The effectiveness of Problem Solving Therapy in stroke patients.

No registrations found.

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

Summary

ID

NL-OMON21620

Source
NTR

Brief title
PST in stroke

Health condition

Stroke

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: NWO

Intervention

Outcome measures

Primary outcome

The primary outcome measures are coping style and quality of life. These are measured using validated questionnaires at timepoints T0 (before intervention), T1 (after intervention), T2 (6 months after intervention) and T3 (12 months after intervention).

Secondary outcome

The secondary outcome measures are health care consumption, depression and participation. These are measured using validated questionnaires at timepoints T0 (before intervention), T1 (after intervention), T2 (6 months after intervention) and T3 (12 months after intervention). The cost-effectiveness of the intervention will be assesses as well.

Study description

Background summary

In the Netherlands, approximately 40.000 persons a year suffer from stroke. Stroke can have consequences in all areas of a person's life. If not coped with optimally, this life event will have a negative effect on the quality of life. Coping style is a persons preferred way of dealing with different circumstances. Coping style may be influenced by intervention. The aim of this study is to investigate the effectiveness of Problem Solving Therapy, a group training to improve coping style and quality of life of stroke patients. A randomized trial will be performed to assess the effectiveness of Problem Solving Therapy.

Study objective

After receiving PST, stroke patients will have a more effective coping style followed by a better quality of life.

Study design

Measurements are taken within three weeks before the intervention, within 10 days after the intervention, 6 months and 12 months after the intervention.

Intervention

Patients in the treatment condition will receive Problem Solving Therapy (PST), a group training for 8 weeks, in addition to standard care. The therapy teaches patients to solve problems in a systematic way, which we expect to influence coping style and quality of life. Patients in the control condition will receive standard care only.

Contacts

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Eligibility criteria

Inclusion criteria

1. First and only stroke;

2. Between 18 and 75 years of age;

3. Being treated in the outpatient phase of rehabilitation;

4. Able to follow a 1 hour groupsession each week;

5. Legally capable.

Exclusion criteria

1. Progressive neurological disorders;

2. Life expectancy less than 12 months;

3. Insufficient understanding of the Dutch language;

4. Drug or alcohol abuse;

5. Subdural haematoma.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Active

Recruitment

NL

Recruitment status: Pending

Start date (anticipated):   01-01-2011

Enrollment: 200

Type: Anticipated

Ethics review

Positive opinion

Date: 30-08-2010

Application type: First submission

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
NTR-new	NL2401
NTR-old	NTR2509
Other	NWO : 056-11-010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A