A randomised controlled comparison of alternative strategies in stroke care

L Kalra,1* A Evans,1 I Perez,1 M Knapp,2 C Swift3 and N Donaldson4

1 Department of Diabetes, Endocrinology and Internal Medicine, Guy’s, King’s & St Thomas’ School of Medicine, London, UK
2 Centre for Economics of Mental Health, David Goldberg Centre, Institute of Psychiatry, London, UK
3 Department of Health Care of Elderly, Guy’s, King’s & St Thomas’ School of Medicine, London, UK
4 Department of Biostatistics, Guy’s, King’s & St Thomas’ School of Medicine, London, UK

* Corresponding author

Executive summary

Health Technology Assessment 2005; Vol. 9: No. 18
Objectives
The objectives of the clinical evaluation were:

- to compare a range of outcomes at 3, 6 and 12 months between stroke patients managed on the stroke unit, on general wards with stroke team support or at home by a specialist domiciliary care team
- to derive prognostic variables that will help to identify patients suitable for management at home and those requiring hospital-based care (targeting of strategy)
- to describe the organisational aspects of individual strategies of stroke care
- to evaluate the acceptability of various strategies to patients and to professionals involved in care provision.

The aims of the economic evaluation were:

- to collect data on service use (all agencies), accommodation and caregiver support in order to calculate the associated costs with each of the three modes of stroke rehabilitation (preserving data at individual level)
- to describe service receipt and costs during the 12-month follow-up period for each sample
- to examine interindividual differences in total and component costs by reference to the alternative interventions and the associations with characteristics of individuals
- to analyse, at both aggregate and individual levels, the links between costs and outcomes, investigating which option is most cost-effective.

Design
A prospective, single-blind, randomised controlled trial was undertaken in patients recruited from a community-based stroke register.

Methods
Setting
The study was conducted in a suburban district in south-east England. The health and social care needs of the district were provided for by a co-terminus hospital trust, a community health trust, a family health services authority and social services.

Participants
Patients with disabling stroke (persistent neurological deficit affecting continence, mobility or self-care abilities and requiring multidisciplinary treatment) who could be supported at home were included. Patients with severe strokes, unusual or atypical neurological features or severe premorbid disability were excluded.

Interventions
The stroke unit provided 24-hour care provided by a specialist multidisciplinary team based on clear guidelines for acute care, prevention of complications, rehabilitation and secondary prevention.

The stroke team involved management on general wards with specialist team support. The team undertook stroke assessments and advised ward-based nursing and therapy staff on acute care, secondary prevention and rehabilitation aspects.

Domiciliary care provided management at home under the supervision of a GP and stroke specialist with support from specialist team and community services. Support was provided for a maximum of 3 months.

Main outcome measures
The primary measure was death or institutionalisation at 1 year. Secondary measures involved dependence, functional abilities, mood, quality of life, resource use, length of hospital stay, and patient, carer and professional satisfaction.

Results
Of the 979 patients on the stroke register, 457 (47%) were randomised. Of these, 152 patients were allocated to the stroke unit, 152 patients to stroke team and 153 patients to domiciliary stroke care (average age 76 years, 48% women). The groups were well matched for baseline characteristics, stroke type and severity, level of
impairment and initial disability. Fifty-one (34%) patients in the domiciliary group were admitted to hospital after randomisation. Mortality and institutionalisation at 1 year were lower on stroke unit compared with the stroke team [21/152 (14%) versus 45/149 (30%), \( p < 0.001 \)] or domiciliary care [21/152 (14%) versus 34/144 (24%), \( p = 0.03 \)]. Significantly fewer patients on the stroke unit died compared with those managed by the stroke team [13/152 (9%) versus 34/149 (23%), \( p = 0.001 \)]. The proportion of patients alive without severe disability at 1 year was also significantly higher on the stroke unit compared with the stroke team [129/152 (85%) versus 99/149 (66%), \( p < 0.001 \)] or domiciliary care [129/152 (85%) versus 102/144 (71%), \( p = 0.002 \)]. These differences were present at 3 and 6 months after stroke.

Stroke survivors managed on the stroke unit showed greater improvement on basic activities of daily living compared with other strategies (change in Barthel Index 10 versus 7, \( p < 0.002 \)). Achievement of higher levels of function was not influenced by strategy of care. Quality of life at 3 months was significantly better in stroke unit and domiciliary care patients (EuroQol score 75 versus 60, \( p < 0.005 \)). There was greater dissatisfaction with care on general wards compared with stroke unit or domiciliary care.

Poor outcome with domiciliary care was seen in patients with Barthel Index <5 [odds ratio (OR) 10, 95% confidence interval (CI) 2.2 to 45] and incontinence (OR 4, 95% CI 0.8 to 17). Poor outcome on general wards was associated with Barthel Index <5 (OR 4.2, 95% CI 1.1 to 15), incontinence (OR 5.2, 95% CI 1.7 to 16) and age over 75 years (OR 3.4, 95% CI 1.2 to 9.4).

The total costs of stroke per patient over the 12-month period were £11,450 for the stroke unit, £9527 for the stroke team and £6840 for home care. More than half the total costs were incurred in the first 3 months. However, the mean costs per day alive for the stroke unit were significantly less than those for the specialist stroke team (£37.98 versus £50.90, \( p = 0.046 \)) patients, but no different to those for domiciliary care patients.

Costs for the domiciliary group were significantly less than for those managed by the specialist stroke team on general wards.

**Conclusions**

Stroke units were found to be more effective than a specialist stroke team or specialist domiciliary care in reducing mortality, institutionalisation and dependence after stroke.

In the authors’ opinion, a role for specialist domiciliary services for acute stroke was not supported. One-third of the patients in this group were admitted to hospital despite high levels of support in the community. The domiciliary service would be difficult to replicate in settings with less complementary configuration of services and would apply to a small proportion of stroke patients.

Management of stroke patients on general medical wards, even with specialist team support, cannot be recommended because of the high mortality and dependence rate.

The stroke unit intervention was less costly per patient day alive and more effective than the stroke team intervention. The stroke unit was more effective and of equivalent cost compared with home care. Hence, the stroke unit is a more cost-effective intervention than either the stroke team or home care.

Further research is needed to understand processes contributing to the reduction in mortality on stroke units, to determine the generalisability of these results and to determine factors that will influence the implementation of the findings of this study in clinical practice.

**Publication**

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the ‘National Knowledge Service’ that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, consumer groups and professional bodies such as Royal Colleges and NHS Trusts. Research suggestions are carefully considered by panels of independent experts (including consumers) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or designing a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a limited time period.

The research reported in this monograph was commissioned by the HTA Programme as project number 93/03/26. As funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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