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

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Registration date 04/01/2010	**Overall study status** Completed	
Last Edited 13/08/2012	**Condition category** Circulatory System	

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
Netherlands
5902 RG

Sponsor type
Government

Website
http://www.vgz.nl/

ROR

https://ror.org/04983vw43

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?
Protocol article	protocol	26/05/2010		Yes	No