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A structured training programme for caregivers of inpatients after stroke (TRACS): a cluster randomised controlled trial and cost-effectiveness analysis

Anne Forster, Josie Dickerson, John Young, Anita Patel, Lalit Kalra, Jane Nixon, David Smithard, Martin Knapp, Ivana Holloway, Shamaila Anwar, Amanda Farrin, on behalf of the TRACS Trial Collaboration

Summary

Background Most patients who have had a stroke are dependent on informal caregivers for activities of daily living. The TRACS trial investigated a training programme for caregivers (the London Stroke Carers Training Course, LSCTC) on physical and psychological outcomes, including cost-effectiveness, for patients and caregivers after a disabling stroke.

Methods We undertook a pragmatic, multicentre, cluster randomised controlled trial with a parallel cost-effectiveness analysis. Stroke units were eligible if four of five criteria used to define a stroke unit were met, a substantial number of patients on the unit had a diagnosis of stroke, staff were able to deliver the LSCTC, and most patients were discharged to a permanent place of residence. Stroke units were randomly assigned to either LSCTC or usual care (control group), stratified by geographical region and quality of care, and using blocks of size 2. Patients with a diagnosis of stroke, likely to return home with residual disability and with a caregiver providing support were eligible. The primary outcome for patients was self-reported extended activities of daily living at 6 months, measured with the Nottingham Extended Activities of Daily Living (NEADL) scale. The primary outcome for caregivers was self-reported burden at 6 months, measured with the caregivers burden scale (CBS). We combined patient and caregiver costs with primary outcomes and quality-adjusted life-years (QALYs) to assess cost-effectiveness. This trial is registered with controlled-trials.com, number ISRCTN 49208824.

Findings We assessed 49 stroke units for eligibility, of which 36 were randomly assigned to either the intervention group or the control group. Between Feb 27, 2008, and Feb 9, 2010, 928 patient and caregiver dyads were registered, of which 450 were in the intervention group, and 478 in the control group. Patients' self-reported extended activities of daily living did not differ between groups at 6 months (adjusted mean NEADL score 27·4 in the intervention group versus 27·6 in the control group, difference –0·2 points [95% CI –3·0 to 2·5], p value=0·866, ICC=0·027). The caregiver burden scale did not differ between groups either (adjusted mean CBS 45·5 in the intervention group versus 45·0 in the control group, difference 0·5 points [95% CI –1·7 to 2·7], p value=0·660, ICC=0·013). Patient and caregiver costs were similar in both groups (length of the initial stroke admission and associated costs were £13 127 for the intervention group and £12 471 for the control group; adjusted mean difference £1243 [95% CI –1533 to 4019]; p value=0·380). Probabilities of cost-effectiveness based on QALYs were low.

Interpretation In a large scale, robust evaluation, results from this study have shown no differences between the LSCTC and usual care on any of the assessed outcomes. The immediate period after stroke might not be the ideal time to deliver structured caregiver training.

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Introduction

Stroke is a common condition with an estimated yearly incidence for first-ever occurrence of 1·65 per 1000 population.[1] Immediate admission to hospital for treatment and rehabilitation is recommended, however, most patients return home with some residual disability.[2] Substantial reliance and burden is placed on informal caregivers, usually family members, to provide assistance with activities of daily living, including dressing and toileting after hospital discharge,[3] which can affect caregivers' physical and psychosocial wellbeing.[4,5] The economic value of the informal care provided is substantial.[6,7] Effective interventions directed at caregivers of patients who have had a stroke are important both to sustain their own health and to improve the recovery and adjustment of the patient who has had a stroke.[8,9]

A systematic, structured training programme for caregivers, delivered in a stroke unit, which included assessment of competencies in skills essential for the day-to-day management of disabled stroke survivors (the London Stroke Carers Training Course, LSCTC) was developed and assessed in a single-centre individually randomised trial.[10] Results from this trial[10] reported a decrease in caregiver burden, anxiety, and depression, improved psychological outcomes for patients, and reduced overall costs largely due to earlier hospital

discharge following the LSCTC compared with usual care.[11] We established the training caregivers after stroke (TRACS) trial to investigate the wider generalisability of the LSCTC intervention and to assess the effectiveness of the LSCTC in improving physical outcomes for the patient and reducing caregiver burden.

Methods

See Online for appendix

Study design and participants

TRACS was a UK, pragmatic, multicentre cluster randomised trial of the LSCTC. We purposely selected the cluster randomised trial design to reduce between-group treatment contamination. Methods have been reported in detail elsewhere.[12] In summary, stroke units were eligible if: four of five criteria used to define a stroke unit were met;[13] a substantial number of patients on the unit had a diagnosis of stroke; staff were able to deliver the LSCTC; and most patients were discharged to a permanent place of residence. We also undertook an embedded process evaluation that will be reported separately.

In keeping with the pragmatic trial design, eligibility criteria were deliberately broad and inclusive. Patients were eligible for participation if they had a confirmed primary diagnosis of new stroke (ischaemic or intracerebral haemorrhage; first or recurrent stroke); were medically stable, likely to return home with residual disability; and, following discharge, had a caregiver available, willing and able to provide support. We defined the caregiver as the main person, other than health, social, or voluntary care provider, helping with activities of daily living or advocating on behalf of the patient. We excluded patient and caregiver dyads if the patient needed palliative care, discharge was planned within 1 week of admission to the stroke unit (insufficient time for exposure to the intervention), or the patient or caregiver was previously registered to the trial.

For the **protocol review in *The Lancet*** see http://www.thelancet.com/protocol-reviews/10PRT-2438

All participants provided written informed consent or assent for participation in the trial. The study protocol was approved by Leeds Research Ethics Committee (reference 07/Q1205/12), and accepted by *The Lancet*.

Randomisation and masking

Cluster randomisation was done centrally at the Clinical Trials Research Unit (CTRU). Stroke units were randomly assigned (1:1) to either the intervention group or the control group, 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 National Sentinel Audit).[13] We used block randomisation (blocks of size 2) to ensure these important covariates were balanced between the arms of the trial.

Researchers independent of clinical teams delivering patient care undertook participant recruitment and collection of baseline data. We completed detailed screening logs throughout the trial to monitor for selection bias. Participants were masked to the stroke unit allocation.

Procedures

The LSCTC is a structured training programme for caregivers, which includes assessment of competencies in knowledge or skills essential for the day-to-day management of disabled survivors of stroke (for example, knowledge of stroke, handling skills for activities of daily living). The programme has 14 components, six components are mandatory, eight non-mandatory dependent on individual patient and caregiver needs (appendix). Caregivers' competency can be checked by observing the skill, or questioning their understanding. The LSCTC was modified for national rollout by the multidisciplinary team who delivered the LSCTC in the single-centre study.[10] They developed an intervention manual and caregiver training record, and devised and delivered a training programme to members of the multidisciplinary team in intervention sites through centrally organised training days. Staff attending the training were tasked with cascading the LSCTC to other members of the multidisciplinary team and were provided with materials (slides and recordings of talks) to support them in doing so. Subsequently, staff were to gradually increase delivery of the LSCTC until it became an integral part of the ward care process. After the initial training meeting, intervention stroke units were given 4–6 months to implement the LSCTC into standard ward practice.

We used the caregiver training record to measure the intervention unit's compliance with LSCTC provision and to estimate its costs. The LSCTC developers agreed a definition of compliance as: indication on the training record that training on the six mandatory components had been delivered and competency achieved by the caregiver, or the record was signed off by a member of the multidisciplinary team indicating that all necessary training had been delivered and competency achieved.

Stroke units randomly assigned to the control group were asked to continue usual care as recommended in national guidelines.[14]

Patient baseline data included: sex, age, ethnic origin, education, employment, living arrangements, relationship to caregiver, previous stroke, disability before stroke, date and type of stroke, test of cognition,[15] and language impairment. We collected the six components of the Edinburgh stroke casemix adjuster[16] to enable adjustment for stroke severity. For the caregiver, we recorded sex, age, ethnic origin, physical ability (modified Rankin scale), education, and employment. We noted the incidence of falls between recruitment and discharge as an expected serious adverse event.

We recorded primary and secondary outcomes via self-completed questionnaires in hospital at baseline, and via postal questionnaires at 6 and 12 months. Where the patient was unable to complete the questionnaire independently, the caregiver could provide help or complete the questionnaire by proxy. We compared details of proxy completion between the two groups of the study.

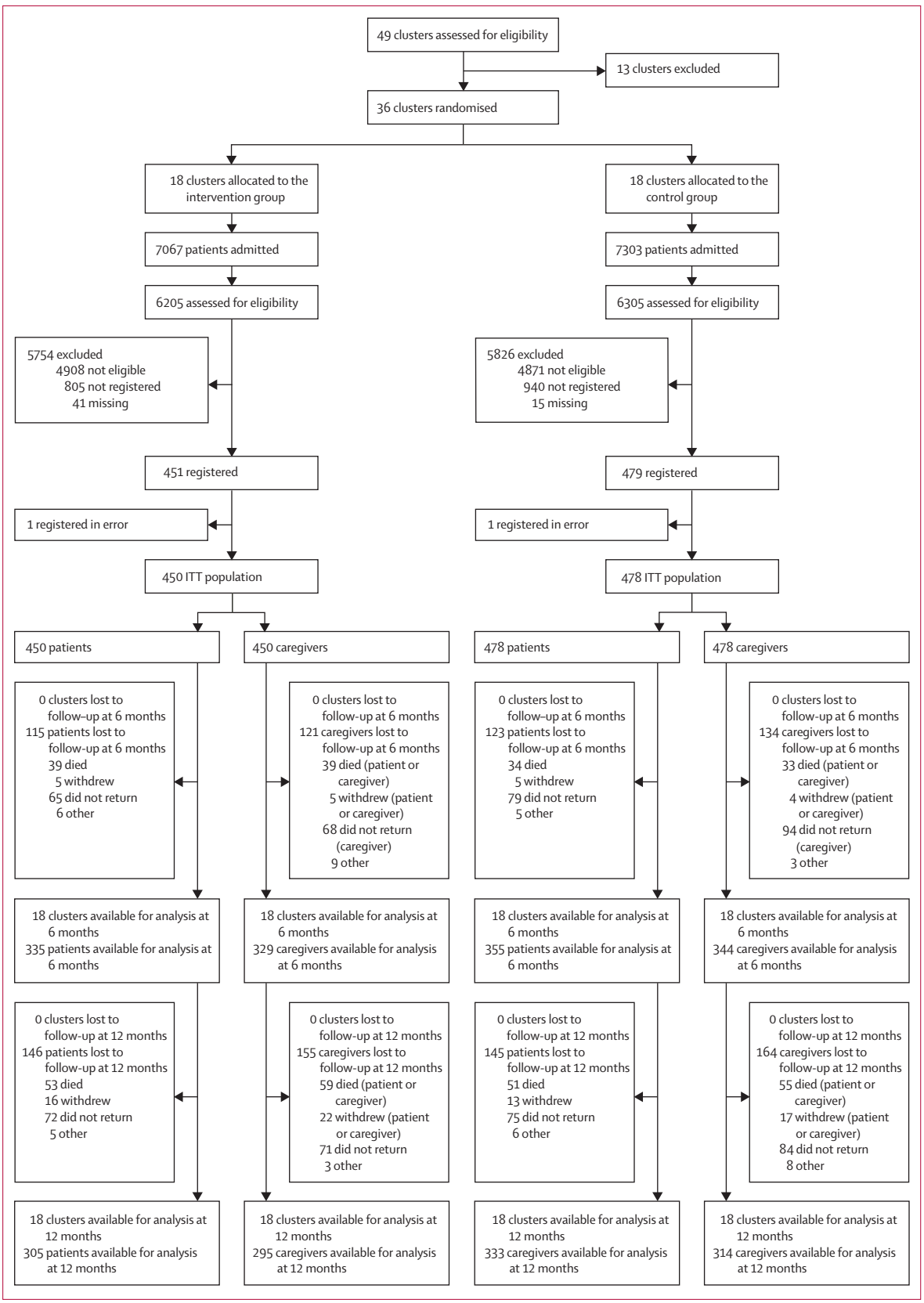

Figure 1: **Trial profile**

	Intervention (n=450)	Control (n=478)
Age	71·0 (12·76)	71·3 (12·18)
NEADL score before stroke	52·0 (15·77)	52·3 (15·80)
Barthel index score after stroke	12·2 (5·38)	12·6 (5·45)
Women	193 (43%)	216 (45%)
Language impairment*	118 (26%)	112 (23%)
Cognitive impairment†	135/370 (36%)	145/391 (37%)
Patient relationship to caregiver		
Partner	314 (70%)	315 (66%)
Daughter or son	118 (26%)	135 (28%)
Other	18 (4%)	28 (6%)

Data are mean (SD) or number of patients (%). NEADL=Nottingham extended activities of daily living. *Includes patients with dysphasia or receptive aphasia. †Of those able to express verbally or in writing (as measured by 6-item cognitive impairment test).

Table 1: **Baseline characteristics and clinical details of patients**

	Intervention (n=450)	Control (n=478)
Age (years)	61·1 (14·64)	60·8 (13·91)
Women	310 (69%)	325 (68%)
Number of individuals having left education at age 16 years or younger	317 (70%)	339 (71%)

Data are mean (SD) or number of individuals (%).

Table 2: **Baseline characteristics of caregivers**

Statistical analysis

The primary outcome for patients was self-reported functional independence in extended activities of daily living (ADL) measured at 6 months after recruitment using the Nottingham Extended Activities of Daily Living (NEADL).[17,18] The primary outcome for caregivers was self-reported burden using the caregivers burden scale (CBS) measured at 6 months.[19] Secondary outcomes for patients were self-reported versions of: the hospital anxiety and depression scale (HADS), EQ-5D and quality-adjusted life-years (QALYs) generated from it using societal weights, Barthel Index, and Stroke Impact Scale (SIS).[20–23] Secondary outcomes for caregivers were self-report versions of Frenchay activities index,[24] HADS, and EQ-5D and QALYs generated from it. We used an adapted self-complete client service receipt inventory (CSRI) to measure patient and caregiver resource use (use of services before stroke and after discharge).[11,25] We recorded patient and caregiver deaths, hospital readmissions, and institutionalisations. We obtained process data before, during, and after recruitment at every participating stroke unit to monitor any changes in eligibility in stroke units and in the process of care that prepared patients and caregivers for discharge in those units.

We calculated that 36 stroke units, each recruiting 25 patients, resulting in 450 patients per group, would provide close to 90% power at 5% significance level to detect a six-point difference on the NEADL, a difference agreed as clinically relevant.[26] The sample size incorporated 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)[27] and 25% loss to follow-up. The power of the trial was adversely affected 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%, we increased the trial sample size from 900 to 950 patient and caregiver dyads, allowing up to 35 dyads per stroke unit to compensate for lower recruitment at some centres.

We undertook analyses and data summaries on an intention-to-treat basis—we analysed all patients registered for active follow-up within a stroke unit according to the group that that stroke unit was randomly assigned to, regardless of non-compliance. We did all statistical testing at a 2-sided 5% significance level.

Since the trial was cluster randomised, we compared the primary outcome measures, the 6-month NEADL score and the CBS, between the intervention and control groups using a two-level hierarchical model, with patients (or caregivers) nested within stroke units. We adjusted for patient-level baseline covariates (baseline NEADL, sex, caregiver's education, caregiver baseline HADS score, Edinburgh stroke casemix adjuster), and stroke unit-level covariates (geographical region, key 12 indicator score, and number of beds in every centre) in the model. We analysed secondary outcomes for patients and caregivers using similar multilevel models. We reported effect sizes, 95% CIs, and adjusted ICCs. We summarised death, hospital admission, and institutionalisation by treatment group but undertook no formal statistical comparison between the intervention and control groups.

We did the analyses assuming data missing completely at random using complete cases. We used various sensitivity analyses to examine the robustness of the conclusions of the primary analysis, a sensitivity analysis including patients who had died (assuming a NEADL score of 0), a repeat of the primary analysis assuming data are missing at random, and a sensitivity analysis excluding proxy responses. A secondary analysis explored the relationship between outcome and compliance with the LSCTC.

Economic evaluation

The prospective economic evaluation assessed the cost-effectiveness of the LSCTC for patients and caregivers at 6 months (appendix). We combined patient and caregiver health and social care service and societal costs with NEADL (patient), CBS (caregiver), and QALY outcomes. We attached unit costs to individual-level resource use quantities to calculate a cost per participant. We included the development and staff training costs associated with

the LSCTC. We compared costs and QALYs and examined the probability of cost-effectiveness by constructing cost-effectiveness acceptability curves using threshold ranges of £0–2000 for point gains on the NEADL and CBS and £0–50 000 for QALY gains. This trial is registered with controlled-trials.com, number ISRCTN 49208824.

Role of the funding source

The trial was a major collaborative effort with colleagues in the National Institute for Health Research (NIHR) Stroke Research Network. The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication. AP had full access to the health economics data. AFa had full access to all the data and acts as statistical guarantor.

Results

36 UK stroke units in four geographical regions (Yorkshire, the North West, the South West Peninsula, and London and the southeast) were randomised in the trial. 49 stroke units in these regions expressed an interest in TRACS, 41 completed feasibility questionnaires, 39 were eligible, and 36 completed approval processes in time to be entered for randomisation (figure 1). Between Feb 27, 2008, and Feb 9, 2010, 12 510 patients and caregivers were screened, and 928 patient and caregiver dyads were registered in the trial (450 in the intervention group, 478 in the control group), 35% of the 2675 eligible patient and caregiver dyads (figure 1). The groups were well balanced at baseline (tables 1 and 2, appendix). There were more male patients than female patients in both groups. Caregivers were younger than patients, most caregivers had left education at age 16 years or younger, more women than men were acting as caregivers in both groups, and in most cases they were the patients' partner. The response rates for the endpoints at 6 and 12 months were: 690 (74%) of 928 patients at 6 months (335 patients in intervention group and 355 patients in control group) and 638 (69%) of 928 patients at 12 months (305 patients in intervention group and 333 patients in control group), and 673 (73%) of 928 caregivers at 6 months (329 caregivers in intervention group and 344 caregivers in control group) and 609 (66%) of 928 caregivers at 12 months (295 caregivers in intervention group and 314 caregivers in control group).

The patient primary outcome of the NEADL score at 6 months did not differ significantly between groups, neither did the caregiver primary outcome of the CBS at 6 months (table 3). We also noted no differences in patient and caregiver secondary endpoints at 6 or 12 months (appendix). Sensitivity analyses done on the primary outcomes confirmed the conclusions of the primary analyses (data not shown).

	Intervention		Control		Difference (SE)	95 % CI of the difference	p value	Adjusted ICC
	Mean (SE)	N	Mean (SE)	N				
NEADL score	27·4 (1·00)	330	27·6 (0·99)	348	−0·2 (1·34)	−3·0 to 2·5	0·866	0·027
Total CBS score	45·5 (0·83)	325	45·0 (0·83)	340	0·5 (1·08)	−1·7 to 2·7	0·660	0·013

NEADL=Nottingham extended activities of daily living. CBS=caregiver burden scale. ICC=intraclass correlation coefficient.

Table 3: **Primary outcomes, adjusted scores, differences, p values, and ICC according to questionnaire**

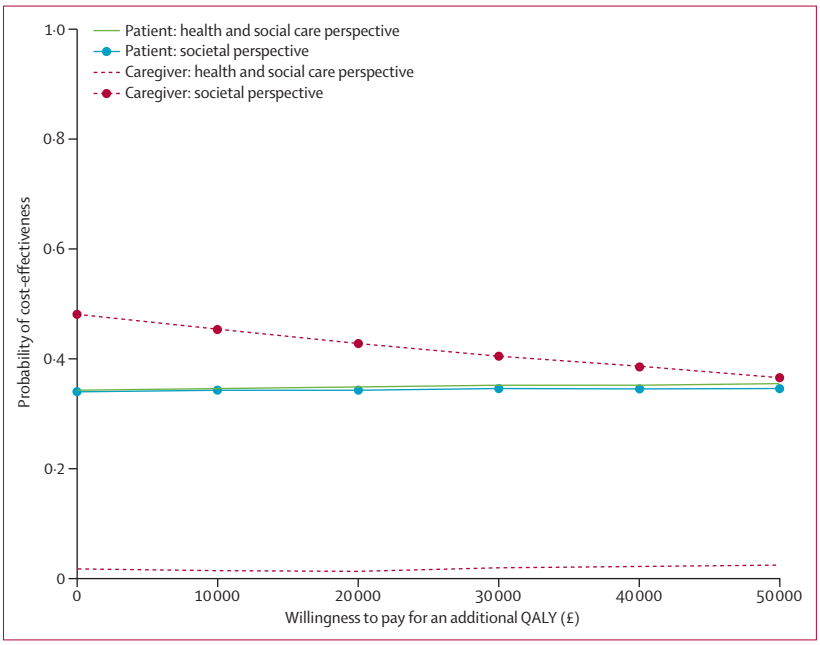

Figure 2: **Probability that the intervention is cost effective compared with the control at 6 months, from every cost perspective, for a range of willingness to pay values for an additional QALY**
QALY=quality-adjusted life-year.

Average intervention compliance was 44% (196 of 450); half the participating centres had a compliance rating of more than 60%. 124 (28%) of 450 training records were not completed by the sites (appendix). Results from an exploratory analysis showed no relation between increased patient functional independence or lower caregiver burden in stroke units with greater intervention compliance (appendix). Intervention delivery was not associated with increased risk of inpatient falls (50 in the intervention group *vs* 42 in the control group). The number of deaths, hospital readmissions, or institutionalisation rates did not differ between the intervention and control groups at either 6 or 12 months after registration (data not shown). The process data revealed changes to inpatient care in just one centre; carer involvement was reduced in an intervention centre (data not shown).

The mean cost per patient of the LSCTC training and development was £82 in those receiving inputs and £39 when including zero costs for those either receiving no LSCTC inputs or with missing data regarding such

inputs. The length of the initial stroke admission and associated costs were similar in both groups (£13 127 for the intervention group and £12 471 for the control group; adjusted mean difference £1243 [95% CI −1533 to 4019]; p=0·380). Total health and social care costs for patients and societal costs for patients or caregivers did not differ between groups at 6 months, 12 months, or over 1 year (appendix). Caregivers in the intervention group had higher health and social care costs at 6 months (adjusted mean difference £207 [95% CI 5–408], p=0·045). This difference was no longer present at 12 months or over 1 year (appendix). We noted no evidence of significant differences in QALYs for patients or caregivers at any assessment point (appendix).

For the threshold ranges examined, probabilities of the cost-effectiveness of the LSCTC in the patient evaluation peaked at 51% based on the NEADL. In the caregiver evaluation, the probability of cost-effectiveness reached 62% from a health and social care perspective and 68% from a societal perspective based on the CBS, although it is unknown what the willingness to pay for a CBS point improvement would be in practice. From the health and social care perspective, probabilities of cost-effectiveness based on QALYs were low at a maximum of 36% in the patient evaluation and just 2% in the caregiver evaluation (figure 2). Thus the intervention is unlikely to be considered cost-effective within current policy thresholds of £20 000 to £30 000 per QALY gained.

Discussion

A Cochrane review of eight studies (n=1007) examined the effectiveness of non-pharmacological interventions for caregivers of stroke survivors in reducing caregiver burden or enhancing caregiver wellbeing.[28] The review concluded that previous studies have methodological limitations; further robust evaluation was required; and the effects of caregiver interventions on the patient also need to be assessed. The LSCTC was the most promising intervention reviewed. The TRACS trial was a pragmatic, multicentre, cluster randomised controlled trial of the LSCTC complex intervention. Patients who had had a stroke attending intervention stroke units did not show a clinically significant improvement in functional independence compared with patients who had had a stroke attending the control stroke units at 6 months after registration. The burden for caregivers of patients attending intervention stroke units did not significantly differ with that of caregivers of patients attending the control stroke units at 6 months. Other physical and psychological outcomes did not differ for patients and caregivers. Patient costs were similar and caregiver costs were higher in the intervention group, and the LSCTC is unlikely to be cost effective (panel).

The LSCTC was initially assessed in a single-centre individually randomised trial that reported a range of benefits.[10] That study involved a smaller cohort of patients and caregivers and was delivered by the multidisciplinary team who had developed the intervention and who might have had particular expertise and commitment. This expertise might not have been replicated in the range of stroke units who delivered the intervention in this trial. In the 10 years since the single-centre study,[10] stroke care might have improved in a way consistent with some of the LSCTC practices. However, our process evaluation indicates that it is unlikely that standard care has improved to such a degree that caregivers' needs have been successfully met (publication in preparation). It is possible that the immediate post-stroke period, when potential caregivers are coming to terms with their new situation, might 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.

The TRACS trial included stroke units from different health-care settings (acute and community hospitals in rural and urban settings) in four disparate geographical regions. Eligibility criteria were purposely inclusive to ensure that a representative population of patients who have had a stroke was recruited. We were careful to choose outcomes that were known to be valid reliable and sensitive to change in this population. The numbers of participants and their baseline characteristics were well balanced between the study groups, demonstrating that selection bias was avoided. Loss of power caused by the unequal cluster sizes was compensated for by increasing recruitment beyond 900. The follow-up rate of 75% at 6 months required for the power calculation was nearly achieved. We are therefore confident that the TRACS trial results are robust and generalisable to all patients who have had a stroke and their informal caregivers in stroke units across the UK.

Panel: Research in context

Systematic Review

A Cochrane review from 2011[28] has summarised the effectiveness of non-pharmacological interventions for caregivers of stroke survivors in reducing caregiver burden or enhancing caregiver wellbeing.[28] In eight randomised trials including 1007 participants, an intervention that focused on preparing participants for the work of caring for a stroke survivor (the LSCTC) was the most promising intervention. However, the evidence for this was from a single-centre randomised trial.[10] We searched the scientific literature before the publication of the Cochrane review[28] on the effectiveness of caregiver interventions, and we identified no effective early training programmes for caregivers of patients after stroke, other than the LSCTC.

Interpretation

The purpose of TRACS was to assess if the LSCTC continued to show benefits to caregivers and patients who have had a stroke if implemented as a part of standard practice in stroke units across the UK. The TRACS trial (n=928) has almost doubled the sample size of the Cochrane Review, providing conclusive evidence that recovery of patients who have had a stroke, caregivers' burden, or other physical and psychological outcomes do not differ between the LSCTC and usual care, nor is the LSCTC 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.

In keeping with the pragmatic nature of the trial, the LSCTC intervention was implemented in accord with usual NHS practices for a new service initiative and used methods that would be acceptable and feasible to multidisciplinary teams and NHS management to allow widespread dissemination if effectiveness was proven. The intervention was acceptable to the staff attending the training days, with recognition of the importance of each of the core competencies, demonstrating face validity for the intervention. The intent was that the training was cascaded down by staff attending the training days to other ward colleagues. It might be that this commonly used cascade method was not as effective as we would have wished. A more intensive (but thus less pragmatic and more resource intensive) strategy to implement the intervention might have been more successful. A component of the intervention was the completion of the caregiver training record. Completed training records were returned to the Trial Manager and included as a standard monitoring report to the Trial Management Group and Trial Steering Committee. Half of the participating centres had a compliance rating of over 60%. Such a compliance rate is compatible with other trials assessing complex interventions in stroke rehabilitation.[29] Some units did not implement the LSCTC as robustly as envisaged, however, analyses of patient independence and caregiver burden showed no associations with levels of intervention compliance.

In conclusion, we have undertaken a robust multicentre, cluster randomised trial, showing that this method is feasible in stroke rehabilitation research. The intervention was associated with benefits in a single-centre evaluation but these benefits have not been replicated in this large, pragmatic multicentre trial. There was no difference between the LSCTC and usual care with respect to improving functional independence of patients who have had a stroke, reducing caregivers' burden, or improving 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 integrated intervention approach might be more relevant, whereby initial hospital training is supported with follow-up training after discharge delivered by community-based teams.

Contributors

AFo contributed to the study conception and design, data acquisition and interpretation, and drafting of the report. JD contributed to the study design, data acquisition and interpretation, and drafting of the report. JY contributed to the study conception and design, data interpretation, and commented on the draft of the report. AP contributed to the study design, data analysis and interpretation, and drafting of the report. LK contributed to the study conception and design, and commented on the draft of the report. JN contributed to the study conception and the design of the study, interpretation of data, and commented on the draft of the report. DS contributed to the study design, and commented on the draft of the report. MK contributed to the study design, and commented on the draft of the report. IH contributed to the analysis of the data and drafting of the report. SA contributed to data acquisition, and commented on a draft of the report. AFa contributed to the study conception and design, statistical guarantor and data acquisition, data analysis and interpretation, and drafting of the report.

TRACS Trial Collaboration

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TRACS Trial Management Group Anne Forster, John Young, Josie Dickerson, Anita Patel, Lalit Kalra, David Smithard, Jane Nixon, Martin Knapp, Ivana Holloway, Shamaila Anwar, and Amanda Farrin.
Trial Steering Committee Peter Langhorne (Chair), Avril Drummond, Kerry Hood, and Helen Rodgers.
Data Monitoring Committee Derick Wade (Chair), Audrey Bowen, and John Norrie.
TRACS intervention delivery team: Anne Melbourn, Jayne Steadman, and Margreet Wittink.

Participating stroke units (number of dyads recruited)

Airedale General Hospital (34): S Mawyer, S Williamson, and P Garnett. *Blackpool Victoria Hospital (27)*, K Waywell, J Howard, H Goddard, S Preston, J McIlmoyle, and M J O'Donnell. *Budleigh Salterton Hospital and Crediton Hospital (31)*: T Ayers, L Barron, and A Bowring. *Calderdale and Huddersfield NHS Foundation Trust (20)*: G Seebass, I Shakir, C Button, J Greig, D Nicholson, M Barber, T Smith, and P Finn. *Camborne Redruth Community Hospital (21)*: S Coltman, G Courtald, and S Connife-Jones. *Cumberland Infirmary (24)*: P Davies, C Hagon, and L Pearce. *Darent Valley Hospital (30)*: S Hussein, T Daniels, and J Hancock. *Dewsbury and District Hospital (33)*: P Datta, G Bateman, and K Mallinder. *Ellesmere Port/ Countess of Chester Hospitals (32)*: K Chatterjee, C Kelly, K James, and C Child. *Fairfield General Hospital (18)*: K Kawafi, A Bell, S Moulton, and C Curley. *Harrogate District Hospital (25)*, S Brotheridge, J Strover, A Norton, and A Wray. *Salford Royal NHS Foundation Trust (27)*: S Moss, J Stevens, R Marsh, and E Barberan. *Kent and Canterbury Hospital (12)*: H Baht, B Bourne. *King's College Hospital (38)*: L Kalra, E Jay, C Potter, A Davies, A M Murtagh, and M Fitzpatrick. *Macclesfield District General Hospital (23)*: C Davison, H Rooney, B Simpson, and S Bailey. *Mile End Hospital (23)*: P Gompertz, T Sachs, and H Kariuki. *Mount Gould Hospital (35)*: C Gatehouse, B Hyams, C Brown, and R Truscott. *Newton Abbot Hospital (29)*: R Allison, N Wedge, S Thomas, A Beck, and H Nott. *Royal Oldham Hospital (25)*: E Walker and S Parnell. *Pinderfields General Hospital (30)*: M Carpenter, A Needle, C Holland, V Newton, and AM Doran. *Queen Elizabeth The Queen Mother Hospital (13)*: G Guna, J Idris, and S Jones. *Rochdale Infirmary (26)*: S Powell, N Thomas, R Namushi, and N Saravanan. *Rotherham District General Hospital (26)*: J Okwera, K McNulty, and L Strachan. *Scarborough General Hospital (16)*: J Paterson, R Rose, S Jamieson, M Sellers, A Davidson, M Foden, and L Beadle. *Sheffield Teaching Hospitals NHS Foundation Trust (23)*: A Jones, R Palmer, S Ross, and C Draper. *Sussex Rehabilitation Centre, BSUH (35)*: A Harper, J Breeds, G Spurling, and K Stephenson. *Southport and Ormskirk Hospital NHS Trust (17)*, H Duff, M Marshall, S Wright, and R Lawrence. *St Helens and Knowsley NHS Trust (14)*: V Gowda, S Dealing, R Brown, A Ledger, G Fletcher, and R Irving. *St Luke's Hospital (35)*: C Patterson, L Johnston, J Stevens, D Walshaw, A Adams, and S Oxley. *St Thomas' Hospital (19)*: A Rudd. *University Hospital Aintree (35)*: H Martin, E Bacabac, and V Sutton. *West Cumberland Hospital (32)*: O Orugun and R Jolly. *Weston General Hospital (17)*: G Saunders and H Dymond. *William Harvey Hospital (25)*: D Smithard and A Reid. *Williton Hospital (35)*: S Glanfield and L Caudwell. *York Teaching Hospital NHS Foundation Trust (26)*: J Coyle, E Iveson, C Rhymes, M Keeling, S Craigie, and J Heppel.

Conflicts of interest

We declare that we have no conflicts of interest.

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