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

Published: 23-09-2011
Last updated: 19-03-2025

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

## Summary

### ID

NL-OMON38360

**Source**
ToetsingOnline

**Brief title**
ReStoRe: RCT Self-Management Study

### Condition

- Central nervous system vascular disorders

**Synonym**
Cerebrovasculair Accident, stroke

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** VSB fonds en de Nederlandse Harstichting

## Intervention

**Keyword:** intervention, patient and partner, self-management, stroke

## Outcome measures

### Primary outcome

The main study parameters will concern patients* and partners* appraisals of their proactive coping competencies and participatione. Proactive coping will be measured with the Utrecht Proactive Coping Competence Scale, UPCC, for patient and partner. Participation in society in terms of subjective experienced restriction will be measured with the restriction subscale Utrecht Scale for Evaluation of Rehabilitation-Participation, USER-P.

### Secondary outcome

Secondary parameters of the study will concern self-efficacy measured with the General Self Efficacy Scale (GSES), participation in society in terms of objective frequency and subjective satisfaction measured with the USER-p frequency and satisfaction subscales, life satisfaction with three Visual Analogue Scales (3 questions), health related quality of life measured with the Short Stroke-Specific Quality of Life scale (SSQoL-12), general quality of life measured with the Six Dimensional EuroQoL (EQ-6D), care-related quality of life measured with the CarerQol questionnaire, emotional functioning with the Hospital Anxiety and Depression Scale (HADS), and caregiver burden measured with the expanded Cargiver Strain Index (CSI+).

# Study description

## Background summary

Nowadays, the yearly incidence of stroke patients ranges between 34,000 and 41,000 in the Netherlands and an increase in the number of patients is expected in the coming years due to the ageing population. The majority of these patients return home after discharge from hospital or rehabilitation treatment. However, a considerable number of these patients report significant long term consequences concerning psychosocial functioning in terms of decreased quality of life and life satisfaction , emotional complaints such as anxiety and depression , and social reintegration problems such as problems in return to work, social relations and leisure time .
At the moment, only a small proportion of the home living stroke patients receive formal in- or outpatient supporting services after their discharge from hospital or rehabilitation centre. In daily life, patients often rely on informal carers, usually 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.

## Study objective

The purpose of this study is to investigate the clinical effectiveness of a self management group intervention for stroke patients with social reintegration problems and their partners compared to a control group education intervention. The main research questions are:

Does an intervention aimed at proactive coping strategies and self-management result in an increased use of proactive coping strategies and increased participation in society in terms of subjective experienced restriction in stroke patients and their partners?

Additionally, does the self-management intervention lead to increased levels of self-efficacy, participation in society in terms of objective frequency and subjective satisfaction, life satisfaction, and quality of life, and less emotional problems in stroke patients and partners, and to decreased levels of burden in partners?

Next to this question related to the clinical effectiveness of this intervention the economic impact will be examined:

*What are the additional costs and additional outcomes of the self management

intervention compared to the education intervention?

## Study design

This study has a multi-centre randomized controlled trial design. At least 106 stroke patients, and their partners, will participate in this study. They will be recruited based on case finding in the participating hospitals and rehabilitation centres. Subjects who are involved in the study will be followed for approximately 12 months. We expect that 10 hospitals/ rehabilitation centers will participate in our study. The University Medical Centre Utrecht (UMCU) already consented to participate.

## Intervention

The self-management intervention will last ten weeks comprising six two-hour group sessions, and a two-hour booster session. Participants will discuss the themes *lifestyle and fitness*, *social support and relations*, *participation in society* and *coping with negative feelings*, and will formulate realistic and feasible theme related goals according the five stage model of proactive coping during this intervention. During the week following the session, action plans will be executed and progression will be registered. If participants have questions or fail to complete their homework, they can contact their therapist by email. Group sessions will take place in groups of four patients, their possible partners and two health care professionals. Therapists will receive a guideline and participants will receive a workbook.

## Study burden and risks

Participants are offered either the self management or the control intervention; both have potential benefit. At the moment care as usual is no care or only one or two follow up visits after discharge home. Measurements will take place at four different moments (before treatment, after treatment and at 3 and 9 months follow up). Measurements are conducted in the form of self-report questionnaires. The baseline measurement (T0) will be conducted by the researcher in a face-to-face interview in which the study is explained in detail. The other measurements are conducted by sending the questionnaires to the patients home (T1, T2 and T3). Patients and partners are asked to fill in the questionnaires within 2 weeks. After this 2-week period, the researcher contacts the participants to either thank them for their participation and/or asks them to provide missing information if needed. There are no known risks for subjects participating in this study. Subjects will participate in this study for one year.

# 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

The inclusion criteria of this study for stroke patients are:
(1) Clinical 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 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 |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Completed |
| Start date (anticipated): | 27-02-2012 |
| Enrollment: | 170 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 23-09-2011 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 25-01-2012 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 20-06-2012 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 05-11-2012 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# Study registrations

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

No registrations found.

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

ID: 23898
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| Other | aanvraag ingediend (www.trialregister.nl), wordt momenteel verwerkt, nummer nog niet toegekend |
| CCMO | NL36187.041.11 |

**Register ID**

OMON NL-OMON23898