

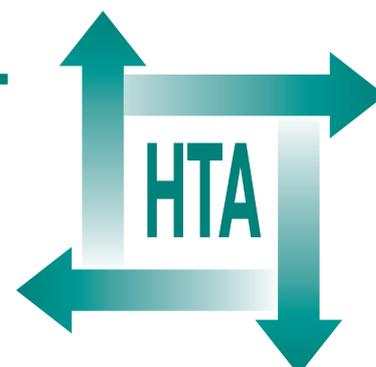
A randomised controlled comparison of alternative strategies in stroke care

L Kalra, A Evans, I Perez, M Knapp, C Swift
and N Donaldson



May 2005

**Health Technology Assessment
NHS R&D HTA Programme**





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A randomised controlled comparison of alternative strategies in stroke care

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Abstract

A randomised controlled comparison of alternative strategies in stroke care

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Objectives: To compare outcomes between stroke patients managed on the stroke unit, on general wards with stroke team support or at home by specialist domiciliary team and to derive prognostic variables that will identify patients most suitable for management by each strategy. To describe organisational aspects of individual strategies of stroke care and to evaluate cost-effectiveness of each strategy and its acceptability to patients, carers and professionals.

Design: Prospective single-blind randomised controlled trial undertaken in patients recruited from a community-based stroke register.

Setting: Suburban district in south-east England.

Participants: Patients with disabling stroke who could be supported at home.

Interventions: The stroke unit gave 24-hour care provided by specialist multidisciplinary team based on clear guidelines for acute care, prevention of complications, rehabilitation and secondary prevention. The stroke team provided 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 involved 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 were dependence, functional abilities, mood, quality of life, resource use, length of hospital stay, and patient, carer and professional satisfaction.

Results: Of the 457 patients randomised, 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 stroke team or domiciliary care. Significantly fewer patients on the stroke unit died compared with those managed by the stroke team. The proportion of patients alive without severe disability at 1 year was also significantly higher on the stroke unit compared with stroke team or domiciliary care. 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. 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. There was greater dissatisfaction with care on general wards compared with stroke unit or domiciliary care. Poor outcome with domiciliary care and on general wards was associated with Barthel Index <5, incontinence and, on general wards, age over 75 years. The total costs of stroke per patient over the 12-month period were £11,450 for stroke unit, £9527 for stroke team and £6840 for home care. However, the mean costs per day alive for the stroke unit were significantly less than those for the specialist stroke team patients, but no different from 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. A role for specialist domiciliary services for acute stroke is not supported by this study. Management of patients with strokes on general medical wards, even with specialist team input, is not supported by this study. 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 when compared to home care. Hence, the stroke unit is a more cost-effective intervention than either stroke team or home care. Further research is needed to understand processes contributing to the reduction in mortality on stroke units and to determine the generalisability of these results and the factors that will influence the implementation of the findings of this study in clinical practice.



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List of abbreviations

A&E	accident and emergency	NA	not applicable
ADL	activities of daily living	NS	not significant
BI	Barthel Index	OPS	Orpington Prognostic Scale
CI	confidence interval	OR	odds ratio
CSRI	Client Service Receipt Inventory	PACS	partial anterior circulation syndrome
CT	computed tomography	PIU	Patient Interaction Unit
FAI	Frenchay Activities Index	POCS	posterior circulation syndrome
HADS	Hospital Anxiety and Depression Scale	QALY	quality-adjusted life-year
HC	home care	RCT	randomised controlled trial
HR	hazard ratio	RR	relative risk
ICER	incremental cost-effectiveness ratio	ST	stroke team
IQR	interquartile range	SU	stroke unit
ITT	intention-to-treat	TACS	total anterior circulation syndrome
LACS	lacunar syndrome	TIA	transient ischaemic attack
LTFU	lost to follow-up	WTE	whole-time equivalent
mRS	modified Rankin Scale		

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.



Executive summary

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.

Chapter I

Introduction

Scientific evaluation of services

Scientific evaluation to assess the value of novel services has tended to focus on methodologies more appropriate for single defined interventions where other variables are known or controlled. There is a risk that such evaluation does not reflect 'real-world' conditions, where a high proportion of patients may not meet strict inclusion criteria or interventions may be delivered by staff who do not perform as well as in trials. Many services are complex and consist of a variety of components that are connected to form a whole. Evaluation of any single component without reference to others will result in erroneous conclusions on overall clinical effectiveness, which may have a profound effect on healthcare policy.

Complex services can be investigated by defining the core purpose of the system and its essential components.¹ These include:

- customers: the patients who are beneficiary of the services
- actors: the staff undertaking the running of the service
- transformation process: the main activity (interventions) of the system
- *Weltanschauung*: the wider perception of the value of the system
- owners: those with the power to stop the transformation
- environmental constraints: elements outside the system that influence the functioning of the system.

A successful complex system is the synthesis of research-based knowledge and real-world factors into an effective system. The methodology of this study reflects these principles, which have also been used in the preparation of this report.

Chapter 2

Background to the project

Overview of stroke

Stroke is the single most expensive disorder managed in general hospitals and accounts for nearly 4% of the total NHS expenditure.² Stroke patients occupy nearly 21% of general medical beds in hospitals and there is evidence that poor coordination between hospital and community services results in about 40% of all hospital resources for stroke being used by 5–10% of patients who need major long-term support in homes or in the community rather than hospital care.³

The burden of stroke is likely to escalate significantly in future because demographic changes will result in an increase in first ever strokes in England and Wales by the year 2023.⁴ Most of these strokes will occur in elderly people because of an age-related increase in incidence. Older patients are more likely to be hospitalised because of higher levels of frailty, co-morbidity, additional disabilities and social isolation.³ As mortality will be high in this group of patients, there will be only modest increases in the number of severely disabled people in the community.⁴ Hence, it appears that the increased burden of healthcare of stroke patients will primarily be that of caring for those in acute stages of stroke, whether it be in hospitals or in the community.

It may not be possible to provide effective stroke services in future if the present patterns of hospital-based provision were to continue. The bulk of the health costs of stroke is due to hospitalisation rather than to therapy or medical input.⁵ Literature suggests that it should be possible to manage a greater proportion of stroke patients at home, thus reducing service costs significantly.⁶ There are, however, concerns about patients who may be disadvantaged by being denied access to acute hospital care, because the effectiveness of care at home compared with organised care (e.g. on a stroke unit) in hospitals is not known. The feasibility, practicality and real costs of providing quality services at home, and the acceptability of the change in philosophy of care to patients, their families and the primary healthcare team, also need to be investigated before widespread implementation.

Organisation of stroke care

Many of the problems associated with stroke care stem from poor organisation and coordination of rehabilitation input.⁷ The major problems identified included misunderstanding and breakdown of communication among professionals, patients and their carers, ill-considered admission to hospitals and poor planning of discharges with insufficient attention being paid to the impact of stroke on patients' families. These criticisms have led to several initiatives to provide more effective and organised stroke care using a range of strategies, including stroke care areas on general medical wards, stroke units (acute and rehabilitation) and stroke teams. The meta-analysis of pooled data from studies that compared coordinated specialist care with non-specialist provision using a randomised controlled design has shown that organised stroke care reduces mortality and mortality of dependence by 28% and the length of hospital stay by 10%.⁸ Although the review showed that organised care was superior to conventional care, the data were not sufficient to provide conclusive evidence on the superiority of any one method of organisation over others. A direct comparison of different methods of organised stroke care was recommended to identify the best strategy to manage stroke patients.

Strategies for stroke care

Several strategies have been suggested for managing stroke patients.⁹ The strategies central to this project are stroke unit, hospital stroke teams and home care.

Stroke units

The establishment of stroke units is a much favoured and the most researched strategy of providing stroke care. There have been several well-controlled studies on stroke units which suggest that:

- Management on stroke units is associated with reduction in stroke-related mortality. The improvement in mortality does not appear to result in an increase in morbidity. An overview of stroke trials⁸ showed an odds reduction of

28% for mortality within 3 months, which appears to be sustained at 1 year. This odds reduction is greater than that reported for any currently available medical or surgical intervention.

- A significantly higher number of patients may regain functional independence on stroke units. If institutionalisation, no matter how imperfect, were to be used as a proxy measure for poor functional outcome, most studies show significant reductions for patients managed on stroke units. These studies also emphasise the importance of admission to stroke units soon after onset, early commencement of therapy and active family participation in the rehabilitation process.¹⁰
- Appropriate patient selection may enhance the effectiveness of stroke unit rehabilitation. Inpatient rehabilitation on a stroke unit may not be cost-effective in patients who have mild strokes and would do well whatever the rehabilitation input. Similarly, other strategies may be more appropriate for patients with very severe deficits who would be unable to tolerate or not respond to the intensive input provided on stroke units.

Despite several studies over the past two decades stroke units were not incorporated into mainstream clinical practice until recently, for the following reasons.

- Patient selection criteria in most studies are not defined and there appears to be considerable variation in the type of patients included in different studies and even among patients included in the same study.
- There is considerable variation in the number of eligible patients who were finally included in different studies. It is, hence, not possible to generalise the results of these studies to clinical practice.
- The assessment and outcome measures used in different studies vary considerably and have been applied at different points during the rehabilitation process.
- Despite adequate randomisation, the intensity and nature of therapy intervention have not been documented in most studies, making them difficult to interpret or replicate.
- Some studies have proved inconclusive because of inadequate sample sizes and statistical problems.
- The effect of publication bias in favour of 'positive' studies cannot be ignored and may influence the results of overviews on the benefits of stroke rehabilitation.

Hospital stroke teams

Geographically defined stroke units are perceived as being expensive and have limited capacity that may lead to problems of access. A specialist stroke team, which consults throughout the hospital and provides continuity of care across the hospital/community interface, may overcome this limitation and has the added advantage of disseminating specialist practice to other settings where stroke patients may be managed.

In comparison to stroke units, stroke teams have merited little research interest and data on their effectiveness remain equivocal. Care by a specialist team within normal hospital provision was investigated in a randomised controlled study in Canada.¹¹ The study on 130 stroke patients within 7 days of stroke showed a non-significant decrease in mortality (25% versus 34%), but significant improvement in functional recovery in men, but not in women, associated with stroke team intervention. Although the study concluded that hospital stroke team intervention was beneficial, its small sample size, opposing results in men and women and short follow-up period (5 weeks poststroke) limit the value of this conclusion. The feasibility of such teams in Britain has been investigated and supported,¹² although their effectiveness remains to be evaluated.

The need for organising multidisciplinary stroke care, multiprofessional and multiagency liaison, negotiations with patients and families in goal-setting and discharge planning identifies a role for hospital stroke teams that needs proper evaluation. These teams have the potential to improve the quality of discharges and facilitate improved functioning across the hospital/community interface. Stroke teams could be particularly useful in settings where it may not be possible to establish stroke units because of financial or logistic considerations. They also have an important role in the management of patients who are not managed on stroke units because of ineligibility or unavailability of beds.

Home care for stroke

The importance of early, organised hospital-based management has been emphasised in various professional recommendations for stroke care and is essential for wider use of thrombolysis and other acute interventions.^{13–15} Despite professional consensus, nearly 20–50% of acute stroke patients in some settings (notably in the UK) are not managed in hospitals.¹⁶

Specialised care at home has achieved variable success as an alternative means of providing organised multidisciplinary care and several observational studies have suggested that outcome in terms of physical independence is equally good in patients treated at home compared with conventional hospital services.⁹ This is supported by evidence from a large randomised controlled trial (RCT), which showed that intensive specialist care for defined conditions (hospital at home) achieved outcomes similar to, if not better than those achieved in hospitals.¹⁷ Only a very small proportion of patients managed at home had a diagnosis of stroke, and the validity or generalisability of these findings in the majority of stroke patients remains open to question. A controlled trial on managing acute stroke patients at home by providing additional home care and rehabilitation services showed that there were no differences in the hospital admission rates, functional recovery, social outcome or carer stress between the intervention and control groups.¹⁸ However, patients were not randomised at the point of entry and only 31% of the trial patients were managed exclusively at home. In addition, comparisons with stroke unit care were not undertaken.

Other studies have concentrated on the benefits of early supported discharge in stroke patients to improve outcome and reduce length of hospitalisation.^{19–21} A randomised study in 331 patients in London showed that there were no differences in outcome on a range of measures between patients who were managed in hospital for the entire episode compared with those discharged earlier but supported by intensive therapy input at home.¹⁹ On average, 6 days of hospital stay per patient were reduced in the intervention group, which received one visit daily from the physiotherapist and the occupational therapist along with 3 hours per day of personal care from social services for 3 months. The criteria for early discharge were arbitrary, and it could be argued that the ability to transfer independently would constitute routine, rather than early, discharge criteria on some units.

Early and coordinated intervention by the multidisciplinary team at home following an acute stroke may be a feasible option that can reduce hospital admissions and hospital lengths of stay. These teams have the potential to mobilise health and social services resources appropriate to patient needs. These considerations are of particular importance in the current climate of health service provision, with increased emphasis on provision of

quality services within the community and patient-orientated care.

Conclusions and limitations of available research

Several studies in stroke rehabilitation have shown that organisation of care, in hospitals and in the community, leads to improved outcome at reduced costs. Most studies, however, have compared highly organised interventions, whether they be in the hospital or in the community, with poorly organised conventional care. The benefits seen in such studies may be a result of increased awareness or additional input in the intervention group or diversion of resources from the control group. It is quite possible that the benefits of a stroke unit may be no greater than well-organised stroke team care on general medical wards, or those of home-care teams no greater than hospital care, if this were to be well organised. Most community studies have ignored the non-health costs to patients or other agencies involved in patient care, thus underestimating costs of care. This makes comparison of the cost-effectiveness of different strategies difficult to evaluate.

The heterogeneity of the stroke population is also an important consideration. The cost-effectiveness of different approaches may vary between different patient groups depending on demographic, disease and psychosocial characteristics. As major costs of stroke are related to hospitalisation rather than to therapy or medical input, the role of domiciliary rehabilitation to support early discharges has been investigated. The cost benefits of early supported discharge schemes appear to be marginal, and providing total care at home following acute stroke may be even more cost-effective than expediting discharge from hospital with community support. However, there are no data available on the type of patients for whom such an approach would be safe or feasible. Definition of patient groups in whom different strategies can be implemented is essential to provide an effective and safe service.

Another important shortcoming in current stroke rehabilitation literature centres around the multiplicity of assessment procedures. Although comprehensive and repeated multidisciplinary assessments of impairment and disability are key to evaluating any rehabilitation process, there is little agreement on appropriate assessments in stroke patients. This has resulted in the use of a large number of measures, which are often

unstandardised and applied at different points in time during rehabilitation. Meaningful interpretation and reliable comparison of the results of stroke studies are, hence, not possible and require the use of standardised assessment procedures in stroke studies evaluating different strategies of care provision.

Finally, the success of any stroke strategy depends not only on its cost-effectiveness, but also on its feasibility and acceptability to patients, carers, GPs, primary care teams and other professionals (e.g. the social services, therapy services) affected by the service. Although central to any long-term programme, there are no studies comparing the acceptability of the different strategies proposed for stroke care.

Reasons for undertaking the project

Despite the obvious advantages of organisation of services, there has been little progress until recently because of the fear that changes in pre-existing services may incur large costs but bring only small benefits. The authors believe that the changes occurring in the NHS have resulted in the right climate in which alternative strategies of stroke care can be successfully implemented, if supported by high-quality data on their effectiveness and cost-effectiveness at the operational level. Other factors that contribute to the timeliness (and ultimately the success) of this project are:

- priority given to the provision of stroke services by the *Health of the nation* document
- setting and monitoring of standards in patient care, which has been responsible for altering present hospital-centred systems towards more patient-orientated systems
- implementation of the Community Care Act, which promotes collaboration between health and social services with flexible use of resources, which allows a greater range of services to be provided at home.

The important issue in stroke management is no longer whether organised care is better than conventional care, but identifying the best strategy to manage stroke patients. Stroke units are effective, but may be expensive and have limited capacity. This can be overcome by developing stroke teams that provide 'consultation-only' input in the management of stroke on general wards, but their effectiveness is unknown. There is considerable philosophical and financial pressure to shift the focus of stroke management away from hospitals and towards the community. The direct costs of stroke care at home are likely to be a fraction of hospital costs, but the effectiveness and 'hidden costs' of this strategy are not known. Poorly considered and inadequately evaluated implementation of any strategy would be expensive and detrimental to patient care in the long run. It is important that healthcare practices, both within and outside the hospital, are subjected to careful evaluation before widespread implementation.

Chapter 3

Objectives of the project

The objectives of the clinical evaluation were:

1. 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 specialist domiciliary care team.
2. To derive prognostic variables that will help to identify patients suitable for management at home and those requiring hospital-based care (targeting of strategy).
3. To describe the organisational aspects of individual strategies of stroke care.
4. To evaluate the acceptability of various strategies to patients and to professionals involved in care provision.

The aims of the economic evaluation were:

1. 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).
2. To describe service receipt and costs during the 12-month follow-up period for each sample.
3. To examine interindividual differences in total and component costs by reference to the alternative interventions and the associations with characteristics of individuals.
4. To analyse, at both aggregate and individual levels, the links between costs and outcomes, investigating which option is most cost-effective.

Chapter 4

Methods

Setting of the study

Bromley is a largely middle-class suburban outer London borough with a population of 283,000 residents. The population is weighted towards the older age groups and has a higher proportion of people aged over 75 years than the rest of London or England and Wales. Among those aged 85 years or more, the majority (80%) live in private households. Although comparatively healthy and affluent, Bromley has pockets of deprivation where people have greater health needs.

Data extracted from the Casemix Management Information System for Bromley in the years preceding the project show an annual incident stroke rate of 650 per year. Approximately 78% of these patients were hospitalised, occupying 19,700 hospital bed-days. Of these patients, 36% died, 56% returned home and the remaining 8% were discharged to institutional care.

The health and social care needs of the district were provided for by a single hospital trust (Bromley Hospitals NHS Trust), a single community health provider (Ravensbourne NHS Trust), a single family health services authority (Bromley FHSA) and a single social services agency (Bromley Social Services), which were all co-terminus. In addition, the area had a single dedicated health commissioning agency (Bromley Health Authority), with close relationships with local providers.

Organisational aspects

A multidisciplinary steering group was set up to oversee the operational aspects of the project. This group consists of Dr J Spiby (Director of Public Health), Ms J Moggeridge (Deputy Director of Social Services and in-charge of Community Care), Mr B Porter (Service Manager for Community Care), Mrs B Dey (Head of District Nursing), Dr Abdul Tavabie (GP nominated by the Local Medical Committee), Ms R Gibb (Service Manager, Directorate of Medicine), Ms A Melbourne (Stroke Coordinator) and L Kalra.

The objectives of the steering group included consultation and negotiations with various service

providers (Bromley Hospital NHS Trust, Ravensbourne NHS Trust and Bromley Social Services) to address concerns, identify limitations of individual services and formulate solutions based on multidisciplinary and interagency collaboration to ensure provision of services essential for the success of the project. The steering group also ensured that the research team had access to relevant data collected routinely by other agencies (district nursing and social services) involved with the project.

A project evaluation committee was established to oversee the conduct of the research project, review the relevance, completeness and accuracy of data collected, and refine or amend the protocol if indicated on review of study progress. This group consisted of Professor CG Swift, Professor M Knapp, Dr I Perez (Stroke Research Fellow), Dr A Evans and L Kalra.

An operational policy for providing comprehensive stroke services (stroke unit, stroke team and domiciliary stroke team) was agreed to by various service providers (hospital and community), GPs and social services (Appendix 1). These included guidelines for hospital admission, logistics of inpatient care and domiciliary provision, as well as roles of various professionals involved in stroke care. Bromley Health and Bromley Hospitals Trust gave the lead consultant responsibility for overall stroke care to Dr L Kalra, which ensured that all stroke patients in Bromley were referred to a single point of contact and could be identified for study purposes.

The project was approved by the local ethics committee, community services committee, social services panel, medical consultants committee, hospital services board and the local medical committee.

Education sessions were held for GPs, multidisciplinary hospital staff, community health services, and social service managers and carers. Operational and evaluation aspects of the study were presented by relevant members of the project team at these meetings and practical issues identified by participants were discussed. In addition, all general practices in the area were

visited to seek support from local doctors. Particular emphasis was paid to the care aspects of patients being managed at home and mechanisms to ensure early hospital admission for these patients in case of problems.

New practices developed for the project

Joint assessment/purchasing by health and social services

The prompt availability of personal care for stroke patients being managed at home was seen as a potential stumbling block for the project. The process of assessment for personal care (undertaken by social services) can take several days and it may not have been possible to maintain patients at home despite their fulfilling study criteria.

This was prevented by implementing an innovative scheme that made it possible to provide immediate personal care to stroke patients who stayed at home. The major features of this scheme were as follows.

- District nurses could assess stroke patients for personal care needs and use the social services budget to buy personal care to maintain the patient at home.
- District nurses would provide personal care for 2 days, until mainstream social services could be started.
- A detailed formal assessment of these clients would be undertaken by a social worker within 1 week for appropriateness of the care package and longer term provision.

The social services organised study days for district nurses and the stroke team for training in assessment of personal care needs and access to social service resources. Attendance was obligatory before using the scheme.

Integrated multidisciplinary stroke record

Traditional patient records based on the hospital model were not adequate to obtain or communicate all the necessary patient information required in the management of patients with complex needs and multiple professional interventions, whether the patient was at home or in the hospital. A multidisciplinary record was created with an interdisciplinary integrated care pathway to facilitate the management of these patients. All medical, nursing and therapy notes

were incorporated into a single document, which was used in all stroke patients included in the project. The record had a section for comprehensive assessment of the patients' medical, nursing, rehabilitation and social care needs, and incorporated well-validated measures for monitoring progress in the major domains of stroke rehabilitation.

This record was different from the research data collection forms used for outcome assessment.

Guidelines for investigation and secondary prevention

As a large proportion of stroke patients in the project were to be managed at home or on general wards, there was a risk that they may not have the same access to investigations or secondary prevention as patients in the specialist setting. In view of this, guidelines for investigation and secondary prevention were developed and agreed to by the medical staff. These guidelines were made available to all wards in the hospital and included in the clerking proforma for stroke patients. Compliance with the guidelines was at the discretion of individual consultants responsible for the care of the patient.

Investigations and secondary prevention for patients being managed at home were the responsibility of the specialist stroke team. Appointments for all tests, including specialised blood tests, neuroimaging, carotid duplex studies and echocardiography (if clinically indicated), were arranged on the same day so that the patient would not have to keep returning to the hospital. The results of these investigations were reviewed before the patient returned home, in case further investigations or alterations in treatment were needed. These results and treatment schedules were communicated to the GP.

The stroke register

A population-based stroke register that recorded all strokes in patients over 16 years of age was set up with standard criteria. The register provided the sampling frame for the RCT on different strategies of stroke care. It collected key demographic, clinical and outcome data in keeping with the core data set of major stroke registries.²² Additional data at different time-points were collected on patients participating in other aspects of the project as required by the methodology of the particular project.

Notification

The register was coordinated by a clerical assistant and data were collected prospectively by the registry team, comprising a research registrar, a nurse and a consultant physician. Cases were identified by:

- hospital surveillance, which included all hospitals within the Bromley NHS Trust and hospitals in the neighbouring districts (Queen Mary's Hospital Sidcup, King's College Hospital, Mayday University Hospital)
- community surveillance, which included GP surgeries (51 practices, 104 GPs), district nurses, community therapy services and social services referrals in Bromley
- other notification sources, which included accident and emergency records, hospital wards, requests for computed tomographic (CT) scans, hospital coding records, bed managers and hospital medical staff.

Methods to ensure complete ascertainment of cases included wide dissemination of the project objectives within the hospitals and the community, locality seminars and visits to all surgeries before starting the project. The research associate contacted local hospital sources on a daily basis. Community sources and other hospitals were contacted by telephone on a weekly basis. Rapid access to a weekly stroke clinic and domiciliary assessment on the same or next day for suspected strokes was also made available to GPs to encourage notification. The completeness of the register was verified by 3-monthly cross-checks against the hospitals admissions database in local and neighbouring hospitals and 6-monthly checks against general practice records, community nursing and therapy referrals.

Assessment and data collection

Initial assessments were performed by a doctor to confirm the diagnosis within 48 hours of notification. The WHO definition of stroke was used²³ and the diagnosis of stroke was made on clinical criteria. Data were collected from the patient, general practice records and hospital notes. Patients with transient neurological deficits in whom the deficit resolved within 24 hours were not included in the register. Although data were collected on all patients suspected to have a stroke, those in whom the diagnosis was equivocal or not supported by subsequent investigations were excluded.

Information collected included date of stroke, delay between stroke and presentation,

demographic details, family support and networks, premorbid activities of daily living (ADL), demography, risk factor profile, preventive interventions before stroke, clinical status and stroke severity, prognostic variables, subtypes of stroke, processes of care and outcome (*Table 1*).

Analysis

Descriptive data on patient demography, risk factor profile, premorbid function, social support, stroke subtype and severity and the level of impairment and initial disability are presented. A comparison of risk factor profile for different stroke subtypes was undertaken. Prior management of risk factors was assessed as a surrogate measure of unmet prevention needs in the local community. The reasons for hospital admission were analysed to identify the main causes for seeking hospital care and compared with the first assessment undertaken in the hospital.

TABLE 1 Minimum data set on the stroke register

Patient information	Demographic details Details of accommodation and social support Premorbid function Date of stroke Date of presentation to health services Reasons for hospital admission
Stroke information	Type of stroke (pathology, aetiology, clinical) Severity of neurological deficit Previous cerebrovascular disease Co-morbidity and additional impairments Stroke risk factors and their management Assessment of swallowing, continence, consciousness Barthel ADL Index at baseline
Outcome	Mortality Institutionalisation Barthel ADL Index Rankin Scale
Services issues	Number of patients receiving specialist stroke care Duration between: stroke and referral referral and assessment assessment and provision of service Length of hospital stay (for hospitalised patients)

The randomised study

Subjects

Patients were recruited from the population-based stroke register described above. The WHO definition of stroke was used and the diagnosis of stroke made on clinical criteria. Patients were included within 72 hours of stroke onset. The research team was notified by telephone or fax by GPs for patients at home, and by accident and emergency (A&E) services for suspected stroke patients presenting to the casualty department. Initial assessments were undertaken by a doctor to confirm the diagnosis and eligibility for inclusion.

Patients with disabling stroke (persistent neurological deficit affecting continence, mobility or self-care abilities and requiring multidisciplinary treatment) who could be supported at home with nursing, therapy and social services input on initial assessment were included in the study. Patients with mild stroke, severe strokes (unconscious, swallowing problems not amenable to dietary modification, heavy nursing needs), already admitted to hospitals, and those with unusual or atypical neurological features who required specialised assessments or investigation to establish a diagnosis of stroke were excluded. Patients who were institutionalised or had severe disability (Rankin 4 or 5) before stroke were also excluded.

Baseline assessments

Baseline assessments were undertaken at home or in the A&E department before randomisation (Table 2). These included patient demography, co-morbidity, premorbid function, social networks,²⁴ stroke subtype,²⁵ stroke severity using a validated neurological scale,²⁶ a score for the level of motor, proprioceptive and cognitive impairments²⁷ and a 20-point scale for ADL [Barthel Index (BI)], consisting of feeding, dressing, toilet use and mobility assessments.²⁸ Prognostic characteristics such as level of consciousness, motor impairment, sensory and perceptual problems, speech and swallowing problems, mood disturbances and eligibility for the study were also assessed.

Randomisation

Randomisation was unstratified and undertaken using the block randomisation technique. This method was used to ensure that the number of patients who were allocated to the stroke unit or to domiciliary services at any one time did not exceed the capacity of these services to admit these patients, which would have resulted in a

significant bias in the study. In addition, block randomisation allowed fair allocation of workload between professionals and guarded against the potential bias due to changing practices in any one setting (stroke unit, general wards or domiciliary care) over the 2-year duration of the study, which would have resulted from uneven recruitment between interventions at the beginning or the end of the study.

The allocation schedule was prepared using computer-generated random numbers in blocks of 30 before the study began. Each number was assigned to stroke unit, general medical ward or domiciliary care, depending on divisibility by three. Once ten numbers had been assigned to any one intervention, the remaining numbers were shared between the other interventions until ten numbers had been allocated to each intervention in the block. Eleven such blocks were prepared and stored on a computer in an administrative office remote from the study setting. A clerical officer, unconnected with patient assessment or management, was responsible for maintaining the randomisation schedule and allocating patients to different interventions. The research staff were alerted to potential subjects by the A&E, hospital admissions or GP. Once eligibility has been determined by responsible assessors, they contacted the office on the telephone with patient name and hospital number only. The officer entered consecutive patients in strict order of referral on the database and conveyed the corresponding allocation to the assessor.

A potential source of bias is the subversion of randomisation if small blocks (six to eight patients) are used, especially when treatment cannot be truly blinded (e.g. trials on thrombolysis). To prevent inadvertent error from this source, randomisation was conducted in blocks of 30 in an office remote from patient treatment areas, so that it would not be possible for those enrolling patients to guess allocation for the vast majority of subjects.

Interventions

Stroke unit

Care on the stroke unit (acute and rehabilitation) was provided by a stroke physician supported by a multidisciplinary team with specialist experience in stroke management. There were clear guidelines for acute care, prevention of complications, rehabilitation and secondary prevention, and a culture of joint assessments, goal setting, coordinated treatment and discharge planning.

TABLE 2 Assessments and evaluations undertaken in patients participating in the RCT

(a) Clinical	
Baseline assessments on randomisation	<ul style="list-style-type: none"> Patient demography Social network (<i>patient network index</i>) Premorbid environment Premorbid statutory/non-statutory support Premorbid function Clinical examination to include: <ul style="list-style-type: none"> subtype of stroke (<i>pathology, aetiological and clinical classification</i>) extent and severity of neurological deficit (<i>Orgogozo score</i>) neuroimaging, duplex ultrasonography, echocardiography, etc. previous cerebrovascular disease standard prognostic characteristics co-morbidity and additional impairments stroke risk factors and management before stroke secondary stroke prevention needs Orpington Prognostic Scale (OPS) (motor, balance, proprioception and cognition) Rivermead Perceptual Assessment Battery, if applicable Barthel ADL Index Functional Ambulation Categories Frenchay Aphasia Screening Test Assessment of swallowing Hospital Anxiety and Depression Scale (HADS)
Outcome measures at 3, 6 and 12 months	<ul style="list-style-type: none"> Mortality Institutionalisation Admission/readmission to hospitals Barthel ADL Index Rankin Scale Frenchay Activities Index (FAI) HADS Quality of life for patient and carer (EuroQol)
(b) Process measures	
Access to specialist care	<ul style="list-style-type: none"> Proportion of patients eligible for the intervention Proportion of eligible patients actually included Duration between stroke onset and treatment
Processes of care	<ul style="list-style-type: none"> Investigations/interventions for stroke Stroke-related complications Compliance to treatment guidelines Secondary prevention
Resource use	<ul style="list-style-type: none"> Length of hospital stay (for hospitalised patients) Duration of specialist team input (for home care) Grade and speciality of professionals involved Nature and duration of input in domiciliary care: <ul style="list-style-type: none"> medical (stroke team and GP) therapy input (stroke team and others) district nursing care manager Personal care/social services use Adaptations, aids and equipment provided Readmissions/outpatient attendances (CSRI) Support from non-NHS sources (CSRI) Health economy measures (CSRI)
Acceptability measures	<ul style="list-style-type: none"> Patient satisfaction Carer satisfaction GP satisfaction Care manager/worker satisfaction District nurse satisfaction
CSRI, Client Service Receipt Inventory.	

The acute medical treatment was standardised for diagnostic evaluation (stroke-specific clinical assessments, investigations, imaging), monitoring (blood pressure, temperature, oxygen saturation, blood glucose, fluid and electrolytes, nutrition) and prevention of complications (positioning, screening for aspiration, infections, thromboprophylaxis, etc.). The role of thrombolysis in acute stroke had not been established at the time of this study and was not used in any patient. Antioedema agents were used selectively and limited to patients with rapidly deteriorating consciousness levels and midline shift on CT scan. A coordinated multidisciplinary approach was adopted towards rehabilitation, with emphasis on early mobilisation. All patients had an individualised rehabilitation plan with clearly defined goals based on joint assessments. Patient participation was encouraged, with focus on motivation and providing an enriched environment.

Medically stable stroke patients were assessed comprehensively for need and the home environment, previous functional status and expectations of rehabilitation outcome. These issues and postdischarge support available were discussed with patients and their families. The goals of rehabilitation were set by the team, against which the patients' subsequent progress was measured. A plan of management, individualised to each patient's needs, was formulated and communicated to the various professionals involved in the patient's care, the patient and the family. All patients were screened and managed for stroke risk factors and secondary prevention. There was close liaison between various disciplines, with problems being addressed as they arose. Discharges were planned in advance, and spouses and relatives were encouraged to participate in the rehabilitation process.

Stroke team

Patients allocated to stroke team care were managed on general wards and remained under the care of admitting physicians. All patients were seen by a specialist team, which consisted of a doctor (specialist registrar grade), a nurse (grade G), a physiotherapist (senior I) and an occupational therapist (senior I) with expertise in stroke management. Patients were assessed at the time of admission by the specialist team, which undertook a comprehensive diagnostic evaluation and assessment for medical, nursing and therapy needs. A plan for investigations and acute management based on standardised guidelines as used on the stroke unit was recommended for implementation by the ward team.

Although generic staff on the ward provided the day-to-day treatment, the team advised on specialist aspects of stroke care. It reviewed progress and treatment goals of individual patients with the ward team and helped in discharge planning and setting up of postdischarge services. In addition, the team provided counselling, education and support to the family, identified expectations and advised about realistic outcomes in the context of previous morbidity and present deficits. Although guidelines and advice were provided for stroke care, investigations, management and secondary prevention remained the responsibility of the admitting team.

Domiciliary care

Patients allocated to domiciliary care were managed in their own home by a specialist team consisting of a doctor (specialist registrar), a nurse (G grade) and therapists (senior I grades), with support from district nursing and social services for nursing and personal care needs. Patients were under the joint care of the stroke physician and GP. Investigations, including CT scanning, were performed on an outpatient basis. Therapy was provided by members of the specialist stroke team. Each patient had an individualised integrated care pathway outlining activities and the objectives of treatment, which was reviewed at weekly multidisciplinary meetings. This support was provided for a maximum of 3 months (see Appendix 1).

Patients were withdrawn from domiciliary care and admitted to the stroke unit if there was deterioration in clinical status or neurological examination, development of new problems, need for specialist investigations, excessive care needs that could not be met at home, or through patient or GP choice or stroke team decision. The reasons for withdrawal were recorded. These patients were monitored for outcome and included in the intention-to-treat (ITT) analysis.

Assessments

Outcome

Outcome was assessed at 3, 6 and 12 months after stroke onset. An independent observer, who was unaware of treatment allocation, assessed patients in their own environment. The only exceptions to this were 16 patients (six in the stroke unit, seven in the stroke team, three in the domiciliary group) still in hospital at 3 months, in which case location may have identified allocation. Assessments in these patients were undertaken by other members of the project. The independent assessor was asked to guess the allocation of the 435 patients

completing 1 year of follow-up at the end of the study, and was correct for 178 (41%) patients (κ 0.12).

The primary outcome measure was death or institutionalisation at 1 year. Dependence was measured using the modified Rankin Scale (mRS), a categorical seven-point scale that assesses overall function; death is rated as 6,²⁹ and the BI. The mRS score at 1 year was dichotomised to classify patients who were independent and those who required minor assistance for day-to-day activities (mRS 0, 1, 2 or 3) as having a good outcome. The BI was similarly dichotomised for dependency, and BI scores of 15–20 were classified as favourable.³⁰

Secondary outcome measures included the Orgogozo scale,²⁶ BI and FAI for disability,³¹ the mRS for handicap²⁹ and EuroQol for quality of life of patients and their carers.³² In addition to group medians at different time-points, the mean change over time in individual patients for these variables was analysed to prevent the possibility of a significant change being missed because of variability between individuals.

Many of the analyses undertaken in stroke survivors to assess differences in outcome between the three strategies were not prespecified and the study was not powered for these outcomes. However, these differences are of interest and need to be interpreted in the light of the limitations of similar post hoc analyses.

Resource use

The structure required to provide each strategy of stroke care was recorded, as well as the number and grade of health, social services and other professionals involved. All visits by the stroke team were documented and the use of NHS and other resources was recorded. Information was collected on the duration and nature of medical, nursing and therapy input, the nature and intensity of personal care, and the overall utilisation of social services and community resources. Measures included length of hospital stay, rehabilitation sessions, nursing and medical input. The use of specialist investigations and outpatient rehabilitation facilities was recorded. Extra input from family members, friends or voluntary organisations was documented using the CSRI.³³ Data on social services utilisation (number and duration of personal care visits, tasks undertaken, aids and appliances supplied) were also obtained from patients and the social services.

Assessment of acceptability

All patients and carers in the study were asked to complete a satisfaction questionnaire at 3 months. GPs, therapists, district nurses, therapists and care managers involved with the care of patients were asked to complete specially designed open and closed questionnaires with particular reference to the impact on workload and perceived advantages and disadvantages, both for the patient and for the professional.

Data analysis and statistical techniques

Sample size calculations

The sample size was calculated using pooled data from the first systematic review of stroke unit care discussed by the Stroke Unit Trialist Collaboration in 1994. The odds ratio (OR) for death or institutionalisation was 0.7 [95% confidence interval (CI) 0.6 to 0.8] for stroke unit relative to conventional care. Based on these estimates a sample size of 740 patients in each limb would be required if a conventional fixed sample design was used. Recruitment of such numbers is not feasible in tightly controlled single-centre studies, nor is it possible to include multiple centres because of variations in service provision. Hence, the smallest sample size required to detect a significant effect was determined by using the sequential analysis framework.³⁴ Sequential tests generally allow one to achieve the same level of power for a given treatment effect as large trials and there is no limitation as to when to perform analyses. However, it is good practice to analyse when at least 20% of the maximum sample has accumulated since this provides enough information for covariate adjustment. A sample size of 138 patients corresponded to 20% of the 90th percentile of the sample size for this sequential design. A sample size of 150 patients in each limb will also be adequate to detect a 2-point difference in BI scores and one category of difference in mRS with a power of 0.8 at 5% significance levels.

Comparisons of outcome

Data were analysed on an ITT basis. Means, standard deviation, medians, interquartile ranges (IQRs) and statistical tests for significance were calculated. The Kruskal–Wallis test was used for continuous variables (e.g. age, length of stay and therapy input) because of the skewed distributions. The χ^2 test was used for discrete variables (e.g. stroke subtype, mortality, institutionalisation and the dichotomised mRS and BI). The main outcome measures analysed were ‘mortality’ and ‘mortality or institutionalisation’. Logistic regression models were fitted to the data to adjust

for the independent effects of demographic, clinical and stroke characteristics at 3, 6 and 12 months. In addition, Cox's regression models were fitted at 12 months to account for the precise event times and the patients lost to follow-up.

Targeting of intervention

The time interaction with strategy groups was assessed using repeated measures analysis. The indicator of the event variable at 3, 6 and 12 months after stroke was used as a within-subject response and strategy type as a between-subject factor. The effect of baseline variables on mortality or institutionalisation, within each of the three strategy groups, was assessed using logistic regression models. The logistic equation classified patients into two risk groups (good and bad outcome) and was used to define patient characteristics that allowed optimal allocation to strategy group. A similar approach was followed with respect to mRS (0–3 versus 4–6) and BI scores (15–20 versus 0–16), recorded as a binary indicator at 3, 6 and 12 months after stroke.

Analysis of cost-effectiveness

The economic analyses followed the familiar stages of an economic evaluation.³⁵ From the design of the trial, the economic evaluation was fully integrated into the effectiveness evaluation, with the same criteria adopted for eligibility, randomisation and intervention modes. A societal perspective was adopted. In principle, the measurement of costs should cover every facet of a patient's treatment, support, lifestyle and activities that might be affected by the mode of intervention. In practice, some elements have to be omitted. The evaluation collected data on all formal health and social care services used by study members (as detailed earlier). Data were collected at baseline (retrospective measurement of service use over the 3 months before stroke), and at 12 months with retrospective measurement since the date of the stroke. With the exception of details of the stroke admission and therapy inputs (which were recorded on an ongoing basis as part of the trial), all necessary data were collected during patient assessment interviews by staff working on the trial. For this purpose, a specially adapted version of the CSRI³⁶ was developed, piloted and incorporated into the clinical assessment schedule. Caregiver support from relatives and friends was also measured using the CSRI.

Costs were calculated from these service utilisation measures for each patient. Costs were attached to each service or element of support in turn, using the best available estimates of long-run marginal

opportunity cost, where 'marginal' refers to the addition to total cost attributable to the inclusion of one more patient, and 'opportunity cost' refers to the opportunities forgone by not using a resource in its best alternative use. The short-run average revenue cost (obtained from a complete set of agency accounts), plus appropriately measured capital and overhead elements, is usually sufficiently close for these purposes to the long-run marginal cost for many services used by people with health problems.

Unit costs were obtained from local services wherever possible to approximate the actual cost of the interventions and their impacts. National statistics were used in the absence of local costs, taken mainly from Netten and colleagues.³⁷ All costs were standardised to 1997/98 prices. Details of all unit costs used are set out in Appendix 2. Unit costs were combined with resource volumes to obtain a cost per patient over the entire period of participation in the trial. Caregiver support from relatives and friends was also measured, but is reported in natural time units.

All costs are reported as mean values with standard deviations. Differences between groups were tested using the Student's *t*-test. Economic evaluations often find that costs are skewed, because a small number of patients make use of high-cost services such as inpatient hospital treatment, violating the normality assumption underpinning the validity of the *t*-test.³⁸ To allow for skewed summary costs (cost per day alive), 500 bootstrap replications of the original data were performed and the resulting mean differences, pseudo *t*-values and percentile confidence intervals were compared with the *t*-test results. All reported *t*-test results were found to be robust in the sense that the results from the significance tests were identical between the *t*-tests and bootstrap analyses. All poststroke figures exclude 12 patients who were lost to follow-up during the 12-month assessment period.

Comparing costs between the three interventions is of interest in its own right, but it is more important to examine cost data alongside evidence on effectiveness. Two approaches were adopted. The primary outcome measure (death or institutionalisation) was combined with total service cost to compute cost-effectiveness ratios for comparison between the three interventions. The simplest decision rule in a cost-effectiveness analysis of this kind is then to conclude that the intervention with the lowest cost per unit of (primary) outcome is the more efficient. A

limitation of this analysis is that it misses the full richness of effectiveness data, which is an informational disadvantage in its own right, but which also might hide important insights if, for example, the various dimensions of outcome do

not move in concert. As several outcome measures of interest were included in the trial, a cost–consequences analysis was also carried out, comparing costs and multiple outcomes between the three arms of the trial.

Chapter 5

Results

The stroke register

A total of 1206 suspected strokes was notified to the stroke register between October 1995 and March 1998 (*Table 3*). Of these, 102 (8%) patients had transient ischaemic attacks (TIAs), 69 (6%) other neurological disease and 56 (5%) had metabolic, metastatic, drug-induced or infective disorders. A diagnosis of stroke was confirmed in 979 (81%) patients over the 30-month period giving an annual stroke incidence rate of 1.7/1000 population for suspected stroke and 1.4/1000 population for clinical stroke for the catchment area. This estimated incidence rate is lower than that suggested by the Oxfordshire Community Stroke Project,³⁹ but similar to that reported in more recent studies conducted in areas with comparable demographic and population characteristics.⁴⁰ However, it is important to note that this was not a population-based incidence study, and the size and structure of the local population were not studied in detail to allow comparisons of incidence rates. The small proportion of patients with a mild stroke in the study suggests that this group was under-represented and may be responsible for some of the observed differences with previous studies.

The baseline demographic characteristics of patients on the register are shown in *Table 4*. The demographic characteristics of patients on the stroke register were comparable to other community registers^{39,41} and showed that the majority of stroke occurred in older patients, many of whom lived alone. Co-morbidity was common

and 807 (82%) patients had other associated cardiovascular disease (*Table 4*). The most common risk factors were hypertension and previous cerebrovascular or cardiovascular disease.

The baseline stroke characteristics are summarised in *Table 5*. A firm pathology could not be established in 117 of the 979 patients included in the register because they did not have CT scans. Reasons for failure to scan included those with severe stroke where death was imminent, severely disabled patients with multiple strokes, stroke deaths in the community and delayed notification of patients managed at other hospitals or in the community. Ischaemic strokes were seen in 754 (87%) of the 862 patients who had CT scans. In these patients with ischaemic stroke, 153 (20%) had TACS, 298 (39%) had partial anterior circulation syndrome, 117 (16%) had features of posterior circulatory syndromes and 186 (25%) had lacunar syndromes. The distribution of various stroke subtypes was similar to that described in the Oxfordshire Community Stroke Project.²⁵ The number of patients who could be assessed for any stroke-related impairments varied according to the level of consciousness, communication problems, cognitive abilities and the degree of cooperation required from the patient. The frequency of these impairments in the number of patients who could be assessed for the impairment is given in *Table 5*. The distribution of various impairments associated with stroke was similar to other large prevalence studies,⁹ suggesting that the baseline population for evaluating different strategies of stroke management was representative of the

TABLE 3 The stroke register from 1 October 1995 to 31 March 1998 (30 months)

	<i>n</i>	(%)
Total no. of notifications for suspected stroke	1206	(100)
Diagnosis not stroke	227	(18.8)
TIA or deficits lasting for <24 hours	102	(8.5)
Other neurological disease (subarachnoid haemorrhage, tumour, demyelination, dementia, psychiatric illness)	69	(5.7)
Non-neurological disease (metabolic, metastatic, drug induced, infective)	56	(4.6)
Confirmed stroke	979	(81.2)

TABLE 4 The stroke register: patient characteristics

Total no. of patients	979
Average age of patients (years)	76.8 ± 17.4 (26–101)
No. of women	523 (53.4%)
Living alone	264 (27%)
Risk factor profile	
Hypertension (systolic BP > 160 mmHg and/or diastolic >95 mmHg)	453 (46%)
Diabetes mellitus (fasting blood glucose >7.8 mmol l ⁻¹)	124 (13%)
Current smoker	162 (16%)
Previous strokes/TIA	235 (24%)
Atrial fibrillation	205 (21%)
Peripheral vascular disease	142 (15%)
Carotid bruits	87 (9%)
Hyperlipidaemia (cholesterol >5.8 mmol l ⁻¹ , triglyceride >2.0 mmol l ⁻¹)	174 (18%)
Ischaemic heart disease	337 (34%)
Premorbid Rankin <3	784 (80%)
Housebound or in institutional care	81 (8%)

BP, blood pressure.

TABLE 5 The stroke register: stroke characteristics of all patients

	n (%)
Stroke pathology	862/979 (88%)
Ischaemic	754/862 (87%)
Haemorrhage	108/862 (13%)
Stroke subtype	
TACS	153/754 (20%)
PACS	298/754 (39%)
POCS	117/754 (16%)
LACS	186/754 (25%)
Stroke-related impairments	
Motor weakness	642/930 (69%)
Sensory loss	134/744 (18%)
Hemianopia	157/842 (19%)
Neglect	92/656 (14%)
Dysphasia	151/842 (18%)
Dysphagia	353/930 (38%)
Incontinence	281/979 (29%)
Median initial BI (IQR)	9 (4–14)

TACS, total anterior circulation syndrome; PACS, partial anterior circulation syndrome; LACS, lacunar syndrome; POCS, posterior circulatory syndromes; IQR, interquartile range.

communities in which most general hospital services operate.

Outcome

Of the 979 patients included on the register, 27% were dead, 16% in institutional care and 57% were living at home at the end of 1 year (Table 6). Two-thirds of those at home were reasonably

TABLE 6 The stroke register: major outcome measures

Total no. of patients	979
Cumulative mortality:	
7 days	83 (8%)
30 days	159 (16%)
6 months	207 (21%)
1 year	261 (27%)
Institutionalisation at 1 year	158 (16%)
Rankin <3 at 1 year	374 (38%)
Disabled and at home	186 (19%)
Median length of hospital stay (IQR)	14 (7–56)

independent and did not need any help with their basic ADL. The remaining survivors at home were moderately to severely dependent and were supported by statutory services and/or informal carers. The better outcome compared with other community registers may be due to the effects of organised stroke services already present in the district and patient inclusion in the RCT.

Patterns of hospital admission

Nearly 80% of stroke patients were admitted to local hospitals (Table 7). Most patients presented within 24 hours of stroke and one-quarter within 6 hours of onset. All patients presenting to the A&E department were admitted, except for those referred to the stroke team and randomised to the home care limb of the project. Less than half of the patients were admitted for further

TABLE 7 The stroke register: reasons for admission

Total no. of patients	979
Number of patients admitted to Bromley Hospitals	755 (77%)
Time between onset and admission	
Within 6 hours	212 (28%)
Within 12 hours	387 (51%)
Within 24 hours	619 (82%)
Source of admission	
Direct GP admission	244 (32%)
A&E	327 (43%)
Stroke team decision	51 (7%)
Stroke in hospital	38 (5%)
Others (transfers, clinics, consultant domiciliary visits)	95 (13%)
Reasons for admission (A&E and GP patients)^a	
Diagnostic uncertainty	86/571 (15%)
Need for further investigations	94/571 (16%)
Acute interventions	37/571 (6%)
Specialist stroke management	219/571 (38%)
Patient living alone	182/571 (32%)
High dependency/cannot be managed at home	289/571 (51%)
Diagnosis of stroke	117/571 (20%)
Patient/family choice (if decision not to admit)	56/571 (10%)
^a More than one reason in some patients.	

TABLE 8 Primary reasons for exclusion from the study

	n (%)
Stroke patients on the register	979
Admitted to other hospitals	57 (5.8)
Managed at home by GP	69 (7.0)
Admitted from residential or nursing home	49 (5.0)
Previously severely handicapped (mRS 4 or 5)	32 (3.2)
Mild stroke not requiring rehabilitation ^a	44 (4.5)
Severe stroke requiring hospitalisation ^a	193 (19.7)
Eligible to participate in study	535 (54.6)
Not offered to the study	21
Participating in acute intervention drug trials	23
Refused consent	34
Randomised	457 (46.6)
^a Predefined criteria for exclusion.	

investigations or specialist management of stroke. The major reason for admission was the need for nursing and social care because of high dependence. Factors that correlated with hospital admission were age (OR 1.4, 95% CI 1.01 to 1.6), living alone (OR 1.9, 95% CI 1.3 to 2.7) and stroke severity (OR 1.2 per 1-point decrease in Barthel ADL, 95% CI 1.03 to 3.9). There was no correlation with gender, risk factor profile, co-morbidity, GP, locality or days of the week (weekend versus weekdays).

The randomised controlled trial

Patients

The study sample was recruited from the 979 (81%) patients with a clinical diagnosis of stroke. Of these, 444 were excluded because they were admitted to other hospitals or managed at home by the GP without referral to the stroke team, had severe pre-existing disability or did not fulfil eligibility criteria because of severe or mild strokes (Table 8). A further 78 patients were excluded because of lack of consent or other reasons. All together, 457 patients meeting inclusion criteria were randomised. Of the patients randomised, 152 were assigned to stroke unit care, 152 to stroke team care and 153 to domiciliary care (Figure 1).

Study progress

In total, 344 (75%) patients were recruited to the study within 24 hours, 72 (16%) between 24 and 48 hours and 41 (9%) between 48 and 72 hours of stroke onset. There were no significant differences in the duration between stroke onset and referral and referral and commencement of input between the three groups. Investigations after randomisation showed non-stroke diagnoses in ten patients (stroke unit $n = 4$, stroke team $n = 2$, home care $n = 4$), who were included in the ITT analysis. The analysis also included 51 patients in the domiciliary care limb who were admitted to

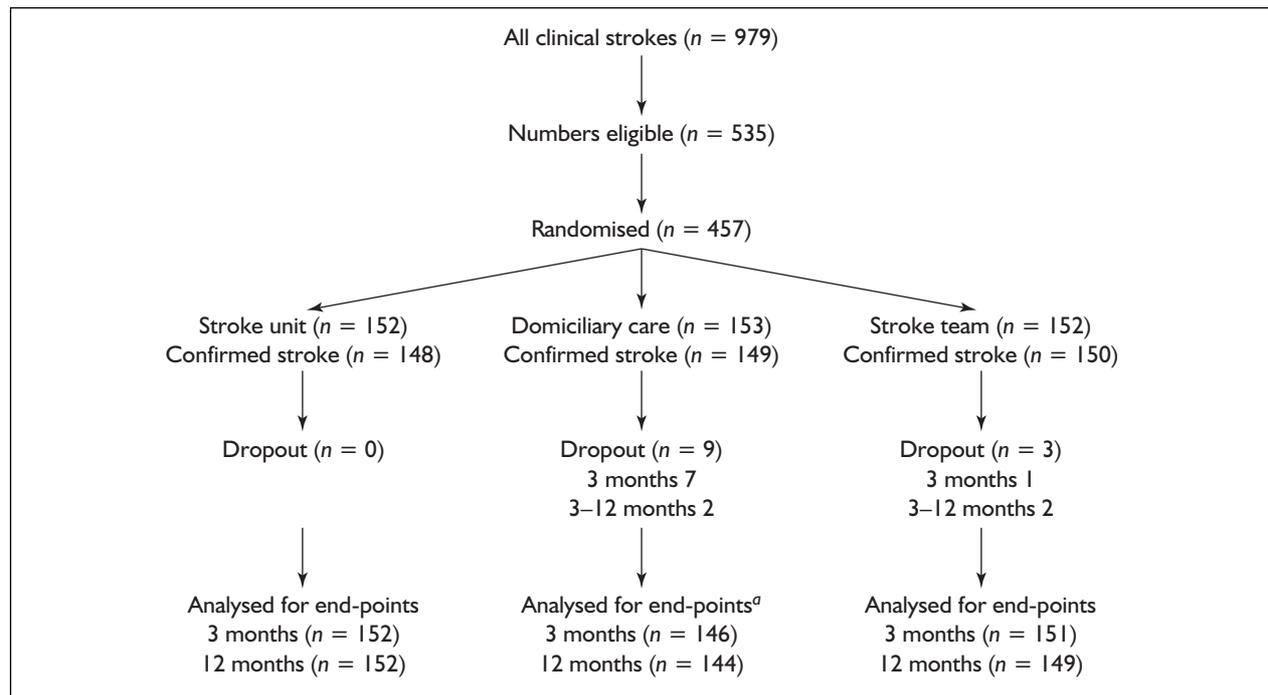


FIGURE 1 Trial profile. ^a 51 patients in this group were hospitalised within 2 weeks of randomisation but are included in the ITT analysis.

the stroke unit within 2 weeks of randomisation. Reasons for admission were clinical deterioration ($n = 12$), need for further investigations ($n = 2$), excessive care needs ($n = 15$) and patient/GP choice ($n = 22$).

Nine patients in the domiciliary care group and three in the stroke team group were lost to follow-up at 12 months. All completed assessments in these patients were included in the analysis (end-point rather than last assessment carried forward basis).

Baseline characteristics

The baseline characteristics of patients, stroke type and severity, level of impairment and initial disability were well matched across the three groups (Table 9). The mean age of patients and gender distribution was comparable to the stroke register. Nearly one-third of the patients included in the study lived alone and the majority were independent before the stroke. Stroke subtype classification showed a higher proportion of patients with partial anterior syndromes and lacunar infarcts, and a lower proportion of patients with total anterior circulation syndromes compared with the stroke register. The mean neurological, impairment and disability scores were comparable between the three groups. The median BI placed all groups at the moderately to severely disabled level.³⁰

Outcome

Mortality, institutionalisation and dependence

Patients managed on the stroke unit were less likely to die or be institutionalised compared with those managed at home (14% versus 24%) or managed by the stroke team (14% versus 30%) at 1 year (Table 10). These differences in the primary end-point were also present at 3 and 6 months after stroke. Mortality was significantly higher in patients managed by the stroke team compared with the stroke unit at all time-points. Mortality in patients managed at home was higher than that on the stroke unit at 3 months, but not at 6 and 12 months. The plot of cumulative survival in the three groups is shown in Figure 2.

All baseline prognostic variables were entered into multiple logistic regression model for mortality or institutionalisation in patients with a confirmed diagnosis of stroke (excluding ten patients with a non-stroke diagnosis), which showed an independent effect of age, baseline BI and dysphasia at all time-points. After adjusting for these variables, the odds of dying or being institutionalised at 1 year were 3.2 greater for stroke team patients and 1.8 for patients receiving specialist home care compared with stroke unit care. Cox's regression analysis also showed better outcome in stroke unit patients compared with stroke team [hazard ratio (HR) 2.4] or home care (HR 1.7) for mortality or institutionalisation after

TABLE 9 Baseline characteristics of patients

	SU (n = 152)	ST (n = 153)	HC (n = 152)
Demography			
Median age (years) (IQR)	75 (72–84)	77.3 (71–83)	77.7 (67–83)
No. of females (%)	69 (46.6)	76 (50.6)	68 (45.6)
Living alone (%)	50 (33.7)	55 (36.6)	50 (33.5)
Premorbid independence			
Continence	146	147	148
Dressing	146	143	142
Mobility	145	146	146
Risk factor profile (%)			
Previous stroke/TIA	39 (26)	43 (29)	44 (30)
Hypertension	67 (45)	72 (48)	71 (48)
Diabetes mellitus	16 (11)	24 (16)	23 (15)
Atrial fibrillation	35 (24)	41 (27)	24 (16)
Smoking	28 (19)	21 (14)	23 (15)
Ischaemic heart disease	33 (22)	38 (25)	31 (21)
Carotid bruit	5 (3)	8 (5)	5 (3)
Stroke characteristics			
Left/right	76/69	67/76	76/70
Cerebral haemorrhage (%)	19 (12.8)	14 (9.3)	10 (6.7)
TACS	18	11	14
PACS	77	81	82
LACS	42	43	47
POCS	11	15	6
Inattention	45	41	41
Dysphasia	52	46	45
Incontinence	48	50	49
Median Orgogozo score (IQR)	75 (46–90)	80 (60–90)	85 (58–90)
OPS (1.6–6.8), median (IQR)	3.2 (2.4–4.4)	3.2 (2.4–4.4)	2.8 (2.0–4.0)
BI (0–20), median (IQR)	8 (5–12)	9 (5–12)	10 (4–14)

SU, stroke unit; ST, stroke team; HC, home (domiciliary) care.

adjustment for age, initial BI score and dysphasia (Table 11). Common causes of death were chest infection, dehydration/renal failure and pulmonary embolus in the first 3 months, and stroke recurrence or unrelated illness thereafter (Table 12). There were no significant differences in the proportion of patients being institutionalised in each group.

A favourable outcome (BI score 15–20) in ADL at 3 months was seen in 82% patients in the stroke unit group compared with 70% patients in the stroke team and 74% patients in the home care group (Table 10). There was no significant change in this measure in any of the groups between 3 and 12 months. Dependency measured by the mRS paralleled BI scores (Table 10). The absolute difference between the stroke unit and stroke team for patients who were independent or had minor levels of disability (good outcome) was 18%, and

that between stroke unit and home care was 14% (Figure 3). However, using a different dichotomisation where only total independence (mRS score 0, 1 to 2) was a good outcome, there were no significant differences between the three groups included in the study (Figure 3).

Functional outcome in survivors

A range of functional assessments was undertaken in the 376 (84% of the 447 patients included in the trial) stroke survivors. Of these, 138 (93% of the 148 randomised) were managed on the stroke unit, 115 (77% of the 150 randomised) were managed by the stroke team on general wards and 123 (83% of the 149 randomised) were managed at home by the specialist domiciliary care team. These differences in sample sizes were due to a larger proportion of patients surviving in the stroke unit group compared with the other two groups. Baseline comparisons showed that the

TABLE 10 Mortality, institutionalisation and dependence at 3, 6 and 12 months on an ITT analysis^a

End-point	SU	ST	HC	SU vs ST		SU vs HC		ST vs HC	
				RR (95% CI)	p	RR (95% CI)	p	RR (95% CI)	p
Mortality or institutionalisation (%)									
3 months	15/152 (9.9)	30/151 (19.9)	29/146 (19.9)	0.50 (0.29–0.87)	0.01	0.50 (0.29–0.87)	0.01	1.00 (0.96–1.04)	0.99
6 months	19/152 (12.5)	37/149 (24.8)	34/144 (23.6)	0.40 (0.24–0.67)	0.001	0.42 (0.24–0.75)	0.003	1.05 (0.71–1.56)	0.81
12 months	21/152 (13.8)	45/149 (30.2)	34/144 (23.6)	0.46 (0.30–0.72)	0.001	0.59 (0.37–0.95)	0.03	1.28 (0.87–1.87)	0.20
Mortality (%)									
3 months	6/152 (3.9)	18/151 (11.9)	14/146 (9.6)	0.33 (0.14–0.77)	0.01	0.41 (0.17–0.98)	0.05	1.24 (0.64–2.38)	0.52
6 months	10/152 (6.6)	25/149 (16.8)	19/144 (13.2)	0.39 (0.20–0.76)	0.006	0.50 (0.25–1.02)	0.06	1.27 (0.74–2.19)	0.39
12 months	13/152 (8.6)	34/149 (22.8)	21/144 (14.6)	0.37 (0.21–0.66)	0.001	0.59 (0.31–1.11)	0.10	1.56 (0.96–2.53)	0.07
Institutionalisation (%)									
3 months	9/152 (5.9)	12/151 (7.9)	15/146 (10.3)	0.75 (0.33–1.69)	0.49	0.58 (0.27–1.26)	0.17	0.77 (0.37–1.61)	0.49
6 months	9/152 (5.9)	12/149 (8.1)	15/144 (10.4)	0.74 (0.33–1.67)	0.47	0.57 (0.26–1.24)	0.16	0.78 (0.39–1.57)	0.48
12 months	8/152 (5.3)	11/149 (7.4)	13/144 (9.0)	0.71 (0.29–1.72)	0.45	0.58 (0.25–1.35)	0.21	0.82 (0.38–1.75)	0.61
mRS 0–3 (%)									
3 months	125/152 (82.8)	111/151 (73.5)	107/145 (73.8)	1.13 (1.01–1.28)	0.04	1.12 (0.99–1.26)	0.06	1.00 (0.86–1.15)	0.96
12 months	129/152 (85.4)	99/149 (66.4)	102/144 (70.8)	1.29 (1.13–1.47)	0.001	1.21 (1.07–1.37)	0.002	0.94 (0.81–1.09)	0.42
mRS median (IQR)									
3 months	2 (2–3)	3 (2–4)	2 (1–3)	–	0.09	–	0.92	–	0.10
12 months	2 (1–3)	2 (1–5)	2 (1–4)	–	0.005	–	0.14	–	0.34
BI 15–20 (%)									
3 months	123/152 (81.5)	106/151 (70.2)	106/145 (73.1)	1.16 (1.02–1.32)	0.02	1.11 (0.99–1.25)	0.09	0.96 (0.83–1.11)	0.58
12 months	131/152 (86.8)	102/149 (68.5)	102/144 (70.8)	1.27 (1.12–1.44)	0.001	1.22 (1.09–1.37)	0.001	0.97 (0.85–1.11)	0.65

^a Data include ten patients who had a non-stroke diagnosis. RR, relative risk.

TABLE 11 Multiple logistic and Cox's regression tables for mortality and mortality or institutionalisation for randomised patients with stroke^a

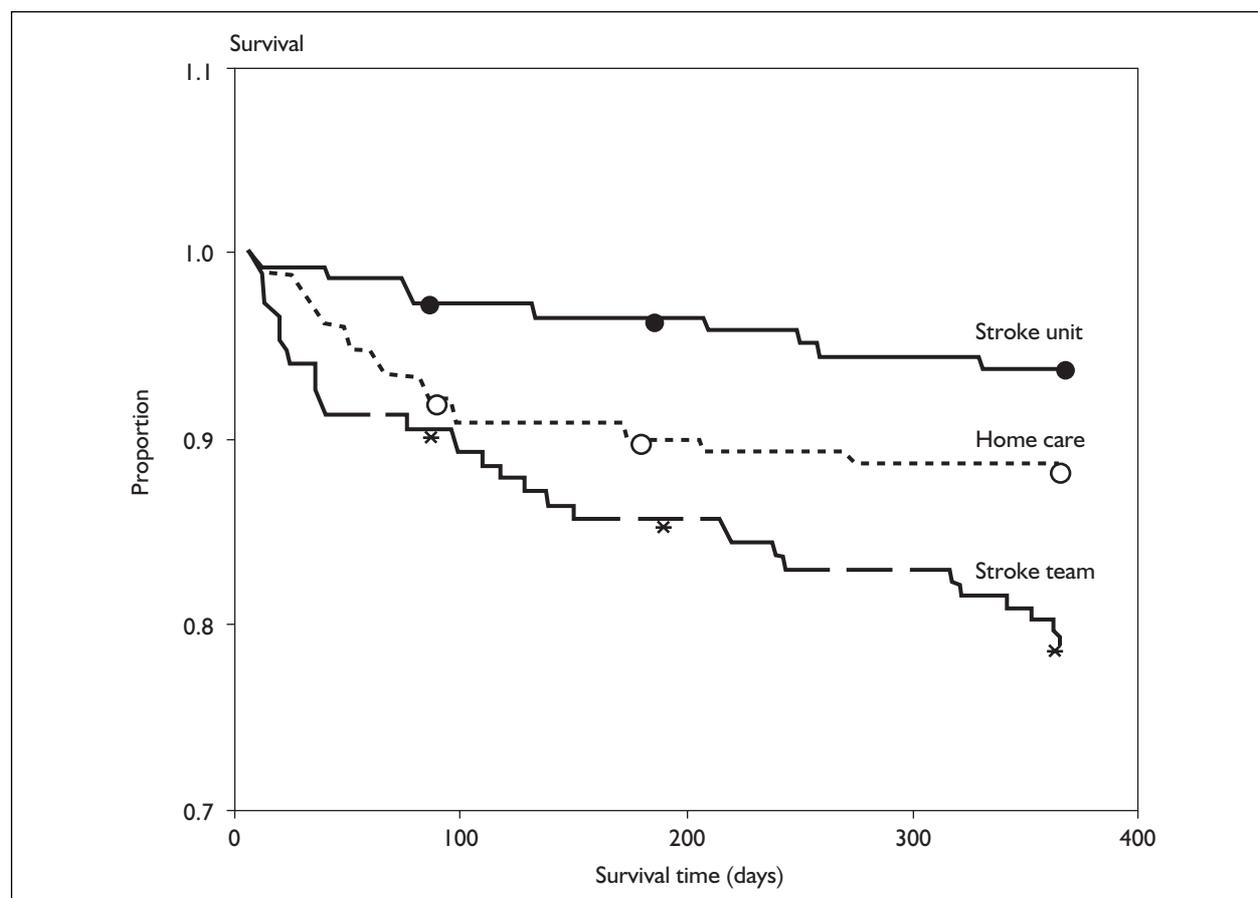
	3 months				1 year				Survival model			
	Events	OR	95% CI	p	Events	OR	95% CI	p	HR	95% CI	p	
Mortality												
Age	28	1.1	1.0 to 1.1	0.05	55	1.04	1.0 to 1.1	0.03	1.04	1.0 to 1.1	0.03	
Dysphasia	28	3.9	1.6 to 9.2	0.002	55	2.01	1.1 to 3.7	0.03	1.9	1.1 to 3.2	0.02	
BI	28	0.8	0.7 to 0.9	0.000	55	0.9	0.8 to 1.0	0.0002	0.9	0.9 to 0.95	0.0001	
Strategy												
Stroke unit	3				9							
Stroke team	15	5.4	1.4 to 21	0.01	30	3.9	1.7 to 9.0	0.001	3.3	1.6 to 7.1	0.002	
Home care	10	2.9	0.7 to 12	0.14	16	1.8	0.8 to 4.4	0.20	1.8	0.8 to 4.1	0.17	
Mortality or Institutionalisation												
Age	66	1.1	1.0 to 1.1	0.001	91	1.1	1.0 to 1.1	0.001	1.1	1.0 to 1.1	0.0001	
Dysphasia	66	2.4	1.2 to 4.5	0.01	91	2.0	1.1 to 3.4	0.02	1.6	1.0 to 2.5	0.02	
BI	66	0.7	0.7 to 0.8	0.000	91	0.8	0.8 to 0.9	0.0000	0.8	0.8 to 0.9	0.0000	
Strategy												
Stroke unit	12				18							
Stroke team	28	2.5	1.1 to 6	0.04	43	3.2	1.6 to 6.4	0.001	2.4	1.4 to 4.2	0.002	
Home care	26	1.8	1.1 to 4.3	0.03	30	1.8	1.0 to 3.8	0.03	1.7	1.0 to 3.0	0.04	

^a Data exclude ten patients with a non-stroke diagnosis.

TABLE 12 Causes of mortality in stroke patients included in the study^a

Cause of death	0–3 months			4–12 months		
	SU	ST	HC	SU	ST	HC
Stroke extension	0	2	2	0	0	0
Stroke recurrence	0	1	1	0	5	1
Chest infection	1	4	2	2	3	1
Other infections/septicaemia	0	1	2	1	1	0
Dehydration/renal failure	0	4	1	0	0	0
Pulmonary embolus	1	2	1	0	0	1
Acute myocardial infarction	1	0	0	1	2	2
Heart failure	0	0	0	0	1	0
Unrelated causes	0	1	1	2	2	1
Uncertain causes	0	1	1	1	2	0

^a Data exclude ten patients with a non-stroke diagnosis.

**FIGURE 2** Kaplan–Meier survival curves for different strategies of care after acute stroke

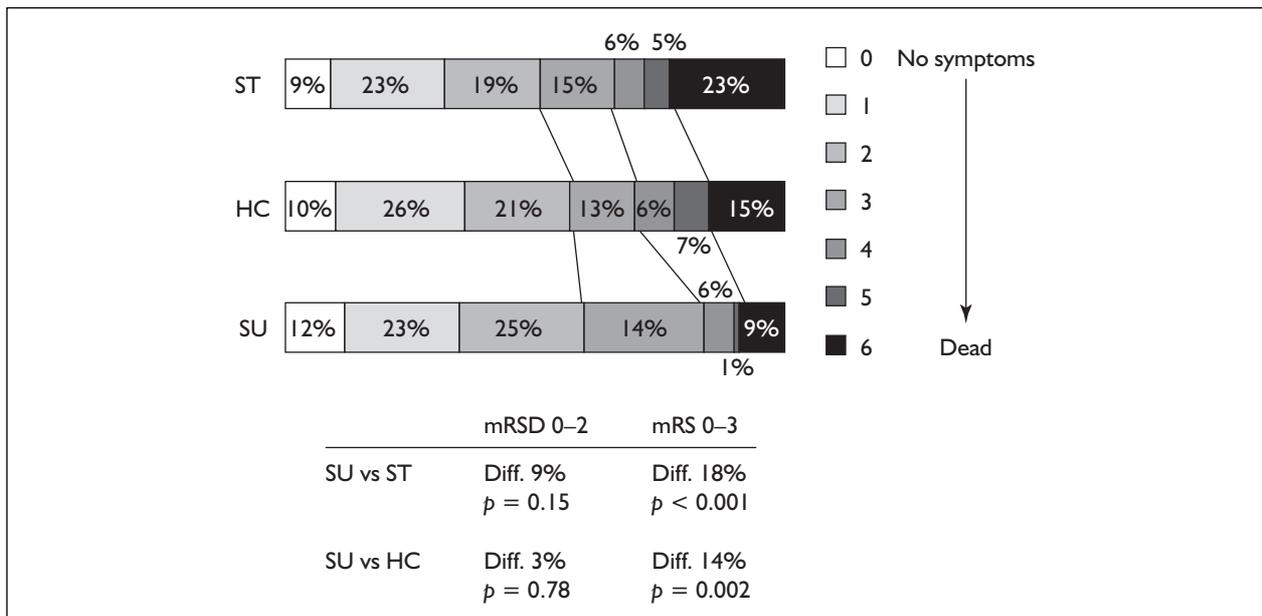


FIGURE 3 Distribution of mRS scores at 1 year

groups remained comparable for age, gender and premorbid functional abilities (Table 13). Survivors in the stroke unit group had greater impairments compared with other groups (Table 13). Although the initial BI was lower in stroke unit survivors, this difference was not statistically significant.

All groups showed good recovery in personal ADL ability, achieving median BI scores of more than 18 by 12 weeks (Table 14). Group comparisons in survivors did not show significant differences in the median BI scores at 3, 6 and 12 months between the strategies. However, survivors managed on the stroke unit showed a significantly greater change in the BI at 6 months (median change 9 versus 7, $p < 0.02$) and 1 year (median change 10 versus 7, $p < 0.002$), when adjusted for differences in baseline. Although this suggests that stroke units may have a beneficial role in improving personal care abilities in stroke survivors, the validity of this observation is limited because of ceiling effect in the BI, which may limit the extent of change measured in other groups.

Functional abilities beyond those required for basic self-care were measured using the FAI. The estimated premorbid FAI scores were comparable between the three groups and showed an average level of function (Table 14). The difference between prestroke and poststroke function was greatest in those managed on the stroke unit and least in those managed at home. Although this suggests that home care may be better in

improving higher levels of function in stroke survivors, the validity of this finding may be limited by the differences in initial stroke severity of survivors between the groups.

Subgroup analyses

As there were differences in stroke severity between groups, survivors were stratified according to their BI score at the time of randomisation (Table 15). This analysis showed that the stroke unit was associated with the best outcome for patients with more severe strokes (initial BI 0-4). The median BI scores for these patients managed on the stroke unit were higher at 3 months (15 versus 10) and at 12 months (17 versus 11) compared with stroke team or domiciliary care. Most of these patients were severely limited for wider ADL and none of these patients returned to their premorbid function (as measured by the FAI), regardless of the strategy used.

The majority of survivors with other stroke severity (BI ≥ 5) achieved a high degree of independence in basic ADL, regardless of the strategy used (Table 15). Patients with BI of 5-9 managed at home showed significantly greater return to premorbid activity levels on the FAI compared with stroke team or stroke unit management. There were no differences in personal or broader ADL between the three strategies in patients with lesser stroke severity (BI ≥ 10), who as a group returned to previous levels of functioning by the end of 1 year after stroke (Table 15).

TABLE 13 Baseline characteristics of survivors in the randomised trial

	SU (n = 138)	ST (n = 115)	HC (n = 123)	p-Value
Demography				
Median age (years) (IQR)	75.1 (67.1–82.5)	76.6 (69.5–82.1)	77.3 (70.8–83.4)	0.29
No. of women (%)	65 (47.1)	56 (48.7)	55 (44.7)	0.83
Living alone (%)	49 (35.5)	51 (44.3)	38 (30.9)	0.09
Premorbid independence				
Contenance	138	113	122	0.69
Dressing	138	111	119	0.27
Mobility	138	114	121	0.45
Stroke characteristics				
Left/right	72/62	52/57	66/54	0.52
Cerebral bleed (%)	17 (12.3)	9 (7.8)	6 (5.1)	0.94
Stroke subtype				
TACS	17	9	9	0.47
PACS	70	55	67	
LACS	40	39	40	
POCS	11	12	6	
Inattention (%)	49 (35.5)	33 (28.7)	46 (37.4)	0.34
Dysphasia (%)	47 (34.1)	32 (27.8)	35 (28.5)	0.51
Incontinence (%)	42 (30.4)	37 (32.2)	31 (25.2)	0.50
Orgogozo score (0–100), median (IQR)	75 (45–90)	85 (70–90)	85 (60–90)	0.04
OPS (1.6–6.8), median (IQR)	3.6 (2.4–4.4)	3.2 (2.4–4.0)	3.2 (2.0–3.6)	0.03
BI (0–20), median (IQR)	8 (5–13)	10 (6–12)	10 (6–15)	0.18

TABLE 14 Functional ability in stroke survivors at 3, 6 and 12 months

	SU (n = 138)	ST (n = 115)	HC (n = 123)	Differences between groups
BI				
Week 12	18 (16–20)	19 (17–20)	19 (17–20)	NS
Week 26	19 (17–20)	19 (17–20)	20 (17–20)	NS
Week 52	19 (17–20)	19 (17–20)	20 (17–20)	NS
Change in BI				
Week 0 to Week 12	9 (5–12)	8 (5–11)	7 (3–10)	SU vs HC $p < 0.02$
Week 0 to Week 52	10 (6–13)	8 (6–11)	7 (3–10)	SU vs HC $p < 0.002$
FAI				
Premorbid	27 (23–34)	27 (20–33)	28 (20–33)	NS
Week 26	17 (7–25)	19 (8–27)	21 (7–30)	NS
Week 52	20 (8–27)	19 (7–29)	21 (9–30)	NS
Change in FAI				
Premorbid to 26 weeks	–9 (–1 to –22)	–5 (0 to –14)	–3 (0 to –11)	HC vs SU $p < 0.005$
Premorbid to 52 weeks	–5 (–1 to –14)	–4 (0 to –14)	–3 (0 to –11)	HC vs SU $p < 0.01$
Data are shown as median (IQR). NS, not significant.				

The influence of age on functional outcome between strategies was assessed by dichotomising survivors into those 75 years or younger and those over 75 years of age (Table 16). There were no significant differences in the median BI at 3, 6 or

12 months in either age group between the three strategies. In addition, recovery in personal ADL score was comparable between older and younger patients for each strategy. This suggested that there was no interaction between age and strategy

TABLE 15 Subgroup analysis of functional recovery in stroke survivors, stratified by initial disability at the time of randomisation

	BI 0-4 (n = 82)			BI 5-9 (n = 105)			BI 10-14 (n = 112)			BI > 14 (n = 77)		
	HC (n = 27)	ST (n = 22)	SU (n = 33)	HC (n = 25)	ST (n = 35)	SU (n = 45)	HC (n = 37)	ST (n = 44)	SU (n = 31)	HC (n = 34)	ST (n = 14)	SU (n = 29)
BI												
Week 12	10 (4-16)	13 (4-16)	15 (11-17)	19 (17-20)	18 (17-19)	18 (17-19)	20 (19-20)	19 (18-20)	20 (18-20)	20 (19-20)	20 (20-20)	20 (20-20)
Week 52	11 (5-16)	15 (5-17)	17 (15-18)	20 (18-20)	19 (17-20)	19 (17-20)	20 (19-20)	20 (18-20)	20 (18-20)	20 (20-20)	20 (20-20)	20 (20-20)
FAI												
Premorbid	20 (16-32)	26 (15-33)	27 (20-34)	23 (16-32)	27 (19-33)	30 (26-36)	30 (25-35)	28 (21-34)	25 (20-31)	29 (24-33)	29 (21-34)	27 (23-36)
Week 26	3 (1-9)	4 (0-8)	6 (3-13)	18 (7-23)	13 (6-23)	14 (8-24)	25 (17-33)	25 (17-33)	20 (12-17)	26 (19-32)	24 (17-32)	23 (17-27)
Week 52	4 (0-12)	3 (0-7)	7 (3-22)	21 (8-24)	13 (8-26)	16 (8-26)	27 (16-34)	23 (14-31)	24 (12-29)	25 (19-32)	26 (19-31)	26 (20-30)
Change in FAI												
0 to 52 weeks	-14 (-25 to -6)	-18 (-25 to -5)	-14 (-22 to -8)	-3 (-9 to 0)	-6 (-15 to -2)	-10 (-19 to -4)	-2 (-7 to 0)	0 (-6 to 0)	-2 (-6 to -1)	-1 (-6 to 0)	-2 (-6 to 0)	-1 (-2 to 0)

Data are shown as median (IQR).
 SU better than ST and HC in BI for 0-4 group ($p < 0.02$ and $p < 0.0006$, respectively). HC better than ST and SU for FAI in 5-9 group only ($p < 0.05$ and $p < 0.02$, respectively).

TABLE 16 Subgroup analysis of functional recovery in stroke survivors, stratified by age

	Subjects ≤ 75 years of age (n = 165)			Subjects > 75 years of age (n = 211)			Differences between groups	
	SU (n = 67)	ST (n = 50)	HC (n = 48)	SU (n = 70)	ST (n = 65)	HC (n = 76)	≤ 75 years	> 75 years
BI								
Week 12	19 (17-20)	20 (18-20)	20 (19-20)	18 (16-20)	18 (15-19)	18 (15-20)	NS	NS
Week 26	19 (17-20)	20 (19-20)	20 (19-20)	19 (17-20)	18 (16-20)	18 (14-20)	NS	NS
Week 52	19 (17-20)	20 (19-20)	20 (20-20)	19 (17-20)	18 (15-20)	19 (15-20)	NS	NS
Change in BI								
Week 0 to Week 12	10 (7-12)	8 (5-11)	6 (2-10)	8 (5-10)	8 (6-11)	8 (5-10)	SU vs HC p < 0.01	NS
Week 0 to Week 52	11 (7-14)	8 (6-12)	6 (2-10)	8 (5-12)	8 (5-11)	8 (4-11)	SU vs HC p < 0.008	NS
FAI								
Premorbid	27 (21-35)	27 (21-34)	28 (23-33)	28 (23-34)	27 (17-33)	26 (19-33)	No significant difference between age groups	
Week 26	18 (7-25)	22 (14-30)	26 (13-32)	17 (7-26)	13 (6-24)	17 (4-24)	SU vs HC p < 0.008	
Week 52	19 (8-26)	24 (11-31)	27 (15-32)	21 (7-28)	13 (4-26)	17 (5-26)	SU vs HC p < 0.003	

Data are shown as median (IQR).

The marked differences for change in BI between SU and HC may be due to the ceiling and floor effect associated with the score. Note that there was no difference in baseline FAI between age groups, suggesting that age in itself is not disabling.

TABLE 17 HADS and EuroQol scores for survivors, by strategy

	SU (n = 138)	ST (n = 115)	HC (n = 123)	Differences between groups
HADS				
Anxiety at 12 weeks	3 (2–5)	4 (2–6)	3 (1–6)	NS
Anxiety at 1 year	2 (1–4)	2 (1–5)	2 (1–5)	NS
Depression at 12 weeks	3 (2–7)	3 (1–7)	3 (1–6)	NS
Depression at 1 year	2.5 (1–5)	3 (1–5)	2 (1–5)	NS
Euroqol analogue scores				
EuroQol at 12 weeks	75 (50–85)	60 (50–75)	72.5 (60–85)	SU vs ST $p < 0.01$ HC vs ST $p < 0.005$
EuroQol at 1 year	80 (65–90)	75 (55–85)	75 (60–90)	NS
Data are shown as median (IQR).				

for personal ADL and old patients benefited as much from stroke unit care as younger patients.

The premorbid FAI score was comparable between younger and older patients. Older patients as a group did not return to their previous levels of functioning at 6 or 12 months, regardless of the strategy used. Younger patients managed at home returned to their previous level of function by 6 months after stroke. In contrast, younger patients managed on the stroke unit had not returned to previous levels of function even 1 year after stroke.

Psychological and quality of life measures

There were no significant differences in the levels of anxiety and depression measured using the HADS⁴² between patients managed on the stroke unit, those managed by the stroke team on general medical wards and those managed at home (Table 17). In general, patients exhibited low levels of anxiety and depression as a group at all time points up to 1 year. Quality of life measured using an analogue scale showed that patients on the stroke unit and those managed at home had significantly higher ratings compared with patients managed on the general ward by the stroke team at 12 weeks. These differences disappeared by the end of 1 year after stroke.

An overall analogue representation of quality of life allows cost–utility comparisons, but may mask significant differences between different domains contributing to the overall quality of life or differences between stroke patients. In view of this, further analysis was undertaken to assess changes in individual domains for the three interventions at 3 months (Table 18) and at 1 year (Table 19). The influence of stroke severity on mood and quality of life measures was analysed by stratifying patients according to initial BI scores and comparing outcome for each strategy (Table 20).

There were no significant differences in patients reporting ‘no problems’ in the domains of mobility, self-care, pain and psychological functioning at 3 or 12 months with any of the three strategies (Tables 18 and 19). The only significant difference was in the activities domain at 3 months, where a significantly greater proportion of patients managed at home reported no problems compared with those in hospital, whether they were managed on the stroke unit or on general wards with stroke team support ($\chi^2 = 13.977$, $p < 0.001$). Overall, the domains of mobility and activity were affected more significantly than those of self-care, pain or psychological functioning at 3 months and 1 year, regardless of strategy of care ($\chi^2 = 41.954$, $p < 0.0001$).

Patients with more severe strokes had significantly higher depression scores for all strategies of care compared with patients who had less severe strokes (Table 20). This difference was most marked for patients managed on general wards by the stroke team. There were no significant differences between the stroke unit care and care at home for mood outcomes.

Patients with more severe strokes had worse quality of life scores at 12 weeks and 1 year regardless of the strategy of management (Table 20). Patients with more severe strokes had higher quality of life scores at 12 weeks and 1 year with stroke unit care compared with those managed at home or by the stroke team. Despite a positive trend in all scores, the difference was significant only between stroke unit and stroke team care at 1 year. In patients with less severe strokes, higher quality of life scores, both at 12 weeks and 1 year, were seen in patients managed at home. These differences were significant at 12 weeks and 1 year.

TABLE 18 Quality of life (EuroQol) scores by domain for patients managed at home, by a stroke team or on the stroke unit at 3 months

EuroQol domain	Strategy	n	No problems	Some problems	Severe problems	Missing	LTFU/dead
Mobility	HC	131	60 (46)	58 (44)	9 (7)	4 (3)	18
	ST	135	53 (39)	65 (48)	9 (7)	8 (6)	15
	SU	144	70 (49)	68 (47)	4 (3)	–	6
Self-care	HC	131	90 (69)	32 (24)	5 (4)	4 (3)	18
	ST	135	81 (60)	43 (32)	3 (2)	8 (6)	15
	SU	144	93 (65)	48 (33)	1 (1)	–	6
Activities	HC	131	51 (39)	59 (45)	17 (13)	4 (3)	18
	ST	135	25 (19)	72 (53)	30 (22)	8 (6)	15
	SU	144	27 (19)	86 (60)	29 (20)	–	6
Pain	HC	131	88 (67)	37 (28)	2 (2)	4 (3)	18
	ST	135	97 (72)	30 (22)	0	8 (6)	15
	SU	144	93 (65)	46 (32)	3 (2)	–	6
Psychological functioning	HC	131	83 (63)	42 (32)	2 (2)	4 (3)	18
	ST	135	80 (59)	42 (31)	5 (4)	8 (6)	15
	SU	144	89 (62)	49 (34)	4 (3)	–	6

Data are shown as n (%).
n, total number of responses possible (denominator), including those missing; LTFU, lost to follow-up/unable to complete questionnaire.

TABLE 19 Quality of life (EuroQol) scores by domain for patients managed at home, by a stroke team or on the stroke unit at 12 months

EuroQol domain	Strategy	n	No problems	Some problems	Severe problems	Missing	LTFU/dead
Mobility	HC	123	66 (54)	49 (40)	5 (4)	3 (2)	26
	ST	116	58 (50)	50 (43)	4 (3)	4 (3)	34
	SU	137	83 (60)	50 (38)	2 (1)	–	13
Self-care	HC	123	88 (72)	28 (23)	4 (3)	3 (2)	26
	ST	116	83 (72)	27 (23)	2 (2)	4 (3)	34
	SU	137	97 (72)	37 (27)	1 (1)	–	13
Activities	HC	123	57 (46)	49 (40)	14 (12)	3 (2)	26
	ST	116	46 (40)	51 (44)	15 (13)	4 (3)	34
	SU	137	58 (44)	63 (46)	14 (10)	–	13
Pain	HC	123	94 (77)	25 (20)	1 (1)	3 (2)	26
	ST	116	87 (75)	22 (19)	3 (3)	4 (3)	34
	SU	137	102 (74)	32 (23)	2 (2)	–	13
Psychological functioning	HC	123	91 (74)	27 (22)	2 (2)	3 (2)	26
	ST	116	85 (73)	24 (21)	4 (3)	4 (3)	34
	SU	137	100 (74)	33 (24)	2 (1)	–	13

Data are shown as n (%).
n, total number of responses possible (denominator), including those missing.

The findings are limited because of the imbalance in stroke severity between the survivors in various limbs of the study, the post hoc nature of subgroup analyses and the small sample size of each subgroup. In view of this, multiple regression

using stepwise deletion was undertaken in the whole survivor group to see whether strategy of care remained a significant variable in improving outcome after adjusting for other baseline prognostic variables included in *Table 13*. The

TABLE 20 Subgroup analysis of mood and quality of life aspects in stroke survivors, stratified by initial disability at the time of randomisation

	BI 0-4 (n = 82)			BI 5-9 (n = 105)			BI 10-14 (n = 112)			BI > 14 (n = 77)		
	HC (n = 27)	ST (n = 22)	SU (n = 33)	HC (n = 25)	ST (n = 35)	SU (n = 45)	HC (n = 37)	ST (n = 44)	SU (n = 31)	HC (n = 34)	ST (n = 14)	SU (n = 29)
HADS-A 12 week	4.5 (3-7)	5 (3-7)	4 (1-6)	3 (1-6)	4 (1-6)	3 (1-6)	2 (1-3.5)	3.5 (1-6)	3 (1.5-4)	2 (1-7)	3 (2-3)	3 (2-5.5)
HADS-A 1 year	3 (1-5)	3 (2-6)	3 (1-5)	3 (0-6)	2 (1-5)	2 (1-4)	1 (0-3)	2 (0-4)	2 (0-3)	3 (1-5)	2 (1-4)	2 (0.5-4.5)
HADS-D 12 week	6 (4-8)	8 (3-9)	5 (3-9)	3 (1-4.5)	3 (2-7)	3 (2-6)	3 (1-6.5)	3 (1-6)	3 (1-6)	2 (1-3)	2 (1-4.5)	2 (1-4)
HADS-D 1 year	4.5 (2-7)	5 (1-7)	4 (2-8)	2.5 (1-7)	3 (1-6)	4 (2-5)	2 (0-3)	2 (0-4)	2 (1-3)	2 (1-4)	2 (0-3.5)	1 (0-2.5)
EuroQol 12 weeks	55 (35-65)	50 (35-60)	60 (40-80)	70 (60-83)	65 (50-75)	75 (60-80)	77 (65-89)	67 (50-79)	75 (53-86)	75 (70-90)	62 (50-90)	75 (70-90)
EuroQol 1 year	60 (50-75)	50 (30-75)	75 (55-85)	75 (50-85)	75 (65-85)	80 (55-85)	85 (75-90)	75 (51-89)	82.5 (70-90)	85 (74-90)	80 (64-95)	85 (75-95)
EQ52: SU vs ST $p < 0.03$												
EQ12: HC vs ST $p < 0.014$												
EQ52: HC vs ST $p < 0.033$												
EQ12: HC vs ST $p < 0.03$												
Data are shown as Median (IQR).												
HADS-A, Hospital Anxiety and Depression Scale (Anxiety score); HADS-D, Hospital Anxiety and Depression Scale (Depression score); EQ12, EuroQol at 12 weeks; EQ52, EuroQol at 1 year.												

outcome measures of interest were the BI, FAI and quality of life scores. Adjustment was also made for depression and anxiety in the regression for quality of life. The results of the analysis are

presented in *Table 21*. Stroke unit care was a significant independent determinant of BI score at 1 year, but there were no differences for other outcomes.

TABLE 21 Multiple regression tables for BI, Frenchay Activities Index and quality of life at 12 months in stroke survivors

Predictive factor	Regression coefficient	t-Value	p-Value
BI at 1 year			
Age (years)	-0.06	-4.56	<0.001
OPS	-1.65	-11.27	<0.001
Incontinence at presentation	-1.87	-4.79	<0.001
Randomisation to HC	-1.42	-4.02	<0.001
Randomisation to ST	-0.96	-2.70	<0.001
Variability explained (R^2) by the above factors = 48.3%			
FAI at 1 year			
Age	-0.18	-3.49	0.001
Female gender	2.91	2.82	0.005
OPS	-4.71	-5.45	<0.001
BI at randomisation	0.52	3.54	<0.001
Variability explained (R^2) by the above factors = 33%			
EuroQoL (visual analogue scale) at 1 year			
BI at randomisation	0.98	5.16	<0.001
Living alone at randomisation	-6.81	-3.27	0.001
Variability explained (R^2) by the above factors = 9.6%.			

TABLE 22 Patient satisfaction

	n	Strongly agree	Agree	Disagree	Strongly disagree
(a) Domiciliary care^a					
I have been treated with kindness and respect	126	79 (63)	45 (36)	2 (1)	0
The staff attended well to my personal needs	84	36 (43)	39 (46)	9 (11)	0
I felt able to talk to staff about my problems	126	43 (34)	64 (51)	19 (15)	0
I have been given all the information about the cause and nature of my illness	126	34 (27)	64 (54)	23 (18)	1 (1)
The doctors have done everything they can to get me well again	126	50 (40)	75 (59)	1 (1)	0
I am happy with the amount of recovery I have made since my illness	126	39 (31)	56 (44)	19 (15)	12 (10)
I am satisfied with the type of treatment the therapists have given me	126	67 (54)	51 (40)	8 (6)	0
I have had enough therapy	126	37 (30)	58 (46)	28 (22)	3 (2)
I was given all the information I wanted about allowances and services I may need at home	88	13 (15)	38 (43)	32 (36)	5 (6)
Things were well organised at home	60	35 (58)	24 (40)	1 (2)	0
I got all the support I need from services such as meals on wheels, home help, district nursing	36	14 (39)	21 (58)	1 (3)	0
I am satisfied with the amount of contact I have had with the stroke team	126	39 (31)	79 (63)	8 (6)	0

continued

TABLE 22 Patient satisfaction (cont'd)

	<i>n</i>	Strongly agree	Agree	Disagree	Strongly disagree
(b) Stroke team^b					
I have been treated with kindness and respect	128	90 (70)	38 (30)	0	0
The staff attended well to my personal needs	128	51 (40)	67 (52)	9 (7)	1 (1)
I felt able to talk to staff about my problems	128	11 (8)	78 (61)	38 (30)	1 (1)
I have been given all the information about the cause and nature of my illness	128	14 (11)	73 (57)	35 (27)	6 (5)
The doctors have done everything they can to get me well again	128	37 (29)	90 (70)	0	1 (1)
I am happy with the amount of recovery I have made since my illness	128	29 (23)	50 (39)	36 (28)	13 (10)
I am satisfied with the type of treatment the therapists have given me	128	55 (43)	63 (49)	8 (6)	2 (2)
I have had enough therapy	128	29 (23)	68 (53)	24 (19)	7 (5)
I was given all the information I wanted about allowances and services I may need at home	116	2 (2)	62 (53)	47 (41)	5 (4)
Things were well organised at home	73	30 (41)	41 (56)	2 (3)	
I got all the support I need from services such as meals on wheels, home help, district nursing	48	14 (29)	31 (65)	2 (4)	1 (2)
I am satisfied with the amount of contact I have had with the stroke team	128	17 (13)	96 (75)	15 (12)	0
(c) Stroke unit^c					
I have been treated with kindness and respect	142	91 (64)	47 (33)	3 (2)	1 (1)
The staff attended well to my personal needs	142	48 (34)	79 (56)	12 (8)	3 (2)
I felt able to talk to staff about my problems	142	19 (13)	95 (67)	27 (19)	1 (1)
I have been given all the information about the cause and nature of my illness	142	25 (17)	85 (60)	31 (22)	1 (1)
The doctors have done everything they can to get me well again	142	55 (39)	84 (59)	2 (1)	1 (1)
I am happy with the amount of recovery I have made since my illness	142	40 (28)	62 (44)	25 (17)	15 (11)
I am satisfied with the type of treatment the therapists have given me	142	67 (47)	70 (49)	4 (3)	1 (1)
I have had enough therapy	142	34 (24)	68 (48)	32 (23)	8 (5)
I was given all the information I wanted about allowances and services I may need at home	124	9 (7)	72 (58)	36 (29)	7 (6)
Things were well organised at home	106	37 (35)	63 (59)	6 (6)	0
I got all the support I need from services such as meals on wheels, home help, district nursing	43	7 (16)	33 (77)	3 (7)	0
I am satisfied with the amount of contact I have had with the stroke team	142	32 (23)	106 (75)	4 (3)	0
Data are shown as <i>n</i> (%).					
<i>n</i> , patients who considered that the question applied to them.					
^a 23 patients were 'excluded' (dysphasia, dead or LTFU).					
^b 22 patients were 'excluded' (dysphasia, dead or LTFU).					
^c Six patients were 'excluded' (dysphasia or dead).					

Acceptability and satisfaction with care

The patient satisfaction with care received was assessed at 3 months in all groups. This time-point

was chosen as it marked the end of the active intervention phase. A small number of patients could not respond to the questionnaire and there were some inconsistencies in responses because some patients believed that certain questions did

TABLE 23 Summary scores on the patient satisfaction questionnaire (number of patients as a proportion of responders) at 3 months

	Strongly agree			Agree			Disagree			Strongly disagree		
	SU	ST	HC	SU	ST	HC	SU	ST	HC	SU	ST	HC
I have been treated with kindness and respect	64%	70%	63%	33%	30%	36%	2%	0%	1%	1%	0%	0%
The staff attended well to my personal needs	34%	40%	43%	56%	52%	46%	8%	7%	11%	2%	1%	0%
I felt able to talk to staff about my problems	13%	8%	34%	67%	61%	51%	19%	30%	15%	1%	1%	0%
I have been given all the information about the cause and nature of my illness	17%	11%	27%	60%	57%	54%	22%	27%	18%	1%	5%	1%
The doctors have done everything they can to get me well again	39%	29%	40%	59%	70%	59%	1%	0%	1%	1%	1%	0%
I am happy with the amount of recovery I have made since my illness	28%	23%	31%	44%	39%	44%	17%	28%	15%	11%	10%	10%
I am satisfied with the type of treatment the therapists have given me	47%	43%	54%	49%	49%	40%	3%	6%	6%	1%	2%	0%
I have had enough therapy	24%	23%	30%	48%	53%	46%	23%	19%	22%	5%	5%	2%
I was given all the information I wanted about allowances and services I made need at home	7%	2%	15%	58%	53%	43%	29%	41%	36%	6%	4%	6%
Things were well organised at home	35%	41%	58%	59%	56%	40%	6%	3%	2%	0%	0%	0%
I got all the support I need from services such as meals on wheels, home help, district nursing	16%	29%	39%	77%	65%	58%	7%	4%	3%	0%	2%	0%
I am satisfied with the amount of contact I have had with the stroke team	23%	13%	31%	75%	75%	63%	3%	12%	6%	0%	0%	0%

TABLE 24 Carer satisfaction questions [number of carers dissatisfied (strongly disagree) as a proportion of responders]

	Strongly agree			Agree			Disagree			Strongly disagree		
	SU (n = 103)	ST (n = 87)	HC (n = 98)	SU (n = 103)	ST (n = 87)	HC (n = 98)	SU (n = 103)	ST (n = 87)	HC (n = 98)	SU (n = 103)	ST (n = 87)	HC (n = 98)
The person I am caring for has been treated with kindness and respect	58 (56)	38 (44)	56 (57)	42 (41)	46 (53)	38 (39)	3 (3)	2 (2)	4 (4)	0	1 (1)	0
The staff attended well to their personal needs ^a	33 (32)	10 (12)	22 (30)	54 (52)	56 (64)	39 (54)	16 (16)	19 (22)	9 (13)	0	2 (2)	2 (3)
I am satisfied that the staff have done everything possible to make them well again	34 (33)	22 (25)	39 (40)	66 (64)	54 (62)	50 (51)	3 (3)	10 (12)	9 (9)	0	1 (1)	0
The stroke team staff recognise the difficulties of caring for someone who has had a stroke ^b	11 (11)	8 (11)	32 (36)	74 (71)	52 (69)	47 (53)	14 (14)	15 (20)	10 (11)	4 (4)	0	0
I am satisfied with the type of therapy my relative/friend has had	36 (35)	18 (21)	42 (44)	62 (60)	57 (65)	48 (49)	4 (4)	11 (13)	5 (5)	1 (1)	1 (1)	2 (2)
My relative/friend has had enough therapy	17 (17)	7 (8)	27 (28)	52 (50)	44 (50)	44 (45)	27 (26)	31 (36)	18 (18)	7 (7)	5 (6)	9 (9)
I was given all the information I wanted about allowances and services ^c	16 (17)	2 (3)	8 (12)	61 (65)	44 (65)	38 (56)	15 (16)	20 (29)	21 (31)	2 (2)	2 (3)	1 (1)
Things were well organised at home ^d	24 (35)	11 (27)	20 (43)	40 (58)	23 (56)	24 (51)	5 (7)	7 (17)	2 (4)	0	0	1 (2)
As a carer, I get all the support I need from services, e.g. home help, district nurses ^e	2 (9)	6 (30)	5 (25)	13 (59)	7 (35)	9 (45)	6 (27)	7 (35)	5 (25)	1 (5)	0	1 (5)
I am satisfied with the amount of contact I have had with the stroke team staff	21 (20)	4 (5)	31 (32)	70 (68)	71 (82)	54 (56)	12 (12)	11 (13)	12 (12)	0	1 (1)	0

Data are shown as n (%).

^a n (HC) = 72.

^b n (ST) = 75; n (HC) = 89.

^c n (SU) = 94; n (ST) = 68; n (HC) = 68.

^d n (SU) = 69; n (ST) = 41; n (HC) = 46.

^e n (SU) = 22; n (ST) = 20; n (HC) = 20.

not apply to them. The responses from each group are presented in *Table 22(a-c)* and a summary of all responses in *Table 23*. Carers' satisfaction with different strategies of care was assessed using a similar questionnaire (*Table 24*).

Patients were more satisfied with the care provided by the domiciliary stroke team compared with the stroke unit or stroke team (*Table 23*). This was significant for being able to talk about problems with professionals ($\chi^2 = 25.425, p < 0.0001$), information on the nature and cause of the stroke ($\chi^2 = 8.561, p = 0.014$), organisation of care at home ($\chi^2 = 11.518, p < 0.003$), support from community services ($\chi^2 = 13.194, p = 0.001$) and the amount of contact with the specialist team ($\chi^2 = 9.378, p = 0.009$).

There were significant differences in carers' satisfaction with management between the three different strategies (*Table 24*). On the whole, carers rated care provided on general wards supported by the stroke team as less satisfactory than that provided on the stroke unit or at home. Major items contributing to differences in satisfaction were attention to personal needs of the patient

($\chi^2 = 13.059, p = 0.001$), recognition of problems associated with caring for stroke patients ($\chi^2 = 22.028, p < 0.0001$), amount of therapy provided ($\chi^2 = 13.796, p = 0.001$), information on benefits and services ($\chi^2 = 10.564, p = 0.005$) and the level of contact with the specialist team ($\chi^2 = 23.782, p < 0.0001$).

Although patients and carers generally agreed on the areas where care was considered less satisfactory, carers tended to be less satisfied than patients on the amount of therapy input, information on support and benefits and contact with the specialist teams.

Professional acceptability of domiciliary care

The acceptability of a domiciliary service for acute stroke patients was evaluated using a questionnaire completed by various professionals involved with the care of stroke patients at home. These included the GPs, district nurses and social services care managers. The number of professionals involved with the project was too small to allow any meaningful statistical analysis. A summary of their views is presented in *Table 25*.

TABLE 25 Professional acceptability of domiciliary care for acute stroke patients

	GP (n = 48)			DN (n = 18)			SSCM (n = 6)		
	Yes	No	DK	Yes	No	DK	Yes	No	DK
Do you think all stroke patients should be admitted to hospital?	15 (31%)	28	5	8	8	2	4	1	1
Were you confident in looking after this patient at home?	25 (52%)	6	17	15	3	0	4	2	0
Did you receive adequate support from the stroke team?	39 (81%)	6	3	15	3	0	5	1	0
Did you receive adequate support from other professionals?	28 (58%)	6	14	17	1	0	5	1	0
Has the domiciliary stroke service increased your workload?	16 (33%)	28	4	16	1	1	6	0	0
Do you consider that the stroke domiciliary service provides an appropriate alternative to hospital for:									
All patients?	3 (6%)	–	–	2	–	–	0	–	–
Most patients?	10 (21%)	–	–	7	–	–	2	–	–
Some patients?	33 (69%)	–	–	8	–	–	4	–	–
No patients?	2 (4%)	–	–	1	–	–	0	–	–
Were the guidelines for admission helpful?	39 (81%)	3	6	14	1	3	NA	NA	NA
Would you support the establishment of a domiciliary stroke service for selected patients?	28 (58%)	4	16	18	0	0	3	1	2

DN, district nurse; SSCM, social services care manager; DK, don't know; NA, not applicable.

Organisational evaluation of different settings in the project

An organisational audit of the settings for different interventions was undertaken to evaluate differences between settings and the changes needed to the infrastructure for undertaking the project. The major differences in organisation of care were the

lack of 24-hour medical cover in patients managed at home and the limited access to dedicated social services support on general medical wards (Table 26). An assessment of staff knowledge and skills showed significant differences in the planning of management, education and team working between settings before the project, which were addressed as a part of the study (Table 27).

TABLE 26 Organisational evaluation of interdisciplinary services available in the three settings before and during the project

	SU		ST		HC	
	Before	Project	Before	Project	Before	Project
Medical care						
Specialist consultant responsibility	Yes	Yes	No	No	No	No
Specialist consultant input/review	Yes	Yes	No	Yes	No	Yes
Access to 24-hour medical care	Yes	Yes	Yes	Yes	No	No
Early access to						
Imaging	Yes	Yes	No	Yes	No	Yes
Physiotherapy	Yes	Yes	No	Yes	No	Yes
Occupational therapy	Yes	Yes	No	Yes	No	Yes
Speech and language therapy	Yes	Yes	Yes	Yes	Yes	Yes
Dietetics	Yes	Yes	No	Yes	No	No
Psychology	No	No	No	No	No	No
Social worker attached to team	Yes	Yes	No	No	No	Yes
Social worker attends multidisciplinary team meetings	Yes	Yes	No	No	No	Yes
Specialist medical/nursing support for						
24-hour care	Yes	Yes	No	No	No	No
Continence advice	No	No	No	No	Yes	Yes
Prevention of stroke-related complications	Yes	Yes	No	Yes	No	Yes

TABLE 27 Organisational evaluation of staff knowledge, skills and team working in the three settings before and during the project

	SU		ST		HC	
	Before	Project	Before	Project	Before	Project
Day-to-day management planned by staff expert in stroke care						
Medical	Yes	Yes	No	No	No	Yes
Nursing	Yes	Yes	No	No	No	Yes
Therapy	Yes	Yes	No	Yes	No	Yes
Programme of continuing education						
For qualified staff	Yes	Yes	No	Yes	No	Yes
For non-qualified staff	Yes	Yes	No	Yes	No	Yes
Team working						
Single set of multidisciplinary notes	Yes	Yes	No	Yes	No	Yes
Local weekly multidisciplinary team meetings	Yes	Yes	No	Yes	No	Yes
Participation of consultant/GP in weekly multidisciplinary team meetings	Yes	Yes	No	No	No	No
Local agreed measures for stroke	Yes	Yes	No	Yes	No	Yes
Local guidelines on continence	Yes	Yes	Yes	Yes	Yes	Yes
Local guidelines on pressure areas	Yes	Yes	Yes	Yes	Yes	Yes
Local guidelines on swallowing	Yes	Yes	No	Yes	No	Yes
Information on support patient/carer organisations	Yes	Yes	No	Yes	No	Yes

TABLE 28 Length of hospital stay and therapy input (ITT analysis)

	SU	ST	HC
Length of hospital stay (days)			
Mean (SD)	32.0 (29.6)	29.5 (40.1)	48.9 (26.6) ^a
Median (IQR)	21.5 (8–48)	16 (10–35)	–
Physiotherapy			
No. of patients treated (%)	147 (99)	146 (97)	148 (99)
Duration per patient (hours), median (IQR)	22.0 (12.5–40.7)	5.3 (2.7–10.6)	8.0 (3.0–13.8)
Occupational therapy			
No. of patients treated (%)	148 (100)	130 (87)	148 (99)
Duration per patient (hours), median (IQR)	6.0 (3.0–12.0)	2.0 (1.0–4.0)	3.0 (2.0–6.0)
Speech therapy			
No. of patients treated (%)	105 (71)	70 (47)	73 (49)
Duration per patient (hours), median (IQR)	4.2 (2.3–8.4)	2.3 (1.2–4.4)	2.0 (1.2–4.2)
^a For 51 patients requiring hospital admission from home according to predetermined criteria. Duration for therapy has been computed for those patients actually receiving treatment.			

TABLE 29 Proportion of patients dead or institutionalised, by strategy group and time

Strategy	3 months	6 months	12 months	Overall
SU	0.08 (0.03–0.13)	0.11 (0.05–0.16)	0.12 (0.06–0.18)	0.10 (0.05–0.15)
ST	0.18 (0.13–0.23)	0.22 (0.17–0.28)	0.27 (0.22–0.33)	0.23 (0.17–0.28)
HC	0.18 (0.13–0.23)	0.21 (0.15–0.26)	0.21 (0.16–0.27)	0.20 (0.15–0.25)
Overall	0.15 (0.12–0.17)	0.18 (0.15–0.21)	0.20 (0.17–0.24)	
Data shown as proportion (95% confidence interval).				

Summary resource use

The total duration of hospital stay was comparable between patients managed on the stroke unit and those managed by the stroke team (Table 28). The mean length of stay of the 51 patients admitted to hospital from domiciliary care was 48.6 ± 26.7 days (median 50 days, IQR 27–65). The proportion of patients receiving different types of therapy input was comparable for the three groups, except for speech and language therapy, which was available to a higher proportion of patients on the stroke unit (Table 28). Patients on the stroke unit received significantly more therapy from all disciplines compared with those managed by the stroke team or at home. There were no significant differences in the duration of therapy between the stroke team and the home care group.

A detailed health economic evaluation will be presented in a later section.

Targeting of strategy

An important objective of the study was to identify prognostic variables that will help to identify patients suitable for management at home and those requiring hospital-based care. This was achieved by undertaking further analysis of the database to investigate the interactions between prognostic variables, strategy of care and outcome. The outcome measures of interest were mortality and/or institutionalisation, BI and mRS. The BI was dichotomised to a good outcome (BI 16–20) or a bad outcome (BI 0–15). The mRS was similarly dichotomised to good (mRS 0–3) and bad outcomes (mRS 4–6).

An indicator of the event variable of main outcomes (as defined above) at 3, 6 and 12 months after stroke was used as a within-subject response in a repeated measures model, with strategy type as a between-subject factor. If an

TABLE 30 Logistic regression model for mortality and institutionalisation, by strategy group

	3 months			6 months			12 months		
	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
Stroke unit									
BI <5	5.2	1.5 to 21	0.02	2.4	0.6 to 9.8	0.24	1.9	0.5 to 7.6	0.37
Incontinence	4.8	1.0 to 23	0.05	3.7	1.0 to 14	0.05	3.8	1.1 to 13	0.03
Dysphasia	3.1	0.9 to 12	0.08			NS			NS
Stroke team									
Age >75 years	3.4	1.2 to 9.4	0.02	2.6	1.1 to 6.4	0.04	5	1.4 to 19	0.01
BI <5	4.2	1.1 to 15	0.03	6.1	1.7 to 23	0.01	1.7	0.7 to 4.5	0.3
Incontinence	5.2	1.7 to 16	0.004	2.9	1.1 to 8.0	0.04	4.4	1.7 to 11	0.01
Home care									
BI <5	8.4	1.9 to 38	0.005	10.0	2.2 to 45	0.003	10.0	2.2 to 45	0.003
Incontinence	12	1.8 to 78	0.01	5.0	1.0 to 22	0.05	4.0	0.8 to 17	0.08

interaction with the strategy groups was found, the effect of the baseline variables on the event was assessed within each of the three strategy groups using logistic regression models. These models were adjusted for baseline variables that were shown to be significant in influencing outcome in the previous logistical analysis (see *Table 11*).

Mortality or institutionalisation

Although there was no significant time effect for mortality or institutionalisation ($p = 0.79$), there was a significant time interaction with strategy groups ($p = 0.008$). *Table 29* shows the estimated mean effects by period.

Table 30 presents the results of the logistic regression models for the outcome 'mortality or institutionalisation', by strategy group. These analyses showed that age above 75 years and admission BI score below 5 were highly significant predictors of unfavourable outcome in the stroke team group. The age of the patients was not a significant prognostic variable in the stroke unit and home care groups. BI score on admission and incontinence were the most important predictors of outcome in the home care group, although incontinence showed a significant effect only at 3 months ($p = 0.006$). Incontinence was the only significant predictor of outcome in the stroke unit group. This effect was borderline and diminished towards the end of the follow-up period. The negative effect of age over 75 years increased throughout the 3–6–12-month period.

Table 31 shows the results of the discriminant analysis, identifying the risk factors that predispose a patient to bad outcome by strategy group.

TABLE 31 Factors that predispose to high risk of death or institutionalisation, by strategy group

Strategy	3 months	6 months	12 months
SU	None	None	None
ST	BI <5 Incontinence	BI <5 Incontinence Age >75 years	BI <5 Age >75 years
HC	BI <5 Incontinence	BI <5 Incontinence	BI <5 Incontinence

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Neither a significant time effect ($p = 0.50$) nor a time interaction with strategy groups was detected ($p = 0.37$). *Table 32* shows the estimated mean effects by period.

Table 33 presents the results of the logistic regression models for the outcome BI 15 or lower, analysed by strategy group. These analyses showed that age over 75 years and incontinence were highly significant predictors of unfavourable outcome for the stroke team patients at 3 months. The effect of incontinence was increased by the end of the 12-month period. In contrast, age did not show any significance in the stroke unit and home care groups.

The most important predictor of outcome throughout the period 3–6–12 months in the home care group was BI score on admission, although incontinence increased its effect, showing significance only at 12 months. Incontinence was the only significant predictor of outcome in the stroke unit group. This effect was constant

TABLE 32 Proportion of patients with BI score ≤ 15 , by strategy group

Strategy	3 months	6 months	12 months	Overall
SU	0.21 (0.15–0.27)	0.14 (0.09–0.20)	0.14 (0.08–0.19)	0.16 (0.11–0.21)
ST	0.20 (0.14–0.26)	0.17 (0.11–0.23)	0.17 (0.11–0.23)	0.18 (0.12–0.23)
HC	0.21 (0.15–0.27)	0.20 (0.14–0.26)	0.19 (0.13–0.24)	0.20 (0.15–0.25)
Overall	0.21 (0.17–0.24)	0.17 (0.14–0.20)	0.16 (0.13–0.20)	

Data shown as proportion (95% confidence interval).

TABLE 33 Logistic regression models for BI score ≤ 15 , by strategy group

	3 month			6 months			12 months		
	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
Stroke unit									
Incontinence	6.7	2.9 to 16	0.000	7.8	2.8 to 22	0.0001	6.7	2.3 to 19	0.004
Stroke team									
Age >75 years	4.7	1.7 to 13	0.003	7.6	1.9 to 28	0.004	11	2 to 58	0.004
Incontinence	4.6	1.9 to 11	0.001	8.9	3.1 to 26	0.0001	24	6 to 97	0.000
Home care									
BI <5	50	5 to 483	0.001	29	4.2 to 205	0.001	17	2.8 to 100	0.002
Incontinence	7.8	2 to 43	0.05	4.8	1.0 to 23	0.05	6.6	1.3 to 34	0.02

TABLE 34 Factors that predispose to poor functional outcome, by strategy group

Strategy	3 months	6 months	12 months
SU	None	None	None
ST	Age >75 years Incontinent	Age >75 years Incontinent	Age >75 Incontinent
HC	BI <5	BI <5	BI <5 Incontinent

throughout the period of study. *Table 34* shows the risk factors that predispose a patient to be in the high risk by strategy group.

Similar results were obtained for logistic models for the mRS as an outcome measure, which paralleled those obtained for the dichotomised BI.

Economic evaluation

Table 35 summarises the proportion of patients in each group using health, social care and voluntary sector services from the time of stroke to the point of the 12-month assessment. It can be seen that a large number of different services was used in the 12-month period. These were delivered by a range of public and other agencies. Although health

service utilisation rates were high, patients also made considerable use of social care services. Inpatient admission rates in the 12-month period after the stroke were 28.6% for the stroke team group, 22.1% for the home care group and 18.2% for the stroke unit group. A similar pattern was observed for admission to nursing or residential care homes, with the proportion of patients admitted being slightly higher in the stroke team group than in the home care group, which in turn was slightly higher than in the stroke unit group.

The intensity of use of each of these services (*Table 36*) was weighted by its unit cost to give the aggregate cost of formal care support over the course of the evaluation period. It should be noted that duration, as well as number, of contacts for some services were taken into consideration, but only details for the number of contacts have been given in *Table 36*. The duration of contacts varied considerably and was dependent on several other unrelated factors, such as availability of transport and personal contact. Hence, local unit costs and charges (Appendix 2) or national statistics for an average visit or contact were used when local costs were unavailable.³⁷ *Table 37* reports total health and social services costs per patient excluding the small numbers lost to follow-up, but not making any allowance for people who died during the assessment period. These costs therefore appear somewhat low for

TABLE 35 Percentage using health, social and voluntary services and specialised accommodation between time of stroke and 12-month follow-up assessment

	SU (n = 148)	ST (n = 147)	HC (n = 140)
Initial stroke episode			
Admission for stroke	100.0	100.0	32.9
Stroke team coordinator	–	100.0	100.0
Stroke team physician	–	100.0	100.0
Physiotherapy	99.3	98.0	97.1
Occupational therapy	100.0	86.4	98.6
Speech and language therapy	70.3	46.3	50.7
12 months after stroke			
<i>Secondary care</i>			
Admission	18.2	28.6	22.1
Outpatient department	58.1	61.2	50.0
A&E	4.7	6.1	7.1
Day hospital	1.4	2.1	2.1
<i>Community-based care</i>			
GP home visit	34.5	44.2	35.7
GP surgery visit	59.5	55.8	62.1
District nurse	11.5	10.9	5.7
Dentist	20.9	26.5	25.0
Optician	24.3	18.4	16.4
Chiropodist	19.6	21.8	19.3
Osteopath	1.4	–	0.7
Chiropractor	–	–	1.4
Counselling	1.4	–	–
Geriatrician	0.7	6.1	2.9
Psychologist	1.4	0.7	2.1
Acupuncturist	0.7	–	–
Social worker	4.1	2.7	2.1
Personal care	22.3	12.2	11.4
Cleaning	11.5	11.6	2.9
Shopping	10.1	11.6	5.0
Meals on wheels	5.4	3.4	2.1
Frozen meals	6.1	4.1	5.0
Social services day centre	5.4	3.4	3.6
Social club	6.1	4.1	5.0
Lunch club	–	0.7	–
Voluntary day centre	5.4	8.8	3.6
<i>Specialised accommodation</i>			
Nursing/residential home	8.8	13.6	10.7
Respite care	0.7	3.4	2.1

groups in which there were more deaths. Notwithstanding this limitation, it can be seen that more than half of the total cost was accounted for by the initial treatment of stroke in all of the three arms of the trial. Within this episode, the majority of total cost was accounted for by inpatient admissions (77% for stroke unit, 84% for stroke team, 74% for home care). In the 12-month period after stroke, secondary care services (inpatient admissions, outpatient visits, day hospital visits and A&E attendances) together accounted for somewhat smaller proportions of total cost than in the initial stroke episode (35% for stroke unit, 35% for stroke team, 27% for home care). In this period, specialised accommodation

costs tended to dominate (38% of total cost for stroke unit, 47% for stroke team, 57% for home care). It should be reiterated that these costs do not take into account differences in mortality rates between the groups.

To adjust for mortality rate differences, health and social services costs per day alive were calculated, again excluding people who were lost to follow-up during the 12-month assessment period. The results are summarised in *Tables 38–40*. During the initial stroke episode, mean cost per day alive was £29.96 for stroke unit patients, £38.25 for stroke team and £26.29 for home care. In the 12-month period following stroke the ranking had changed,

TABLE 36 Quantities of resource use (users only) between time of stroke and 12-month follow-up assessment

	SU	ST	HC
Initial stroke episode			
Admission (days)	32.9 (29.3)	25.7 (26.6)	48.9 (26.6)
Stroke team coordinator (days)	–	84.6 (19.9)	78.7 (23.5)
Stroke team physician (hours)	–	2.0 (0)	2.0 (0)
Physiotherapy (PIU)	199.1 (203.5)	60.0 (86.8)	64.2 (66.0)
Occupational therapy (PIU)	18.7 (29.0)	7.3 (16.6)	9.8 (10.2)
Speech and language therapy (minutes)	554.2 (946.1)	240.7 (243.2)	261.3 (492.3)
12 months after stroke			
<i>Secondary care</i>			
Admissions (days)	22.3 (25.7)	18.2 (19.8)	15.7 (18.0)
Outpatients (visits)	1.9 (1.2)	2.3 (2.0)	1.9 (1.1)
A&E (visits)	1.0 (0)	1.0 (0)	1.7 (1.3)
Day hospital (visits)	8.0 (9.9)	31.7 (43.9)	1.0 (0)
<i>Community-based care</i>			
GP at home (visits)	1.9 (1.7)	1.9 (1.7)	1.5 (0.7)
GP at surgery (visits)	2.7 (3.0)	2.2 (1.3)	2.6 (2.7)
District nurse (visits)	3.7 (3.6)	2.6 (1.7)	2.9 (1.1)
Dentist (visits)	1.5 (0.9)	1.4 (0.8)	1.7 (1.2)
Optician (visits)	1.2 (0.4)	1.3 (0.5)	1.2 (0.5)
Chiropodist (visits)	2.0 (1.4)	2.4 (1.2)	2.6 (1.8)
Osteopath (visits)	1.5 (0.7)	–	1.0 (0)
Chiropractor (visits)	–	–	1.0 (0)
Counselling (visits)	3.5 (3.5)	–	–
Geriatrician (visits)	1.0 (0)	1.0 (0)	1.3 (0.5)
Psychologist (visits)	2.5 (0.7)	3.0 (0)	2.0 (1.0)
Acupuncturist (visits)	2.0 (0)	–	–
Social worker (visits)	1.8 (0.8)	2.8 (2.2)	1.3 (0.6)
Personal care (contacts)	280.7 (230.1)	353.0 (245.2)	302.6 (253.4)
Cleaning (contacts)	14.4 (13.7)	23.8 (18.6)	24.3 (18.2)
Shopping (contacts)	24.9 (19.0)	25.3 (21.1)	28.0 (21.0)
Meals on wheels (meals)	93.0 (123.6)	207.2 (175.2)	103.3 (90.6)
Frozen meals (meals)	15.6 (8.0)	26.2 (11.4)	16.1 (7.7)
Social services day centre (visits)	16.3 (12.3)	39.6 (42.1)	20.8 (18.7)
Social club (visits)	28.1 (30.6)	39.7 (32.2)	31.7 (33.5)
Lunch club (visits)	–	36.0 (0)	–
Voluntary day centre (visits)	24.1 (20.1)	29.8 (32.6)	15.2 (7.3)
<i>Specialised accommodation</i>			
Nursing/residential home (weeks)	32.6 (14.7)	33.8 (15.1)	42.0 (11.7)
Respite care (days)	14.0 (12.6)	25.2 (18.3)	27.7 (18.3)
Data are shown as mean (SD).			
PIU, Patient Interaction Unit.			

with mean costs per day alive being £8.02 for stroke unit patients, £12.65 for stroke team and £9.78 for home care.

Summing the initial stroke episode costs and the other costs in the 12-month period, the stroke unit mean of £37.98 is significantly less ($p = 0.046$) than the mean cost for stroke team patients (£50.90). The mean cost for stroke unit patients is no different to the mean cost for home care patients (£36.07, $p = 0.765$). Costs for the home care group were significantly less than costs for the stroke team group ($p = 0.055$).

The costs just presented do not include the informal care inputs by co-resident or non-co-resident caregivers. *Table 41* summarises the number of hours of caregiver inputs in the 12-month assessment period. The table distinguishes co-residents from non-residents, and for each caregiver type also distinguishes personal care, transport, meal preparation, housework, DIY, gardening, shopping, outings and socialising. The figures in *Table 41* give an indication of the intensity of caregiver inputs (average per week) during the period in which sample members needed such support. The annual

TABLE 37 Health, social and voluntary services costs (£) per patient

	SU (n = 148)	ST (n = 147)	HC (n = 140)
Initial stroke episode			
Admission for stroke	6821 (6295)	4973 (4608)	2859 (4880)
Stroke team coordinator	–	334 (79)	311 (93)
Stroke team physician	–	47 (0)	47 (0)
Therapy	2005 (1793)	599 (818)	668 (603)
Total	8825 (7441)	5952 (5054)	3856 (5062)
12 months after stroke			
Secondary care	931 (2464)	1262 (2805)	803 (2062)
Community-based care	706 (1473)	632 (1557)	492 (1459)
Specialised accommodation	987 (3591)	1681 (4673)	1689 (5047)
Total	2625 (4582)	3575 (5705)	2984 (5749)
Total from time of stroke to 12-month follow-up	11450 (9745)	9527 (8664)	6840 (9353)
Data are shown as mean £ (SD).			

TABLE 38 Health, social and voluntary services costs (£) per patient per day alive

	SU (n = 148)	ST (n = 147)	HC (n = 140)
Mean days alive (SD)	351 (59)	313 (113)	331 (96)
Initial stroke episode			
Admission for stroke	23.95 (33.09)	33.36 (57.33)	22.25 (52.98)
Stroke team coordinator	–	1.42 (0.99)	0.91 (0.40)
Stroke team physician	–	0.36 (0.73)	0.27 (0.66)
Therapy	6.01 (5.37)	3.11 (4.90)	2.95 (3.94)
Total	29.96 (36.14)	38.25 (62.18)	26.29 (56.59)
12 months after stroke			
Secondary care	3.17 (8.44)	5.76 (22.40)	3.66 (13.99)
Community-based care	2.02 (4.07)	1.89 (4.44)	1.40 (4.00)
Specialised accommodation	2.83 (10.04)	5.00 (13.26)	4.72 (13.87)
Total	8.02 (13.81)	12.65 (26.03)	9.78 (19.97)
Total from time of stroke to 12-month follow-up	37.98 (41.68)	50.90 (66.04)	36.07 (63.96)
Data are shown as mean £ (SD).			

totals presented account for the total duration for which care was received over the 12-month assessment period and thus summarise the total amount of care actually received per patient.

Caregiver inputs over the periods in which group members were alive are summarised in *Table 42*. The total number of hours received per patient day alive was 3.98 in the stroke unit group, 2.44 in the stroke team group and 2.7 in the home care group. It would therefore appear to be the case that the stroke unit group received significantly more care than both the stroke team group ($p = 0.015$) and the home care group ($p = 0.051$). These

differences came to light only after analysis of data, and possible explanations include increased substitution of caring tasks by social services help or alternatively increased expectations of support from patients managed on the stroke unit.

Sensitivity analysis involving the inclusion of informal care costs increased overall costs considerably. For example, stroke unit group costs rose by 45% or 134%, depending on whether minimum wage or home help worker rates were applied to care hours, respectively. Total costs were highest for patients managed on the stroke unit and lowest for those managed at home, regardless

TABLE 39 Differences between groups for health, social and voluntary services costs per patient

	SU vs HC			ST vs SU			ST vs HC					
	Mean difference	95% CI	t-Value	p-Value	Mean difference	95% CI	t-Value	p-Value	Mean difference	95% CI	t-Value	p-Value
Initial stroke episode												
Admission for stroke	3961.41	2650 to 5273	5.945	0.000	-1847.92	-3112 to -584	-2.878	0.004	2113.49	1009 to 3218	3.768	0.000
Stroke team coordinator	-310.57	-327 to -294	-37.79 ^a	0.000	333.71	321 to 347	51.51 ^a	0.000	23.14	3 to 44	2.211	0.028
Stroke team physician	1336.41	1029 to 1644	8.570	0.000	-1405.97	-1726 to -1089	-8.67	0.000	-69.57	-237 to 98	-0.817	0.415
Therapy	4969.23	3499 to 6439	6.657	0.000	-2873.32	-4331 to -1416	-3.882	0.000	2095.90	920 to 3271	3.509	0.001
Total												
12 months after stroke												
Secondary care	128.09	-400 to 657	0.477	0.634	330.62	-274 to 935	1.076	0.283	458.71	-112 to 1029	1.584	0.114
Community-based care	214.29	-126 to 555	1.240	0.216	-74.49	-422 to 273	-0.422	0.673	139.81	-211 to 491	0.784	0.434
Specialised accommodation	-701.67	-1723 to 320	-1.353	0.177	694.02	-262 to 1650	1.430	0.154	-7.65	-1137 to 1122	-0.013	0.989
Total	-359.28	-1562 to 843	-0.588	0.557	950.15	-236 to 2137	1.576	0.116	590.87	-740 to 1922	0.874	0.383
Total cost from time of stroke to 12-month follow-up	4609.94	2392 to 6828	4.092	0.000	-1923.17	-4037 to 190	-1.791	0.074	2686.78	593 to 4780	2.526	0.012

^a t-Value cannot be computed because the standard deviations of both groups are zero.

TABLE 40 Differences between groups for health, social and voluntary services costs per patient per day alive

	SU vs HC			ST vs SU			ST vs HC					
	Mean difference	95% CI	t-Value	p-Value	Mean difference	95% CI	t-Value	p-Value	Mean difference	95% CI	t-Value	p-Value
Initial stroke episode												
Admission for stroke	1.70	-8.62 to 12.03	0.325	0.745	9.41	-1.34 to 20.15	1.724	0.086	11.11	-1.73 to 23.95	1.703	0.090
Stroke team coordinator	-0.91	-0.98 to -0.84	-25.84	0.000	1.42	1.26 to 1.58	17.432	0.000	0.51	0.34 to 0.69	5.794	0.000
Stroke team physician	-0.27	-0.38 to -0.16	-4.896	0.000	0.36	0.24 to 0.48	5.987	0.000	0.09	-0.07 to 0.25	1.082	0.280
Therapy	3.06	1.97 to 4.15	5.537	0.000	-2.90	-4.08 to -1.72	-4.848	0.000	0.16	-0.88 to 1.19	0.303	0.762
Total	3.67	-7.42 to 14.76	0.652	0.515	8.29	-3.39 to 19.96	1.398	0.163	11.96	-1.88 to 25.79	1.701	0.090
12 months after stroke												
Secondary care	-0.49	-3.15 to 2.17	-0.362	0.717	2.59	-1.29 to 6.46	1.314	0.190	2.10	-2.27 to 6.46	0.946	0.345
Community-based care	0.62	-0.32 to 1.56	1.305	0.193	-0.13	-1.10 to 0.85	-0.258	0.797	0.49	-0.49 to 1.48	0.987	0.325
Specialised accommodation	-1.89	-4.71 to 0.94	-1.317	0.189	2.17	-0.53 to 4.87	1.582	0.115	0.28	-2.87 to 3.43	0.175	0.861
Total	-1.76	-5.76 to 2.25	-0.864	0.388	4.63	-0.16 to 9.41	1.905	0.058	2.87	-2.54 to 8.28	1.044	0.297
Total from time of stroke to 12-month follow-up	1.91	-10.69 to 14.52	0.299	0.765	12.91	0.24 to 25.59	2.007	0.046	14.83	-0.29 to 29.94	1.930	0.055

TABLE 41 Poststroke caregiver inputs (hours)

	SU (n = 148)	ST (n = 147)	HC (n = 140)
No. received care, n (%)	93 (62.8)	98 (66.7)	100 (71.4)
No. of weeks received care, mean (SD)	26.93 (21.13)	21.44 (20.61)	19.48 (20.13)
From co-residents			
Personal care per week	2.14 (3.71)	1.03 (2.18)	2.38 (4.01)
Transport per week	0.87 (2.35)	0.70 (1.51)	0.67 (1.12)
Meal preparation per week	1.74 (3.58)	0.66 (2.14)	1.11 (2.65)
Housework per week	1.15 (2.49)	0.75 (1.68)	1.12 (2.22)
DIY per week	0.11 (0.50)	0.09 (0.33)	0.17 (0.62)
Gardening per week	0.29 (0.81)	0.17 (0.58)	0.39 (0.94)
Shopping per week	0.62 (1.03)	0.42 (0.85)	0.56 (0.88)
Outings per week	2.68 (15.82)	1.33 (8.99)	0.24 (0.79)
Socialising per week	32.28 (39.67)	28.56 (39.69)	39.74 (41.95)
Total per average week	41.88 (50.53)	33.71 (44.35)	46.38 (48.15)
Total over 12 months	1312.19 (2177)	718.11 (6778)	899.18 (1760)
From non-residents			
Personal care per week	0.03 (0.22)	0.12 (0.67)	0.26 (1.50)
Transport per week	0.27 (0.62)	0.33 (0.74)	0.34 (0.93)
Meal preparation per week	0.07 (0.39)	0.16 (0.79)	0.31 (1.58)
Housework per week	0.22 (0.80)	0.24 (0.72)	0.29 (1.35)
DIY per week	0.18 (0.45)	0.12 (0.38)	0.12 (0.41)
Gardening per week	0.07 (0.35)	0.08 (0.38)	0.09 (0.59)
Shopping per week	0.25 (0.62)	0.42 (0.82)	0.88 (8.45)
Outings per week	0.20 (0.56)	0.49 (2.91)	0.16 (0.67)
Socialising per week	2.83 (8.30)	3.07 (8.96)	2.35 (8.36)
Total per average week	4.13 (10.45)	5.03 (11.54)	4.79 (16.51)
Total over 12 months	114.51 (409)	127.44 (348)	79.70 (283)
Total over 12-month assessment period from co-residents and non-residents	1435.63 (2278)	845.55 (1549)	978.88 (1749)
Data are shown as mean hours (SD).			

TABLE 42 Post-stroke caregiver inputs (hours) per day alive

	SU (n = 148)	ST (n = 147)	HC (n = 140)
Total from co-residents per day alive	3.63 (5.99)	2.09 (4.23)	2.46 (4.82)
Total from non-residents per day alive	0.33 (1.13)	0.35 (0.95)	0.23 (0.80)
Total per day alive from co-residents and non-residents	3.98 (6.25)	2.44 (4.36)	2.70 (4.79)
Data are shown as mean hours (SD).			

of how costings were undertaken. Including informal care magnified cost differences between stroke unit and stroke team care, but reduced the previously significant difference between stroke team and home care costs ($p = 0.043$) to non-significant levels.

Cost-effectiveness and cost-utility

Combining the cost and effectiveness data is important in a trial of this kind. As already noted,

the stroke unit was more effective than the stroke team and more effective than home care on a number of outcome dimensions. The primary outcome measure (avoidance of death and/or institutionalisation) suggested that the stroke unit was significantly more effective than the stroke team and home care. The stroke unit was also significantly less costly than the stroke team, but the same cost as the home care intervention. By this effectiveness criterion and these cost results,

TABLE 43 Cost-effectiveness of each intervention for favourable outcomes

	SU (n = 148)	ST (n = 147)	HC (n = 140)
Cost per day alive	£37.98	£50.90	£36.07
Probability of avoiding death/institutionalisation	87.16	69.39	77.86
Cost per death/institutionalisation avoided	0.44	0.73	0.46
Cost per day alive	£37.98	£50.90	£36.07
Probability of favourable outcome on BI	88.5	69.4	72.9
Cost per favourable outcome on BI	0.43	0.73	0.49

TABLE 44 ICERs for stroke unit over domiciliary care from different cost perspectives^a

Cost perspective	Additional cost per additional 1% of deaths/institutionalisations avoided	Additional cost per additional QALY gained
Immediate care costs	£534	£67,323
Total health and social care costs	£496	£64,097
Total cost including informal care costs based on minimum wage rate ^b	£682	£89,132
Total cost including informal care costs based on home help rate ^b	£1,033	£136,609

^a Cost-utility calculations exclude ten people with missing EuroQol data at several assessment points.
^b Cost estimates exclude one person from the SU group with incomplete informal care data. Therefore, the total number of death/institutionalisations avoided was reduced to 128 and the total QALYs gained were reduced to 42.66 for the cost-effectiveness and cost-utility calculations, respectively.

therefore, the stroke unit is clearly a more cost-effective intervention than either the stroke team or home care. The same cost-effectiveness dominance applies if the outcome measure is favourable outcome on the BI (percentage of patients with scores of 15–20). These initial cost-effectiveness results are presented in *Table 43*. The cost measure is cost per day alive, and the effectiveness measures are (1) probability of avoiding death and institutionalisation, and (2) probability of favourable outcome on the BI.

A further set of analyses examined the relationships between baseline characteristics, including scores on key indicators of morbidity and disability, and costs over the 12-month assessment period, including the costs of the initial stroke episode. These regression analyses allow adjustment for baseline characteristics before making comparisons between the three arms of the trial. Given that the randomisation in the trial was entirely satisfactory, there should be no difficulty, but such analyses can provide reassurance. Significantly lower costs per day alive were found for stroke unit patients compared with

stroke team patients, and no difference between stroke unit and home care patients.

The percentage of patients who avoided death/institutionalisation was 87%, 69% and 78% in the stroke unit, stroke team and home care groups, respectively; and mean quality-adjusted life-years (QALYs) gained were 0.297, 0.216 and 0.221, respectively. When comparing cost-effectiveness for more than two strategies, incremental cost-effectiveness ratios (ICERs) are calculated using rules of dominance. Strategies are ranked by cost, from the least expensive to the most expensive, and then if a strategy is more expensive and less effective than the previous strategy, it is said to be dominated and is excluded from the calculation of ICERs. On this basis, the stroke team was dominated by home care on both outcome measures, from all cost perspectives, thus reducing the comparison to stroke unit versus home care.

As the stroke unit did not dominate home care, ICERs were calculated to indicate the additional outcomes obtained for the additional costs of the stroke unit (*Table 44*). The additional cost of

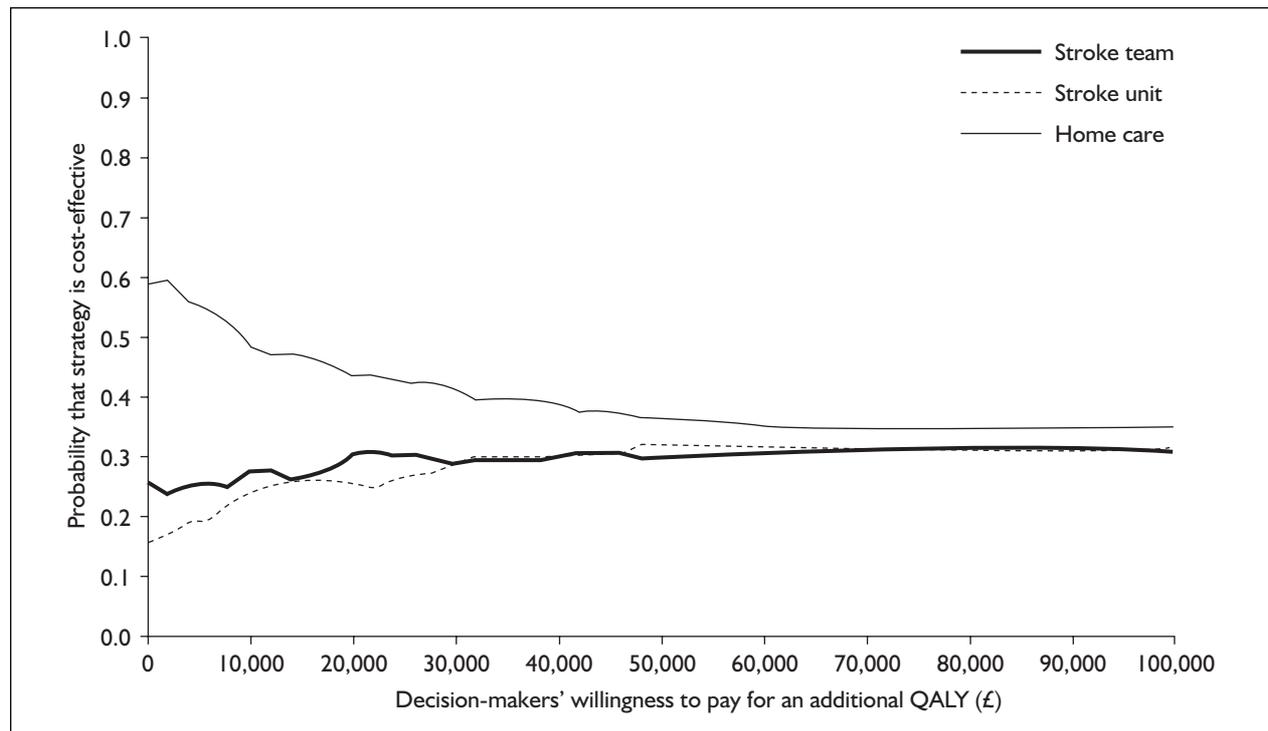


FIGURE 4 Cost-effectiveness acceptability curves: probability that each strategy is cost-effective for a range of values of decision-makers' willingness to pay for an additional QALY

avoiding an additional 1% of death/institutionalisations in the stroke unit group was £534 based on immediate care costs alone and £496 from the perspective of total health and social care costs over 12 months. This increased to £682 when informal care costs (based on lower rates) were added to health and social care costs, and doubled to £1033 on the basis of the broadest cost perspective incorporating the higher informal care rates. ICERs per additional QALYs gained ranged between £64,097 and £136,609 depending on the cost perspective taken. To explore the uncertainty around decisions based on ICERs, *Figure 4* additionally reports the estimated probability that each strategy is cost-effective for a range of potential maximum values that health and social services would be willing to pay for an additional QALY. If decision-makers were willing to pay nothing for QALY gains, there is a 59% probability that home care is the most cost-effective (i.e. optimal) of the three strategies

(and a 16% and 26% probability that the stroke unit and stroke team, respectively, is the most cost-effective). The probability that home care is the most cost-effective strategy decreases with increasing levels of willingness to pay for QALY gains, levelling out at around the £60,000 threshold, but remains higher than the other two strategies across the full range of specified values. Correspondingly, the probability of the cost-effectiveness of the other two strategies generally increases up to the £60,000 threshold (as the sum of probabilities for all strategies must sum to 1.0 at any given level of willingness to pay); however, the relative cost-effectiveness of these two is less clear, with probabilities equalising at the £16,000 threshold and beyond £30,000. At a willingness to pay of £30,000 per additional QALY (the implicit current threshold value per QALY in the UK), the probability that the stroke unit and stroke team are the most optimal of the three strategies is equal at 29%, and higher for home care at 42%.

Chapter 6

Discussion

Objective 1: 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 specialist domiciliary care team

It is widely accepted that organised stroke care, as provided on a stroke unit, saves lives, reduces dependence and shortens the duration of inpatient rehabilitation.⁸ However, stroke unit care is a 'black box' intervention and there is great variation in the way stroke care is organised, with different units having different policies and processes of care. Analysis of processes on stroke units suggests that there are some core processes that are common to all units and include multidisciplinary coordination, staff specialisation and better communication with patients and their carers.¹⁰ The question then is: can organised care in different settings, for example at home or on general medical wards, achieve outcomes similar to those seen on stroke units?

Mortality, institutionalisation and dependence

This study shows that the benefits of specialised care on a stroke unit in reducing mortality, institutionalisation and dependence are not matched by other methods of delivering specialised care in hospital or at home, even in carefully defined patients. The benefits of stroke unit care were present from the outset and lasted throughout the 1-year follow-up period. Patients managed on general wards with specialist team support had a continuing high death rate and higher levels of dependence at all time-points up to 1 year. Patients in the domiciliary arm of the study had a high death rate initially which stabilised on follow-up, probably because one-third of these patients were transferred to the stroke unit within the first few days for management. It is quite possible that the higher mortality seen on general wards would have been replicated in the domiciliary setting if this had not been the case. The absolute difference between patients who were alive and independent or had minor disability was

18% between stroke unit and stroke team and 14% between the stroke unit and domiciliary care. The numbers needed to treat for stroke unit care to have an effect are 6 and 7 respectively, which are lower than most other therapies including thrombolysis.⁴³ The study provides strong support for early specialist management of all stroke patients, even in those with moderate severity.

A possible criticism of this study is the huge treatment effect seen with respect to deaths associated with stroke unit care. As such large treatment effects are rarely seen in clinical studies, it was important to exclude the possibility of bias from various sources in the present study. One reason for the modest treatment effects in many trials (which is often overlooked) is the trend towards undertaking large multicentre 'megatrials', which include dissimilar settings in different geographical areas with variable population characteristics. Despite defined inclusion criteria, subject selection is likely to be heterogeneous as it is not possible to control for the whole range of variables that influence outcome.⁴⁴ In addition, there are likely to be differences in the delivery of intervention between centres.⁴⁵ This unavoidable variability can result in marked effects in some centres being diluted by no changes (or even opposite effects) in others; consequently, a modest treatment effect is seen for the study as a whole.^{8,44,45} A treatment effect as large as 66–80% has been seen in other tightly controlled studies.^{46,47}

Inadequately powered studies that have small sample sizes are open to type I and type II errors. The sample size chosen for this study is considerably smaller than that required for a conventional fixed sample design. However, a study of this nature would only have been possible in the unique service environment of the current setting and it would not have been feasible to recruit the sample size required by conventional calculations. This problem was overcome by using the sequential analysis framework.³⁴ Sequential tests generally allow one to achieve the same level of power for a given treatment effect as large trials and there is no limitation as to when to perform analyses. It is good practice to analyse when at

least 20% of the maximum sample has accumulated since it has been seen to provide enough information to do covariate adjustment. The limitation of this type of analysis is that the p -value may be over-optimistic, as in any multiple t -testing procedure without Bonferroni correction.³⁴ However, this was not the case because the p -value of a sequential design that stops at the first (and only) interim inspection is not changed by this adjustment. In addition, the adjustment of the bias introduced by stopping precisely when a significant advantage of one of the treatments was observed yielded similar results to those of the conventional analysis; the median unbiased estimator for the hazard ratio was 0.51 (95% CI 0.3 to 0.75).

It may be possible to subvert randomisation in small blocks (six to eight patients) used in many Phase II studies, especially when treatment cannot be truly blinded (e.g. trials on thrombolysis). However, randomisation was conducted in 16 blocks of 30 for this study using a blinded schedule accessed by a clerical officer, which would make it impossible for those enrolling patients to guess allocation for the vast majority of subjects included in the study. It is not always possible to mask allocation during assessment in health service studies because location or social conversation may inadvertently identify allocation. This anticipated bias was kept to a minimum by using independent observers who were solely responsible for assessment and using outcome measures (e.g. mortality and institutionalisation) that were not subject to observer bias for this part of the study.

The authors suspect that differences in mortality represent major differences in the acute medical care of stroke patients in different settings. An analysis of processes of care between the best (stroke unit) and the worst outcome (general wards) groups in this study showed that although both groups were comprehensively assessed and investigated, greater attention was paid to the assessment of consciousness levels, swallowing and communication on the stroke unit. A significantly greater proportion of patients on the stroke unit had their CT scans within 48 hours. A higher proportion of patients on the stroke unit received oxygen, antipyretics if febrile, anti-aspiration measures and early nutrition. The processes of multidisciplinary care and coordination were significantly different between the stroke unit and the general medical wards, despite ongoing support being provided by a specialist team. Stroke-related complications and stroke

progression were more common in patients on general wards.⁴⁸ It is possible that differences in enthusiasm, specialisation or attitudes between the staff on the stroke unit and those involved in other forms of care may also have influenced outcome.

Although the number of patients receiving different types of therapy input was generally comparable between the three groups, patients managed on the stroke unit received significantly greater amounts of therapy compared with other groups. Theoretically, it is possible that patients managed by the stroke team or those managed at home may have achieved equally good functional outcomes if they had received equivalent duration of therapy. However, it would be difficult (and expensive) to replicate this environment and specialisation for all areas in which stroke patients are managed in clinical practice. The decreased amounts of rehabilitation therapy may explain better functional outcome in survivors, but cannot explain the higher death rates in these settings. What is clear is that 24-hour, consistent, structured and dedicated care based on core principles of stroke management could not be reproduced at the same level of intensity at home or on general wards, even with specialist support.

Functional outcomes

If alternative strategies of stroke care do not compare with stroke units in reducing mortality, do they achieve similar or better functional or psychological outcomes in stroke survivors? This is a more difficult question to answer because of the imbalances created by higher mortality in patients in the stroke team and domiciliary care groups, which resulted in more disabled people surviving on the stroke unit. Data for personal ADL (Barthel Index) showed that stroke survivors managed on the stroke unit improved to a greater extent compared with other strategies. This was confirmed on multiple regression analysis undertaken to adjust for differences in prognostic variables because of unequal survival between groups. The difference between strategies was most marked for survivors at the more severe end of the stroke spectrum (initial BI 0–4) and was not present in survivors with relatively less severe strokes (initial BI of ≥ 5). The BI scores of survivors with less severe strokes managed using different strategies were comparable at all time-points and all patients achieved independence in basic ADL at 3 months after stroke.

The major limitation of the BI is that it has a ceiling effect and is not sensitive to further improvements once independence in basic ADL is

achieved. A broader measure, the FAI, was used to detect more subtle differences in function between the groups. Overall, survivors with more severe strokes (initial BI 0–4) remained very limited for wider ADL tasks regardless of the strategy of care, probably because most did not achieve independence in basic ADL tasks. Survivors who recovered basic ADL skills (BI 17–20) showed significant recovery in wider ADL abilities. Although group comparisons suggested that survivors with initial BI of 5–9 regained greater function with domiciliary care, strategy of care was not an independent determinant of FAI scores in the multiple regression model.

Data on functional recovery suggested that there was a hierarchy in which activities improved and patients needed to achieve basic ADL skills before progressing to higher levels of function. The study highlights the importance of choosing the right instruments to measure this change; whereas BI was very sensitive to changes in basic ADL activities, it was insensitive to further improvement. In contrast, FAI would not have detected improvements in basic abilities, but could detect subtle differences in wider ADL abilities. The BI alone was not an adequate global measure for function as suggested previously.⁴⁹ A combination of BI and FAI was more informative and should be used for comprehensive assessment of global functional outcome in outcome research.⁵⁰ The study also showed that whereas strategy of care is important for attaining independence in basic ADL function in more severely disabled patients, achievement of higher levels of function is not influenced by strategy of care.

Psychological outcomes

In general, anxiety and depression were not a major problem in this group of patients and there were no significant differences in the levels of anxiety or depression between patients managed in any of the three groups. This is in contrast with findings in literature, which show that significant proportions of patients suffer from poststroke depression.⁵¹ This apparent difference may be due to several reasons. Patients in this study were selected for moderate levels of disability and all of them received some form of specialised care. Nearly 80% of survivors achieved independence in basic functional abilities regardless of strategy of care and over 50% were able to perform at higher levels of function by the end of 3 months. Finally, the consent procedures resulted in all patients knowing that they were receiving some form of specialist care and believed that 'all that could be done was being done', as seen in the satisfaction questionnaire.

Hence, there is a possibility that the very act of participation in the trial may have contributed independently to mood and motivation.

Despite conceptual and methodological limitations, quality of life is being used increasingly as an outcome measure in stroke care.⁵² EuroQol has been validated for use in stroke patients and was the preferred measure for this study.⁵³ A particular problem in this study was that quality of life before and after the stroke could not be assessed because there was no premorbid baseline for comparison. A possible alternative would be to use patient estimates of premorbid quality of life. Pilot work showed that this methodology was open to serious bias. Many patients tended significantly to overestimate their premorbid quality of life, which was not supported by later assessments for function or reports from relatives or friends.

Survivors managed on general wards with specialist team support reported poorer quality of life on the visual analogue scale compared with other strategies at 3 months but not at 1 year after stroke. This observation is interesting in view of the fact that active intervention in all strategies was provided in the first 3 months, after which all patients were managed in non-specialised community settings and received the same type of care. This suggests that specialist input may influence patients' quality of life, but the beneficial effect is lost once the support is withdrawn. It also suggests that direct involvement of the specialist team in day-to-day management may have a greater impact than advisory support to generic ward teams.

The most important domains of quality of life affected by stroke were mobility and activities. Few survivors reported problems with self-care abilities, pain or psychological functioning. In general, the patients' rating of their quality of life was better than expected from previous data⁵⁴ and consistent with a recent study which showed that the impact of stroke on the quality of life may be overestimated in some patients.⁵⁵

Resource utilisation outcomes

The study showed that although health service utilisation rates are quite high, patients also make considerable use of social care services in the year following a stroke. 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 of 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 from home care patients. Costs for the domiciliary group were significantly less than for those managed by the specialist stroke team on general wards.

A 'mixed' approach was adopted for the cost-utilisation analysis, and the researchers were as explicit as possible in describing the costing methods. The mixed approach combines elements of the 'bottom-up' approach, where all service elements of an intervention are designed and costed to compute the incremental costs of each element, with a 'top-down' approach, where the incremental costs of individual elements are derived from the summation of total costs of a service. Although this method is less than ideal, it was necessary in a study of this size that contained a wide range of potential resource use implications. This mixed approach is quite common in health economic evaluations and does not add significant bias to the findings of the study.⁵⁶

The reliability and validity of using retrospective patient-reported service use data after 12 months can also be questioned. Great attention was paid to the completeness and accuracy of such data and the clinical interviewer was especially energetic in chasing (and, where possible, also checking) service utilisation data. Some data came from the files/records of service providers, so that the time elapsed would not have caused undue problems. However, collecting service use data retrospectively over 12 months is less than ideal, but was believed to have been handled well by the research team. In addition, the CSRI, an instrument originally developed for assessing health, social services and informal care resource use for mental health interventions, was adapted for the purposes of the study. This instrument is a checklist of all possible services that may be used by patients, which is then tailored to the clinical context, location and research design following a procedure that has become fairly standard practice in economic evaluations. In this instance, the instrument was adapted for use in acute stroke patients being managed both at home and in the hospital by discussing all the items included in the checklist for relevance and sensitivity (and including new items) with local service providers as well as by the research team. The resulting checklist was piloted in representative patients and, after further discussion and minor changes, was used for the study. Service-specific adaptations to the CSRI have been validated in other settings in relation to the economics of mental health.⁵⁶

Therapy costs may be double-counted for some of those people admitted to the stroke unit or others admitted to hospital. Although the unit cost of hospital care already included an element of therapy costs, more detailed patient-level therapy costs were estimated separately on the basis of actual inputs received. Unfortunately, the therapy element within the unit cost estimate (provided by the Trust) could not be identified clearly enough to be removed. Given the size of the therapy costs in relation to admission costs, it is highly likely that these therapeutic inputs have been significantly underestimated in the reported unit cost of the stroke unit. Indeed, for 23 patients in the stroke unit group, the patient-level therapy cost exceeded the cost of their stroke admission. Consequently, the unavoidable measurement error stemming from this double-counting is unlikely to be large.

The analysis of uncertainty around the cost-effectiveness is important because it is possible that if patients who were hospitalised were excluded, home care would be cost neutral compared with the stroke unit. Hence, there is a possibility that there is a subgroup of patients for whom home care may be the most cost-effective option. However, current data are insufficient to identify this group reliably.

Limitations of the randomised comparisons

The findings reported above need to be interpreted in the context of the limitations of this study. The study was a pragmatic service intervention trial in mainstream practice and despite efforts to control as many variables as possible, it was still open to a certain amount of bias inherent in such studies. Only patients with moderate levels of stroke severity were included, which may limit its generalisation to other levels of stroke severity. It would be unethical to randomise patients with very severe strokes to management at home because of their heavy nursing needs and evidence that these patients are best cared for on stroke units.⁵⁷ Patients with mild stroke were excluded because there was insufficient evidence to warrant admitting these patients to hospital and their needs were being met by neurovascular clinics and community rehabilitation services.^{58,59}

It was not possible to blind assessment of outcome rigorously in all patients because location or patient conversation may have identified allocation in some cases. All possible measures were taken to maintain masked conditions for assessment, which included an independent

observer for outcome assessments who was not involved in the initial assessment, allocation or management of patients. Other observers were used for assessments that may have led to inadvertent unmasking of allocation (16 out of 1259 assessments). The independent observer was able to guess patient allocation correctly in 41% patients (kappa 0.12), which suggests poor agreement and demonstrates the adequacy of masking procedures.

Mortality and institutionalisation were chosen as primary outcome measures because these are least susceptible to observer bias. Assessing good outcome in terms of dependence was more difficult. Many studies in acute intervention have used total independence as a good outcome and all other levels of dependence as a bad outcome.²⁹ This may not be true for stroke management as a whole, where the major objective is to reduce disability. Many professionals and patients regard the ability to live at home with intermittent support as a good outcome compared with high dependence or institutional care.⁵⁵ The present study looked not only at the proportion of patients who were alive and fully independent (as in acute intervention studies), but also at the proportion of patients who did not have severe disability (as in most rehabilitation studies), to provide a balanced view of outcome.

A major problem in longitudinal studies is bias due to patients lost to follow-up. In this study 12 patients were lost to follow-up. This was addressed by seeking information on mortality from the registrar's office locally and at the national level. Information on institutionalisation was sought from the Social Services Continuing Care Register (which identified all patients receiving support) and by contacting all local nursing homes. As this did not exclude the possibility of missing some patients who may have moved away, sensitivity analyses for the worst possible outcome (assuming that all patients lost to follow-up had died) and the best possible outcome (assuming that all had survived) were undertaken. These analyses did not vary significantly from the main analysis.

The influence of the environment of the study to observed outcomes cannot be ignored. The study was undertaken in a largely middle-class suburban outer London borough and there may be an interaction between the acceptability of domiciliary care and education, affluence, living accommodation, informal support and cultural beliefs. In addition, institutionalisation may have been confounded by the socio-economic

narrowness of the population. These factors influence the generalisability of the findings of this study to more deprived settings or areas with complex health and social care infrastructures, where it may not be possible to provide the level of coordinated input seen in this study.

Which strategy provides the greatest benefits?

The study has shown that 24-hour specialist management on a dedicated stroke unit provided by staff knowledgeable about the core principles of stroke management saves lives, reduces dependence, and is associated with better recovery and quality of life in stroke patients particularly those at the more severe end of the stroke spectrum.

The importance of strategy in later stages of stroke management in this selected group of patients is less clear. It appears that stroke patients who survive and those with lower levels of disability do equally well with any form of organised stroke care. The caveat to this is patients who are managed by non-specialists on general medical wards, where, in this study, a higher mortality rate was shown.

Objective 2: to identify prognostic variables that will help to identify patients suitable for management at home and those requiring hospital-based care (targeting of strategy)

The need for specialist management in patients with the possibility of a diagnosis other than stroke, atypical or severe strokes, high dependence or special needs (e.g. swallowing problems) is accepted.⁶⁰ These reasons resulted in nearly half of stroke patients on the stroke register being excluded from randomisation in this study because few people would argue against hospitalisation of these patients.

Criteria for definite hospital admission

- Severe stroke:
 - impaired consciousness
 - swallowing problems
 - double incontinence
 - two or more impairments
 - brainstem signs.
- Unusual neurological features/require specialist assessments:
 - age less than 60 years
 - no vascular risk factors

- unclear or atypical history
- use of anticoagulants
- severe hypertension
- suspicion of vasculitis, thrombotic or bleeding disorder.
- Presentation within 6 hours of onset:
 - suitable for thrombolysis.

The question of alternative strategies for stroke care arises in the other half of stroke patients with clear diagnosis and less severe strokes. The benefits of hospital admission have not always been clear in this group and there was an opinion that organised specialist care at home which provides diagnostic, therapy and care support could achieve similar outcomes to stroke unit care.¹⁵ The need for accurate identification of stroke patients who may be at risk in non-hospital settings becomes even more important in districts where as many as 30–50% of patients are managed at home.

This study showed that even in this carefully selected group of disabling stroke patients, nearly one-third had to be admitted to hospital despite high levels of support from the specialist stroke team and community services operating in the most favourable configuration of health and social services. Multiple regression analysis showed that stroke severity and incontinence were the most important predictors of mortality, institutionalisation and dependence for patients managed at home. The parameters that identified those who were likely to have a poor outcome if managed at home were:

- total anterior circulation syndrome
- BI ≤ 4
- OPS > 4
- urinary incontinence
- dysphasia
- living alone (lack of competent care).

The debate over managing even moderately disabled acute stroke patients at home or in settings other than a stroke unit has been superseded by recent research supporting intensive investigation and monitoring in all patients^{61,62} and thrombolytic interventions in some patients.⁶³

There was little difference between the prognostic factors for poor outcome between patients managed at home and those managed on general medical wards in hospital, even with specialist support in both settings. Patients with the above prognostic characteristics did equally

badly on general medical wards as they did at home, with comparable levels of mortality, institutionalisation and dependence. This suggested that the important variable was not admission to hospital, but the 24-hour availability of specialised care. If this care was not available, there seemed to be little advantage in admitting this particular group of patients to hospital, and this may explain the lack of difference between hospital and home care seen in previous studies.¹⁸

There was one very important and rather surprising difference between care at home and care in the hospital. Age over 75 years was a significant predictor of poor outcome on general wards, but not on the stroke unit or in domiciliary care. Why this should be so is not entirely clear. The most obvious explanation is that patients on the stroke unit and those in domiciliary care were directly managed by specialists in stroke, whereas the specialists had an advisory role only for patients managed on general medical wards. It is possible that the management of the older stroke patient was more aggressive, with higher expectations of outcome in the stroke unit or domiciliary settings. It is also possible that awareness of the higher frequency of stroke-related complications and their non-specific presentation in this group led to early detection and treatment, which may not have happened on the general medical ward.

The quality of stroke management is dependent not only on principles of multidisciplinary assessments and coordinated rehabilitation, but also on understanding of stroke mechanisms, neurological injury, acute medical care and principles of intervention. This expertise or experience may not be widely available even in specialities with a tradition of managing stroke patients suggesting the need to consider further training programmes.

Objective 3: to describe the organisational aspects of different strategies of stroke care

The way in which different strategies were organised has been detailed in previous sections of the report. However, it is important to remember that a randomised controlled study is essentially an experiment in which patients are carefully selected, interventions are regulated and delivered by enthusiastic professionals, and all variables are optimised to support the hypothesis. The

important question is whether these conditions and the benefit can be replicated in the real world and the impact that they will have on provision of mainstream services. These were examined using the 'soft systems' model for complex services.¹

A community-based stroke register was used to collect information on all stroke patients during the study. As the validity of any stroke register depends on complete and accurate ascertainment of cases, this was ensured by using standard definitions, a prospective study design, an adequate and defined population, notification by multiple and overlapping sources, and audit of the register against data from other sources. The difficulties in ascertaining strokes that were fatal, those occurring while away from home and those in severely disabled institutionalised patients are acknowledged. Although attempts were made to identify all minor events from GP records, clinic referrals and regular check of radiology records, there is a possibility that some patients may have been missed. Except for these few exceptions, the methodology of the register identified the vast majority of stroke patients in the district during the study period.

Data showed that nearly 20% of notifications for stroke had other diagnoses, which highlighted the level of misdiagnosis and the need for specialist assessments of all suspected stroke patients. This is important for reasons of clinical governance, epidemiology and service planning. Alternative strategies could be considered 'safe' in less than 50% of stroke patients, of whom only two-thirds of patients managed at home would have been appropriate for this intervention. In other words, of the 600 patients seen annually in an average district general hospital, management at home could be considered an option in 150 (25%) patients only if:¹⁵

- appropriate diagnostic assessments could be undertaken
- care services were able to provide adequate and flexible support
- the service was part of a specialist stroke service.

The stroke team and the domiciliary stroke service required extra staffing resources over and above those dedicated to the stroke unit. This amounted to 1.0 whole-time equivalent (WTE) physiotherapist, 1.0 WTE occupational therapist, 0.5 WTE specialist registrar, 0.2 WTE consultant, 0.3 WTE speech and language therapist and 0.5 WTE nursing stroke coordinator input. This does not take into account the extra input provided by

district nursing and social services, which would not have been necessary if these patients had been hospitalised. The levels of staffing in the study are likely to be an underestimate of needs in service settings because of enthusiasm of the professionals involved and the added value of research that motivated higher levels of performance than can be expected in clinical practice.

Considerable changes in the processes of care and infrastructure were needed to provide the domiciliary service and the specialist stroke team support on general medical wards. The details of these changes are summarised in Chapters 4 and 5. To summarise, a whole new policy of stroke care had to be developed and agreed to by various stakeholders in the system. New practices for referral, assessment and investigations (many with budgetary consequences) had to be developed and piloted before setting up the service. The processes of care for stroke patients within different settings had to be audited. Practice development and staff training were undertaken as detailed in Chapter 5. For example, a joint health and social services initiative whereby health professionals had access to social services budgets was developed specifically for the study at a time when these concepts had not been evaluated or widely accepted. The process developed not only was feasible, but also resulted in prevention of delays and better care for patients at home. This initiative was seen to have significant implications for provision of care in the community for other conditions and was implemented across the district.

It needs to be emphasised that many of the organisational changes required for this study were possible because of:

- provision of health and social care needs by a single hospital trust, a single community health provider, a single family health services authority and a single social services agency, which were all co-terminus
- close functioning between primary and secondary care, health commissioning and provider trusts, and health and social services
- prioritisation of stroke care provision by the Health Authority and the provider trusts
- implementation of Community Care Act and development of new initiatives within social services
- well-developed stroke services in the district and a high level of commitment to the project from individual professionals in the hospital and the community.

Objective 4: to evaluate the acceptability of various strategies to patients and to professionals involved in care provision

The major advantage of treatment at home is its flexibility in adapting treatment, especially rehabilitation, to the patients' needs in their own environment. The study showed some advantages in terms of a higher level of ADL in patients and better quality of life in survivors managed at home, which was reflected in significantly greater patient satisfaction with care provided compared with other strategies. The major areas contributing to this satisfaction were being able to talk about stroke and related problems with visiting professionals, better organisation of services at home and the high level of personal contact with the specialist team. Although the carers shared these views, they tended to be less satisfied than patients with the amounts of therapy input, information on support and benefits, and contact with the specialist team.

Carers were significantly more dissatisfied with the care provided on general wards with specialist team support compared with the stroke unit or care at home. Major factors contributing to dissatisfaction included attention to the personal needs of the patients and recognition of problems associated with the care of stroke patients. In addition, more carers were dissatisfied with the amount of therapy, information and contact with specialist teams in this group compared with the stroke unit or domiciliary group. In general, domiciliary care appeared to be acceptable to patients, carers and professionals under certain conditions. Management on general wards with specialist support appeared to be the only strategy causing concerns.

Professional acceptance of domiciliary care was more difficult to assess because of the relatively small numbers of professionals involved and their relatively little involvement in the day-to-day care of the patient. Overall, most GPs believed that some stroke patients could be managed at home as

long as the responsibility of care was shared with hospital-based specialist services, which ensured rapid access to investigations, fast track admission to hospital in case of problems and specialist input into patient care. Other professionals shared these views. Overall, there was general support for the establishment of a domiciliary stroke service as long as adequate resources were available to offer a reliable service.

Although domiciliary care for stroke was acceptable to most patients, carers and professionals, this conclusion needs to be qualified. The findings may represent an optimistic view of acceptability because only enthusiastic patients and professionals may have participated in the study or responded to the questionnaires. It is also likely that the service was viewed favourably by professionals involved because of the high level of input and personal contact provided by the research team, which reduced their own involvement in patient care. These patient and provider characteristics may not be replicated in mainstream practice, which may change perceptions of benefits or acceptability expressed by patients, carers or professionals.

Limitations of assessment of acceptability

The acceptability of services in this project was assessed as a secondary outcome to provide a context for the randomised controlled study on outcomes. This assessment was heavily reliant on the self-completion of satisfaction survey and it is important to acknowledge that satisfaction is only one of the components of acceptability, and others were not measured. The instrument used for patient and carer satisfaction was similar to that used in other studies on stroke outcome and has been shown to be valid and reliable in similar studies.⁶⁴ However, the reliability or validity of the modified version was not tested before the study and is one of the limitations of the methodology. The issue of acceptability would have been better addressed by qualitative interview techniques, which would have led to better in-depth understanding of the issues involved.

Chapter 7

Conclusions

Although stroke unit care has been proven to be effective, there were concerns that it may be expensive, selective, inaccessible or inappropriate for all stroke patients. It was hypothesised that alternative methods of organised stroke care, such as hospital at home or specialist stroke teams, may be equally effective but incur a fraction of costs associated with stroke units.

Specialised care at home has achieved variable success as an alternative means of providing organised multidisciplinary care for defined conditions.^{6,17} The possibility of managing stroke patients at home is attractive, especially as previous studies suggest that most stroke patients are admitted to hospital for nursing, therapy or social needs⁵ and that acute stroke care at home is feasible in clinical practice.¹⁸ A specialist stroke team¹¹ which consults throughout the hospital is another method of organising stroke care that offers the advantages of unlimited capacity and dissemination of specialist practice to other settings.

The present study adds further weight to the view that all acute stroke patients should be admitted to a specialised stroke unit as soon as possible. Such a policy is supported by the recommendations of the Helsingborg declaration and those of the American Heart Association.^{13,14} In the authors' opinion, this is particularly indicated for patients in whom there is a possibility of a diagnosis other than stroke, severe strokes, high dependence or special needs (e.g. swallowing problems).

A role for specialist domiciliary services for acute stroke is not supported by this study. Nearly one-third of the patients in this group were admitted to hospital despite well-defined criteria for patient selection and high levels of support from the specialist stroke team, GPs, district nursing and personal care services operating in the best possible configuration of health and social

services. In addition, the overall outcome for patients managed at home may not be as good as suggested by this study because of the influence of stroke unit care in the 51 patients admitted to hospital. It will be difficult to replicate domiciliary stroke care in settings with less complementary configurations of health and social care providers, and even if this were possible, the service would apply only to a small proportion of stroke patients.

Management of stroke patients on general medical wards, even with specialist team support, is not supported by this study. The high mortality rate throughout suggests that despite specialist advice, management of stroke-related complications and secondary prevention may be suboptimal in these patients. This strategy of care was also associated with poorer functional outcomes in survivors and increased dissatisfaction with care, which suggests that direct care by specialists could not be replaced by an advisory role to generic multidisciplinary teams. It also suggests the need to train medical and other staff in the specialist aspects of stroke care to reduce the mortality and morbidity secondary to stroke.

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 when compared with home care. It can be concluded that the stroke unit is a more cost-effective intervention than either the stroke team or home care.

This study provides further support for early specialist care on dedicated units for all stroke patients regardless of stroke severity. In the authors' opinion, the most pragmatic strategy for effective stroke care appears to be early management on stroke units before specialised rehabilitation or early supported discharge and rehabilitation at home, depending on the needs and circumstances of individual patients.

Chapter 8

Recommendations for future research

This study raises several new issues which need investigation.

Although stroke unit care is associated with significant reductions in mortality and dependence, the exact nature of stroke unit care remains poorly defined. A major limitation of existing research is that processes of management have not been studied in great detail and most information is either superficial or based on selective case studies. The translation of trial efficacy of stroke units into clinical effectiveness in mainstream practice requires the replication of not only the structure, but also the processes associated with favourable treatment outcome. Hence, objective measurement of processes of stroke care within the context of a randomised study using objective criteria for processes or events is required to inform practice. Measurement of processes of care is complex and presents the particular problem of quantifying quality. In addition, specialist management consists of several elements working together and it may be difficult to discriminate between individual processes. It may be possible to overcome some of these problems by categorising processes into theoretically defined and clinically relevant domains, which can then be used to analyse differences between settings. As some processes may be interdependent, this dependency and their relationship to the frequency of complications can be explored by further analysis to identify the processes most strongly related with favourable outcome.

The question of patients' and carers' perceptions of services, satisfaction with the care provided and the acceptability of different forms of care was not addressed adequately in this study. Only one aspect of acceptability (patient satisfaction) was evaluated and the questionnaire used did not allow the full richness of patient experience to be explored. Further research to investigate issues relating to patient experience and choice with different strategies of providing stroke care are needed using qualitative techniques such as focused interviews and discussion groups in which common themes can be identified to inform and enrich clinical practice. It will also be important to explore the relationships between patient satisfaction and variables such as patient characteristics, stroke

severity, level of residual dependence and individual processes of management to help to develop patient-focused management strategies.

Although the quantity (duration) of therapy provided has been reported in this study, the quality of therapy and various techniques may have been responsible for some of the favourable outcomes seen with stroke unit care. Research into therapy inputs in stroke has been severely impeded by the variability of techniques used,⁶⁵ but it remains important to determine the influence of different techniques on eventual outcome in stroke. It is also important to know whether more of such desirable interventions happen on the stroke unit and may explain the differences seen between specialist and generic settings.

The important question in any RCT is its generalisability to service settings. To a great extent, this study was possible because of the favourable configuration of health and social services in a largely affluent area in southern England. As the probability of key events such as hospitalisation and institutionalisation can vary massively on the basis of existing NHS facilities and socio-economic circumstances of the patients' families, it will be very useful to compare an identical set of clinical arrangements in a different socio-economic and NHS setting.

It is well known that the real-world effectiveness of proven interventions may be at variance from their efficacy in an RCT, depending on the structure of the population and the proportion of patients eligible for the chosen intervention. In addition, healthcare or social services staff delivering a mainstream service may not be as dedicated or enthusiastic as staff involved in research. There is also a possibility that the favoured intervention (e.g. stroke unit or home care) may not perform as well as it does in research projects because of day-to-day operational problems that may have been circumvented during the trial period. Hence, it is important to evaluate proven interventions in different clinical settings using techniques other than the RCT methodology. The soft systems approach suggested by Checkland and Scholes¹ is ideal for such investigations and could be used for further research.

Chapter 9

Problems encountered

Staff recruitment

The national shortage of therapy staff (physiotherapists and occupational therapists) at the beginning of the project and the changing structure of medical training at the middle grade level resulted in considerable difficulties in recruiting appropriate staff for the project. The response to national advertisements was poor and it was feared that the national staff shortage would be a serious threat to the successful completion of the project.

In view of this, suitably qualified, enthusiastic and research-orientated staff working within participating trusts were encouraged to apply for the posts. Financial and academic support was provided for higher qualifications from departmental resources. Four of the six research fellows obtained their masters degree during the project and one is currently compiling his thesis for the award of a doctorate. However, there was a possibility that recruitment of staff from other patient care areas to the project may have resulted in a degree of reduction of service within those areas and affected the general services of provider trusts.

Support from GPs

Despite support from the local medical committee and other general practice agencies, a significant proportion of GPs were not enthusiastic about their patients being randomised to the domiciliary limb of the project in the initial stages. There were strong concerns about clinical and legal responsibility of managing disabled patients with a neurological problem at home and providing overall medical and social care for these patients. These concerns were managed by emphasising the criteria for hospital admission for patients being managed at home and ensuring that these patients could be rapidly admitted to the stroke unit at the GP's request. In addition, assurances were given on providing medical assessment at home on the day of the stroke or rapid assessments on the medical assessment unit, early availability of personal care and sharing the clinical and legal responsibility for care.

The number of GP referrals to the team increased considerably as a result of increasing confidence in the domiciliary stroke team and the programme of visits to individual surgeries after the first 6 months. Further partnerships with general practitioners were developed with regular reports of the progress of the project, seminars and educational sessions undertaken in local surgeries. Although data were not collected formally, there was an impression within the domiciliary team that some GPs preferred to keep their moderately disabled acute stroke patients at home rather than sending them to hospital, by the end of the study, because of perceived advantages of quality of care and improved outcome.

Methodological problems

Ethical issues

The study group is aware of some concerns expressed outside the district about the ethics of keeping stroke patients at home in preference to admitting them to hospital following an acute episode. These concerns were identified at the beginning of the project and it has been made clear from the outset that the project would be limited to patients who fulfilled the strict criteria for inclusion, were willing to stay at home and had their GP's consent. The right of the GP to admit these patients to hospital without giving a reason was fundamental to the local medical committee's approval of the project. The process of constant review by the stroke team and other professionals involved with the project ensured that problems were identified early and appropriate intervention, including hospital admission, was undertaken without delay. The study was approved by the local medical ethics committee and there was no evidence in the literature at the time of commencement of the study (which pre-dates the Helsingborg declaration) to support early admission to hospitals for this group of patients. Preliminary data and interim analyses did not show that patients in the domiciliary limb were being disadvantaged by a lack of investigative or therapy input.

Protocol changes

The register showed that a large proportion of

stroke patients were admitted from A&E, rather than by GP referrals. As several of these patients were suitable for inclusion in the project, the protocol was modified to include eligible patients from this source. These patients were notified urgently to the stroke team, who assessed them for eligibility and randomised them to different allocations within the project after obtaining their and the GP's consent and ensuring that adequate support would be available from the social services. This strategy was necessary to meet recruitment targets and to make the findings more generalisable to the local population of stroke patients.

Data collection

The research workers experienced difficulties in obtaining data collected by other agencies because of logistics and problems of perceived ownership. Although sharing of these data had been agreed at the outset of the study, changes in service policies and appointment of new senior managers in collaborating trusts required renegotiation of previous arrangements. This activity was labour intensive and time consuming, but the research team was successful in gaining access to service data, essential for health economics analyses.

Ascertainment of stroke

The problems encountered with the stroke register were acknowledged in the interim reports and were similar to those experienced by others in maintaining a comprehensive community-based stroke register.

Complete data sets were missing for some patients managed in other hospitals, those managed at home by community services or GPs (especially if they had had a mild stroke or if the stroke was very severe and death was expected) and those referred to clinics other than those run by the stroke services. Additional information in these patients was collected from a range of other sources, but the researchers were unable to achieve 100% completion of all data items for all patients.

Despite the simplicity of the definition of stroke, accurate classification and diagnosis continued to present problems. About 13% of patients notified as stroke did not actually have stroke on clinical and radiological assessments. Patients most likely to be misdiagnosed were those with primary cerebral neoplasia or metastases, worsening of pre-existing neurological deficits owing to intercurrent illness, or vascular dementias. In

many of these patients a clear history was not available on presentation, but subsequent assessment by the stroke team and neuroimaging showed no evidence of new pathology. This emphasises the need for CT scans for all stroke patients, as this may affect diagnosis and future management.

Susceptibility to service pressures

Social services

Introduction of community care charges

The domiciliary limb of the project was put at risk because of proposed changes in personal care services and charging policies, which were being considered by the social services in 1995. Although personal care was provided by the social services, it was not seen as a health-related need and was subject to a means-tested charge based on local policies. The charge at the beginning of the project was nominal (£6.89 per week) regardless of the level of services being used. The new proposal outlined plans to replace this with a new means-tested charge of £3.85 per hour, being introduced in October 1995.

There was a potential that these changes in social services would seriously affect the randomisation process, as patients may be admitted for financial rather than health reasons. The options considered by the steering group included requesting the social services to waive these charges for patients in the stroke study (which was seen as being inequitable to other patients in a similar position who were not part of the project), requesting additional funding from the local joint commissioning group (which may divert funds from other development projects) or using funds from other research sources to underwrite these costs (which would not reflect true service settings). In the end, problems anticipated with the introduction of community care charges failed to materialise.

Implementation of continuing care guideline

There were concerns about the implementation of the Continuing Care guidelines [HSG (95)8], which may have an adverse effect on the project. The model of joint assessment and purchasing between health and social services, developed for the stroke project, is being extended to the strategy for implementing continuing care guidelines for patients in the community. The effect of HSG (95)8 on the project was monitored closely, but did not appear to influence the destination of discharge within study patients.

Health services

Winter pressures

It is well known that health services projects, such as this one, will be susceptible to changes and pressures in mainstream service provision. Patient recruitment had to be suspended on two occasions for a total period of 8 weeks over the duration of the project. The first suspension of randomisation was necessitated by reduced community support because of staff shortages and the demand on these services from other sources, especially during the holiday period. The second (and longer) suspension was necessary because of a shortage of acute beds owing to unprecedented patient admissions during the winter of 1996/97, and it was no longer possible to randomise patients to the stroke team or to the stroke unit. It was also necessary to suspend randomisation during this period because the number of beds on the stroke unit was doubled to accommodate general patients, resulting in a loss of specialisation, dilution of specialist input and disruption of rehabilitation programmes. *Table 8* includes all patients with stroke, as registration was not stopped at the time of suspending randomisation.

Internal market

As this project depended heavily on smooth functioning between different provider agencies, it was always at risk because of changes in the commissioning process or in relationships between different provider agencies. Although the project continued to be well supported by all partners, especially the district nursing and social services, changes in the commissioning process (e.g. tendering of community services, cost-improvement schemes, pressure to develop new programmes within existing resources) resulted in considerable knock-on effects.

There was a potential risk that continued support for the project may be used as a bargaining point in negotiations for other unrelated services within the district. It was possible to keep the project on course by anticipating these problems and undertaking intensive negotiations with appropriate agencies. The economic value of this input in terms of time and effort spent is difficult to quantitate, but should not be underestimated. It highlights the need for clear specifications for interagency liaison and explicit funding for support services in providing domiciliary care for acute stroke or other similar services.

GP referrals

The temporary suspension of randomisation presented problems because some GPs received the impression that the project had been discontinued. The project team had to spend considerable amounts of time revisiting local surgeries to enable the project to regain momentum. In addition, concerns were expressed in primary care about the possibility of the stroke model of service provision being extrapolated to other areas of care without appropriate consultation or resources, thus increasing the GPs' workload. There were also concerns that a high-profile project such as the stroke project may divert attention and community resources from other priority areas, although this was not borne out by project monitoring and hospital or community activity analyses undertaken by the health authority.

Equipment

The timely provision of appropriate aids and equipment to stroke patients managed at home was a continuing problem. There was no clear understanding between hospital services, community services and the social services about which agency would be responsible for providing necessary aids and adaptations to these patients. There was a view that the management of acute stroke patients at home was an extension of hospital services for a health need, and that the hospital should be responsible for equipment for these patients. A contrasting view saw the equipment needed by patients as being essential to meet their care needs in the community and, hence, a community care/social services responsibility.

The timely availability of equipment was also an issue because some of the aids required were not available immediately through community services. It was normal practice for the domiciliary stroke team to provide the necessary equipment from hospital sources on initial assessment to bridge the urgent-needs gap. This was followed by negotiations with district nurses and social services for longer term provision of aids and equipment on a patient-to-patient basis.



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Contributions of authors

Lalit Kalra (Professor of Stroke Medicine) was responsible for the conception, design, initiation and overall coordination of the study, analysis and interpretation of data, drafting of the paper and its intellectual content. Andrew Evans (Clinical Lecturer in Stroke Medicine) was responsible for assessments, collation, analysis and interpretation of data and writing of the paper. Inigo Perez (Research Fellow) was involved with the design of the study, day-to-day administration of the project, data collection, collation and interpretation. Martin Knapp (Professor of Health Economics) was involved in the conception and design of the study, interpretation of data and critical review of the paper. Cameron Swift (Head of Department of Health Care of The Elderly) was involved in the conception of the study, interpretation of the data and critical review of the publication. Nora Donaldson (Statistician) was the independent statistician and provided statistical input to the design, data analysis, interpretation and writing of the paper.

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Appendix I

Operational policy (community aspects)

Introduction

The alternative strategies of stroke care programme is an evaluation of the effectiveness, feasibility and acceptability of different approaches of stroke management in defined patient groups. One aspect of the project involves the provision of acute stroke care at home undertaken in collaboration with Bromley Health, Bromley Hospitals, Ravensbourne Trust and Bromley Social services.

This aspect of stroke care provision will be facilitated by:

- establishment of a stroke team comprising a physiotherapist, occupational therapist and medical input, which will work closely with GPs and community services
- agreements between social services and district nurses whereby district nurses will perform initial assessments for nursing and personal care needs and access appropriate services, depending on availability. The district nurses will provide personal care for up to 48 hours if appropriate and subject to resources. A more complete assessment by care managers will follow. This arrangement is limited to stroke patients participating in the project.

Patient criteria

Stroke patients, regardless of age, were considered for inclusion. Stroke will be defined by the standard WHO definition of acute onset of neurological deficit (usually focal) lasting for more than 24 hours with no apparent cause other than vascular disease.

Specific exclusions

- Patients with a presumptive diagnosis of stroke in whom unequivocal deficits cannot be demonstrated
- patients with neurological deficit secondary to an epileptic episode
- patients with old stroke with worsening deficit on the same side
- patients in whom the focal neurological deficit could be secondary to metastatic or metabolic disease

- patients in whom the stroke is a minor complication in a more significant underlying illness such as dementia or chronic disability.

Operational plan

Initial GP assessment of stroke patient:

- Assess medical and neurological problems.
- Decide need for hospitalisation.

Guidelines for emergency hospital admissions:

- unconscious patient
- unable to swallow: risk of aspiration pneumonia
- care needs in excess of those that can be provided at home
- faecal incontinence
- rapidly evolving/unusual neurological deficit
- patient on anticoagulation
- environmental problems, including lack of competent carer.

The ethical and logistic problems in applying strict criteria to prevent hospital admissions are acknowledged and the GPs will have a right to admit all such patients in whom they feel that hospitalisation is in the patient's best interest.

All other patients will be referred to the project.

GPs will be required to:

- refer to the central stroke office at Orpington Hospital. There will be a direct line to the stroke office as well as facility to fax through referrals. The stroke office will work from Monday to Friday, from 9.00 am to 5.00 pm. The stroke office will alert the stroke team and also the district nurse to provide initial assessment of care needs. Following the assessment and confirmation of eligibility, the stroke office will determine the setting of patient management and let the GP know of patients being managed at home
- alert district nursing, who will perform nursing/personal care assessments. The district nurses will undertake initial assessment for care

needs and will be able to set up services. They will liaise with social services for a more detailed assessment and appropriate service provision. They will also refer the patient to the central stroke office, if this has not been undertaken previously.

The dual referral strategy has been adopted to ensure that no stroke patients in the community are missed and that adequate care/therapy arrangements are made.

Domiciliary management

The **GP will retain the clinical responsibility** for patients managed in the community, but will be supported by the stroke team.

The **stroke team** will consist of the stroke nurse (coordinator), doctor, physiotherapist and occupational therapist, and will be supported by the district nurses and social services care managers. They will liaise closely with the GP and the stroke consultant to maintain continuity of care, provide timely information on progress and be responsive to general practice concerns and comments.

It will be possible to **admit patients** being managed at home to hospital at any time for the following reasons:

- deterioration in clinical or neurological status
- development of new problems
- need for specialist investigations
- excessive care needs which could not be met at home
- patient, GP or stroke team decision.

The specialist team will:

- perform baseline routine investigations and arrange further outpatient assessments or investigations as appropriate. Patients managed at home will be reviewed in a stroke clinic as appropriate
- assess the patient for multidisciplinary needs. Assessments to include detailed nursing, physiotherapy and occupational therapy assessments; speech and language therapy referral if appropriate
- liaise with other professionals to develop an individualised nursing plan, therapy plan and care management plan. A multidisciplinary record has been developed to facilitate the process and will be kept with the patient
- undertake rehabilitation up to a maximum period of 3 months using individualised therapy programmes and monitor progress
- initiate secondary prevention and prevention of stroke-related complications
- provide feedback to GPs, district nurses and care managers and inform of significant changes
- develop contacts with community services for necessary equipment (subject to availability) and transfer of care and maintenance therapy at the end of 3 months (in accordance with existing patterns)
- direct patients/carers towards appropriate counselling and voluntary information services.

Patients' progress will be monitored on a regular basis in multidisciplinary meetings. The team will review patients on the basis of comprehensive assessments, goals and progress. Problems in rehabilitation of individual patients will be discussed at these meetings. The GP will be invited to these meetings and patient/carer involvement encouraged as appropriate. Specialist support will be provided from the hospital to support the 'shared care' with GPs.

Appendix 2

Unit costs

All unit costs are standardised to 1997/98 prices.

TABLE 45 Stroke team

	Unit cost (£)	Source	Notes
Stroke team coordinator per year (G grade nurse)	29779.41 (3.95 per patient per day)	1	Based on manager of a day ward. Includes London multiplier. Cost per patient day derived by dividing annual cost by the total number of patient days worked. Total number of patient days estimated by summing the number of days on which all stroke team and home care patients were alive (and therefore available to receive the service) within the first 3 months of their stroke
Stroke team doctor per hour (clinical research fellow)	23.43	1	Basic salary and London weighting based on actual cost for the physician. All other on-costs based on unit cost for senior house officer in Netten <i>et al.</i> Overhead and capital elements include London multiplier. Excludes cost of qualifications and ongoing training
Physiotherapist per PIU/per hour	8.27/49.83	2	
Occupational therapist per PIU/per hour	8.27/49.83	2	
Hospital speech and language therapist per hour of patient contact	32.82	1	Includes London multiplier

TABLE 46 Day hospital services

Per day	Unit cost (£)	Source	Notes
General surgery	62.00	1	Generic day hospital cost used as proxy
Psychiatry	57.00	1	
Urology	62.00	1	Generic day hospital cost used as proxy

TABLE 47 Inpatient services

Per inpatient day	Unit cost (£)	Source	Notes
Stroke unit	199.33	2	
General medical ward	254.25	2	
Geriatric medicine ward	123.27	1	
Neurosurgery ward	516.85	8	
Renal unit	211.00	1	Generic ward cost used as proxy
Rehabilitation ward	145.36	1	
Vascular surgery ward	295.93	8	General surgery ward used as proxy
Psychiatric ward	135.00	1	
General surgery ward	295.93	8	
Orthopaedic ward	300.70	8	Orthopaedic surgery ward used as proxy
Cardiac surgery ward	635.06	8	Cardiothoracic surgery ward used as proxy
Coronary care unit	363.55	9	

TABLE 48 Outpatient services, per attendance

	Unit cost (£)	Source	Notes
A&E	98.00	1	
Cardiology	67.00	1	
Neurology	84.41	2	
General medicine	77.00	2	
Geriatric medicine	77.00	2	
Stroke clinic	84.00	2	
General surgery	57.00	2	
Diabetes clinic	60.00	1	Generic outpatient cost used as proxy
ENT	60.00	1	Generic outpatient cost used as proxy
Haematology	52.00	1	
Neurosurgery	140.75	8	
Ophthalmology	60.00	1	Generic outpatient cost used as proxy
Urology	65.00	1	Genitourinary medicine department used as proxy
Dermatology	47.00	1	
Gynaecology	60.00	1	Generic outpatient cost used as proxy
Orthopaedics	60.00	1	Generic outpatient cost used as proxy
Pain clinic	67.00	1	Rheumatology department used as proxy
Psychiatry	97.00	1	
Radiotherapy	47.15	8	
Rehabilitation medicine	388.00	1	
Rheumatology	67.00	1	

TABLE 49 Community-based health services

	Unit cost (£)	Source	Notes
GP per surgery consultation	11.78	1	Includes practice nurse costs, excludes qualification costs
GP per home visit	29.02	1	Includes practice nurse costs, excludes qualification costs
Dentist per 20-minute visit	16.27	3	
Dentist per 20-minute home visit	16.27 + 1.03 travel	3	
Optician per visit	13.59	4	
District nurse per hour of patient contact	42.70	1	Includes London multiplier, excludes qualification costs
District nurse per hour of home visit	45.37 + 1.03 travel	1	Includes London multiplier, excludes qualification costs
Chiropodist per clinic hour	9.86	1	Includes London multiplier, excludes qualification costs
Chiropodist per home visit hour	18.48 + 1.03 travel	1	Includes London multiplier, excludes qualification costs
Osteopath per session	17.54	5	
Chiropractor per session	24.37	5	
Acupuncture per session	22.42	5	
Geriatrician per patient-related hour	77.34	1	Medical consultant used as proxy. Includes London multiplier.
Psychologist per hour of client contact	62.36 + 1.03 travel	1	Clinical psychologist used as proxy. Includes London multiplier
Counsellor per hour of client contact	62.36 + 1.03 travel	1	Clinical psychologist used as proxy. Includes London multiplier

TABLE 50 Voluntary services

	Unit cost (£)	Source	Notes
Voluntary organisation day-care centre per session	20.52	1	Based on 50% of LA day care for elderly people. Includes London multiplier
LA, local authority.			

TABLE 51 Social services

	Unit cost (£)	Source	Notes
Social worker per hour of client contact	94.85 + 1.03 travel	1	Includes London multiplier
Home care worker per hour	9.44	4	Includes travel
Domestic help	9.93	6	Excludes patient cost
Personal care	10.61	6	Excludes patient cost
Freezer meals/meals on wheels per meal	2.00	6	Excludes patient cost
Social club	12.31	1	Based on 30% of LA day centre for elderly people
Social services day-care centre per session	41.04	1	LA day care for elderly people used as proxy. Includes London multiplier
Residential home per week	260.72 to 290.00	7	Only includes cost to social services
Nursing home per week	400.00 to 435.63	7	Only includes cost to social services

TABLE 52 Other services

	Unit cost (£)	Source	Notes
Respite care per day	60.61	1	Independent (private and voluntary) nursing homes for elderly people used as proxy. Establishment costs per short-term resident week including London multiplier = £424.27 per week
Sheltered housing per week	121.00	1	Fee for LA sheltered housing for elderly people. Excludes personal living expenses and other health and social services costs
Special sheltered housing per week	169.00	1	Fee for LA very sheltered housing for elderly. Excludes personal living expenses and other health and social services costs

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7. Personal communication with Contracts Manager, Bromley Social Services, May 2000. Fees for seven residential homes and six nursing homes were provided at 2000/01 prices. These were deflated to 1997/98 prices using actual annual percentage fee increases since 1998: April 1998 3.7%, April 1999 3.0%, April 2000 0.4%. Average residential home and nursing home fees were 277.02 and 419.34 per week, respectively. These average rates were applied to patients for whom no facility addresses were available and for those residing in homes outside the borough.
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Appendix 3

The CONSORT table

TABLE 53 The CONSORT table

Heading	Subheading	Descriptor	Was it reported?
Title		Identify the study as a randomised trial	Yes
Abstract		Use a structured format	Yes
Introduction		State prospectively defined hypothesis, clinical objectives, and planned subgroup or covariate analyses	Yes
Methods	Protocol	Describe: Planned study population together with inclusion/exclusion criteria Planned interventions and their timing Primary and secondary outcome measure(s) and the minimum important difference(s), and indicate how the target sample size projected Rationale and methods for statistical analyses, detailing main comparative analyses and whether they were completed on intention-to-treat basis Prospectively defined stopping rules (if warranted)	Yes
	Assignment	Describe: Unit of randomisation (e.g. individual, cluster, geographic) Method used to generate the allocation schedule Method of allocation concealment and timing of assignment Method to separate the generator from the executor of assignment	Yes
	Masking (blinding)	Describe mechanism (e.g. capsules, tablets); similarity of treatment characteristics (e.g. appearance, taste); allocation schedule control (location of code during trial and when broken); and evidence for successful blinding among participants, person doing intervention, outcome assessors and data analysts	Yes
Results	Participant flow and follow-up	Provide a trial profile (figure) summarising participant flow, numbers and timing of randomisation assignment, interventions and measurements for each randomised group	Yes
	Analysis	State estimated effect of intervention on primary and secondary outcome measures, including a point estimate and measure of precision (confidence interval) State results in absolute numbers when feasible (e.g. 10/20, not 50%) Present summary data and appropriate descriptive and inferential statistics in sufficient detail to permit alternative analyses and replication Describe prognostic variables by treatment group and any attempt to adjust for them Describe protocol deviations from the study as planned, together with the reasons.	Yes
Comment		State specific interpretation of study findings, including sources of bias and imprecision (internal validity) and discussion of external validity, including appropriate quantitative measures when possible State general interpretation of the data in light of the totality of the available evidence	Yes



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We look forward to hearing from you.