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Abstract

A cluster randomised controlled trial and economic evaluation of a structured training programme for caregivers of inpatients after stroke: the TRACS trial

A Forster,[1]* J Dickerson,[1] J Young,[1] A Patel,[2] L Kalra,[3] J Nixon,[4] D Smithard,[3] M Knapp,[2,5] I Holloway,[4] S Anwar[4] and A Farrin[4] on behalf of the TRACS Trial Collaboration

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Background: The majority of stroke patients are discharged home dependent on informal caregivers, usually family members, to provide assistance with activities of daily living (ADL), including bathing, dressing and toileting. Many caregivers feel unprepared for this role and this may have a detrimental effect on both the patient and caregiver.

Objective: To evaluate whether or not a structured, competency-based training programme for caregivers [the London Stroke Carer Training Course (LSCTC)] improved physical and psychological outcomes for patients and their caregivers after disabling stroke, and to determine if such a training programme is cost-effective.

Design: A pragmatic, multicentre, cluster randomised controlled trial.

Setting: Stratified randomisation of 36 stroke rehabilitation units (SRUs) to the intervention or control group by geographical region and quality of care.

Participants: A total of 930 stroke patient and caregiver dyads were recruited. Patients were eligible if they had a confirmed diagnosis of stroke, were medically stable, were likely to return home with residual disability at the time of discharge and had a caregiver available, willing and able to provide support after discharge. The caregiver was defined as the main person – other than health, social or voluntary care provider – helping with ADL and/or advocating on behalf of the patient.

Intervention: The intervention (the LSCTC) comprised a number of caregiver training sessions and competency assessment delivered by SRU staff while the patient was in the SRU and one recommended follow-up session after discharge. The control group continued to provide usual care according to national guidelines. Recruitment was completed by independent researchers and participants were unaware of the SRUs' allocation.

Main outcome measures: The primary outcomes were self-reported extended ADL for the patient and caregiver burden measured at 6 months after recruitment. Secondary outcomes included quality of life, mood and cost-effectiveness, with final follow-up at 12 months.

Results: No differences in primary outcomes were found between the groups at 6 months. Adjusted mean differences were –0.2 points [95% confidence interval (CI) –3.0 to 2.5 points; $p = 0.866$; intracluster correlation coefficient (ICC) = 0.027] for the patient Nottingham Extended Activities of Daily Living score and 0.5 points (95% CI –1.7 to 2.7 points; $p = 0.660$; ICC = 0.013) for the Caregiver Burden Scale. Furthermore, no differences were detected in any of the secondary outcomes. Intervention compliance varied across the units. Half of the participating centres had a compliance rating of >60%. Analysis showed no evidence of higher levels of patient independence or lower levels of caregiver burden in the SRUs with better levels of intervention compliance. The economic evaluation suggests that from a patient and caregiver perspective, health and social care costs, societal costs and outcomes are similar for the intervention and control groups at 6 months, 12 months and over 1 year.

Conclusions: We have conducted a robust multicentre, cluster randomised trial, demonstrating for the first time that this methodology is feasible in stroke rehabilitation research. There was no difference between the LSCTC and usual care with respect to improving stroke patients' recovery, reducing caregivers' burden, or improving other physical and psychological outcomes, nor was it cost-effective compared with usual care. Compliance with the intervention varied, but analysis indicated that a dose effect was unlikely. It is possible that the immediate post-stroke period may not be the ideal time for the delivery of structured training. The intervention approach might be more relevant if delivered after discharge by community-based teams.

Trial registration: Current Controlled Trials ISRCTN49208824.

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Contents

List of abbreviations

6CIT	Six-item Cognitive Impairment Test
ADL	activities of daily living
AE	adverse event
CBS	Caregiver Burden Scale
CEAC	cost-effectiveness acceptability curve
CI	confidence interval
CSRI	Client Service Receipt Inventory
CTRU	Clinical Trials Research Unit
DMEC	Data Monitoring and Ethics Committee
EQ-5D	European Quality of Life-5 Dimensions
FAI	Frenchay Activities Index
GP	general practitioner
HADS	Hospital Anxiety and Depression Scale
HRG	Healthcare Resource Group
ICC	intracluster correlation coefficient
ICER	incremental cost-effectiveness ratio
ITT	intention to treat
LSCTC	London Stroke Carers Training Course
MDT	multidisciplinary team
MeSH	medical subject heading
MRC	Medical Research Council
NEADL	Nottingham Extended Activities of Daily Living
NICE	National Institute for Health and Care Excellence (formerly National Institute for Health and Clinical Excellence)
NIHR	National Institute for Health Research
NSSA	National Sentinel Stroke Audit
PI	principal investigator
QALY	quality-adjusted life-year
R&D	research and development
RCP	Royal College of Physicians of London
RCT	randomised controlled trial
RUSAE	related and unexpected serious adverse event
SAE	serious adverse event
SD	standard deviation
SE	standard error
SIS	Stroke Impact Scale
SRN	Stroke Research Network
SRU	stroke rehabilitation unit
TMG	Trial Management Group
TRACS	Training Caregivers After Stroke
TSC	Trial Steering Committee

Scientific summary

Background

Stroke is the commonest cause of severe disability in the community. After discharge from hospital many patients will require continuing help with activities of daily living (ADL), such as moving, bathing, dressing and toileting. This help is often provided by informal caregivers. This burden of care, however, has an important effect on caregivers' well-being, with nearly half of caregivers reporting health problems and two-thirds a decline in social life, and there are high self-reported levels of strain.

Reducing the burden of caregiving after stroke may not only improve the caregiver's health but may also enhance the recovery and adjustment of the stroke patient. A Cochrane review has examined the effectiveness of interventions for caregivers of stroke survivors in reducing caregiver burden or enhancing caregiver well-being. This review concluded that, at present, it is not possible to determine the usefulness of any existing interventions. In the Cochrane review, the intervention identified as having the most potential to benefit both caregivers and patients was a caregiver training programme designed and evaluated by Kalra *et al.* in a London stroke unit (Kalra L, Evans A, Perez I, Melbourn A, Patel A, Knapp M, *et al.* Training care givers of stroke patients: randomised controlled trial. *BMJ* 2004;**328**:1099–101). The intervention was the London Stroke Carer Training Course (the LSCTC), a training programme for caregivers, which included training on knowledge and skills essential for the day-to-day care of disabled stroke survivors. The results of the study suggested that providing caregivers with the LSCTC was associated with a significant reduction in health-care costs, caregiver burden, and a significant improvement in caregiver and patient mood and health-related quality of life. However, generalisability was limited because the training programme was tested in a single hospital, delivered by the team who were responsible for developing the intervention and who might be expected to have heightened motivation and expertise, and the patient population was predominantly recruited from a middle-class suburban area that might be more responsive to a training programme.

The aim of the TRACS (Training Caregivers After Stroke) trial was to assess the effectiveness of the LSCTC once embedded in usual practice in stroke units across the UK, thereby testing wider generalisability in settings in which the population, health and social care provision differ.

Objectives

The primary patient objective of the trial was to determine whether or not the provision of the LSCTC improves functional independence in extended ADL for patients after disabling stroke. The primary caregiver objective was to determine whether or not the provision of the LSCTC reduces burden for caregivers of patients after disabling stroke. The secondary objectives were to determine whether the provision of the LSCTC was (1) associated with improved physical and psychological outcomes for patients after disabling stroke; (2) associated with improved physical and psychological outcomes for caregivers of patients after disabling stroke; and (3) cost-effective.

Methods

The TRACS trial was a pragmatic, multicentre, cluster randomised controlled trial.

Setting

Thirty-six stroke rehabilitation units (SRUs) participated in TRACS in four geographical regions in the UK. SRUs were eligible to participate if they met four out of five key criteria used to define a stroke unit, as suggested by the Royal College of Physicians of London for the National Sentinel Stroke Audit (NSSA) 2006.

Randomisation

The unit of randomisation was the SRU. SRUs were randomised on a 1 : 1 basis to either the intervention or the control group. The randomisation was stratified by geographical region and quality of care (defined as being on and above, or below, the median on the key 12-indicator score of the 2006 NSSA). Block randomisation was used to ensure that these important covariates were balanced between the arms of the trial.

Intervention

Stroke rehabilitation units randomised to the intervention group were required to incorporate the LSCTC as a part of their usual care, so that every eligible caregiver received this training. The LSCTC consists of 14 training components (six mandatory) that were identified as important knowledge/skills that caregivers would need to be able to care for the stroke patient after discharge home. The LSCTC was delivered to caregivers while the patient was an inpatient in the SRU, with one recommended 'follow through' session provided in person or by telephone after hospital discharge. A key component of the LSCTC was the requirement for the multidisciplinary team (MDT) to check the caregiver's competency on each of the training components delivered and to 'sign off' the competency as achieved. Training would continue until the caregiver was deemed competent (or until it was agreed by the MDT that the caregiver was unable to become competent). This permitted the level of training to be both individualised to the caregiver and standardised across the SRUs.

Control

Stroke rehabilitation units randomised to the control group were asked to continue usual practice, providing care based on the National Clinical Guidelines for stroke.

Participants

Patients were eligible for TRACS if they had a confirmed primary diagnosis of new stroke, were medically stable, were likely to return home with residual disability, and had a caregiver available, willing and able to provide support after discharge. The caregiver was defined as the main person, other than health, social or voluntary care provider, helping with ADL and/or advocating on behalf of the patient. Patient and caregiver dyads were excluded if the patient was in need of palliative care, if discharge was planned within 1 week of admission to the SRU, or if the patient or caregiver were registered to the trial on a previous admission.

Patients and caregivers in both arms of the study consented to data collection and questionnaire completion. Participant recruitment and baseline assessments were undertaken by researchers independent of the clinical MDT. Eligible patients and caregivers in the intervention arm received the LSCTC as a part of standard care, whether or not they consented to the study procedures. Participants were blinded to the SRUs allocation, and the MDT staff in each SRU were not informed of the patients/caregivers who had consented to study procedures.

Outcome measures

The primary patient outcome was functional independence, measured at 6 months using the Nottingham Extended Activities of Daily Living (NEADL) scale. The primary caregiver outcome was caregiver burden, measured at 6 months using the Caregiver Burden Scale (CBS). Secondary patient outcomes included self-report measures of mood [Hospital Anxiety and Depression Scale (HADS)], health state [EuroQol 5-dimension health-state measure: European Quality of Life-5 Dimensions (EQ-5D)], ADL (Barthel Index), functional ability and health-related quality of life [Stroke Impact Scale (SIS)], death, hospital readmission and institutionalisation, all measured at both 6 and 12 months after recruitment, and with the NEADL scale at 12 months.

Secondary caregiver outcomes included self-report measures of social restriction [Frenchay Activities Index (FAI)]; mood (HADS); health state (EQ-5D); death; hospitalisation and institutionalisation at 6 and 12 months, and caregiver burden (CBS) at 12 months.

The TRACS trial also assessed the cost-effectiveness and cost–utility of the LSCTC for both patients and caregivers from health and social care and societal perspectives. Costs were combined with the NEADL score and quality-adjusted life-years (QALYs) for patients and the CBS and QALYs for caregivers. Resource use was measured using the self-completed Client Service Receipt Inventory. Hospital records were checked for patient hospital readmissions and caregiver hospital admissions at 6 and 12 months post registration.

Sample size

The original target recruitment was 900 patient and caregiver dyads, 25 dyads from each of the 36 SRUs. The sample size calculations assumed a clinically relevant six-point difference in the patient primary outcome measure (NEADL). Thirty-six SRUs, each recruiting 25 patients, would result in 450 patients in each group and provide close to 90% power at 5% significance level to detect the clinically relevant difference of six points on the NEADL score. A sample size of 900 patients provides more than 85% power at the 5% significance level to detect an effect size of one-third in any of the other outcomes. The power of the trial was adversely affected, however, by a higher than expected loss to follow-up and unequal cluster sizes. By estimating maximum and minimum cluster sizes, the predicted imbalance decreased the power by 1–3%. To preserve final power of 90%, the trial sample size was increased to between 950 and 1000 patient and caregiver dyads, with a maximum of 35 dyads from each of the 36 SRUs to compensate for low recruitment at some centres.

Results

In total, 930 patients were registered between February 2008 and February 2010, of whom 928 patients and their caregivers provided consent to the trial (450 LSCTC, 478 control).

No evidence of a clinical or statistical difference was found between the groups in the patient primary outcome at 6 months measured by the NEADL scale [adjusted mean score in intervention 27.4, in control 27.6, difference –0.2 points, 95% confidence interval (CI) –3.0 to 2.5 points; p-value = 0.866; adjusted intracluster correlation coefficient (ICC) = 0.027].

Similarly, no evidence of a clinical or statistical difference was found between the groups in the caregivers' primary outcome at 6 months, measured by the CBS (adjusted mean score in intervention 45.5, in control 45.0, difference 0.5 points, 95% CI –1.7 to 2.7 points; p-value = 0.660, adjusted ICC = 0.013).

In terms of other physical and psychological outcomes for patients, no differences between the two groups of patients were found in any of the secondary end points at 6 months: anxiety (HADS) [adjusted mean score in intervention 6.7, in control 6.6, difference 0.1 points (95% CI –0.5 to 0.7 points, p-value = 0.629, adjusted ICC = 0)], depression (HADS) [adjusted mean score in intervention 7.3, in control 7.2, difference 0.1 points (95% CI –0.5 to 0.7 points; p-value = 0.759; adjusted ICC = 0)], ADLs (Barthel Index) [adjusted mean score in intervention 14.2, in control 14.1, difference 0.1 points (95% CI –0.6 to 0.7 points; p-value = 0.825; adjusted ICC = 0)], health state (EQ-5D) (adjusted mean score in intervention 0.441, in control 0.443, difference –0.002 points; p-value = 0.946; adjusted ICC = 0) or SIS physical domain [adjusted mean score in intervention 52.7, in control 52.0, difference 0.7 points (95% CI –2.3 to 3.7 points; p-value = 0.641; adjusted ICC = 0.001).

At 12 months, no differences between patient groups were found in extended ADLs (NEADL), anxiety (HADS), depression (HADS), ADLs (Barthel Index), health state (EQ-5D) or SIS physical domain.

Comparison of caregiver self-reported outcomes at 6 months detected no differences between the two groups in anxiety (HADS) [adjusted mean score in intervention 7.0, in control 7.5, difference –0.5 points

(95% CI –1.2 to 0.1 points; *p*-value = 0.084; adjusted ICC = 0.016)], depression (HADS) [adjusted mean score in intervention 5.2, in control 5.5, difference –0.3 points, 95% (CI –0.9 to 0.3 points; *p*-value = 0.308; adjusted ICC = 0.013)], social restriction (FAI) [adjusted mean score in intervention 31.4, in control 32.2, difference –0.8 points (95% CI –1.82 to 0.26 points; *p*-value = 0.136; adjusted ICC = 0)] or health state (EQ-5D) (adjusted mean score in intervention 0.777, in control 0.790, difference –0.014 points; *p*-value = 0.358; adjusted ICC = 0).

Similarly, analysis of caregiver self-reported outcomes at 12 months found no differences between the groups in burden experienced by caregivers (CBS), anxiety (HADS), depression (HADS), social restriction (FAI) or health state (EQ-5D).

Thus, overall there is no evidence that the LSCTC improves patients' physical or psychological outcomes following stroke at 6 and 12 months, and there is no evidence that it reduces caregivers' burden or improves their physical or psychological outcomes.

Intervention compliance, as assessed by completed and returned caregiver training records, varied across the units; half of the participating centres had a compliance rating of > 60%. Compliance analysis shows no evidence of higher levels of patient independence or lower levels of caregiver burden in the SRUs with better levels of intervention compliance.

Patients in both groups had similar length of stay for the initial stroke admission, and patients and caregivers had similar total health and social care and societal costs at all assessment points. Total LSCTC development and staff training costs were £102,577. When applied to intervention group individuals proportionately to the amount of caregiver training received, this resulted in a mean cost of £39 per patient/caregiver dyad. There were no significant differences in patient or caregiver QALYs. For patients and caregivers, probabilities of cost-effectiveness based on QALYs were low.

Conclusions

We have conducted a robust multicentre cluster randomised trial: the world's largest completed stroke rehabilitation trial. The sample size of 930 patients and caregiver dyads is far greater than any study previously reported. We have demonstrated for the first time that this methodology can feasibly be implemented in stroke rehabilitation research. The intervention evaluated had reported benefits in a previous single-centre evaluation but these benefits have not been replicated in this large, multicentre trial. There was no difference between the LSCTC and usual care with respect to improving stroke patients' recovery, reducing caregivers' burden or improving other physical and psychological outcomes, nor is it cost-effective when compared with usual care.

Training in the intervention was provided at national training days during which materials were provided to support cascade training to other members of the multidisciplinary stroke team. This had variable success and has implications for the implementation of other service changes. Compliance with the intervention varied across stroke units but analysis demonstrated no link between the degree of compliance and associated patient or caregiver outcomes, indicating that a dose effect is unlikely. The LSCTC provided a structured framework for caregiver training. It is possible that the immediate post-stroke period, when potential caregivers are coming to terms with their new situation, may not be the ideal time for the delivery of structured training. The intervention approach might be more relevant if delivered after discharge by community-based teams.

Trial registration

This trial is registered as ISRCTN49208824.

Funding

This project was funded by the MRC and is managed by the NIHR (project number 09/800/10) on behalf of the MRC–NIHR partnership, and will be published in full in *Health Technology Assessment*; Vol. 17, No. 46. See the NIHR Journals Library website for further project information.

Chapter 1 Introduction

Stroke remains a major health problem in the 21st century, with incidence rates of 1.65 per 1000 population for first-ever strokes.[1] After the recommended hospital admission, most patients are discharged home with some residual disability.[2] There is considerable reliance on informal caregivers, usually family members, to provide assistance with activities of daily living (ADL), including bathing, dressing, and toileting after hospital discharge.[3] For some, this informal care avoids or delays admission to institutional care, and the economic value of the informal care provided is considerable.[4] Indeed, it is suggested that the economic costs of informal care total £2.4B annually, almost equivalent to the hospital and social care costs that total £2.8B annually.[5]

This burden of care also has an important effect on caregivers' physical and psychosocial well-being,[6] with up to 48% of caregivers reporting health problems, two-thirds a decline in social life[7] and high self-reported levels of strain. With the current emphasis on shorter hospital stays, caregivers will play an increasingly important role in the care and continued rehabilitation of patients after stroke. The successful adjustment of patients and their caregivers to the aftermath of stroke is clearly interlinked. Caregivers have an important role in enhancing patients' rehabilitation, and coping strategies that lead to negative experiences are associated with increasing dependence.[8] The caregivers of patients with poor physical and emotional states often have poor emotional outcomes themselves.[9] Effective interventions directed at caregivers of stroke patients are essential, as they may not only improve their own health but may also improve the recovery and adjustment of the stroke patient.[10] However, despite the physical, psychological and social consequences of caregiving, its economic cost to society and its importance in patient recovery, caregivers' central role is often given low priority in the management of stroke.[11]

Previous research

A range of systematic reviews of qualitative[7,12] and quantitative[13] stroke literature have confirmed the diversity, complexity and frequency of problems faced by patients and caregivers during recovery from, and adjustment to, a disabling stroke. A Cochrane review has summarised the effectiveness of non-pharmacological interventions for caregivers of stroke survivors in reducing caregiver burden or enhancing caregiver well-being.[14] In eight randomised controlled trials (RCTs) involving 1007 participants, interventions evaluated were categorised as support and information provision;[15–18] caregiver training programme;[19] and psychoeducational.[20–24] Three of these studies were inpatient interventions;[15,17,19] one was started as inpatient and crossed over into the community,[21] two were conducted post discharge in the non-acute phase,[18,22] and the location of delivery of two was unclear,[16,20] although participants were recruited as inpatients. The comparator in six of the studies was usual care,[15–19,21] one study used a crossover wait list design[20] and one study used written information on stress management.[22]

Only one study – the caregiver training programme[19] – was seen to have a significant effect on reducing caregiver burden. The combined results of the support and information provision,[15–18] and the psychoeducational[20–22] interventions revealed no impact on caregiver burden.

A number of secondary outcomes were examined by the studies. Two studies (one support and information provision[16] and one psychoeducational[20]) assessed global measures of stress or distress, and revealed no significant benefit of the intervention over usual care. One study (caregiver training programme[19]) assessed anxiety, and the analysis conducted by the reviewers revealed no significant effect of the intervention on caregiver anxiety. Of the five studies measuring depression,[16,18–21] only the caregiver training programme[19] was seen to have a significant beneficial effect. Three studies[15,16,19] (the caregiver training programme[19] and two support and information provision interventions[15,16]) assessed health-related quality of life. The caregiver training programme[19] demonstrated a significant improvement in the intervention group, one support and information provision study showed no significant benefit,[15] and the second support and

information provision study[16] showed significant improvements in 5 out of 8 SF-36 health domains. The review authors conclude that, with limited available studies the caregiver training programme[19] was the most promising intervention. However, the evidence for this was from one single-centre RCT.[19]

The conclusions of the Cochrane review support the findings of earlier reviews of stroke caregiver interventions:[10,23,24] that previous studies have methodological limitations; further robust evaluation is required; and the effects of caregiver interventions on the patient also need to be assessed.

In the Cochrane review, the caregiver training programme,[19] which included education and some practical 'hands-on' skills training, was identified as having the most potential to benefit both caregivers and patients. This is supported by evidence from our Cochrane review of information provision ($n = 17$ trials), which concluded that stroke education programmes improve patient and carer knowledge of stroke, aspects of patient satisfaction, and reduce patient depression scores.[25,26] There was also some evidence that education interventions that actively involve patients and carers and include planned follow-up for clarification and reinforcement are likely to be more successful than simply providing information.[25,26] Furthermore, caregivers have identified the information and skills training required to implement physical care as their most important pre-discharge needs.[27] Although caregiver support is a key component of stroke unit care, caregivers report that there are missed opportunities for structured skills training prior to the stroke patients discharge,[28] and that support, as currently provided, is not compatible with their expressed needs, and their ability to care is not assessed.[10,27]

Caregiver training programme

Literature searches conducted by the authors prior to publication of the Cochrane review on the effectiveness of caregiver interventions identified no effective early training programmes for caregivers of patients after stroke, other than the caregiver training programme evaluated by Kalra *et al.*[19] in an individually randomised single-centre study. This intervention – the London Stroke Carers Training Course (LSCTC) – was a systematic and structured training programme for caregivers, which included assessment in competencies in skills essential for the day-to-day management of disabled stroke survivors. The LSCTC was based on a survey among stroke caregivers, asking them to identify major problems experienced after hospital discharge. Although many reported satisfaction with involvement in discharge planning, most found themselves unprepared for the task of providing 'hands-on' care at home. The components of the LSCTC were therefore devised to address the knowledge and skills required to effectively care for stroke patients on discharge from hospital.

The single-centre study participants were 300 patients and caregivers admitted to a stroke rehabilitation unit in south London, UK.[19] Patients and caregivers were block randomised to receive either usual care or the LSCTC prior to discharge home. The primary outcome was the cost to health and social services during the first year of stroke. Total health and social care costs over 1 year were significantly lower in the intervention group, with a mean difference of £4043.[29] This cost difference was largely due to a shorter length of stay for patients in the intervention group than in the control group. There was no difference in quality-adjusted life-years (QALYs) in caregivers.[29] Significant secondary outcomes for caregivers receiving the intervention included a reduction in caregiver burden (as measured by the Caregiver Burden Scale; CBS[30]), improved quality of life [EuroQol 5-dimension health-state measure: European Quality of Life-5 Dimensions (EQ-5D) visual analogue scale[31]] and mood [Hospital Anxiety and Depression Scale (HADS)[32]]. There was no significant difference in social activity levels [Frenchay Activities Index (FAI)[33]]. For the patients whose caregivers had received the training, there was a significant improvement in quality of life (EQ-5D visual analogue scale) and mood (HADS). No significant differences were seen in patients' physical recovery (Barthel Index[34] and modified Rankin Scale[35]), mortality or institutionalisation.[19]

Justification for the current study

There were important limitations to the generalisability of the findings of the study of Kalra *et al.*[19] The LSCTC was tested in a single centre, delivered by the LSCTC development team, who might be expected to have heightened motivation and expertise, and the patient population was predominantly recruited from a middle-class suburban area, and might be more responsive to a training and education programme. In addition, having demonstrated benefit for caregivers on a range of domains, it was important to evaluate the effectiveness of the LSCTC programme on improving patient outcomes. The aim of the TRACS (Training Caregivers after Stroke) trial was to assess the effectiveness of the LSCTC on patient outcomes (once embedded in usual practice) in stroke units across the UK, thereby testing wider generalisability in settings in which the population, health and social care provision differ.

Chapter 2 The intervention: the London Stroke Carers Training Course

Development of the modified London Stroke Carers Training Course

The LSCTC consists of 14 core caregiver competencies that required training and testing. These competencies were important knowledge/skills that informal caregivers would need to be able to care effectively for the stroke patient on discharge home, for example demonstrating understanding of what a stroke is; knowledge of the patient-specific problems associated with stroke (which may be related to speech, mobility, memory, diet and swallowing, vision and reading, washing and dressing, transfer and walking); knowledge of how to manage and provide support for personal ADLs, including continence management if required. Modification of the LSCTC was required for the multicentre TRACS trial to allow the intervention to be implemented in different NHS settings, and by members of the stroke rehabilitation units' (SRUs') multidisciplinary teams (MDTs) with a range of skills and expertise. The LSCTC was modified and a training programme for staff was developed by the original LSCTC MDT (AM, MW and JS), based on what had worked in the single-centre study and what could be transferred to other settings. The modified LSCTC maintained the original structure of 14 core competencies; six of the training components were listed as mandatory, requiring the MDT to train all caregivers on these items, and the remaining eight components were to be completed as appropriate dependent on each individual patient's ability and their caregiver's needs. A full description of the 14 training components is provided in *Table 1*. To facilitate replicable delivery, a training manual was created, which described in detail the objective of each training component and recommendations on how to deliver the information/training, resources available (i.e. relevant stroke association information leaflets), and suggested ways to assess the caregivers competency (verbal/observations, etc.). A summary of the underpinning principles was also provided; for example, training should be individualised to the caregivers at the required level and should be based on the needs of the patient. Further modifications were made following pilot use of the modified LSCTC by the SRUs randomised to the intervention.

London Stroke Carers Training Course Caregiver training record

To support the training and standardisation of delivery of the LSCTC, a structured training record was created, which listed the 14 training components and provided a section to indicate whether or not that particular component was mandatory/appropriate for the individual carer. If mandatory/appropriate, the component could be ticked off once the training had been given, and the caregiver's competency could be signed off once assessed. A further section allowed documentation of the total time taken to deliver the training. On the final page, space was provided to document progress of training and so the record acted as a work in progress throughout the patient's stay and a way of communicating training progress and ongoing needs throughout the team. For each caregiver the MDT staff were asked to complete a training record. A copy of the training record can be seen in *Appendix 1*.

Training of the intervention

Two training sessions were provided for the SRUs randomised to deliver the LSCTC. The training days were delivered by the original LSCTC development team and were held over 2 days, 1 month apart. The same sessions were repeated twice; once in Leeds for the Yorkshire and North West centres and once in London for the London and the South East and South West Peninsula centres. The aim of the first

TABLE 1 The London Stroke Carers Training Course training components

The caregiver has demonstrated a knowledge and understanding of:	
1	His/her relative having had a stroke **(mandatory)**
2	What a stroke is **(mandatory)**
3	His/her relative's specific stroke-related problems. Possible incomplete recovery and residual unresolved problems: (a) Communication and reading (b) Cognition (c) Personality and mood changes (d) Diet and swallowing (e) Vision (f) Personal ADL (g) Transfers and mobility **(as appropriate)**
4	The importance of a healthy lifestyle and secondary preventions: (a) Control of blood pressure (b) Use of aspirin/warfarin or similar (c) Smoking (d) Appropriate diet, including prevention of excess weight gain (e) Exercise (f) Pain management **(mandatory)**
5	Dietary needs and feeding techniques: (a) Special diet (b) Techniques to assist eating, including use of specialist equipment if necessary **(as appropriate)**
6	How to communicate with dysphasic relative **(as appropriate)**
7	How to manage relative's personal washing, dressing, toiletry needs **(as appropriate)**
8	The importance of limb positioning and the management of pressure areas and skin integrity **(as appropriate)**
9	Continence management **(as appropriate)**
10	Bowel management, fluid and dietary intake for the prevention of constipation **(as appropriate)**
11	Appropriate techniques and ability in: (a) Safe transfers (b) Safely assisting mobility (c) Floor routine following a fall (d) Safely assisting in climbing stairs (e) Good use of a wheelchair (f) Use of aids **(as appropriate)**
12	The importance of compliance with medication (including supervision of self-medication or routine medication) **(mandatory)**
13	Post-discharge arrangements and where and whom to seek help from after discharge **(mandatory)**
14	Adapting the knowledge and skills taught to the home environment following discharge (follow-up visit or telephone call) **(mandatory)**

training day was to ensure that the MDTs delivering the LSCTC were clear about what they needed to deliver to the caregivers, and to consider how best to implement the training within their local unit. The day covered, through presentations and group workshops, the background to the LSCTC, the training components and suggested delivery and use of the training records (see *Appendix 2*). This training day was filmed and provided the basis for a training CD to be used to cascade the training to all staff on the SRUs. Staff were provided with the training manual (see *Appendix 3*).

After the first session, the attendees were required to cascade the LSCTC training to the rest of the MDT on their SRUs. The LSCTC was then piloted on a small number of caregivers on each SRU, including completion of the training record. A second training day was held approximately 1 month later. This session allowed open discussion on possible refinement of delivery of the LSCTC by the MDT and modification of the training manual and records (see *Appendix 2*). After this meeting the LSCTC was gradually implemented as a part of standard practice on the SRUs. All centres then received a visit from the TRACS trial manager who used the completed training records as a basis for discussions on structure and process. Further local training sessions were arranged if necessary to provide feedback and support, and discuss any problems with LSCTC provision. The programme was then delivered for a duration of 24 months while the TRACS trial recruitment took place.

Training attendees

The TRACS team suggested that at least two key MDT members from each of the 18 intervention centres attended the initial training days. In practice, 1–13 members from each centre attended, with an average of three attendees per centre. The attendees came from a range of disciplines, primarily senior physiotherapists, senior occupational therapists and senior nurses, but also included Band 5 nurses, consultant physicians and senior speech and language therapists. The attendees were identified as 'TRACS champions,' who had responsibility to cascade the intervention within their site.

All centres were offered a local refresher course by the TRACS trial manager midway through the trial in September–October 2008. In total, 13 out of 18 centres received this refresher training; four centres said that they were completing the LSCTC successfully and did not require further training [three such centres did have good return rates of the training records, one centre (294) had not yet returned the records so compliance could not be assessed]. One centre remained non-compliant and refused further training. As the TRACS trial recruitment period was extended for an additional 10 months, a further central training day was provided in London in August 2009; staff from 11 centres attended this day.

London Stroke Carers Training Course delivery

The LSCTC was designed to be delivered to caregivers while the patient was an inpatient with one 'follow through' session provided in person or by telephone after hospital discharge. The training was individualised to the caregivers' required level of understanding. The timing of the sessions was not dictated, and could begin at anytime from admission, and throughout the patients stay, depending on when the team felt it appropriate for that particular caregiver, along with other factors, such as varying lengths of stay and local procedures. It was recognised that different components could be covered in a number of different ways, by different professionals depending on individual circumstances.

A key component of the LSCTC was the requirement to check each caregiver's competency on each of the training components delivered and for an appropriate member of the MDT to 'sign off' the competency as achieved. Competency was defined as 'The caregiver has taken on board the knowledge/skills required to be able to deliver the support that that patient needs'. Training would continue until the caregiver was deemed competent (or until it was agreed by the MDT that the caregiver was unable to become competent). This allowed the level of training to be both individualised to the caregiver and standardised across SRUs.

Monitoring of delivery

The completed LSCTC training record for all trial participants was returned to the trial manager and was included as a standard monitoring report to the Trial Management Group (TMG) and Trial Steering Committee (TSC). This enabled monitoring of compliance with the intervention delivery in the SRUs, and the time taken and competencies achieved by each caregiver. In instances where there were concerns about SRU compliance, the trial manager directly engaged with the sites to explore difficulties. The chief investigator wrote to the local principal investigators (PIs) of two units to express concerns.

Chapter 3 Methods

Trial design

Training Caregivers After Stroke was a pragmatic, multicentre, cluster RCT designed to evaluate whether or not a structured, competency-based training programme for caregivers (LSCTC) improved physical and psychological outcomes for patients and their caregivers after disabling stroke and to determine if such a training programme was cost-effective.

Training Caregivers After Stroke was designed as a pragmatic trial. Thus the eligibility criteria were broad and inclusive, the intervention was highly flexible in application and was delivered in a full range of SRUs by the local MDT staff. Monitoring of participant and practitioner compliance/adherence was unobtrusive with no special strategies to improve compliance. Outcomes were objective and meaningful to patients. The primary analysis was intention to treat (ITT) as a test of whether or not the treatment worked in the context of all inherent real-life noise.[36]

Figure 1 summarises the study methods, and the study protocol can be viewed in *Appendix 4*.

Justification of a cluster randomised design

The cluster randomised trial design was purposely selected to reduce between-group treatment contamination. Within the pragmatic trial, the LSCTC intervention was incorporated into usual practice and delivered by the whole MDT. If randomisation had been at the level of individual patients, the MDT would have had to operate two approaches (usual care and the LSCTC) with an associated high risk of between-group contamination as it would not have been possible to blind members of the MDT, thus it seemed likely that the new care process would have been extended to patients in the usual care group. Randomisation was therefore at the level of the (service) stroke unit. In order to minimise selection bias, there was a clear separation between the provision of the intervention by clinical staff and the recruitment and consent of patients and caregivers by research practitioners.

Primary objectives

The primary patient objective of the trial was to determine whether or not the provision of the LSCTC improved functional independence. The primary caregiver objective was to determine whether or not the provision of the LSCTC reduced burden for caregivers.

Secondary objectives

The secondary objectives were to determine whether or not the provision of the LSCTC (1) improved physical and psychological patient outcomes in the long term, (2) improved physical and psychological caregivers outcomes and (3) was cost-effective based on (a) patient outcomes, from both health/social care and societal perspectives and (b) caregiver outcomes, from a health-care perspective.

Stroke unit (cluster) eligibility

Stroke rehabilitation units were eligible to participate in the TRACS trial if they met four out of five key criteria used to define a stroke unit, as suggested by the Royal College of Physicians of London (RCP) for the

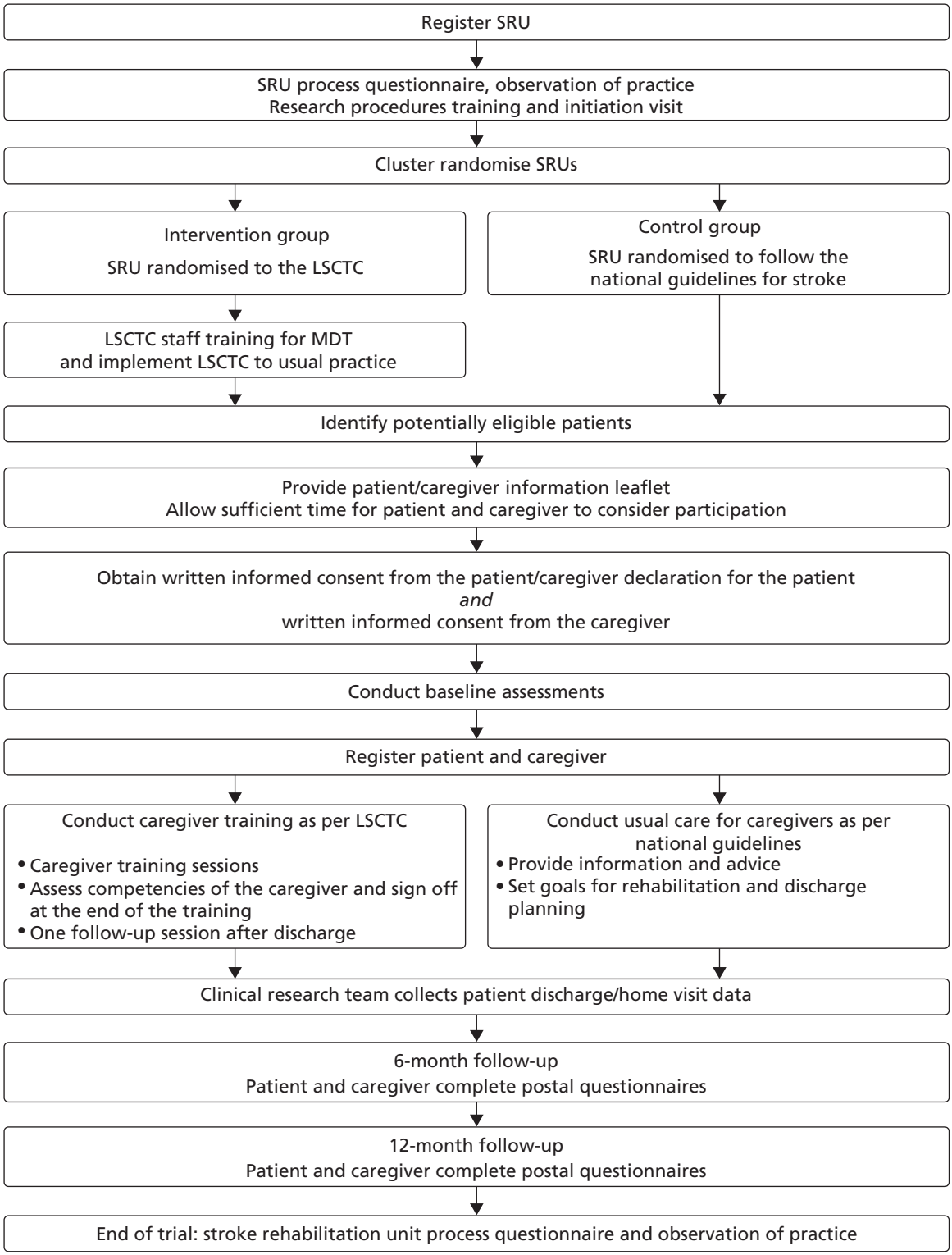

FIGURE 1 Study flow chart.

National Sentinel Stroke Audit (NSSA) 2006.[37] The five key criteria are (1) consultant physician with responsibility for stroke, (2) formal links with patient and caregiver organisations, (3) MDT meetings at least weekly to plan patient care, (4) provision of information to patients about stroke and (5) continuing education programmes for staff. Additional eligibility criteria were that a substantial number of patients on the unit had a diagnosis of stroke, the unit was able to deliver the LSCTC and the majority of patients were discharged to a permanent place of residence.

Randomisation and stratification

Cluster randomisation of the 36 eligible SRUs was performed centrally at the Clinical Trials Research Unit (CTRU). SRUs were randomised on a 1:1 basis to either the intervention or the control group. The randomisation was stratified by geographical region (Yorkshire, the North West, the South West Peninsula, and London and the South East) and quality of care (defined as being on and above, or below, the median on the key 12-indicator score of the 2006 NSSA[37]). Block randomisation was used to ensure these important covariates were balanced between the arms of the trial.

Intervention units

In SRUs randomised to the intervention group, usual care was augmented by provision of a modified LSCTC programme (as described in *Chapter 2*), incorporated into ward practice and delivered to all patients on the SRU if a caregiver was available. Recruitment was opened 4–6 months after the initial training meeting, providing sufficient time for the implementation of the LSCTC into standard ward practice.

Control units

Stroke Rehabilitation Units randomised to the control arm were asked to continue with their usual care, based on National Clinical Guidelines.[38,39] As a minimum, this care involved:

- weekly MDT meetings
- information provision to patients and carers
- ad hoc training of skills to caregivers (e.g. percutaneous endoscopic gastrostomy feeds, transfers, etc.).

Stroke rehabilitation units in the control arm opened to recruitment at the same time as the intervention centres.

Details of usual involvement of patients and caregivers on the SRUs was collected via interviews with senior staff prior to randomisation, and during and at the end of participant recruitment (details below).

Process information

Process data were collected before, during and after recruitment at each participating SRU to monitor any changes in eligibility in SRUs, and in the process of care that prepared patients and caregivers for discharge in SRUs. Data were collected on the NSSA scores completed during the trial (2006 and 2008); ward type (combined acute and rehabilitation or rehabilitation); number of stroke beds; MDT staff ratios; use of community and early supported discharge stroke teams; and usual MDT working. Senior MDT staff (where possible, therapy and nursing staff) were asked open-ended questions to describe usual ward practice and discharge preparation, and how patients and caregivers were involved with this. Responses were recorded on the first visit, and on following visits the initial responses were cross-checked with the new responses and any changes/additions/losses to service updated. Any such changes were monitored by the trial manager through visits to the centres and discussions with the researchers, PIs and MDTs, and were reported back to the TMG for discussion and decision-making.

Participant eligibility

Patients were eligible for TRACS if they had a confirmed primary diagnosis of new stroke, were medically stable, were likely to return home with residual disability, and had a caregiver available, willing and able to provide support after discharge. The caregiver was defined as the main person, other than health, social, or voluntary care provider, helping with ADL and/or advocating on behalf of the patient. Written informed patient consent/caregiver declaration and caregiver consent were obtained prior to any trial-specific procedures. Patient and caregiver dyads were excluded if the patient was in need of palliative care, if discharge was planned within 1 week of admission to the SRU, or if the patient or caregiver was previously registered to the trial.

Blinding

Participant recruitment and baseline assessments were undertaken by researchers independent of the clinical MDT. The clinical MDTs in both the intervention and control arms conducted the LSCTC/usual care with all eligible patients' caregivers whether or not they consented to study procedures. The MDTs were not informed of which patients/caregivers consented to study procedures. Participants were blinded to the SRUs allocation.

Participant recruitment

Screening

All patients admitted to the SRUs were screened for eligibility for the TRACS trial. The researchers completed a screening log that included reasons why patients were not eligible, reasons for which patients/caregivers did not consent and length of stay and anonymous patient demographic information (age, ethnicity, usual living circumstances, and relationship to caregiver). The screening data permitted monitoring of rates of identification, recruitment and refusals at all sites, as well as a comparison of the patient populations being admitted and recruited into the two arms of the study.

Recruitment

To avoid selection bias, participants were recruited by researchers from the Stroke Research Network (SRN) who were independent of the clinical MDT. Where researchers worked part-time as clinical staff, they were not permitted to recruit into TRACS, and other SRN researchers came into that SRU at least weekly to screen and recruit participants into the study.

Written informed consent was obtained from both patients and caregivers. When patients were unable to provide written consent owing to stroke-related disability and/or a lack of mental capacity, a caregiver declaration was obtained. For patients who were unable to consent for themselves, this study complies with the Mental Capacity Act 2005.[40] In such cases, the caregiver acted as consultee.

Patients and caregivers in both arms of the study consented to data collection and questionnaire completion.

Registration

To be registered into the study, the patient and caregiver dyad must have provided written informed consent and completed the baseline questionnaires. The researcher was also required to collect all necessary baseline information after consent but prior to registration. Registration was performed centrally using an automated 24-hour telephone registration system at the CTRU, University of Leeds, Leeds, UK.

Withdrawal

Patients and caregivers were free to withdraw at any time from the study without giving reasons and without prejudicing the patient's treatment. Where patients or caregivers requested to withdraw from the study

procedures, there was clarification of whether this was withdrawal from postal follow-up or from medical records searches or both.

Primary outcomes

The primary patient outcome was functional independence measured at 6 months using the Nottingham Extended Activities of Daily Living (NEADL) scale.[41,42]

The primary caregiver outcome was caregiver burden measured at 6 months using the CBS.[30]

Secondary outcomes

Secondary patient outcomes included self-reported measures of mood (HADS[32]); health state (EQ-5D);[31,43,44] ADLs (Barthel Index);[34,45] functional ability and health-related quality of life [Stroke Impact Scale (SIS)];[46–51] death; hospital readmission and institutionalisation, all measured at both 6 and 12 months after recruitment, and functional independence (NEADL) at 12 months.

Secondary caregiver outcomes included self-reported measures of social restriction (FAI);[33,52] mood (HADS); health state (EQ-5D); death; hospitalisation and institutionalisation at 6 and 12 months, and caregiver burden (CBS) at 12 months.

The cost-effectiveness of the LSCTC for both patients and caregivers was also assessed. Resource use was measured using the self-completed Client Service Receipt Inventory (CSRI).[29,53] Hospital records were checked for patient hospital readmissions and caregiver hospital admissions at 6 and 12 months post registration.

Assessment instruments

Nottingham Extended Activities of Daily Living Scale

Functional independence was measured using the NEADL scale.[41,42] It was designed as a postal questionnaire and assesses aspects of physical and social independence performance across 22 items [score range is from 0 (low independence) to 66 (high independence)] grouped in four categories (mobility, kitchen, domestic and leisure activities). It has been widely used as an outcome measure in rehabilitation trials.[54,55] It has proven validity, reliability[56] and has demonstrated responsiveness to change and able to discriminate between services.[57]

Hospital Anxiety and Depression Scale

Both patients and caregivers mood was assessed using the 14-component HADS.[32] It was initially developed as an instrument to identify anxiety disorders and depression in medical outpatients,[32] but has since proven to exhibit wider generalisability.[58] HADS score is reported from 0 (normal level of anxiety/depression) to 21 (abnormal level of anxiety/depression).

EuroQol 5-dimension health-state measure

The non-disease-specific EQ-5D instrument[31,43,44] was used to evaluate health-related quality of life of both patients and caregivers via a six-component questionnaire. It was developed to yield a fundamental index of health, which can be used to calculate QALY gains and, thus, facilitates the health economic evaluation. EQ-5D is scored from –0.59 (worst possible health state) to 1 (full health).

Barthel Index

Patient ADL and mobility were assessed using the Barthel Index.[34,45] This instrument was used to evaluate patients' disability and level of dependence on their caregiver via assessment of their ability in bathing,

transferring from bed to chair, dressing, feeding, mobility, climbing stairs, toilet use, grooming, and bladder and bowl continence. Barthel Index is scored 0 (dependent) to 20 (independent).

Stroke Impact Scale

Functional ability and health-related quality of life of the patients was measured using the SIS.[46,47,50,51] This scale consists of eight components measuring strength, memory and thinking, emotion, communication, activities and independent ADL, mobility, hand function, and social participation. It was developed for use as a self-reporting questionnaire, which has proven to be reliable, valid and sensitive to change.[49,51] SIS has also been validated for use as a postal questionnaire.[48] Each domain is scored from 0 (worst) to 100 (best).

Client Service Receipt Inventory

Data on patient sociodemographics and use of health and other formal care services and informal care were collected using a CSRI validated for use with stroke patients.[29,53] A reduced form of this instrument was used with caregivers.

Caregiver Burden Scale

Caregiver burden was measured using a proven and reliable CBS.[30] This 22-item scale assesses various aspects of caregiver burden including general strain, isolation, disappointment, emotional involvement and environment. CBS is scored from 22 to 88, with a higher score representing a more subjective burden.

Frenchay Activities Index

The social restriction on caregivers was assessed using the FAI.[33,52] Although initially validated to assess the activities of acute stoke patients, this assessment instrument is applicable to caregivers of patients with disabling stroke.[19] FAI scores are from 0 (inactive) to 45 (highly active).

Caregiver time logs and training records

Multidisciplinary team staff in the control centres were requested to complete caregiver time logs (see *Appendix 1*) for two periods of 3 months during recruitment. These logs recorded the time that all MDT staff spent with patients' caregivers. MDT staff in the intervention centres were requested to complete training records (see *Appendix 1*) throughout the trial as a part of the LSCTC intervention. The training records logged the time that all MDT staff spent delivering the LSCTC with patient's caregivers. The control and intervention logs of MDT time were used to assess the costs associated with delivering the LSCTC. The training records were also used to monitor compliance with the LSCTC in each intervention centre. Caregiver time logs and training records were completed on all eligible patients' caregivers; the logs for caregivers who did not consent to trial procedures were returned to the trial team without any identification on them.

Further data on the costs of implementing the LSCTC were collected by logging the time taken for all MDT staff to attend the training days and for all MDT staff to cascade/receive cascaded training on the SRUs.

Baseline and follow-up data

Baseline patient information collected included demographic details (age, sex, ethnicity, living circumstances, relationship of patient to the caregiver, education and employment), pre-stroke Barthel Index, modified Rankin Scale, classification of stroke, language ability, Six-item Cognitive Impairment Test (6CIT)[59] and the Edinburgh stroke case-mix factors.[60] Caregiver information collected included demographic details (age, sex, ethnicity, education and employment) and modified Rankin Scale. The baseline patient questionnaire included pre-stroke NEADL scale, HADS, EQ-5D, Barthel Index, SIS[46–48,50,51] and CSRI. The caregiver questionnaire included FAI, HADS, EQ-5D and the CSRI (details below).

The 6- and 12-month questionnaires for the patients collected the same measurements as the baseline questionnaire. At 12 months an additional question was included to ask if the patient had been aware of receiving different treatment because of this research. The 6- and 12-month questionnaires for the caregivers collected the same measurements as the baseline questionnaire, and also included the CBS and questions relating to caregiver preparation to care for their relative/friend at the time of their discharge from hospital

(6 months only); if the caregiver was still caring for the patient; caregiver's stroke knowledge;[61,62] and if the caregiver had been aware of receiving/being denied an enhanced training package (at 12 months only).

Researchers at each site collected patient and caregiver hospital readmissions and deaths using the local health records.

Procedures for data collection

Baseline questionnaires were completed by the patient and caregiver after consent, but prior to registration. Where patients were unable to complete the baseline questionnaire owing to stroke-related disabilities, a friend/relative could complete the questionnaire using the patient's verbal responses. Where the patient could not understand the questions and/or communicate responses, a friend/relative could complete the questionnaire on their behalf. Details of proxy completion were collected and comparisons between the two arms of the study were undertaken. MDT staff and the researchers were not permitted to help with questionnaire completion. Data were collected by the researcher after consent but prior to registration from both the patient and the caregiver. Discharge details and the occurrence of any expected adverse events (AEs) or serious AEs (SAEs) were collected at the point of discharge.

Patients and caregivers were followed-up by postal questionnaires at 6 and 12 months post registration administered by CTRU. CTRU staff were blinded to the allocation of the SRUs.

Postal reminders were used if the questionnaires were not returned within 2 weeks, followed by a telephone reminder 2 weeks later if the questionnaire had still not been received. If the questionnaire was still outstanding, then, where possible, a telephone interview was conducted to obtain the primary outcomes. General practitioner (GP) checks confirmed that the patient and caregiver were alive prior to contact. If the patient had died, then no further follow-up was undertaken. If the caregiver had died, then patient follow-up was still undertaken.

The cut-off point for questionnaires to be considered for primary end point at 6 months was set at 10 months since registration: follow-up for patients and caregivers started at 6 months post registration.

Intervention compliance

The training records were used to evaluate each intervention centres compliance with the intervention. A definition of compliance was agreed by the LSCTC development team independent of the research team. Following consideration of what was felt to be a minimal acceptable level of training input for each caregiver and recognising that heterogeneity of the patient and caregiver dyads. Compliance was defined as follows:

It was indicated on the training record that training on all six mandatory components was delivered and competency achieved by the caregiver, and/or the training record was signed off by a member of the MDT, indicating that all necessary training had been delivered and competency achieved.

Sample size

The original target recruitment was 900 patient and caregiver dyads, 25 dyads from 36 SRUs. The sample size calculations assumed that a clinically relevant difference was six points [as defined in the Trial of Occupational Therapy And Leisure (TOTAL) study[54,63]] in the patient primary outcome measure (NEADL). A range of three to nine points was taken to be a clinically relevant difference in previous studies. We have defined six points as a difference of clinical relevance to the patient and caregiver (patient requiring less help in at least two activities) and also substantive enough to influence commissioners to change service delivery. Thirty-six stroke rehabilitation units, each recruiting 25 patients, would result in 450 patients in each group and provide close to 90% power at 5% significance level to detect a clinically relevant difference of six points on the NEADL scale [scored 0–66, standard deviation (SD) 18]. The sample size incorporates an inflation factor of 1.9 owing to clustering [cluster size of 19 after loss to follow-up; intracluster correlation coefficient (ICC) no greater than 0.05[64]] and 25% loss to follow-up. The assumption that the ICC would be no larger than 0.05 was based on methodological research[65] showing that ICCs for patient outcomes in

the community are generally <0.05. A sample size of 900 patients provided more than 85% power at the 5% significance level to detect an effect size of one-third in any of the other outcomes. Such an effect size is usually considered moderate. So, for instance, this ensured more than 85% power to detect a difference of 4.3 points on the CBS at 6 months, assuming the same variability as in the single-centre study[19] (i.e. SD of 12.9 at 6 months).

Revised sample size

The power of the trial was, however, adversely affected by a slightly higher than expected loss to follow-up and unequal cluster sizes. By estimating maximum and minimum cluster sizes[66] the predicted imbalance decreased the power by 1–3%. To preserve final power of close to 90%, the trial target was increased to between 950 and 1000 patient and caregiver dyads, with a maximum of 35 dyads from each of the 36 SRUs to compensate for low recruitment at some centres.

Analysis methods

All data analyses were conducted to a prespecified analysis plan. All data analyses were performed using SAS version 9.2 (SAS Institute Inc., Cary, NC, USA). All hypothesis testing was performed at the 5% two-sided significance level. Analysis of health economic data was performed using SPSS (SPSS Inc., Chicago, IL, USA).

Populations

The ITT population was defined as all patients registered for active follow-up regardless of non-compliance with the intervention. All patients (and the corresponding caregivers) within a stroke unit were analysed according to the intervention that stroke unit was randomised to. All analyses and data summaries were carried out using the ITT population. Patients whose written informed consent had not been received were not included in this population. The analysis population included all patients returning 6-month questionnaires.

Baseline characteristics

The baseline characteristics of the ITT population were tabulated using frequencies and summary statistics for each treatment group. Two-sample *t*-tests to compare percentages and means, weighted by the number of patients in treatment and control centres, were used to detect potential bias in recruitment.

Primary analysis

For all analyses, means and 95% confidence intervals (CIs) together with values of unadjusted and adjusted ICCs are reported. Summaries from raw and predicted data from the final model are provided.

Patients

The primary analysis was based on a complete case analysis, with no substitution for missing outcome data. The ITT analysis included all patients with a valid 6-month NEADL score. The 6-month NEADL score was compared between the intervention and control groups using two-level multilevel modelling, with patients and SRUs being the level one and level two units, respectively. The model was adjusted for:

- *The following patient-level covariates (level 1)* Patient baseline NEADL score, sex, caregiver's education (age caregiver left education: ≤ 16 years, >16 years) and caregiver baseline HADS score, the Edinburgh stroke case-mix adjuster (which includes age; whether or not patient lived alone before the stroke; whether or not the patient was independent in everyday activities before stroke; whether or not the patient can talk or he/she orientated in time, place and person; whether or not the patient can lift both arms; whether or not the patient can walk without help from another person), *and*
- *The following stroke unit-level covariates (level 2)* The key 12-indicator score, geographical region and number of beds in each centre.

A number of sensitivity analyses were used to examine the robustness of the conclusions of the primary analysis. First, the analysis was undertaken including patients who died and assumed a NEADL score of 0 (worst possible outcome). Second, an analysis without proxy responses was performed to assess the impact of proxy responses. Third, the time of completion of 6-month questionnaires was compared between both arms using a *t*-test and, if significant, a sensitivity analysis would be undertaken to determine if the results were influenced by patients responding late in the follow-up period.

Caregivers

The primary analysis of caregiver outcomes was based on a complete case analysis with no substitution for missing data. The ITT analysis included all caregivers with a valid 6-month CBS score. The 6-month CBS was compared between the intervention and control groups using two-level multilevel modelling, with patients and SRUs being the level 1 and level 2 units, respectively. The model was adjusted for:

- The following caregiver-level covariates (level 1): caregiver baseline HADS anxiety and depression scores, age, sex, caregiver's education (age caregiver left education: ≤16 years, >16 years).
- The following stroke unit-level covariates (level 2): the key 12 indicator score, geographical region, and number of beds in each centre. [In the analysis, the age that the caregiver left education is used as a binary covariate '≤16 years' and '>16 years'. Unknown and missing categories were investigated and based on caregiver baseline data compared with the general characteristics; these were imputed accordingly (in all instances they fell into the category 'Age caregiver left education "≤16 years"').]

The sensitivity analysis relating to time of questionnaire completion was repeated for caregivers.

Secondary analyses

All analyses of secondary end points were conducted on the ITT population. Means, 95% CIs and values of unadjusted and adjusted ICCs are reported. Summaries from raw and predicted data from the final model are provided.

Two-level random intercept models were used, with patients being level one and stroke units being level two. Fixed parts were patient-level covariates (level one), stroke unit-level covariates (level two) and treatment. Data were assumed missing at random.

Patient end points at 6 months

The 6-month HADS scores, EQ-5D score, Barthel Index and SIS were summarised by treatment group. For SIS, the score was summarised for each domain separately and included the four physical domains as one (strength, hand function, mobility and ADL/instrumental ADL).

The 6-month HADS scores, EQ-5D score, Barthel Index and SIS were compared between the intervention and control groups using two-level multilevel modelling, with patients and stroke rehabilitation units being the level 1 and level 2 units, respectively. The model was adjusted for the same variables as in the primary patient end point apart from the baseline NEADL score. The baseline HADS scores, EQ-5D score, Barthel Index and SIS were used when comparing the 6-month HADS scores, EQ-5D score, Barthel index and SIS, respectively, between the two groups.

Patient end points at 12 months

The 12-month NEADL score, HADS scores, EQ-5D score, Barthel Index and SIS were summarised by treatment group.

The 12-month NEADL score, HADS scores, EQ-5D score, Barthel Index and SIS were compared between the intervention and control groups using the same process as for end points at 6 months.

Caregiver end points at 6 months

The 6-month FAI, HADS and EQ-5D scores were summarised by treatment group.

The 6-month FAI, HADS and EQ-5D scores were compared between the intervention and control groups using two-level multilevel modelling, with patients and stroke rehabilitation units being the level 1 and level 2 units, respectively. The model for HADS scores was adjusted for the same variables as in the primary caregiver end point. The rest was adjusted for the same variables as in the primary caregiver end point apart from the baseline HADS scores. The baseline FAI and EQ-5D score was when comparing the 6-month FAI and EQ-5D score, respectively, between the two groups.

Caregiver end points at 12 months

The 12-month CBS, FAI, HADS and EQ-5D scores were summarised by treatment group.

The 12-month CBS, FAI, HADS and EQ-5D scores were compared between the intervention and control groups using the same process as for caregivers at 6 months.

Process data

Data in intervention and control sites collected before trial commenced and during trial were summarised by the trial manager to ascertain whether or not care has changed over the course of the trial. During the trial, the number of training records received from the SRUs was summarised. The data from the training records were summarised for all intervention patients in terms of the number of mandatory and non-mandatory components delivered and the number of these where the caregiver achieved competence.

The proportion of training records compliant with the intervention by the SRU was summarised. The number of caregivers achieving competence for each component was also summarised.

The relationship between patient and caregiver outcome and compliance with intervention was explored. Number of mandatory components achieved as per training records completion was summarised.

Safety

Falls – the number of patient falls between registration and discharge were summarised by arm and centre. The number of falls that resulted in a SAE was presented by arm as well as the mean number of falls (of those patients who fell).

The percentage of patients and caregivers who died from any cause between registration and 12-month follow-up were summarised by arm and centre and the cause of death was presented. No statistical comparison between the intervention and control groups was undertaken. The number of patients' and caregivers' admissions or readmissions (self-reported and researcher completed) to a hospital, nursing home or residential care home, was summarised at the 6- and 12-month follow-ups by arm. No statistical comparison between the intervention and control groups was undertaken. Related and unexpected serious adverse events (RUSAEs) were listed and detailed, up to, and including, the 12-month follow-up.

Economic evaluation

The purpose of the economic evaluation was to examine the cost-effectiveness and cost–utility of the LSCTC. There were two parallel economic evaluations: one for patients and another for caregivers. The primary economic evaluation was cost-effectiveness analyses based on the patient and caregiver primary outcome measures (NEADL and CBS, respectively). The secondary economic evaluation was cost–utility analyses based on QALYs.

Perspective

The patient and caregiver evaluations were each undertaken from (a) a health and social care cost perspective and (b) a societal cost perspective. Health and social care costs included nursing/residential care; hospital inpatient, outpatient, day hospital and accident and emergency services; and primary care/community-based health/social care services. Societal costs included all of these categories plus informal care costs.

Time horizon

In keeping with the outcomes analyses, the cost-effectiveness and cost–utility analyses were primarily focused on findings at 6 months. We further examined costs and outcomes at 12 months and over one year to enable a more direct comparison of findings with the single-centre study on which this one was based.[19,29] One-year costs were estimated as the sum of costs from the 6- and 12-month assessments and 1-year QALYs were the sum of QALYs at 6 and 12 months. The time horizon was limited to 1 year because we focused on within-trial costs only.

Resource-use data

Data on the use of health and social care and informal care were collected at the individual-level using a CSRI[29] that was specifically adapted for use with stroke patients. A reduced version of this instrument was used with caregivers, containing questions about their use of core health and social care services and informal care that they provided. For both patients and caregivers, the CSRI was administered as a face-to-face interview at the baseline assessment (with reference to the previous 3 months) and then as a self-complete postal questionnaire alongside other measures at 6 and 12 months (with reference to the time since previous assessment).

Costs

Individual-level resource-use quantities were combined with unit costs to calculate a cost per participant. Unit cost estimates, their sources and any assumptions made for their estimation are in *Appendix 5* and are summarised in *Table 2*. National unit costs were used where possible to represent the geographical spread of the sites and to facilitate the generalisability of results.

TABLE 2 Summary of unit costs

Category	Unit	Unit cost (£, 2009–10)
Residential care home stay	Night	74
Nursing home stay	Night	73
Inpatient services: stroke, acute	Bed-day	294
Inpatient services: stroke, acute	Stay	2808
Inpatient services: stroke, rehabilitation	Bed-day	361
Inpatient services: other	Bed-day	Range 110–1229
Inpatient services: other	Stay	Range 110–3877
Day hospital/day-case services	Activity	Range 368–1149
Outpatient services and procedures	Visit	Range 5–785
Primary care/community-based services	Contact	Range 6–129
Primary care/community-based services	Hour	Range 23–158
Primary care/community-based services	Item	Range 3–6
Value of caregiver time: average wage	Hour	15
Value of caregiver time: home care worker	Hour	28

Costs of the initial stroke admission were estimated by multiplying length of stay by the unit cost for a non-elective long-stay unit cost from the 2009–10 NHS reference costs[67] (£294). If either the admission or discharge date was missing, then an average admission cost for the same service was applied (£2808).

Costs of other hospital admissions were estimated similarly by mapping participant-reported specialty or reason for the admission to Healthcare Resource Groups (HRGs) and then applying weighted average non-elective, long-stay bed-day or admission costs for each of those HRGs. Where participants did not state a specialty, the reason for the admission was used to infer specialty. Alternative assumptions were necessary for a few specialties that did not readily fit into a HRG (see *Appendix 5*).

Where multiple specialties were reported for one admission, an average weighted unit cost across all relevant specialties was used. For admissions with no information on specialty or reason, an average cost of all HRGs was applied. Outpatient costs were estimated using the same approach.

The patient CSRI included a question asking respondents to report use of any other services not covered by the previous questions. Many responses to this question were for services already itemised in the instrument. We report these total 'other' costs separately rather than amalgamate them into the specific resource categories.

Informal care represents an important input to the health of people with stroke. We estimated the monetary value of such inputs using the opportunity cost approach,[68] which involves valuing caregivers' time according to the opportunities they have forgone owing to time spent care giving. Often the opportunity forgone is paid employment and so the monetary value attached to this could be wages forgone. For care provided by the main caregiver enrolled in the trial, we distinguished opportunity costs as either lost employment or lost leisure on the basis of their employment status at each assessment. Where it was assumed that the caregiver could otherwise have been working (those working part-time and those unemployed and seeking work), we applied the national average wage. Where it was assumed that the caregiver was unlikely to instead be working (those working full-time, at home not seeking work, retired, redundant/early retired, unable to work and students), we applied an estimate of the cost of leisure time. For anyone whose employment status was 'other' or missing (and for other caregivers), we applied the average of the two unit costs. We assumed that if the main caregiver lived with the patient, all reported live-in informal care inputs were by that caregiver and that all live-out inputs were provided by others. Conversely, if the main caregiver did not live with the patient, we assumed that all live-out informal care inputs were provided by that person and that all live-in inputs were provided by others.

The cost of the LSCTC was incorporated into the evaluation. We included only the costs of its development and staff training, not the cost of delivery to caregivers, as the latter is inherently included in the unit cost applied to the stroke admission given that it was part of routine practice in the intervention arm stroke units. Developing and delivering the staff training to ensure that ward staff were competent in delivering the LSCTC to caregivers was a multistage process consisting of the following key resource components:

The project team:

- developing the staff training package
- preparing and delivering four core training days
- preparing and delivering one refresher training day
- delivering local refresher training sessions at all intervention sites.

Ward staff:

- attending the core training days
- attending the refresher training day
- receiving local refresher training

- delivering cascading training session to other ward staff
- attending cascaded training session.

There were three elements of data collection to measure the resources associated with each of these components. First, resources associated with all main training events were recorded by the staff associated with delivering those events. Second, ward staff attending these events and then cascading that training to other staff on their ward recorded the time, profession and salary band for all of the staff involved with delivering and receiving that cascaded training. Third, ward staff providing training inputs to caregivers recorded those time inputs on a training record. Resulting cost estimates are summarised in *Table 3*, with further details of each component described in *Appendix 6*.

We transformed the total cost of the development and staff training into an average cost per minute of input to caregivers to enable the cost of LSCTC to vary at the individual level according to inputs provided, rather than be a fixed cost across all participants. We calculated this as follows. First, we multiplied the average amount of time spent with each caregiver in the trial intervention arm (136 minutes) by the total number of eligible patients identified during the screening/recruitment process ($n = 1256$) to estimate the total caregiver input time that the LSCTC development and staff training potentially 'purchased' (170,816 minutes/2846 hours). We then divided the total training cost (£102,577 including development costs) by this total input time to estimate the training cost per minute of caregiver input provided (£0.60). This cost per minute was applied to each intervention arm participant according to the amount of time input provided by ward staff to the caregiver.

Total costs were computed for each patient and caregiver at each assessment point (baseline, 6 months, 12 months and 1 year), from both perspectives. It was not necessary to discount costs or outcomes because the evaluation covered only 1 year. All unit costs were standardised at 2009–10 levels, where relevant.

Outcome measures for the economic evaluation

Patients:

- NEADL score at 6 months (primary patient outcome measure) and 12 months
- QALYs between baseline and 6 months, between 6 months and 12 months and over 1 year.

TABLE 3 The London Stroke Carers Training Course unit cost: summary of all staff training components

Staff training component	Costs (£, 2009–10 prices)
1. Core training and refresher training: development	7680
2. Core training: preparation	3554
3. Refresher training: preparation	753
4. Core training: delivery	23,317
5. Refresher training: delivery	5603
6. Local refresher visits: delivery	16,593
7. Ward staff time	45,077
Total including development costs	**102,577**
Total excluding development costs	**94,897**
Cost per minute of input to caregivers, including development costs	**0.60**
Cost per minute of input to caregivers, excluding development costs	**0.56**

Caregivers:

- CBS at 6 months (primary caregiver outcome measure) and 12 months
- QALYs between baseline and 6 months, between 6 months and 12 months and after 1 year.

The concept of utility refers to the value of a particular level of health status (or improvement on level of health status) and can be measured by the preferences of individuals or society for any set of health outcomes. The most common value-based measure of health outcomes used in cost–utility analysis is the QALY.[69] The quality adjustment is based on a set of utilities, one for each possible predefined health state. QALYs are calculated by multiplying the preference value for a particular health state by the time spent in it. For example, if a health state associated with receiving a particular intervention is valued at 0.6, 2 years in that health state equates to 1.2 QALYs. Results of cost–utility analyses are usually expressed in terms of additional cost per additional QALY gained by undertaking one intervention instead of another. In this study, health states were measured using the EQ-5D[31] at baseline, 6 months and 12 months. Utility weights from a UK general population survey[70] were attached to health states at each time point, with appropriate adjustments for the period of time involved. Utility weights and QALY gains were not estimated for those who died (or were lost to follow-up), as such cases were not included in the primary analysis and would anyway have missing resource-use/cost data. QALYs were then estimated using linear interpolation to calculate the area under the QALY curve as follows:

$$\text{6-month QALYs} = [(\text{baseline utility} + \text{6-month utility}) / 2] \times 0.5 \text{ years} \quad (1)$$

$$\text{12-month QALYs} = [(\text{6-month utility} + \text{12-month utility}) / 2] \times 0.5 \text{ years} \quad (2)$$

$$\begin{aligned}\text{1-year QALYs} = {} & [(\text{baseline utility} + \text{6-month utility}) / 2] \times 0.5 \text{ years} \\ & + [(\text{6-month utility} + \text{12-month utility}) / 2] \times 0.5 \text{ years}\end{aligned} \quad (3)$$

Cost-effectiveness and cost–utility analyses

Cost-effectiveness/cost–utility analysis is concerned with linking costs with outcomes and comparisons between two or more alternatives.

The primary economic evaluation at 6 months, the cost-effectiveness analyses, involved examining the following four cost–outcome combinations between the two randomisation groups.

Patients:

- the additional cost per additional point improvement on the NEADL scale from the health and social care perspective
- the additional cost per additional point improvement on the NEADL scale from the societal perspective.

Caregivers:

- the additional cost per additional point improvement on the CBS from the health and social care perspective
- the additional cost per additional point improvement on the CBS from the societal perspective.

The secondary economic evaluation at 6 months, the cost–utility analyses, involved the following four further cost–outcome combinations:

Patients:

- the additional cost per additional QALY from the health and social care perspective
- the additional cost per additional QALY from the societal perspective.

Caregivers:

- the additional cost per additional QALY from the health and social care perspective
- the additional cost per additional QALY from the societal perspective.

Further considering cost-effectiveness and cost–utility over 1 year involved examining these cost–outcome combinations once more. There were thus a total of 16 cost–outcome combinations to consider.

Cost-outcome comparisons between the intervention and control groups can produce one of four outcomes:

- If costs are lower and outcomes are higher for one group, then it is considered to 'dominate' the other and is clearly more cost-effective.
- If outcomes are similar between groups, then the one with lower costs can be regarded as more cost-effective (or if costs are similar between groups then the one with better outcomes is regarded as more cost-effective).
- If both costs and outcomes are lower for one group, then there are value judgements involved in trading off outcomes for cost savings.
- If both costs and outcomes are higher for one group, then it falls on relevant decision-makers to decide whether or not the additional benefits are worth paying for. In this scenario, results of a cost-effectiveness/cost–utility analysis are generally expressed as incremental cost-effectiveness ratios (ICERs), which represent the additional cost associated with one additional unit of the outcome for one person; these are calculated by dividing the mean difference in cost by the mean difference in outcome.

Each of these scenarios can be represented on a cost-effectiveness plane (*Figure 2*), in which the vertical axis represents the additional costs of one intervention against another, and the horizontal axis represents the additional outcomes. The location of a co-ordinate representing incremental cost and incremental outcome indicates which of the four scenarios the cost-effectiveness finding falls into.

We constructed cost-effectiveness planes using non-parametric bootstrapped regressions (5000 replications, with replacement) of study group upon 6-month health and social care costs, patient and caregiver QALYs, total NEADL score and total CBS score, in turn, with cluster adjustment for centre and baseline values of the dependent variable (except in the case of CBS), age and sex included as covariates. The resulting coefficients of group differences were saved and plotted using scatter graphs (Stata version 10.1, StataCorp LP, College Station, TX, USA) in relevant cost–outcome combinations.

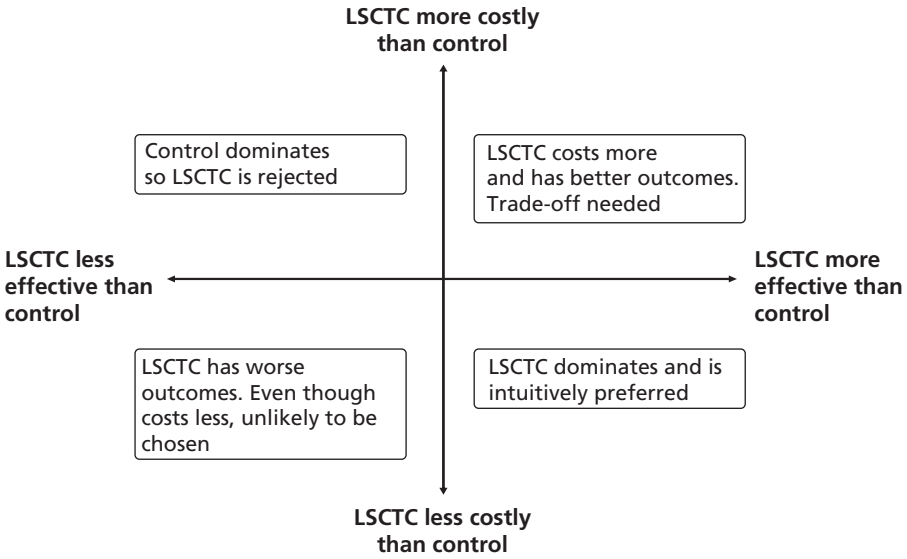

FIGURE 2 Cost-effectiveness plane.

We calculated ICERs for any cost–outcome combinations where the intervention group had higher costs and better outcomes (the top-right quadrant of the cost-effectiveness plane). Although ICERs have been one of the most common ways of presenting the results of cost-effectiveness analyses, they carry two important limitations. First, they are point estimates that do not provide information about the uncertainty surrounding the estimates, a problem that is compounded with the complexity of examining CIs around ICERs. Second, their use to decision-makers is limited as they provide no information about what an 'acceptable' level of cost-effectiveness would be, or whether or not the likelihood of cost-effectiveness would differ according to how much decision-makers would be willing to invest. Both of these limitations can be addressed by cost-effectiveness acceptability curves (CEACs) based on the net benefit approach.[71] We use CEACs alongside cost-effectiveness planes to examine any uncertainty surrounding the cost-effectiveness and cost–utility results.

Net benefits provide a single summary monetary measure of costs and outcomes for each individual (removing the need to examine ratios) and account for the value (λ) that a decision-maker would be willing to pay for a greater net benefit. They are calculated as follows:

$$\text{Net benefit} = (\lambda \times \text{outcome}) - \text{cost} \quad (4)$$

For each cost–outcome combination, a series of net benefits were calculated for a range of relevant λ values. For the QALY-based analyses, these values ranged from £0 to £50,000 (£10,000 increments), to incorporate the £20,000–30,000 per QALY gain threshold range currently specified for National Institute for Health and Care Excellence (NICE) decision-making in England and Wales.[72] For the NEADL- and CBS-based analyses, the 'acceptable threshold' is unclear so we examined a range that incorporated NEADL- and CBS-related ICER values at 6 months, £0–2000 (£500 increments). Net benefits were then compared at the level of randomisation group using non-parametric bootstrapped regressions (5000 replications, with replacement) of study group upon net benefit, with a cluster adjustment for centre and baseline values of costs from the relevant perspective, age and sex, baseline utility for QALY-based CEACs and baseline NEADL score for NEADL-based CEACs included as covariates. For each value of λ, the proportion of iterations indicating a higher net benefit for the LSCTC group were calculated and plotted. These plots formed the CEACs, which represent the probability of the LSCTC group being cost-effective compared with the control for a range of values that a decision-maker would be willing to pay for an additional unit of the NEADL score, CBS score and QALYs.

Statistical analyses

All cost and QALY data are reported as mean values with SDs. To accommodate a cluster randomisation design, differences in costs between groups were tested by multilevel modelling using the xtreg procedure in Stata 10.1, from which we report 95% CIs and *p*-values for the differences in means. Baseline values of the dependent variable, age and sex (plus baseline NEADL score for patients) were included as covariates. Individuals were analysed according to the group to which they were randomised. As described above, net benefit comparisons for the purpose of CEAC constructions were undertaken using non-parametric bootstrapped regressions (5000 replications, with replacement), controlling for site clusters.

Missing data

The base-case economic evaluation was based on available cases (i.e. it did not impute missing data due to loss of follow-up) under the assumption that loss of follow-up was missing at random. However, we report CSRI and EQ-5D completion rates and describe baseline characteristics of those with and without these data at the primary end point – 6 months.

Resource-use data from the CSRI formed the basis of the total cost calculations for each participant. Self-complete applications of such complex instruments inevitably include missing items on returned questionnaires and to allow the computation of total costs that reflect variations in resource use rather than variations in data completeness, we imputed missing cost items on returned CSRIs as follows. If there was no report of use of a particular resource, we assumed that it was not used and thus imputed a zero cost.

If a participant reported using a resource but not the quantity used, we imputed the cost of that resource use based on the mean cost for participants with data for that item at the same assessment point and in the same randomisation group (this was done separately for patients and caregivers). All such imputations were made to the cost data, rather than the resource-use data. Therefore, resource-use data are based on data availability for each item with no imputation for missing values.

Missing data transformations (or lack of) for the NEADL scale and CBS were as for the main outcomes analyses. Missing EQ-5D data were not imputed.

Sensitivity analyses

We altered some key assumptions made in the economic evaluation to explore their consequences for the results at the primary end point – 6 months.

Our first sensitivity analysis concerned the LSCTC development and staff training costs. Training record return rates were low so there were a significant number of intervention arm participants with missing data on ward staff time inputs to caregivers. As we estimated individual-level LSCTC development and staff training costs on the basis of time spent with caregivers, we were unable to allocate any LSCTC costs to many participants. For analysis purposes, such individuals were allocated a zero LSCTC cost. This may obviously have led us to underestimate the contribution of LSCTC costs to total care costs. We therefore examined the effect on patient and caregiver total health and social care costs at the primary end point, 6 months, of imputing LSCTC costs for intervention group participants with missing training records. Imputation values were based on the mean LSCTC cost for those with training record data (£81.90).

In the base-case analyses, we estimated informal care costs using the opportunity cost approach. However, there are controversies in valuing informal care,[73] and it is important to explore alternative approaches given the notable size of informal care costs in this group. Therefore, our second sensitivity analysis examined the effect of adopting a replacement cost approach to informal care, i.e. the cost of replacing informal care inputs with paid professionals. We applied the cost of a local authority home care worker and examined the effect on patient and caregiver total societal costs at the primary end point – 6 months.

Our final two sensitivity analyses examined the effect of loss of follow-up by imputing missing patient and caregiver health and social care costs and QALYs at the primary end point, 6 months. We used the multiple imputation procedure in Stata 10.1. Cost imputations were based on key variables expected to predict follow-up costs: randomisation group, sex, baseline age and baseline total health and social care costs. Predictor variables for QALY imputations were the same except that they included baseline utility score rather than cost.

For each of these four sensitivity analyses, we report the same statistics around means and mean differences (and the same covariates for comparisons of means) as for the base-case analyses, and we also examine the impact of the alternative scenarios on CEACs.

Definition of end of trial

The end of the trial was defined as the date that the last 12-month postal questionnaire was completed.

Adverse events and safety monitoring

Events such as patient falls and caregiver musculoskeletal injury represent an inherent consequence of an active rehabilitation process and, therefore, cannot be entirely avoided. Similarly, in this patient population, acute illness resulting in hospitalisation, new medical problems and deterioration of existing medical problems were expected. In recognition of this, events fulfilling the definition of an AE or an

expected SAE were not reported in this study, with the following exceptions: patient falls with or without fracture that occurred at any time between the date of consent and date of discharge; patient and/or caregiver death (SAE); patient and/or caregiver hospital admissions and readmissions for any reason (SAE); patient and/or caregiver institutionalisation (AE); and patient and/or caregiver treatment on an emergency outpatient basis (AE). Summaries of the above expected AEs and SAEs by treatment arm were reported quarterly to the Data Monitoring and Ethics Committee (DMEC).

Data monitoring

Data were monitored for quality and completeness by the CTRU, using established verification, validation and checking processes. Missing data (except patient and caregiver completed data items collected via the baseline and postal questionnaires) were chased until received, confirmed as not available, or the trial was at analysis.

Data Monitoring and Ethics Committee

An independent DMEC was established to review the safety and ethics of the trial. Detailed unblinded reports were prepared for the DMEC during set-up and annually during the recruitment and intervention periods. SAEs were summarised by treatment group in a quarterly report sent to the DMEC, to enable monitoring of safety rates between control and intervention sites.

Trial Steering Committee

A TSC was established to provide overall supervision of the trial, in particular trial progress, adherence to protocol, patient safety and consideration of new information. The committee met once during the set-up period and 6-monthly thereafter for the duration of the trial.

Trial Management Group

The TMG consisted of the report authors, who met monthly during study set-up and recruitment. The TMG monitored rates of recruitment and refusals at sites and between study arms, LSCTC compliance in the intervention centres, data quality and compliance, protocol adherence, and potential changes to the process of care at centres.

Ethical approval

The study protocol was approved by Leeds Research Ethics Committee (REC), reference 07/Q1205/12. Local REC approval and research and development (R&D) approval was obtained at each NHS trust prior to cluster randomisation.

Amendments to the study protocol following commencement of recruitment

Sample size

Originally the recruitment target was 900 patients, 25 dyads from each of the 36 participating SRUs. However, as described in the sample size section above, the power of the trial was adversely affected by a higher than expected loss to follow-up (expected to be closer to 30% than the predicted 25%) and unequal cluster sizes. By estimating maximum and minimum cluster sizes[74] the predicted imbalance decreased the power by 1–3%. To preserve final power of close to 90%, the trial target was increased to between 950 and 1000 patient and caregiver dyads. The maximum number of dyads that could be recruited from each SRU was raised to 35 to compensate for some low-recruiting centres. In one SRU, the upper limit was increased to 38 to compensate for a very low questionnaire response rate at this centre.

Inclusion criteria

Deletion of the words 'competent to undergo training' from the definition of a caregiver, as caregivers in the control arm will not undergo structured training.

Informed consent

The statement 'patients and caregivers will be given at least 24 hours to consider participation' has been replaced with 'patients and caregivers will be given sufficient time to consider participation'.

In accordance with The Mental Capacity Act 2005,[40] the term 'caregiver assent' has been replaced throughout the protocol with the preferred recommended term 'caregiver declaration'.

Data collection

Addition of residential/nursing home option to the living circumstances of patients collected on the screening log.

An additional question has been inserted into the 12-month follow-up questionnaire asking if the patient was aware of receiving/being denied better treatment because of this research.

The question asking if the caregiver was aware of receiving/being denied an enhanced training package will be collected only at 12-month (not 6-month) follow-up.

Typo: Deletion of the modified Rankin Score from the data being collected on the screening log.

Typo: The ITT statement has been amended to clarify that all patients and caregivers who are registered into the study will be considered as part of the ITT population and efforts will be made to follow them up when appropriate.

References for the stroke knowledge question have been added.[36,37]

Literature review search strategy

Literature searches were completed using the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EBSCO, The Cochrane Library (Wiley Online Library), EMBASE (OVID), MEDLINE (OVID), and PsycINFO (OVID), from January 1999 to November 2011. The International Standard Randomised Controlled Trial Number (ISRCTN) registry was also searched manually. *Appendix 7* provides the full search strategy used.

Chapter 4 Results

Recruitment and randomisation of stroke rehabilitation units

Cluster-level recruitment

Forty-nine SRUs expressed an interest in TRACS, and 41 SRUs completed feasibility questionnaires and were assessed for eligibility. Of these 41 SRUs, two did not meet the centre eligibility criteria and three satisfied the centre eligibility criteria, but did not complete ethics/R&D approval processes in time to be entered for randomisation.

The 36 SRUs were randomised equally between control and intervention, stratified by geographical region and NSSA score. After randomisation, the characteristics of the SRUs were found to be balanced between random allocations (*Table 4*). Once randomised, all 36 SRUs participated throughout the course of the trial period (see *Figures 5* and *6*).

Participant flow and recruitment

Screening for trial participation

Patient and caregiver dyads were identified and recruited between February 2008 and February 2010. Overall, 14,370 patients went through the screening process, 7067 in intervention and 7303 in control sites, and 12,510 patients were assessed for eligibility, 6205 in intervention and 6305 in control sites. Of these, 2675 (21.4%) were deemed eligible and 1024 consented (8.2% of assessed, 38.3% of eligible), 490 in intervention and 479 in control sites (see *Figure 3* and *Table 5*). Reasons for non-registration of patients are summarised in *Figure 3*. The number of assessed patients varied between SRUs from 149 to 831 patients (*Table 6*).

In total, 930 (7.4% of assessed, 34.8% of eligible) patients were registered into the trial (see *Table 5*). The number of patient and caregiver dyads recruited per SRU ranged from 13 to 38 per centre. The proportion of recruited dyads out of assessed ranged from 3.6% to 18.6% per SRU.

Characteristics of screened participants

Table 7 summarises the characteristics of screened patients. The groups were well balanced with respect to baseline characteristics.

The mean age of screened patients was 74.4 (SD 13.39) years and the average length of hospital stay was 27.9 (SD 33.07) days. In total, there were 5967 (47.7%) males; the majority of patients were white (11,628, 92.9%); 4922 (39.3%) patients lived alone; 6227 (49.8%) patients co-habited and 691 (5.5%) were nursing or residential care home residents.

The caregiver resided with 5015 (40.1%) patients. In most cases, the caregiver was the patient's family member: partner in 5047 (40.3%) and offspring in 3587 (28.7%) cases.

Sample size

In total, 930 patients and their caregivers were registered between February 2008 and February 2010 (*Figure 4*). The number of patient and caregiver dyads recruited per SRU ranged from 13 to 38 per centre. Although, this is above the original target sample size and below the revised sample size of 950 patients and caregivers, it still provides us with over 80% power to detect a clinically relevant difference of six points on the NEADL scale.

TABLE 4 Characteristics of randomised centres

Centre	Intervention (*n* = 18)	Control (*n* = 18)
Geographical region,* n *(%)		
North West	6 (33.3)	6 (33.3)
London and the South East	4 (22.2)	4 (22.2)
South West Peninsula	3 (16.7)	3 (16.7)
Yorkshire	5 (27.8)	5 (27.8)
NSSA 2006 score		
Mean (SD)	67.8 (13.09)	68.5 (13.55)
Median	68.0	68.5
No. of beds		
Mean (SD)	18.6 (7.40)	18.5 (7.68)

TABLE 5 Screened patients

Admitted, *n*	Assessed/screened, *n* (%)[a]	Eligible, *n* (%)	Consented, *n* (%)	%[b]	Registered, *n* (%)
Intervention					
7067	6205 (87.8)	1256 (20.2)	490 (7.9)	39.0	451 (7.3)
Control					
7303	6305 (86.3)	1419 (22.5)	534 (8.5)	37.6	479 (7.6)
Total					
14,370	**12,510 (87.1)**	**2675 (21.4)**	**1024 (8.2)**	**38.3**	**930 (7.4)**

a For assessed patients, percentages are calculated from 'admitted' patients.
b Percentages are calculated from 'eligible' patients.
Percentages are calculated from 'assessed' patients.

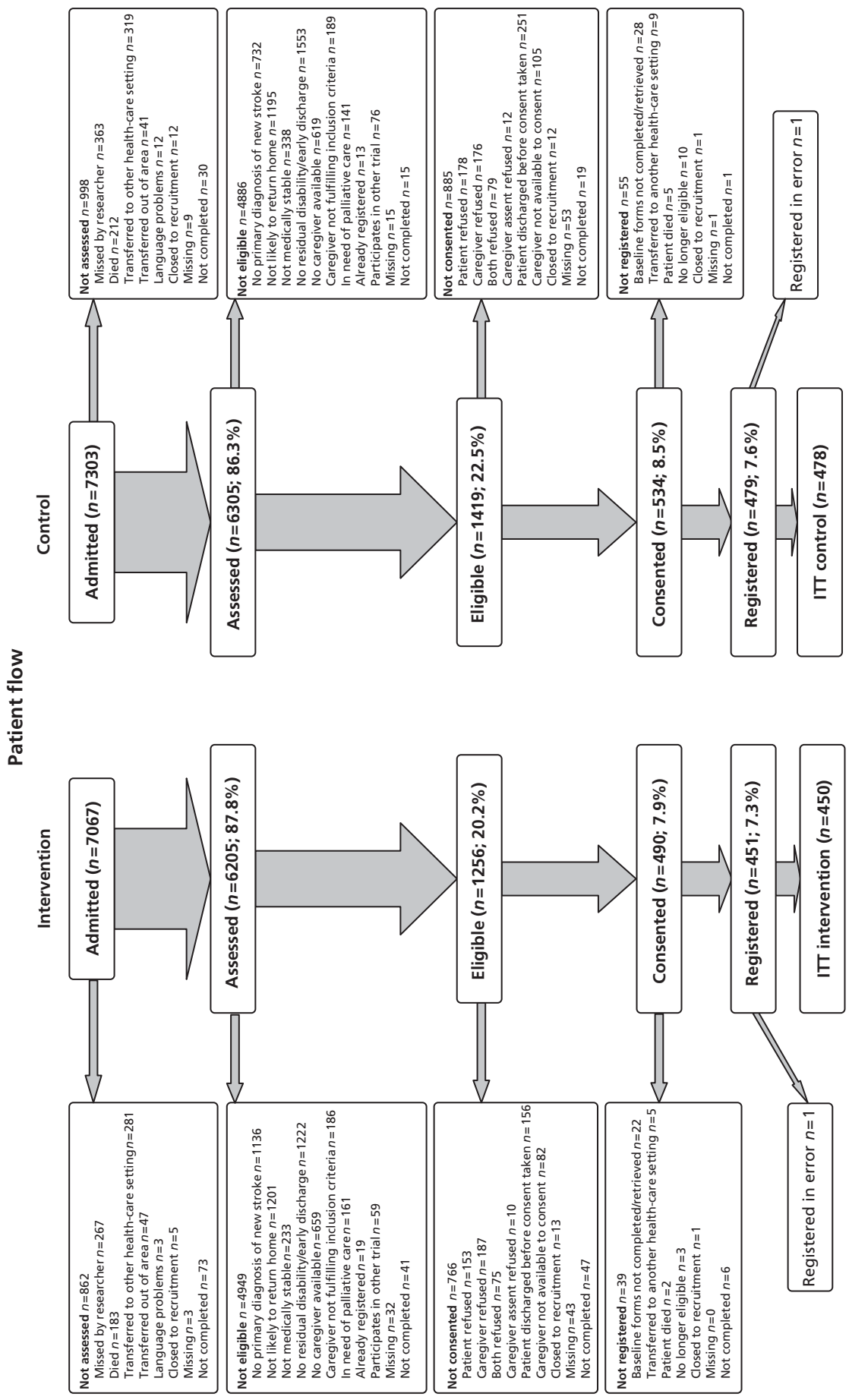

FIGURE 3 Flow of patients from admission to registration: by treatment arm. Percentage is calculated out of 'assessed patients', apart from 'assessed', for which percentage is calculated out of 'admitted'.

TABLE 6 Screened patients by centre: non-registration

Centre	Admitted, *n*	Assessed/screened, *n* (%)[a]	Eligible, *n* (%)	Consented, *n* (%)	Consented, %[b]	Registered, *n* (%)
Intervention						
1	183	149 (81.4)	45 (30.2)	23 (15.4)	51.1	20 (13.4)
2	178	173 (97.2)	52 (30.1)	21 (12.1)	40.4	21 (12.1)
3	766	637 (83.2)	71 (11.1)	24 (3.8)	33.8	24 (3.8)
4	865	831 (96.1)	75 (9.0)	33 (4.0)	44.0	30 (3.6)
5	611	579 (94.8)	60 (10.4)	35 (6.0)	58.3	33 (5.7)
6	219	211 (96.3)	85 (40.3)	38 (18.0)	44.7	32 (15.2)
7	563	445 (79.0)	84 (18.9)	33 (7.4)	39.3	27 (6.1)
8	230	222 (96.5)	53 (23.9)	25 (11.3)	47.2	23 (10.4)
9	376	360 (95.7)	115 (31.9)	30 (8.3)	26.1	29 (8.1)
10	542	362 (66.8)	67 (18.5)	25 (6.9)	37.3	25 (6.9)
11	318	194 (61.0)	30 (15.5)	16 (8.2)	53.3	16 (8.2)
12	256	227 (88.7)	106 (46.7)	38 (16.7)	35.8	35 (15.4)
13	167	162 (97.0)	70 (43.2)	16 (9.9)	22.9	14 (8.6)
14	373	362 (97.1)	107 (29.6)	38 (10.5)	35.5	35 (9.7)
15	673	645 (95.8)	69 (10.7)	24 (3.7)	34.8	19 (2.9)
16	277	227 (81.9)	55 (24.2)	17 (7.5)	30.9	17 (7.5)
17	202	171 (84.7)	44 (25.7)	27 (15.8)	61.4	25 (14.6)
18	268	248 (92.5)	68 (27.4)	27 (10.9)	39.7	26 (10.5)
Total	**7067**	**6205 (87.8)**	**1256 (20.2)**	**490 (7.9)**	**39.0**	**451 (7.3)**
Control						
19	314	310 (98.7)	74 (23.9)	39 (12.6)	52.7	34 (11.0)
20	929	720 (77.5)	135 (18.8)	32 (4.4)	23.7	27 (3.8)
21	244	235 (96.3)	84 (35.7)	36 (15.3)	42.9	31 (13.2)
22	260	225 (86.5)	44 (19.6)	20 (8.9)	45.5	18 (8.0)
23	514	403 (78.4)	78 (19.4)	26 (6.5)	33.3	25 (6.2)
24	373	284 (76.1)	54 (19.0)	13 (4.6)	24.1	12 (4.2)
25	688	566 (82.3)	88 (15.5)	44 (7.8)	50.0	38 (6.7)
26	189	182 (96.3)	65 (35.7)	25 (13.7)	38.5	23 (12.6)
27	285	270 (94.7)	92 (34.1)	35 (13.0)	38.0	35 (13.0)
28	354	265 (74.9)	85 (32.1)	27 (10.2)	31.8	23 (8.7)
29	775	747 (96.4)	103 (13.8)	37 (5.0)	35.9	30 (4.0)
30	311	285 (91.6)	56 (19.6)	17 (6.0)	30.4	13 (4.6)
31	188	158 (84.0)	46 (29.1)	28 (17.7)	60.9	26 (16.5)

TABLE 6 Screened patients by centre: non-registration (*continued*)

Centre	Admitted, *n*	Assessed/screened, *n* (%)[a]	Eligible, *n* (%)	Consented, *n* (%)	Consented, %[b]	Registered, *n* (%)
32	679	529 (77.9)	107 (20.2)	29 (5.5)	27.1	25 (4.7)
33	513	473 (92.2)	58 (12.3)	21 (4.4)	36.2	17 (3.6)
34	188	188 (100)	67 (35.6)	37 (19.7)	55.2	35 (18.6)
35	261	249 (95.4)	84 (33.7)	32 (12.9)	38.1	32 (12.9)
36	238	216 (90.8)	99 (45.8)	36 (16.7)	36.4	35 (16.2)
Total	**7303**	**6305 (86.3)**	**1419 (22.5)**	**534 (8.5)**	**37.6**	**479 (7.6)**
Overall total	***14,370***	***12,510 (87.1)***	***2675 (21.4)***	***1024 (8.2)***	***38.3***	***930 (7.4)***

a Percentages are out of 'admitted'.
b Percentages are out of 'eligible'.
Percentages are calculated out of 'assessed'.

TABLE 7 Characteristics of screened participants

Baseline characteristics	Intervention (*N* = 6205)	Control (*N* = 6305)	Total (*N* = 12,510)
Age (years): mean (SD)	74.1 (13.72), *n* = 6154	74.7 (13.04), *n* = 6224	74.4 (13.39), *n* = 12,378
Length of hospital stay (days): mean (SD)	27.3 (34.47), *n* = 5860	28.5 (31.65), *n* = 6076	27.9 (33.07), *n* = 11,936
Sex (*n*, %), male	2931 (47.2)	3036 (48.2)	5967 (47.7)
Ethnicity (*n*, %), white	5742 (92.5)	5886 (93.4)	11,628 (92.9)
Living circumstances (*n*, %):			
Lives alone	2518 (40.6)	2404 (38.1)	4922 (39.3)
Co-habits	3013 (48.6)	3214 (51.0)	6227 (49.8)
Nursing/residential care home	368 (5.9)	323 (5.1)	691 (5.5)
Missing	306 (4.9)	364 (5.8)	670 (5.4)
Co-resident caregiver (*n*, %)	2356 (38.0)	2659 (42.2)	5015 (40.1)
The caregiver is the patients … (*n*, %):			
Partner	2528 (40.7)	2519 (40.0)	5047 (40.3)
Daughter/son	1914 (30.8)	1673 (26.5)	3587 (28.7)
Other relative	421 (6.8)	375 (5.9)	796 (6.3)
Other non-relative	144 (2.3)	157 (2.5)	301 (2.4)
No carer	887 (14.3)	1078 (17.1)	1965 (15.7)
Missing	311 (5.0)	503 (8.0)	814 (6.5)

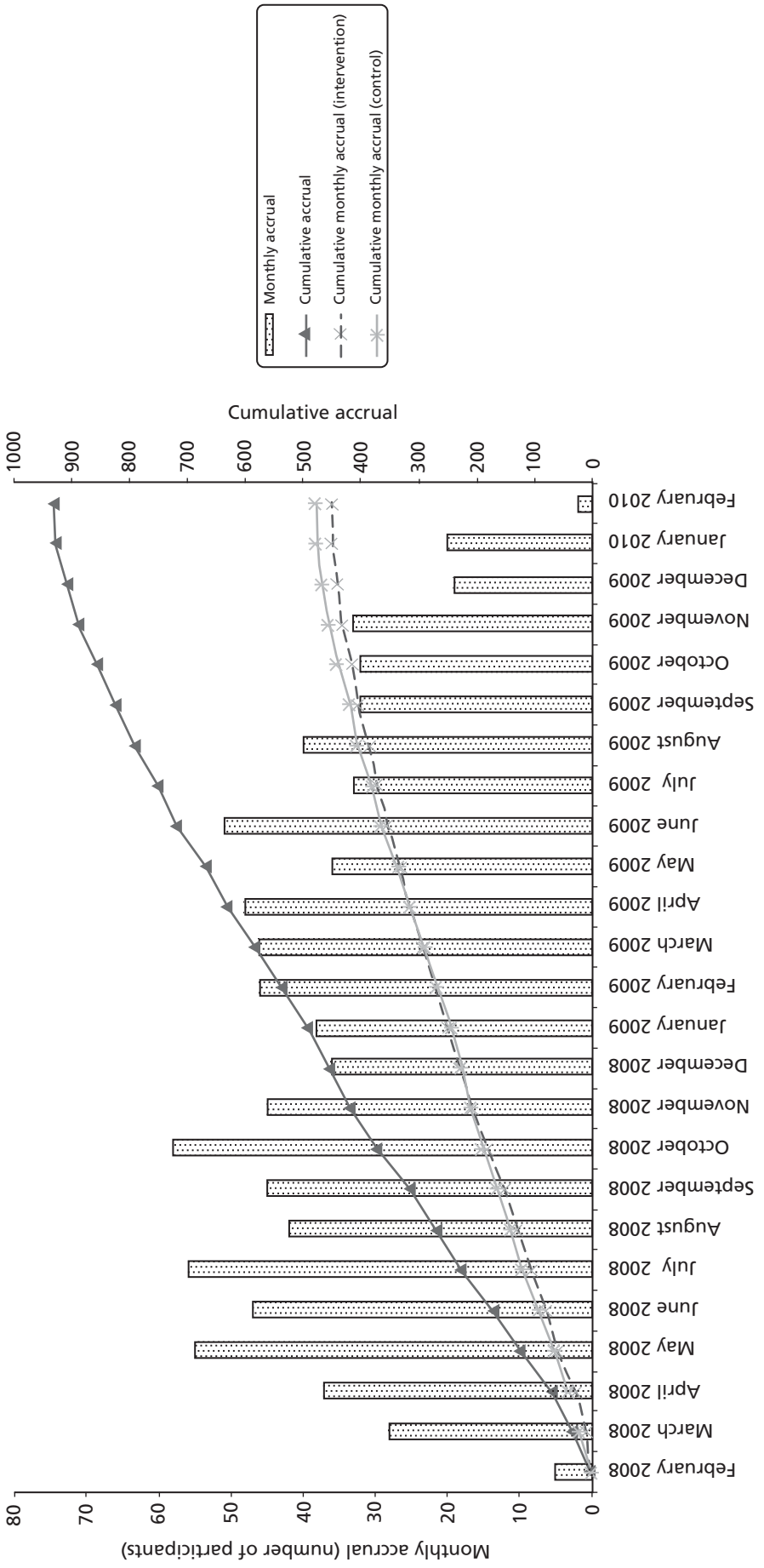

FIGURE 4 Accrual into TRACS trial: monthly, overall, cumulative and target accrual.

Analysis populations

Confirmation of written informed consent could not be obtained centrally for two patients (one in each of the two randomised groups); therefore, these patients were not included in the ITT population.

The ITT population contains a total of 928 patients (intervention $n=450$, control $n=478$).

Trial conduct

A CONSORT (Consolidated Standards of Reporting Trials) flow diagram of trial progress and loss to follow-up for SRUs (clusters) and individual participants (patients and caregivers) is presented in *Figures 5* (patients) and *6* (caregivers).

Baseline data

Patient summaries

Baseline characteristics and clinical details of the ITT population are presented in *Tables 8–11*. The two groups were well balanced with respect to these characteristics.

The mean age at registration was 71.0 (SD 12.76) years and 71.3 (SD 12.18) years in the intervention and control groups, respectively. There were more males than females: 257 (57.1%) in the intervention group and 262 (54.8%) in the control group, respectively. The majority of the participants were of white ethnic background: 429 (95.3%) in the intervention group and 444 (92.9%) in the control group. Most patients had a formal education: 427 (94.9%) in the intervention group and 457 (95.6%) in the control group.

At the time of registration, most patients were retired: 311 (69.1%) and 337 (70.5%) in the intervention and control groups, respectively, followed by patients in full employment, 80 (17.8%) in the intervention group and 77 (16.1%) in the control group.

The majority of patients' preferred language was English, 439 (97.6%) in the intervention group and 467 (97.7%) in the control group.

In most cases, the caregiver was the patient's close relative: partner [314 (69.8%) in intervention and 315 (65.9%) in control] or offspring [118 (26.2%) in intervention and 135 (28.2%) in control]. A small proportion of patients lived alone before the stroke: 66 (14.7%) in intervention and 85 (17.8%) in control groups.

The majority of the patients had received no more education since leaving school [270 (60%) intervention; 291 (61.1%) control] and the majority of the patients left education by the age of 16 years [328 (72.9%) intervention; 381 (79.7%) control].

The clinical details of the patient population include the clinical and pathological classification of current stroke and patient abilities following stroke. The majority of patients had ischaemic stroke [380 (84.4%) intervention; 401 (83.9%) control]. Some patients had experienced a previous stroke: 71 (15.8%) in intervention and 96 (20.1%) in control. The number of patients with dysphasia was similar across both groups: 118 (26.2%) intervention and 112 (23.4%) in control.

Researcher-completed patient baseline scores for the Barthel Index, modified Rankin Scale and 6CIT are displayed in *Table 12*. Scores were similar across both groups. Over one-third of patients able to complete the cognitive assessment (6CIT) demonstrated a cognitive impairment [135 (36.5%) intervention; 145 (37.1%) control].

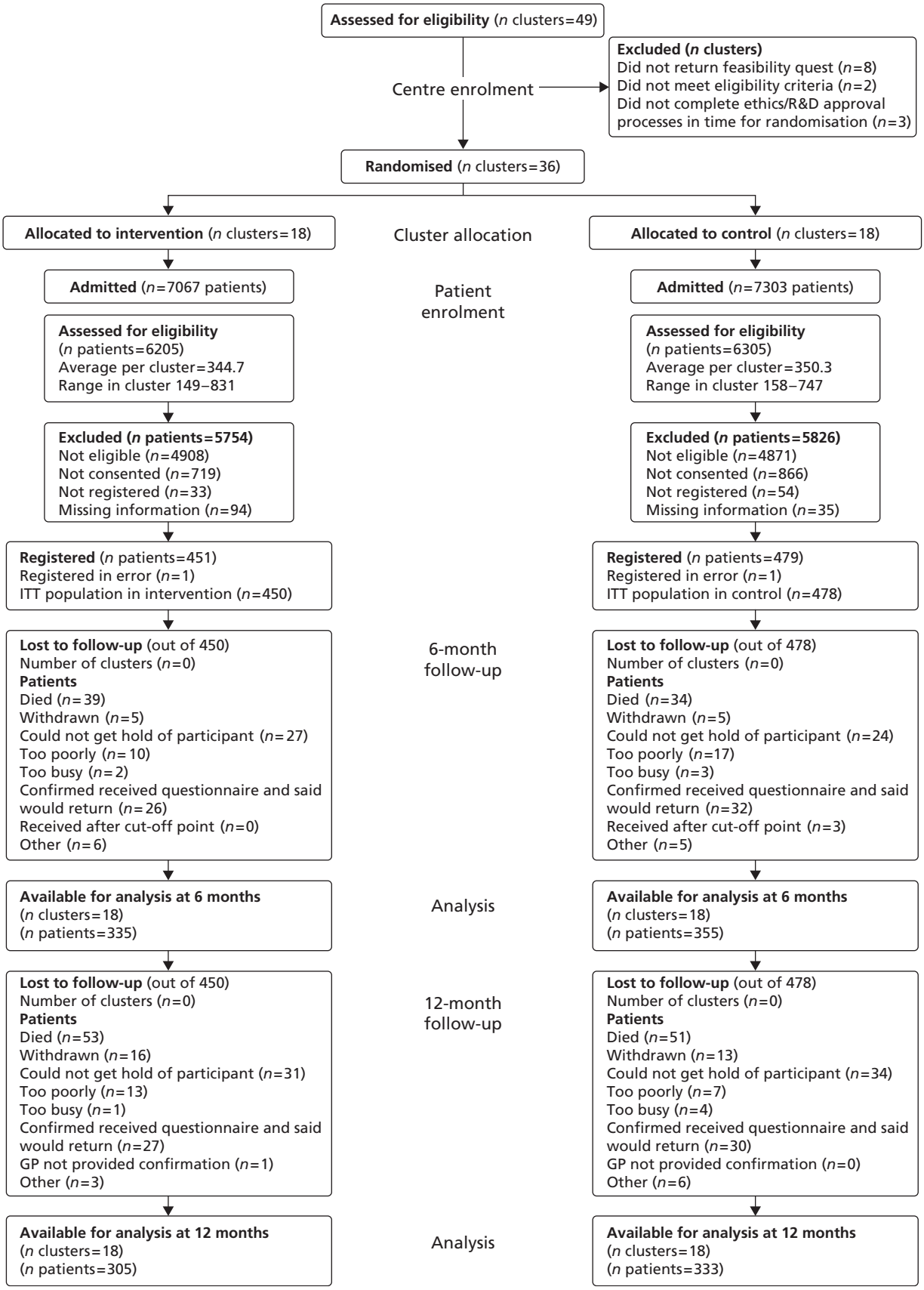

FIGURE 5 Clusters and patients.

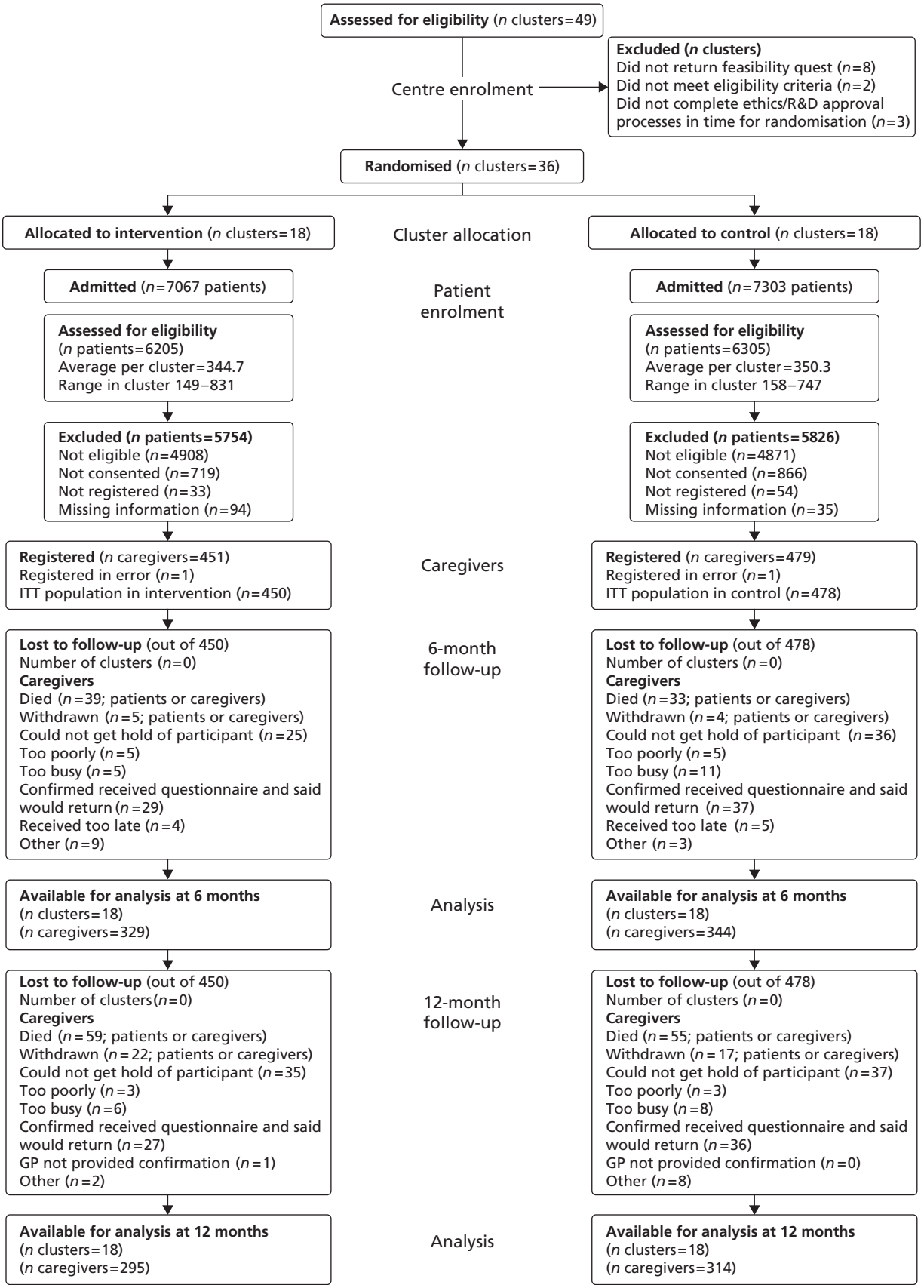

FIGURE 6 Clusters and caregivers.

TABLE 8 Patient demographics (age, sex, ethnicity, education and employment)

Demographics	Intervention (*N* = 450)	Control (*N* = 478)
Age (years), mean (SD)	71.0 (12.76), *n* = 450	71.3 (12.18), *n* = 478
Sex, *n* (%): male	257 (57.1)	262 (54.8)
Ethnicity, *n* (%): white	429 (95.3)	444 (92.9)
Formal education, *n* (%): yes	427 (94.9)	457 (95.6)
Employment,* n *(%)		
Retired	311 (69.1)	337 (70.5)
Working full time (≥ 30 hours per week)	80 (17.8)	77 (16.1)
Working part time (< 30 hours per week)	18 (4.0)	21 (4.4)
Unable to work (for medical and other reasons)	17 (3.8)	16 (3.3)
Other[a]	24 (5.3)	27 (5.6)

a Includes categories 'at home and not looking for work', 'unemployed and looking for work', 'made redundant/early retirement' and 'other'.

TABLE 9 Patient demographics (language, relationship with carer, living circumstances before stroke)

Demographics	Intervention (*N* = 450)	Control (*N* = 478)
Patient's preferred language,* n *(%)		
English	439 (97.6)	467 (97.7)
If other, speaks and understands English?		
Yes	6 (1.3)	3 (0.6)
No	5 (1.1)	8 (1.7)
Patient–caregiver relationship,* n *(%)		
Partner	314 (69.8)	315 (65.9)
Daughter/son	118 (26.2)	135 (28.2)
Other relative	17 (3.8)	23 (4.8)
Other non-relative	1 (0.2)	5 (1.0)
Did the patient live alone before the stroke?* n *(%)		
Yes	66 (14.7)	85 (17.8)

TABLE 10 Patient demographics (further education)

Demographics	Intervention (*N* = 450)	Control (*N* = 478)
More education since leaving school,* n *(%)		
Yes	156 (34.7)	163 (34.1)
No	270 (60.0)	292 (61.1)
No formal education	23 (5.1)	21 (4.4)
Missing	1 (0.2)	2 (0.4)
Age patient left education,* n *(%)		
≤ 16 years	328 (72.9)	381 (79.7)
> 16 years	97 (21.6)	76 (15.9)
No formal education	23 (5.1)	21 (4.4)
Unknown	1 (0.2)	0 (0.0)
Missing	1 (0.2)	0 (0.0)

TABLE 11 Patient's current stroke details and ability (after this stroke)

Stroke details/ability	Intervention (*N* = 450)	Control (*N* = 478)
Pathological classification of current stroke,* n *(%)		
Cerebral infarction	380 (84.4)	401 (83.9)
Primary intracerebral haemorrhage	56 (12.4)	72 (15.1)
Subarachnoid haemorrhage[a]	6 (1.3)	5 (1.0)
Other	7 (1.6)	0 (0.0)
Missing	1 (0.2)	0 (0.0)
Clinical classification of stroke symptoms,* n *(%)		
Left hemiparesis	217 (48.2)	253 (52.9)
Right hemiparesis	203 (45.1)	187 (39.1)
Brain stem	16 (3.6)	20 (4.2)
Other	14 (3.1)	18 (3.8)
Has the patient had a previous stroke?* n *(%)		
Yes	71 (15.8)	96 (20.1)
No	376 (83.6)	381 (79.7)
Missing	3 (0.7)	1 (0.2)
Orientated in time, place and person,* n *(%)		
Yes	380 (84.4)	397 (83.1)
No	70 (15.6)	81 (16.9)
Able to lift both arms off the bed,* n *(%)		
Yes	303 (67.3)	327 (68.4)
No	146 (32.4)	151 (31.6)
Missing	1 (0.2)	0 (0.0)

continued

TABLE 11 Patient's current stroke details and ability (after this stroke) (*continued*)

Stroke details/ability	Intervention (*N* = 450)	Control (*N* = 478)
Able to walk without help from others,* n *(%)		
Yes	148 (32.9)	159 (33.3)
No	301 (66.9)	319 (66.7)
Missing	1 (0.2)	0 (0.0)
Patient's language ability,* n *(%)		
Normal	290 (64.4)	307 (64.2)
Dysphasia	118 (26.2)	112 (23.4)
Dysarthria	42 (9.3)	58 (12.1)
Missing	0 (0.0%)	1 (0.2)
Does the patient intend to live alone after discharge?* n *(%)		
No	399 (88.7)	401 (83.9)
Are the patient and caregiver intending to live together after discharge?* n *(%)		
Yes	376 (83.6)	386 (80.8)

a Subarachnoid haemorrhages were not intentionally included in this trial; however, a small number were recruited early on in the trial before this eligibility criteria were clarified to the researchers.

TABLE 12 Patient baseline scores (researcher completed): Barthel Index, modified Rankin Scale and 6CIT

Index/scale	Intervention (*N* = 450)	Control (*N* = 478)
Barthel Index pre stroke (0–20)*[a], n *(%)		
Mean (SD)	19.2 (2.22), *n* = 450	18.8 (2.77), *n* = 478
6CIT (0–28)*[b], n *(%)		
Number (%) of 6CIT scores recorded (only patients who were able to complete those)	370 (82.2)	391 (81.8)
Normal	235 (63.5)	246 (62.9)
Impaired	135 (36.5)	145 (37.1)
Modified Rankin Scale (0–5)*[c], n *(%)		
Missing	3 (0.7)	0 (0.0)
0	1 (0.2)	3 (0.6)
1	3 (0.7)	4 (0.8)
2	44 (9.8)	43 (9.0)
3	137 (30.4)	148 (31.0)
4	244 (54.2)	258 (54.0)
5	18 (4.0)	22 (4.6)

a Barthel Index: 0 = dependent, 20 = independent.
b 6CIT: ≥ 8 = normal, 9–19 = moderate impairment, ≥ 20 = severe impairment.
c Modified Rankin Scale: 0 = no symptoms, 5 = severe disability.

Patient-completed baseline questionnaires

Patient-completed scores for Barthel Index, NEADL scale, HADS, EQ-5D and SIS are displayed in *Tables 13–14*. Scores were also similar across both groups. The HADS questionnaire was also summarised categorically: 171 intervention patients (38.0%) and 210 control patients (43.9%) had raised anxiety levels, whereas 188 (41.8%) intervention patients and 209 (43.7%) control patients had raised levels of depression.

Caregiver summaries

The caregiver baseline demographics of the ITT population are displayed in *Tables 15–17*. The mean caregiver age was 61.1 (SD 14.64) years and 60.8 (SD 13.91) years in the intervention and control groups, respectively. In contrast with patients, more females than males were acting as caregivers in both groups: 310 (68.9%) in the intervention group and 325 (68.0%) in the control group. The majority of caregivers were of white ethnic background: 430 (95.6%) in the intervention group and 446 (93.3%) in the control group.

A large proportion of caregivers were retired [195 (43.3%) in the intervention group and 221 (46.2%) in the control group], followed by caregivers in full- and part-time employment [187 (41.5%) in the intervention group and 188 (39.3%) in the control group].

TABLE 13 Patient baseline scores (patient completed): Barthel Index, NEADL scale, HADS and EQ-5D

Index/scale	Intervention ($N=450$)	Control ($N=478$)
NEADL score (0–66)[a]		
Mean (SD)	52.0 (15.77), $n=443$	52.3 (15.80), $n=474$
Barthel Index post stroke (0–20)[b]		
Mean (SD)	12.2 (5.38), $n=442$	12.6 (5.45), $n=473$
HADS (0–21)[c]**, n *(%)*		
HADS Anxiety score		
Normal	256 (56.9)	254 (53.1)
Borderline abnormal	83 (18.4)	98 (20.5)
Abnormal	88 (19.6)	112 (23.4)
Missing	23 (5.1)	14 (2.9)
Mean (SD)	6.7 (4.47), $n=427$	7.3 (4.65), $n=464$
HADS Depression score		
Normal	241 (53.6)	254 (53.1)
Borderline abnormal	77 (17.1)	86 (18.0)
Abnormal	111 (24.7)	123 (25.7)
Missing	21 (4.7)	15 (3.1)
Mean (SD)	7.3 (4.68), $n=429$	7.6 (4.81), $n=463$
EQ-5D index[d] ***(–0.59, 1)***		
Mean (SD)	0.360 (0.375), $n=426$	0.380 (0.357), $n=459$

a Pre-stroke NEADL score: 0 = low independence, 66 = high independence.
b Barthel Index: 0 = dependent, 20 = independent.
c HADS score: normal (0–7), borderline (8–10), abnormal (11–21).
d EQ-5D: –0.59 = worst possible health, 1 = full health.

TABLE 14 Patient baseline scores (patient completed): SIS

SIS	Intervention (*N* = 450)	Control (*N* = 478)
SIS (0–100)[a]		
Strength score		
Mean (SD)	42.4 (27.00), *n* = 414	45.7 (29.14), *n* = 440
ADL score		
Mean (SD)	43.6 (27.23), *n* = 431	46.3 (26.72), *n* = 466
Mobility score		
Mean (SD)	41.1 (29.29), *n* = 424	43.2 (29.06), *n* = 459
Hand function score		
Mean (SD)	26.9 (33.00), *n* = 426	28.6 (34.02), *n* = 440
Physical domains score		
Mean (SD)	39.7 (25.19), *n* = 434	42.3 (25.47), *n* = 466
Memory score		
Mean (SD)	66.7 (29.85), *n* = 431	67.9 (29.74), *n* = 467
Mood score		
Mean (SD)	69.0 (18.48), *n* = 425	69.7 (17.80), *n* = 462
Communication score		
Mean (SD)	76.4 (28.02), *n* = 433	76.9 (28.85), *n* = 471

a SIS: 0 = worst, 100 = best.

TABLE 15 Caregiver demographics (age, sex, ethnicity, education and employment)

Demographics	Intervention (*N* = 450)	Control (*N* = 478)
Age (years), mean (SD)	61.1 (14.64), *n* = 450	60.8 (13.91), *n* = 478
Sex, *n* (%): male	140 (31.1)	153 (32.0)
Ethnicity, *n* (%): white	430 (95.6)	446 (93.3)
Formal education, *n* (%): yes	435 (96.7)	464 (97.1)
Employment,* n *(%)		
Retired	195 (43.3)	221 (46.2)
Working full-time (≥ 30 hours per week)	127 (28.2)	123 (25.7)
Working part time (< 30 hours per week)	60 (13.3)	65 (13.6)
Other[a]	68 (15.1)	69 (14.4)

a Includes categories 'student', 'at home and not looking for work', 'unemployed and looking for work', 'made redundant/ took early retirement', 'unable to work' and 'other'.

TABLE 16 Caregiver demographics (language, place of residence)

Demographics	Intervention (*N* = 450)	Control (*N* = 478)
Caregiver's preferred language, [a] **n *(%)***		
English	447 (99.3)	475 (99.4)
In the last 12 months, has the caregiver resided with the patient?* n *(%)		
Yes	356 (79.1)	364 (76.2)

a All caregivers with preferred language 'other' spoke and understood English.

TABLE 17 Caregiver demographics: further education

Demographics	Intervention (*N* = 450)	Control (*N* = 478)
More education since leaving school,* n *(%)		
Yes	199 (44.2)	211 (44.1)
No	233 (51.8)	245 (51.3)
No formal education	15 (3.3)	13 (2.7)
Missing	3 (0.7)	9 (1.9)
Age caregiver left education, [a] **n *(%)***		
≤ 16 years	317 (70.4)	339 (70.9)
> 16 years	133 (29.6)	139 (29.1)

The majority of caregivers had formal education [435 (96.7%) in intervention and 464 (97.1%) in control], with most caregivers leaving education by the age of 16 years [317 (70.4%) in the intervention group and 339 (70.9%) in the control group].

Nearly all caregivers' preferred language was English [447 (99.3%) in intervention and 475 (99.4%) in control]. The majority of caregivers lived with the patient during the last 12 months [356 (79.1%) in the intervention group and 364 (76.2%) in the control group].

Researcher completed caregiver modified Rankin Scale scores are summarised in *Table 18*. The majority of caregivers had a score of 0 or 1 [427 (94.9%) in the intervention group and 453 (94.7%) in the control group].

The baseline scores in FAI, HADS and EQ-5D completed by caregivers show similarities between the treatment groups (*Table 19*). The HADS questionnaire was summarised categorically. A sizeable proportion of caregivers showed raised levels of anxiety at baseline [236 (52.5%) in the intervention group and 238 (49.8%) in the control group], whereas 122 (27.1%) intervention caregivers and 122 (25.5%) control caregivers had raised levels of depression.

Cluster-level balance

Two-sample *t*-tests weighted by inverse number of patients in each centre were used to compare baseline characteristics of patients and caregivers between intervention and control groups. These tests showed that there are no statistically significant differences between patients (*Tables 20* and *21*) or caregivers (*Tables 22* and *23*).

TABLE 18 Caregiver baseline scores (researcher completed): modified Rankin Scale

Modified Rankin Scale (0–5[a])	Intervention (*N* = 450), *n* (%)	Control (*N* = 478), *n* (%)
0	387 (86.0)	385 (80.5)
1	40 (8.9)	68 (14.2)
2	16 (3.6)	19 (4.0)
3	6 (1.3)	4 (0.8)
4	1 (0.2)	2 (0.4)

a Modified Rankin Scale: 0 = no symptoms, 5 = severe disability. There are no caregivers with modified Rankin Scale of 5.

TABLE 19 Caregiver baseline scores (caregiver completed): FAI, HADS and EQ-5D

Index/scale	Intervention (*N* = 450)	Control (*N* = 478)
FAI (range 0–45)[a]		
Mean (SD)	32.9 (7.99), *n* = 441	33.5 (7.40), *n* = 470
HADS (0–21[b]***),*** n ***(%)***		
HADS Anxiety score, n *(%)*		
Normal	206 (45.8)	232 (48.5)
Borderline abnormal	94 (20.9)	90 (18.8)
Abnormal	142 (31.6)	148 (31.0)
Missing	8 (1.8)	8 (1.7)
Mean (SD)	8.3 (4.87), *n* = 442	8.0 (4.74), *n* = 470
HADS Depression score, n *(%)*		
Normal	320 (71.1)	349 (73.0)
Borderline abnormal	69 (15.3)	81 (16.9)
Abnormal	53 (11.8)	41 (8.6)
Missing	8 (1.8)	7 (1.5)
Mean (SD)	5.2 (4.25), *n* = 442	5.0 (3.89), *n* = 471
EQ-5D index (–0.59, 1)[c]		
Mean (SD)	0.797 (0.232), *n* = 438	0.791 (0.245), *n* = 471

a FAI: 0 = inactive, 45 = active.
b HADS: normal (0–7), borderline (8–10), abnormal (11–21).
c EQ-5D: –0.59 = worst possible health, 1 = full health.

TABLE 20 *t*-Tests to compare means: baseline data – patients

Patient baseline details	Total	Intervention, mean (SD)	Control, mean (SD)	*p*-value (two-sided)
Barthel Index pre stroke score	36	19.3 (0.12)	18.7 (0.21)	0.0536
6CIT score	36	7.9 (0.49)	8.3 (0.61)	0.6082
Age (years)	36	70.2 (0.86)	71.1 (0.87)	0.5326
Barthel Index post-stroke score	36	12.1 (0.26)	12.8 (0.30)	0.1467
NEADL pre-stroke score	36	52.8 (0.75)	51.2 (1.03)	0.2848
SIS Physical score	36	38.3 (1.47)	42.1 (1.29)	0.0994
SIS Memory score	36	66.4 (1.88)	68.1 (2.01)	0.5731
SIS Mood score	36	68.3 (1.07)	70.6 (0.88)	0.1437
SIS Communication score	36	77.0 (1.39)	77.4 (1.45)	0.8697
SIS Recovery score	36	44.3 (1.41)	48.3 (1.23)	0.0739
EQ-5D score	36	0.4 (0.02)	0.4 (0.02)	0.4499
HADS Anxiety score	36	7.0 (0.30)	7.1 (0.20)	0.9262
HADS Depression score	36	7.5 (0.28)	7.4 (0.24)	0.8535

Two-sample *t*-test to compare means, weighted by inverse number of patients.

TABLE 21 *t*-Tests to compare percentages: baseline data – patients

Patient baseline details	Total	Intervention, % (SD)	Control, % (SD)	*p*-value (two-sided)
Sex: male	36	55.4 (2.03)	54.7 (1.80)	0.8162
Ethnicity: white	36	95.4 (1.79)	94.8 (2.17)	0.8674
Left education aged ≤ 16 years	36	70.5 (3.43)	76.1 (3.30)	0.305
Independent before this stroke: yes	36	92.0 (1.28)	89.1 (1.74)	0.24
Lived alone before this stroke: yes	36	14.5 (1.99)	16.3 (2.29)	0.622
Intends to live alone after discharge: no	36	89.9 (1.63)	84.7 (2.23)	0.1033
Pathological classification of stroke: cerebral infarction	36	84.8 (1.57)	85.2 (1.52)	0.8897
Clinical classification of stroke: left hemiparesis	36	48.4 (2.50)	54.0 (2.28)	0.1579
Previous stroke: no	36	84.2 (2.17)	78.7 (1.95)	0.1093
Patient can talk and orientated	36	85.4 (2.38)	85.5 (2.42)	0.9663
Can lift both arms off the bed	36	67.7 (3.77)	67.1 (3.17)	0.9096
Patient can walk without help of others	36	32.0 (3.31)	34.5 (2.84)	0.6283
Normal language ability	36	63.7 (3.63)	66.0 (2.95)	0.6728

Two-sample *t*-test to compare percentages, weighted by inverse number of patients.

TABLE 22 *t*-Tests to compare means: baseline data – caregivers

Caregiver baseline details	Total	Intervention, mean (SD)	Control, mean (SD)	*p*-value (two-sided)
Age (years)	36	60.9 (0.95)	61.3 (1.48)	0.8541
EQ-5D score	36	0.8 (0.02)	0.8 (0.01)	0.838
HADS Anxiety score	36	8.3 (0.27)	8.0 (0.22)	0.4811
HADS Depression score	36	5.4 (0.27)	5.0 (0.14)	0.2081
FAI score	36	33.1 (0.39)	33.3 (0.37)	0.7845

Two-sample *t*-test to compare means, weighted by inverse number of patients.

TABLE 23 *t*-Tests to compare percentages: baseline data – caregivers

Caregiver baseline details	Total	Intervention, % (SD)	Control, % (SD)	*p*-value (two-sided)
Sex: male	36	32.8 (2.22)	32.2 (2.01)	0.8656
Ethnicity: white	36	95.5 (1.82)	95.0 (2.11)	0.8713
In full-time employment	36	30.4 (1.96)	26.4 (2.94)	0.3358
Modified Rankin scale = 0	36	87.9 (2.24)	82.3 (2.21)	0.1303

Two-sample *t*-test to compare percentages, weighted by inverse number of patients.

Trial outcomes

Questionnaire follow-up

Efforts were made to follow all patients and caregivers when appropriate. For primary end point, the cut-off period was set at 10 months. With this cut-off time-point, only three patients' questionnaires and 10 caregivers' questionnaires were excluded.

Patients

At 6 months for patient primary end point, the overall response rate for received questionnaires was 74.4% in the intervention group and 74.3% in the control group, 74.4% overall. A detailed summary of the reasons as to why questionnaires were not received is shown in *Table 24*. The main reasons for not returning the questionnaires were patients' deaths [73 (7.9%)], patients confirming that they would return questionnaire but questionnaire was never received [58 (6.3%)] and inability to get hold of participant [51 (5.5%)].

The response rate at 12 months was 67.8% in the intervention group and 69.6% in the control group, 68.8% in total (*Table 25*). The main reasons for not returning the questionnaires at this time-point were patients' deaths [104 (11.2%)], inability to get hold of participant [65 (7.0%)] and patients confirming that they would return questionnaire but questionnaire was never received [54 (6.1%)].

Caregivers

Table 26 displays the response rate for caregivers' questionnaires at 6 months. Overall, 72.5% were received, 73.1% in the intervention and 72.0% in the control group. The main reasons for questionnaires not received were patients' deaths [70 (7.5%)], caregiver said that they would return questionnaire but questionnaire was never received [66 (7.1%)] and inability to get hold of caregiver [61 (6.6%)].

The response rates for caregivers' questionnaires at 12 months are summarised in *Table 27*. The number of received questionnaires at 12 months was lower than at 6 months. Overall, 65.6% were received: 65.6% in

TABLE 24 Patients' questionnaires follow-up at 6 months

Patient follow-up	Intervention (*N* = 450), *n* (%)	Control (*N* = 478), *n* (%)	Total (*N* = 928), *n* (%)
Questionnaire			
Received	329 (73.1)	348 (72.8)	677 (73.0)
Received over the telephone	6 (1.3)	7 (1.5)	13 (1.4)
Patient died	39 (8.7)	34 (7.1)	73 (7.9)
Patient withdrew	5 (1.1)	5 (1.0)	10 (1.1)
Received too late	0 (0.0)	3 (0.6)	3 (0.3)
Questionnaire not returned	71 (15.8)	81 (16.9)	152 (16.4)
Reasons questionnaires not received			
Too poorly	10 (2.2)	17 (3.6)	27 (2.9)
Could not get hold of participant	27 (6.0)	24 (5.0)	51 (5.5)
Confirmed received questionnaire and said that would return	26 (5.8)	32 (6.7)	58 (6.3)
Too busy	2 (0.4)	3 (0.6)	5 (0.5)
Other	6 (1.3)	5 (1.0)	11 (1.2)

TABLE 25 Patients' questionnaires follow-up at 12 months

Patient follow-up	Intervention (*N* = 450), *n* (%)	Control (*N* = 478), *n* (%)	Total (*N* = 928), *n* (%)
Questionnaire			
Received	300 (66.7)	329 (68.8)	629 (67.8)
Received over the telephone	5 (1.1)	4 (0.8)	9 (1.0)
Patient died	53 (11.8)	51 (10.7)	104 (11.2)
Patient withdrew	16 (3.6)	13 (2.7)	29 (3.1)
GP not provided confirmation (patient)	1 (0.2)	0 (0.0)	1 (0.1)
Questionnaire not returned	75 (16.7)	81 (16.9)	156 (16.8)
Reasons questionnaires not received			
Too poorly	13 (2.9)	7 (1.5)	20 (2.2)
Could not get hold of participant	31 (6.9)	34 (7.1)	65 (7.0)
Confirmed received questionnaire and said that would return	27 (6.0)	30 (6.3)	57 (6.1)
Too busy	1 (0.2)	4 (0.8)	5 (0.5)
Other	3 (0.7)	6 (1.3)	9 (1.0)

the intervention group and 65.7% in the control group. The main reasons for questionnaires not received were patients' deaths [104 (11.2%)], not being able to get hold of participant [72 (7.8%)] and caregiver said that they would return questionnaire but questionnaire was never received [63 (6.8%)].

Proxy responses

Proxy responses, where the entire questionnaire was completed on patients' behalf without consulting them, were anticipated. At baseline, 63 (6.8%) of questionnaires were via a proxy response; at 6 months and 12 months, 37 (5.5%) and 41 (6.5%), respectively, were via a proxy response (*Table 28*).

TABLE 26 Caregivers' questionnaires: follow-up at 6 months

Caregiver follow-up	Intervention (*N* = 450), *n* (%)	Control (*N* = 478), *n* (%)	Total (*N* = 928), *n* (%)
Questionnaire			
Received	327 (72.7)	336 (70.3)	663 (71.4)
Received over the telephone	2 (0.4)	8 (1.7)	10 (1.1)
Patient died	37 (8.2)	33 (6.9)	70 (7.5)
Caregiver died	2 (0.4)	0 (0.0)	2 (0.2)
Both withdrew	5 (1.1)	4 (0.8)	9 (1.0)
Received too late	4 (0.9)	5 (1.0)	9 (1.0)
Questionnaire not returned	73 (16.2)	92 (19.2)	165 (17.8)
Reasons questionnaires not received			
Too poorly	5 (1.1)	5 (1.0)	10 (1.1)
Could not get hold of participant	25 (5.6)	36 (7.5)	61 (6.6)
Confirmed received questionnaire and said that would return	29 (6.4)	37 (7.7)	66 (7.1)
Too busy	5 (1.1)	11 (2.3)	16 (1.7)
Other	9 (2.0)	3 (0.6)	12 (1.3)

TABLE 27 Caregivers' questionnaires: follow-up at 12 months

Caregiver follow-up	Intervention (*N* = 450), *n* (%)	Control (*N* = 478), *n* (%)	Total (*N* = 928), *n* (%)
Questionnaire			
Received	292 (64.9)	313 (65.5)	605 (65.2)
Received over the telephone	3 (0.7)	1 (0.2)	4 (0.4)
Patient died	53 (11.8)	51 (10.7)	104 (11.2)
Caregiver died	6 (1.3)	4 (0.8)	10 (1.1)
Patient withdrew	1 (0.2)	1 (0.2)	2 (0.2)
Caregiver withdrew	8 (1.8)	5 (1.0)	13 (1.4)
Both withdrew	13 (2.9)	11 (2.3)	24 (2.6)
GP not provided confirmation (patient)	1 (0.2)	0 (0.0)	1 (0.1)
Questionnaire not returned	73 (16.2)	92 (19.2)	165 (17.8)
Reasons questionnaires not received			
Too poorly	3 (0.7)	3 (0.6)	6 (0.6)
Could not get hold of participant	35 (7.8)	37 (7.7)	72 (7.8)
Confirmed received questionnaire and said that would return	27 (6.0)	36 (7.5)	63 (6.8)
Too busy	6 (1.3)	8 (1.7)	14 (1.5)
Other	2 (0.4)	8 (1.7)	10 (1.1)

TABLE 28 Patients whose outcomes were collected via a proxy response[a]

Questionnaire	Intervention, *n* (%)	Control, *n* (%)	Total, *n* (%)
Baseline	33 (7.3), *n* = 450	30 (6.3), *n* = 478	63 (6.8), *n* = 928
6 months	15 (4.5), *n* = 330	22 (6.3), *n* = 348	37 (5.5), *n* = 678
12 months	22 (7.3), *n* = 301	19 (5.8), *n* = 330	41 (6.5), *n* = 631

a Whole questionnaire completed on patients' behalf without consulting them.

Primary outcomes

Patients

Table 29 summarises the unadjusted NEADL scores for patients. Overall, NEADL scores were similar between the two treatment groups; the mean score decreased at 6 months post stroke when compared with pre-stroke level and minimally increased at 12 months.

Mean adjusted NEADL scores for 6 months were calculated and shown in *Table 30*, adjusted for patient- and SRU-level covariates (see *Chapter 3*). Results were similar to the unadjusted results, the adjusted NEADL mean score for the intervention was 27.4 [standard error (SE) 1.00] and for the control 27.6 (SE 0.99), with a mean difference of –0.2 points [95% confidence interval (CI) –3.0 to 2.5 points; $p = 0.866$] and an adjusted ICC of 0.027, indicating that there is no evidence of a statistically significant difference between the treatment groups in NEADL scores at 6 months.

In the trial protocol, a clinically relevant difference was defined as 6 (SD 18) points on the NEADL scale. Given these results, differences between the groups at 6 months were minimal and did not reach either clinical or statistical significance.

Caregivers

Table 31 summarises the unadjusted CBS scores and subscales for caregivers. Overall, the total and subscales CBS scores were similar between the groups at 6 and 12 months.

The mean adjusted CBS scores at 6 months were calculated, *Table 32*, adjusted for patient-level and SRU-level covariates (see *Chapter 3*). Results were similar to the unadjusted results, the adjusted CBS mean score for intervention was 45.5 (SE 0.83) and for control 45.0 (SE 0.83), with a mean difference of 0.5 points (95% CI –1.7 to 2.7 points; $p = 0.660$) and adjusted ICC of 0.013, indicating that there is no evidence of statistically significant difference between the groups in caregiver burden at 6 months.

Sensitivity analyses

Sensitivity analyses for patient primary end point

A sensitivity analysis including patients who had died was undertaken and assumed that these patients had a NEADL score of 0. This sensitivity analysis showed results similar to the primary analysis: the adjusted scores were similar between the groups; the adjusted NEADL mean score for the intervention group was 24.2 and for the control group was 25.1, with –0.9 (95% CI –3.5 to 1.8; $p = 0.507$) point difference and adjusted ICC of 0.019, again indicating no evidence of a difference between the groups (see *Table 80*).

A sensitivity analysis without proxy responses was performed to assess the impact of proxy responses on the analysis of the primary end point. This sensitivity analysis also showed results similar to the primary analysis: the adjusted mean NEADL score for the intervention group was 28.2 points and for the control group was 28.6 points, with –0.4 (95% CI –3.4 to 2.5; $p = 0.766$) point difference and adjusted ICC of 0.038 (see *Appendix 8*, *Table 80*).

TABLE 29 Patients' primary outcome at different time points by arm

Patients' NEADL scores: unadjusted scores						
	Baseline[a]		6 months		12 months	
Questionnaire	Intervention, mean (SD), *n*	Control, mean (SD), *n*	Intervention, mean (SD), *n*	Control, mean (SD), *n*	Intervention, mean (SD), *n*	Control, mean (SD), *n*
NEADL	52.0 (15.77), 443	52.3 (15.80), 474	26.9 (17.68), 330	26.6 (17.60), 348	28.7 (18.49), 301	28.3 (17.86), 330

a Baseline NEADL score is the score before the patient's stroke.

TABLE 30 Patients' adjusted scores, difference, *p*-value and ICC

Patients' primary outcome at 6 months – adjusted score							
Questionnaire	Intervention, mean (SE), *n*	Control, mean (SE), *n*	Difference (SE)	95% CI of the difference	*p*-value	Unadjusted ICC	Adjusted ICC
NEADL	27.4 (1.00), 330	27.6 (0.99), 348	–0.2 (1.34)	(–3.0 to 2.5)	0.866	0.016	0.027

TABLE 31 Caregivers' primary outcome at different time points by arm

CBS: caregivers' questionnaire scores: unadjusted means				
	6 months		12 months	
Questionnaire	Intervention, mean (SD), *n*	Control, mean (SD), *n*	Intervention, mean (SD), *n*	Control, mean (SD), *n*
Total CBS[a] score (0–88)	46.3 (14.97), 325	45.8 (14.30), 340	45.9 (15.01), 291	45.2 (14.22), 314
Subscales				
General strain	2.3 (0.81), 325	2.3 (0.787), 340	2.3 (0.82), 291	2.3 (0.79), 314
Isolation	2.2 (0.82), 324	2.2 (0.86), 340	2.2 (0.79), 291	2.2 (0.83), 314
Disappointment	2.2 (0.83), 325	2.2 (0.78), 343	2.2 (0.81), 291	2.1 (0.76), 314
Emotional involvement	1.6 (0.67), 325	1.6 (0.67), 340	1.6 (0.71), 291	1.7 (0.70), 314
Environment	1.8 (0.71), 324	1.7 (0.67), 340	1.7 (0.72), 291	1.6 (0.65), 314

a CBS: 0 = no burden, 88 = severe burden. CBS was not measured at baseline.

Sensitivity analyses for both patient and caregiver primary end point

The time of completion of questionnaires for primary end points was compared between arms. No statistically significant differences were found for patients (difference –1.2 days, 95% CI –3.4 to 1.0 days; $p = 0.2862$) or caregivers (difference 0 days, 95% CI –2.1 to 2.2 days; $p = 0.9836$) (see *Table 81*).

Secondary outcomes

Patients

Unadjusted Barthel Index, EQ-5D, HADS and SIS mean scores are shown in *Table 33*. Mean scores, differences in means, 95% CIs, *p*-values, unadjusted and adjusted ICCs for the questionnaires adjusted for patient- and SRU-level covariates are displayed in *Tables 34 and 35*. Overall, at both 6 and 12 months there was no evidence of statistically significant differences in patients' physical and psychological outcomes between intervention and control groups.

Caregivers

Unadjusted HADS, EQ-5D and FAI mean scores are shown in *Table 36*. Mean scores for the questionnaires, differences in means, 95% CIs, *p*-values, unadjusted and adjusted ICCs adjusted for caregiver- and SRU-level covariates at 6 months are displayed in *Tables 37 and 38*. Overall, at both 6 and 12 months, there was no evidence of statistically significant differences in caregivers' physical and psychological outcomes between intervention and control groups.

Compliance

Intervention compliance

This section summarises the training records documented by the MDT in intervention centres and provides data related to the delivery of intervention. The number of training records completed and available for analysis is displayed in *Table 39*. There were 124 (27.6%) training records not completed by the sites.

In total, 196 (43.6%) records were defined as intervention compliant. *Table 40* provides a summary of intervention compliance by SRUs; the percentage of compliant records varied from 0.0% to 92.9%. The number of mandatory components achieved by caregivers is summarised in *Table 41*. *Appendix 8* (see *Tables 75* and *76*) summarises the number of non-mandatory components achieved by caregivers.

TABLE 32 Caregivers' adjusted 6-month scores, difference, *p*-value and ICC

CBS: caregivers' primary end point at 6 months: adjusted score							
Questionnaire	Intervention, mean (SE), *n*	Control, mean (SE), *n*	Difference (SE)	95% CI of the difference	*p*-value	Unadjusted ICC	Adjusted ICC
Total CBS score	45.5 (0.83), 325	45.0 (0.83), 340	0.5 (1.08)	(–1.7 to 2.7)	0.660	0.019	0.013

TABLE 33 Patients' secondary outcomes at different time points by arm

Patients' questionnaire scores: unadjusted means						
	Baseline		6 months		12 months	
Questionnaire	Intervention, mean (SD), *n*	Control, mean (SD), *n*	Intervention, mean (SD), *n*	Control, mean (SD), n	Intervention, mean (SD), *n*	Control, mean (SD), *n*
Barthel Index pre stroke	19.2 (2.22), 450	18.8 (2.77), 478	N/A	N/A	N/A	N/A
Barthel Index post stroke	12.2 (5.38), 442	12.6 (5.45), 473	14.1 (5.14), 323	13.9 (5.13), 346	14.4 (5.07), 297	14.4 (5.02), 325
EQ-5D	0.360 (0.375), 426	0.380 (0.357), 459	0.439 (0.344), 319	0.443 (0.348), 334	0.473 (0.345), 287	0.465 (0.344), 311
HADS Anxiety	6.7 (4.471), 427	7.3 (4.66), 464	6.7 (4.61), 323	6.8 (4.27), 340	6.3 (4.36), 294	6.7 (4.32), 318
HADS Depression	7.3 (4.68), 429	7.6 (4.81), 463	7.4 (4.37), 323	7.5 (4.32), 341	7.1 (4.36), 294	7.5 (4.27), 320
SIS Strength[a]	42.4 (27.00), 414	45.7 (29.14), 440	48.1 (25.36), 294	49.0 (26.56), 318	48.7 (25.17), 275	50.2 (27.94), 303
SIS Activity[a]	43.6 (27.23), 431	46.3 (26.72), 466	54.2 (27.13), 324	53.6 (27.12), 345	56.5 (27.47), 296	54.1 (27.98), 324
SIS Mobility[a]	41.1 (29.29), 424	43.2 (29.06), 459	57.6 (28.32), 323	57.0 (27.50), 341	58.5 (27.96), 295	57.6 (27.60), 319
SIS Hand[a]	26.9 (33.00), 426	28.6 (34.02), 440	38.3 (35.93), 316	38.4 (36.09), 332	40.7 (36.35), 293	39.0 (36.32), 310
SIS Physical	39.7 (25.19), 434	42.3 (25.47), 466	51.7 (25.81), 323	51.6 (26.28), 342	53.3 (25.63), 295	52.0 (26.47), 320
SIS Memory	66.7 (29.85), 431	67.9 (29.74), 467	68.9 (27.58), 317	68.9 (28.11), 343	70.9 (27.79), 293	68.7 (27.04), 320
SIS Mood	69.0 (18.48), 425	69.7 (17.80), 462	69.3 (18.71), 316	67.9 (18.42), 338	68.5 (17.90), 285	67.4 (18.68), 318
SIS Communication	76.4 (28.02), 433	76.9 (28.85), 471	79.2 (24.72), 321	79.7 (25.09), 340	78.3 (25.19), 296	78.0 (25.90), 322
SIS Recover	45.5 (23.62), 382	49.2 (23.42), 403	52.6 (23.77), 255	53.1 (23.78), 293	54.3 (23.94), 245	54.6 (24.11), 274
SIS Social Participation[b]	N/A	N/A	49.3 (29.13), 307	50.0 (30.68), 329	52.9 (30.30), 286	52.3 (31.21), 309

N/A, not applicable.
a SIS Strength, Activity, Mobility and Hand domains are part of the SIS Physical domain.
b SIS Social Participation was not measured at baseline.

TABLE 34 Patients' adjusted questionnaire scores by arm at 6 months

Questionnaire	Intervention, mean (SE), *n*	Control, mean (SE), *n*	Difference (SE)	95% CI of the difference	*p*-value	Unadjusted ICC	Adjusted ICC
Barthel Index	14.2 (0.24), 323	14.1 (0.23), 346	0.1 (0.31)	–0.6 to 0.7	0.825	0.001	0.000
EQ-5D	0.441 (0.0170), 319	0.443 (0.0169), 334	–0.002 (0.0225)	–0.048 to 0.045	0.946	0.009	0.000
HADS Anxiety	6.7 (0.22), 323	6.6 (0.21), 340	0.1 (0.29)	–0.5 to 0.7	0.629	0.000	0.000
HADS Depression	7.3 (0.22), 323	7.2 (0.21), 341	0.1 (0.29)	–0.5 to 0.7	0.759	0.000	0.000
SIS Physical	52.7 (1.10), 323	52.0 (1.08), 342	0.7 (1.46)	–2.3 to 3.7	0.641	0.004	0.001
SIS Memory	70.1 (1.26), 317	70.4 (1.23), 343	–0.3 (1.66)	–3.7 to 3.1	0.836	0.000	0.000
SIS Mood	70.1 (0.99), 316	68.6 (0.96), 338	1.5 (1.30)	–1.1 to 4.2	0.244	0.000	0.000
SIS Communication	80.1 (1.07), 321	80.9 (1.05), 340	–0.8 (1.41)	–3.6 to 2.1	0.582	0.008	0.000
SIS Recover	54.0 (1.72), 255	53.9 (1.67), 293	0.1 (2.30)	–4.6 to 4.8	0.974	0.014	0.038
SIS Social Participation	49.5 (1.98), 307	50.6 (1.97), 329	–1.1 (2.67)	–6.6 to 4.4	0.683	0.025	0.026

TABLE 35 Patients' adjusted questionnaire scores by arm at 12 months

Questionnaire	Intervention, mean (SE), *n*	Control, mean (SE), *n*	Difference (SE)	95% CI of the difference	*p*-value	Unadjusted ICC	Adjusted ICC
NEADL	29.6 (0.98), 301	29.1 (0.95), 330	0.5 (1.30)	–2.2 to 3.2	0.696	0.002	0.015
Barthel Index	14.6 (0.25), 297	14.4 (0.24), 325	0.2 (0.33)	–0.5 to 0.8	0.595	0.002	0.000
EQ-5D	0.487 (0.0187), 287	0.458 (0.0184), 311	0.028 (0.0248)	–0.022 to 0.079	0.252	0.007	0.006
HADS Anxiety	6.4 (0.23), 294	6.6 (0.22), 318	–0.2 (0.30)	–0.9 to 0.3	0.355	0.000	0.000
HADS Depression	6.9 (0.25), 294	7.3 (0.25), 320	–0.4 (0.33)	–1.1 to 0.3	0.191	0.001	0.014
SIS Physical	54.5 (1.18), 295	52.0 (1.14), 320	2.4 (1.56)	–0.8 to 5.6	0.121	0.001	0.000
SIS Memory	71.8 (1.35), 293	69.3 (1.31), 320	2.5 (1.78)	–1.1 to 6.1	0.162	0.000	0.000
SIS Mood	68.6 (1.02), 285	67.2 (0.98), 318	1.4 (1.34)	–1.3 to 4.2	0.287	0.000	0.000
SIS Communication	79.7 (1.14), 296	78.5 (1.10), 322	1.3 (1.50)	–1.8 to 4.4	0.390	0.000	0.000
SIS Recover	56.1 (1.43), 245	55.4 (1.41), 274	0.8 (1.88)	–3.1 to 4.6	0.683	0.008	0.000
SIS Social Participation	53.4 (1.78), 286	52.5 (1.75) 309	0.9 (2.37)	–3.9 to 5.8	0.700	0.000	0.000

TABLE 36 Caregivers' secondary outcomes at different time points by arm

Caregivers' questionnaire scores: unadjusted means						
	Baseline		6 months		12 months	
Questionnaire	Intervention, mean (SD), *n*	Control, mean (SD), *n*	Intervention, mean (SD), *n*	Control, mean (SD), *n*	Intervention, mean (SD), *n*	Control, mean (SD), *n*
HADS Anxiety	8.3 (4.87), 442	8.0 (4.74), 470	7.1 (4.59), 318	7.5 (4.53), 334	7.2 (4.53), 286	7.4 (4.66), 311
HADS Depression	5.2 (4.25), 442	5.0 (3.89), 471	5.3 (4.12), 318	5.6 (4.33), 334	5.4 (4.27), 286	5.4 (4.19), 312
EQ-5D	0.797 (0.232), 438	0.791 (0.245), 471	0.785 (0.244), 317	0.781 (0.225), 333	0.809 (0.200), 284	0.769 (0.240), 312
FAI	32.9 (7.99), 441	33.5 (7.40), 470	31.5 (7.01), 321	32.3 (6.87), 333	31.8 (6.85), 286	32.4 (7.14), 313

CBS scores are in *Table 31*.

TABLE 37 Caregivers' adjusted questionnaire scores by arm at 6 months

Questionnaire	Intervention, mean (SE), *n*	Control, mean (SE), *n*	Difference (SE)	95% CI of the difference	*p*-value	Unadjusted ICC	Adjusted ICC
HADS Anxiety	7.0 (0.23), 318	7.5 (0.23), 334	–0.5 (0.30)	–1.2 to 0.1	0.084	0.013	0.016
HADS Depression	5.2 (0.22), 318	5.5 (0.22), 334	–0.3 (0.28)	–0.9 to 0.3	0.308	0.006	0.013
EQ-5D	0.777 (0.0114), 317	0.790 (0.0114), 333	–0.014 (0.0147)	–0.044 to 0.016	0.358	0.000	0.000
FAI	31.4 (0.40), 321	32.2 (0.40), 333	–0.8 (0.51)	–1.82 to 0.26	0.136	0.000	0.000

TABLE 38 Caregivers' adjusted questionnaire scores by arm at 12 months

Questionnaire	Intervention, mean (SE), *n*	Control, mean (SE), *n*	Difference (SE)	95% CI of the difference	*p*-value	Unadjusted ICC	Adjusted ICC
Total CBS score	44.8 (0.97), 291	43.8 (0.96), 314	1.0 (1.27)	–1.6 to 3.6	0.435	0.037	0.032
HADS Anxiety	6.9 (0.26), 286	7.0 (0.26), 311	–0.1 (0.34)	–0.9 to 0.5	0.636	0.018	0.024
HADS Depression	5.2 (0.22), 286	5.2 (0.22), 312	–0.0 (0.28)	–0.6 to 0.5	0.889	0.010	0.000
EQ-5D	0.806 (0.0122), 284	0.787 (0.0119), 312	0.019 (0.0154)	–0.013 to 0.050	0.240	0.000	0.000
FAI	31.9 (0.41), 286	32.6 (0.41), 313	–0.7 (0.52)	–1.7 to 0.4	0.217	0.022	0.000

TABLE 39 Number of training records completed

Training records completed	Registered (*N* = 450), *n* (%)
Yes	326 (72.4)
Confirmed not completed by site	96 (21.3)
Confirmed lost by site	27 (6.0)
Missing	1 (0.2)

TABLE 40 Intervention compliant records

SRU	Registered patients	Intervention compliant, *n* (%)
Intervention	450	196 (43.6)
1	20	0 (0.0)
2	21	13 (61.9)
3	24	16 (66.7)
4	30	11 (36.7)
5	32	0 (0.0)
6	32	2 (6.3)
7	27	8 (29.6)
8	23	20 (87.0)
9	29	22 (75.9)
10	25	3 (12.0)
11	16	14 (87.5)
12	35	3 (8.6)
13	14	13 (92.9)
14	35	25 (71.4)
15	19	7 (36.8)
16	17	13 (76.5)
17	25	6 (24.0)
18	26	20 (76.9)

TABLE 41 Number of mandatory components achieved

No. of components achieved	Registered (*N* = 450), *n* (%)	Cumulative, *n* (%)
6	96 (21.3)	96 (21.3)
5	56 (12.4)	152 (33.8)
4	31 (6.9)	183 (40.7)
3	34 (7.6)	217 (48.2)
2	29 (6.4)	246 (54.7)
1	28 (6.2)	274 (60.9)
0[a]	52 (11.6)	326 (72.4)
Missing	124 (27.6)	450 (100.0)

a Training record was returned, but the information on mandatory components achieved was not completed.

Intervention compliance and participant outcomes

The relationship between centre-level compliance with the intervention and mean patient NEADL score at 6 months is displayed in *Figure 7* and mean caregiver CBS score at 6 months is in *Figure 8*. The tables show no evidence of higher levels of patient independence or lower level of caregiver burden in the SRUs with better levels of intervention compliance.

Control group compliance

A summary of the numbers of time logs completed by MDTs in control SRUs is shown in *Table 42* and by site in *Appendix 8* (see *Table 77*).

Time spent with caregivers

The overall time spent with caregivers was similar in the two groups [median of 118 minutes (range 10 to 900 minutes) in the intervention group (training records) and 133 minutes (range 1 to 1130 minutes) in control group (time logs)] (*Table 43*; *Figures 9* and *10*).

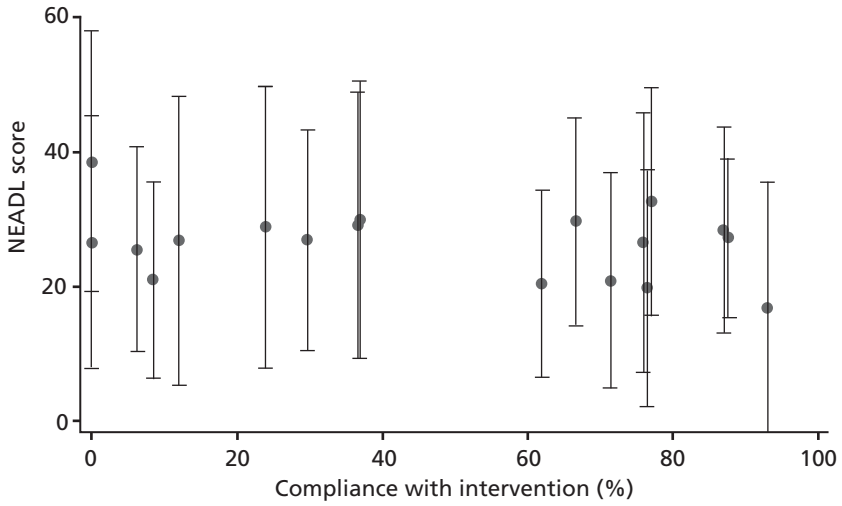

FIGURE 7 Nottingham Extended Activities of Daily Living scores at 6 months and site compliance with intervention. Plot of means with SD bars.

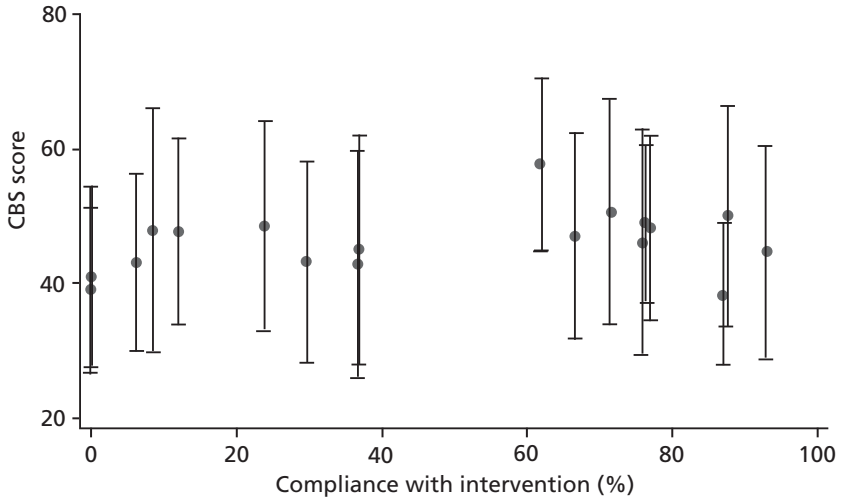

FIGURE 8 Caregiver Burden Scale scores at 6 months and site compliance with intervention. Plot of means with SD bars.

TABLE 42 Number of time logs completed

Time logs completed	Registered (*N* = 478), *n* (%)
Yes	211 (44.1)
No	5 (1.0)
Not required	174 (36.4)
Confirmed not completed by site	79 (16.5)

TABLE 43 Time spent with caregiver

Time spent with caregiver (minutes)	Intervention	Control
n	214	180
Mean (SD)	136.5 (118.12)	200.3 (189.12)
Median (range)	117.5 (10–900)	132.5 (1–1130)
Missing	236	298

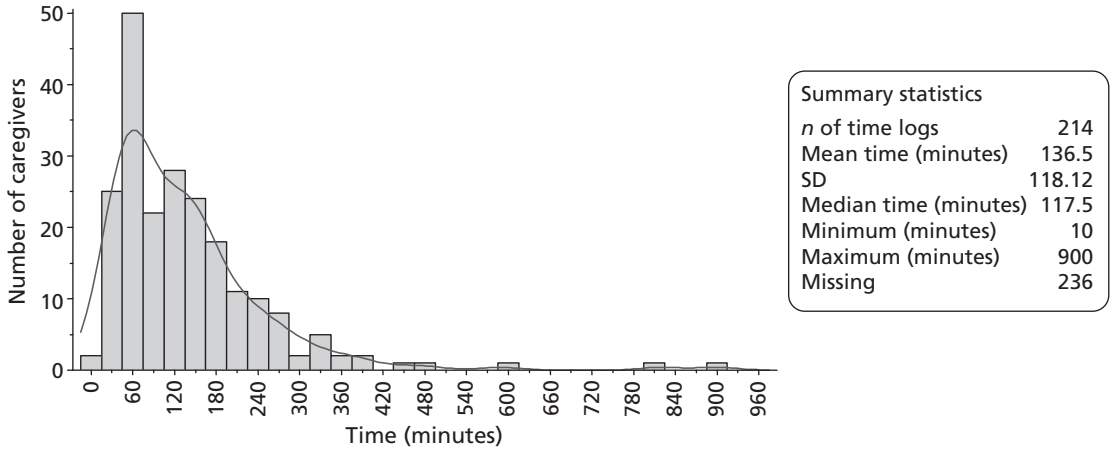

FIGURE 9 Overall time spent with caregiver: intervention.

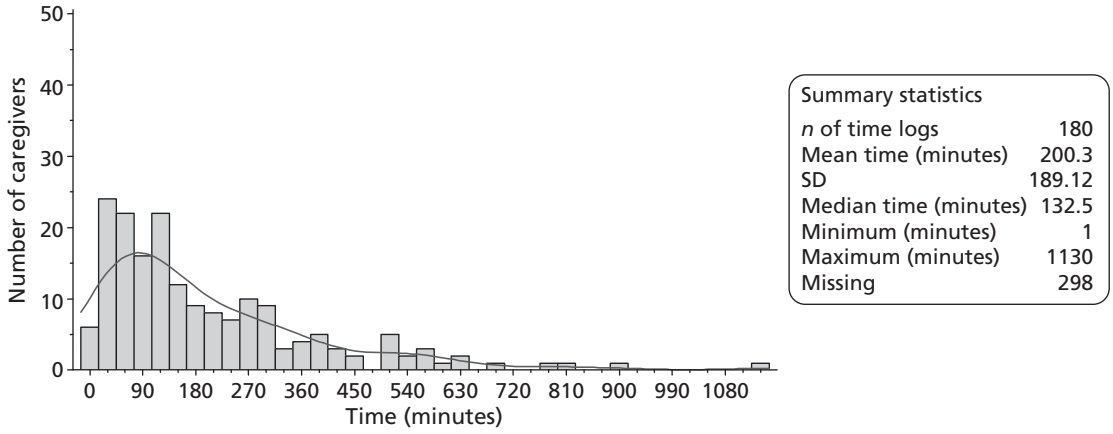

FIGURE 10 Overall time spent with carergiver: control.

Patient safety: expected adverse events/serious adverse events

Falls

Summaries of the number of patients with falls, number of reported patients' falls and number of SAEs by arm are shown in *Table 44* (and by SRUs in *Appendix 8*, *Table 78*). In each group there were 35 patients who fell one or more times. The mean number of falls per patient who fell was 1.4 (SE 0.88) in the intervention group and 1.2 (SE 0.76) in the control group. Two falls in the intervention group and three in the control group resulted in SAEs.

No RUSAEs were reported.

Deaths

The numbers of patients' and caregivers' deaths by treatment arm are shown in *Table 45*. There were 12 patients that died before discharge; six in each group. There were 41 (9.1%) patient deaths in the

TABLE 44 Summaries of patients' falls between registration and discharge

Summaries of patients' falls between registration and discharge	Intervention (*N* = 45)	Control (*N* = 478)
Missing form, *n* (%)	1 (0.2)	0 (0.0)
No. of discharge forms received, *n* (%)	449 (99.8)	478 (100.0)
No. of patients who fell one or more times, *n* (%)	35 (7.8)	35 (7.3)
No. of reported falls	50	42
Mean no. (SE) of falls	1.4 (0.88)	1.2 (0.76)
Median	1.0	1.0
Range	(1–5)	(1–5)
No. of reported SAEs	2	3
Mean no. (SE) of falls that resulted in SAEs (of those who fell)	0.1 (0.24)	0.1 (0.28)
Median	0.0	0.0
Range	(0–1)	(0–1)

TABLE 45 Patient and caregiver deaths between registration and the end of 6- and 12-month follow-up

Deaths	Intervention (*N* = 450), *n* (%)	Control (*N* = 478), *n* (%)
No. of patient deaths		
6 months	41 (9.1)	35 (7.3)
12 months	12 (2.7)	20 (4.2)
No. of caregiver deaths		
6 months	2 (0.4)	1 (0.2)
12 months	4 (0.9)	3 (0.6)
Overall		
No. of patient deaths	53 (11.8)	55 (11.5)
No. of caregiver deaths	6 (1.3)	4 (0.8)

After the patient's death, the caregiver was not followed up.

intervention group and 35 (7.3%) in the control group by 6 months and a further 12 (2.7%) in intervention and 20 (4.2%) in control by 12 months.

Overall, six (1.3%) caregivers deaths in intervention and four (0.8%) in control were reported. If the patient died, the caregiver was no longer followed up.

Process data

A summary of the process data collected by the trial manager on the visits before (2007) and after (2009/2010) recruitment at both control and intervention centres is provided in *Appendix 8*, *Table 85*. Data collected during recruitment (2008) did not vary from that collected after recruitment had completed. The organisational structure and the process of care on the majority of stroke units did not change significantly throughout the trial. Significant changes to the standard process of care of involving patients and their carers during the inpatient stay was seen in just one centre. Four other centres experienced significant changes to their organisational structure, which did not impact upon the process of care of involving patients and their caregivers. A brief description of these centres is provided in *Appendix 8*, *Table 86*.

Chapter 5 Economic evaluation

Client Service Receipt Inventory and European Quality of Life-5 Dimensions completion rates

Tables 46 and *47* summarise CSRI and EQ-5D completion rates, respectively, at each assessment point. Both measures had similar completion rates at each assessment point and rates were balanced between the intervention and control arms. *Table 48* characterises subsamples with both cost and outcome data at 6 months, a necessary requirement for inclusion in the CEAC-based analyses. Although differences were not explored statistically, the baseline characteristics of patients and caregivers with the necessary data at 6 months appeared similar to those of the full sample. Therefore, results based on those followed up are likely to generally be representative of the full sample.

Resource use

Resource-use differences were not compared statistically, firstly because the economic evaluation was focused on costs and cost-effectiveness and, secondly, to avoid problems associated with multiple testing. Therefore, resource-use patterns are described without statistical comparisons.

Tables 49–54 show resource use at each assessment point. These tables are limited to inpatient services plus other items used by at least 10% of responders in either trial arm at that time point. Full resource-use data are provided in *Appendix 9*. The length of the initial stroke admission was similar in both groups (see *Table 50*). Other resource use also appeared broadly comparable between the two groups at baseline, 6 months and 12 months. As could be expected, patients' use of inpatient services (other than the stroke admission), outpatient services, hospital physiotherapy and hospital occupational therapy increased during the post-stroke period compared with baseline. It is also interesting to note that caregiver's use of inpatient and outpatient services increased notably during the post-stroke period. With regards to community-based services, patients most commonly used dentist, chiropodist and optician services at all three time points. Services most used by caregivers were outpatient services, GP, practice nurse and repeat prescriptions. In comparison with formal care inputs, patient informal care rates were very high. Care to patients from non-resident informal caregivers increased at each time point.

Costs and quality-adjusted life-years

The mean cost of the LSCTC training and development was £39 (*Table 55*). This is the mean across the whole intervention group, including those allocated zero costs for either receiving no LSCTC inputs or with missing data regarding such inputs. The mean cost among only those receiving inputs was £82.

The mean cost of the initial stroke admission was similar between groups (mean difference £1243, 95% CI –£1533 to £4019; see *Table 55*). Total health and social care and societal costs were broadly similar between both randomisation groups at all assessment points (*Tables 56–58*), except that caregivers in the intervention arm had higher health and social care costs at 6 months (+£207, 95% CI £5 to £408; see *Table 58*). This difference was no longer present at 12 months and was not apparent when costs from the two assessment points were combined as 1-year costs. There were also no differences in QALYs for patients or caregivers at any of the assessment points (*Table 59*). Although the direction of the between-group difference is opposite in the patient (positive) and caregiver (negative) evaluations the mean differences are so small that they are essentially zero. It should also be noted that comparisons of costs and outcomes do not account for the correlation between these parameters.

TABLE 46 Client Service Receipt Inventory completion rates

Patients			Caregivers		
Baseline *n* (%)	6 months *n* (%)	12 months *n* (%)	Baseline *n* (%)	6 months *n* (%)	12 months *n* (%)
***Intervention* (n = *450*)**					
442 (98)	327 (73)	298 (66)	442 (98)	327 (73)	286 (64)
***Control* (n = *478*)**					
474 (99)	348 (73)	327 (68)	474 (99)	340 (71)	313 (66)
***Total* (n = *928*)**					
916 (99)	675 (73)	625 (67)	916 (99)	667 (72)	599 (65)

TABLE 47 European Quality of Life-5 Dimensions completion rates

Patients			Caregivers		
Baseline *n* (%)	6 months *n* (%)	12 months *n* (%)	Baseline *n* (%)	6 months *n* (%)	12 months *n* (%)
***Intervention* (n = *450*)**					
426 (95)	319 (71)	287 (64)	438 (97)	323 (72)	284 (63)
***Control* (n = *478*)**					
459 (96)	337 (71)	311 (65)	471 (99)	338 (71)	313 (65)
***Total* (n = *928*)**					
885 (95)	656 (71)	598 (64)	909 (98)	661 (71)	597 (64)

TABLE 48 Baseline characteristics of the full sample and subsamples included in the 6-month analyses

	Full sample (*n* = 928)		Subsample with both costs and NEADL data at 6 months (*n* = 663)		Subsample with both costs and QALY data at 6 months: (*n* = 630)	
Baseline characteristics	Valid *n*		Valid *n*		Valid *n*	
Patients						
Age (years), mean	928	71	663	71	630	71
Male, *n* (%)	928	519 (56)	663	384 (58)	630	365 (58)
Baseline NEADL total score	917	52.15	659	53.53	–	–
Baseline utility score	885	0.37	–	–	630	0.40
	Full sample (*n* = 928)		Subsample with both costs and CBS data at 6 months (*n* = 652)		Subsample with both costs and QALY data at 6 months (*n* = 649)	
	Valid *n*		Valid *n*		Valid *n*	
Caregivers						
Age (years), mean	928	61	652	62	649	62
Female, *n* (%)	928	635 (68)	652	448 (69)	649	444 (68)
Baseline utility score	909	0.79	–	–	649	0.80

TABLE 49 Patient resource use at baseline (for previous 3 months)[a]

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[b]	SD	*N* users/valid *n*	Mean[b]	SD
Inpatient services	Bed-days	42/441	14	21	67/472	11	14
Outpatient services	Activities/visits	111/437	2	2	126/466	2	3
Community-based services							
GP							
Surgery visit	Visits	225/408	2	2	251/428	2	2
Practice nurse							
Surgery visit	Visits	111/383	2	1	124/392	2	2
Repeat prescription	Occurrences	235/393	3	1	294/417	2	2
Chiropodist	Contacts	58/411	2	1	63/436	2	2
Dentist	Contacts	61/410	1	1	65/433	2	1
Optician	Contacts	62/408	1	< 1	79/431	1	1
Informal care from co-residents							
Personal care	Hours	55/427	170	361	67/458	203	419
Providing transport	Hours	83/430	101	322	94/453	83	151
Preparing meals	Hours	110/429	156	258	127/454	125	111
Housework/laundry	Hours	110/426	111	260	113/458	98	112
DIY	Hours	53/420	127	446	68/446	40	47
Gardening	Hours	87/423	73	289	90/447	45	57
Shopping	Hours	117/429	77	247	130/453	55	51
Outings	Hours	82/428	106	327	92/447	60	48
Socialising	Hours	104/427	270	387	128/451	407	576
Help managing finances	Hours	99/430	64	275	104/455	37	34
Informal care from non-residents							
Providing transport	Hours	43/421	32	44	63/443	38	52
Housework/laundry	Hours	38/423	48	65	52/443	43	56
Gardening	Hours	26/421	21	21	50/437	19	21
Shopping	Hours	46/423	32	32	57/441	28	27
Outings	Hours	45/423	36	50	57/441	41	39
Socialising	Hours	53/419	113	196	69/442	140	343

a Inpatient services plus other items used by at least 10% of either group.
b Mean for valid users only.

TABLE 50 Patient resource use at 6 months (in previous 6 months)[a]

Resource	Unit	Intervention (*N* = 450)			Control (*N* = 478)		
		N users/valid *n*	Mean[b]	SD	*N* users/valid *n*	Mean[b]	SD
Initial stroke admission	Bed-days	448/448	45	33	478/478	42	29
Other inpatient services	Bed-days	56/319	12	22	65/338	8	10
A&E	Occurrences	52/311	2	1	63/338	1	1
Outpatient services	Activities/visits	178/308	3	4	158/328	3	5
Physiotherapist, hospital[c]	Visits	97/258	9	16	114/289	9	78
Occupational therapist, hospital[c]	Visits	30/235	4	3	50/267	8	12
Community-based services							
GP							
Surgery visit	Visits	177/270	3	2.	202/301	3	2
Home visit	Visits	124/252	2	2	135/267	2	2
Telephone call	Calls	85/230	2	1	95/247	2	2
Practice nurse							
Surgery visit	Visits	116/241	3	3	116/250	3	3
Physiotherapist							
Home visit	Visits	159/264	9	8	158/285	11	11
Occupational therapist							
Home visit	Visits	164/270	8	9	144/284	6	8
Speech and language therapist							
Home visit	Visits	65/262	7	8	65/271	7	6
Social worker							
Home visit	Visits	65/274	2	2	70/297	2	2
Telephone call	Calls	31/274	4	2	49/297	3	1
Repeat prescription	Occurrences	208/264	5	3	253/288	5	3
Community/district nurse	Contacts	112/261	5	4	108/277	6	7
Chiropodist	Contacts	60/242	2	1	84/274	2	1
Dentist	Contacts	58/243	2	1	79/261	2	1
Optician	Contacts	66/247	1	1	92/264	2	1
Home help personal care	Visits	71/275	87	134	70/297	81	117
Informal care from co-residents							
Personal care	Hours	206/302	226	332	211/317	324	449
Providing transport	Hours	190/286	130	223	193/304	138	159
Preparing meals	Hours	224/295	286	292	237/316	305	213
Housework/laundry	Hours	228/299	220	293	239/313	238	198
DIY	Hours	119/272	108	321	139/300	67	90
Gardening	Hours	159/284	91	228	166/304	73	69
Shopping	Hours	225/300	108	202	231/315	133	116

TABLE 50 Patient resource use at 6 months (in previous 6 months)[a] (*continued*)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[b]	SD	*N* users/valid *n*	Mean[b]	SD
Outings	Hours	182/288	127	223	187/310	132	122
Socialising	Hours	213/289	980	1293	213/307	775	936
Help managing finances	Hours	205/296	90	212	203/312	125	267
Informal care from non-residents							
Personal care	Hours	52/281	83	168	59/308	133	143
Providing transport	Hours	102/282	50	113	118/311	45	55
Preparing meals	Hours	53/278	28	28	57/305	95	131
Housework/laundry	Hours	54/279	55	62	67/305	101	103
DIY	Hours	56/274	27	30	48/303	36	59
Gardening	Hours	61/276	26	22	56/304	25	31
Shopping	Hours	75/280	45	64	81/306	52	44
Outings	Hours	96/285	47	69	86/305	67	82
Socialising	Hours	113/281	105	138	110/300	122	141
Help managing finances	Hours	43/278	29	20	53/304	62	93

a Inpatient services plus other items used by at least 10% of either group.
b Mean for valid users only.
c Separate to other outpatient visits.

TABLE 51 Patient resource use at 12 months (in previous 6 months)[a]

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[b]	SD	*N* users/valid *n*	Mean[b]	SD
Inpatient services	Bed-days	43/288	9	12	58/312	9	12
A&E	Occurrences	48/284	2	1	52/311	2	1
Outpatient services	Activities/ visits	126/281	3	2	130/310	3	3
Physiotherapist, hospital[c]	Visits	61/244	9	8	58/284	9	7
Community-based services							
GP							
Surgery visit	Visits	167/246	3	2	197/276	3	2
Home visit	Visits	86/227	2	2	86/237	2	2
Telephone call	Calls	56/202	2	2	69/232	3	4
Practice nurse							
Surgery visit	Visits	110/223	2	3	135/248	3	3
Physiotherapist							
Home visit	Visits	54/232	8	11	44/265	6	8
Repeat prescription	Occurrences	191/234	5	4	226/265	5	3
Community/district nurse	Contacts	67/233	6	8	82/275	6	9

continued

TABLE 51 Patient resource use at 12 months (in previous 6 months)[a] (*continued*)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[b]	SD	*N* users/valid *n*	Mean[b]	SD
Chiropodist	Contacts	78/241	2	1	80/273	2	2
Dentist	Contacts	84/231	2	1	73/259	2	1
Optician	Contacts	69/223	2	1	75/261	1	1
Informal care from co-residents							
Personal care	Hours	153/263	256	376	170/285	319	352
Providing transport	Hours	139/253	110	104	158/281	150	146
Preparing meals	Hours	175/263	281	157	206/287	318	216
Housework/laundry	Hours	170/258	207	159	200/280	185	154
DIY	Hours	97/247	46	45	116/268	56	61
Gardening	Hours	123/250	74	87	134/273	73	87
Shopping	Hours	174/257	101	85	183/279	115	93
Outings	Hours	143/251	113	102	152/277	138	135
Socialising	Hours	163/251	646	694	165/282	866	1000
Help managing finances	Hours	161/259	145	491	163/283	76	80
Informal care from non-residents							
Providing transport	Hours	73/254	50	47	86/284	40	52
Preparing meals	Hours	39/255	70	59	50/286	91	137
Housework/laundry	Hours	40/255	82	65	60/287	88	107
Gardening	Hours	50/251	27	24	52/281	46	74
Shopping	Hours	44/256	59	62	70/287	43	43
Outings	Hours	63/256	39	48	79/287	42	60
Socialising	Hours	77/252	124	149	90/286	114	168

a Inpatient services plus other items used by at least 10% of either group.
b Mean for valid users only.
c Separate to other outpatient visits.

TABLE 52 Caregiver resource use at baseline (in previous 3 months)[a]

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[b]	SD	*N* users/valid *n*	Mean[b]	SD
Inpatient services	Bed-days	7/440	< 1	1	16/470	< 1	4
Outpatient services	Activities/visits	88/440	2	2	92/470	2	2
Community-based services							
GP							
Surgery visit	Visits	199/425	2	1	228/460	2	1
Practice nurse							
Surgery visit	Visits	120/404	2	1	101/430	2	3
Repeat prescription	Occurrences	214/415	2	1	229/443	2	1
Informal care provided to patient							
Personal care	Hours	72/420	117	173	105/451	83	107
Providing transport	Hours	141/419	58	98	158/448	58	72
Preparing meals	Hours	228/426	104	96	240/455	124	209
Housework/laundry	Hours	229/421	77	114	254/452	87	113
DIY	Hours	88/412	35	79	101/442	30	44
Gardening	Hours	159/423	32	64	158/451	34	35
Shopping	Hours	233/422	44	59	264/452	45	50
Outings	Hours	140/414	60	87	163/443	65	83
Socialising	Hours	239/425	281	409	269/448	274	400
Help managing finances	Hours	175/425	27	57	193/450	35	46

a Inpatient services plus other items used by at least 10% of either group.
b Mean for valid users only.

TABLE 53 Caregiver resource use at 6 months (in previous 6 months)[a]

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[b]	SD	*N* users/valid *n*	Mean[b]	SD
Inpatient services	Bed-days	20/320	< 1	2	15/335	< 1	1
Outpatient services	Activities/visits	83/315	3	3	93/326	3	2
Community-based services							
GP							
Surgery visit	Visits	176/290	3	2	197/318	3	2
Practice nurse							
Surgery visit	Visits	116/267	2	2	111/287	2	2
Repeat prescription	Occurrences	152/273	4	2	178/299	5	3
Informal care provided to patient							
Personal care	Hours	238/306	222	332	243/323	370	601
Providing transport	Hours	201/295	140	220	201/309	144	172
Preparing meals	Hours	282/310	253	239	295/330	286	227
Housework/laundry	Hours	278/310	182	202	295/325	218	223
DIY	Hours	130/285	99	311	151/290	56	62
Gardening	Hours	181/294	82	210	196/307	64	71
Shopping	Hours	281/307	109	182	297/321	111	107
Outings	Hours	205/293	114	204	214/310	123	132
Socialising	Hours	271/303	741	984	262/317	679	1023
Help managing finances	Hours	258/309	70	172	268/317	72	96

a Inpatient services plus other items used by at least 10% of either group.
b Mean for valid users only.

TABLE 54 Caregiver resource use at 12 months (in previous 6 months)[a]

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	**Unit**	***N* users/valid *n***	**Mean[b]**	**SD**	***N* users/valid *n***	**Mean[b]**	**SD**
Inpatient services	Bed-day	18/282	< 1	2	15/306	< 1	3
Outpatient services	Activities/visits	71/275	3	3	82/303	2	2
Community-based services							
GP							
Surgery visit	Visits	151/263	2	2	191/290	2	2
Practice nurse							
Surgery visit	Visits	105/239	2	1	124/263	2	2
Repeat prescription	Occurrences	139/238	4	2	164/264	4	2
Informal care provided to patient							
Personal care	Hours	187/256	244	346	207/288	279	398
Providing transport	Hours	173/251	108	107	188/279	150	149
Preparing meals	Hours	243/265	265	197	265/296	298	206
Housework/laundry	Hours	229/260	195	181	257/289	192	179
DIY	Hours	129/241	47	70	136/268	47	48
Gardening	Hours	155/252	70	87	182/280	77	136
Shopping	Hours	233/257	107	96	259/286	150	252
Outings	Hours	181/244	104	103	196/280	147	149
Socialising	Hours	229/256	644.	767	234/282	667	883
Help managing finances	Hours	222/264	61	88	225/290	84	107

a Inpatient services plus other items used by at least 10% of either group.
b Mean for valid users only.

TABLE 55 Patients: mean costs by resource category at baseline (for the previous 3 months), 6 months (previous 6 months) and 12 months [previous 6 months (£, 2009–10 prices)]

	Intervention ($n = 450$)			Control ($n = 478$)			Intervention – control[a]		
Resource	Valid *n*	Mean	SD	Valid *n*	Mean	SD	Mean difference	95% CI	*p*-value
LSCTC development and staff training	450	39	64	478	0	–	41	26 to 57	0.000
Stroke admission	450	13,127	9670	478	12,471	8666	1243	–1533 to 4019	0.380
Institutionalisation									
Baseline	442	11	209	474	18	231	–7	–36 to 21	0.608
6 months	327	274	1516	348	159	619	137	–32 to 306	0.113
12 months	298	162	631	327	194	785	–17	–129 to 95	0.766
Secondary care									
Baseline	442	625	2832	474	824	2892	–199	–670 to 173	0.294
6 months	327	1150	3547	348	1121	2541	56	–410 to 522	0.813
12 months	298	822	2027	327	986	2468	–124	–522 to 273	0.540
Community-based services									
Baseline	442	208	500	474	206	450	2	–59 to 64	0.946
6 months	327	1380	1777	348	1317	1652	57	–260 to 373	0.726
12 months	298	1042	1690	327	1267	2418	–212	–689 to 265	0.383
Other health and social care services									
Baseline	442	10	107	474	6	53	4	–7 to 15	0.451
6 months	327	9	45	348	26	260	–18	–47 to 11	0.221
12 months	298	9	66	327	19	140	–12	–34 to 9	0.269
Informal care									
Baseline	442	2390	10,102	474	2086	3698	304	–668 to 1277	0.539
6 months	327	11,033	11,783	348	10,841	8721	300	–1216 to 1817	0.698
12 months	298	8404	9126	327	9323	8582	–872	–2449 to 704	0.278

a Comparisons of 6- and 12-month costs includes covariates for the baseline value of the same cost category, baseline age, baseline NEADL score and sex.

TABLE 56 Caregivers: mean costs by resource category at baseline (for the previous 3 months), 6 months (previous 6 months) and 12 months [previous 6 months (£, 2009–10 prices)]

	Intervention ($n = 450$)			Control ($n = 478$)			Intervention – control[a]		
Resource	Valid *n*	Mean	SD	Valid *n*	Mean	SD	Mean difference	95% CI	*p*-value
LSCTC development and staff training	450	39	64	478	0	–	41	26 to 57	0.000
Institutionalisation									
Baseline	Not assessed at baseline			Not assessed at baseline					
6 months	327	0	–	340	0	–	–	–	–
12 months	286	0	–	313	1	6	–1	–2 to 0.4	0.248
Secondary care									
Baseline	442	109	373	474	373	4130	–276	–661 to 109	0.161
6 months	327	364	1719	340	209	616	166	–30 to 362	0.096
12 months	286	241	935	313	284	1331	–31	–217 to 155	0.742
Community-based services									
Baseline	442	61	91	474	62	94	–1	–13 to 11	0.835
6 months	327	118	157	340	123	151	–5	–37 to 28	0.781
12 months	286	100	132	313	116	141	–16	–39 to 8	0.196
Informal care									
Baseline	442	2570	4166	474	2606	3042	–49	–518 to 419	0.836
6 months	327	10,626	8950	340	10,949	8836	–145	–1471 to 1180	0.830
12 months	286	9370	7094	313	10,055	7125	–643	–1758 to 471	0.258

a Comparisons of 6- and 12-month costs includes covariates for the baseline value of the same cost category, baseline age and sex.

TABLE 57 Patients: mean total costs at baseline (for the previous 3 months), 6 months (previous 6 months), 12 months (previous 6 months) and over 1 year (£, 2009–10 prices)

	Intervention ($n = 450$)			Control ($n = 478$)			Intervention – control[a]		
Costs	Valid *n*	Mean	SD	Valid *n*	Mean	SD	Mean difference	95% CI	*p*-value
Total health and social care									
Baseline	442	855	2974	474	1054	2975	–200	–585 to 186	0.310
6 months[b]	327	15,861	11,565	348	15,541	10,234	1184	–1505 to 3872	0.388
12 months	298	2037	2804	327	2465	4041	–347	–1119 to 425	0.378
1 year[b]	272	17,406	12,741	298	17,752	12,235	563	–2986 to 4112	0.756
Total societal									
Baseline	442	3243	10,642	474	3140	4952	105	–959 to 1168	0.847
6 months[b]	327	26,894	16,832	348	26,381	14,274	1127	–1681 to 3935	0.432
12 months	298	10,440	9889	327	11,788	9738	–1234	–2953 to 485	0.159
1 year[b]	272	37,453	23,667	298	37,884	19,993	167	–4163 to 4497	0.940

a Comparisons of 6- and 12-month costs includes covariates for the baseline value of the same cost category, baseline age, baseline NEADL score and sex.
b Including the cost of LSCTC development and staff training and the initial stroke admission.

TABLE 58 Caregivers: mean total costs at baseline (for the previous 3 months), 6 months (previous 6 months), 12 months (previous 6 months) and over 1 year (£, 2009–10 prices)

	Intervention ($n = 450$)			Control ($n = 478$)			Intervention – control[a]		
Costs	Valid *n*	Mean	SD	Valid *n*	Mean	SD	Mean difference	95% CI	*p*-value
Total health and social care									
Baseline	442	170	396	474	435	4131	–277	–663 to 108	0.159
6 months[b]	327	525	1756	340	331	672	207	5 to 408	0.045
12 months	286	341	993	313	401	1375	–47	–241 to 147	0.636
1 year[b]	268	785	1604	285	708	1785	96	–186 to 379	0.505
Total societal									
Baseline	442	2741	4204	474	3041	5057	–327	–926 to 273	0.286
6 months[b]	327	11,151	9084	340	11,280	8902	99	–1248 to 1446	0.885
12 months	286	9711	7119	313	10,455	7247	–644	–1777 to 489	0.265
1 year[b]	268	21,147	14,434	285	22,024	13,774	–574	–3112 to 1964	0.658

a Comparisons of 6- and 12-month costs includes covariates for the baseline value of the same cost category, baseline age and sex.
b Including the cost of LSCTC development and training.

TABLE 59 Patients and caregivers: utility scores and QALYs[a]

	Intervention ($n=450$)			Control ($n=478$)			Intervention – control[b]		
QALYs	Valid *n*	Mean	SD	Valid *n*	Mean	SD	Mean difference	95% CI	*p*-value
Patients, utility scores									
Baseline	426	0.36	0.37	459	0.40	0.36	–0.02	–0.08 to 0.04	0.538
6 months	319	0.44	0.34	337	0.44	0.35	0.00	–0.04 to 0.05	0.835
12 months	287	0.47	0.35	311	0.46	0.34	0.03	–0.02 to 0.08	0.290
Patients to QALYs									
6 months	309	0.21	0.16	324	0.21	0.15	0.00	–0.01 to 0.01	0.835
12 months	258	0.24	0.16	276	0.23	0.16	0.01	–0.01 to 0.03	0.443
1 year	249	0.46	0.30	266	0.45	0.30	0.01	–0.02 to 0.05	0.520
Caregivers to utility scores									
Baseline	438	0.80	0.23	471	0.79	0.25	0.01	–0.03 to 0.04	0.660
6 months	323	0.78	0.24	338	0.78	0.23	–0.02	–0.04 to 0.01	0.239
12 months	284	0.81	0.20	313	0.77	0.24	0.02	–0.01 to 0.05	0.236
Caregivers to QALYs									
6 months	317	0.40	0.10	333	0.39	0.11	–0.00	–0.01 to 0.0	0.239
12 months	262	0.40	0.10	283	0.39	0.11	–0.00	–0.01 to 0.01	0.950
1 year	257	0.80	0.19	279	0.78	0.20	–0.00	–0.02 to 0.02	0.674

a Available case analysis excluding those who died or were lost to follow-up.

b Comparisons of 6- and 12-month costs includes covariates for baseline utility score, baseline age, and sex (and baseline NEADL score for patients).

Sensitivity analyses

All sensitivity analyses confirmed conclusions from the base-case conclusions except for sensitivity analysis 2, adopting the replacement cost approach for informal care, which led to the between group difference in mean societal costs for caregivers changing from £99 to –£831. However, although the direction of difference changed, the difference between groups remained statistically non-significant. Substituting the base-case value with this new value for the consideration of related ICERs (*Table 60*) would result in the intervention group dominating the control group based on CBS scores (the only case of the intervention group's dominance at the primary end point of 6 months) and an unlikely trade-off of lower costs for fewer QALYs.

TABLE 60 Sensitivity analyses

	Intervention ($n = 450$)			Control ($n = 478$)			Intervention – control[a]		
Analysis	Valid *n*	Mean	(SD)	Valid *n*	Mean	(SD)	Mean difference	95% CI	*p*-value
Sensitivity analysis 1: effect on total health and social care costs at 6 months of imputing missing LSCTC costs									
Patient base case	327	15,861	11,565	348	15,541	10,234	1184	–1505 to 3872	0.388
Patient sensitivity analysis	327	15,904	11,560	348	15,541	10,234	1126	–1464 to 3916	0.372
Caregiver base case	327	525	1756	340	331	672	207	5 to 408	0.045
Caregiver sensitivity analysis	327	568	1758	340	331	672	249	47 to 451	0.015
Sensitivity analysis 2: effect on total societal costs at 6 months of adopting the replacement cost approach for informal care									
Patient base case	327	26,894	16,832	348	26,381	14,274	1127	–1681 to 3935	0.432
Patient sensitivity analysis	327	60,386	45,696	348	59,066	37,289	1860	–4377 to 8097	0.559
Caregiver base case	327	11,151	9084	340	11,280	8902	99	–1248 to 1446	0.885
Caregiver sensitivity analysis	327	43,117	34,614	340	44,759	31,573	–831	–6886 to 5224	0.788
Sensitivity analysis 3: effect on total health and social care costs at 6 months of imputing missing cost data at 6 months									
Patient base case	327	15,861	11,565	348	15,541	10,234	1184	–1505 to 3872	0.388
Patient sensitivity analysis	450	15,875	9857	478	15,550	8736	995	–1275 to 3267	0.390
Caregiver base case	327	525	1756	340	331	672	207	5 to 408	0.045
Caregiver sensitivity analysis	450	536	1497	478	348	702	207	62 to 353	0.005
Sensitivity analysis 4: effect on total QALYs at 6 months of imputing missing QALYs at 6 months									
Patient base case	309	0.21	0.16	324	0.21	0.15	0.00	–0.01 to 0.01	0.835
Patient sensitivity analysis	450	0.20	0.15	478	0.20	0.15	0.00	–0.01 to 0.01	0.744
Caregiver base case	317	0.40	0.10	333	0.39	0.11	–0.00	–0.01 to 0.00	0.239
Caregiver sensitivity analysis	450	0.39	0.10	478	0.39	0.11	–0.00	–0.01 to .000	0.098

a Comparisons of 6-month costs includes covariates for the baseline value of the same cost category or outcome, baseline age and sex (and baseline NEADL score for patients).

Cost-effectiveness and cost–utility

Of the 16 cost–outcome combinations examined for the cost-effectiveness and cost–utility analyses, none was based on statistically significant between-group differences for both cost and outcome elements. The intervention group 'dominated' in seven combinations, the control group 'dominated' in five, the intervention group had both higher costs and better outcomes in nine, and the remaining three involved an unlikely trade-off of lower costs for worse outcomes. Where relevant, indicative ICERs are presented for information (*Table 61*), but these and the term 'dominates' should be interpreted with caution for most combinations given the small magnitude and lack of statistical significance in differences in costs or outcomes except for caregivers having higher health and social care costs at 6 months. ICERs ranged from £96 for an additional point improvement on the CBS based on 1-year health and social care costs for caregivers to £1.18M for an additional patient QALY based on their health and social care costs at 6 months.

Cost-effectiveness planes show that although differences in patient health and social care costs, NEADL scores (*Figure 11*) and QALYs (*Figure 12*) between the two groups do vary around the point estimates, they are strongly centred around zero, i.e. no difference in either costs or outcomes. In contrast, the caregiver cost-effectiveness planes suggest that health and social care costs are higher in the intervention group and, while CBS differences are clustered around zero (i.e. no difference; *Figure 13*), QALYs differences are clustered to the left of zero (i.e. lower in the intervention group; *Figure 14*).

Figures 15–18 show probabilities that the intervention group is cost-effective compared with the control group. In the patient evaluation, probabilities of cost-effectiveness were similar from both cost perspectives. Maximum probabilities of cost-effectiveness for the threshold ranges examined for each outcome measure were 51% at £2000 for an additional point improvement on the NEADL scale (see *Figure 15*)

TABLE 61 Patients and caregivers: ICERs for intervention over control at 6 months and over 1 year for each cost perspective

Cost perspective	Additional cost per additional point on the NEADL scale	Additional cost per additional point on the CBS	Additional cost per additional QALY
Patients, 6 months			
Health and social care	Control dominates (£1184/–0.2)	N/A	£1,184,000 (£1184/0.001)
Societal	Control dominates (£1127/–0.2)	N/A	£1,127,000 (£1127/0.001)
Patients, 1 year			
Health and social care	1126 (£563/0.5)	N/A	£51,182 (£563/0.011)
Societal	334 (£167/0.5)	N/A	£15,182 (£167/0.011)
Caregivers, 6 months			
Health and social care	N/A	414 (£207/0.5)	Control dominates (£207/–0.004)
Societal	N/A	198 (£99/0.5)	Control dominates (£99/–0.004)
Caregivers, 1 year			
Health and social care	N/A	£96 (£96/1)	Control dominates (£96/–0.004)
Societal	N/A	Intervention dominates (–£574/1)	Not applicable (–£574/–0.004)

N/A, not applicable.

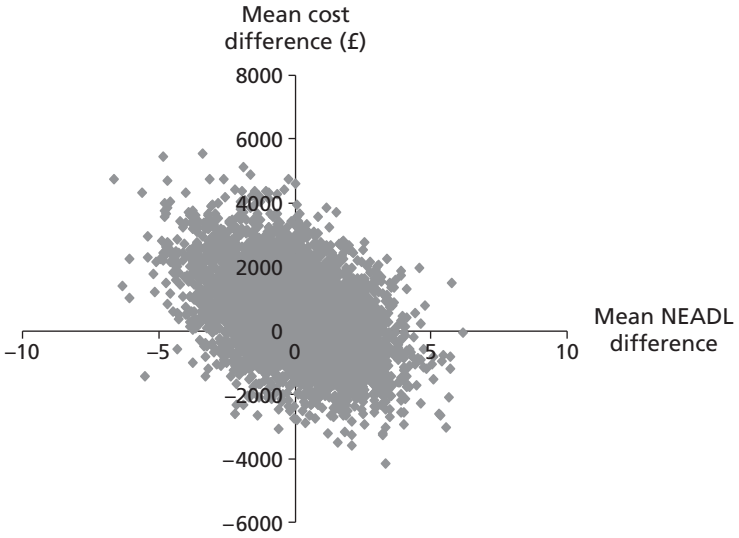

FIGURE 11 Patients: cost-effectiveness plane of incremental total health and social care costs and point changes on the NEADL scale at 6 months.

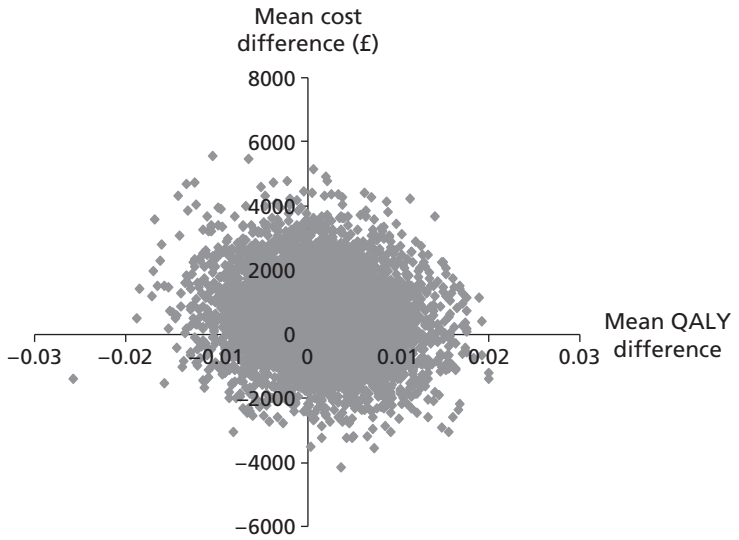

FIGURE 12 Patients: cost-effectiveness plane of incremental total health and social care costs and QALYs at 6 months.

and 34% for an additional QALY (this was the same across all QALY thresholds examined) (see *Figure 16*). In the caregiver evaluation, probabilities of cost-effectiveness were higher based on the societal perspective than for the health and social care perspective, given that the latter costs were higher in the intervention group compared with the control group. Probabilities of cost-effectiveness were reasonable for CBS point improvements (see *Figure 17*), up to a maximum of 62% and 68% from the health and social care and societal perspectives, respectively, at the maximum threshold examined (£2000), although it is unknown what the willingness to pay for a CBS point improvement would be in practice. However, as for the patient evaluation, probabilities of cost-effectiveness based on QALYs were low (see *Figure 18*), not exceeding 2% from the health and social care perspective for the range examined. Thus, the intervention is unlikely to be considered cost-effective from either patient or caregiver perspectives at current policy thresholds of £20,000–30,000 per QALY gained.

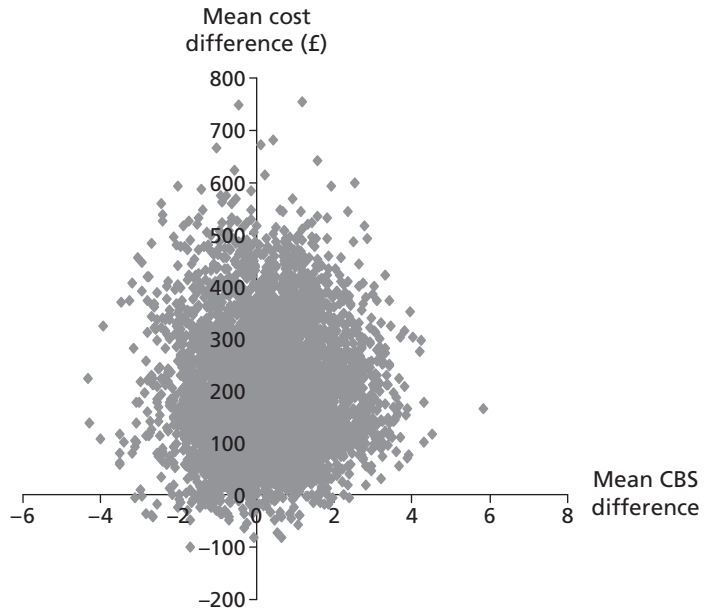

FIGURE 13 Caregivers: cost-effectiveness plane of incremental total health and social care costs and point changes on the CBS at 6 months.

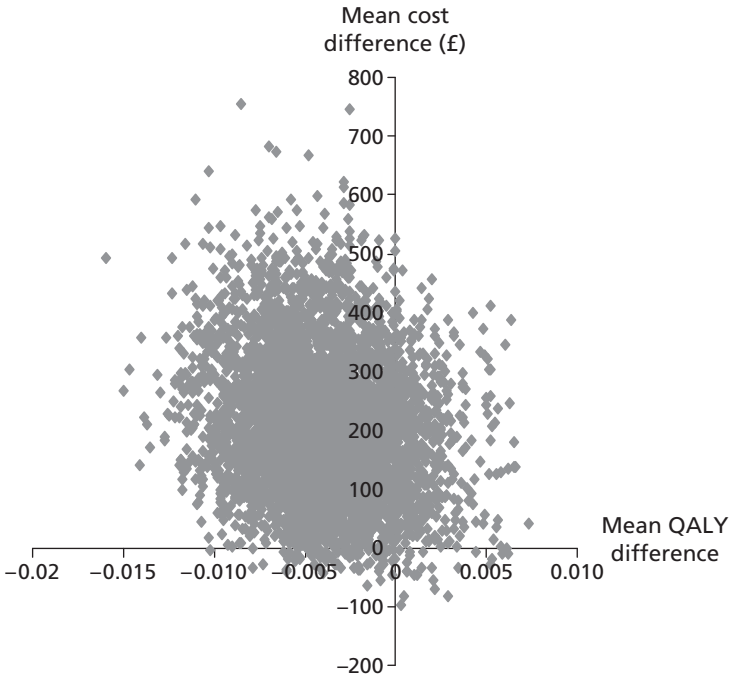

FIGURE 14 Caregivers: cost-effectiveness plane of incremental total health and social care costs and QALYs at 6 months.

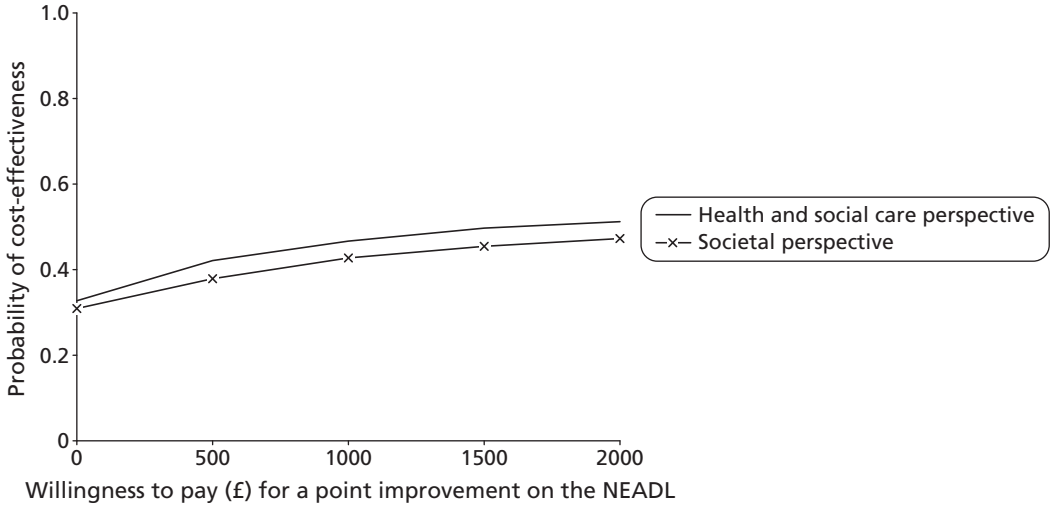

FIGURE 15 Patients: probability that the intervention is cost-effective compared with the control at 6 months, from each cost perspective, for a range of willingness-to-pay values for an additional point improvement on the NEADL scale.

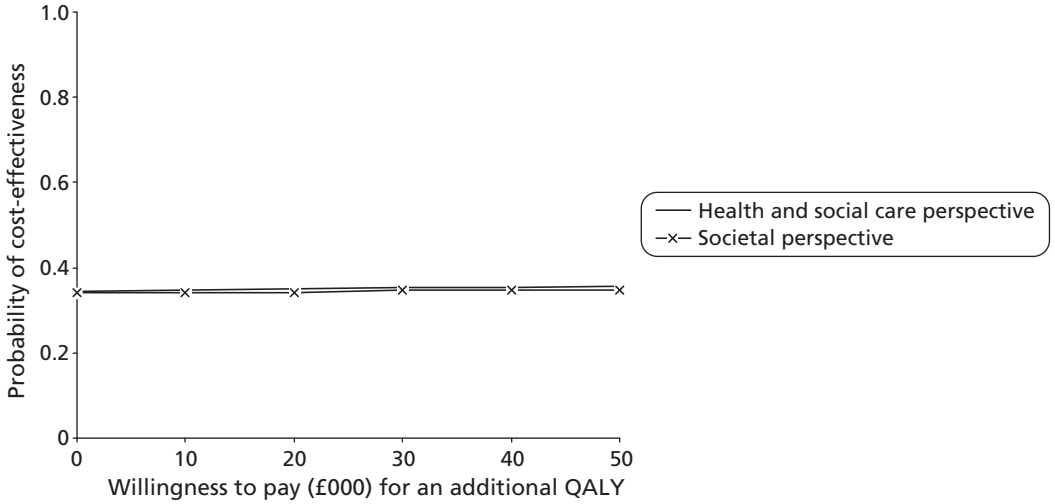

FIGURE 16 Patients: probability that the intervention is cost-effective compared with the control at 6 months, from each cost perspective, for a range of willingness-to-pay values for an additional QALY.

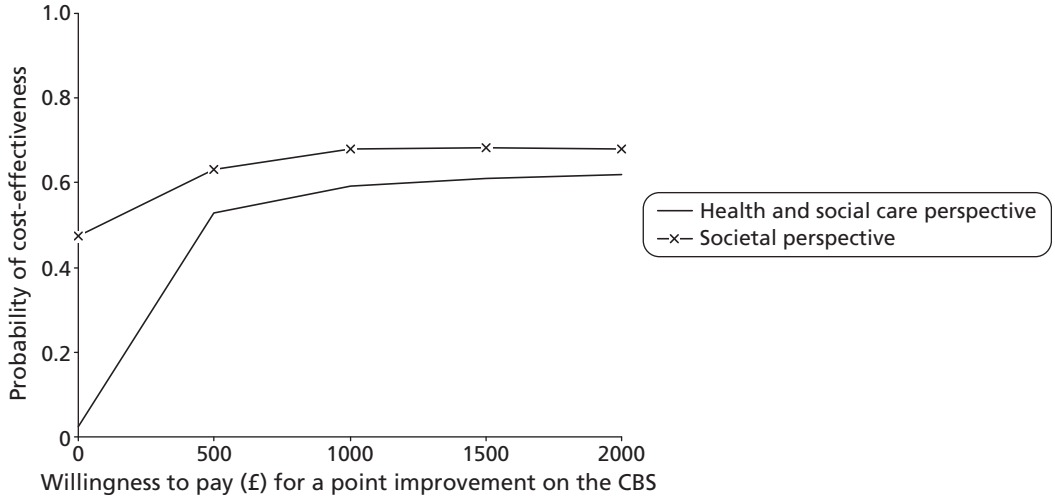

FIGURE 17 Caregivers: probability that the intervention is cost-effective compared with the control at 6 months, from each cost perspective, for a range of willingness-to-pay values for an additional point improvement on the CBS.

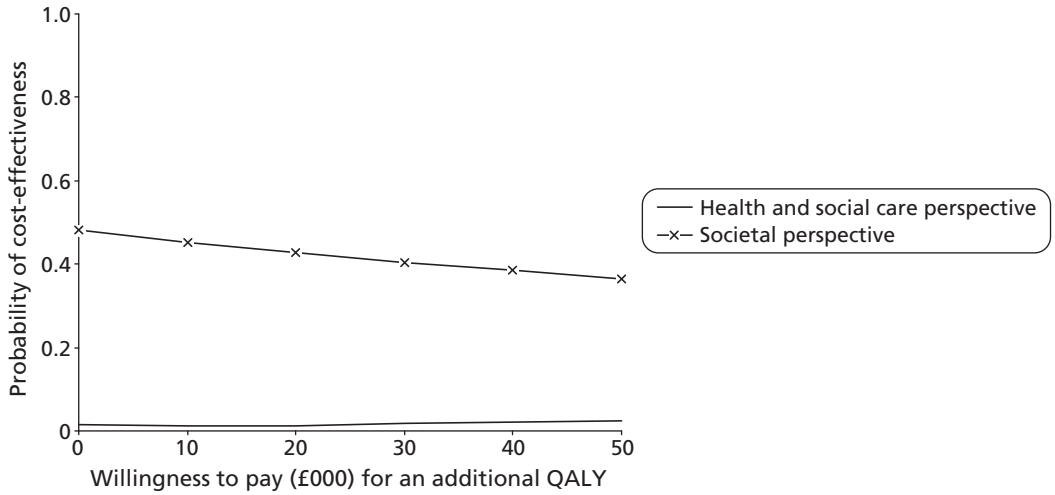

FIGURE 18 Caregivers: probability that the intervention is cost-effective compared with the control at 6 months, from each cost perspective, for a range of willingness-to-pay values for an additional QALY.

Chapter 6 Discussion

Key findings

The TRACS trial was a pragmatic, multicentre cluster RCT of a complex intervention. The trial was designed to evaluate the effectiveness of the LSCTC (LSCTC compared with usual care when implemented in SRUs across the UK in different health-care settings, with different patient populations). The trial evaluated whether the LSCTC improved physical and psychological outcomes for patients and their caregivers after disabling stroke, and sought to determine if such a training programme was cost-effective. Eighteen SRUs were randomised to implement the intervention as a part of their standard practice, and 18 SRUs were randomised to continue usual practice. A total of 928 patient and caregiver dyads were recruited into the trial: 450 in the intervention arm and 478 in the control arm.

Primary outcomes

Stroke patients attending intervention SRUs did not demonstrate a clinically significant improvement in functional independence compared with stroke patients attending the control SRUs at 6 months post registration. The burden for caregivers of stroke patients attending intervention SRUs was not significantly different to that of caregivers of stroke patients attending the control SRUs at 6 months. There was no difference in patient recovery or caregiver burden between the intervention and control groups.

Secondary outcomes

There were no statistically significant differences in stroke patients' mood, health state, functional ability and health-related quality of life or in the number of deaths, hospital readmissions or institutionalisations between the intervention and control arms at both 6 and 12 months post registration. Similarly, there were no statistically significant differences in caregivers' social restriction, mood, health state, or any difference in deaths, hospitalisation and institutionalisation at 6 or 12 months for those caregivers of patients attending intervention SRUs compared with those attending control SRUs. There was no difference in the outcome of patients' and caregivers' physical and psychological well-being between the intervention and control groups.

Economic evaluation

The economic evaluation suggests that from a patient perspective, health and social care costs, societal costs and outcomes are similar for the intervention and control groups at 6 months, 12 months and over 1 year. CEACs based on the net benefit approach, which accounted for uncertainty around point estimates of differences and potential willingness-to-pay thresholds of up to £2000 per point improvement on the NEADL scale and up to £50,000 for an additional QALY, suggest that the intervention group is less likely to be cost-effective than the control group.

From a caregiver perspective, societal costs and outcomes are similar between the two groups at 6 months, 12 months and over 1 year. Health and social care costs were on average £207 higher (95% CI £5 to £408) in the intervention group at 6 months, but this difference was no longer apparent at 12 months or over 1 year. Caregiver CEACs suggested that the intervention group is less likely to be cost-effective than the control group based on QALYs for thresholds up to £50,000 per QALY gain, but, based on the CBS, it has between 53% and 63% probability of cost-effectiveness for thresholds of £500 to £2000 per point

improvement on this scale from the health and social care perspective and 63–68% from the societal perspective. The value of a one point change in this measure and the willingness to pay for it from a policy-making viewpoint is unclear.

Informal care costs were considerable in size and notably increased total care costs. However, conclusions were broadly similar from both health and social care and societal perspectives.

The ability of the EQ-5D to detect changes in quality of life in these patient and caregiver groups is unclear and needs further exploration.

Safety

Training of caregivers was not detrimental to patients. No unexpected SAEs occurred in the trial, and the number of falls between registration and discharge from the SRU were minimal in both control and intervention arms.

Comparison of Training Caregivers After Stroke with the single-centre study

The LSCTC was evaluated in a single-centre RCT of 300 patients by Kalra *et al.*[19] This study reported a significant cost reduction for those patients treated using the LSCTC, as well as a significant reduction in caregiver burden, and improved quality of life and mood for both patients and their caregivers. The TRACS trial assessed the LSCTC using a multicentre, pragmatic design, wherein the LSCTC was implemented as a part of standard practice and delivered by all members of the MDT, and its effectiveness was assessed across different health-care settings and a larger heterogeneous population. The large multicentre pragmatic RCT did not replicate the findings of the single-centre study. The LSCTC does not provide any benefit to patients' long-term recovery or psychological well-being, nor does it reduce caregivers' burden or enhance psychological well-being compared with usual care. The LSCTC was found to be no more cost-effective than standard care.

It is important to note that the recruitment of patients in the single-centre study took place almost 10 years ago. Since that time stroke guidance has highlighted the importance of involving caregivers throughout the stroke patients stay on the SRU.[39,75] Comparison of the caregiver burden scores in the single-centre study at 3 months (intervention median = 43; control median = 51) and the TRACS trial at 6 months (intervention mean = 46.3; control mean = 45.7) suggest that caregivers may receive more support, resulting in less burden. However, although some of the differences identified in the single-centre study may have been lost as general stroke care has improved, we believe that it is unlikely that standard care has improved to such a degree that caregivers needs have been successfully met. Indeed, the caregiver burden scores in both the intervention and control arms indicate a level of burden that still needs addressing, with a score of 45 relating to a high level of caregiver burden.

Strengths and limitations of the study

The TRACS trial is the largest stroke rehabilitation trial completed to date (worldwide), with 930 patient and caregiver dyads registered to the trial. It successfully recruited to target, demonstrating that large, multicentre cluster RCTs of stroke rehabilitation are feasible.

The TRACs trial was one of the first large multicentre stroke rehabilitation trials to use the new SRN. The establishment of the local SRNs helped to determine the geographical regions selected for participation in the TRACS trial. The availability of SRN researchers in hospitals across entire regions allowed TRACS centres

to be recruited from an excellent spread of locations and health service types – from rural community hospitals in the South West Peninsula to large urban acute hospitals in central London. The SRN researchers assisted with the successful minimisation of selection bias in the TRACS trial, allowing recruitment by research staff that was entirely independent of the clinical MDTs. The invaluable support of the SRN no doubt ensured the successful recruitment of clusters and participants to target in the TRACS trial. In addition, the design of the TRACS trial has been a pioneer in bridging the chasm between clinical staff and research, by involving members of the MDTs in the research process. Many of the PIs in TRACS were senior therapists/nurses, and all participating MDTs have received an insight into the research process as a consequence of taking part in this pragmatic trial.

Study design

The TRACS trial followed closely the Medical Research Council (MRC) guidance on the evaluation of a complex intervention: a cluster RCT design was chosen as the most appropriate design for the evaluation of the LSCTC; outcome measures were carefully considered; an economic evaluation was conducted; and process data were collected. In addition, a parallel, complementary process evaluation study [funded by the National Institute for Health Research (NIHR) Research for patient benefit funding stream] was conducted to examine the nature and influence of SRU contexts on team- and patient-focused practices, on implementation processes of the LSCTC, and on the beliefs, understanding and actions of health professionals, stroke survivors and caregivers. The findings of this study have proved invaluable in interpreting the TRACS trial results and are discussed further below.

Internal validity

Clusters

Thirty-six clusters were randomised equally between control and intervention study arms, stratified by geographical region and NSSA score. Following randomisation, the characteristics of the SRUs were found to be well balanced. No clusters were lost to follow-up during the trial. However, some units struggled to achieve the target recruitment of 25 patient and caregiver dyads. Low recruitment in some SRUs was compensated for by increasing the recruitment target in high-recruiting SRUs. The loss of power in the trial caused by the unequal cluster sizes was compensated for by increasing the target recruitment beyond 900.

The process data collected in the TRACS trial indicates that, aside from the implementation of the LSCTC, there were few changes to the process of care affecting the involvement of patients and caregivers on SRUs throughout the course of the trial. More specialised stroke community teams and early supported discharge teams have emerged since the beginning of the trial but were still only present in one-third of the participating SRUs, and were balanced between study arms. Changes in the process of care take a long time to implement, and have not influenced the overall standards of care in the control and intervention SRUs taking part in the TRACS trial.

Recruitment

Recruitment of patients and caregivers commenced after cluster randomisation of the SRUs. The large sample size required in this trial, and the restricted length of hospital stay for all stroke patients, meant that it was not possible to identify and recruit the entire trial cohort prior to cluster randomisation. Therefore, the trial was carefully designed to avoid selection bias. Researchers independent of the clinical teams were used to screen and recruit participants. Attempts were made to ensure that the MDTs were unaware of which patients' and caregivers' had consented to provide trial data in study procedures, and MDT staff in the intervention arm were required to complete the LSCTC for all eligible participants regardless of trial participation. All participants were blinded to the SRUs treatment allocation. These design features proved successful as both the numbers of participants recruited and their baseline characteristics were well balanced between the study arms, demonstrating a lack of selection bias in the recruitment of participants. The follow-up rate of 75% at 6 months required for the power calculation was nearly achieved in the trial, with an actual follow-up rate of 74.4% for patients and 72.5% for caregivers.

Generalisability

Four disparate geographical regions ensured a good representation of different health-care settings (acute/community hospitals in rural and urban settings) and different SRU set-ups (combined acute and rehabilitation, and rehabilitation). The eligibility criteria in TRACS were kept to a minimum in keeping with the pragmatic trial design, to ensure that a representative stroke patient population was recruited. Patients with language and cognitive impairment were included, and there was no 'cut-off' level of age or disability. The results of the TRACS trial should be generalisable to all stroke patients returning home requiring support from informal caregivers, and to these informal caregivers, in SRUs across the UK.

Implementation of a complex intervention

As a pragmatic trial, the intervention was implemented as it would have been with any service initiative within the NHS. The challenges of implementation were considered carefully in designing the delivery of the training, and included choosing a method that (1) would be acceptable and feasible to MDT staff and NHS management; (2) could easily be replicated in SRUs across the UK at the end of the trial; and (3) would allow successful implementation of the LSCTC programme. Training was provided at two national training days for each intervention site, during which practical issues of implementation were discussed. This was supported by a training manual, CD and training records. The SRUs were asked to implement and embed the intervention on the wards over a 4- to 6-month period prior to the start of patient recruitment. The intent was that the training was cascaded down by staff who attended the training day to other staff on the wards. It may be that this commonly used 'cascade' method was not as effective as we would have wished and that other methods for implementing such service improvements should be considered.

The lack of in-depth piloting of the modified LSCTC and its implementation may be viewed as a weakness of the present study. Although piloting was conducted on a sample of caregivers in each of the intervention centres prior to the second training day, this may not have allowed sufficient insight into the complexities involved in successfully implementing a complex intervention as a part of standard care.

Intervention compliance

The intervention was accepted well by the staff attending the training days, with recognition of the importance of each of the core competencies, demonstrating 'face validity' for the intervention. A component of the intervention was the completion of the TRACS training record (see *Appendix 1*). Completed training records were returned to the trial manager and included as a standard monitoring report to the TMG and TSC. This enabled us to monitor the intervention delivery and the compliance for each patient in terms of competencies obtained. We felt that this level of monitoring was in keeping with the pragmatic trial design. Concerns about compliance were explored by the trial manager. In two instances for which compliance was very poor, letters were sent from the chief investigator to the local PIs and these were followed up with visits from the trial manager. Higher-level monitoring, for example, by check visits to the intervention units, would be potentially threatening to participating staff, probably observe unrepresentative practice, provide only a few observations and be research resource intensive.

The completion and return of this record varied across the SRUs, with an overall compliance rate of 43.6% (range 0.0–92.9%). These data indicate that some units did not implement the LSCTC as robustly as envisaged; however, half of the participating centres had a compliance rating of over 60% (one-third >75%). The measure of compliance, provided by the TRACS development team, was defined as completion of all six mandatory components of the training or sign-off of the training record by clinical staff. This may be a strict assessment of compliance. Compliance rates are compatible with other trials evaluating complex interventions.

To our knowledge, no other study has evaluated a novel, complex intervention delivered by the whole MDT on a stroke unit. Moreover, few studies have assessed the compliance of the interventions that they are evaluating. Four previous studies[15,17,19,76] have investigated inpatient interventions delivered by a specialist individual or team on a SRU. However, only one of these studies measured and reported compliance with the intervention. In this study, completed by Larson *et al.*,[15] compliance (defined as patient attendance at a minimum of five out of the six education sessions offered) was 50%. It is disappointing that some centres do not appear to have implemented the intervention consistently, but it is emphasised that the compliance analysis show no evidence of higher levels of patient independence or lower level of caregiver burden in the SRUs with better levels of intervention compliance.

Complementary Process Evaluation Study (separate papers in preparation)

A complementary, independent process evaluation study was conducted alongside the TRACS trial. This study investigated the implementation of the LSCTC, and the views of MDT staff, patients and caregivers on the LSCTC in a sample of six intervention SRUs. Observations and interviews were also completed in four control SRUs so that comparisons could be made. The findings of the process evaluation study has provided valuable and insightful data to inform interpretation of the TRACS trial results.

Interpretation of results

The observations conducted on the SRUs in the process evaluation study reflected the completion rate of training records in the main trial – the LSCTC was observed successfully in some SRUs, some of the time in other SRUs, and not at all in one SRU. The key findings of the process evaluation study were that the LSCTC was only one of a number of competing priorities for SRU teams. Members of staff were trained to deliver the LSCTC and then expected to train their teams but training did not reach all staff, particularly nurses. Therapy staff were the most actively involved with training delivery in the observed units. Different disciplines often worked separately with caregivers rather than the MDT working together as a team. Caregiver training was typically delivered very late in the inpatient stay. Staff concern with reducing risk and safe discharge often meant caregiver training involved passive observation and not active engagement and practice. For caregivers, the stroke was a shock, this impacted on their understanding of what had happened and readiness to participate in training. After discharge, caregivers' recall of information and training was very limited.

The LSCTC was implemented using cascade training. Although training did occur in all centres, the staff attending varied, and the time available to cascade the training was relatively brief. In general, nurses received less training, and for a shorter amount of time. Training tools were left on each unit to help support new members of staff, but the process evaluation study suggests that these resources were not well utilised.

Stroke survivors' abilities could change rapidly once at home, so home visits and early supported discharge schemes provided opportunities for in situ training, which was valued. Caregivers perceived the training to be important, but it only addressed one of many areas of adjustment with which to cope.

It may be speculated from process evaluation work that the intervention was more robustly implemented when key members of the MDT took ownership of the LSCTC and training records. This form of working is more similar to that used in the single-centre study, for which the training was completed by a small, highly experienced, team.

Economic evaluation

The economic evaluation from the patient perspective suggests that the intervention and control groups have similar costs and outcomes at all of the assessment points considered. From the caregiver perspective, the intervention group had higher health and social care costs at 6 months (for equivalent outcomes). Costs

and outcomes over the longer term and from the societal perspective were similar, and illustrate that increasing the breadth and length of such an evaluation can provide alternative conclusions. However, even 1 year is a relatively short time horizon in the context of a lifetime and it is unclear whether or not our findings would hold over patient and caregiver lifetimes.

The cost findings are in contrast with those from the single-centre study,[19,29] which found a statistically significant difference in total patient health and social care costs over 1 year of £4043 in favour of the intervention group, largely due to a lower length of stay (–12 days) for the initial stroke admission. Total patient health and social care costs over 1 year in the present study were £563 lower in the control group (although not statistically significant) and we found no difference in the average length of stroke unit stay for the initial stroke admission (45 and 42 days in the intervention and control groups, respectively), which interestingly was similar to that for the control group in the single-centre study (43 days). It is unclear whether the intervention, or the way it was implemented, simply did not impact on discharge practices in the study stroke units, or whether or not other factors (e.g. care standards) differed over time and place to reduce the potential for earlier discharge that existed in the single-centre study.

With regards to caregiver costs, we cannot discount the possibility that providing caregivers with more structured training increased their use of health and social care resources and their provision of informal care to the patient as an appropriate response to their and the patients' needs. However, if this was the case, any potential benefits of this were not evident in the outcome measures we examined.

Examining cost and outcome differences based on point estimates gave a mixed set of conclusions across the various time point and perspectives but the meaningfulness of these is unclear given the lack of statistically significant differences in costs and outcomes except for higher caregiver health and social care costs at 6 months. There were no differences in patient or caregiver QALYs at 6 months, 12 months or over 1 year, and CEACs based on patient and caregiver QALYs suggested that the intervention group was less likely to be cost-effective compared with the control group. The single-centre study on which this was based[19,29] also failed to detect any QALY differences. As we used no additional health-related quality-of-life measure, it is unclear whether there truly were no differences or whether the EQ-5D was unable to detect changes in quality of life. Any such limitation of the EQ-5D may be addressed in future research with the new five-level version (EQ-5D-5L), which has been developed to improve the instrument's sensitivity and to reduce its ceiling effects.

Patient CEACS based on the NEADL score suggested equivalent probabilities of cost-effectiveness for the two groups but caregiver CEACs based on the CBS suggested 53–68% probability of cost-effectiveness for thresholds of £500–2000 per point improvement on the CBS. However, the value of a one point change in this measure and the willingness to pay for it from a policy-making viewpoint is unclear.

The cost of developing the intervention and training ward staff in its use was estimated at an average of £39 per patient/caregiver dyad across the whole intervention group. The average cost was higher at £82 when considering only those known to have received some caregiver training. This is relatively inexpensive in the context of the average cost of an acute stroke bed-day (£294) and the average stroke admission cost in this sample (£13,127 and £12,471 in the intervention group and control group, respectively). We did not include the cost of delivering the intervention to caregivers to avoid double-counting admission costs. However, this exclusion is unlikely to have affected the findings, first because these costs are likely to be small in the context of total care costs and, second, because there was little difference in the amount of time spent with caregivers in each group.

Although the difficulties of reliably assessing informal care inputs is well known, the study suggests that the informal care burden for caregivers of stroke patients is sizeable. Patient care costs were 70% higher in both intervention and control groups at 6 months when informal care costs were added in. Caregiver costs were 21% and 34% higher in the intervention and control groups, respectively, when the costs of the inputs they provided were considered. These care inputs and their costs remained high at 12 months, thus the

informal care burden is both significant in size and duration. The impact of patients' strokes on caregivers' own health is further evidenced by the noticeable increase in their use of community- and secondary-based care in the post-stroke period compared with baseline.

There were two main limitations with the economic evaluation, both of which are common to evaluations of this type. First, resource-use data were collected retrospectively by self-report as this was the most efficient way of collecting data for a large sample, across a large geographical area and from a broad perspective incorporating primary health care, secondary health care, social care and informal care. Such data may be subject to recall bias, but a trade-off between reliability and scope was necessary given the trial design. Second, the cost-effectiveness and cost–utility analyses were performed on subsamples of cases with available data for both costs and relevant outcomes. However, overall follow-up rates were very good given the features of the trial (multicentre, older participants, follow-up period 6/12 months after the acute event), and sensitivity analyses that imputed missing costs and QALY data suggested that findings from the incomplete sample analyses were fairly robust.

Overall evidence

A recent Cochrane review has examined the effectiveness of non-pharmacological interventions for caregivers of stroke survivors in reducing caregiver burden or enhancing caregiver well-being.[14] Eight relevant studies were found that assessed information and support interventions, psychoeducational interventions and caregiver training. The combined sample size of the eight studies was 1007. The conclusions of this review was that it is not, at present, possible to determine the usefulness of information and support interventions, or psychoeducational interventions on reducing caregiver burden, or enhancing their psychological well-being or health-related quality of life. The results of the caregiver training programme in the single-centre study looked promising, appearing to reduce caregiver burden, depression, and improve health-related quality of life for caregivers. The purpose of TRACS was to see if this caregiver training programme – the LSCTC, continued to show benefits to caregivers and stroke patients if it was implemented as a part of standard practice in SRUs across the UK. The TRACS trial ($n = 928$) has almost doubled the sample size of the Cochrane Review, providing conclusive evidence that there is no difference between the LSCTC and usual care with respect to stroke patients' recovery, caregivers' burden, or other physical and psychological outcomes, nor is it cost-effective when compared with usual care. Caregivers need more than just an inpatient structured training programme to improve the patients and their own outcomes.

The findings of the process evaluation study completed in parallel with TRACS suggest that caregiver training while the stroke patient is in hospital may not be the optimal time to complete such training. The LSCTC competes with other priorities for MDT staff, and caregivers are experiencing stress, making any such training less effective at that time point. Caregiver training in the community, by a dedicated experienced team, might be more beneficial for patients and their caregivers.

Of the eight studies reviewed by Legg *et al.*,[14] three interventions were completed while the stroke patient was still in hospital, one was completed both as an inpatient and continued once at home, two were longer-term community interventions and the location of delivery of two were unclear, although both recruited patients in the acute inpatient setting. The timing/setting of the intervention in these studies did not have any clear influence on the effectiveness of these interventions.

Chapter 7 Conclusions

Implications for clinical practice

The intervention evaluated had reported benefits in a previous single-centre evaluation but these benefits have not been replicated in this large, multicentre trial in which the intervention was evaluated in a range of settings with a greater diversity of patient populations. There was no difference between the LSCTC and usual care with respect to improving stroke patients' recovery, reducing caregivers' burden, or improving other physical and psychological outcomes, nor is it cost-effective when compared with usual care.

Compliance with the intervention varied across stroke units but analysis demonstrated no link between the degree of compliance and associated patient or caregiver outcomes, indicating that a dose effect is unlikely. The LSCTC provided a structured framework for caregiver training. It is possible that the immediate post-stroke period, when potential caregivers are coming to terms with their new situation, may not be the ideal time for the delivery of structured training. The intervention approach might be more relevant if delivered after discharge by community-based teams.

Implications for research

The TRACS trial is the world's largest completed stroke rehabilitation trial. We have demonstrated for the first time that this methodology can feasibly be implemented in stroke rehabilitation research, which represents a major step forward in research methodology for this large client group. The TRACS trial fills some of the gaps in evidence of the recent Cochrane review. Despite the promising results of the single-centre study, the results of TRACS provides conclusive evidence that there is no difference between the LSCTC and usual care on stroke patients' functional independence, caregivers' burden, or other physical and psychological outcomes, nor is it cost-effective when compared with usual care. Caregivers need more than just an inpatient structured training programme to improve the patients and their own outcomes.

Future studies should consider carefully the optimal delivery of any caregiver interventions – whether or not the staff have the time and opportunity to implement the intervention, and when is the optimal timing of the intervention for the caregiver. Caregiver interventions may be more effective in the post-acute phase, once patients are back home and caregiving has become a reality.

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Appendix 1 London Stroke Carers Training Course training record and control time log

TRACS
TRAINING CAREGIVERS AFTER STROKE

Page 1 of 4

Training Record

Patient Initials	Patient Date of Birth	Caregiver Initials	Caregiver Date of Birth
	Day Month Year		Day Month Year

- **Sessions could be practical, information giving, or a mixture of the two** depending on the needs of the individual caregiver
- Training should be delivered by the most appropriate member of the MDT
- **Please note, all mandatory training sections MUST be delivered**
- Please complete back page for every session you complete with a caregiver

Training Component	Appropriate? *Please tick* Yes	No	Training Delivered? *Please tick* Yes	No	Total Time (mins)	Competency item *The caregiver has demonstrated knowledge and understanding of:*	Achieved? *Please tick* Yes	No	Date Achieved	Competancy signed off by (Staff Initials)
1. Introduce her/himself to the caregiver. The caregiver will be informed of the patient's condition	**Mandatory**		☐	☐		His/her relative having had a stroke.	☐	☐	Day Month Year	
2. Provide the caregiver with appropriate information leaflets	**Mandatory**		☐	☐		What a stroke is.	☐	☐	Day Month Year	
Ensure that the caregiver reads the booklet and encourage caregiver to raise any queries.	**Mandatory**		☐	☐						
3. Identify and explain the relative's specific stroke-related problems and expected recovery to the caregiver:										
a) Communication and reading	☐	☐	☐	☐		His/her relatives specific stroke related problems.	☐	☐	Day Month Year	
b) Cognition	☐	☐	☐	☐						
c) Personality and mood changes	☐	☐	☐	☐						
d) Diet and Swallowing	☐	☐	☐	☐						
e) Vision	☐	☐	☐	☐		Possible incomplete recovery and residual unresolved problems	☐	☐	Day Month Year	
f) Personal Activities of Daily Living (PADL)	☐	☐	☐	☐						
g) Transfers and Mobility	☐	☐	☐	☐						

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computerised	verified/checked	monitored	Patient ID	*Form continues on next page* ►►
Date Initials	Date Initials	Date Initials	N Centre no.	Trial no.

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TRACS
TRAINING CAREGIVERS AFTER STROKE

Training Record

Training Component	Appropriate? *Please tick* Yes	No	Training Delivered? *Please tick* Yes	No	Total Time (mins)	Competency item *The caregiver has demonstrated knowledge and understanding of:*	Achieved? *Please tick* Yes	No	Date Achieved	Competancy signed off by (Staff Initials)
4. Advice on:						The importance of a healthy lifestyle and secondary prevention.	☐	☐	Day Month Year	
a) Control of blood pressure	Mandatory		☐	☐						
b) Use of aspirin/ warfarin or similar	☐	☐	☐	☐						
c) Smoking	☐	☐	☐	☐						
d) Appropriate diet, including prevention of excess weight gain	Mandatory		☐	☐						
e) Exercise	Mandatory		☐	☐						
f) Pain management	☐	☐	☐	☐						
5. Teach caregiver specific skills relating to:						Dietary needs and feeding techniques (if appropriate).	☐	☐	Day Month Year	
a) Special diet	☐	☐	☐	☐						
b) Techniques to assist eating, including use of specialist equipment if necessary.	☐	☐	☐	☐						
6. Teach strategies to enhance communication and comprehension.	☐	☐	☐	☐		How to communicate with dysphasic relative	☐	☐	Day Month Year	
7. Teach Personal Activities of Daily Living techniques.	☐	☐	☐	☐		How to manage relative's personal washing, dressing, toiletry needs.	☐	☐	Day Month Year	
8. Provide the caregiver with information on appropriate limb positioning, including prevention of pressure sores, and maintenance of circulation and skin integrity.	☐	☐	☐	☐		The importance of limb positioning and the management of pressure areas and skin integrity.	☐	☐	Day Month Year	
9.Teach the caregiver continence management.	☐	☐	☐	☐		Continence management.	☐	☐	Day Month Year	

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Date	Initials	Date	Initials	Date	Initials

Patient ID
N Centre no. Trial no.

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TRACS
TRAINING CAREGIVERS AFTER STROKE

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Training Record

Patient Initials	Patient Date of Birth	Caregiver Initials	Caregiver Date of Birth
	Day Month Year		Day Month Year

Training Component	Appropriate? *Please tick* Yes	No	Training Delivered? *Please tick* Yes	No	Total Time (mins)	Competency item *The caregiver has demonstrated knowledge and understanding of:*	Achieved? *Please tick* Yes	No	Date Achieved	Competancy signed off by (Staff Initials)
10. Teach the caregiver bowel management, fluid and dietary intake for the prevention of constipation.	☐	☐	☐	☐		Bowel management, fluid and dietary intake for the prevention of constipation.	☐	☐	Day Month Year	
11. Teach the caregiver appropriate techniques for:						– *and ability in:*				
a) Safe transfers	☐	☐	☐	☐		Safe transfers	☐	☐	Day Month Year	
b) Safe assisted mobility	☐	☐	☐	☐		Safely assisting mobility	☐	☐	Day Month Year	
c) Knowledge of floor routine following a fall	☐	☐	☐	☐		Floor routine following a fall	☐	☐	Day Month Year	
d) Safely assist in climbing the stairs	☐	☐	☐	☐		Safely assisting in climbing stairs	☐	☐	Day Month Year	
e) Good use of the wheelchair	☐	☐	☐	☐		Good use of a wheelchair	☐	☐	Day Month Year	
f) Use of aids	☐	☐	☐	☐		Use of aids	☐	☐	Day Month Year	
12. Teach the importance of compliance with medication e.g. self-medication and the caregiver's ability to supervise medication	**Mandatory**		☐	☐		The importance of compliance with medication (including supervision of self- or routine medication).	☐	☐	Day Month Year	
13. Explain and provide information about post discharge arrangements e.g. home visit findings and recommendations, local support groups, type and frequency of services arranged by Social Services, support of the hospital stroke and community team	**Mandatory**		☐	☐		Post-discharge recommendations Where and whom to seek help from after discharge.	☐ ☐	☐ ☐	Day Month Year Day Month Year	
14. Complete 'Follow Up' session after discharge	**Mandatory**		☐	☐		Following discharge, the caregiver demonstrates they have successfully adapted their knowledge and skills to the home environment	☐	☐	Day Month Year → Was this a: ☐ Home visit or ☐ Phone call	

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Date	Initials	Date	Initials	Date	Initials

Patient ID N Centre no. Trial no.

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TRACS
TRAINING CAREGIVERS AFTER STROKE

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Training Record

Session	Training component(s) covered (please enter number(s))	**Time spent with carer (in mins)**	Date	Signed	Profession and band
1			Day Month Year		
2			Day Month Year		
3			Day Month Year		
4			Day Month Year		
5			Day Month Year		
6			Day Month Year		
7			Day Month Year		
8			Day Month Year		
9			Day Month Year		
10			Day Month Year		
11			Day Month Year		
12			Day Month Year		

Additional comments

To be completed by the caregiver:

I have received information from staff about my relative's/friend's stroke

Signature _____ **Date** Day Month Year

On completion of training, this record must be checked and signed by a designated member of staff.

Clinical Staff member

Name _____ Position _____

Signature _____ Date Day Month Year

Thank you

Please retain a photocopy of this form and return the original to:
CTRU, University of Leeds, 17 Springfield Mount, Leeds, LS2 9NG Telephone: 0113 343 2653 Fax: 0113 343 147

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Date	Initials	Date	Initials	Date	Initials

Patient ID

N Centre no. Trial no.

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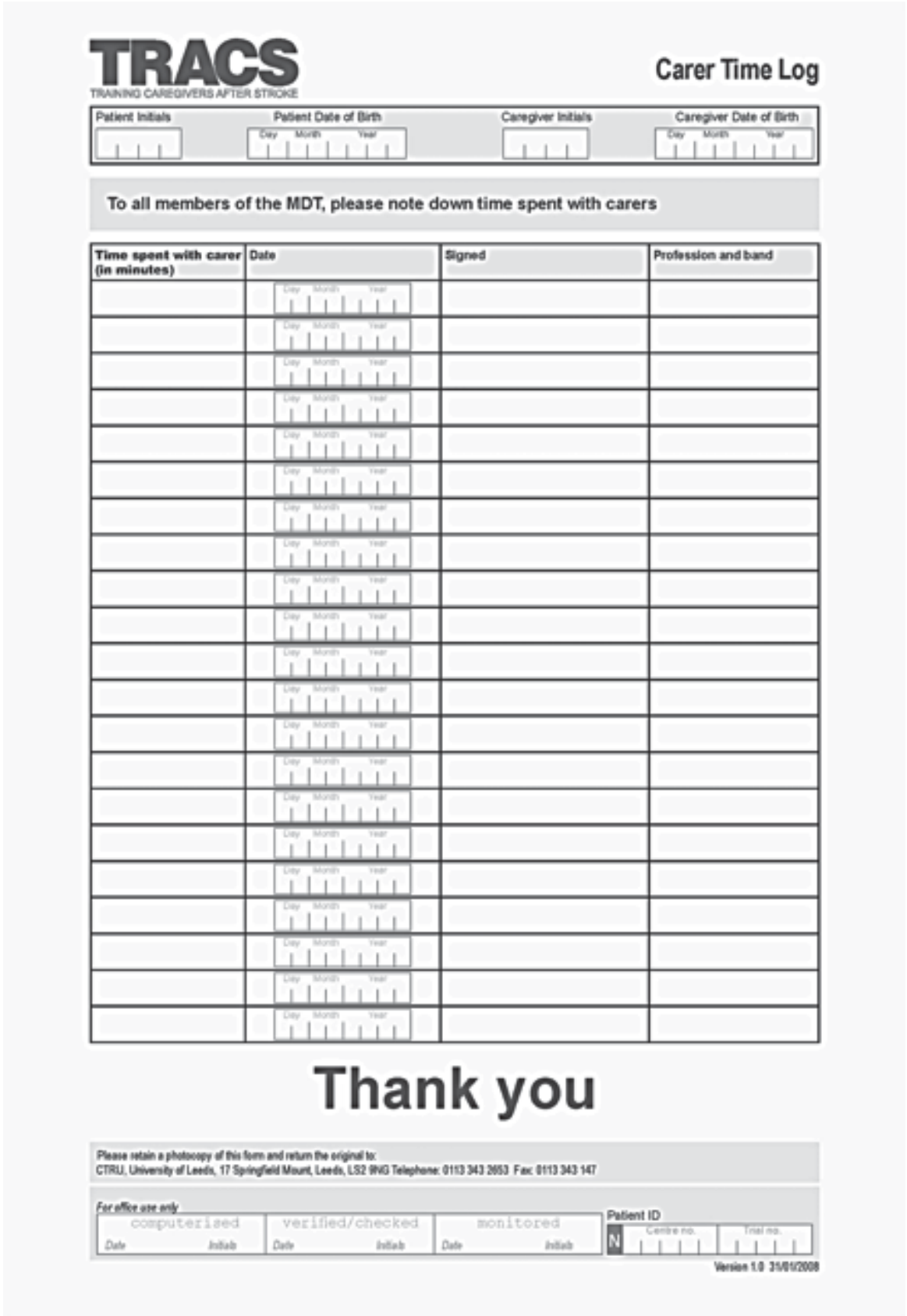

TRACS
TRAINING CAREGIVERS AFTER STROKE

Carer Time Log

Patient Initials	Patient Date of Birth	Caregiver Initials	Caregiver Date of Birth
	Day Month Year		Day Month Year

To all members of the MDT, please note down time spent with carers

Time spent with carer (in minutes)	Date	Signed	Profession and band
	Day Month Year		
	Day Month Year		
	Day Month Year		
	Day Month Year		
	Day Month Year		
	Day Month Year		
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Thank you

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computerised	verified/checked	monitored	Patient ID
Date Initials	Date Initials	Date Initials	N Centre no. Trial no.

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Appendix 2 Outline of the London Stroke Carers Training Course training days

Day 1

Session	Given by	Time (minutes)	Brief description
1. Introduction	AF	20	Introduction to the day
			Background to the intervention – the problems of carer burden in stroke
2. Principles of the training programme	AM	5	Background and development of the LSCTC in the single-centre study
	MW	5	Introduction and description of the LSCTC (using training manual)
	JS	5	Recommended delivery of LSCTC to carers
	JS	15	Assessing carers competency
	JS	5	The 14 training components – suggested delivery, suggested resources to aid training and a recommended strategy for checking off the competencies
3. Workshops 1 and 2	All	120	In local teams – go through competency items 1–14 (done over two sessions) and discuss how to approach the delivery of each item – who will deliver it, and how best to deliver it in your stroke unit
			Feedback and discussion from all teams
4. Discussion	JS	30	Questions, comments and discussion of issues arising during the workshops
5. Completing the training records	AF	20	Explanation of the training record, and how to complete it
6. Summing up	AF	10	Summing up of day and further questions discussed

Day 2

Session	Given by	Time (minutes)	Brief description
1. Cascading of LSCTC to the MDT	All	30	Discussion of any issues, questions, tips for cascading the LSCTC to local stroke unit teams
2. Review of training components	JS	30	Refresher of each training component, suggested delivery, suggested resources and recommended strategy for checking competency
3. Practical issues of delivering the components	All	30	Open discussion of the practical issues of delivering the components and assessing competency
4. Practical issues of using the training record	All	30	Open discussion of the training record, recommendations for changes
5. Next steps	AF	30	Implementing the LSCTC as a part of standard practice
6. Discussion	All	30	Open session for further questions and answers

Appendix 3 London Stroke Carers Training Course training manual

TRAINING MANUAL

The training and information delivered to the carer should relate to the individual needs of the stroke patient they will be caring for:

	Item	Component	Delivery	Comments/Resources	Assessment strategy
knowledge	1	Introduce her/himself to the caregiver. Inform the caregiver of the patient's condition.	Give as much or as little info relating to the patient's condition as the caregiver wants (links with item 3 below).	None required	Check the caregiver's understanding verbally
	2	Provide the caregiver with appropriate information leaflets	Encourage the caregiver to read the information & to raise any queries.	Local booklets/ Stroke Association information sheets	Not required
	3	Identify and explain the relative's specific stroke related problems and expected recovery to the caregiver:	Deliver verbally using any visual resources available in the department, if required.	Local booklets/information sheets Stroke Association leaflets Stroke Association website	Check the caregiver's understanding verbally
		a) Communication and reading	Discussion with caregiver relating to individual patients condition.	This might overlap with issues relating to vision (section 3e). Stroke Association fact sheet sheet No.3 Communication problems after Stroke	Check the caregiver's understanding verbally
		b) Cognition	Discussion with caregiver relating to individual patients condition. Include perceptual problems	Stroke Association Fact sheet. No.7 Cognitive problems after Stroke.	Check the caregiver's understanding verbally
		c) Personality and mood changes	Discussion with caregiver relating to individual patients condition. Include possible future mood	Stroke Association Fact sheet. No. 10 Psychological effects of stroke	Check the caregiver's understanding verbally

Item	Component	Delivery	Comments/Resources	Assessment strategy
		changes as part of the rehabilitation process.		
	d) Diet and swallowing	Discussion with caregiver relating to individual patients condition. Can include nil by mouth or PEG feed explanation if appropriate to the patient.	Stroke Association Fact sheet. No 5. Swallowing problems after Stroke. Stroke Association Fact sheet. No. 8 Diet and stroke	Check the caregiver's understanding verbally
	e) Vision	Discussion with caregiver relating to individual patients condition. Distinguish between physical and perceptual problems.	Stroke Association Fact sheet. No. 37 Visual problems after Stroke.	Check the caregiver's understanding verbally
	f) Personal Activities of Daily Living (PADL)	Discuss with caregivers how the patient's individual condition affects their PADL. Include the management and impact of visual, physical, sensory and cognitive effects of stroke.	(This can have an overlap when you are discussing cognition, mood, and vision.) Links with skills item 7.	Check the caregiver's understanding verbally
	g) Transfers and mobility	Discuss with caregivers how the patient's individual condition affects their transfers and mobility. Include the management and impact of physical effects of stroke e.g. spasticity, weakness, pain	(This links with skills item 11a) Stroke Association Fact sheet. No 33. Physical effects of Stroke. Stroke Association Fact sheet. No 30. Pain after stroke.	Check the caregiver's understanding verbally
4	Advice on:			
	a) Control of blood pressure	Explain the importance of blood pressure control and	Stroke Association Fact sheet. No 6. High Blood pressure and	Check the caregiver's understanding verbally

	Item	Component	Delivery	Comments/Resources	Assessment strategy
			medication compliance. Refer to RCP guidelines	stroke	
		b) Use of aspirin/warfarin or similar.	Explain regime and discuss cautions.	Refer to Unit's own policy Stroke Association Fact sheet. No.11 Asprin and Stroke.	Check the caregiver's understanding verbally
		c) Smoking	Discuss relationship between smoking and health.	Consider referral to smoking cessation services. Local and national leaflets Stroke Association fact sheet no.19 Smoking and Stroke.	Check the caregiver's understanding verbally
		d) Appropriate diet including prevention of excessive weight gain	General discussion about the need for a balanced healthy diet and issues that might arise for the patient where weight gain is excessive.	Stroke Association fact sheet no 8 Diet and stroke	Check the caregiver's understanding verbally
		e) Exercise	Discuss how targeted exercise can assist with recovery. Discuss with the caregiver how graded exercise can provide health benefits to patients following stroke.	Stroke Association Resource sheet No.7 Gentle exercise.	Check the caregiver's understanding verbally
		f) Pain management	Explain the causes of pain, medication & positioning	Stroke Association Fact sheet No. 30. Pain after stroke	Check the caregiver's understanding verbally
Skill	5	Teach caregiver specific skills relating to			
		a) Special diet	Demonstrate different textures of food and liquid.	Local information/resources	Check understanding verbally.

TRACS Training Manual

Item	Component	Delivery	Comments/Resources	Assessment strategy
				Observe caregiver's skills with patient.
	b) Techniques to assist eating including use of specialist equipment if necessary	Demonstrate to caregiver techniques and or equipment appropriate to patient's needs and encourage participation. If equipment is needed, explain how it can be obtained.	Local information/resources Stroke Association Resource sheet No-3 Catalogues: Aids and equipment	Observe caregiver's skills with patient.
6	Teach strategies to enhance communication with and understand of the patient.	Explain communication techniques appropriate to patient's needs. Practice with the caregiver and the patient.	'Connect' resources; stroke and aphasia handbook. www.ukconnect.org/ Local information/resources	Observe caregiver's skills with patient
7	Teach Personal Activities of Daily Living techniques if appropriate.	Demonstrate to caregiver techniques appropriate to their relative's needs and encourage participation. Include handling of the affected arm/ leg, dealing with sensory loss, reduced vision, cognition issues. If equipment is needed, explain how it can be obtained.	Local information/resources Stroke Association Resource sheet No-3 Catalogues: Aids and equipment	Observe caregiver's skills with patient.
8	Provide the caregiver with information on appropriate limb positioning including prevention of pressure sores, and maintenance of circulation and skin integrity.	Discuss positioning with caregiver and demonstrate where this is appropriate. Explain how and why skin integrity is compromised by weakness, movements and reduced sensation. Demonstrate use of positioning aids	Local information/resources Local positioning leaflets.	Check the caregiver's understanding verbally, and observe practical skills in positioning.
9	Teach the caregiver continence management.	Discuss methods for managing continence according to Unit guidelines.	Local information/resources Stroke Association fact sheet No.12 Stroke and continence	Check the caregiver's understanding verbally Observe caregiver's skills with patient.

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	Item	Component	Delivery	Comments/Resources	Assessment strategy
	10	Teach the caregiver bowel management, fluid and dietary intake for the prevention of constipation.	Discuss how to manage incontinence and constipation.	Local information/resources Local guidelines, local continence services.	Check the caregiver's understanding verbally
	11	Teach the caregiver appropriate techniques for:			
		a) Safe transfers	Practical demonstration, encouraging the caregiver to participate.	Local information/resources Examples include: Use of hoist Bed, Chair, Commode Wheelchair, Car Bath, Toilet Stair lift where appropriate	Check the caregiver's understanding verbally Observe caregiver's skills with patient.
		b) Safe assisted mobility	Practical demonstration, encouraging the carer to participate.	Sit to stand Turning	Check the carer's understanding verbally Observe carer's skills with patient.
		c) Knowledge of floor routine following a fall	Agree whether assisted recovery should be attempted independently or with help. When to call an ambulance Using care-link alarms Where appropriate only, practice with carer and patient. Suggest backward chaining.	Local information/resources	Check the carer's understanding verbally Observe carer's skills with patient.
		d) Safely assist in climbing the stairs	Demonstrate to the carer how to assist the patient in climbing and descending stairs where appropriate.	Local information/resources	Check the carer's understanding verbally. Observe carer's skills with patient.
		e) Good use of the wheelchair	Brakes Arm rests Cushion, Footplates Seatbelt	Local information/resources Stroke Association fact sheet No.35 Stroke and Wheelchairs	Check the carer's understanding verbally. Observe carer's skills

	Item	Component	Delivery	Comments/Resources	Assessment strategy
			Folding Contact details for maintenance		with patient.
		f) Use of aids	Discuss safe use of walking aids with the carer. Explain Maintenance and checking procedures.	Local information/resources	Check the carer's understanding verbally. Observe carer's skills with patient.
	12	Teach the importance of compliance with medication e.g. self-medication and the caregiver's ability to supervise medication.	Discuss appropriate to the patient's needs and medical condition	Local information/resources Local discharge information Local pharmacies	Check the carer's understanding verbally. Observe carer's skills with patient.
	13	Explain and provide information about discharge arrangements e.g. home visit findings and recommendations, local support groups, type and frequency of services arranged by Social Services, support of the hospital stroke and community team.	Explain and discuss implication of the home environment on the patient functioning and how this can/ can't be resolved.	Local discharge policy Stroke Association Resource sheet No.9 Leisure activities after stroke Stroke Association Resource sheet No. 12 Telephone-linked alarm systems	Check the carer's understanding verbally.
	14	Following discharge the caregiver demonstrates they have successfully adapted their knowledge and skills to the home environment	Complete 'Follow Up' session with caregiver post-discharge. This follow up could be done by a member of the stroke team, or a community team. The follow up should check that the caregiver has retained the knowledge and the skills acquired during the training programme and give them an opportunity to ask questions. This can be done as a visit or by phone		Check the caregiver's understanding verbally.

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Appendix 4 Protocol – Version 7.0

TRACS

TRAINING CAREGIVERS AFTER STROKE

A cluster randomised controlled trial of a structured training programme for caregivers of in-patients after stroke

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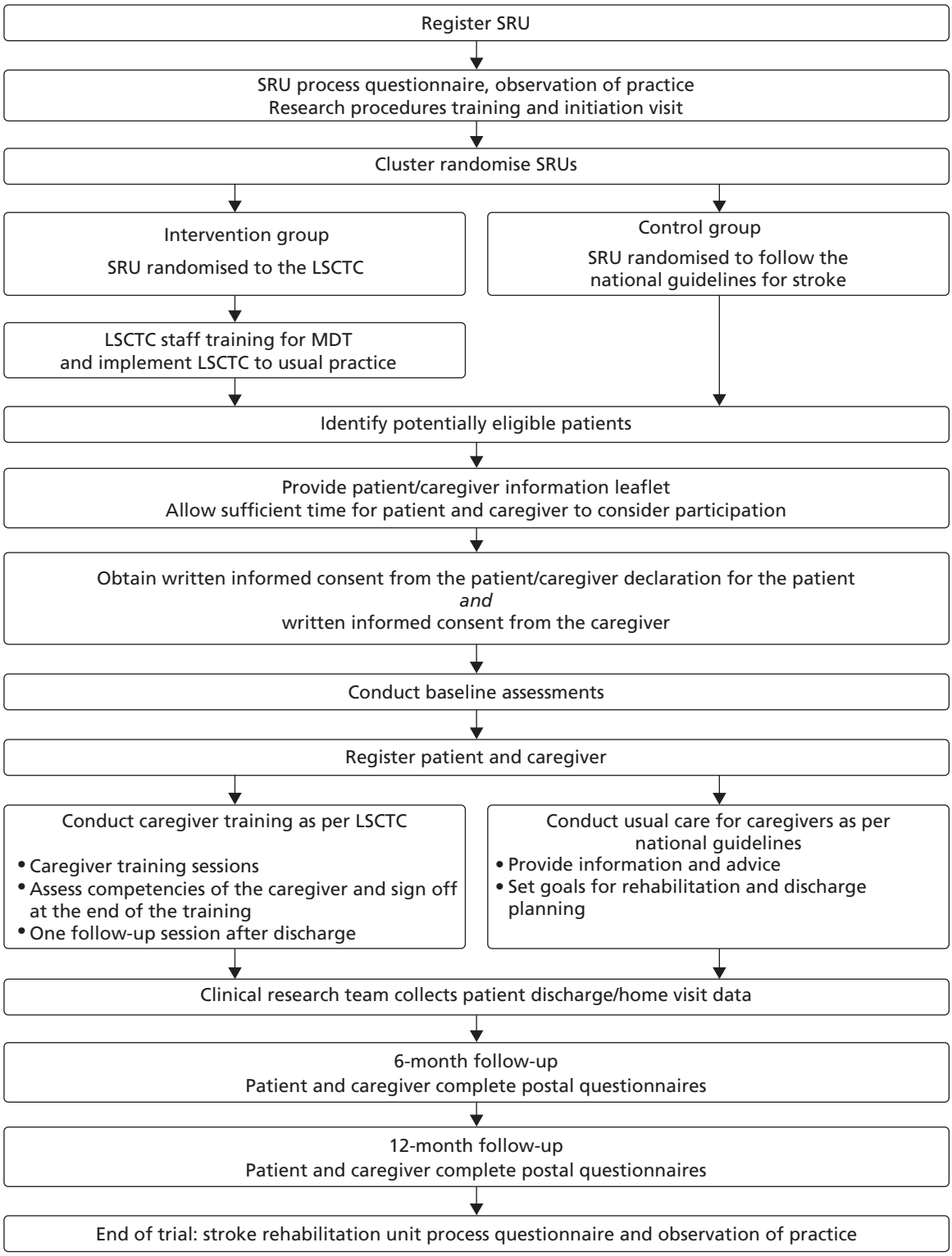
TRIAL SUMMARY

This cluster, randomised, controlled trial is designed to evaluate the clinical and cost-effectiveness of a structured, competency-based training programme for caregivers of stroke patients returning home with stroke-related disabilities. The trial aims to recruit 950–1000 patients and caregivers in 36 stroke rehabilitation units. The intervention developed by Kalra and colleagues is known as the London Stroke Carer Training Course (LSCTC) and comprises a number of carer training sessions, competency assessment and one follow up session after discharge. The multidisciplinary teams (MDTs) in the units randomised to the intervention group will be trained to deliver the LSCTC, whilst those randomised to the control group will continue to provide usual care as per the National Guidelines. The primary outcomes are extended activities of daily living for the patient and caregiver burden measured at six months after recruitment. Secondary outcomes include cost-effectiveness, with final follow-up at twelve months.

FLOWCHART


Register SRU
SRU process questionnaire, observation of practice
Research procedures training and initiation visit
Cluster randomise SRUs
Intervention group
SRU randomised to the LSCTC
Control group
SRU randomised to follow the national guidelines for stroke
LSCTC staff training for MDT and implement LSCTC to usual practice
Identify potentially eligible patients
Provide patient/caregiver information leaflet
Allow sufficient time for patient and caregiver to consider participation
Obtain written informed consent from the patient/caregiver declaration for the patient
and
written informed consent from the caregiver
Conduct baseline assessments
Register patient and caregiver
Conduct caregiver training as per LSCTC
• Caregiver training sessions
• Assess competencies of the caregiver and sign off at the end of the training
• One follow-up session after discharge
Conduct usual care for caregivers as per national guidelines
• Provide information and advice
• Set goals for rehabilitation and discharge planning
Clinical research team collects patient discharge/home visit data
6-month follow-up
Patient and caregiver complete postal questionnaires
12-month follow-up
Patient and caregiver complete postal questionnaires
End of trial: stroke rehabilitation unit process questionnaire and observation of practice

BACKGROUND

A cluster randomised controlled trial of a structured training programme for caregivers of in-patients after stroke

Stroke remains a major health problem in the 21st Century with incidence rates of 1.65 per 1000 population for first ever strokes [1]. Robust evidence supports the recommendation that patients with moderate or severe symptoms should be referred to hospital with the expectation of admission to a stroke unit [2]. Stroke is a family illness generating considerable personal, financial and societal burdens. After a recommended initial hospital admission [2], up to 80% of patients are discharged home and many will be dependent on informal caregivers, usually family members, to provide assistance with activities of daily living, including bathing, dressing, and toileting [3]. For some, this avoids or delays admission to institutional care and the economic value of the informal care provided is considerable [4]. This burden of care, however, has an important effect on caregivers' physical and psychosocial well-being [5] with up to 48% of caregivers reporting health problems, two-thirds a decline in social life [6] and high self-reported levels of strain. These issues are compounded by families being over-protective and a perception of lack of respite with reluctance to leave the patient alone [3]. With the current emphasis on shorter hospital stays caregivers will play an increasingly important role in the care and continued rehabilitation of patients after stroke. The successful adjustment of patients and their caregivers to the aftermath of stroke is clearly interlinked. Caregivers have an important role in enhancing patients' rehabilitation, and coping strategies that lead to negative experiences are associated with increasing dependence [7]. The caregivers of patients with poor physical and emotional states are likely to have poor emotional outcomes themselves [8]. Effective training of caregivers therefore should not only improve their own health but also the recovery and adjustment of the stroke patient [9]. However, despite the physical, psychological and social consequences of caregiving, its economic benefit to society and its importance in patient recovery, caregivers' central role is often given low priority in the management of stroke [10] and there are missed opportunities for structured skills training [11]. Caregivers identify information and skills training required to implement physical care as the most important pre-discharge needs [12]. Caregiver support is a key component of stroke unit care yet, as currently provided, is not compatible with their expressed needs and their ability to care is not assessed [9, 12].

These deficiencies have recently been addressed in a single centre, randomised controlled trial (RCT) by Kalra *et al*. [13]. They reported the effectiveness of a purposely designed systematic and structured training programme for caregivers which included assessment in competencies in skills essential for the day-to-day management of disabled stroke survivors (The London Stroke Carer Training Course, LSCTC). The LSCTC was effective in decreasing caregiver burden and in decreasing their anxiety and depression, improving psychological outcomes for patients and reducing overall costs [14]. However, there are important limitations to the generalisability of the trial findings as the LSCTC was tested in a single centre, delivered by a separate specialist team that might be expected to have heightened motivation and expertise, and the patient population was predominantly recruited from a middle class suburban area who might be more responsive to a training and education programme. In addition, having demonstrated benefit for caregivers on a range of domains, it is now important to evaluate the effectiveness of the LSCTC programme on improving patient outcomes. We therefore seek to embed the LSCTC in usual practice and thereby test wider generalisability in settings where the population, health and social care provision are different.

AIMS AND OBJECTIVES

The aim of the TRACS trial is to evaluate the clinical and cost-effectiveness of a structured competency based caregiver-training programme (LSCTC) on improved patient outcomes in patients with a confirmed primary diagnosis of new stroke by comparison to usual practice according to the National Guidelines for Stroke.

Primary Patient Objective:

The primary patient objective of the trial will be to determine whether a structured, competency-based training programme (LSCTC) for caregivers improves physical outcomes for patients after disabling stroke.

Primary Caregiver Objective:

The primary caregiver objective of the trial will be to determine whether a structured, competency-based training programme (LSCTC) for caregivers reduces burden for caregivers of patients after disabling stroke.

Secondary Objectives:

The secondary objectives are:

1. To determine whether the provision of the LSCTC for caregivers improves physical and psychological outcomes for patients after disabling stroke;
2. To determine whether the provision of the LSCTC for caregivers improves physical and psychological outcomes for caregivers of patients after disabling stroke;
3. To assess whether such a training programme is cost-effective based on (a) patient outcomes, from both health/social care and societal perspectives and (b) caregiver outcomes, from a health care perspective.

DESIGN

TRACS has been designed as a pragmatic, multicentre, cluster randomised, controlled trial with blinded follow-up. 950–1000 stroke patients with residual disability and their caregivers will be recruited, where the patient is likely to return home with the support of the caregiver. The unit of randomisation will be the participating stroke rehabilitation units, 18 will deliver the London Stroke Carer Training Course (LSCTC) to all caregivers of in-patients and 18 will continue to deliver usual care as per the National Guidelines for Stroke. Blinded follow-up will be through postal questionnaire at six and twelve months after recruitment.

A cluster randomised trial design has been purposely selected to reduce between-group treatment contamination. Although patient-level randomisation was used in the earlier single centre study [13], the LSCTC was delivered by a small, purposefully trained team (nurse and therapists) and intensive monitoring was required to reduce treatment contamination. However, in routine stroke unit care, the LSCTC intervention will not be delivered by a discrete team but will be incorporated into usual practice by the whole multidisciplinary team (MDT). Patient level randomisation has the consequence therefore that the MDT will need to operate two approaches (usual care and the LSCTC). The risk of contamination will be high as it will not be possible to blind members of the MDT and the new care process is likely to be extended to patients in the usual care group. Monitoring to reduce opportunities for treatment contamination, as undertaken in the single centre study, would be considerably more difficult in the context of a multi centre trial. Randomisation will therefore be at the level of the stroke unit. In order to minimise selection bias, there will be a clear separation between the provision of the intervention by clinical staff and the recruitment and consent of patients and caregivers by the research practitioners.

CENTRE ELIGIBLITY, RANDOMISATION AND PROCESS EVALUATION

CENTRE ELIGIBILITY

Stroke rehabilitation units will be defined according to the definition provided by the Royal College of Physicians of London for the National Sentinel Stroke Audit 2006 [15].

The 5 key criteria are:

- Consultant physician with responsibility for stroke
- Formal links with patient and caregiver organisations
- Multidisciplinary meetings at least weekly to plan patient care
- Provision of information to patients about stroke
- Continuing education programmes for staff.

A stroke unit will be defined by the presence of 4/5 of these criteria. Additional criteria will be that a substantial number of patients on the unit will have a diagnosis of stroke, that the unit will be able to deliver the LSCTC and that the majority of patients are discharged to a permanent place of residence.

CENTRE RANDOMISATION

Eligible centres that agree to participate will be registered and randomised to the trial. The Principal Investigator for each centre will provide the following information prior to randomisation:

- Name of Stroke unit
- Stroke unit centre code
- Stroke unit address and telephone number
- Geographical region
- Name of Consultant physician with responsibility for stroke
- Name of main contact
- Confirmation of willingness to participate
- Score on the key 12 indicator score of the 2006 National Stroke Audit (NSSA) [15]
- Average monthly admission figures for past 12 months
- Number of beds
- Confirmation that a substantial number of patients on the unit will have a diagnosis of stroke
- Confirmation of eligibility by confirming at least 4/5 of the following centre eligibility criteria:
    - Consultant physician with responsibility for stroke
    - Formal links with patient and caregiver organisations
    - Multidisciplinary meetings at least weekly to plan patient care
    - Provision of information to patients about stroke
    - Continuing education programmes for staff.

Cluster randomisation will be performed centrally at the Clinical Trials Research Unit (CTRU). The eligible stroke rehabilitation units will be randomised on a 1:1 basis to either the intervention group or the control group. The randomisation will be stratified by the following stroke unit co-variates: geographical region and quality of care (as defined by on and above or below the median score on the key 12 indicator score of the 2006 National Stroke Audit (NSSA) [15]). Block randomisation will ensure these important covariates are balanced between the arms of the trial.

Staff Training in Centres Randomised to the Intervention (LSCTC)

Training on the implementation and delivery of the LSCTC will be provided at each of the 18 stroke rehabilitation units randomised to the intervention prior to commencement of patient recruitment. The training will be provided by an LSCTC training team who were part of the LSCTC implementation team in the initial single centre study [13]. The LSCTC training team will not be involved in the research procedures. An initial meeting will discuss the structured competencies based training and practical implementation aspects, re-enforced by illustrative cases and involving sessions of role play. Each unit will be provided with the competencies assessment tool presented in a 'training manual' and required to develop an initial case load of patients and caregivers. These practical experiences will be used for discussion at a second centrally based training session which staff from the 18 stroke rehabilitation units will attend four weeks after the first. Subsequent to this, the staff will gradually increase the delivery of the LSCTC until it becomes an

integral part of the ward care process. Members of the trial team will visit each site and use the completed caregivers' competencies assessment tool as a basis for discussions on structure and process. A further training session will be arranged if necessary to provide feedback and support, and discuss any problems with LSCTC provision. The LSCTC training team will be available, by telephone, to provide clinical support throughout the intervention period. Stroke units will open to recruitment three to six months after the initial training meeting when the research practitioners are happy that the LSCTC has been implemented correctly.

PROCESS EVALUATION

Process data will be used to inform the health economic quantification and describe the care process that prepares patients and caregivers for discharge in the participating centres (stroke rehabilitation units). Data will be collected at the following time points:

Pre-recruitment

A process questionnaire will be completed by the Research Manager, Principal Investigator and the stroke rehabilitation unit MDT.

Observations of current practice.

Process case report forms (CRFs) to record staff time input into caregiver support will be completed by the MDT.

During the Trial

A process questionnaire will be completed by the trial researchers and the stroke rehabilitation unit MDT.

Observations of current practice will be undertaken by a researcher independent of trial procedures*.

Process case report forms (CRFs) to record staff time input into caregiver support will be completed by the MDT.

Qualitative interviews will be conducted with a purposeful sample of stroke patients and caregivers up to three months post discharge from a participating stroke rehabilitation unit*.

Additional questions regarding caregiver support will be added to the six month follow–up caregiver postal questionnaire pack (see section 0).

When Recruitment has ended

Qualitative interviews will be conducted with a purposeful sample of MDT members to capture their experience of delivering the intervention*.

*Please note that the activities denoted (*) above will be incorporated into a process evaluation sub-study and separate ethical approval will be sought.

PATIENT AND CAREGIVER ELIGIBILITY

INCLUSION CRITERIA:

All patients with the following characteristics are eligible for this trial:

- Have a confirmed primary diagnosis of new stroke.
- Are medically stable.
- Are likely to return home with residual disability at the time of discharge.

- Have a caregiver available, defined as the main person, other than health, social, or voluntary care provider, helping with activities of daily living and/or advocating on behalf of the patient, is willing and able to provide support to the patient after discharge.
- Written informed patient consent/a caregiver declaration and caregiver consent will be obtained prior to any trial specific procedures.

Exclusion Criteria:

Unless the patients exhibit the following characteristics:

- In need of palliative care.
- If discharge is planned within one week of admission to the current stroke unit.
- If the patient or caregiver was registered to the trial on a previous admission.
- Patients involved in other stroke research network adopted studies will also be recruited into this study unless: 1) the patient is recruited into the ActNoW study (which assesses intensive speech therapy versus no speech therapy); 2) the patient is first recruited into another trial involving 6 and 12 months follow up questionnaires (currently only the STICH study).

PATIENT AND CAREGIVER RECRUITMENT AND REGISTRATION

SCREENING

The clinical research team will complete a log of all patients and caregivers screened for eligibility including those who are not registered either because they are ineligible or because they decline participation. Anonymised information will be collected including:

- the reason not eligible for trial participation or
- eligible but declined
- eligible and consented
- age
- gender
- ethnicity
- relationship of the patient to the caregiver
- living circumstances (live alone , co-habit or in residential/nursing home)
- living circumstances (caregiver co-resident or non-resident)
- length of hospital stay.

RECRUITMENT PROCESS

Recruitment to the trial and baseline assessment will be undertaken by a member of the clinical research team, (independent of the clinical team) who will visit the stroke rehabilitation units at least once a week to liaise with the clinical team, assess patient and caregiver suitability and obtain informed consent from both patients and caregivers to undertake baseline and follow-up assessments. Rates of identification, recruitment and refusals will be monitored for all sites (see Section 8.1) Identification rates will be monitored against past admission rates for each site.

INFORMED CONSENT

A verbal explanation of the trial and Patient and Caregiver Information Sheets will be provided by the clinical research team for the patient and caregiver to consider. These will include detailed information about the rationale, design and personal implications of the study. Following information provision, patients and caregivers will be given sufficient time to consider participation and will be given the opportunity to discuss the trial with their family and healthcare professionals before they are asked whether they would be willing to take part in the trial. Information about the trial will be repeated again if the patients and caregivers require time to consider their participation and the ***participants*** (patient and caregiver)

will again have the opportunity to ask questions and confer with other members of their family. Consent will then be taken. The right of the patient and caregiver to refuse consent without giving reasons will be respected.

Assenting patients and caregivers will then be invited to provide informed, written consent to complete baseline and follow up assessments. For patients unable to read/sign the consent form due to stroke related disabilities, and for those with problems of comprehension, a caregiver declaration will be sought. For patients unable to consent for themselves, this study complies with the Mental Capacity Act (MCA) 2005. In such cases, the caregiver will act as consultee. The caregiver will be advised to set aside their own views and provide advice on the participation of the patient in the research, taking into consideration the patient's wishes and interests. Research participants will not be required to do anything which is contrary to any advance decisions or statements that have been made by them in relation to their treatment or any other matter. Advance decisions made by the patient about their preferences and wishes will always take precedence.

The caregiver will also be approached to provide consent on their own behalf. Formal assessment of eligibility and informed consent will be undertaken by a member of the clinical research team. The patient and caregiver will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment. The original consent forms will be retained in the investigator site file. A copy of the patient and caregiver consent forms will be given to the patient and caregiver respectively. Further copies will be filed in the patient hospital notes and a fourth set of copies will form part of the central study archive and be returned to the CTRU.

Informed written patient consent/caregiver declaration and caregiver consent for entry into the trial will be obtained prior to patient and caregiver registration. The responsibility for the overall care of the patient remains with the attending clinical teams.

REGISTRATION

Patients and caregivers will be registered with the CTRU following informed consent, confirmation of eligibility and collection of baseline data. Registration will be performed centrally using the CTRU automated 24-hour telephone registration system. Authorisation codes and PINs, provided by the CTRU, will be required to access the registration system.

When eligibility has been confirmed and the necessary details obtained (see Section 0) patients and caregivers will be allocated trial numbers.

DIRECT LINE FOR 24-HOUR REGISTRATION: +44 (0)113 343 4928

TREATMENT

All patients in this study will be treated within an organised stroke service (stroke unit). The clinical research team will be available to all participating stroke units (control and intervention groups) to provide support regarding the research procedures.

USUAL CARE (CONTROL GROUP)

In stroke rehabilitation units randomised to the control group, usual care for caregivers following national guidelines [2] will include:

- provision of information on stroke and its consequences, prevention, and management options
- involvement in goal setting for rehabilitation and discharge planning

- encouragement to attend nursing and therapy activities to learn about patients' abilities and informal instruction on facilitating transfers, mobility and activities of daily living tasks
- advice on community services, benefits and allowances, including contact information provided for voluntary support services for caregivers.

CAREGIVER TRAINING PROGRAMME (INTERVENTION GROUP)

In stroke rehabilitation units randomised to the intervention group usual care will be augmented by provision of the LSCTC programme incorporated into ward practice (see Section 0). Caregivers will receive sessions of the structured training programme depending on need [12, 13]. Caregivers' competencies will be assessed (and signed off) at the end of training. In addition, one "follow through" session will be provided either through a telephone call or home visit by an appropriate member of the clinical team (member of MDT, community stroke team or other professional who normally completes such a follow up on discharge) to adapt skills learnt to the home environment.

As part of the LSCTC programme, caregivers will receive:

Instruction by appropriate professionals on common stroke related problems and their prevention, management of pressure areas and prevention of bed sores, continence, nutrition, positioning, gait facilitation, and advice on benefits and local services.

"Hands-on" training in lifting and handling techniques, facilitation of mobility and transfers, continence, assistance with personal activities of daily living and communication, tailored to the needs of individual patients.

WITHDRAWAL

In line with usual clinical care, cessation or alteration of regimes at any time will be at the discretion of attending clinical teams, clinicians or the patients and caregivers themselves. Where caregivers or patients wish to withdraw, there will be clarification of whether this is withdrawal from postal or medical records follow up or both.

DATA COLLECTION/ASSESSMENTS

Participating stroke rehabilitation units will be expected to maintain a file of essential trial documentation (Investigator Site File), which will be provided by CTRU, and keep copies of all completed CRFs for the trial. Stroke rehabilitation unit usual practice will be determined by the process evaluation (see section 0).

Patient and caregiver assessments will be undertaken as follows:

- Registration and Baseline (after consent but prior to registration)
- Discharge/Home visit
- 6-month follow-up
- 12-month follow-up.

REGISTRATION AND BASELINE DATA

Patients and caregivers who meet the inclusion criteria and provide informed written consent (for baseline assessment and follow-up) will be registered to the trial. The TRACS research practitioners will provide details at registration, including:

- Patient details including initials and date of birth
- Caregiver details including initials and date of birth
- Centre code
- Name of the research practitioner conducting the registration

- Confirmation of eligibility
- Confirmation of written informed consent

The TRACS clinical research team will also record additional baseline information including:

Centre details:

- Hospital name
- Centre code
- Name of the research practitioner conducting the registration.

Patient details:

- Name
- Gender
- Date of birth (age to be calculated*)
- Ethnicity
- NHS ID
- Hospital ID
- Confirmation of eligibility
- Modified Rankin score [16]
- Living circumstances*
- Relationship of the patient to the caregiver
- Address and telephone number
- GP address and telephone number
- Preferred language
- Education and employment
- Name of attending physician
- Date of patient admission
- Date of stroke
- Classification of stroke type
- Language ability
- Short Orientation-Memory-Concentration Test (6CIT) [17]
- Pre-stroke independence*
- Verbal subsection of the Glasgow Coma Scale [17, 18]
- Ability to lift both arms off the bed*
- Ability to walk independently*
- Barthel Index [19] (pre-stroke activities of daily living)
- Previous stroke

Caregiver details:

- Name
- Gender
- Date of birth
- Ethnicity
- Confirmation of eligibility
- Modified Rankin score [16]
- Address and telephone number
- GP address and telephone number
- Preferred language
- Education and employment

The patients will complete the following questionnaires at baseline; details on proxy completion will also be collected:

- The Nottingham Extended Activities of Daily Living Scale (NEADL) [20, 21] for pre-stroke independence
- Hospital Anxiety and Depression Scale (HADS) [22] (post stroke mood)
- EQ-5D [23–25] (post stroke health state)
- Barthel Index [19, 26] (post-stroke activities of daily living)
- Stroke Impact Scale [27–30] (post stroke functional ability and health related quality of life)
- Patient Client Service Receipt Inventory (CSRI) [14, 31] (pre-stroke economic outcome)

The caregivers will complete the following questionnaires at baseline:

- Frenchay activities index [32, 33] (social restriction)
- HADS [22] (mood)
- EQ-5D [23–25] (post-stroke health state)
- Caregiver Client Service Receipt Inventory (CSRI; pre-stroke economic outcome)

The six factors (highlighted by *) from the Edinburgh stroke case mix adjuster [34, 35] will enable an adjustment for case mix to be made.

Patients and caregivers will be provided with change of address cards to be returned to the CTRU by post if required.

DISCHARGE/HOME VISIT DATA

The TRACS clinical research team will record the following information for patients at discharge:

- Date of discharge.
- Destination at discharge.
- Pre-discharge home visit details.
- Details of Expected Serious Adverse Events (see Section 0) between the date of consent and date of discharge
- Documented evidence regarding the patient's care process.

ADDITIONAL DATA COLLECTED FOR THE INTERVENTION GROUP

During the LSCTC intervention period (between the date of consent and date of the home visit) members of the stroke rehabilitation unit MDT will record their inputs into delivering the LSCTC (for the purposes of the economic evaluation) and caregiver compliance with the LSCTC including:

- number of training sessions
- time taken
- competencies sign off

FOLLOW-UP DATA

Patients and caregivers will be followed-up by the CTRU via postal questionnaires at six and twelve months. This will be supported by postal and telephone reminders if questionnaires are not returned within two weeks. If necessary, a 'masking' system will be used so that research administration staff can undertake telephone reminders blind to the patients' and caregivers' regional telephone code. All losses to follow-up, through death, withdrawal and loss of contact will be fully reported by the clinical research team. Completion rates will be monitored as agreed by the DMEC, TSC and TMG in the monitoring schedule. If completion falls below an acceptable standard agreed by the DMEC, TSC and TMG, patients and caregivers may be contacted by telephone to complete the primary outcome measures (NEADL and caregiver burden scale).

All patients and caregivers who are registered into the study will be considered as part of the intention to treat population and efforts will be made to follow them up when appropriate.

The CTRU will check with the GP whether the patient and caregiver are alive prior to contact. If the patient has died, no further follow-up will be undertaken. If the caregiver has died, patient follow-up will still be undertaken. In both cases their death will be recorded on the appropriate form and the cause will be established through contact with the GP and reference to electronic or paper health records. When patient and caregiver survival status has been established postal questionnaires will be sent out by the CTRU.

The following questionnaires will be included in the postal packs for patients:

- NEADL [20, 21]
- HADS [22] (mood)
- EQ-5D [23–25] (health state)
- Barthel Index [19, 26] (activities of daily living)
- Stroke Impact Scale [27–30] (functional ability and health related quality of life)
- Patient CSRI [14, 31] (economic outcome).
- If the patient was aware of receiving / being denied better treatment because of this research (at 12 month follow-up only).

The following questionnaires will be included in the postal packs for caregivers:

- Caregivers Burden Scale [36]
- Frenchay activities index (social restriction) [32–33]
- HADS [22] (mood)
- EQ-5D [23–25] (health state)
- Caregiver CSRI (economic outcome)
- Additional questions relating to:
    - Caregiver support during the intervention period (at six month follow-up only)
    - If the caregiver is still caring for the patient
    - If the caregiver was aware of receiving / being denied an enhanced training package (at 12 month follow-up only)
    - Caregiver's stroke knowledge [37, 38].

The TRACS team will record the following information for patients and if necessary caregivers, at six and twelve months post registration using electronic or paper health and patient social care records:

- Death
- Hospital re-admissions
- Institutionalisation
- Treatment on an emergency outpatient basis.

ASSESSMENT INSTRUMENTS

The assessment instruments have been incorporated into patient and caregiver assessment packs. All instruments have been used extensively in previous stroke research, are sensitive to change, valid and reliable. They have been reviewed by the Consumer Research Advisory Group attached to the Academic Unit of Elderly Care and Rehabilitation who felt that the questions were understandable, relevant and appropriate. Information on who completed the outcome measures will be requested, proxy responses will be allowed. Where the patient is unable to complete the questionnaire due to stroke related disabilities (visual/motor) a friend/relative/carer can complete the questionnaire using the patient's verbal responses. Where the patient is unable to communicate answers and/or understand the questions, a proxy can complete

the questionnaire entirely on the patient's behalf. The number of proxy responses will be compared between the two groups.

Nottingham Extended Activities Of Daily Living Scale (NEADL)

Physical and social independence will be measured using the Nottingham Extended ADL Scale (NEADL) [20, 21]. It was designed as a postal questionnaire and assesses aspects of physical and social independence performance across 22 items (score range 0–66) grouped in four categories (mobility, kitchen, domestic and leisure activities). It has been widely used as an outcome measure in rehabilitation trials [39, 40]. It has proven validity, reliability [41] and has demonstrated responsiveness to change and able to discriminate between services [42].

Hospital Anxiety And Depression Scale (HADS)

Both patients and caregivers mood will be assessed using the 14 component Hospital Anxiety and Depression Scale (HADS) [22]. It was initially developed as an instrument to identify anxiety disorders and depression in medical outpatients [22], but has since proven to exhibit wider generalisability [43].

EQ-5D

The non-disease-specific EQ-5D instrument [23–25] will be used to evaluate health-related quality of life for both patients and caregivers via a six component questionnaire. It was developed to yield a fundamental index of health, which can be used to calculate quality-adjusted life-year (QALY) gains, and thus will facilitate the health economic evaluation.

Barthel Index

Patient activities of daily living and mobility will be assessed using the Barthel Index [19, 26]. This instrument will be used to evaluate the patient's disability and level of dependence on their caregiver via assessment of their ability in bathing, transferring from bed to chair, dressing, feeding, mobility, climbing stairs, toilet use, grooming, and bladder and bowl continence.

Stroke Impact Scale

Functional ability and health related quality of life of the patients will be measured using the Stroke Impact Scale [27–30]. This scale consists of eight components measuring strength, memory and thinking, emotion, communication, activities and independent activities of daily living, mobility, hand function, and social participation. It was developed for use as a self reporting questionnaire, which has proven to be reliable, valid and sensitive to change [27, 44]. SIS has also been validated for use as a postal questionnaire [45].

Client Service Receipt Inventory (CSRI)

Data on patient socio-demographics and use of health and other formal care services and informal care will be collected using a Client Service Receipt Inventory validated for use with stroke patients [14, 31]. A reduced form of this instrument will be used with caregivers.

Caregiver Burden Scale

Caregiver burden will be measured using a proven and reliable Caregiver Burden Scale [36]. This 22-item scale will assess various aspects of caregiver burden including general strain, isolation, disappointment, emotional involvement and environment.

Frenchay Activities Index

The social restriction on caregivers will be assessed using the Frenchay Activities Index [32, 33]. Although initially validated to assess the activities of acute stoke patients, this assessment instrument is applicable to caregivers of patients with disabling stroke [13].

Definition of End of Trial

The end of the trial is defined as the date the last twelve month postal questionnaire pack is completed.

SERIOUS ADVERSE EVENTS PROCEDURES

GENERAL DEFINITIONS

An adverse event (AE) is:

- any unintentional, unfavourable clinical sign or symptom
- any new illness or disease or the deterioration of existing disease or illness
- any clinically relevant deterioration in any laboratory assessments or clinical tests.

A serious adverse event (SAE) is defined in general as an untoward event which:

- is fatal or life threatening
- requires or prolongs hospitalisation
- is significantly or permanently disabling or incapacitating
- constitutes a congenital anomaly or a birth defect or
- may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

A SAE occurring to a research participant, where in the opinion of the chief investigator the event is related and unexpected will be reported to the main Research Ethics Committee (REC).

The National Research Ethics Service (NRES) defines related and unexpected SAEs as follows:

- 'related' – that is, it resulted from administration of any research procedures; and
- 'unexpected' – that is, the type of event is not listed in the protocol as an expected occurrence.

TRACS OPERATIONAL DEFINITIONS

Events such as patient falls and caregiver musculoskeletal injury represent an inherent consequence of an active rehabilitation process and therefore cannot be entirely avoided. Similarly, in this patient population, acute illness resulting in hospitalisation, new medical problems and deterioration of existing medical problems are expected.

Expected AE/SAEs – not reportable

In recognition of this, events fulfilling the definition of an adverse event (except those listed in Section 0) will not be reported in this study.

In addition, Serious Adverse Events will not be reported as follows:

- Episode of acute illness (e.g. further stroke, cardiovascular event, infection) occurring between the time of consent and date of discharge.

Expected AEs/SAEs – standard reporting

The following Serious Adverse Events are not common but are expected within the patient study population during patient hospitalisation and will be reported by the clinical research team between the date of consent and date of discharge using a standardised discharge CRF.

- Patient falls with or without fracture will be reported when they occur at any time between the date of consent and date of discharge.

The following AEs and SAEs are expected within the patient study population following discharge from hospital and will be established during follow-up and self-reported by patients within the Client Service

Receipt Inventory. The TRACS clinical research team will also collect this data using electronic or paper health and social care records:

- Death (SAE)
- Hospital admissions and re-admissions for any reason (SAE)
- Institutionalisation (AE)
- Treatment on an emergency outpatient basis (AE).

In addition, caregiver hospitalisation, institutionalisation and death are expected and will be subject to standard reporting using the caregiver postal questionnaire pack at follow-up. If necessary The TRACS clinical research team will also collect this data using electronic or paper health and social care records

As these events are expected within the study population they will not be subject to expedited reporting to the main REC. They will however, be included in the annual safety report provided to the main REC.

Unexpected and related SAEs – expedited reporting

All Related/Unexpected SAEs occurring to either the patient or caregiver from the date of consent up to twelve months post registration must be recorded on the Related/Unexpected Serious Adverse Event Form and faxed to the CTRU **within 24 hours** of the clinical research staff becoming aware of the event. The original form should also be posted to the CTRU in real time and a copy retained on site.

For each Related/Unexpected SAE the following information will be collected:

- date of SAE
- full details in medical terms with a diagnosis, if possible
- its duration (start and end dates; times, if applicable)
- action taken
- outcome.

Any follow-up information should be faxed to CTRU as soon as it is available. Events will be followed up until the event has resolved or a final outcome has been reached.

CTRU Fax number for reporting Related/Unexpected Serious Adverse Events: 0113 343 1471

All Related/Unexpected SAEs will be reviewed by the Chief Investigator and subject to expedited reporting to the Sponsor and the main REC by the CTRU on behalf of the Chief Investigator within 15 days.

Responsibilities of the Chief Investigator, CTRU, Trial Steering Committee (TSC), Data Monitoring and Ethics Committee (DMEC) and Sponsor will be detailed in a study specific Work Instruction.

HEALTH ECONOMICS

Given that health care resources are finite it is important to demonstrate the economic implications of any new intervention. The single centre study found that LSCTC reduced costs, largely as a result of reduced length of stay. It is unclear whether this finding is generalisable to other settings due to variations across stroke rehabilitation units in, for example, discharge policies, availability of beds, staff mix and patient case-mix. Therefore, a comprehensive economic evaluation will assess the cost-effectiveness of the LSCTC in this multi-centre trial, based on both patient and caregiver outcomes. It will be carried out from a health care perspective for the caregiver outcome evaluation, and both a health/social care perspective (health care resources and other formal care agencies) and a societal perspective (health care resources, other formal care agencies and informal care inputs) for the patient outcome evaluation and will follow the familiar stages of an economic evaluation [46]. Briefly, this involves measuring the resources associated with each treatment

approach from the chosen analysis perspective(s), estimating the total costs of those resources and then, importantly, linking costs with outcomes. The economic evaluation will be fully integrated into the effectiveness evaluation, with the same criteria adopted for trial eligibility, randomisation and intervention modes.

Data will be collected retrospectively at baseline (for the previous three months) and then at 6 and 12 months (for the time since previous assessment) which will allow estimation of total costs over 1 year (and therefore a comparison with the cost findings from the single centre study). Data on use of health and other formal care resources and informal care will be collected using a Client Service Receipt Inventory (CSRI) validated for use with stroke patients [14, 31]. A reduced version of this instrument, containing questions about use of core health care services, will be used with caregivers. In both cases, it will be completed as a self-complete questionnaire alongside other measures at baseline, 6 months and 12 months. Self-reports of patient and carer inpatient admissions will be verified against hospital records.

Unit costs will be attached to each service or element of support in turn, using the best available estimates of long-run marginal opportunity cost which will include capital and overhead elements. National unit costs will be used where possible to facilitate generalisability of results, with new local estimations calculated where necessary. Informal care costs will be estimated using the opportunity cost method (the value of the opportunities forgone by caregivers as a result of time spent on caregiving). The cost of LSCTC inputs (including staff training) will be incorporated into the evaluation. Average unit costs per session of LSCTC will be calculated and multiplied by the number of sessions received by each caregiver. If necessary, adjustments will be made to unit costs of the stroke rehabilitation units in order to avoid double-counting staff inputs. Unit costs will be combined with resource volumes to obtain a total cost per patient, from each analysis perspective, at each assessment point, for both patient and caregiver evaluations and over the entire period of participation in the trial.

All costs will be reported as mean values with standard deviations. To accommodate a cluster randomisation design, differences in costs between groups will be tested by multi level modelling.

The primary economic analysis will take the form of a cost-effectiveness analysis. This will involve combining and comparing total average costs from each analysis perspective with the primary outcome measures (patient NEADL and Caregiver Burden Scale) in the form of incremental cost-effectiveness ratios (ICERs) to represent additional cost per additional point on the NEADL for the patient evaluation and the Caregiver Burden Scale for the caregiver evaluation.

A secondary economic analysis will examine quality of life outcomes through cost-utility analyses, again from each analysis perspective, exploring cost per quality-adjusted life-year (QALY) gained for both patients and caregivers. Health states will be measured at each assessment point (baseline, 6 months and 12 months) using the EQ-5D. Utility weights from a United Kingdom general population survey [47] will be applied to these health states to calculate quality-adjusted life-years. Quality-adjusted life-year outcomes will be examined in terms of change between post-stroke and each follow-up point, using linear interpolation to calculate the area under the QALY curve. Given the wide range of other outcome domains of interest in the study, a supplementary cost-consequence analysis will additionally present total average costs for each trial arm alongside all outcome measures.

Sensitivity analyses will alter any key assumptions made in the economic analyses (e.g. unit costs of stroke rehabilitation units, LSCTC and informal care) to explore the consequences for the results. Uncertainty around the cost-effectiveness and cost-utility of LSCTC will also be explored using incremental cost-effectiveness planes and cost-effectiveness acceptability curves (CEACs) based on the net benefit approach [48]. The CEAC reveals to the decision-maker the likelihood of LSCTC being cost-effective relative to usual care given different (implicit monetary) values placed on incremental improvements in the NEADL, Caregiver Burden Scale and QALYs. CEACs will be based on bootstrapped (to account for non-normally distributed data) regressions of study group upon net benefits, controlling for clusters.

ENDPOINTS

In common with other stroke rehabilitation trials [39, 40] the primary outcome point is at six months with final follow-up at 12 months to assess whether any intervention effect is sustained.

PRIMARY ENDPOINTS

Patient endpoint

- Nottingham Extended Activities of Daily Living (NEADL) [20, 21] as completed by the patient at six months.

Caregiver endpoint

- Caregivers Burden Scale [36] as completed by the caregiver at six months.

SECONDARY ENDPOINTS

Patient endpoints at six months

- Hospital Anxiety and Depression Scale (HADS) (mood) [22]
- EQ-5D (health state) [23–25]
- Barthel Index (activities of daily living) [19, 26]
- Stroke Impact Scale [27–30] (functional ability and health related quality of life)
- Death
- Hospital re-admission
- Institutionalisation
- Total costs

Patient endpoints at twelve months

- Nottingham Extended Activities of Daily Living (NEADL)
- Hospital Anxiety and Depression Scale (HADS)
- EQ-5D
- Barthel Index
- Stroke Impact Scale
- Death
- Institutionalisation
- Hospital re-admission
- Total costs

Caregiver endpoints at six months

- Frenchay activities index [32, 33] (social restriction)
- HADS
- EQ-5D
- Death
- Hospitalisation
- Institutionalisation
- Total costs

Caregiver endpoints at twelve months

- Caregivers Burden Scale
- Frenchay activities index (social restriction)
- HADS
- EQ-5D
- Death
- Hospitalisation
- Institutionalisation
- Total costs

STATISTICAL CONSIDERATIONS

SAMPLE SIZE

Thirty-six stroke rehabilitation units each recruiting 25 patients, will result in 450 patients in each group and provide close to 90% power at 5% significance level to detect a clinically relevant difference of six points (as defined in the TOTAL study [39, 49]) on the primary patient outcome, the NEADL (scored 0–66, SD 18). A range of 3–9 points has been taken to be a clinically relevant difference in previous studies. We have taken 6 points as a difference of clinical relevance to the patient and caregiver (patient requiring less help in at least two activities) and also substantive enough to influence commissioners to change service delivery. The sample size takes account of an inflation factor of 1.9 due to clustering (cluster size of 19 after loss to follow-up; Intracluster Correlation Coefficient (ICC) no greater than 0.05 [50]) and 25% loss to follow-up. The assumption that the ICC will be no larger than 0.05 is based on methodological research [51] showing that ICCs for patient outcomes in the community are generally less than 0.05. This sample size of 900 patients will provide more than 85% power at the 5% significance level to detect an effect size of one third in any of the other outcomes. Such an effect size is usually considered moderate. So, for instance, this will ensure more than 85% power to detect a difference of 4.3 points on the Caregiver Burden Scale at six months, assuming the same variability as in the single centre study [13] (i.e. ds of 12.9 at 6 months). Although the differences observed in the single centre study were larger (6.2, 6.7, 8.7 at 3, 6 and 12 months respectively), it is unrealistic to predict that a multi-centre trial would find such large effects. In addition with a sample of 900 the trial will have more than 85% power to detect the annual admission cost difference of £3175 as found in the single centre study [14].

The power of the trial is adversely affected by a higher than expected loss to follow-up (likely to be closer to 30%) and unequal cluster sizes (extent of the imbalance unknown until end of recruitment). Hence, to preserve final power of close to 90%, the trial should aim to recruit between 950 and 1000 patients.

ACCRUAL

Based on a recently completed study [52] involving six stroke units and an ongoing pilot, it is anticipated that 40% of patients/caregivers on a stroke unit will fulfil the entry criteria. Based on recruitment rates in previous studies [53, 54] and the ongoing pilot study, it is conservatively estimated that at least 50% of these will provide informed consent. The average number of patients admitted annually per unit is at least 120, this provides a pool of 4,320 to recruit from and therefore it is estimated that a recruitment rate of 75 patients per month, just over 2 per month for each participating site is more than achievable.

Statistical Analysis

Statistical analysis is the responsibility of the CTRU Statistician. A final statistical analysis plan will be written and reviewed before any final analysis is undertaken. All statistical testing will be performed at a 2-sided 5% significance level.

ANALYSIS POPULATIONS

The Intention to Treat (ITT) population is defined as all patients registered for active follow-up regardless of non-compliance with the intervention. All patients (and the corresponding caregivers) within a stroke unit will be analysed according to the intervention that stroke unit was randomised to. All analyses and data summaries will be carried out using the ITT population.

A per-protocol analysis will be considered if there are a considerable number of protocol violators. This decision will be made jointly by the trial statistician in co-operation with other members of the Trial Management Group on examination of the population. The decision will be made without reference to the endpoint data.

OUTLINE ANALYSIS PLAN

As the trial is cluster randomised, the primary outcome measures, the six month NEADL score and the Caregiver Burden Scale, will each be compared between the intervention and control groups using a two-level hierarchical model, with patients (or caregivers) nested within stroke rehabilitation units. Patient-level covariates, such as patient baseline scores, the Edinburgh stroke case-mix adjuster [35], and the caregiver baseline HADS score, and stroke unit-level covariates, such as the key 12 indicator score will be included in the analysis. Secondary outcomes for patients and caregivers will be analysed using similar multi-level models. Effect sizes and 95% confidence intervals will be reported**.**

Three of the secondary caregiver outcomes (death, hospitalisation and institutionalisation) will be summarised by treatment group. No formal statistical comparison between the intervention and control groups will be undertaken for these outcomes.

A secondary analysis will explore the relationship between outcome and compliance with the LSCTC (e.g. number of sessions, number of formal competency assessments conducted and 'signed off'). Process data collected in the control stroke units will be summarised at each time point to ascertain whether care in the control arm has changed over the course of the trial.

The proportion of non-responders will be compared between randomised groups. Missing items within individual outcome measures will be treated according to instructions for that particular measure. Simple imputation will be used if there are no instructions. A sensitivity analysis will be performed using the last available observation of the NEADL for all patients lost to follow-up to assess the impact of missing follow-up data on the analysis of the primary endpoint. Further secondary analyses will utilise a two-stage model incorporating deaths and primary outcomes, if there is a large number of deaths or an imbalance in the death rates between the two arms.

The number of patients reporting a SAE and details of all SAEs will be reported for each treatment group.

All outcomes will be analysed at the end of the trial but recruitment and safety will be monitored at regular intervals. Outcomes will be summarised once during recruitment for monitoring by the Data Monitoring and Ethics Committee (DMEC).

INTERIM ANALYSIS

No formal interim analyses are planned.

PLANNED SUB-GROUP ANALYSES

No sub-group analyses are planned.

DATA MONITORING

DATA MONITORING

Data will be monitored for quality and completeness by the CTRU, using established verification, validation and checking processes. Missing data, except individual data items collected via the postal questionnaires, will be chased until it is received, confirmed as not available, or the trial is at analysis. Reminders will be sent to patients and caregivers if postal questionnaires are not returned on time.

Rates of recruitment and refusals will be monitored for all sites on a monthly basis to check for differential recruitment rates between control and intervention sites. The completed competencies assessment tool for all trial participants in the intervention units will be returned to the CTRU and a summary of this will be included in a standard monitoring report to the Trial Management Group (TMG), Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC). This will enable monitoring of the intervention delivery and compliance.

The CTRU, Academic Unit of Elderly Care and Rehabilitation and the University of Leeds (Sponsor) reserve the right to intermittently conduct source data verification on a sample of patients. Source data verification will involve direct access to patient notes at the participating stroke rehabilitation units and the collection of copies of consent forms and other relevant investigation reports. A monitoring schedule including primary end point, compliance and safety data will be defined and agreed by the DMEC, TSC and TMG.

DATA MONITORING AND ETHICS COMMITTEE

An independent DMEC will be established to review the safety and ethics of the trial. Detailed unblinded reports will be prepared by the CTRU for the DMEC during set-up and annually thereafter. SAEs will be summarised by treatment group in a monthly report sent to the DMEC. This will enable monitoring of safety rates between control and intervention sites.

TRIAL STEERING COMMITTEE (TSC)

A TSC will be established to provide overall supervision of the trial, in particular trial progress, adherence to protocol, patient safety, and consideration of new information. The committee will meet once during the set-up period and every six months thereafter for the duration of the trial.

CLINICAL GOVERNANCE ISSUES

To ensure responsibility and accountability for the overall quality of care received by patients during the study period, clinical governance issues pertaining to all aspect of routine management will be brought to the attention of the DMEC and where applicable to individual NHS Trusts.

QUALITY ASSURANCE AND ETHICAL CONSIDERATIONS

QUALITY ASSURANCE

The trial will be conducted in accordance with current MRC Good Clinical Practice (GCP) guidelines, NHS Research Governance Framework and through adherence to CTRU Standard Operating Procedures (SOPs).

ETHICAL CONSIDERATIONS

The trial will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, October 2000. Informed written consent will be obtained from the patients and caregivers prior to registration into the study. The right of a patient and caregiver to refuse participation without giving reasons will be respected. The patient and caregiver will remain free to withdraw at any time from the study without giving reasons and without prejudicing the patient's further treatment. The study will be submitted to and approved by a main Research Ethics Committee (REC) and the appropriate REC for each participating stroke unit prior to entering

patients and caregivers into the study. The CTRU will provide the main REC with a copy of the final protocol, patient and caregiver information sheets, consent forms and all other relevant study documentation.

CONFIDENTIALITY

All information collected during the course of the trial will be kept strictly confidential. Information will be held securely on paper and electronically at the CTRU. The CTRU will comply with all aspects of the 1998 Data Protection Act and operationally this will include:

- consent from patients to record personal details including name, date of birth, address and telephone number, NHS ID, hospital ID, GP name and address;
- consent from caregivers to record personal details including name, date of birth, address and telephone number, GP name and address;
- appropriate storage, restricted access and disposal arrangements for patient and caregiver personal and clinical details;
- consent from patients and caregivers for access to their medical records by responsible individuals from the research team or from regulatory authorities, where it is relevant to trial participation;
- consent from patients and caregivers for the data collected for the trial to be used to evaluate safety and develop new research;
- patient and caregiver name, address and telephone number will be collected when a patient and caregiver are registered into the trial but all other data collection forms that are transferred to or from the CTRU will be coded with a trial number and will include two patient and caregiver identifiers, usually their initials and date of birth.

If a patient or caregiver withdraws consent from further trial participation their data will remain on file and will be included in the final study analysis.

ARCHIVING

At the end of the trial, data will be securely archived at the CTRU and participating stroke rehabilitation units for a minimum of 5 years. If a patient or caregiver withdraws consent for their data to be used, it will be confidentially destroyed.

STATEMENT OF INDEMNITY

This trial is sponsored by the University of Leeds and the University of Leeds will be liable for negligent harm caused by the design of the trial. The NHS has a duty of care to patients treated, whether or not the patient is taking part in a clinical trial, and the NHS remains liable for clinical negligence and other negligent harm to patients under this duty of care.

STUDY ORGANISATIONAL STRUCTURE

RESPONSIBILITIES

Chief Investigator

As defined by the NHS Research Governance Framework, the Chief Investigator is responsible for the design, management and reporting of the study.

Clinical Trials Research Unit (CTRU)

The CTRU will have responsibility for conduct of the trial in accordance with the Research Governance Framework, MRC GCP standards and CTRU SOPs.

OPERATIONAL STRUCTURE

Trial Management Group (TMG)

The TMG, comprising the Chief Investigator, research manager, CTRU team and co-investigators will be assigned responsibility for the clinical set-up, on-going management, promotion of the trial, and for the interpretation of results**.** Specifically the TMG will be responsible for (i) protocol completion, (ii) CRF development, (iii) obtaining approval from the main REC and supporting applications for Site-Specific Assessments (SSA), (iv) completing cost estimates and project initiation, (vi) appointing and facilitating the TSC and DMEC, (vii) reporting of serious adverse events, (vii) monitoring of screening, recruitment, consent, treatment and follow-up procedures, safety, data quality and compliance (viii) interpretation of results and contribution to publications.

Clinical Trials Research Unit (CTRU)

The CTRU will provide set-up and monitoring of trial conduct to CTRU SOPs and MRC GCP standards including randomisation design and implementation, patient and caregiver registration, database development and provision, protocol development, CRF design, trial design, monitoring schedule and statistical analysis of clinical endpoints for the trial. In addition the CTRU will support main REC, SSA and R&D submissions and clinical set-up, ongoing management including training, monitoring reports and promotion of the trial. The CTRU will be responsible for the database administrative functions, data management including postal follow-up and telephone reminders, safety reporting, all statistical analyses of clinical endpoints and drafting of publications. The CTRU will have responsibility for the conduct of the study in accordance with the Research Governance Framework and CTRU SOPs.

Clinical Research Team

The Clinical Research Team will comprise the Research Manager, Senior Clinical Research Practitioners and Clinical Research Practitioners organised in a hub and spoke model. The Research Manager will be based at Bradford and will be responsible for the day-to-day running of the trial, centre set-up, liaison with, recruitment and supervision of the other clinical research team members. They will also co-ordinate the centre initiation and LSCTC training.

The Research Practitioners will lead the implementation of the trial across geographical regions to recruit patients and caregivers and undertake data collection.

LSCTC Training Team

The LSCTC training for staff at the stroke rehabilitation units randomised to the intervention group will be provided by an 'LSCTC training team', who were part of the LSCTC implementation team in the initial single centre study [13].

Multidisciplinary Teams at Participating Stroke Rehabilitation Units

The intervention (usual care or LSCTC) will be delivered by the MDTs at the participating stroke rehabilitation units.

Health Economics

Anita Patel and Martin Knapp will assist the CTRU in database development and will be responsible for the design of the economic questionnaires, collation of unit costs, and the conduct, interpretation and writing up of the economic evaluation.

Trial Steering Committee (TSC)

The Trial Steering Committee, with an Independent Chair, will provide overall supervision of the trial, in particular trial progress, adherence to protocol, patient safety and consideration of new information. It will include an Independent Chair and not less than two other independent members. The Chief Investigator and other members of the TMG will attend the TSC meetings to present and report progress.

Data Monitoring and Ethics Committee (DMEC)

The DMEC will review the safety and ethics of the trial by reviewing interim data during recruitment.

PUBLICATION POLICY

The success of the trial depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the trial, through authorship and contributor ship. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content;
- and final approval of the version to be published;
- and that all these conditions must be met (www.icmje.org).

In light of this, the Chief Investigator, research manager, Co-Applicants and relevant senior CTRU staff will be named as authors in any publication. In addition, all collaborators will be listed as contributors for the main trial publication, giving details of roles in planning, conducting and reporting the trial.

To maintain the scientific integrity of the trial, data will not be released prior to the end of the trial, either for trial publication or oral presentation purposes, without the permission of the Trial Steering Committee or the Chief Investigator. In addition, individual collaborators must not publish data concerning their patients which is directly relevant to the questions posed in the trial until the main results of the trial have been published.

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APPENDIX A: ABBREVIATIONS

AE	Adverse Event
CEACs	Cost-Effectiveness Acceptability Curves
COREC	Central Office for Research Ethics Committees
CRF	Case Report Form
CSRI	Client Service Receipt Inventory
CTRU	Clinical Trials Research Unit
DMEC	Data Monitoring and Ethics Committee
GCP	Good Clinical Practice
HADS	Hospital Anxiety and Depression Scale
ICC	Intracluster Correlation Coefficients
ICERs	Incremental Cost-Effectiveness Ratios
LSCTC	London Stroke Carer Training Course
MCA	Mental Capacity Act 2005
MDT(s)	Multidisciplinary Team(s)
MRC	Medical Research Council
NEADL	Nottingham Extended Activities of Daily Living Scale
NN	Named Nurse
NSA	National Stroke Audit
PI	Principal Investigator
QALY	Quality-Adjusted Life-Year
R&D	Research & Development
RCT	Randomised Clinical Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event

SOP	Standard Operating Procedure
SRN	Stroke Research Network
SSA	Site Specific Authorisation
Stroke unit	Organised Stroke Service
TMG	Trial Management Group
TSC	Trial Steering Committee

APPENDIX B: TRIAL MANAGEMENT GROUP

The TMG includes those listed as key contacts and the following Co-applicants:

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APPENDIX C: COMMITTEE TERMS OF REFERENCE

TRIAL STEERING COMMITTEE

- To provide overall supervision of the trial.
- To monitor and supervise the progress of the trial towards its interim and overall objectives, adherence to protocol and patient accrual within the set time-frame.
- To review at regular intervals relevant information from other sources (e.g. other related trials), and recommend appropriate action (e.g. changes to trial protocol, stopping or extending the trial).
- To consider the recommendations of the Data Monitoring and Ethics Committee.
- To recommend appropriate action in the light of points 1, 2, 3 and 4 to ensure that the rights, safety and well-being of the trial participants are the most important considerations, and prevail over the interests of science and society.
- In light of 1, 2, 3 and 4 to inform the MRC and relevant Research Boards on the progress of the trial.
- To advise the MRC on publicity and presentation of all aspects of the trial.

DATA MONITORING AND ETHICS COMMITTEE

- To determine if interim analyses of trial data should be undertaken.
- To consider the data from interim data monitoring/analyses plus any additional safety issues for the trial and relevant information from other sources.
- In the light of 2. (above), and ensuring that ethical considerations are of prime importance, to report (following each DMEC meeting) to the Trial Steering Committee and to recommend on the continuation of the trial.
- To consider any requests for release of interim trial data and to make recommendations to the TSC on the advisability of this.
- In the event of further funding being required, to provide to the TSC and MRC appropriate information and advice on the data gathered to date that will not jeopardise the integrity of the study.

APPENDIX D: STUDY ASSESSMENT SCHEDULE

				Recruitment Starts ↓							
	Pre-Cluster Randomisation	Cluster Randomisation	Post-Cluster Randomisation	Consent	Post-Consent, Pre-Registration	Patient & Caregiver Registration	Caregiver LSCTC (including follow up)	Patient Discharge	6 Month Follow-Up	12 Month Follow-Up	End of Trial
REGULATORY											
Centre details & research procedures training/initiation visit	All										
Observation of ward practice	Researchers/ MDT										Researchers/ MDT
Cluster (centre) randomisation		CTRU									
If randomised to the intervention group: LSCTC multidisciplinary team training & implementation to usual practice			MDT								
Patient written informed consent or caregiver declaration Caregiver written informed consent				Researchers							
Patient and Caregiver details					Researchers						
Patient and Caregiver registration						Researchers via CTRU					
MEDICAL											
Patient: Rankin score; stroke type; classification; languange ability; 6CIT score; pre-stroke independence; verbal subsection of the Glascow Coma Scale; ability to walk independently & lift both arms off the bed; living circumstances; previous stroke, Barthel Index. Caregiver: Rankin score.					Researchers						
Expected Serious Adverse Events								Researchers			
Delivery of LSCTC							MDT				
QUESTIONNAIRES											
Process questionnaire	PI/MDT	MDT									PI/MDT
Patient and Caregiver Questionnaires					Researchers						
Patient and Caregiver Postal Questionnaires									CTRU	CTRU	
Telephone reminders for unreturned postal questionnaires									CTRU	CTRU	

Appendix 5 Unit costs

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
Residential and nursing home				
Residential care home	Night	74	The NHS Information Centre SCS[77]	
Nursing home	Night	73		
Inpatient services				
A – Nervous system	Bed-day	334	Department of Health[67]	Tab TNEI_L: Weighted mean of codes A
B – Eyes and periorbita	Bed-day	554	Department of Health[67]	Tab TNEI_L: Weighted mean of codes B
C – Mouth, head, neck and ears	Bed-day	468	Department of Health[67]	Tab TNEI_L: Weighted mean of codes C
D – Respiratory system	Bed-day	308	Department of Health[67]	Tab TNEI_L: Weighted mean of codes D
E – Cardiac surgery and primary cardiac conditions	Bed-day	417	Department of Health[67]	Tab TNEI_L: Weighted mean of codes E
F – Digestive system	Bed-day	388	Department of Health[67]	Tab TNEI_L: Weighted mean of codes F
G – Hepatobiliary and pancreatic systems	Bed-day	369	Department of Health[67]	Tab TNEI_L: Weighted mean of codes G
H – Musculoskeletal system	Bed-day	445	Department of Health[67]	Tab TNEI_L: Weighted mean of codes H
J – Skin, breast and burns	Bed-day	370	Department of Health[67]	Tab TNEI_L: Weighted mean of codes J
K – Endocrine and metabolic system	Bed-day	308	Department of Health[67]	Tab TNEI_L: Weighted mean of codes K
L – Urinary tract and male reproductive systems	Bed-day	326	Department of Health[67]	Tab TNEI_L: Weighted mean of codes L
M – Female reproductive system and assisted reproduction	Bed-day	535	Department of Health[67]	Tab TNEI_L: Weighted mean of codes M
N – Obstetrics	Bed-day	755	Department of Health[67]	Tab TNEI_L: Weighted mean of codes N

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
P – Diseases of childhood and neonates	Bed-day	493	Department of Health[67]	Tab TNEI_L: Weighted mean of codes P
Q – Vascular system	Bed-day	438	Department of Health[67]	Tab TNEI_L: Weighted mean of codes Q
S – Haematology, chemotherapy, radiotherapy and specialist palliative care	Bed-day	404	Department of Health[67]	Tab TNEI_L: Weighted mean of codes S
W – Immunology, infectious diseases and other contacts	Bed-day	327	Department of Health[67]	Tab TNEI_L: Weighted mean of codes W
Mental health	Bed-day	318	Department of Health[67]	Index tab TMHIP unit cost (Mental Health Inpatients). Assumption made that this is per day even though this is not stated
Geriatric	Bed-day	361	Department of Health[67]	Costed as 'Inpatient stroke rehabilitation'
Accident and emergency	Occurrence	110	Department of Health[67]	Index tab weighted average for all accident and emergency services unit costs (TAandEMSAD, TAandEMSNA, TAandEMinAD, TAandEMinNA, TAandEWiCAD, TAandEWiCNA, TNon24HRDEPAD, TNon24HRDEPNA)
Oncology/cancer	Bed-day	404	Department of Health[67]	Costed as 'Inpatient general medical'
Surgery	Bed-day	404	Department of Health[67]	Costed as 'Inpatient general medical'
Intensive care	Bed-day	1229	Department of Health[67]	Index tab TCCSALCCU (Critical Care Services – Adult) unit cost. Assumption made that this is per day even though this is not stated. This assumption is based on a NICE reference which states critical care in the NHS reference costs is per day[78]
Stroke, acute	Bed-day	294	Department of Health[67]	Tab TNEI_L: Weighted average of AA22Z (Non-Transient Stroke or Cerebrovascular Accident, Nervous system infections or Encephalopathy) and AA23Z (Haemorrhagic Cerebrovascular Disorders)
Stroke, rehabilitation	Bed-day	361	Department of Health[67]	Tab TREHAB_CSRS_LEVEL_1_BEDDAY_APC: VC04Z (Rehabilitation for stroke) cost. Assumption this is per bed-day.
General medical	Bed-day	404	Department of Health[67]	TNEI_L tab: weighted average of all costs
Unknown/other	Bed-day	404	Department of Health[67]	Costed as 'Inpatient general medical'
Clinical decision unit	Occurrence	110	Department of Health[67]	Costed as 'Inpatient A&E'
Intermediate care	Bed-day	240	Curtis 2010[79]	

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
Inpatient services				
A – Nervous system	Stay	2415	Department of Health[67]	Tab TNEI_L: Weighted mean of codes A
B – Eyes and periorbita	Stay	2007	Department of Health[67]	Tab TNEI_L: Weighted mean of codes B
C – Mouth, head, neck and ears	Stay	1879	Department of Health[67]	Tab TNEI_L: Weighted mean of codes C
D – Respiratory system	Stay	1999	Department of Health[67]	Tab TNEI_L: Weighted mean of codes D
E – Cardiac surgery and primary cardiac conditions	Stay	1941	Department of Health[67]	Tab TNEI_L: Weighted mean of codes E
F – Digestive system	Stay	2197	Department of Health[67]	Tab TNEI_L: Weighted mean of codes F
G – Hepatobiliary and pancreatic systems	Stay	2505	Department of Health[67]	Tab TNEI_L: Weighted mean of codes G
H – Musculoskeletal system	Stay	3492	Department of Health[67]	Tab TNEI_L: Weighted mean of codes H
J – Skin, breast and burns	Stay	2495	Department of Health[67]	Tab TNEI_L: Weighted mean of codes J
K – Endocrine and metabolic system	Stay	1794	Department of Health[67]	Tab TNEI_L: Weighted mean of codes K
L – Urinary tract and male reproductive systems	Stay	2276	Department of Health[67]	Tab TNEI_L: Weighted mean of codes L
M – Female reproductive system and assisted reproduction	Stay	1701	Department of Health[67]	Tab TNEI_L: Weighted mean of codes M
N – Obstetrics	Stay	2174	Department of Health[67]	Tab TNEI_L: Weighted mean of codes N
P – Diseases of childhood and neonates	Stay	1534	Department of Health[67]	Tab TNEI_L: Weighted mean of codes P
Q – Vascular system	Stay	3877	Department of Health[67]	Tab TNEI_L: Weighted mean of codes Q
S – Haematology, chemotherapy, radiotherapy and specialist palliative care	Stay	2547	Department of Health[67]	Tab TNEI_L: Weighted mean of codes S

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
W – Immunology, infectious diseases and other contacts	Stay	1865	Department of Health[67]	Tab TNEI_L: Weighted mean of codes W
Oncology/cancer	Stay	2267	Department of Health[67]	Costed as 'Inpatient general medical'
Surgery	Stay	2267	Department of Health[67]	Costed as 'Inpatient general medical'
Stroke, acute	Stay	2808	Department of Health[67]	Tab TNEI_L: Weighted average of AA22Z (Non-Transient Stroke or Cerebrovascular Accident, Nervous system infections or Encephalopathy) and AA23Z (Haemorrhagic Cerebrovascular Disorders)
General medical	Stay	2267	Department of Health[67]	TNEI_L tab: weighted average of all costs
Unknown/other	Stay	2267	Department of Health[67]	Costed as 'Inpatient general medical'
Day hospital/day cases				
A – Nervous system	Activity	625	Department of Health[67]	TDC tab: Weighted mean of codes A
B – Eyes and periorbita	Activity	760	Department of Health[67]	TDC tab: Weighted mean of codes B
C – Mouth, head, neck and ears	Activity	736	Department of Health[67]	TDC tab: Weighted mean of codes C
D – Respiratory system	Activity	562	Department of Health[67]	TDC tab: Weighted mean of codes D
E – Cardiac surgery and primary cardiac conditions	Activity	1149	Department of Health[67]	TDC tab: Weighted mean of codes E
F – Digestive system	Activity	578	Department of Health[67]	TDC tab: Weighted mean of codes F
G – Hepatobiliary and pancreatic systems	Activity	845	Department of Health[67]	TDC tab: Weighted mean of codes G
H – Musculoskeletal system	Activity	1058	Department of Health[67]	TDC tab: Weighted mean of codes H
J – Skin, breast and burns	Activity	668	Department of Health[67]	TDC tab: Weighted mean of codes J
K – Endocrine and metabolic system	Activity	368	Department of Health[67]	TDC tab: Weighted mean of codes K

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
L – Urinary tract and male reproductive systems	Activity	507	Department of Health[67]	TDC tab: Weighted mean of codes L
M – Female reproductive system and assisted reproduction	Activity	703	Department of Health[67]	TDC tab: Weighted mean of codes M
N – Obstetrics	Activity	530	Department of Health[67]	TDC tab: Weighted mean of codes N
P – Diseases of childhood and neonates	Activity	652	Department of Health[67]	TDC tab: Weighted mean of codes P
Q – Vascular system	Activity	785	Department of Health[67]	TDC tab: Weighted mean of codes Q
S – Haematology, chemotherapy, radiotherapy and specialist palliative care	Activity	476	Department of Health[67]	TDC tab: Weighted mean of codes S
V – Multiple trauma, emergency medicine and rehabilitation	Activity	917	Department of Health[67]	TDC tab: Weighted mean of codes V
W – Immunology, infectious diseases and other contacts	Activity	421	Department of Health[67]	TDC tab: Weighted mean of codes W
Unknown day hospital	Activity	673	Department of Health[67]	Index tab: Unit cost for day cases HRG data – (TDC)
Outpatient services				
Accident and emergency	Activity	113	Department of Health[67]	Total – OPATT Tab: Service code 180
Allergy	Activity	139	Department of Health[67]	Total – OPATT Tab: Service code 317
Anticoagulant service	Activity	25	Department of Health[67]	Total – OPATT Tab: Service code 324
Audiology	Activity	158	Department of Health[67]	Total – OPATT Tab: Service code 840
Stroke rehabilitation day unit	Activity	167	Department of Health[67]	TDCFRAD tab: Stroke patient – DCF10
Breast surgery	Activity	119	Department of Health[67]	Total – OPATT Tab: Service code 103

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
Burns care	Activity	123	Department of Health[67]	Total – OPATT Tab: Service code 161
Cardiology	Activity	124	Department of Health[67]	Total – OPATT Tab: Service code 320
Chemical pathology	Activity	73	Department of Health[67]	Total – OPATT Tab: Service code 822
Clinical genetics	Activity	588	Department of Health[67]	Total – OPATT Tab: Service code 311
Clinical haematology	Activity	131	Department of Health[67]	Total – OPATT Tab: Service code 303
Clinical immunology	Activity	195	Department of Health[67]	Total – OPATT Tab: Service code 316
Obstetrics	Activity	109	Department of Health[67]	Total – OPATT Tab: Service code 501
Colorectal surgery	Activity	104	Department of Health[67]	Total – OPATT Tab: Service code 104
Dermatology	Activity	93	Department of Health[67]	Total – OPATT Tab: Service code 330
Dietetics	Activity	50	Department of Health[67]	Total – OPATT Tab: Service code 654A, Adult (19 years and over only)
Endocrinology	Activity	136	Department of Health[67]	Total – OPATT Tab: Service code 302
Ear, nose and throat	Activity	85	Department of Health[67]	Total – OPATT Tab: Service code 120
General medicine	Activity	142	Department of Health[67]	Total – OPATT Tab: Service code 300
General surgery	Activity	112	Department of Health[67]	Total – OPATT Tab: Service code 100
Geriatric medicine	Activity	199	Department of Health[67]	Total – OPATT Tab: Service code 430
Gynaecology	Activity	112	Department of Health[67]	Total – OPATT Tab: Service code 502
Haemophilia	Activity	785	Department of Health[67]	Total – OPATT Tab: Service code 309
Hepatology	Activity	172	Department of Health[67]	Total – OPATT Tab: Service code 306
Maxillofacial surgery	Activity	102	Department of Health[67]	Total – OPATT Tab: Service code 144
Medical gastroenterology	Activity	123	Department of Health[67]	Total – OPATT Tab: Service code 301M
Medical oncology	Activity	135	Department of Health[67]	Total – OPATT Tab: Service code 370
Nephrology	Activity	156	Department of Health[67]	Total – OPATT Tab: Service code 361
Neurology	Activity	165	Department of Health[67]	Total – OPATT Tab: Service code 400

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
Neurosurgery	Activity	162	Department of Health[67]	Total – OPATT Tab: Service code 150
Nuclear medicine	Activity	136	Department of Health[67]	Total – OPATT Tab: Service code 371
Occupational therapy	Activity	61	Department of Health[67]	Total – OPATT Tab: Service code 651A, Adult (19 years and over only)
Ophthalmology	Activity	80	Department of Health[67]	Total – OPATT Tab: Service code 130
Oral surgery	Activity	113	Department of Health[67]	Total – OPATT Tab: Service code 140
Orthodontics	Activity	109	Department of Health[67]	Total – OPATT Tab: Service code 143
Orthoptics	Activity	53	Department of Health[67]	Total – OPATT Tab: Service code 655
Pain management	Activity	124	Department of Health[67]	Total – OPATT Tab: Service code 191
Palliative medicine	Activity	185	Department of Health[67]	Total – OPATT Tab: Service code 315
Physiotherapy	Activity	39	Department of Health[67]	Total – OPATT Tab: Service code 650A, Adult (19 years and over only)
Plastic surgery	Activity	86	Department of Health[67]	Total – OPATT Tab: Service code 160
Podiatry	Activity	39	Department of Health[67]	Total – OPATT Tab: Service code 653
Rehabilitation	Activity	122	Department of Health[67]	Total – OPATT Tab: Service code 314
Rheumatology	Activity	137	Department of Health[67]	Total – OPATT Tab: Service code 410
Speech and language therapy	Activity	80	Department of Health[67]	Total – OPATT Tab: Service code 652A, Adult (19 years and over only)
Spinal injuries	Activity	300	Department of Health[67]	Total – OPATT Tab: Service code 323
Thoracic surgery	Activity	216	Department of Health[67]	Total – OPATT Tab: Service code 173
Transplantation surgery	Activity	231	Department of Health[67]	Total – OPATT Tab: Service code 102
Trauma and orthopaedics: non-trauma	Activity	96	Department of Health[67]	Total – OPATT Tab: Service code 110N, used when type of orthopaedics unspecified
Trauma and orthopaedics: trauma	Activity	99	Department of Health[67]	Total – OPATT Tab: Service code 110T
Urology	Activity	99	Department of Health[67]	Total – OPATT Tab: Service code 101

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
Dental medicine specialties	Activity	87	Department of Health[67]	Total – OPATT Tab: Service code 450
Vascular surgery	Activity	126	Department of Health[67]	Total – OPATT Tab: Vascular surgery – 107
Respiratory	Activity	145	Department of Health[67]	Total – OPATT Tab: Service code 340
Diabetic medicine	Activity	127	Department of Health[67]	Total – OPATT Tab: Service code 307
Mental health/psychiatry	Activity	174	Department of Health[67]	A weighted average of all Mental Health Consultant Services from hospital outpatient settings was calculated. Index tab: variables: TMHCSOPFAF, TMHCSOPFANF, TMHCSOPFUAF, TMHCSOPFUANF, TMHCSOPSSFAF, TMHCSOPSSFANF, TMHCSOPSSFUAF, TMHCSOPSSFUANF
Imaging – generic	Activity	116	Department of Health[67]	Index tab: TDIAGIM_OP unit cost (Diagnostic imaging: outpatient)
Patient transport services	Activity	31	Department of Health[67]	Index tab: TPTS_OP unit cost (Patient transport services)
Primary care trust dietician	Activity	54	Department of Health[67]	TOCS tab (Other community services): N800 unit cost (Community dietician)
Elderly day unit	Activity	181	Department of Health[67]	TDCFRAD tab (Day care facilities: regular attendances): DCF20 (Elderly patient)
Stroke generic	Activity	165	Department of Health[67]	Costed as 'Outpatient – neurology'
Vascular general	Activity	142	Department of Health[67]	Costed as 'Outpatient – general medicine'
Walk-in centre	Activity	54	Department of Health[67]	Index tab: TAandEWiCNA unit cost (Costed as Accident and emergency services: walk in centres: not leading to admitted)
Paramedic service without accident and emergency attendance	Activity	222	Department of Health[67]	Index tab: TPARB unit cost (Paramedic services: Category B/Amber)
Community mental health team	Activity	45	Curtis 2010[79]	Costed as per hour of face-to-face contact divided by 2 to assume 1–2-hour appointments
Wheelchair services	Year	85	Curtis 2010[79]	Costed as self propelled chair per year
Outpatient procedures				
Sigmoidoscopy	Procedure	207	Department of Health[67]	TOPROC tab: Diagnostic or therapeutic rigid sigmoidoscopy 19 years and over: FZ57Z
DEXA scan	Scan	78	Department of Health[67]	TDIAGIM_OP Tab: DEXA Scan – RA15Z

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
CT/CAT scan	Scan	100	Department of Health[67]	TDIAGIM_OP Tab: Computerised tomography scan, one area, no contrast – RA08Z
Colonoscopy	Procedure	271	Department of Health[67]	TOPROC tab: Therapeutic colonoscopy 19 years and over -FZ53Z
Electrocardiogram	Procedure	127	Department of Health[67]	TOPROC tab: Electrocardiogram monitoring and stress testing – EA47Z
Ultrasound	Procedure	55	Department of Health[67]	TDIAGIM_OP Tab: Ultrasound scan more than 20 minutes – RA24Z
Eye test	Procedure	30	Department of Health[67]	TDADS Tab: Diabetic retinal screening – DA11
MRI	Procedure	175	Department of Health[67]	TDIAGIM_OP Tab: Magnetic resonance imaging scan, one area, no contrast – RA01Z
X-ray	Procedure	29	Department of Health[67]	Total – OPATT Tab: Direct access plain film – DAPF
Blood test	Procedure	5	Department of Health[67]	TDAPS Tab: Phlebotomy – DAP839
Endoscopy	Procedure	88	Department of Health[67]	TOPROC tab: Upper genital tract laparoscopic/endoscopic major procedures – MA08Z
Community-based services				
GP surgery, surgery	Visit	32	Curtis 2010[79]	Average surgery consultation lasting 11.7 minutes. Includes direct care staff costs; excludes qualification costs
GP, home	Visit	106	Curtis 2010[79]	Average home visit lasting 23.4 minutes. Includes travel time and direct care staff costs; excludes qualification costs
GP, telephone consultation	Call	19	Curtis 2010[79]	Average telephone consultation lasting 7.1 minutes. Includes direct care staff costs; excludes qualification costs
Practice nurse surgery, surgery	Consultation	10	Curtis 2010[79]	Excludes qualification costs
Practice nurse, telephone call	Consultation	6	Curtis 2010[79]	Assumed ratio of time spent on telephone consultation compared with face-to-face consultation is same as for a GP (60.68%). On this basis, a face-to-face nurse consultation of 15.5 minutes at £10, translates to a 9.4-minute telephone consultation at £6.07
Repeat prescription request (without nurse/doctor contact)	Call	14	Curtis 2010[79]	Assumed 5 minutes of GP time i.e. 5 × £2.70 per surgery/clinic minute. Includes direct care staff costs; excludes qualification costs

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
Physiotherapist home, home	Visit	41	Curtis 2010[79]	Average home visit lasting 1 hour. Includes travel time and travel costs; excludes qualification costs
Physiotherapist surgery, surgery	Visit	15	Curtis 2010[79]	Excludes qualification costs
Physiotherapist visit elsewhere (not private)	Visit	15	Curtis 2010[79]	Excludes qualification costs
Occupational therapist, home	Visit	42	Curtis 2010[79]	Average home visit lasting 1 hour. Includes travel time and travel costs; excludes qualification costs
Occupational therapist surgery	Visit	15	Curtis 2010[79]	Excludes qualification costs
Occupational therapist visit elsewhere (not private)	Visit	15	Curtis 2010[79]	Excludes qualification costs
Speech and language therapist, home	Visit	41	Curtis 2010[79]	Average home visit lasting 1 hour. Includes travel time and travel costs; excludes qualification costs
Speech and language therapist, surgery	Visit	15	Curtis 2010[79]	Excludes qualification costs
Speech and language therapist visit elsewhere (not private)	Visit	15	Curtis 2010[79]	Excludes qualification costs
Community or district nurse	Visit	24	Curtis 2010[79]	Community nurse average home visit lasting 20 minutes. Includes travel time and costs; excludes qualification costs
Health visitor	Visit	37	Curtis 2010[79]	Health visitor average home visit lasting 20 minutes. Includes travel time and costs; excludes qualification costs
Geriatrician	Contact	49	Curtis 2010[79]	Assumed 20-minute contact with medical consultant (£146 per patient-related hour). Excludes qualification costs
Psychiatrist	Contact	129	Department of Health[67]	Index Tab: TMHCSCFUAF unit cost (Mental Health Consultant Services (Community Setting) – Follow-up contact face to face)
Psychologist	Contact	81	Curtis 2010[79]	Per hour of client contact. Assumed 1-hour contact
Chiropodist	Visit	11	Curtis 2010[79]	Per clinic visit
Chiropractor	Contact	28	NHS choices – chiropractor[80]	Assumed mid-point cost per session from range of £20-£35 per 30-minute appointment

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
Osteopath	Contact	43	NHS choices – osteopathy[81]	Assumed mid-point cost per session from range of £35-£50 per 30–40 minute contact
Dentist	Activity	90	Department of Health[67]	TOCS tab (Other community services): CN20 unit cost (Community dental services)
Optician	Eye test	19	Boots website[82]	Eye test rate (£20) at Boots Opticians, as at 15 November 2011 deflated to 2010 rate using Consumer Price Index
Day hospital	Half day	91	Department of Health[67]	TDCFRAD tab (Day care facilities: regular attendances): half of DCF20 unit cost (Elderly patient)
Social club	Session	36	Curtis 2010[79]	Local authority day care for older people
Lunch club	Visit	12	Curtis 2010[79]	Costed as a meal and one-quarter of other running costs of a voluntary day care for older people
Drop-in centre	Session	36	Curtis 2010[79]	Local authority day care for older people
Meals on wheels	Meal	6	Curtis 2010[79]	Average cost per local authority meal on wheels
Frozen meals	Meal	3	Curtis 2010[79]	Assume half the average cost per local authority meal on wheels
Home care worker	Hour	28	Curtis 2010[79]	Local authority home care worker per hour of face-to-face contact. Weighted average accounting for different rates for day/evening/weekday/weekends
Social worker	Hour	158	Curtis 2010[79]	Per hour of face-to-face contact. Excludes qualification costs
Social worker, telephone call	Call	14	Curtis 2010[79]	Assumed 15 minutes of social worker time based on £55 per hour of client related work. Excludes qualification costs
Social services day care centre	Visit	36	Curtis 2010[79]	Local authority day care for older people
Intermediate care team	Hour	23	Curtis 2010[79]	Assumed the cost of a lower cost professional: clinical support worker nursing (community); per hour spent with a patient

Item	Unit	Unit cost (£) 2009–10 prices	Source	Notes
Value of time				
National average wage (opportunity cost)	Hour	15	*ONS Annual Survey of Hours and Earnings, 2010 Revised*[83]	Table 1.5a: hourly pay gross for all employees, UK, 2010. Mean, not affected by absence = £14.60
Leisure time cost (opportunity cost)	Hour	5	Department for Transport 2011[84]	Cost of leisure: £5.42 (£4.46 per hour is the value of non-working time per person in 2002 according to the department of transport then inflated up to 2009)
Average opportunity cost	Hour	10	*ONS Annual Survey of Hours and Earnings, 2010 Revised*[83] and Department for Transport. 2011[84]	Assumed an average of the national average wage (£14.60) and the cost of leisure time (5.42 hours) in the absence of information on whether or not the carer would instead have worked
Home help cost (replacement cost)	Hour	28	Curtis 2010[79]	Home help cost: £25 weekday; £30 weekday evening; £37 Saturday; £50 Sunday; all costs per hour of face-to-face contact. Weighted average £27.69
Other services				
Cardiac rehabilitation nurse at home	Hour	78	Curtis 2010[79]	Costed as community nurse specialist. Per hour of client contact (excluding qualification costs) plus travel cost per visit
Care on call – weekly visit alarm pendant	Home visit	9	Curtis 2010[79]	Costed as clinical support worker nursing (community, includes travel)
NHS Direct	Call	15	NHS direct[85]	

TREHAB_CSRS_LEVEL_1_BEDDAY_APC, 'Complex specialised' rehabilitation services; TDC, Day cases HRG data; OPATT, Outpatient attendances; TPTS_OP, Patient transport services: outpatient; TOCS, Other community services; TDCFRAD, Day care facilities: regular attendances; taandewicna, Accident and emergency services: walk in centres: not leading to admitted; TPARB, Paramedic services: category B/amber; TOPROC, Outpatient procedures; TDIAGIM_OP, Diagnostic imaging: outpatient; TDADS, Direct access: diagnostic services; TDAPS, Direct access: pathology services; TMHCSCFUAF, Mental health consultant services (community setting) – follow-up contact face to face; taandemsad, Accident and emergency services: leading to admitted; taandemsna, Accident and emergency services: not leading to admitted; taandeminad, Accident and emergency services: minor injury service: leading to admitted; taandeminna, Accident and emergency services: minor injury service: not leading to admitted; taandewicad, Accident and emergency services: walk in centres: leading to admitted; taandewicna, Accident and emergency services: walk in centres: not leading to admitted; tnon24hrdepad, Non 24 hr aande/casualty department: leading to admitted; tnon24hrdepna, Non 24 hr aande/casualty department: not leading to admitted; TMHCSOPFAF, Mental health consultant services (Outpatient Setting) – first attendance face to face; TMHCSOPFANF, Mental health consultant services (outpatient setting) – first attendance non-face to face; TMHCSOPFUAF, Mental health consultant services (outpatient setting) – follow-up attendance face to face; TMHCSOPFUANF, Mental health consultant services (outpatient setting) – follow-up attendance non-face to face; TMHCSOPSSFAF, Mental health consultant services (outpatient setting) – specialist services first attendance face to face; TMHCSOPSSFANF, Mental health consultant services (outpatient setting) – specialist services first attendance non-face to face; TMHCSOPSSFUAF, Mental health consultant services (outpatient setting) – specialist services follow-up attendance face to face; TMHCSOPSSFUANF, Mental health consultant services (outpatient setting) – specialist services follow-up attendancen non-face to face.

Appendix 6 Calculation of London Stroke Carer Training Course training costs

Table 62 summarises costs related to each component of the LSCTC development and staff training. *Tables 63–73* provide further details of the calculations of each of the components.

TABLE 62 London Stroke Carers Training Course unit cost: summary of all staff training components

LSCTC development and staff training	Costs (£, 2009–10 prices)
1. Core training and refresher training: development[a]	
Staffing costs, main training	6662
Staffing costs, refresher training	1017
Total	7680
2. Core training: preparation	
Staffing costs	3554
Total	3554
3. Refresher training: preparation	
Staffing costs, training team	753
Total	753
4. Core training: delivery	
Staffing costs, training team	10,230
Other costs	13,086
Total	23,317
5. Refresher training: delivery	
Staffing costs, training team	3197
Other costs	2407
Total	5603
6. Local refresher visits: delivery	
Staffing costs, training team	12,513
Other costs	4080
Total	16,593

continued

TABLE 62 London Stroke Carers Training Course unit cost: summary of all staff training components (*continued*)

LSCTC development and staff training	Costs (£, 2009–10 prices)
7. Ward staff time	
Attendance at main training	27,667
Attendance at refresher training	4626
Local cascaded training, trainers	1577
Local cascaded training, trainees	6881
Attendance at local refresher training	4327
Total	45,077
Total cost	
Total including development costs	102,577
Total excluding development costs	94,897
Cost per minute of input to caregivers, including development costs[b]	0.60
Cost per minute of input to caregivers, excluding development costs[b]	0.56

a The development of the training programme and materials was a thorough process that would not require the same level of inputs for future implementation or major reworking for several years. We report the unit cost with and without this component because although it was a necessary cost for implementation of the intervention, such development costs are not always considered in cost-effectiveness analyses.

b We transformed the total costs of the development and staff training into an average cost per minute of caregiver training to enable this cost to vary at the individual level according to inputs provided to each caregiver, rather than be a fixed cost across all participants. We calculated this as follows. First, we multiplied the average amount of time spent with each caregiver in the trial intervention arm (136 minutes) by the total number of eligible patients identified during the screening/recruitment process ($n = 1256$) to estimate the total caregiver input time that the staff training potentially 'purchased' (29,210 minutes/487 hours). We then divided the total training cost (£102,577 including development costs) by this total input time to estimate the training cost per minute of caregiver input provided (£0.60). This cost per minute was applied to each intervention arm participant according to the amount of time input provided by ward staff to the caregiver.

TABLE 63 Staff time unit costs (£) 2009–10

Salary grade, band and point	Salary, basic[86]	Salary, on-costs	[a]Salary, overheads[79]	Salary, total per annum	[b,c]Salary, total per hour worked[87]	Salary, total per minute worked
Training team						
Academic Grade 8, point 37[88]	36,715	11,015	47,730	95,459	56.39	0.94
Academic Grade 6, point 26[88]	26,523	7957	34,480	68,960	40.74	0.68
Academic Grade 10, point 52[88]	57,201	17,160	74,361	148,723	87.86	1.46
NHS Band 7, point 35	39,273	11,782	18,855	69,909	41.30	0.69
NHS Band 7, point 31	34,410	10,323	16,520	61,253	36.19	0.60
NHS Band 5, point 20	23,345	7004	11,208	41,556	24.55	0.41
NHS Band 4, point 14	19,495	5849	9359	34,703	20.50	0.34
Ward staff						
NHS Band 1, point 2[d]	13,588	4076	6523	24,188	14.29	0.24
NHS Band 2, point 4	14,359	4308	6894	25,560	15.10	0.25
NHS Band 3, point 9	16,698	5009	8017	29,724	17.56	0.29
NHS Band 4, point 14	19,495	5849	9359	34,703	20.50	0.34
NHS Band 5, point 20	23,345	7004	11,208	41,556	24.55	0.41
NHS Band 6, point 26	28,816	8645	13,834	51,295	30.30	0.51
NHS Band 7, point 30	33,436	10,031	16,052	59,519	35.16	0.59
NHS Band 8, point 42	53,256	15,977	25,568	94,800	56.00	0.93
[c]NHS Senior House Officer[80]	31,900	7818	6422	46,140	21.65	0.36
[c]NHS Consultant[79]	120,200	31,482	42,361	194,043	108.25	1.80
[c]NHS Social worker[79]	30,633	9010	19,850	59,493	39.66	0.66

a Assuming 100% full economic cost overhead rate for university-employed staff, 36.93% indirect and capital overheads for NHS Bands 2–8 staff as per a hospital physiotherapist unit cost,[87] and overheads as specified in the unit costs for medical and social worker staff.[88]

b Assuming 27 days' annual leave, 8 bank holidays and a 37.5-hour working week as NHS terms and conditions of service.[87] Excludes additional payments.

c Costs for both consultant and senior house officer (assumed Foundation 1) include additional payments. Working time differed to other staff: 41.4 working weeks per year/43.3 working hours per week for consultants, 44.4 working weeks per year/48 working hours per week for senior house officers and 40 working weeks per year/37.5 working hours per week for social workers.

d Student nurse pay band was unspecified so Band 1 point 2 was assumed.

TABLE 64 London Stroke Carer Training Course unit cost: development of core training and refresher training

Resource	Activity	Hours per activity	Costs (£, 2009–10 prices)
A. Core training: April to November 2007			
Academic Grade 8, point 37	Administration – training manuals, Royal College of Nursing continuing professional development accreditation and talks	35	1974
Academic Grade 8, point 37	Post-meeting feedback	5	282
Academic Grade 8, point 37	Post-meeting compiling compact discs	8	451
NHS Band 7, point 35[a]	Development time	20	818
NHS Band 7, point 35[a]	Development time	17	706
NHS Band 7, point 35[a]	Development time	23	929
Academic Grade 10, point 52[a]	Development time	17	1502
Core training, total development cost			6662
B. Refresher training: August 2009			
Academic Grade 8, point 37	Compiling training manual and training compact disc, version 2	14	789
NHS Band 7, point 35[a]	Development time	2	74
NHS Band 7, point 35[a]	Development time	2	74
Academic Grade 10, point 52[a]	Development time	1	79
Refresher training, total development cost			1017
C. Development, total cost (A+B)			
			7680

a During the first development phase prior to the main training sessions, the four trainers did not distinguish between development of the intervention and preparation for delivering the training events in their records of time inputs because the two activities were closely intertwined. Training delivery would be expected to have some recurrent preparation cost; therefore, we assumed that of the total time recorded by them during the development phase, 90% was for development and 10% for preparation. The latter, 10%, was allocated to the training event preparation component of the LSCTC unit cost.

TABLE 65 London Stroke Carers Training Course unit cost: preparation for four core training days and one refresher training day

Resource	Activity	Hours per activity	Costs (£, 2009–10 prices)
A. Core training: April – November 2007			
Academic Grade 8, point 37	Arranging Leeds training event × 2	10	564
Academic Grade 8, point 37	Arranging Leeds travel and attendance × 2	10	564
Academic Grade 8, point 37	Arranging London training event × 2	10	564
Academic Grade 8, point 37	Arranging London travel and attendance × 2	10	564
NHS Band 5, point 20	Administration – training manuals composition	35	859
NHS Band 7, point 35[a]	Preparation time	2.2	91
NHS Band 7, point 35[a]	Preparation time	1.9	78
NHS Band 7, point 35[a]	Preparation time	2.5	103
Academic Grade 10, point 52[a]	Preparation time	1.9	167
Core training, total preparation cost			3554
B. Refresher training: August 2009			
Academic Grade 8, point 37	Arranging London refresher event	5	282
Academic Grade 8, point 37	Arranging London travel and attendance	5	282
NHS Band 4, point 14	Administration – training manuals and compact disc, version 2	8	164
NHS Band 7, point 35[a]	Preparation time	0.2	8
NHS Band 7, point 3[a]	Preparation time	0.2	8
Academic Grade 10, point 52[a]	Preparation time	0.1	9
Refresher training, total preparation cost			753
C. Preparation, total cost (A + B)			
			4308

a During the first development phase prior to the main training sessions, the four trainers did not distinguish between development of the intervention and preparation for delivering the training events in their records of time inputs because the two activities were closely intertwined. Training delivery would be expected to have some recurrent preparation cost; therefore, we assumed that of the total time recorded by them during the development phase, 90% was for development and 10% for preparation. The latter, 10%, was allocated to the training event preparation component of the LSCTC unit cost.

TABLE 66 London Stroke Carers Training Course unit cost: delivery of four core training days and one refresher training day

Resource	Activity	Hours per activity	Costs (£, 2009–10 prices)
A. Core training: April to November 2007			
Trainers' time			
Academic Grade 8, point 37	Travel and attendance	40	2256
NHS Band 7, point 35	Travel and attendance	36	1487
NHS Band 7, point 35	Travel and attendance	36	1487
NHS Band 7, point 35	Travel and attendance	36	1487
Academic Grade 10, point 52	Travel and attendance	40	3514
A1. Total cost, trainers' time			10,230
Non-staff inputs[a]			
Room hire and catering, Leeds day 1			760
Room hire and catering, Leeds day 2			336
Room hire and catering, London day 1			753
Room hire and catering, London day 2			627
Travel costs, trainers and attendees, Leeds day 1			1423
Travel costs, trainers and attendees, Leeds day 2			1472
Travel costs, trainers and attendees, London day 1			1242
Travel costs, trainers and attendees, London day 2			1051
Royal College of Nursing accreditation			273
Filming and production of training compact discs			4097
Copying compact discs			140
Printing of training manual files and paperwork			284
Printing of training records			629
A2. Total cost, non-staff inputs[a]			13,086
A3. Core training delivery, total cost (A1 + A2)			23,317

TABLE 66 London Stroke Carers Training Course unit cost: delivery of four core training days and one refresher training day (*continued*)

Resource	Activity	Hours per activity	Costs (£, 2009–10 prices)
B. Refresher training: August 2009			
Academic Grade 8, point 37	Travel and attendance	15	846
NHS Band 7, point 35	Travel and attendance	9	372
NHS Band 7, point 35	Travel and attendance	9	372
Academic Grade 10, point 52	Travel and attendance	15	1318
NHS Band 7, point 31	Travel and attendance	8	290
B1. Total cost, trainers' time			3197
Room hire and catering, London			232
Travel costs, trainers and attendees, London			2175
B2. Total cost, non-staff inputs			2407
B3. Refresher training delivery, total cost (B1 + B2)			5603
C. Delivery, total cost (A1 + A2 + B1 + B2)			
			28,920

a Non-staff costs occurring in 2007 were inflated to 2009–10 prices using the Gross Domestic Product deflator: 2.77% for 2007–8 to 2008–9 and 1.63% for 2008–9 to 2009–10.[88]

TABLE 67 London Stroke Carers Training Course unit cost: delivery of local refresher training sessions (November 2007 to July 2009)

Centre	Total[a]	Trainer 1, Academic Grade 8, point 37	Trainer 2, NHS Band 7, point 31	Staffing costs (£, 2009–10 prices)	Other costs (£, 2009–10 prices)	Costs (£, 2009–10 prices)
3	No. of visits	2				
	Total delivery time (minutes)	75				
	Total travel time (minutes)	480				
	Total travel cost (£)	160				
	Total cost (£)	682		522	160	682
5	No. of visits	3				
	Total delivery time (minutes)	60				
	Total travel time (minutes)	720				
	Total travel cost (£)	240				
	Total cost (£)	973		733	240	973
1a	No. of visits	2				
	Total delivery time (minutes)	65				
	Total travel time (minutes)	480				
	Total travel cost (£)	160				
	Total cost (£)	672		512	160	672
1b	No. of visits	3				
	Total delivery time (minutes)	45				
	Total travel time (minutes)	720				
	Total travel cost (£)	240				
	Total cost (£)	959		719	240	959
15	No. of visits	2	2			
	Total delivery time (minutes)	60	90			
	Total travel time (minutes)	480	480			

Centre	Total[a]	Trainer 1, Academic Grade 8, point 37	Trainer 2, NHS Band 7, point 31	Staffing costs (£, 2009–10 prices)	Other costs (£, 2009–10 prices)	Costs (£, 2009–10 prices)
	Total travel cost (£)	160	160			
	Total cost (£)	668	502	850	320	1170
13	No. of visits	2				
	Total delivery time (minutes)	50				
	Total travel time (minutes)	480				
	Total travel cost (£)	160				
	Total cost (£)	658		498	160	658
18	No. of visits	2				
	Total delivery time (minutes)	40				
	Total travel time (minutes)	480				
	Total travel cost (£)	160				
	Total cost (£)	649		489	160	649
7	No. of visits	2				
	Total delivery time (minutes)	120				
	Total travel time (minutes)	480				
	Total travel cost (£)	160				
	Total cost (£)	724		564	160	724
6	No. of visits	3				
	Total delivery time (minutes)	140				
	Total travel time (minutes)	720				
	Total travel cost (£)	240				
	Total cost (£)	1048		808	240	1048

continued

TABLE 67 London Stroke Carers Training Course unit cost: delivery of local refresher training sessions (November 2007 to July 2009) (*continued*)

Centre	Total[a]	Trainer 1, Academic Grade 8, point 37	Trainer 2, NHS Band 7, point 31	Staffing costs (£, 2009–10 prices)	Other costs (£, 2009–10 prices)	Costs (£, 2009–10 prices)
12	No. of visits	2	3			
	Total delivery time (minutes)	105	105			
	Total travel time (minutes)	480	720			
	Total travel cost (£)	160	240			
	Total cost (£)	710	735	1045	400	1445
11	No. of visits	4				
	Total delivery time (minutes)	180				
	Total travel time (minutes)	960				
	Total travel cost (£)	320				
	Total cost (£)	1392		1072	320	1392
17	No. of visits	1	1			
	Total delivery time (minutes)	60	40			
	Total travel time (minutes)	240	240			
	Total travel cost (£)	80	80			
	Total cost (£)	362	248	450	160	610
4	No. of visits	1	1			
	Total delivery time (minutes)	45	30			
	Total travel time (minutes)	240	240			
	Total travel cost (£)	80	80			
	Total cost (£)	348	242	430	160	590
16	No. of visits	3				
	Total delivery time (minutes)	95				
	Total travel time (minutes)	720				

Centre	Total[a]	Trainer 1, Academic Grade 8, point 37	Trainer 2, NHS Band 7, point 31	Staffing costs (£, 2009–10 prices)	Other costs (£, 2009–10 prices)	Costs (£, 2009–10 prices)
	Total travel cost (£)	240				
	Total cost (£)	1006		766	240	1006
14	No. of visits	2				
	Total delivery time (minutes)	40				
	Total travel time (minutes)	480				
	Total travel cost (£)	160				
	Total cost (£)	649		489	160	649
8	No. of visits	2				
	Total delivery time (minutes)	60				
	Total travel time (minutes)	480				
	Total travel cost (£)	160				
	Total cost (£)	668		508	160	668
10	No. of visits	4				
	Total delivery time (minutes)	105				
	Total travel time (minutes)	960				
	Total travel cost (£)	320				
	Total cost (£)	1321		1001	320	1321
9	No. of visits	2				
	Total delivery time (minutes)	75				
	Total travel time (minutes)	480				
	Total travel cost (£)	160				
	Total cost (£)	682		522	160	682

continued

TABLE 67 London Stroke Carers Training Course unit cost: delivery of local refresher training sessions (November 2007 to July 2009) (*continued*)

Centre	Total[a]	Trainer 1, Academic Grade 8, point 37	Trainer 2, NHS Band 7, point 31	Staffing costs (£, 2009–10 prices)	Other costs (£, 2009–10 prices)	Costs (£, 2009–10 prices)
2	No. of visits	2				
	Total delivery time (minutes)	90				
	Total travel time (minutes)	480				
	Total travel cost (£)	160				
	Total cost (£)	696		536	160	696
Delivery of local refresher training, total cost				12,513	4080	16,593
Delivery of local refresher training, average cost per centre				659	215	873

a Trainers' travel time and costs were not measured and were assumed at a notional 4 hours and £80, respectively, per visit.

Note 1a and 1b: These were randomised as a single centre but consisted of two SRUs within the same NHS trust. Consequently, some training was completed separately at each site and so costs were calculated separately.

TABLE 68 London Stroke Carers Training Course unit cost: ward staff costs for attending core training events

Centre	Total[a,b]	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	NHS unknown[c]	Costs (£, 2009–10 prices)
3	*n*	2	1	2			3	
	Attendance time (minutes)	660	300	660			1020	
	Total travel time (minutes)	480	240	480			720	
	Cost (£)	467	275	673			713	2129
5	*n*		1	2			1	
	Attendance time (minutes)		360	660			360	
	Total travel time (minutes)		240	480			240	
	Cost (£)		306	673			246	1225
1a[d]	*n*	1	2.5	4				
	Attendance time (minutes)	360	510	1230				
	Total travel time (minutes)	240	600	960				
	Cost (£)	246	566	1292				2104
1b[d]	*n*	1	2.5	4				
	Attendance time (minutes)	360	510	1230				
	Total travel time (minutes)	240	600	960				
	Cost (£)	246	566	1292				2104
15	*n*	2	1		1			
	Attendance time (minutes)	660	360		360			
	Total travel time (minutes)	480	240		240			
	Cost (£)	467	306		558			1331
13	*n*	1			2			
	Attendance time (minutes)	360			660			
	Total travel time (minutes)	240			480			
	Cost (£)	246			1060			1306
18	*n*	1	4					
	Attendance time (minutes)	360	1320					
	Total travel time (minutes)	240	960					
	Cost (£)	246	1163					1409

continued

TABLE 68 London Stroke Carers Training Course unit cost: ward staff costs for attending core training events (*continued*)

Centre	Total[a,b]	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	NHS unknown[c]	Costs (£, 2009–10 prices)
7	*n*		2	2	2			
	Attendance time (minutes)		660	660	660			
	Total travel time (minutes)		480	480	480			
	Cost (£)		581	673	1060			2314
6	*n*	2		2				
	Attendance time (minutes)	660		660				
	Total travel time (minutes)	480		480				
	Cost (£)	467		673				1140
12	*n*		2	1		1		
	Attendance time (minutes)		660	360		360		
	Total travel time (minutes)		480	240		240		
	Cost (£)		581	354		1080		2015
11	*n*		3					
	Attendance time (minutes)		960					
	Total travel time (minutes)		720					
	Cost (£)		857					857
17	*n*		3	1				
	Attendance time (minutes)		1020	300				
	Total travel time (minutes)		720	240				
	Cost (£)		887	319				1206
4	*n*		2	1				
	Attendance time (minutes)		660	360				
	Total travel time (minutes)		480	240				
	Cost (£)		581	354				935
16	*n*			1				
	Attendance time (minutes)			360				
	Total travel time (minutes)			240				
	Cost (£)			354				354

TABLE 68 London Stroke Carers Training Course unit cost: ward staff costs for attending core training events (*continued*)

Centre	Total[a,b]	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	NHS unknown[c]	Costs (£, 2009–10 prices)
14	*n*		4	2				
	Attendance time (minutes)		1320	720				
	Total travel time (minutes)		960	480				
	Cost (£)		1163	708				1871
8	*n*		3					
	Attendance time (minutes)		1020					
	Total travel time (minutes)		720					
	Cost (£)		887					887
10	*n*		3	4				
	Attendance time (minutes)		660	1380				
	Total travel time (minutes)		720	960				
	Cost (£)		704	1381				2084
9	*n*	2	2					
	Attendance time (minutes)	660	660					
	Total travel time (minutes)	480	480					
	Cost (£)	467	581					1049
2	*n*			4				
	Attendance time (minutes)			1320				
	Total travel time (minutes)			960				
	Cost(£)			1345				1345
Total cost for attending main training events								27,667

a Attendees' travel time was not measured. A conservative estimate of 4 hours per attendee was assumed.

b The sample size refers to the number of each staff band attending across the range of sessions offered (rather than the number of unique staff) and, thus, includes the same ward staff more than once if they attended multiple sessions.

c For staff whose pay band was unknown, the middle band of the qualifying band range, Band 5, and its midpoint, 20, were assumed. For staff for whose band was reported as a range of 5–7, costs were calculated as for the middle Band, 6. For staff whose band was reported as a range of 3–8, costs were calculated as for the middle Band, 7.

d Centres 1a and 1b attendance data for the core training events were combined; therefore, the number of staff in each band and thus the associated time was split evenly between them.

Note 1a and 1b: These were randomised as a single centre but consisted of two SRUs within the same NHS trust. Consequently, some training was completed separately at each site and so costs were calculated separately.

TABLE 69 London Stroke Carers Training Course unit cost: ward staff costs for attending refresher training event

Centre	Total[a,b]	NHS Band 4	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	Costs (£, 2009–10 prices)
3	*n*						
	Attendance time (minutes)						
	Total travel time (minutes)						
	Cost (£)						0
5	*n*						
	Attendance time (minutes)						
	Total travel time (minutes)						
	Cost (£)						0
1a	*n*						
	Attendance time (minutes)						
	Total travel time (minutes)						
	Cost (£)						0
1b	*n*						
	Attendance time (minutes)						
	Total travel time (minutes)						
	Cost (£)						0
15	*n*						
	Attendance time (minutes)						
	Total travel time (minutes)						
	Cost (£)						0
13	*n*		1	1			
	Attendance time (minutes)		360	360			
	Total travel time (minutes)		240	240			
	Cost (£)		246	306			552
18	*n*		2				
	Attendance time (minutes)		720				
	Total travel time (minutes)		480				
	Cost (£)		492				492
7	*n*				1		
	Attendance time (minutes)				360		
	Total travel time (minutes)				240		
	Cost (£)				354		354
6	*n*		1	1			
	Attendance time (minutes)		360	360			
	Total travel time (minutes)		240	240			
	Cost (£)		246	306			552

TABLE 69 London Stroke Carers Training Course unit cost: ward staff costs for attending refresher training event (*continued*)

Centre	Total[a,b]	NHS Band 4	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	Costs (£, 2009–10 prices)
12	*n*						
	Attendance time (minutes)						
	Total travel time (minutes)						
	Cost (£)						0
11	*n*			1			
	Attendance time (minutes)			360			
	Total travel time (minutes)			240			
	Cost (£)			306			306
17	*n*						
	Attendance time (minutes)						
	Total travel time (minutes)						
	Cost (£)						0
4	*n*						
	Attendance time (minutes)						
	Total travel time (minutes)						
	Cost (£)						0
16	*n*						
	Attendance time (minutes)						
	Total travel time (minutes)						
	Cost (£)						0
14	*n*		1		1		
	Attendance time (minutes)		360		360		
	Total travel time (minutes)		240		240		
	Cost (£)		246		354		600
8	*n*	1		1			
	Attendance time (minutes)	360		360			
	Total travel time (minutes)	240		240			
	Cost (£)	204		306			510
10	*n*		1		1		
	Attendance time (minutes)		360		360		
	Total travel time (minutes)		240		240		
	Cost (£)		246		354		600

continued

TABLE 69 London Stroke Carers Training Course unit cost: ward staff costs for attending refresher training event (*continued*)

Centre	Total[a,b]	NHS Band 4	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	Costs (£, 2009–10 prices)
9	*n*			1			
	Attendance time (minutes)			360			
	Total travel time (minutes)			240			
	Cost (£)			306			306
2	*n*				1		
	Attendance time (minutes)				360		
	Total travel time (minutes)				240		
	Cost (£)				354		354
Total cost for attending refresher training event							4626

a Attendees' travel time was not measured. A conservative estimate of 4 hours per attendee was assumed.
b The sample size refers to the number of each staff band attending across the range of sessions offered (rather than the number of unique staff) and, thus, includes the same ward staff more than once if they attended multiple sessions.
Note 1a and 1b: These were randomised as a single centre but consisted of two SRUs within the same NHS trust. Consequently, some training was completed separately at each site and so costs were calculated separately.

TABLE 70 London Stroke Carers Training Course unit cost: ward staff costs for delivering cascaded training

Centre	Total	NHS Band 4	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	Researcher Grade 6	Researcher Grade 8	Costs (£, 2009–10 prices)
3	*n*		5						
	Attendance time (minutes)		300						
	Cost (£)		123						123
5	*n*								
	Attendance time (minutes)								
	Cost (£)								0
1a	*n*								
	Attendance time (minutes)								
	Cost (£)								0
1b	*n*								
	Attendance time (minutes)								
	Cost (£)								0
15	*n*								
	Attendance time (minutes)								
	Cost (£)								0

TABLE 70 London Stroke Carers Training Course unit cost: ward staff costs for delivering cascaded training (*continued*)

Centre	Total	NHS Band 4	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	Researcher Grade 6	Researcher Grade 8	Costs (£, 2009–10 prices)
13	*n*					2			
	Attendance time (minutes)					120			
	Cost (£)					112			112
18	*n*			14					
	Attendance time (minutes)			235					
	Cost (£)			120					120
7	*n*					1		1	
	Attendance time (minutes)					60		60	
	Cost (£)					56		56	112
6	*n*		1		10				
	Attendance time (minutes)		240		480				
	Cost (£)		98		283				382
12	*n*			9					
	Attendance time (minutes)			320					
	Cost (£)			163					163
11	*n*			4					
	Attendance time (minutes)			130					
	Cost (£)			66					66
17	*n*								
	Attendance time (minutes)								
	Cost (£)								0
4	*n*								
	Attendance time (minutes)								
	Cost (£)								0
16	*n*								
	Attendance time (minutes)								
	Cost (£)								0
14	*n*								
	Attendance time (minutes)								
	Cost (£)								0

continued

TABLE 70 London Stroke Carers Training Course unit cost: ward staff costs for delivering cascaded training (*continued*)

Centre	Total	NHS Band 4	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	Researcher Grade 6	Researcher Grade 8	Costs (£, 2009–10 prices)
8	*n*			5					
	Attendance time (minutes)			140					
	Cost (£)			71					71
10	*n*						4		
	Attendance time (minutes)						220		
	Cost (£)						150		150
9	*n*		4	4					
	Attendance time (minutes)		160	150					
	Cost (£)		66	77					142
2	*n*				7				
	Attendance time (minutes)				230				
	Cost (£)				136				136
Total cost for delivering cascaded training									1577

Note 1a and 1b: These were randomised as a single centre but consisted of two SRUs within the same NHS trust. Consequently, some training was completed separately at each site and so costs were calculated separately.

TABLE 71 London Stroke Carers Training Course unit cost: ward staff costs for receiving cascaded training

Centre	Total[a]	Student nurse	NHS Band 2	NHS Band 3	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	NHS Bands 3–8[b]	NHS Bands 5–7[b]	NHS unknown[b]	Costs (£, 2009–10 prices)
3	*n*			9	11	16	1		2				
	Attendance time (minutes)			540	660	960	60		120				
	Cost (£)			157	271	490	35		216				1168
5	*n*												
	Attendance time (minutes)												
	Cost (£)												0
1a	*n*												
	Attendance time (minutes)												
	Cost (£)												0
1b	*n*												
	Attendance time (minutes)												
	Cost (£)												0
15	*n*												
	Attendance time (minutes)												
	Cost (£)												0
13	*n*		6	2	9	6	4	2					
	Attendance time (minutes)		360	120	540	360	240	120					
	Cost (£)		90	35	221	184	142	112					783

continued

TABLE 71 London Stroke Carers Training Course unit cost: ward staff costs for receiving cascaded training (*continued*)

Centre	Total[a]	Student nurse	NHS Band 2	NHS Band 3	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	NHS Bands 3–8[b]	NHS Bands 5–7[b]	NHS unknown[b]	Costs (£, 2009–10 prices)
18	*n*				14	4	3					2	
	Attendance time (minutes)				280	115	45					65	
	Cost (£)				115	59	27					27	227
7	*n*				5	4							
	Attendance time (minutes)				300	240							
	Cost (£)				123	122							245
6	*n*		3	1	3	5	3					2	
	Attendance time (minutes)		720	30	540	225	225					135	
	Cost (£)		180	9	221	115	133					55	713
12	*n*				2	1		1		30	5	40	
	Attendance time (minutes)				30	15		15		2700	100	1200	
	Cost (£)				12	8		14		1593	51	492	2170
11	*n*				1	1						3	
	Attendance time (minutes)				30	40						100	
	Cost (£)				12	20						41	74
17	*n*												
	Attendance time (minutes)												
	Cost (£)												0

Centre	Total[a]	Student nurse	NHS Band 2	NHS Band 3	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	NHS Bands 3–8[b]	NHS Bands 5–7[b]	NHS unknown[b]	Costs (£, 2009–10 prices)
4	*n*												
	Attendance time (minutes)												
	Cost (£)												0
16	*n*												
	Attendance time (minutes)												
	Cost (£)												0
14	*n*												
	Attendance time (minutes)												
	Cost (£)												0
8	*n*	3	5	3	13	2	4					2	
	Attendance time (minutes)	60	100	140	420	120	200					40	
	Cost (£)	14	25	41	172	61	118					16	448
10	*n*		3		5	3							
	Attendance time (minutes)		170		260	180							
	Cost (£)		43		107	92							241
9	*n*											38	
	Attendance time (minutes)											1475	
	Cost (£)											605	605

continued

TABLE 71 London Stroke Carers Training Course unit cost: ward staff costs for receiving cascaded training (*continued*)

Centre	Total[a]	Student nurse	NHS Band 2	NHS Band 3	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	NHS Bands 3–8[b]	NHS Bands 5–7[b]	NHS unknown[b]	Costs (£, 2009–10 prices)
2	*n*				8	5						1	
	Attendance time (minutes)				255	170						40	
	Cost (£)				105	87						16	208
Total cost for receiving cascaded training													6881

a The sample size refers to the number of each staff band attending across the range of sessions offered (rather than the number of unique staff) and, thus, includes the same ward staff more than once if they attended multiple sessions.

b For staff whose pay band was unknown, the middle band of the qualifying band range, Band 5, and its midpoint, 20, were assumed. For staff for whose band was reported as a range of 5–7, costs were calculated as for the middle Band, 6. For staff whose band was reported as a range of 3–8, costs were calculated as for the middle Band, 7.

Note 1a and 1b: These were randomised as a single centre but consisted of two SRUs within the same NHS trust. Consequently, some training was completed separately at each site and so costs were calculated separately.

TABLE 72 London Stroke Carers Training Course unit cost: ward staff costs for receiving local refresher training

Centre	Total[a]	NHS Band 2	NHS Band 3	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	Senior house officer	Social worker	Cost (£, 2009–10 prices)
3	*n*	1		8	1	4		1			
	Attendance time (minutes)	30		270	45	150		45			
	Cost (£)	8		111	23	89		81			311
5	*n*			2	8	6		1		2	
	Attendance time (minutes)			30	135	90		15		30	
	Cost (£)			12	69	53		27		20	181
1a	*n*			6	2	4					
	Attendance time (minutes)			90	90	130					
	Cost (£)			37	46	77					160
1b	*n*			4	3	2		2	2		
	Attendance time (minutes)			50	45	25		25	25		
	Cost (£)			21	23	15		45	9		112
15	*n*	2	1	8	2	1	2				
	Attendance time (minutes)	50	20	200	60	30	60				
	Cost (£)	13	6	82	31	18	56				204
13	*n*			2	6						
	Attendance time (minutes)			40	130						
	Cost (£)			16	66						83
18	*n*				4						
	Attendance time (minutes)				80						
	Cost (£)				41						41
7	*n*	1		3		2	2				
	Attendance time (minutes)	20		140		100	100				
	Cost (£)	5		57		59	93				214

continued

TABLE 72 London Stroke Carers Training Course unit cost: ward staff costs for receiving local refresher training (*continued*)

Centre	Total[a]	NHS Band 2	NHS Band 3	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	Senior house officer	Social worker	Cost (£, 2009–10 prices)
6	*n*	1		7		7				1	
	Attendance time (minutes)	60		320		340				60	
	Cost (£)	15		131		201				40	386
12	*n*	2	1	16	7	3	2	1			
	Attendance time (minutes)	20	45	705	315	135	90	30			
	Cost (£)	5	13	289	161	80	84	54			685
11	*n*			1	9						
	Attendance time (minutes)			60	390						
	Cost (£)			25	199						224
17	*n*	1		6	5	1		2			
	Attendance time (minutes)	40		240	240	40		100			
	Cost (£)	10		98	122	24		180			434
4	*n*			1	6						
	Attendance time (minutes)			30	195						
	Cost (£)			12	99						112
16	*n*			8	2	7		2			
	Attendance time (minutes)			260	65	225		65			
	Cost (£)			107	33	133		117			390
14	*n*	5			6	2		1		1	
	Attendance time (minutes)	110			140	40		10		10	
	Cost (£)	28			71	24		18		7	147
8	*n*			1	3						
	Attendance time (minutes)			30	90						
	Cost (£)			12	46						58

TABLE 72 London Stroke Carers Training Course unit cost: ward staff costs for receiving local refresher training (*continued*)

Centre	Total[a]	NHS Band 2	NHS Band 3	NHS Band 5	NHS Band 6	NHS Band 7	NHS Band 8	NHS consultant	Senior house officer	Social worker	Cost (£, 2009–10 prices)
10	*n*	4		4	5	4					
	Attendance time (minutes)	95		145	125	70					
	Cost (£)	24		59	64	41					188
9	*n*	1		3	5		2				
	Attendance time (minutes)	45		135	210		75				
	Cost (£)	11		55	107		70				243
2	*n*	1		4	3						
	Attendance time (minutes)	45		180	135						
	Cost (£)	11		74	69						154
Total cost for receiving further refresher training											4327

a The sample size refers to the number of each staff band attending across the range of sessions offered (rather than the number of unique staff) and, thus, includes the same ward staff more than once if they attended multiple sessions

Note 1a and 1b: These were randomised as a single centre but consisted of two SRUs within the same NHS trust. Consequently, some training was completed separately at each site and so costs were calculated separately.

TABLE 73 London Stroke Carers Training Course unit cost: total ward staff costs

Centre	Total cost per centre (£, 2009–10 prices)
3	3731
5	1406
1a	2264
1b	2216
15	1536
13	2836
18	2288
7	3240
6	3173
12	5034
11	1526
17	1640
4	1047
16	744
14	2618
8	1975
10	3263
9	2345
2	2196
Total cost for ward staff	45,077
Average ward staff cost per centre	2372

Note 1a and 1b: These were randomised as a single centre but consisted of two SRUs within the same NHS trust. Consequently, some training was completed separately at each site and so costs were calculated separately.

Appendix 7 Literature review search strategy

Note: Searching only for controlled trials.

Added relevant terms:

(community NEAR/2 network*)

(community NEAR/2 support*)

(support* NEAR/2 conversation*)

(patient NEAR/3 feedback)

(patient NEAR/3 education)

ID	Search	Hits	Edit	Delete
#1	Medical subject heading (MeSH) descriptor **Cerebrovascular Disorders**, this term only	1339	Edit	Delete
#2	MeSH descriptor **Basal Ganglia Cerebrovascular Disease** explode all trees	20	Edit	Delete
#3	MeSH descriptor **Brain Ischemia** explode all trees	1862	Edit	Delete
#4	MeSH descriptor **Carotid Artery Diseases** explode all trees	836	Edit	Delete
#5	MeSH descriptor **Stroke**, this term only	3232	Edit	Delete
#6	MeSH descriptor **Brain Infarction** explode all trees	624	Edit	Delete
#7	MeSH descriptor **Cerebrovascular Trauma** explode all trees	19	Edit	Delete
#8	MeSH descriptor **Hypoxia-Ischemia, Brain** explode all trees	87	Edit	Delete
#9	MeSH descriptor **Intracranial Arterial Diseases** explode all trees	772	Edit	Delete
#10	MeSH descriptor **Intracranial Arteriovenous Malformations**, this term only	43	Edit	Delete
#11	MeSH descriptor **Intracranial Embolism and Thrombosis** explode all trees	230	Edit	Delete
#12	MeSH descriptor **Intracranial Hemorrhages** explode all trees	1080	Edit	Delete
#13	MeSH descriptor **Vasospasm, Intracranial**, this term only	84	Edit	Delete
#14	MeSH descriptor **Vertebral Artery Dissection**, this term only	2	Edit	Delete
#15	MeSH descriptor **Aneurysm, Ruptured**, this term only	91	Edit	Delete
#16	MeSH descriptor **Brain Injuries**, this term only	745	Edit	Delete
#17	MeSH descriptor **Brain Injury, Chronic**, this term only	25	Edit	Delete
#18	MeSH descriptor **Carotid Arteries** explode all trees	883	Edit	Delete
#19	MeSH descriptor **Endarterectomy, Carotid**, this term only	424	Edit	Delete
#20	MeSH descriptor **Endarterectomy**, this term only	108	Edit	Delete
#21	MeSH descriptor **Heart Septal Defects, Atrial**, this term only	95	Edit	Delete
#22	MeSH descriptor **Atrial Fibrillation**, this term only	2056	Edit	Delete

ID	Search	Hits	Edit	Delete
#23	(brain* or cerebr* or cerebell* or cortical or vertebrobasilar or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or MCA or "anterior circulation" or "posterior circulation" or "basal ganglia") and (ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus* or hypox* or vasospasm or obstruction or vasculopathy)	8321	Edit	Delete
#24	("lacunar infarct*" or "cortical infarct*")	14	Edit	Delete
#25	(brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraventricular or infratentorial or supratentorial or "basal gangli*" or subarachnoid or putaminal or putamen or "posterior fossa") and (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)	4420	Edit	Delete
#26	("vertebral artery dissection" or "cerebral art* disease*")	39	Edit	Delete
#27	(brain or intracranial or "basal ganglia" or lenticulostriate) and (vascular) and (disease* or disorder or accident or injur* or trauma* or insult or event)	1038	Edit	Delete
#28	(ischemic or ischaemic or apoplectic) and (event or events or insult or attack*)	3721	Edit	Delete
#29	("cerebral vein" or "cerebral venous" or sinus or sagittal) and (thrombo*)	262	Edit	Delete
#30	(CVDST or CVT)	37	Edit	Delete
#31	(intracranial or "cerebral art*" or "basilar art*" or "vertebral art*" or vertebrobasilar or "vertebral basilar") and (stenosis or ischemia or ischaemia or insufficiency or arteriosclero* or atherosclero* or occlus*)	937	Edit	Delete
#32	(venous or arteriovenous or "brain vasc*") and malformation*	199	Edit	Delete
#33	(brain or cerebral) and (angioma* or hemangioma* or haemangioma*)	17	Edit	Delete
#34	(carotid*)	3418	Edit	Delete
#35	("patent foramen ovale" or PFO)	112	Edit	Delete
#36	(atrial or atrium or auricular) and fibrillation	3557	Edit	Delete
#37	("asymptomatic cervical bruit")	7	Edit	Delete
#38	(aphasi* or apraxi* or dysphasi* or dysphagi* or "deglutition disorder*" or "swallow* disorder*" or dysarthri* or hemipleg* or hemipar* or paresis or paretic or hemianop* or hemineglect or spasticity or anomi* or dysnomi* or "acquired brain injur*" or hemiball*)	4485	Edit	Delete
#39	(unilateral or visual or hemispatial or attentional or spatial) and neglect	313	Edit	Delete
#40	(brain or cerebral or intracranial or communicating or giant or basilar or "vertebral artery" or berry or saccular or ruptured) and aneurysm*	1008	Edit	Delete
#41	MeSH descriptor **Aphasia** explode all trees	131	Edit	Delete
#42	MeSH descriptor **Anomia**, this term only	8	Edit	Delete
#43	MeSH descriptor **Hemiplegia**, this term only	377	Edit	Delete
#44	MeSH descriptor **Hemianopsia**, this term only	20	Edit	Delete
#45	MeSH descriptor **Paresis** explode all trees	269	Edit	Delete
#46	MeSH descriptor **Deglutition Disorders**, this term only	404	Edit	Delete
#47	MeSH descriptor **Dysarthria**, this term only	34	Edit	Delete
#48	MeSH descriptor **Pseudobulbar Palsy**, this term only	4	Edit	Delete
#49	MeSH descriptor **Muscle Spasticity**, this term only	429	Edit	Delete
#50	(stroke or poststroke or post NEXT stroke or cerebrovasc* or "brain vasc*" or "cerebral vasc*" or cva* or apoplex* or "ischemi* attack*" or "ischaemi* attack*" or tia* or "neurologic* deficit*" or SAH or AVM)	31,157	Edit	Delete

ID	Search	Hits	Edit	Delete
#51	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50)	43,189	Edit	Delete
#52	(SR-STROKE)	15,097	Edit	Delete
#53	(#51 AND NOT #52)	28,092	Edit	Delete
#54	MeSH descriptor **Caregivers**, this term only	865	Edit	Delete
#55	MeSH descriptor **Friends**, this term only	58	Edit	Delete
#56	MeSH descriptor **Parents** explode all trees	2023	Edit	Delete
#57	MeSH descriptor **Spouses**, this term only	170	Edit	Delete
#58	MeSH descriptor **Visitors to Patients**, this term only	22	Edit	Delete
#59	MeSH descriptor **Home Nursing**, this term only	269	Edit	Delete
#60	MeSH descriptor **Community Networks**, this term only	79	Edit	Delete
#61	MeSH descriptor **Parent-Child Relations** explode all trees	968	Edit	Delete
#62	MeSH descriptor **Interpersonal Relations** explode all trees	3269	Edit	Delete
#63	MeSH descriptor **Family**, this term only	809	Edit	Delete
#64	MeSH descriptor **Family Characteristics** explode all trees	594	Edit	Delete
#65	MeSH descriptor **Family Relations**, this term only	117	Edit	Delete
#66	MeSH descriptor **Intergenerational Relations**, this term only	21	Edit	Delete
#67	MeSH descriptor **Family Therapy**, this term only	573	Edit	Delete
#68	MeSH descriptor **Family Nursing**, this term only	15	Edit	Delete
#69	MeSH descriptor **Family Health**, this term only	301	Edit	Delete
#70	(carer* or caregiv* or "care giv*" or care NEXT giv*)	4765	Edit	Delete
#71	(family or families or spous* or parent or parents or father* or mother* or friend or friends or husband* or wife or wives or partner or partners)	30,648	Edit	Delete
#72	(home or communit*) and (caring or care*) or (community NEAR/2 network*)	16,360	Edit	Delete
#73	(home NEXT based)	1559	Edit	Delete
#74	(community NEXT based) or (community NEAR/2 network*)	3323	Edit	Delete
#75	(homebased or communitybased)	1069	Edit	Delete
#76	"home nursing"	367	Edit	Delete
#77	(non NEXT professional) and (care or nursing)	78	Edit	Delete
#78	(nonprofessional or informal or unpaid) and (care or nursing)	728	Edit	Delete
#79	"next of kin" or (relatives)	33,281	Edit	Delete
#80	(#54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 OR #76 OR #77 OR #78 OR #79)	73,994	Edit	Delete
#81	(#53 AND #80)	5562	Edit	Delete
#82	MeSH descriptor **Community Networks**, this term only	79	Edit	Delete
#83	MeSH descriptor **Social Support**, this term only	1862	Edit	Delete
#84	MeSH descriptor **Social Isolation**, this term only	117	Edit	Delete

ID	Search	Hits	Edit	Delete
#85	MeSH descriptor **Social Welfare**, this term only	39	Edit	Delete
#86	MeSH descriptor **Patient Education as Topic**, this term only	5338	Edit	Delete
#87	MeSH descriptor **Professional-Family Relations**, this term only	110	Edit	Delete
#88	MeSH descriptor **Altruism**, this term only	29	Edit	Delete
#89	MeSH descriptor **Helping Behavior**, this term only	52	Edit	Delete
#90	MeSH descriptor **Social Adjustment**, this term only	753	Edit	Delete
#91	MeSH descriptor **Adaptation, Psychological**, this term only	2471	Edit	Delete
#92	MeSH descriptor **Stress, Psychological**, this term only	2751	Edit	Delete
#93	MeSH descriptor **Anxiety**, this term only	4079	Edit	Delete
#94	MeSH descriptor **Depression**, this term only	4232	Edit	Delete
#95	MeSH descriptor **Emotions**, this term only	1534	Edit	Delete
#96	MeSH descriptor **Family**, this term only with qualifier: **PX**	318	Edit	Delete
#97	MeSH descriptor **Respite Care**, this term only	26	Edit	Delete
#98	MeSH descriptor **Day Care**, this term only	262	Edit	Delete
#99	(attitude* or perception* or belief* or expectation* or satisfaction or emotion* or relationship* or support* or control or adjust* or guid* or information or advi* or help* or train*) and (carer* or caregiv* or "care giv*")	4444	Edit	Delete
#100	(attitude* or perception* or belief* or expectation* or satisfaction or emotion* or relationship* or support* or control or adjust* or guid* or information or advi* or help* or train*) and (care NEXT giv*)	482	Edit	Delete
#101	(anxiet* or stress* or fatigue* or resent* or burden* or cope* or coping)	50,135	Edit	Delete
#102	(moral*) and (oblig* or duty or duties or responsibilit*)	75	Edit	Delete
#103	(social or psychosocial or practical or group*) and (information or advice or help or support or network)	200,444	Edit	Delete
#104	"post discharge" or postdischarge	708	Edit	Delete
#105	(respite)	111	Edit	Delete
#106	MeSH descriptor **Quality of Life**, this term only	11,312	Edit	Delete
#107	(health or problem* or mood*) and (carer* or caregiv* or "care giv*")	3292	Edit	Delete
#108	(health or problem* or mood*) and (care NEXT giv*)	421	Edit	Delete
#109	MeSH descriptor **Self-Help Groups**, this term only	495	Edit	Delete
#110	"self help" NEXT group*	626	Edit	Delete
#111	(selfhelp NEXT group*)	28	Edit	Delete
#112	(self NEXT "help group")	86	Edit	Delete
#113	(community NEAR/2 network*)	118	Edit	Delete
#114	(community NEAR/2 support*)	226	Edit	Delete
#115	(support* NEAR/2 conversation*)	3	Edit	Delete
#116	(patient NEAR/3 feedback)	259	Edit	Delete
#117	(patient NEAR/3 education)	7378	Edit	Delete
#118	(#82 OR #83 OR #84 OR #85 OR #86 OR #87 OR #88 OR #89 OR #90 OR #91 OR #92 OR #93 OR #94 OR #95 OR #96 OR #97 OR #98 OR #99 OR #100 OR #101 OR #102 OR #103 OR #104 OR #105 OR #106 OR #107 OR #108 OR #109 OR #110 OR #111 OR #112)	23,4748	Edit	Delete

Appendix 8 Appendix to *Chapter 4*

Completion of London Stroke Carers Training Course training records

TABLE 74 Completion of competency items (mandatory components)

Training components (mandatory)	Registered (*N* = 450), *n* (%)
Carer has demonstrated understanding of:	
1. Relative having a stroke	
Achieved	232 (51.6)
Not achieved	94 (20.9)
Training record not completed	124 (27.6)
2. What a stroke is	
Achieved	211 (46.9)
Not achieved	115 (25.6)
Training record not completed	124 (27.6)
4. Healthy lifestyle and prevention	
Achieved	220 (48.9)
Not achieved	106 (23.6)
Training record not completed	124 (27.6)
12. Compliance with medication	
Achieved	146 (32.4)
Not achieved	180 (40.0)
Training record not completed	124 (27.6)
13. Post-discharge recommendations and help	
Achieved	199 (44.2)
Not achieved	127 (28.2)
Training record not completed	124 (27.6)
14. Knowledge and skills to home environment	
Achieved	160 (35.6)
Not achieved	166 (36.9)
Training record not completed	124 (27.6)

TABLE 75 Number of non-mandatory components achieved

No. of components achieved	Registered (*N* = 450), *n* (%)	Cumulative *N* patients (%)
8	6 (1.3)	6 (1.3)
7	12 (2.7)	18 (4.0)
6	30 (6.7)	48 (10.7)
5	31 (6.9)	79 (17.6)
4	56 (12.4)	135 (30.0)
3	47 (10.4)	182 (40.4)
2	60 (13.3)	242 (53.8)
1	41 (9.1)	283 (62.9)
0	3 (0.7)	286 (63.6)
Missing	164 (36.4)	450 (100.0)

TABLE 76 Completion of competency items: non-mandatory components

Training components (non-mandatory)	Registered (*N* = 450), *n* (%)
3. Specific stroke-related problems	
Appropriate and achieved	204 (45.3)
Appropriate but not achieved	5 (1.1)
Not completed	79 (17.6)
Not appropriate	38 (8.4)
No training record returned	124 (27.6)
5. Dietary needs and feeding techniques	
Appropriate and achieved	75 (16.7)
Not completed	20 (4.4)
Not appropriate	231 (51.3)
No training record returned	124 (27.6)
6. Communication with dysphasic relative	
Appropriate and achieved	65 (14.4)
Not completed	13 (2.9)
Not appropriate	248 (55.1)
No training record returned	124 (27.6)
7. Managing washing and dressing	
Appropriate and achieved	167 (37.1)
Appropriate but not achieved	1 (0.2)
Not completed	30 (6.7)
Not appropriate	128 (28.4)
No training record returned	124 (27.6)

TABLE 76 Completion of competency items: non-mandatory components (*continued*)

Training components (non-mandatory)	Registered (*N* = 450), *n* (%)
8. Limb positioning and skin integrity	
Appropriate and achieved	131 (29.1)
Appropriate but not achieved	1 (0.2)
Not completed	25 (5.6)
Not appropriate	169 (37.6)
No training record returned	124 (27.6)
9. Continence management	
Appropriate and achieved	60 (13.3)
Not completed	17 (3.8)
Not appropriate	249 (55.3)
No training record returned	124 (27.6)
10. Bowel management	
Appropriate and achieved	54 (12.0)
Appropriate but not achieved	1 (0.2)
Not completed	19 (4.2)
Not appropriate	252 (56.0)
No training record returned	124 (27.6)
11. Assisting mobility and safe transfers	
Appropriate and achieved	239 (53.1)
Not completed	26 (5.8)
Not appropriate	61 (13.6)
No training record returned	124 (27.6)

TABLE 77 Number of time logs completed by site

Centre	Yes, *n* (%)	No, *n* (%)	Not required, *n* (%)	Confirmed not completed by site, *n* (%)	Confirmed lost by site, *n* (%)	Time logs not completed, *n* (%)	Total, *n*
Control	211 (44.1)	4 (0.8)	174 (36.4)	78 (16.3)	9 (1.9)	2 (0.4)	478
19	17 (50.0)	0 (0.0)	14 (41.2)	3 (8.8)	0 (0.0)	0 (0.0)	34
20	18 (66.7)	0 (0.0)	3 (11.1)	6 (22.2)	0 (0.0)	0 (0.0)	27
21	9 (29.0)	0 (0.0)	19 (61.3)	3 (9.7)	0 (0.0)	0 (0.0)	31
22	9 (50.0)	0 (0.0)	9 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	18
23	14 (56.0)	3 (12.0)	7 (28.0)	0 (0.0)	0 (0.0)	1 (4.0)	25
24	1 (8.3)	0 (0.0)	2 (16.7)	9 (75.0)	0 (0.0)	0 (0.0)	12
25	17 (44.7)	1 (2.6)	20 (52.6)	0 (0.0)	0 (0.0)	0 (0.0)	38
26	12 (52.2)	0 (0.0)	8 (34.8)	3 (13.0)	0 (0.0)	0 (0.0)	23

continued

TABLE 77 Number of time logs completed by site (*continued*)

Centre	Yes, *n* (%)	No, *n* (%)	Not required, *n* (%)	Confirmed not completed by site, *n* (%)	Confirmed lost by site, *n* (%)	Time logs not completed, *n* (%)	Total, *n*
27	11 (31.4)	0 (0.0)	14 (40.0)	10 (28.6)	0 (0.0)	0 (0.0)	35
28	7 (30.4)	0 (0.0)	5 (21.7)	11 (47.8)	0 (0.0)	0 (0.0)	23
29	16 (53.3)	0 (0.0)	12 (40.0)	0 (0.0)	1 (3.3)	1 (3.3)	30
30	1 (7.7)	0 (0.0)	3 (23.1)	9 (69.2)	0 (0.0)	0 (0.0)	13
31	12 (46.2)	0 (0.0)	9 (34.6)	5 (19.2)	0 (0.0)	0 (0.0)	26
32	17 (68.0)	0 (0.0)	7 (28.0)	0 (0.0)	1 (4.0)	0 (0.0)	25
33	9 (52.9)	0 (0.0)	2 (11.8)	0 (0.0)	6 (35.3)	0 (0.0)	17
34	11 (32.4)	0 (0.0)	14 (41.2)	9 (26.5)	0 (0.0)	0 (0.0)	34
35	15 (46.9)	0 (0.0)	15 (46.9)	1 (3.1)	1 (3.1)	0 (0.0)	32
36	15 (42.9)	0 (0.0)	11 (31.4)	9 (25.7)	0 (0.0)	0 (0.0)	35

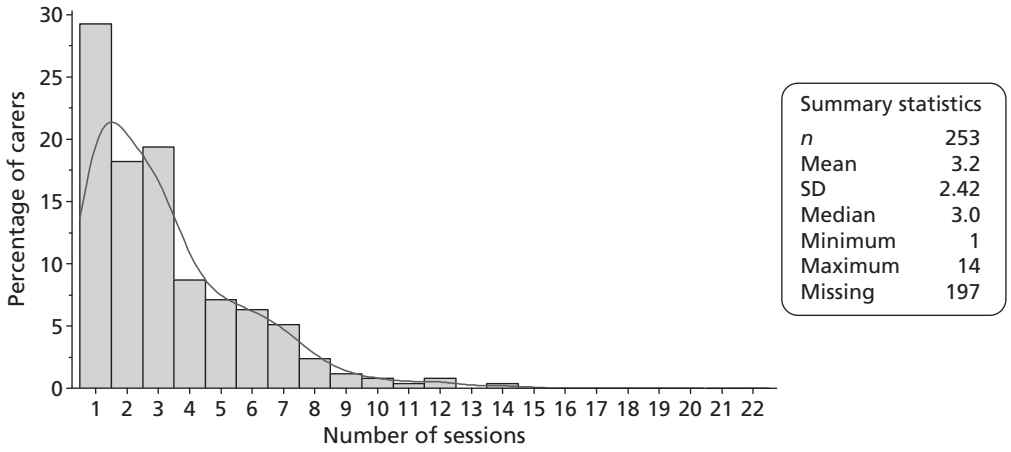

FIGURE 19 Number of training sessions undertaken by carers: intervention. Missing = there is no information about the number of training sessions.

Patient safety

TABLE 78 Number of patients with falls and SAEs by SRUs (% is out of patients registered by the SRU)

SRU	No. registered	Patients with falls, *n* (%)	Patients with SAEs, *n* (%)
Intervention	**450**	**35 (7.8)**	**2 (0.4)**
1	20	1 (5.0)	0 (0.0)
2	21	1 (4.8)	0 (0.0)
3	24	2 (8.3)	0 (0.0)
4	30	2 (6.7)	0 (0.0)
5	32	1 (3.1)	0 (0.0)
6	32	1 (3.1)	0 (0.0)
7	27	0 (0.0)	0 (0.0)
8	23	5 (21.7)	0 (0.0)
9	29	3 (10.3)	0 (0.0)
10	25	1 (4.0)	1 (4.0)
11	16	1 (6.3)	0 (0.0)
12	35	4 (11.4)	0 (0.0)
13	14	2 (14.3)	0 (0.0)
14	35	4 (11.4)	0 (0.0)
15	19	0 (0.0)	0 (0.0)
16	17	3 (17.6)	1 (5.9)
17	25	2 (8.0)	0 (0.0)
18	26	2 (7.7)	0 (0.0)
Control	**478**	**35 (7.3)**	**3 (0.6)**
19	34	2 (5.9)	0 (0.0)
20	27	5 (18.5)	0 (0.0)
21	31	6 (19.4)	0 (0.0)
22	18	3 (16.7)	0 (0.0)
23	25	0 (0.0)	0 (0.0)
24	12	1 (8.3)	1 (8.3)
25	38	2 (5.3)	0 (0.0)
26	23	6 (26.1)	0 (0.0)
27	35	4 (11.4)	1 (2.9)
28	23	0 (0.0)	0 (0.0)
29	30	1 (3.3)	0 (0.0)
30	13	0 (0.0)	0 (0.0)
31	26	0 (0.0)	0 (0.0)
32	25	0 (0.0)	0 (0.0)
33	17	0 (0.0)	0 (0.0)
34	34	1 (2.9)	0 (0.0)
35	32	1 (3.1)	0 (0.0)
36	35	3 (8.6)	1 (2.9)

TABLE 79 List of SAEs

SAE criteria		Description of fall
1	Significantly or permanently disabling or incapacitating	Fainted while in bathroom, low BP 88/46 mmHg
2	Prolonged hospitalisation	Patient found on floor near bed, patient not attempting to get up, appeared confused. Bruising to arm and face
3	Prolonged hospitalisation	No description or explanation possible. X-ray showed fracture of distal clavicle
4	Prolonged hospitalisation	Patient found on floor in bathroom – confirmed with fractured hip. Has had dynamic hip screw
5	Life threatening	Patient was due to be discharged that day – fell while standing leaning on a table. Fractured neck of femur – acute hospitalisation for repair and surgery. Then on 25 August 2009 was transferred to Minehead hospital for rehabilitation after surgery

BP, blood pressure.

Sensitivity analyses

TABLE 80 Results of sensitivity analyses

Patients' primary outcome at 6 months – adjusted scores							
						Unadjusted	Adjusted
Sensitivity analyses	Intervention, mean (SE), *n*	Control, mean (SE), *n*	Difference (SE)	95% CI of the difference	*p*-value	ICC	ICC
Patients that died (NEADL = 0)	24.2 (0.97) 370	25.1 (0.96) 384	–0.9 (1.30)	(–3.5 to 1.8)	0.507	0.016	0.027
Proxy responses excluded	28.2 (1.08) 315	28.6 (1.07) 326	–0.4 (1.45)	(–3.4 to 2.5)	0.766	0.017	0.038

TABLE 81 Time of completion of questionnaires at 6 months (in days)

Questionnaire	Intervention, mean (SD), *n*	Control, mean (SD), *n*	Difference (95% CI)	*p*-value
Patients	201.6 (14.08) 303	202.8 (14.13) 338	–1.2 (–3.4 to 1.0)	0.2862
Caregivers	201.6 (14.28) 304	201.6 (13.12) 320	0 (–2.1 to 2.2)	0.9836

Additional follow-up data

TABLE 82 Additional questions at 12 months: patients

Additional questions	Intervention (*N* = 450), *n* (%)	Control (*N* = 478), *n* (%)	Total (*N* = 928), *n* (%)
Do you think your treatment was different because of the research?			
Yes	34 (7.6)	42 (8.8)	76 (8.2)
No	91 (20.2)	94 (19.7)	185 (19.9)
Not sure	145 (32.2)	154 (32.2)	299 (32.2)
Missing	180 (40.0)	188 (39.3)	368 (39.7)
If yes, how do you think the treatment you received was different?			
Much better	14 (41.2)	17 (40.5)	31 (40.8)
Better	14 (41.2)	23 (54.8)	37 (48.7)
Unsure	5 (14.7)	2 (4.8)	7 (9.2)
Worse	1 (2.9)	0 (0.0)	1 (1.3)

TABLE 83 Additional questions at 6 months: caregivers

Additional questions	Intervention (*N* = 450), *n* (%)	Control (*N* = 478), *n* (%)	Total (*N* = 928), *n* (%)
Do you feel adequately prepared to care for your relative/friend?			
Yes	229 (50.9)	251 (52.5)	480 (51.7)
No	103 (22.9)	93 (19.5)	196 (21.1)
Missing	118 (26.2)	134 (28.0)	252 (27.2)
Are you still caring for your relative/friend?			
Yes	296 (65.8)	323 (67.6)	619 (66.7)
No	37 (8.2)	25 (5.2)	62 (6.7)
Missing	117 (26.0)	130 (27.2)	247 (26.6)
I have received enough information about stroke recovery and rehabilitation			
Yes	255 (56.7)	255 (53.3)	510 (55.0)
No	72 (16.0)	84 (17.6)	156 (16.8)
Missing	123 (27.3)	139 (29.1)	262 (28.2)

TABLE 84 Additional questions at 12 months: caregivers

Additional questions	Intervention (*N* = 450), *n* (%)	Control (*N* = 478), *n* (%)	Total (*N* = 928), *n* (%)
Are you still caring for your relative/friend?			
Yes	266 (59.1)	284 (59.4)	550 (59.3)
No	20 (4.4)	20 (4.2)	40 (4.3)
Missing	164 (36.4)	174 (36.4)	338 (36.4)
Do you think your treatment was different because of the research?			
Yes	28 (6.2)	42 (8.8)	70 (7.5)
No	99 (22.0)	95 (19.9)	194 (20.9)
Not sure	152 (33.8)	168 (35.1)	320 (34.5)
Missing	171 (38.0)	173 (36.2)	344 (37.1)
If yes how do you think the treatment you received was different?			
Much better	9 (32.1)	19 (45.2)	28 (40.0)
Better	12 (42.9)	18 (42.9)	30 (42.9)
Unsure	4 (14.3)	3 (7.1)	7 (10.0)
Worse	3 (10.7)	1 (2.4)	4 (5.7)
Missing	0 (0.0)	1 (2.4)	1 (1.4)

TABLE 85 Stroke unit process data

Intervention centre no.	Hospital type	Unit type	Total bed no., 2007	Stroke rehabilitation bed no.		2006 audit position[b]	2008 audit position[b]	Eligibility[a]		Community team		Early supported discharge		Significant changes during trial
				2007	2009			2007	2009	2007	2009	2007	2009	
1	Acute	R	14	14	14	N/A	Mid	5	5	✗	✗	✗	✗	✗
2	Comm	R	23	11	23	Lower	Lower	5	5	✗	✗	✗	✗	✗
3	Acute	R	20	14	14	Upper	Mid	5	5	✗	✗	✗	✗	✗
4	Acute	A+R	26	23	23	Mid	Lower	5	5	✗	✗	✗	✓	✗
5	Acute	A+R	20	20	20	N/A	Lower	5	5	✗	✗	✗	✗	✗
6	Comm	R	15	14	14	Mid	Mid	4	5	✓	✓	✗	✗	✗
7	Acute	R	18	18	18	Upper	Upper	5	5	✗	✗	✗	✓	✗
8	Acute	A+R	24	24	18	Mid	Mid	5	5	✗	✗	✗	✗	✗
9	Comm	R	15	15	15	Upper	Upper	4	4	✓	✓	✗	✓	✗
10	Acute	A+R	27	16	14	Mid	Upper	5	5	✗	✗	✗	✗	✗
11	Acute	A+R	16	11	11	Lower	Mid	4	5	✗	✗	✗	✗	✓
12	**Comm**[c]	R	30	30	17	Upper	Upper	5	5	✓	✓	✗	✗	✓
13	Comm	R	20	14	14	Mid	Upper	5	5	✗	✓	✓	✓	✗
14	Acute	R	24	24	24	Mid	Mid	5	5	✗	✗	✗	✗	✗
15	Acute	A+R	24	20	19	Upper	Upper	5	5	✓	✓	✗	✓	✓
16	Acute	R	30	10	8	Mid	Lower	5	5	✗	✗	✗	✗	✗

Intervention centre no.	Hospital type	Unit type	Total bed no., 2007	Stroke rehabilitation bed no.		2006 audit position[b]	2008 audit position[b]	Eligibility[a]		Community team		Early supported discharge		Significant changes during trial
				2007	2009			2007	2009	2007	2009	2007	2009	
17	Acute	A+R	24	16	16	Lower	Upper	5	5	✗	✗	✗	✗	✗
18	Acute	R	19	19	19	Lower	Mid	4	4	✓	✓	✗	✗	✗
Summary [totals or means (SD)]	**13 Acute**	**7 A+R**	**22 (4.96)**	**17 (5.35)**	**17 (4.24)**	**5 Upper**	**7 Upper**			**5**	**6**	**4**	**3**	**2**
						7 Mid	**7 Mid**							
	5 Comm	**11 R**				**4 Lower**	**4 Lower**							
19	Acute	A+R	24	24	24	Lower	Upper	4	4	✗	✗	✗	✗	✗
20	Acute	A+R	31	16	16	Lower	Lower	4	5	✗	✓	✗	✓	✗
21	Comm	R	23	15	15	N/A	Mid	4	4	✗	✗	✗	✗	✗
22	Acute	R	25	10	10	Upper	Upper	5	5	✗	✗	✗	✗	✗
23	Acute	A+R	23	23	23	Mid	Mid	4	5	✗	✗	✗	✗	✗
24	Acute	A+R	23	17	15	Mid	Upper	5	5	✗	✗	✗	✗	✗
25	Acute	A+R	20	12	12	Upper	Upper	5	5	✓	✓	✓	✓	✗
26	Comm	R	20	20	16	Upper	Upper	5	5	✓	✓	✗	✓	✗
27	Comm	R	24	24	19	Mid	Lower	5	5	✗	✗	✗	✗	✗
28	Acute	A+R	56	34	34	Mid	Mid	5	5	✗	✗	✓	✓	✗
29	Acute	A+R	26	16	16	N/A	Lower	5	5	✗	✗	✗	✗	✗
30	Acute	A+R	21	14	14	Lower	Mid	5	5	✗	✗	✗	✗	✗
31	Acute	R	15	15	15	Upper	Upper	5	5	✗	✓	✗	✗	✓
32	Acute	A+R	28	16	16	Mid	Mid	5	4	✗	✗	✓	✓	✗

continued

TABLE 85 Stroke unit process data (*continued*)

Intervention centre no.	Hospital type	Unit type	Total bed no., 2007	Stroke rehabilitation bed no.		2006 audit position[b]	2008 audit position[b]	Eligibility[a]		Community team		Early supported discharge		Significant changes during trial
				2007	2009			2007	2009	2007	2009	2007	2009	
33	Acute	A+R	20	12	12	Upper	Upper	5	5	✗	✗	✗	✗	✓
34	Acute	A+R	29	17	17	Upper	Upper	5	5	✗	✗	✗	✓	✗
35	Acute	A+R	18	18	14	Mid	Mid	5	5	✗	✗	✗	✗	✗
36	Comm	R	20	20	20	Mid	Lower	4	5	✗	✗	✗	✗	✗
Summary [totals or means (SD)]	**14 Acute**	**12 A+R**	**25 (8.75)**	**18 (5.66)**	**17 (5.52)**	**6 Upper**	**8 Upper**			**2**	**4**	**3**	**6**	**2**
						7 Mid	**6 Mid**							
	4 Comm	**6 R**				**4 Lower**	**4 Lower**							

A+R, combined acute and rehabilitation stroke unit; Comm, community hospital; N/A, the centre was not comparable between 2006 and 2008; R, rehabilitation stroke unit.

a Eligibility is the number of criteria (out of 5) used to define a stroke unit by the RCP 2006; units had to meet four or more of these criteria.

b Audit score position is the upper/middle/lower quartile on the total process score (not just the key indicator score) on the 2006 and 2008 audits. 'N/A' means that the centre was not comparable between 2006 and 2008. The 2008 NSSA scores were not directly comparable with the 2006 scores, as the key indicator score was based on 12 indicators in 2006, and nine indicators in 2008. The table shows the overall position (upper, middle or lower quartiles) of the total process score of the audit, a comparison that the NSSA 2008 suggested as more useful.

c Centre became acute in 2009.

TABLE 86 A description of changes to process of care in SRUs

Change to process of care	
Centre: 11	
Change	Organisational restructure from combined stroke unit to acute unit with community hospital rehabilitation unit
Date	January 2009
Description	The stroke unit changed from a combined acute and rehabilitation unit to a primarily acute unit (short stay or short-term rehabilitation only), with a new long-term rehabilitation unit in a separate community hospital in a nearby town
Impact	Few patients on the stroke unit were eligible for TRACS owing to the short length of stay, or transfer to another unit rather than discharge home. The new rehabilitation unit did not meet the stroke unit eligibility criteria, so could not be included in TRACS. MDT staff on the stroke unit continued with the LSCTC where possible, but very few patients were eligible for the intervention. Few patients' caregivers were given any training prior to discharge, and few patients and caregivers were eligible for TRACS recruitment
Change to organisational structure of the stroke unit, not affecting usual process of care	
Centre: 33	
Change	Merging of a primary care trust rehabilitation unit with the acute NHS trust combined stroke unit
Date	April 2008
Description	A number of patients admitted to 33 began to be transferred to the second hospital for stroke rehabilitation, as this was now a part of the same NHS trust. This reduced the numbers of eligible TRACS patients at 33, as they were no longer meeting the eligibility criteria of returning home from the participating stroke unit. The second stroke unit met the trial criteria and staff rotated between the two units, had the same training and shared the same stroke care processes. The second centre was included in TRACS as a part of centre 33
Impact	Recruitment was able to continue
Centre: 31	
Change	Loss of the acute stroke unit within the hospital
Date	October 2007 (pre-recruitment)
Description	The acute stroke unit at centre 31 was closed and all strokes admitted to the acute unit at the nearby centre 22. Both units had separate rehabilitation stroke units with independent staff, who were also independent to the acute unit. Following admission to the acute unit, patients were transferred to one of the rehabilitation units at centre 22 or 31
Impact	Organisational issues at the acute unit meant that the transfer system was not working well initially. As a consequence recruitment did not start until June 2008; however, by the end of the study the centre did achieve the recruitment target
Centre: 15	
Change	Stroke unit became a hyperacute stroke unit
Date	November 2008 to January 2010
Description	Centre 15 was preparing to become a hyperacute stroke unit. As a consequence the focus was more on acute care and the average length of stay on the ward was very short at 12 days – not many stay for >7 days to be eligible for TRACS. Centre 15 became a hyperacute ward at the end of 2009 resulting in more acute beds (10, compared with four previously) and 19 short-term rehabilitation beds
Impact	No significant change in usual involvement of patients and carers as a consequence of this organisational change. Staff continued to rehabilitate patients and involve carers as much as possible within the short time frame. The change did have an impact on recruitment, making it hard to find and recruit eligible patients owing to the acute focus

continued

TABLE 86 A description of changes to process of care in SRUs (*continued*)

Centre: 12	
Change	Stroke rehabilitation unit moved from a community hospital to an acute hospital
Date	January 2009
Description	The move was planned prior to randomisation into TRACS, but the timing was not yet agreed. The move took place in January 2009 when the entire centre moved to an acute hospital. The community hospital had two interlinked wards of 30 elderly stroke beds. The new centre comprised of one elderly rehabilitation ward of 25 beds, 17 of which were dedicated stroke beds
Impact	An unforeseen effect of the potential move was a loss of permanent staff at the original site owing to the uncertainty – a lot of the nursing team were bank staff and the physiotherapists and occupational therapists had a high turnover. This centre was an intervention centre and the high staff turnover did affect the implementation of the LSCTC, as training was not cascaded successfully among staff, and low staff moral reduced compliance with the new intervention. A positive effect of the move was a more settled staff team, treating fewer stroke beds, which improved the implementation of, and compliance with, the LSCTC

Appendix 9 Patient and caregiver resource use

TABLE 87 Patient resource use at baseline (in the previous 3 months)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Residential care home	Night	1/439	6.00	–	3/472	19.50	2.12
Nursing home	Night	1/439	–	–	1/474	60.00	–
Inpatient services	Bed-day	42/441	13.61	21.40	67/472	10.63	14.35
Day hospital/day cases	Activity	32/440	1.19	0.47	36/469	1.06	0.23
Accident and emergency	Occurrence	35/442	1.31	0.64	33/469	1.32	0.61
Outpatient services	Activity	111/437	1.88	1.54	126/466	2.24	2.50
Physiotherapist, hospital[b]	Visit	18/424	3.93	2.43	29/450	4.78	5.19
Occupational therapist, hospital[b]	Visit	7/423	3.83	3.54	17/451	3.67	2.35
Speech and language therapist, hospital[b]	Visit	7/424	3.00	2.16	5/448	2.00	1.00
Community-based services							
GP							
Surgery visit	Visit	225/408	2.16	1.60	251/428	2.09	1.61
Home visit	Visit	42/372	1.48	0.82	38/379	1.73	1.70
Telephone call	Call	44/363	1.66	1.09	40/370	1.55	0.89
Practice nurse							
Surgery visit	Visit	111/383	1.82	1.12	124/392	1.96	1.85
Telephone call	Call	9/359	1.75	1.04	13/366	1.80	1.10
Physiotherapist							
Home visit	Visit	6/416	2.17	0.75	5/435	2.25	1.26
Surgery visit	Visit	9/417	2.50	2.45	7/435	7.83	15.77
Elsewhere	Visit	1/416	–	–	2/429	3.00	–
Occupational therapist							
Home visit	Visit	6/417	3.00	2.76	11/439	1.11	0.33
Surgery visit	Visit	1/415	1.00	–	3/434	1.00	–
Elsewhere	Visit	1/417	2.00	–	2/433	–	–
Speech and language therapist							
Home visit	Visit	2/416	1.00	–	0/435	–	–
Surgery visit	Visit	1/417	–	–	0/434	–	–
Elsewhere	Visit	0/415	–	–	0/433	–	–
Social worker							
Home visit	Visit	7/421	3.60	4.72	5/441	1.75	0.96
Telephone call	Call	2/420	2.00	–	7/443	2.50	2.35

continued

TABLE 87 Patient resource use at baseline (in the previous 3 months) (*continued*)

Resource	Unit	Intervention (*N* = 450)			Control (*N* = 478)		
		N users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Repeat prescription	Occurrence	235/393	2.48	1.24	294/417	2.39	1.80
Community/district nurse	Contact	26/413	6.05	11.29	29/442	3.77	4.84
Health visitor	Contact	1/406	1.00	–	3/430	7.00	7.07
Geriatrician	Contact	2/407	1.00	–	1/428	–	–
Psychiatrist	Contact	2/408	1.00	–	6/429	3.00	2.16
Psychologist	Contact	2/407	4.00	1.41	3/428	1.00	0.00
Chiropodist	Contact	58/411	1.53	0.92	63/436	1.83	2.14
Chiropractor	Contact	3/407	3.50	0.71	2/430	4.00	–
Osteopath	Contact	3/406	4.00	4.24	1/428	–	–
Dentist	Contact	61/410	1.39	1.00	65/433	1.54	1.13
Optician	Contact	62/408	1.18	0.43	79/431	1.24	0.52
Day hospital	Half-day	2/421	6.00	–	8/450	2.86	2.91
Social club	Half-day	15/418	9.64	8.07	15/438	7.60	6.31
Lunch club	Visit	9/420	8.38	4.10	12/441	10.60	11.14
Drop-in centre	Visit	2/418	12.00	0.00	6/435	12.67	7.02
Meals on wheels	Meal	4/424	60.00	–	4/451	15.50	20.51
Frozen meals	Meal	8/423	32.67	49.74	7/444	52.00	27.71
Home help: personal care	Visit	9/424	87.00	63.64	10/445	60.20	68.19
Home help: household care	Visit	8/423	15.40	4.22	10/444	16.80	10.73
Home help: shopping care	Visit	4/423	8.00	–	7/443	12.00	0.00
Social services day-care centre	Hour	1/422	–	–	5/443	17.00	26.85
Intermediate care team	Contact	2/420	6.00	–	0/443	–	–
Other services	Occurrence	16/433	3.09	4.18	14/466	1.90	0.99
Informal care from co-residents							
Personal care	Hour	55/427	169.67	360.58	67/458	202.71	418.65
Providing transport	Hour	83/430	100.98	322.55	94/453	82.52	150.68
Preparing meals	Hour	110/429	155.62	258.25	127/454	124.91	111.47
Housework/laundry	Hour	110/426	110.93	260.35	113/458	98.05	112.18
DIY	Hour	53/420	127.40	446.07	68/446	39.89	47.35
Gardening	Hour	87/423	73.40	289.08	90/447	44.90	56.70
Shopping	Hour	117/429	77.08	247.10	130/453	54.29	50.74
Outings	Hour	82/428	105.81	326.87	92/447	59.66	47.53
Socialising	Hour	104/427	269.72	386.63	128/451	407.34	575.97
Help managing finances	Hour	99/430	64.42	274.58	104/455	37.26	33.65

TABLE 87 Patient resource use at baseline (in the previous 3 months) (*continued*)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Personal care	Hour	20/426	28.09	27.70	22/446	55.27	53.55
Providing transport	Hour	43/421	32.36	44.06	63/443	38.16	52.31
Preparing meals	Hour	29/423	58.29	59.55	35/444	81.74	98.63
Housework/laundry	Hour	38/423	47.53	65.11	52/443	43.00	56.16
DIY	Hour	23/420	21.00	21.43	28/435	19.46	21.27
Gardening	Hour	26/421	21.19	20.77	50/437	18.68	21.03
Shopping	Hour	46/423	32.42	32.40	57/441	27.65	26.58
Outings	Hour	45/423	35.80	50.03	57/441	41.42	38.85
Socialising	Hour	53/419	113.12	196.01	69/442	139.97	342.95
Help managing finances	Hour	31/422	28.94	39.35	39/443	21.83	20.26

a Mean for valid user values only.
b Separate to other outpatient visits.

TABLE 88 Patient resource use at 6 months (in the previous 6 months)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Stroke admission	Bed-days	448/448	44.81	32.88	478/478	42.42	29.48
Residential care home	Night	10/315	27.00	16.70	19/339	16.38	13.62
Nursing home	Night	7/313	117.00	96.42	7/327	14.50	96.42
Inpatient services	Bed-day	56/319	12.40	21.82	65/338	8.41	10.15
Day hospital/day cases	Activity	27/314	1.41	0.97	26/336	1.46	0.71
Accident and emergency	Occurrence	52/311	1.68	1.14	63/338	1.39	0.59
Outpatient services	Activity	178/308	2.98	3.82	158/328	3.33	4.76
Physiotherapist, hospital[b]	Visit	97/258	9.20	16.37	114/289	8.56	7.93
Occupational therapist, hospital[b]	Visit	30/235	3.87	3.38	50/267	8.03	11.64
Speech and language therapist, hospital[b]	Visit	33/261	2.64	2.84	32/272	4.24	3.50
Community-based services							
GP							
Surgery visit	Visit	177/270	3.28	2.32	202/301	3.01	2.04
Home visit	Visit	124/252	2.14	1.61	135/267	2.26	1.93
Telephone call	Call	85/230	1.82	1.11	95/247	2.31	1.93

continued

TABLE 88 Patient resource use at 6 months (in the previous 6 months) (*continued*)

Resource	Unit	Intervention (*N* = 450)			Control (*N* = 478)		
		N users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Practice nurse							
Surgery visit	Visit	116/241	3.06	3.34	116/250	2.78	3.14
Telephone call	Call	35/215	2.48	2.83	32/219	2.19	1.55
Physiotherapist							
Home visit	Visit	159/264	8.58	8.33	158/285	10.48	11.32
Surgery visit	Visit	9/231	3.00	1.41	13/252	3.40	2.63
Elsewhere	Visit	6/222	2.20	0.84	14/246	9.43	8.79
Occupational therapist							
Home visit	Visit	164/270	7.50	8.76	144/284	6.10	8.08
Surgery visit	Visit	1/222	–	–	5/246	2.75	0.50
Elsewhere	Visit	5/222	1.80	1.30	10/243	3.67	2.73
Speech and language therapist							
Home visit	Visit	65/262	7.41	7.58	65/271	6.46	5.60
Surgery visit	Visit	1/243	4.00	–	2/250	3.00	0.00
Elsewhere	Visit	6/242	2.50	1.91	12/252	5.43	2.99
Social worker							
Home visit	Visit	65/274	2.38	1.52	70/297	2.32	1.77
Telephone call	Call	31/274	3.65	2.46	49/297	2.78	1.42
Repeat prescription	Occurrence	208/264	4.62	2.72	253/288	4.90	3.22
Community/district nurse	Contact	112/261	4.56	4.47	108/277	6.20	7.30
Health visitor	Contact	25/236	2.73	1.72	19/249	2.93	2.37
Geriatrician	Contact	0/231	–	–	5/242	1.20	0.45
Psychiatrist	Contact	11/235	2.55	2.70	5/244	2.25	0.50
Psychologist	Contact	13/233	2.58	1.83	15/247	2.36	1.60
Chiropodist	Contact	60/242	1.98	1.27	84/274	2.00	1.28
Chiropractor	Contact	3/232	3.33	1.53	1/243	2.00	–
Osteopath	Contact	1/232	2.00	–	0/242	–	–
Dentist	Contact	58/243	2.04	1.43	79/261	1.74	0.94
Optician	Contact	66/247	1.31	0.74	92/264	1.51	1.10
Day hospital	Half-day	15/278	4.36	2.92	20/299	5.80	6.20
Social club	Half-day	15/277	4.64	3.27	19/290	6.56	11.89
Lunch club	Visit	8/277	3.14	1.07	12/291	8.80	15.60
Drop-in centre	Visit	7/275	8.83	8.26	10/294	3.13	1.96
Meals on wheels	Meal	5/277	7.50	6.36	10/300	16.00	19.80
Frozen meals	Meal	9/278	15.00	21.66	10/296	17.00	17.97

TABLE 88 Patient resource use at 6 months (in the previous 6 months) (*continued*)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	**Unit**	***N* users/valid *n***	**Mean[a]**	**SD**	***N* users/valid *n***	**Mean[a]**	**SD**
Home help: personal care	Visit	71/275	87.17	134.38	70/297	80.80	116.76
Home help: household care	Visit	18/273	14.20	15.05	20/293	8.75	6.40
Home help: shopping care	Visit	4/271	14.50	13.44	8/292	–	–
Social services day-care centre	Hour	9/275	3.17	2.04	12/296	4.14	5.34
Intermediate care team	Contact	18/259	6.44	5.03	20/282	7.10	7.93
Other services	Occurrence	27/308	3.29	3.27	20/327	9.69	10.64
Informal care from co-residents							
Personal care	Hour	206/302	225.67	332.01	211/317	323.65	448.95
Providing transport	Hour	190/286	130.18	223.37	193/304	137.68	159.34
Preparing meals	Hour	224/295	286.16	292.26	237/316	305.48	212.73
Housework/laundry	Hour	228/299	220.26	293.08	239/313	238.28	197.90
DIY	Hour	119/272	108.26	321.30	139/300	67.13	90.35
Gardening	Hour	159/284	90.90	228.14	166/304	72.52	69.04
Shopping	Hour	225/300	108.16	202.37	231/315	132.95	116.38
Outings	Hour	182/288	127.10	223.29	187/310	132.41	121.74
Socialising	Hour	213/289	980.38	1293.44	213/307	775.17	935.81
Help managing finances	Hour	205/296	89.61	211.78	203/312	125.49	267.22
Informal care from non-residents							
Personal care	Hour	52/281	83.29	168.43	59/308	133.25	143.09
Providing transport	Hour	102/282	50.10	113.02	118/311	45.02	54.52
Preparing meals	Hour	53/278	28.42	27.81	57/305	95.05	130.70
Housework/laundry	Hour	54/279	55.05	62.17	67/305	101.29	103.46
DIY	Hour	56/274	26.71	30.40	48/303	36.18	58.56
Gardening	Hour	61/276	25.94	22.43	56/304	25.39	30.89
Shopping	Hour	75/280	45.26	64.18	81/306	52.03	43.76
Outings	Hour	96/285	47.02	68.63	86/305	66.87	82.07
Socialising	Hour	113/281	104.76	137.88	110/300	122.31	141.10
Help managing finances	Hour	43/278	29.25	20.23	53/304	62.42	93.37

a Mean for valid user values only.
b Separate to other outpatient visits.

TABLE 89 Patient resource use at 12 months (in the previous 6 months)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Residential care home	Night	17/283	22.33	26.88	25/312	23.41	29.24
Nursing home	Night	10/277	13.00	9.70	7/305	9.33	5.13
Inpatient services	Bed-day	43/288	8.75	12.10	58/312	9.19	12.31
Day hospital/day cases	Activity	31/284	1.29	0.64	28/313	1.29	0.66
Accident and emergency	Occurrence	48/284	1.58	1.45	52/311	1.56	0.92
Outpatient services	Activity	126/281	2.68	2.23	130/310	2.99	2.55
Physiotherapist, hospital[b]	Visit	61/244	8.90	8.28	58/284	8.49	6.78
Occupational therapist, hospital[b]	Visit	23/237	9.00	8.80	17/275	5.73	7.54
Speech and language therapist, hospital[b]	Visit	18/238	7.88	12.78	20/277	4.89	3.77
Community-based services							
GP							
Surgery visit	Visit	167/246	2.96	2.26	197/276	2.67	2.32
Home visit	Visit	86/227	2.25	1.62	86/237	2.20	1.87
Telephone call	Call	56/202	2.13	1.59	69/232	2.71	4.03
Practice nurse							
Surgery visit	Visit	110/223	2.61	2.91	135/248	2.50	2.94
Telephone call	Call	17/195	2.33	1.88	22/213	2.53	2.15
Physiotherapist							
Home visit	Visit	54/232	8.09	10.55	44/265	6.32	7.62
Surgery visit	Visit	6/217	3.75	4.27	18/268	2.85	1.63
Elsewhere	Visit	6/210	4.20	4.49	9/260	13.50	8.80
Occupational therapist							
Home visit	Visit	34/230	7.77	10.08	39/267	4.00	4.32
Surgery visit	Visit	2/220	–	–	9/263	2.50	1.91
Elsewhere	Visit	5/218	2.75	1.50	8/259	11.00	8.55
Speech and language therapist							
Home visit	Visit	31/234	7.04	7.03	32/268	4.18	4.11
Surgery visit	Visit	1/224	6.00	–	6/263	4.50	3.87
Elsewhere	Visit	1/223	1.00	–	8/260	7.00	6.68
Social worker							
Home visit	Visit	21/251	1.63	0.62	34/287	1.91	1.00
Telephone call	Call	10/245	2.33	1.21	24/283	2.11	1.37
Repeat prescription	Occurrence	191/234	5.25	4.19	226/265	4.98	2.67
Community/district nurse	Contact	67/233	5.82	8.18	82/275	5.86	9.06
Health visitor	Contact	6/217	6.83	6.94	12/251	2.09	1.45

TABLE 89 Patient resource use at 12 months (in the previous 6 months) (*continued*)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Geriatrician	Contact	1/212	–	–	1/249	1.00	–
Psychiatrist	Contact	6/215	1.00	0.00	9/250	1.75	1.39
Psychologist	Contact	6/213	1.67	0.58	7/248	1.83	1.33
Chiropodist	Contact	78/241	2.30	1.38	80/273	2.24	1.50
Chiropractor	Contact	6/214	2.67	2.08	4/250	2.25	1.29
Osteopath	Contact	5/212	7.75	11.50	1/247	3.00	–
Dentist	Contact	84/231	1.72	1.36	73/259	1.69	1.03
Optician	Contact	69/223	1.49	1.04	75/261	1.27	0.56
Day hospital	Half-day	12/252	5.00	5.63	12/288	6.91	11.35
Social club	Half-day	14/249	12.38	16.18	19/286	7.85	7.82
Lunch club	Visit	5/243	15.60	19.65	22/285	10.38	9.79
Drop-in centre	Visit	6/245	8.67	9.87	13/285	7.60	9.62
Meals on wheels	Meal	5/252	3.00	–	7/292	180.00	–
Frozen meals	Meal	12/253	13.50	9.98	13/286	15.57	10.69
Home help: personal care	Visit	42/250	92.89	84.71	42/289	164.00	175.57
Home help: household care	Visit	15/250	20.75	10.87	19/287	72.40	105.67
Home help: shopping care	Visit	7/248	–	–	9/284	23.67	2.52
Social services day-care centre	Hour	12/251	12.33	11.50	9/284	58.75	94.64
Intermediate care team	Contact	8/243	204.00	277.19	11/273	13.80	25.83
Other services	Occurrence	14/283	3.00	3.20	18/311	2.62	2.50
Informal care from co-residents							
Personal care	Hour	153/263	255.63	376.21	170/285	318.51	352.46
Providing transport	Hour	139/253	109.69	104.41	158/281	150.18	146.17
Preparing meals	Hour	175/263	280.73	156.79	206/287	318.34	216.04
Housework/laundry	Hour	170/258	207.32	159.25	200/280	184.82	153.80
DIY	Hour	97/247	46.29	45.23	116/268	56.02	61.29
Gardening	Hour	123/250	74.41	86.83	134/273	72.78	86.83
Shopping	Hour	174/257	101.15	85.04	183/279	115.19	92.91
Outings	Hour	143/251	113.41	102.39	152/277	138.42	135.28
Socialising	Hour	163/251	645.96	694.37	165/282	865.98	1000.19
Help managing finances	Hour	161/259	145.16	491.49	163/283	76.23	80.10
Informal care from non-residents							
Personal care	Hour	34/257	89.08	108.84	41/287	78.65	108.78
Providing transport	Hour	73/254	49.53	47.03	86/284	40.15	51.81
Preparing meals	Hour	39/255	70.13	58.81	50/286	90.95	136.70
Housework/laundry	Hour	40/255	81.71	64.93	60/287	87.83	106.61

continued

TABLE 89 Patient resource use at 12 months (in the previous 6 months) (*continued*)

Resource	Unit	Intervention (*N* = 450)			Control (*N* = 478)		
		N users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
DIY	Hour	43/248	53.68	108.21	46/278	36.35	48.84
Gardening	Hour	50/251	27.17	23.55	52/281	45.93	74.34
Shopping	Hour	44/256	59.25	62.26	70/287	42.57	43.15
Outings	Hour	63/256	38.80	48.07	79/287	42.46	60.38
Socialising	Hour	77/252	123.95	149.35	90/286	114.18	168.16
Help managing finances	Hour	33/252	53.50	43.64	43/287	56.15	50.91

a Mean for valid user values only.
b Separate to other outpatient visits.

TABLE 90 Caregiver resource use at baseline (in the previous 3 months)

Resource	Unit	Intervention (*N* = 450)			Control (*N* = 478)		
		N users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Inpatient services	Bed-day	7/440	0.06	0.66	16/470	0.36	3.66
Day hospital/day cases	Activity	21/438	1.15	0.37	21/469	1.19	0.51
Accident and emergency	Occurrence	13/407	1.69	1.70	23/436	1.23	0.61
Outpatient services	Activity	88/440	2.31	2.03	92/470	2.05	1.90
Community-based services							
GP							
Surgery visit	Visit	199/425	1.81	1.21	228/460	1.82	1.13
Home visit	Visit	12/389	1.33	1.00	10/421	1.00	0.00
Telephone call	Call	25/392	1.50	0.96	33/423	1.40	0.89
Practice nurse							
Surgery visit	Visit	120/404	1.61	1.35	101/430	1.83	2.75
Telephone call	Call	2/388	2.00	1.41	13/420	1.45	0.69
Physiotherapist							
Hospital visit	Visit	7/404	3.71	3.20	16/436	5.54	9.51
Home visit	Visit	2/399	2.00	–	2/429	–	–
Surgery visit	Visit	14/402	2.57	1.95	14/431	3.67	5.23
Elsewhere	Visit	0/398	–	–	4/428	4.50	2.12
Repeat prescription	Occurrence	214/415	2.26	1.15	229/443	2.26	1.11
Community/district nurse	Contact	7/398	1.67	0.82	5/434	2.00	1.41
Health visitor	Contact	2/397	1.00	–	4/430	1.50	0.71
Psychiatrist	Contact	40/404	1.41	0.66	34/433	1.38	0.56
Psychologist	Contact	5/397	2.00	1.41	6/431	4.67	2.31
Chiropodist	Contact	7/397	3.00	2.00	6/431	4.25	5.25
Chiropractor	Contact	4/396	4.00	1.41	4/430	1.00	–
Osteopath	Contact	3/400	1.50	0.71	4/430	1.50	0.71

TABLE 90 Caregiver resource use at baseline (in the previous 3 months) (*continued*)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Informal care for patient							
Personal care	Hour	72/420	116.95	172.87	105/451	82.80	106.69
Providing transport	Hour	141/419	58.04	98.00	158/448	57.52	71.90
Preparing meals	Hour	228/426	103.89	96.37	240/455	124.19	208.76
Housework/laundry	Hour	229/421	77.22	113.96	254/452	87.18	113.46
DIY	Hour	88/412	34.65	79.32	101/442	30.35	44.21
Gardening	Hour	159/423	32.13	63.98	158/451	33.87	35.39
Shopping	Hour	233/422	44.28	59.16	264/452	44.60	49.82
Outings	Hour	140/414	59.96	86.75	163/443	65.36	83.45
Socialising	Hour	239/425	281.30	409.07	269/448	274.38	399.62
Help managing finances	Hour	175/425	26.64	56.94	193/450	35.02	45.93

a Mean for valid user values only.

TABLE 91 Caregiver resource use at 6 months (in the previous 6 months)

		Intervention (*N* = 450)			Control (*N* = 478)		
Resource	Unit	*N* users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Residential care home	Night	0/319	–	–	0/333	–	–
Nursing home	Night	0/316	–	–	0/330	–	–
Inpatient services	Bed-day	20/320	0.36	2.29	15/335	0.20	1.33
Day hospital/day cases	Activity	16/315	1.25	0.45	16/327	1.44	0.89
Accident and emergency	Occurrence	20/309	1.74	1.63	24/319	1.33	0.66
Outpatient services	Activity	83/315	2.96	2.64	93/326	2.73	2.16
Community-based services							
GP							
Surgery visit	Visit	176/290	2.85	2.11	197/318	2.58	1.80
Home visit	Visit	16/238	1.77	1.69	12/261	1.27	0.47
Telephone call	Call	37/242	2.09	1.13	47/271	1.95	1.05
Practice nurse							
Surgery visit	Visit	116/267	2.17	1.90	111/287	1.95	1.88
Telephone call	Call	12/234	2.55	1.97	21/262	1.87	1.36
Physiotherapist							
Hospital visit	Visit	10/256	4.78	4.79	15/280	2.31	1.38
Home visit	Visit	4/252	7.25	8.77	6/275	8.75	6.99
Surgery visit	Visit	12/256	2.64	3.26	10/277	3.00	2.26
Elsewhere	Visit	2/249	3.50	3.54	5/272	3.00	1.41

continued

TABLE 91 Caregiver resource use at 6 months (in the previous 6 months) (*continued*)

Resource	Unit	Intervention (*N* = 450)			Control (*N* = 478)		
		N users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Repeat prescription	Occurrence	152/273	4.26	2.34	178/299	4.54	2.89
Community/district nurse	Contact	15/254	4.33	3.97	17/275	3.55	2.73
Health visitor	Contact	3/249	5.00	2.65	4/272	1.50	0.58
Psychiatrist	Contact	33/259	2.00	1.41	44/283	2.15	1.56
Psychologist	Contact	5/246	4.20	2.86	4/273	3.00	1.83
Chiropodist	Contact	5/248	3.00	1.83	5/273	3.75	2.50
Chiropractor	Contact	1/249	2.00	–	6/271	2.67	1.53
Osteopath	Contact	2/251	3.00	0.00	3/271	2.50	2.12
Informal care for patient							
Personal care	Hour	238/306	221.84	331.92	243/323	370.06	600.72
Providing transport	Hour	201/295	140.40	219.80	201/309	144.36	171.54
Preparing meals	Hour	282/310	252.51	239.41	295/330	285.67	227.19
Housework/laundry	Hour	278/310	181.51	201.93	295/325	218.40	222.58
DIY	Hour	130/285	99.12	311.09	151/290	56.34	62.17
Gardening	Hour	181/294	81.84	209.96	196/307	63.76	71.43
Shopping	Hour	281/307	108.58	181.74	297/321	111.38	106.71
Outings	Hour	205/293	113.97	204.40	214/310	123.17	131.61
Socialising	Hour	271/303	740.91	984.28	262/317	679.46	1023.29
Help managing finances	Hour	258/309	69.55	172.02	268/317	72.44	95.80

a Mean for valid user values only.

TABLE 92 Caregiver resource use at 12 months (in the previous 6 months)

Resource	Unit	Intervention (*N* = 450)			Control (*N* = 478)		
		N users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Residential care home	Night	0/281	–	–	2/309	–	–
Nursing home stay	Night	0/281	–	–	0/307	–	–
Inpatient services	Bed-day	18/282	0.27	1.90	15/306	0.27	2.85
Day hospital/day cases	Activity	15/280	1.20	0.41	27/305	1.11	0.32
Accident and emergency	Occurrence	17/267	1.69	1.14	16/293	1.57	1.16
Outpatient services	Activity	71/275	2.89	3.04	82/303	2.42	1.66
Community-based services							
GP							
Surgery visit	Visit	151/263	2.20	1.58	191/290	2.47	1.61
Home visit	Visit	9/216	1.89	1.05	14/236	1.43	1.09
Telephone call	Call	24/218	2.14	2.48	34/234	1.75	0.84

TABLE 92 Caregiver resource use at 12 months (in the previous 6 months) (*continued*)

Resource	Unit	Intervention (*N* = 450)			Control (*N* = 478)		
		N users/valid *n*	Mean[a]	SD	*N* users/valid *n*	Mean[a]	SD
Practice nurse							
Surgery visit	Visit	105/239	1.79	1.31	124/263	1.95	1.55
Telephone call	Call	9/214	2.13	1.89	14/228	1.69	1.18
Physiotherapist							
Hospital visit	Visit	13/233	5.00	3.65	14/254	3.85	3.91
Home visit	Visit	2/229	3.50	0.71	1/243	1.00	–
Surgery visit	Visit	3/230	4.00	4.36	7/246	2.43	1.27
Elsewhere	Visit	0/229	–	–	2/243	3.00	1.41
Repeat prescription	Occurrence	139/238	3.89	1.93	164/264	3.96	2.08
Community/district nurse	Contact	8/232	7.43	11.12	10/250	9.00	10.00
Health visitor	Contact	1/230	–	–	4/244	2.75	1.50
Psychiatrist	Contact	32/240	2.12	1.31	35/254	2.20	1.42
Psychologist	Contact	5/229	6.60	6.88	6/246	5.00	4.30
Chiropodist	Contact	5/230	5.25	2.75	1/244	6.00	–
Chiropractor	Contact	2/230	4.00	–	0/243	–	–
Osteopath	Contact	1/229	2.00	–	3/244	4.00	2.00
Informal care for patient							
Personal care	Hour	187/256	243.81	346.07	207/288	278.90	398.06
Providing transport	Hour	173/251	107.70	106.82	188/279	150.43	148.65
Preparing meals	Hour	243/265	264.64	196.99	265/296	297.91	206.24
Housework/laundry	Hour	229/260	194.84	180.61	257/289	191.98	179.30
DIY	Hour	129/241	47.46	69.61	136/268	46.54	48.18
Gardening	Hour	155/252	69.77	86.61	182/280	77.02	136.17
Shopping	Hour	233/257	106.64	96.55	259/286	150.43	251.86
Outings	Hour	181/244	103.84	102.82	196/280	146.99	148.80
Socialising	Hour	229/256	644.07	767.11	234/282	666.61	882.95
Help managing finances	Hour	222/264	61.35	87.78	225/290	84.19	107.49

a Mean for valid user values only

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