

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 Anwar⁴ and A Farrin⁴ on behalf of the
TRACS Trial Collaboration

¹Academic Unit of Elderly Care and Rehabilitation, Bradford Teaching Hospitals NHS Foundation Trust, Bradford and University of Leeds, Leeds, UK

²Institute of Psychiatry, King's College London, London, UK

³Department of Stroke Medicine, King's College London, London, UK

⁴Clinical Trials Research Unit, University of Leeds, Leeds, UK

⁵Personal Social Services Research Unit, London School of Economics and Political Science, London, UK

*Corresponding author

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Scientific summary

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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 $\pounds 102,577$. When applied to intervention group individuals proportionately to the amount of caregiver training received, this resulted in a mean cost of $\pounds 39$ 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.

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