# Restore: Clinical and cost-effectiveness of self management strategies in stroke patients and their partners.

No registrations found.

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

## Summary

### ID

NL-OMON23898

**Source**
Nationaal Trial Register

**Brief title**
Restore: RCT Self Management

**Health condition**

stroke, CVA (beroerte, CVA)

partners, spouses (partners)

### Sponsors and support

**Primary sponsor:** University Medical Center Utrecht (UMCU)/ Maastricht University
**Source(s) of monetary or material Support:** VSB-foundation and the Dutch Heart Foundation

### Intervention

### Outcome measures

**Primary outcome**

Patients' and partners' appraisals of their proactive coping competencies (assessed with the Utrecht Proactive Coping Competence list, the UPCC) and participation in society (assessed with the Utrecht Scale for Evaluation of Rehabilitation-Participation, the USER-P).

**Secondary outcome**

1. Patients' and partners' self-efficacy (assessed with the General Self Efficacy Scale, the GSES), general quality of life (measured with the Six Dimensional EuroQol, the EQ-6D), emotional functioning (assessed with the Hospital Anxiety and Depression Scale, the HADS);

2. Patients' health related quality of life (assessed with the Short Stroke-Specific Quality of Life scale, the SS-QoL-12) and life satisfaction (assessed with three questions). Partners' care related quality of life (assessed with the CarerQol) and experienced burden (assessed with the Expanded Caregiver Strain Index, the CSI+).

# Study description

**Background summary**

Rationale:

Many stroke patients report long term consequences in psychosocial functioning and social reintegration after discharge to their home situation. At home, patients mainly receive care and support from their family members. This situation can have a negative impact on both the stroke patients and their partners. Therefore, it is important for both patients and caregivers to learn how to deal, manage, cope and live with the long term consequences of the stroke and the considerable impact on their lives. In other chronic patient groups teaching patients self-management strategies resulting in active and realistic goal setting was a successful approach. Several studies have suggested that such interventions can also be effective for stroke patients.

Objective:

The aim of this study is to investigate the clinical and cost-effectiveness of a self-management group intervention aimed at proactive and self-management strategies compared to a control group education intervention for stroke patients and their partners.

Study design:

This study has a multi-centre randomized controlled trial design.

Study population:

At least 106 home-living stroke patients with social reintegration problems and their partners.

Intervention:

Either the 10-week self-management intervention or the 10-week education intervention. Afterwards, all subjects return to care as usual.

Study parameters:

The main study outcomes concern proactive coping measured with the Utrecht Proactive Coping Competence List (UPCC) and participation in society measured with the Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P).
Secondary outcomes comprise self-efficacy (General Self-Efficacy Scale) and emotional functioning (Hospital Anxiety and Depression Scale), general emotional functioning (Six Dimensional EuroQol) of patients and partners, life satisfaction (three questionnaires) and health related quality of life (short Stroke Specific QoL questionnaire) of patients and the partner's care related quality of life (CarerQoL) experienced caregiver burden (Expanded Caregiver Strain Index). A cost-questionnaire will be used to determine the economic impact.

## Study objective

The self management intervention aimed at proactive coping and self management strategies in stroke patients with social reintegration problems and their partners, will result in increased use of proactive coping strategies and increased levels of participation in society, and additionally increased levels of self-efficacy, life satisfaction and quality of life, and less emotional problems in patients and partners and to decreased levels of burden in partners.

## Study design

T0: Before treatment;

T1: After treatment;

T2: 3 months after treatment;

T3: 9 months after treatment.

## Intervention

The self management intervention will last ten weeks, with six two-hour group sessions in the first six weeks and one two-hour booster session one month later. During the sessions participants will practice with an action plan aimed at proactive coping around self set goals and four fixed themes concerning the domains of:

1. Lifestyle and fitness;

2. Social support and relations;

3. Participation in society;

4. Coping with negative feelings will be discussed.

Elements of the intervention are:

1. Provision of information;

2. Guided group discussions;

3. Formulation of goals and action plans;

4. Exercises and homework.

Four stroke patients with their possible partners will be present (total of 4-8 participants). The group sessions will be led by two health care professionals of the participating rehabilitation teams with experience in group counselling and working with brain injury patients.

The control intervention will comprise an education intervention, with 3 one-hour group sessions in the first six weeks and one one-hour booster session one month later. During the sessions participants will receive information around the themes:

1. The brain;

2. A stroke;

3. Consequences of stroke;

4. Prevention of stroke.

Elements of the intervention are:

1. Provision of information;

2. Homework.

Four stroke patients with their possible partners will be present (total of 4-8 participants). The group sessions will be led by one health care professionals of the participating rehabilitation teams.

# Contacts

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# Eligibility criteria

## Inclusion criteria

The inclusion criteria of this study for stroke patients are:

1. Clinically diagnosed symptomatic stroke (ischemic or intracerebral haemorrhagic lesion), first or recurrent, if possible verified by Magnetic Resonance Imaging (MRI) and/ or Computed Tomography (CT) data;

2. Reporting problems in social reintegration represented by at least two scores indicating experienced participation in society restrictions in activities in daily life on the Utrecht Scale for Evaluation of Rehabilitation-participation’s restriction scale (USER-P);

3. Living at home;

4. At least 6 weeks post stroke;

5. Age at least 18 years;

6. Written informed consent.

The inclusion criteria of this study for partners are:

1. Living together with a stroke patient participating in the study;

2. Age at least 18 years;

3. Written informed consent.

## Exclusion criteria

Exclusion criteria of this study for the stroke patients are:

1. An insufficient mental ability to understand, learn from and profit from the self-management treatment on the basis of clinical judgement of the recruiting physician;

2. Inability to function in a group because of behavioural problems as assessed by clinical judgement of the recruiting physician;

3. Insufficient command of the Dutch language communication abilities (score < 5 on the Shortened version of the Aphasia Scale of the Dutch Foundation);

4. Having a major depression based on clinical judgement;

5. Participating in structured, psychological counselling aimed at coping or self management post stroke at moment of recruitment.

Exclusion criteria for the partners are:

1. Inability to function in a group based on clinical judgement of the recruiting physician;

2. Insufficient command of the Dutch language based on clinical judgement.

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-09-2011 |
| Enrollment: | 106 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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|---|---|
| Date: | 30-08-2011 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 38360
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL2905 |
| NTR-old | NTR3051 |
| CCMO | NL36187.041.11 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON38360 |

# Study results

**Summary results**
N/A