

# The (cost)-effectiveness of an early admission to and assessment in the nursing home for stroke patients

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<b>Registration date</b> 04/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/08/2012	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

The (cost)-effectiveness of an early admission to and assessment in the nursing home for stroke patients: a multicentre non-randomised comparative trial

## Study objectives

Demographic developments, increased incidence and prevalence of stroke, the emergence of disease management programs, and changes in the structure of the Dutch Health Care System have led to new strategies to improve the quality, efficiency and logistics of care processes. These developments have led to a redesign of the Maastricht Heuvelland Stroke Service in 2006. The essentials of this redesign are: stroke patients will be admitted to the University Hospital in Maastricht for a maximum of 5 days for diagnosis, early intervention and stabilisation, after which they are discharged to a special assessment and rehabilitation ward in a nursing home. In this nursing home, stroke patients undergo a structured multidisciplinary assessment, lasting a maximum of 5 days, and take part in their first rehabilitation activities. During assessment, the appropriate follow-up treatment is determined. Patients are then admitted to the follow up setting for rehabilitative care. (Cost)-effective integrated stroke care requires a high degree of coordination between professionals in hospitals, nursing homes and home care, a high quality integral assessment in the nursing home and a system of adequately timed patient transitions. The main hypothesis is that the redesigned process of the Stroke Service Maastricht Heuvelland will lead to (cost)-effective care with expected improvement of quality.

The research questions in this study are:

1. What is the effect of early admission to and assessment in the nursing home on functional outcomes, quality of life, and satisfaction with care compared to usual care by a stroke service? [Effect evaluation]
2. From a societal perspective, what is the incremental cost-effectiveness of early admission to and assessment in the nursing home compared to usual care in a stroke service? [Economic evaluation]
3. What are the experiences and opinions of patients and professionals about the newly developed care pathway? [Process evaluation]

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Medical Ethical Committee of the of Maastricht University Medical Centre approved on the 6th April 2009 (ref: MEC 08-2-121)

## Study design

Multicentre non-randomised comparative trial

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

## Study setting(s)

Other

## **Study type(s)**

Quality of life

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Stroke

## **Interventions**

The intervention consists of the execution of a redesigned care pathway for stroke patients admitted to the Maastricht University Medical Centre. Every patient with a suspected stroke will be analysed at the Emergency Ward. In case of a stroke, the patient will be admitted to the stroke unit of the Hospital, where if indicated, thrombolysis will be followed by further diagnosis and treatment. The new aspect of the care pathway consists of a strict discharge regime at the Neurology Department of the Hospital. All necessary testing and treatment can be performed within 5 admission days, after which patients may be discharged. In the redesigned care pathway all stroke patients are discharged to a nursing home with a specialised assessment unit, resulting in a tailored rehabilitation programme. Only patients who can be discharged directly to their home within five days, or patients with complications in need of prolonged hospital care will not be referred to the specialised unit. The nursing home physician examines each patient immediately on arrival in the nursing home and starts up the assessment program. In this program a multidisciplinary team, consisting of a psychologist, physiotherapist, occupational therapist, speech-trainer, and trained nurses, will examine the patient. This team will make recommendations towards the best rehabilitation programme in a combined meeting that takes place within five days after admission. The redesigned stroke service will be compared to "care as usual" provided by the Stroke Service Eindhoven.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Total direct and indirect costs per patient during the first 6 months post-stroke.

The economic evaluation will involve a combination of a cost-effectiveness analysis and a cost-utility analysis. The primary outcome measure of the cost-effectiveness analysis will be the Stroke-Adapted 30-Item Version of the Sickness Impact Profile (SASIP-30). Within the cost-utility analysis, outcomes will be measured by means of standard Dutch version of the Euroqol (EQ-5D). This is a self-administered questionnaire, which will be completed together with a cost questionnaire in which the resource utilisation is recorded. Measurements are taken at baseline and after 3 and 6 months post-stroke.

## **Secondary outcome measures**

1. Instrumental activities of daily living measured by means of the Frenchay Activity Index, assessed at baseline and at 3 and 6 months

2. Handicap measured by means of the Modified Rankin Score, assessed at baseline and at 3 and 6 months
3. Cognitive functioning measured by means of Mini Mental State Examination, Apraxia Test and Star Cancellation Test, assessed at baseline and at 3 and 6 months
4. Anxiety and depression measured by the Hospital Anxiety and Depression Scale, assessed at baseline and at 3 and 6 months
5. Patients' satisfaction with stroke care measured by means of the Satisfaction with Stroke Care Questionnaire, assessed at baseline and at 3 and 6 months
6. Strain on caregivers measured by the Caregivers Strain Index, assessed at baseline and at 3 and 6 months
7. Medical complications occurring within 3 months after stroke. The following diagnoses are regarded as medical complications: a new stroke, epileptic seizures, pneumonia, urinary tract infections, fractures, bedsores, myocardial infarctions, heart failure and atrial fibrillation. The data on the medical complications will be collected from the patients' file.

Background variables:

The following will also be measured, which are considered to be predictors, confounders or effect modifiers. The following personal characteristics are assessed:

8. Age
  9. Sex
  10. Socio-economic status
  11. Risk factors
  12. Co-morbidity
  13. Stroke location
  14. Stroke severity measured by the National Institute of Health Stroke Scale
- All background variables are measured at baseline.

**Overall study start date**

01/04/2009

**Completion date**

01/12/2010

## Eligibility

**Key inclusion criteria**

1. Acute stroke patients' admitted to one of the hospitals participating in the trial
2. Aged 18 years or older
3. Either sex
4. Willingness to participate

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

222 (111 per group)

**Key exclusion criteria**

1. A previous diagnosis of dementia
2. Unable to communicate in Dutch

**Date of first enrolment**

01/04/2009

**Date of final enrolment**

01/12/2010

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**P. Debeyelaan 25**

Maastricht

Netherlands

6202 AZ

## **Sponsor information**

**Organisation**

VGZ Eindhoven (Netherlands)

**Sponsor details**

Prinsessesingel 22

PO Box 3272

Venlo

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5902 RG

**Sponsor type**

Government

**Website**

<http://www.vgz.nl/>

**ROR**

## Funder(s)

### Funder type

Government

### Funder Name

VGZ Eindhoven (Netherlands) - a Health Insurance Company

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	26/05/2010		Yes	No