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SHORT REPORT

Family support for stroke: one year follow up of a randomised controlled trial

J Mant, S Winner, J Roche, D T Wade*J Neurol Neurosurg Psychiatry* 2005;**76**:1006–1008. doi: 10.1136/jnnp.2004.048991

Background: There is evidence that family support can benefit carers of stroke patients, but not the patients themselves.

Objective: To extend the follow up of a single blind randomised controlled trial of family support for stroke patients and carers to one year to ascertain whether there were any late effects of the intervention.

Methods: The study was a randomised controlled trial. Patients admitted to hospital with acute stroke who had a close carer were assigned to receive family support or normal care. Families were visited at home by a researcher 12 months after the stroke, and a series of questionnaires was administered to patient and carer.

Results: The benefits to carers mostly persisted, though they were no longer statistically significant because some patients were lost to follow up. There was no evidence of any effects on patients.

Conclusion: Family support is effective for carers, but different approaches need to be considered to alleviate the psychosocial problems of stroke patients.

In recognition of the impact that stroke has on carers as well as patients,¹ services such as Stroke Association family support have been developed in the United Kingdom which provide information, emotional support, and liaison with other services. The service maintains contact through a combination of home and hospital visits and telephone calls. In the Oxford family support trial, we found that this service was associated with significantly improved quality of life of carers at follow up six months after the stroke, but had no effects on patients.² Other randomised controlled trials of the service in other areas have also found no evidence of benefit to patients with follow up varying from four to nine months after recruitment.^{3 4} The lack of benefit to patients may be attributable to the short duration of follow up in these trials. The service usually maintains contact with a family for a year, and some patients spend a significant proportion of the first six months in hospital, during which time family support might be anticipated to have less impact. We carried out a second follow up of participants in the Oxford trial to investigate the effects of family support on patients and carers one year after the stroke.

METHODS

The methods and principal results of the Oxford family support study have been reported elsewhere.² In brief, patients admitted to hospital with acute stroke who had a close family carer were randomly allocated to receive normal care (controls) or normal care plus contact with a stroke family support organiser (FSO). The level of contact with each family was at the discretion of the FSO. For the one year

follow up (as at six months), the families were visited at home by a researcher who was blinded to intervention group status. The measures used are shown in table 1. The 12 month follow up was carried out before the results of the six month follow up were known. If carers were not present, questionnaires were left for self completion and return by post.

We had estimated that 300 participants would be needed to detect clinically relevant differences between groups with 80% power. Data were analysed using SPSS for windows (version 10.0). The significance of differences between FSO and control groups was assessed with the Mann–Whitney test. To explore the characteristics of carers who dropped out between six and 12 months, six month outcomes where there had been significant differences between intervention and control—the Frenchay activities index, quality of life using the Dartmouth Coop chart, and five dimensions of the SF-36 (energy, mental health, pain, physical function, and general health perception)—were compared in carers who did and did not participate at 12 months. Ethics approval was granted by the Central Oxford research ethics committee.

RESULTS

Of 520 randomised patients, 388 (75%) were still alive at 12 months. Consent was obtained after randomisation, and 50 families declined involvement,² leaving 338 potential participants at 12 months, of whom 296 (90% of intervention group and 86% of control group) were followed up (fig 1). Seventy four per cent of carers in the intervention group and 69% in the control group were followed up. In three cases (all in the intervention group), the carer had died but in the remainder the carer was not available when the patient was interviewed and did not return the questionnaires left for self completion.

Between six and 12 months, the FSO visited 65 families at home (44%), contacted 120 (81%) by telephone at least once, and liaised with other services for 15 families (10%). She visited only four patients in hospital. Twenty seven families (18%) had no contact with the FSO after six months. The average number of contacts of any sort between six and 12 months was three (as compared with five in the first six months). Patients in the intervention group who were followed up had significantly more contact with the FSO, with a mean total number of contacts of 7.8 (n = 148) over the twelve months, as compared to 5.1 (n = 45) contacts in those not followed up (p<0.001).

Carer outcomes (table 1) were similar to those obtained at six month follow up² in that all but two of the differences were in favour of the intervention, and of the same order of magnitude with two exceptions. For both the Frenchay activities index and the mental health component of the SF-36, the differences observed at 12 months was smaller than those seen at six months. Patient outcomes (table 1) were

Abbreviations: FSO, family support organiser; SF-36, short form 36 item health assessment questionnaire

Table 1 Carer and patient outcomes one year after stroke

Outcome measures	Median (IQR) scores		Difference between scores*	Range of scale (bad-good)	Number of complete responses		
	FS	C			FS	C	p Value
Carers							
Frenchay activities index	32 (28 to 35)	32 (28 to 36)	0.0	0 to 45	103	96	0.97
GHQ-28	17 (10 to 24)	17 (13 to 23)	+0.3	84 to 0	93	90	0.38
Caregiver strain index SF-36	4 (1 to 6)	3 (1 to 6)	-0.3	13 to 0 0 to 100	107	100	0.37
Change in health	50 (25 to 50)	50 (25 to 50)	-3.2		106	101	0.18
Energy and vitality	55 (35 to 70)	55 (35 to 60)	+5.2		103	93	0.05
Mental health	76 (64 to 88)	72 (60 to 84)	+1.7		101	95	0.25
Pain	88.9 (55.6 to 100)	72.2 (55.6 to 100)	+5.7		108	98	0.08
Physical function	90 (70 to 100)	80 (65 to 95)	+4.9		103	94	0.08
Role limitation (emotional)	100 (100 to 100)	100 (66.7 to 100)	+1.9		106	95	0.65
Role limitation (physical)	100 (75 to 100)	100 (50 to 100)	+7.8		106	95	0.23
Social function	100 (88.9 to 100)	100 (77.8 to 100)	+3.2		98	87	0.51
General health perception	82 (61.5 to 87)	72 (54.2 to 87)	+5.3		105	93	0.07
Dartmouth co-op chart							
Physical fitness	3 (2 to 4)	3 (2 to 4)	+0.2	5 to 1	91	83	0.38
Feelings	2 (1 to 3)	2 (1 to 3)	+0.2		90	81	0.19
Daily activities	1 (1 to 2)	1 (1 to 3)	+0.3		91	82	0.06
Social activities	1 (1 to 1)	1 (1 to 2)	+0.2		89	83	0.14
Pain	3 (1 to 4)	3 (1 to 4)	+0.2		89	83	0.36
Change in health	3 (3 to 3)	3 (3 to 3)	+0.2		92	81	0.09
Overall health	3 (2 to 3)	3 (2 to 4)	+0.1		92	83	0.54
Social support	1 (1 to 3)	1 (1 to 3)	+0.2		91	84	0.48
Quality of life	2 (2 to 3)	2 (2 to 3)	+0.2		90	82	0.19
Patients							
Barthel index	17 (13 to 19)	18 (15 to 20)	-1.0	0 to 20	146	148	0.06
Rivermead mobility index	9 (4 to 13.75)	11 (7 to 13)	-1.0		144	146	0.17
Frenchay activities index	13.5 (6 to 28)	15.5 (6 to 25)	+0.2		142	138	0.92
London handicap scale	63.4 (54.6 to 75.3)	63.4 (55.1 to 74.1)	+0.5		135	144	0.98
HADS							
Anxiety	4 (2 to 7)	4 (2 to 7)	-0.3	21 to 0	119	118	0.58
Depression	5 (3 to 7)	5 (3 to 7)	-0.2		115	109	0.51
Dartmouth co-op chart							
Physical fitness	5 (4 to 5)	5 (4 to 5)	0	5 to 1	145	146	0.92
Feelings	2 (1 to 3)	2 (1 to 3)	-0.1		142	145	0.32
Daily activities	3 (2 to 4)	3 (2 to 4)	0		143	146	0.88
Social activities	2.5 (1 to 4)	3 (1 to 4)	+0.1		142	145	0.48
Pain	3 (1 to 4)	3 (1 to 4)	-0.2		145	145	0.36
Change in health	3 (3 to 3)	3 (3 to 3)	0		141	146	0.79
Overall health	3 (3 to 4)	3 (3 to 4)	+0.1		141	146	0.59
Social support	1 (1 to 1)	1 (1 to 2)	+0.1		140	147	0.33
Quality of life	2 (2 to 3)	2 (1 to 3)	0		139	146	0.47

*Difference between mean family support and mean control scores; positive difference in means always favours intervention. C, control; FS, family support; GHQ-28, 28 item version of the general health questionnaire; HADS, hospital anxiety and depression scale; IQR, interquartile range; SF-36, 36 item short form health assessment questionnaire.

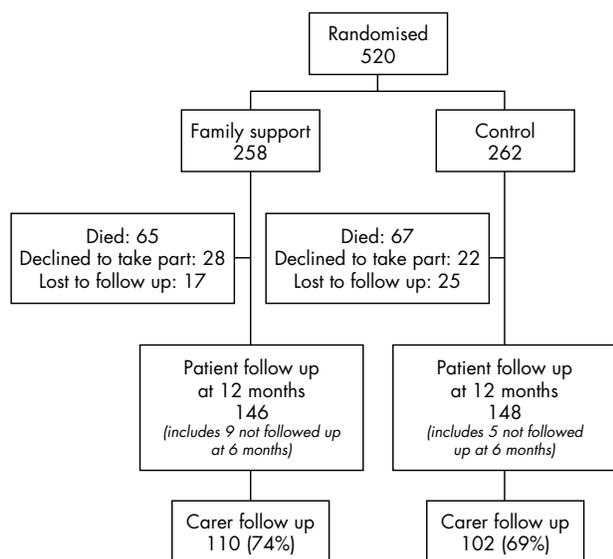


Figure 1 Patient flows through the study.

also similar to those obtained at the six month follow up: some differences favoured the FSO group and some the control group. None of the differences was statistically significant.

For six of the seven measures tested, carers who were followed up at both six and 12 months had better mean outcomes at six months than carers who were only followed up at six months. For one of these measures (SF-36 general health perception), the difference was statistically significant (72.2 v 63.6, p = 0.02).

DISCUSSION

We found no evidence of benefit to stroke patients from a family support service at one year. In contrast to our earlier report,² we also found no significant benefits to carers at one year. Nevertheless, the 12 month carer outcomes were broadly similar to the six month outcomes. Fifty five fewer carers were followed up at 12 months than at six months, so the likeliest explanation for the non-significant results for carers at 12 months is loss of statistical power. This will have been exacerbated by differential loss to follow up of carers with worse outcomes at six months. In contrast, adequate power was maintained to detect any important differences affecting patients at one year. Within the intervention group,

patients with greater contact with the FSO were more likely to be followed up. The impact of this on the results is difficult to predict. On the one hand, families with more contact with the FSO tended to have worse outcomes,² but on the other hand, they will have been more likely to have derived benefit. The negative result of this study is consistent with another trial of a related intervention—specialist nurse support—which followed up stroke patients for one year.⁵ While family support is effective for carers, different approaches such as formal training of carers⁶ need to be considered to address the psychosocial problems of stroke patients.

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