Coping in stroke patients: the effectiveness of Problem Solving Therapy

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Primary objective:Are coping style and quality of life different in patients receiving PST from patients receiving standard care after the intervention, after 6 months and after 12 months?
Secondary objectives:1. Are amount of health care...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON38227

Source
ToetsingOnline

Brief title
Effectiveness of PST in stroke

Condition

- Central nervous system vascular disorders

Synonym
cerebral vascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Rijndam Revalidatiecentrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Coping, Problem Solving Therapy, Stroke

Outcome measures

Primary outcome

The primary outcome measures are differences in coping style and quality of life between patients in the intervention and control group.

Secondary outcome

Secondary outcome measures are differences in health care consumption, depression, social participation and executive functioning between patients in the intervention and control group. Another secondary outcome measure is the cost-effectiveness of the intervention.

Study description

Background summary

In the Netherlands, 41.000 people suffer stroke each year. Over 3% of total health care costs are related to the treatment of stroke. Therefore, stroke is an important social problem. The question arises as how quality of life can be optimized after stroke, in order to minimize health care consumption and control the costs.
The average value stroke patients assign to quality of life is much lower than the average value assigned by a healthy reference population. Coping style is considered an important psychosocial factor with regard to quality of life of stroke patients. Coping style refers to the preferred style of dealing with different situations. By means of intervention coping styles can be influenced. Furthermore, stroke patients make less use of active, problem-oriented coping styles compared to other brain damaged patients. Consequently, it is important to investigate if coping style as well as quality of life can be improved through intervention. This can possibly be accomplished by increasing insight and teaching skills to solve problems actively in threatening situations.
Problem Solving Therapy (PST) is such an intervention.
Patients receiving PST are expected to learn a more effective coping style and consequently have a better quality of life than patients in the controlgroup.

PST has been proven effective in other patient populations. In stroke patients, incidence of depression is shown to decrease after PST. Effects on coping style and quality of life have not been investigated yet. Furthermore, we will investigate if the therapy will be effective in an open group design, instead of a closed design, whereby the therapy will be implemented more easily in the standard rehabilitation treatment. In an open, continuous group patients can join the group every moment. This design has not been investigated earlier in PST. In this study, we want to add the therapy to standard care just before the moment stroke patients finish their rehabilitation program and are thrown on their own resources. This is the moment where a relapse in quality of life is frequently observed, because patients cannot ask their therapists for help anymore. The cost-effectiveness of PST will be assessed as well. We expect patients to cope better with stressful situations after receiving PST, through which quality of life will increase and health care consumption will decrease, resulting in a reduction in health care costs.

Study objective

Primary objective:
Are coping style and quality of life different in patients receiving PST from patients receiving standard care after the intervention, after 6 months and after 12 months?

Secondary objectives:
1. Are amount of health care consumption, depression, social participation and executive functioning in patients receiving PST different from patients receiving standard care?
2. Is Problem Solving Therapy a cost-effective intervention in stroke patients?

Study design

A randomized controlled trial with one year follow-up will be performed to assess the effectiveness of PST. Patients will be randomized between the intervention and control group. Patients in the interventiongroup will receive PST in addition to standard care. Patients in the controlgroup will receive standard care only. Before the intervention, after the intervention, 6 months and 12 months later patients the outcome variables will be measured.

Intervention

Patients randomly assigned to the treatment condition will receive additional therapy at the end of the usual rehabilitation program for stroke patients. Patients assigned to the control condition will receive standard care only.
The therapy is based on Problem Solving Therapy. PST is a widely used intervention based on a common model of coping with stress. This model states having a chronic disease (suffering and rehabilitating from stroke in this

case) causes some stressful daily problems. These problems increase the chance of experiencing psychological stress and depressive feelings. Therefore, the aim of PST is to improve skills to cope with the stressing daily problems in life after suffering stroke. The intervention is empirically validated and proven effective in other chronically ill patients. The therapy for stroke patients will consist of 8 groupsessions, with a maximum of 6 participants. Solving problems will be structured:
1. defining problems
2. generating alternative solutions for a problem
3. considering the possible consequences of a solution systematically and selecting the best solutions
4. evaluating the results after implementation of the solution.

Study burden and risks

The burden of Problem Solving Therapy for patients in the intervention group will be 1 groupsession each week for 1 hour, during 8 weeks in the rehabilitation centre. Participating in the study does not bring any risks. The only possible negative consequence of the therapy is tiredness, wherefore the patient can be advised by the therapist.
At four timepoints, patients in both groups will be asked to fill in questionnaires with regard to coping style, quality of life, level of functioning, personality characteristics, depression, participation and health care consumption. Furthermore, patients will be given some neuropsychological tests with regard to attention, memory and executive functioning. The first measurement will take about 2 hours, the last 3 measurements will take about 1,5 hours.

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

stroke
between 18 and 75 years of age
treated at the out-patient rehabilitation clinic
able to follow psychotherapy during one hour every week

Exclusion criteria

progressive neurological disorder
life-expectancy less than 12 months
insufficient understanding of Dutch
drug- or alcoholabuse
subdural haematoma
moderate to severe aphasia (as measured by the token test)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2011
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-10-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL34056.078.10