Organising Support for Carers of Stroke Survivors (OSCARSS):
a cluster-randomised controlled trial with economic evaluation

Supplementary Material

Table S1 – Description of intervention and usual care, as intended in OSCARSS (adapted from TIDierR)

	Usual care	**CSNAT-Stroke intervention**
Why	To provide tailored information, specialist support and advice to help people to rebuild their lives after stroke, including carers of stroke survivors.	To provide a person-centred process of assessment and support that is practitioner-facilitated but carer-led and tailored to the carer's individual needs, which are likely to change over time. The intervention assumes that carers may have difficulty considering and expressing their needs.
What (materials and procedures)	Stroke survivors typically trigger referral into the service. Assessment of needs uses standardized paperwork, with most items focused on stroke sequelae and secondary prevention. Items specific to carers, if present during a visit: - A section to note "carer needs" on paperwork with guidance prompts e.g. "is there anything they need help with?"	Materials/procedures include: (A) four-stage process (components outlined below), (B) a needs assessment tool (C) an action plan. 1. Identifying and introducing: Staff identify the carer early and make clear that support is available ('scripts' for sensitive use of the term "carer"). Staff introduce needs assessment tool to carers, during separate time with the carer, providing an opportunity to discuss support needs. 2. Needs assessment Carers given time to consider their support needs, self-completing the tool, identifying the areas in which they need more support and prioritising those most important to them. Staff normalise the practice of having separate time with the carer – as well as stroke survivor, if present - to support each as individuals. 3. Assessment conversation and tailoring An assessment conversation between carer and stroke practitioners identifies the carer's individual support needs and what they feel would be most supportive, within the domains of the needs assessment tool that they have prioritised. Support may be directly delivered by staff at this time (e.g. active listening, information, reassurance, signposting/referrals) but helping carers identify sources of support they may wish to access themselves (self-help) or via family members / friends is also encouraged. Staff create service directories to support signposting/referral. 4. Shared plan for action and review Carers record a plan of supportive input, describing the actions taken/ to be taken by the practitioner or carer to address identified needs, which will be subsequently reviewed, as appropriate. Each stage should be staff-facilitated but carer-led; at all stages the carer should be given the opportunity to say what is most important to them and what they feel would support them.
Who provided	Support Coordinators. Essential criteria for recruitment to this role includes: GCSE education; experience providing care to vulnerable people; good communication skills. Training in stroke and stroke-specific care is provided by the organisation.	Support Coordinators. Additional intervention-specific training provided to staff in clusters allocated to intervention. Training, co-delivered by the service provider and the research team, is with groups of staff over a half-day session involving instructional videos and scripts, role play and workbook completion.
How	Routine support visits are typically home visits that intend to support both stroke survivors and families.	After training, the intervention should be implemented by staff during their routine support visits.
Where	Typically in participants' homes, although support can be provided in hospital and via telephone.	As per usual care.
When and How much	Many services have fixed timepoints for assessing and reviewing needs of stroke survivors, as required. Carer needs are also considered at this time. Support contacts can be conducted in between these times, as required.	The intervention should be used every time a staff member has contact with a carer and requires a minimum of 1 face-to-face support contact with the carer, with reviews likely.
Tailoring and modifications	Support tailored to individuals. Services are organized flexibly according to annually-renewed NHS commissioning and requirements of the local population.	As per usual care, additionally staff training modified for those joining after the primary roll-out of the intervention - adapted to one-to-one delivery by the research team using video conferencing.
How well	No standardized approach specific to carer support is outlined, so no 'fidelity monitoring' of practice is appropriate.	For pragmatic reasons, no shadowing or observation of support contacts delivered nationally was planned. Paper based needs assessment tool and action plan are designed to be left with the carer, so could not be collected for review of intervention adherence. Instead, for each carer referred to the study, staff confirm if they used the needs assessment tool and action plan and record reasons for non-use. Use or non-use is only a proxy indicator for potential intervention adherence. Refresher intervention training delivered, as needed, typically one-to-one and by the research team using video conferencing facilities.

Table S2: Participating cluster characteristics

		Control N=17	Intervention N=18
Size of service indicator: Client caseload during 8 month historic period			
	Mean (SD)	181(117)	197(134)
	Median(range)	147(41 to 496)	163(42 to 534)
Staff employed at cluster point of entry to trial	n	31	39
	Mean (SD)	1.8(0.8)	1.9(1.4)
	Median (range)	2(1 to 3)	1(1 to 6)
	Length of time in post (average if > 1 staff per cluster)		
	less than 24 months n(%)		
	over 24 months n(%)	8(47)	7(39)
		9(53)	11(61)

Cost-effectiveness methods and analysis

Methods

Health benefit

The measure of health benefit used in the economic evaluation was the quality adjusted life year (QALY), derived from the EQ-5D-5L[1] using the crosswalk approach[2]. Participants completed the EQ-5D-5L at study entry, 3 months, and 6 months of follow-up. QALYs were calculated from these data using the area under the curve approach.

Costs

The costs for the economic evaluation include the costs associated with NHS and social care resources used by carers during the study and the direct costs associated with delivering the intervention/control. The intervention-related costs included training for staff and time spent providing support (extracted from service delivery records). The intervention was delivered by coordinators who were employed by the service provider, supporting carers who were recruited for OSCARSS between February 2017 and October 2018. These coordinators supported both the stroke survivors and their carers. The coordinators were asked to record the duration and type of activity related to either carers or stroke survivors. For 38% of the sample separate case records were established for carers and stroke survivors (32% in control group; 44% in intervention group). For the remainder of the sample (62%) there was a single case record on which all activities were recorded. As such it has been necessary (even for cases where there are separate records) to analyse the coordinator time provided by the service provider at the level of the dyad (i.e. survivor and carer). The service provider provided a cost of £17.15 per hour of coordinator time (includes on-costs - national insurance and superannuation). This equates to £0.29 per minute. This unit cost value was multiplied by the number of minutes of care provided in order to estimate the cost of the care provided in the two arms.

Participants completed a service use inventory at 3 months and 6 months of follow-up. For each type of resource the cost was estimated as the quantity of that resource or service used multiplied by nationally applicable unit costs[3,4] (see Table S3).

Table S3. Unit costs used in economic evaluation

Service	Unit cost	Source
GP at clinic	£31	PSSRU[3]
GP home visit	£64	PSSRU[3]
GP phone call	£24	PSSRU[3]
Practice nurse (clinic or phone)	£9	PSSRU[3]
Urgent care: A&E	£160	NHS Database[4]
Urgent care: minor injuries/urgent care centre	£141	NHS Database[4]
Urgent care: walk-in centre	£109	NHS Database[4]
Unplanned admission	£3117	NHS Database[4]
Physiotherapist	£57	PSSRU[3]
Psychiatrist	£109	NHS Database[4]
Counsellor/psychologist	£44	PSSRU[3]
Social worker	£61	PSSRU[3]
Blood test	£2	NHS Database[4]
Diagnostic scan/imaging	£64	NHS Database[4]

Missing data

Data were missing if participants were lost to follow-up, did not complete a particular measure, or only partially completed a measure. If there are a lot of people who have partially-completed a particular measure (e.g. a response for 3 out of 5 domains on the EQ-5D), multiple imputation can be used to estimate responses only for the missing items. However if the majority of missing data is because participants have not completed the measure at all, then a total score can be imputed. There were only 8 people (5 at first follow-up and 3 at 2nd follow-up) who had a partially completed EQ-5D therefore it was preferable to impute total utility scores rather than individual missing EQ-5D items. Costs by healthcare category were imputed for people with missing healthcare usage data. Missing data for regression model covariates were also imputed. Participants with missing utility values at all 3 time points were excluded from the imputation (n=4) as was one participant who could not be matched to a stroke survivor (n=1). Ten datasets were imputed.

Economic evaluation

The primary economic evaluation compared the intervention with usual care from the NHS and social care perspective, followed the principle of intention to treat, and was based on multiple imputed datasets to account for missing costs and health benefit data. Costs and health benefits were measured over the 6-month follow-up period. The output for the economic evaluation is the incremental cost effectiveness ratio (ICER) which brings together costs and health benefits into a single figure.

Regression models, based on multiple imputed datasets, were used to estimate net costs (generalised linear model with gamma family and log link) and net QALYs (linear model) for the intervention arm compared with the control arm. Models were adjusted for the same covariates as the clinical-effectiveness analysis. Net costs were divided by net QALYs to calculate an incremental cost effectiveness ratio (ICER). The estimates of incremental costs and outcomes from the regression models were bootstrapped to simulate 2,000 pairs of net costs and net QALYs which were plotted on a cost-effectiveness plane, as recommended by NICE for health technology appraisals[5].

A series of sensitivity analyses were also conducted, these were:

- complete case analysis (includes only people with complete cost and benefit data)
- per protocol analysis (excludes individuals who violated protocol conditions)
- exclude cost of training coordinators and intervention delivery costs
- alternative measure of health benefit (cost per one-point difference on the primary clinical outcome measure, FACQ carer strain)

Results

EQ-5D data

Summary statistics for the EQ-5D data (utility values and QALYs) are reported in the main body of the paper. Net QALYs for the available and imputed data are reported in Table S4. For both the complete case and imputed data there was no statistically significant difference between the treatment groups in terms of QALYs. However for the imputed data (which was used in the primary analysis) there was a very small QALY loss for the intervention group compared to the control group. In terms of EQ-5D data there was differential attrition between the treatment arms over the 6 month period, 33% in the control arm and 50% in the intervention arm. There were 20 participants with no study entry data for EQ-5D, 5 were in the control arm with the remainder from the intervention arm which also contributes to the unbalanced missing data. This may explain the difference between results based on available and imputed data.

Table S4. Net QALYs over the follow-up period for the intervention group compared with the control group, based on available and multiple imputed datasets

	Available data	**Imputed data**
	Mean (95% CI)	
Net QALYs*	0.009 (-0.016, 0.033) n=238	-0.005 (95% CI -0.025, 0.015) n=409
Adjusted net QALYs**	0.004 (-0.018, 0.026) n=227	-0.004 (95% CI -0.022, 0.014) n=409

*unadjusted for covariates but allowing for intracluster correlation in standard errors **net QALYs calculated using linear regression model adjusted for age, time since stroke, stroke severity, whether or not the carer had any long-term health conditions, cluster size, and years of experience of the coordinator

Costs

There were 47 coordinators trained to deliver the intervention. The duration of training was half a day (225 minutes) per person. The total cost of training was £3067 (i.e. 47*225*£0.29). The cost of training to support one participating dyad was £15 (i.e. £3067/208). The total cost of training coordinators to deliver the intervention has been divided by the number of dyads in randomised clusters to estimate a cost per dyad of £15. However, we know that these same 47 coordinators actually supported far more dyads than this over the duration of the study therefore this 'per dyad' cost is likely to be an overestimation. A sensitivity analysis in which the cost of training is excluded altogether was conducted.

Table S5 shows the number of minutes of coordinator time and the associated cost for each treatment group. The difference in total coordinator costs were £5119, which equates to £25 per dyad.

Table S5. Calculation of intervention cost

	Control (n=206)		**Intervention (n=208)**	
	Number of minutes	Cost	Number of minutes	Cost
Training	n/a	n/a	10575	£3,067
Training cost per dyad	n/a		£15	
Activities	51275	£14,869	58349	£16,921
Activities cost per dyad	£ 72		£ 81	
Total cost	£14,869		£19,988	
Difference in total cost*	£5,119			
Cost per dyad	£ 72		£ 96	
Difference per dyad supported (n=208)	£ 25			

*assumes that the difference in costs is the difference in coordinator activity which is attributable to the intervention therefore approximates the intervention cost

The number of people using the different NHS and social care resources and cost of resources used are summarised in Table S6. The values in the table are a summary of all available data, so for example will include the data from a participant who only has complete data for some categories of resource use but not others. At both time points the proportion of the sample using each service was generally very similar. The one exception was contacts with a practice nurse between 3 and 6 months of follow-up which was reported by a greater proportion of people in the intervention group (43% versus 28%).

Table S6. NHS resources used, by treatment group (available data)

Service	Number (%) using service	
	Control	Intervention
	Study entry to 3 months	
GP at clinic	70/173 (40%)	81/171 (47%)
GP home visit	3/170 (2%)	4/170 (2%)
GP phone call	30/170 (18%)	32/169 (19%)
Practice nurse (clinic or phone)	47/170 (28%)	56/170 (33%)
Urgent care (A&E, minor injuries, walk-in centre, urgent care centre)	20/174 (11%)	23/172 (13%)
Unplanned admission	4/174 (2%)	3/172 (2%)
Physiotherapist	9/165 (5%)	13/169 (8%)
Psychiatrist	1/165 (1%)	0
Counsellor/psychologist	12/165 (7%)	9/169 (5%)
Social worker	8/165 (5%)	10/168 (6%)
Blood test	2/174 (1%)	1/172 (1%)
X-ray, ECG, CT scan	4/174 (2%)	1 (1%)
	3 months to 6 months	
GP at clinic	72/140 (51%)	61/122 (50%)
GP home visit	5/139 (4%)	7/122 (6%)
GP phone call	23/139 (17%)	19/122 (16%)
Practice nurse (clinic or phone)	39/139 (28%)	53/122 (43%)
Urgent care (A&E, minor injuries, walk-in centre, urgent care centre)	13/139 (9%)	15/120 (13%)
Unplanned admission	1/139 (1%)	1/120 (1%)
Physiotherapist	14/141 (10%)	11/118 (9%)
Psychiatrist	2/141 (1%)	1/118 (1%)
Counsellor/psychologist	10/141 (7%)	7/118 (6%)
Social worker	8/141 (6%)	4/118 (3%)
Blood test	1/142 (1%)	1/121 (1%)
X-ray, ECG, CT scan	2/142 (1%)	3/121 (2%)

The mean costs in each group of services is reported in Table S7. The means are all quite small values which reflects that the majority of participants did not use the services and so their individual-level costs are £0. Something to note is the small number of people with total costs at each time point and overall in comparison to the number of people with data for the individual categories. This is because there are a number of participants who have a missing value for just one category which means they are not included in the total. These 'blanks' were be filled in by multiple imputation.

Table S7. Costs (£) of NHS resources used between study entry and 6-month follow-up, by treatment group (available data)

	Mean cost, £ (95% CI)	
	Control	Intervention
	Study entry to 3 months	
Primary care	37 (27, 47) n=142	43 (33, 53) n=148
Community care	13 (4, 22) n=161	22 (6, 37) n=165
Urgent care	13 (2, 24) n=159	3 (0, 8) n=150
Unplanned hospital admissions	72 (2, 142) n=174	54 (0, 116) n=172

Diagnostic tests	1 (0, 3) n=174	0 (0, 1) n=172
Total: study entry to 3 months	102 (17, 187) n=119	57 (33, 80) n=124
	3 months to 6 months	
Primary care	39 (29, 49) n=114	41 (30, 52) n=97
Community care	15 (5, 25) n=135	21 (5, 38) n=114
Urgent care	3 (0, 10) n=127	9 (0, 21) n=107
Unplanned hospital admissions	22 (0, 67) n=139	26 (0, 77) n=120
Diagnostic tests	1 (0, 2) n=142	2 (0, 3) n=121
Total: 3 months to 6 months	49 (33, 64) n=103	109 (22, 196) n=121
Total cost	**119 (25, 214)** **n=78**	**132 (73, 190)** **n=67**

As shown in Table S6, in the period between study entry and the 3-month questionnaire, participants in the control group used more (costly) healthcare than those in the intervention group. The opposite was true for the period between 3 months and 6 months questionnaires. Overall costs were similar but marginally higher in the intervention group.

Table S8 shows the total costs included in the economic evaluation i.e. NHS plus intervention cost. Costs relating directly to the intervention and costs relating to NHS resource use were both higher in the intervention group. This was the case for both the available and imputed data; costs were higher for both groups based on imputed data but the difference between the groups was smaller for the imputed data (£16) than the available data (£37).

Table S8. Breakdown of total cost, by treatment group (available data)

	Mean (95% CI)	
Cost element	Control	Intervention
Intervention: training	0	£15
Intervention: coordinator time supporting dyads	£72	£81
NHS resource use	119 (25, 214)	132 (73, 190)
TOTAL (available data; n=145)	**191 (97, 286)**	**228 (169, 286)**
TOTAL (imputed data; n=409)	**291 (197, 385)**	**307 (213, 402)**

Economic evaluation

The results of the primary and sensitivity analyses are reported in the main body of the paper. The primary analysis is based on multiple imputed datasets; there were higher costs and no health benefits associated with the intervention compared to usual care therefore the intervention is unlikely to be cost-effective. The analysis based on complete cases (those with complete data for costs and QALYs) showed very similar results to the primary analysis; the intervention is unlikely to be cost-effective based on the sub-group of people with complete data. If policy-makers are willing to pay £20,000 to gain one QALY (this is the threshold commonly used by NICE), the probability the intervention is cost-effective compared to usual support is 0.21 when multiple imputation is used and 0.42 based on the complete cases.

The economic evaluation is not sensitive to any of the assumptions explored in the sensitivity analyses i.e. the conclusion remains the same that there is no health benefit but additional cost associated with the intervention therefore it is unlikely to be more cost-effective than usual care.

When the measure of benefit for the economic evaluation was the primary clinical outcome measure (carer strain at 3 months), this echoed the results from the other analyses, there was no improvement associated with the intervention therefore it was still dominated by usual support.

The cost-effectiveness plane for the primary analysis is reported in the main body of the paper (Figure 3). The narrow horizontal spread of the points indicates low uncertainty regarding the health benefit associated with the intervention (i.e. no additional benefit compared to usual care) and the roughly even spread of points either side of the vertical axis indicates that we can be confident that there is no additional benefit associated with the intervention compared to usual support. The broader vertical spread of the points shows that there is more uncertainty around the costs associated with the intervention, although more of the points are above the horizontal axis suggesting that generally the intervention is likely to be more costly than usual care.

Supplementary Discussion

It is unlikely that the intervention is cost-effective compared to usual care. However although the results suggest that the intervention was dominated (i.e. due to QALY loss), because the size of the QALY loss was so small, and not statistically significant, it is more appropriate to consider this as no difference in health.

An important limitation of the economic analysis is the level of missing economic data, only 131 out of 414 (32%) were included in the adjusted complete case analysis. One reason for this is that participants require complete costs (for every category) and utility data from all 3 assessment points to be included in the complete case analysis so there was greater scope for any one data item to be missing. All available data were used to inform the multiple imputation, for example costs were imputed by category rather than total cost, therefore the role of multiple imputation here can be thought of as filling in the blanks. Furthermore, the results from the complete case and multiple imputed data were comparable suggesting that missing data had a limited impact.

References for supplementary material

1 The EuroQoL Group. EQ-5D Products. http://www.euroqol.org/eq-5d-products.html.

2 van Hout B, Janssen MF, Feng Y-S, *et al.* Interim Scoring for the EQ-5D-5L: Mapping the EQ-5D-5L to EQ-5D-3L Value Sets. *Value Heal* 2012; **15**: 708–15.

3 Curtis L, Burns A. PSSRU: Unit Costs of Health and Social Care 2018. 2018.

4 Department of Health and Social Care. National Schedule of Reference Costs 2017-2018. 2018 https://improvement.nhs.uk/resources/reference-costs/.

5 National Institute of Health and Care Excellence (NICE). Guide to the Methods of Technology Appraisal. National Institute for Clinical Excellence, 2013.