptoms, group therapy, stroke

Outcome measures

Primary outcome

The study parameters are mood, depressive symptoms and health related quality of life.

Secondary outcome

nvt

Study description

Background summary

Depression is a frequent consequence of stroke. It has a negative influence on rehabilitation, quality of life and participation in society. In a previous pilot study by Praamstra et al. (2005) the *Coping with depressive symptoms after stroke* course was presented as an individual therapy and evaluated. The course seemed to have some positive effect on mood. The current study investigates an extended version of the course that will be presented as a group therapy.

Study objective

The objective of the study is to investigate the effect of the *Coping with depressive symptoms after stroke* course on depressive symptoms and quality of life in a waiting list controlled study.

Study design

This is a quasi-experimental waiting list controlled study. The first 6 participants will be assigned to the experimental group, the next 6 participants will be the control group. The pre- and posttest consist of several questionnaires. In between the experimental group will receive the course in 12 weekly sessions. During the course both groups report their mood 3 times a week. There will be a short follow-up by phone two months after the course. Afterwards, the participants from the control group will receive the

course when they want.

Intervention

The *Coping with depressive symptoms after stroke* course is a stroke adapted version of the *Coping with depression* course Dutch version by Cuijpers (1995). The course is expanded to give more attention to the theme *relaxation*. The course is given as a group therapy. The course leaders are a psychologist and a physiotherapist.

Study burden and risks

The expanded stroke adapted version of the course is shorter and less bothering to the participants than the original course by Cuijpers. Preferably, the subjects are daycare patients, so that they do not have to travel to the rehabilitation center for this research only.

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

- he/she is receiving treatment in the HRC for stroke
- he/she has sufficient cognitive abilities to follow the intervention, based on clinical judgement of a psychologist, with a Mini Mental State Examination score at least higher than 15
- he/she reports at least one emotional complaint on the CheckList for Cognitive and Emotional Consequences of Stroke (CLCE-24)
- he/she is at least 18 years old

Exclusion criteria

- insufficient understanding of the Dutch language
- severe aphasia
- insufficient physical abilities
- serious vision or hearing problems
- little or no insight into physical functioning, based on clinical judgement
- co-morbid neurological disorders other than stroke
- suffer or have suffered from a serious psychiatric disorder in the last five years for which he/she is treated for more than half a year by a psychiatrist
- he/she did not give permission

Study design

Design

| | |
|---------------------|---------------------------------|
| Study phase: | 2 |
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 10-04-2006
Enrollment: 12
Type: Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC SRL/iRv: St Revalidatie Limburg/iRv Kenniscentrum voor Revalidatie en Handicap (Hoensbroek)

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 | NL11491.022.06 |