

Evaluation of a Stroke Family Support Organiser A Randomized Controlled Trial

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Background and Purpose—There is inconclusive evidence of the effectiveness of the Stroke Family Support Organiser (FSO) service. We report the results from a randomized controlled trial of the service.

Methods—Stroke patients admitted to hospital and their informal caregivers were randomly allocated to receive the FSO service (n=126) or standard care (n=124). Outcome assessments were undertaken 4 and 9 months after recruitment with the General Health Questionnaire 12, Carer Strain Index, Barthel Index, Extended Activities of Daily Living scale, and a specially designed questionnaire to determine knowledge of stroke and satisfaction with services.

Results—There were no significant differences between groups in patients' mood and independence in personal or instrumental activities of daily living or caregivers' mood, strain, or independence. Patients in the intervention group were significantly more knowledgeable about whom to contact for stroke information, reducing the risk of stroke, practical help, community services, and emotional support. Patients in the intervention group were also significantly more satisfied with the stroke information received. Caregivers in the intervention group were significantly more knowledgeable about whom to contact for information on stroke, reducing the risk of stroke, community services, and emotional support. Caregivers in the intervention group were also significantly more satisfied with stroke information.

Conclusions—The FSO service had no significant effect on mood, independence in activities of daily living, or reduction in caregiver strain, but it did increase knowledge of stroke and satisfaction with that knowledge. The results may not be representative of all FSO services, and the sample was small relative to the heterogeneity of the participants. However, results suggest that the policies and training procedures of FSOs need to be evaluated to ensure that a cost-effective service is being provided to stroke patients and their caregivers. (*Stroke*. 2003;34:116-121.)

Key Words: affect ■ caregivers ■ randomized controlled trial ■ rehabilitation ■ stroke management

Stroke is a major cause of long-term disability, often with devastating consequences for individuals and their families. It has been argued that most care and support come from informal sources such as family members, particularly those living with the patient.¹ The cost of replacing the support provided by informal caregivers is considerable.² A service designed to support informal caregivers and enhance their quality of life is likely to have a direct influence on patients' emotional and physical health.³

Patients at risk from less-than-optimal home care and recovery have been found to have caregivers who were more likely to be depressed and have relatively little knowledge of stroke.⁴ Similarly, patients experience physical limitations and emotional distress that are exacerbated by a lack of information about their condition⁵ and poor knowledge of the services and benefits available.⁶ Stroke support services to address these issues are developing but vary considerably in the United Kingdom⁷ and other countries.⁸

There is mixed evidence on which to base the provision of outpatient stroke support services for patients and caregiv-

ers.⁹⁻¹¹ For example, a combined counseling and education program significantly improved caregiver knowledge and stabilized some aspects of family function better than routine care.¹⁰ However, Friedland and McColl¹¹ found no significant differences between a social support intervention group and a control group on psychosocial measures.

Recent trials of the Stroke Association's Family Support Organiser (FSO) service have also failed to show significant psychosocial benefits for patients from the provision of information, emotional support, and liaison with other services.^{12,13} However, caregiver outcomes showed significant psychosocial benefits and satisfaction with knowledge about stroke and stroke services.¹³

The purchase of these services by health authorities is largely dependent on evidence of the effectiveness of the intervention and local need.¹⁴ Therefore, further evaluations of the FSO service in other geographical settings were needed to support the generalizability of findings across locations. We conducted a single-blind, randomized controlled trial to

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evaluate the benefits of a family support organizer in North Nottinghamshire, UK, on patient and caregiver outcomes of emotional health, independence in personal and instrumental activities of daily living, knowledge of stroke, and satisfaction with stroke services.

Methods

Patients admitted to hospitals in North Nottinghamshire with acute stroke (first or recurrent) were eligible for inclusion. They were identified from medical admission wards, a specialist stroke ward, and rehabilitation wards. The medical notes of patients were checked to confirm the presence of stroke. Other patient details pertinent to the study were also obtained from the notes. Patients were excluded if they were unconscious on admission to hospital, were admitted from a nursing home, lived outside a 30-mile radius of the research center, had a main medical problem not related to stroke, or had a prestroke Barthel Index¹⁵ score of <10. Those who had a planned discharge to a nursing home were also excluded.

No limit was set on elapsed time between stroke and recruitment, although the aim was to reach patients within 4 weeks of the stroke. Patients were included if they had no identifiable caregiver. The closest caregiver was defined as "the person, other than a healthcare professional, perceived by the patient or family as normally being most responsible for day-to-day decision making and care."¹³

Patients were approached by an assistant psychologist, usually in hospital, who explained the nature and purpose of the study. Consenting patients and caregivers were randomized by the FSO by a telephone call to an independent center, which held a computer-generated random sequence. Patients and their respective caregivers were allocated to receive the FSO service (intervention group) or to a standard care control group.

Patients and caregivers allocated to the intervention group were contacted by the FSO within 2 weeks of recruitment. The initial contact by the FSO was undertaken to make introductions; to make patients and caregivers aware of the support being offered; to provide an information pack produced by the Stroke Association, UK; and to identify unmet needs in terms of information required about stroke and other concerns about adapting to disability such as benefit entitlement and emotional support. The FSO made an initial contact with the patient in hospital, attended case conferences, and acted as a liaison with the rehabilitation team regarding discharge from hospital. The FSO also made contact with caregivers to assist them with preparations for patients' discharge from hospital. After discharge, the FSO visited patients and caregivers at home to discuss problems, to offer information and emotional support, and to direct them to appropriate services. The content and frequency of the visits were left to the discretion of the FSO and the specific needs and requests of patients and caregivers, but the service provided was based on that of other FSO services.¹⁶

The intervention was provided for up to 9 months after recruitment. Patients and caregivers were asked to complete and return postal questionnaires at 4 and 9 months after recruitment. If they had difficulty completing questionnaires, an independent assessor who was blinded to the group allocation visited them at their place of residence to assist with completion.

The outcome questionnaire included the General Health Questionnaire 12¹⁷ (GHQ-12) to assess patients' mood. Personal self-care was assessed by the Barthel Index,¹⁵ and instrumental activities of daily living were assessed by the Nottingham Extended Activities of Daily Living scale (EADL).¹⁸ A questionnaire was designed specifically to assess patients' perceived knowledge about whom to contact if they required any assistance in obtaining information on stroke, reducing the risk of a future stroke, benefits, community services, practical help, and emotional support. A Likert scale was used that consisted of responses that ranged from 0 ("I have no idea whom to contact") to 3 ("I know whom to contact and have received such information"). A questionnaire was also designed specifically to assess patients' and caregivers' satisfaction with information on stroke, recovery, benefits, reducing the risk of a future stroke, community services, practical help, emotional support, and overall experience with

hospital and community services. The Likert scale ranged from 0 ("I am very dissatisfied") to 4 ("I am very satisfied"). Test-retest analyses over a month showed these questionnaires to have satisfactory reliability ($r_s=0.84$). Caregivers received a questionnaire comprising the GHQ-12, the same measures of knowledge and satisfaction, and the Caregiver Strain Index.¹⁹ This is a scale designed to assess the psychological impact of providing care.

These measures were repeated at 9 months after recruitment. Caregivers' own independence was also assessed with the EADL at 9 months. Except for the GHQ-12 and Caregiver Strain Index, higher scores indicate better outcome. When patients were unable to answer questions, the EADL and Barthel Index scores were obtained from discussions with their informal caregiver or, when appropriate, with allocated nurses in hospital or residential care homes.

Results

The 250 patients randomized between July 1998 and December 2000 represent 45% of all stroke patients we identified on admission to hospital with suspected stroke ($n=554$). The reasons for nonrandomization were the following: were unconscious on admission to hospital ($n=11$), were admitted from a nursing home ($n=38$), lived outside a 30-mile radius ($n=7$), had another main medical problem ($n=35$), had a prestroke Barthel Index score <10 ($n=1$), and had planned discharge to nursing home ($n=35$). There were additional reasons for nonrandomization: refused consent ($n=45$), died before recruitment ($n=52$), did not have stroke ($n=39$), and other (eg, transferred to other hospital, self-discharge before seen by assistant psychologist; $n=41$). One patient was recruited twice in error. Only outcomes from her initial recruitment were used in the results.

The 2 groups were compared in terms of baseline variables. Results are shown in Table 1. Patients in the intervention and control groups were comparable on all baseline variables except for limb weakness. Significantly more patients in the control group than in the intervention group had upper and lower limb weakness ($P=0.02$ and $P=0.05$, respectively). Comparison of Barthel Index scores, using a Mann Whitney *U* test, showed no significant differences between groups in personal self-care before stroke or at the time of recruitment.

The total number of contacts made by the FSO over the 9-month intervention was 779 (mean for each patient, 6.44; range, 0 to 50; SD, 6.82). Contacts included face-to-face contacts with patients (49%) and others (22%) regarding patient care, contact by telephone to patients (27%) and others on the patients' behalf (2%), and contact through letters on patients' behalf (1%). Initial contacts occurred while patients were in hospital (13% of all contacts), but most contacts occurred after discharge from hospital (87%).

Comparison of Outcomes

Of the 250 patients recruited, 212 completed the outcome assessments at 4 months, and 187 the 9-month assessment. The reasons for failure to complete the outcome assessments are shown in the Figure. The 4-month assessment was completed by 159 caregivers; the 9-month assessment, by 146.

Comparison of the groups using a Mann-Whitney *U* test showed no significant differences in patients' mood or independence in personal or instrumental activities of daily living. Results are shown in Table 2. Patients in the interven-

TABLE 1. Baseline Characteristics of Patients Randomized to Intervention and Control Groups

	Intervention Group	Control Group	Comparison*
Patients	n=126	n=124	<i>P</i>
Gender			0.31
Men	67	63	
Women	59	61	
Marital status			0.15
Married	84	68	
Not married	37	50	
Unknown	5	6	
Hemisphere affected			0.32
Left	57	68	
Right	59	48	
Both	10	8	
Stroke type			0.77
Hemorrhage	15	14	
Infarct	101	97	
Other	10	13	
Limb weakness			0.02†
Upper limb	63	78	
Lower limb	69	84	0.05†
Communication difficulties			0.51
None	54	55	
Dysphasic	48	52	
Unspecified problem	24	17	
Incontinence			0.12
Bladder	24	41	
Bowels	14	14	0.96
Age, mean (SD)	69.0 (11.4)	70.2 (9.6)	0.40
Prestroke Barthel, median (IQR)	20 (19–20)	20 (20–20)	0.35
Current Barthel, median (IQR)	10 (5–16)	10 (6–15)	0.66

*Groups were compared using *t* test for age, Mann-Whitney *U* test for Barthel Index, and χ^2 for categorical data.

†Significant at $P < 0.05$.

tion group were significantly more knowledgeable of the resources available to assist them in adjusting to stroke emotionally and physically than patients in the control group. They reported being significantly more knowledgeable about stroke generally and on the measures they could take to reduce the risk of future strokes. Patients in the intervention group also reported being significantly more satisfied with information on reducing the risk of a future stroke and emotional support, but there was no significant difference in overall satisfaction with services received.

There were no significant differences between groups in caregivers' mood, strain, or independence in activities of daily living. Results of caregiver outcomes are shown in Table 3. In the intervention group, caregivers' knowledge of information and community resources was significantly better than that of caregivers in the control group. Caregivers who received input from the FSO were significantly more

knowledgeable about whom to contact for community services and emotional support. They were also significantly more satisfied with information given to reduce the risk of another stroke for the person in their care, as well as significantly more satisfied with information given on practical help and emotional support.

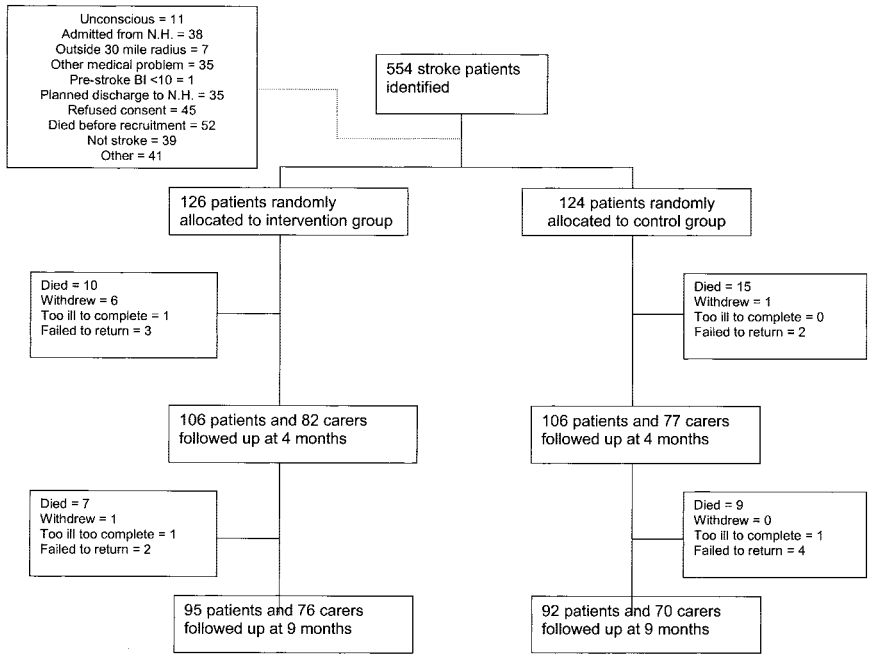
Discussion

The findings from this study are consistent with previous randomized controlled trials of the FSO service.^{11,12} Dennis et al¹² and Mant et al¹³ found no significant effects of the service on patients' mood. We found effects of intervention on patients' knowledge of and satisfaction with hospital and community services. This is also in line with the results of Dennis et al,¹² who found that patient satisfaction was higher after intervention from a stroke family care worker.

We did not detect any psychosocial benefits for caregivers comparable to those reported by Dennis et al¹² and Mant et al.¹³ However, we did find an effect on knowledge and satisfaction of knowledge in caregivers, which was consistent with previous findings,¹² suggesting that our FSO acted primarily as a useful "information provider" and that her presence increased patients' and caregivers' satisfaction with services. However, this raises the issue of whether increasing knowledge and satisfaction are justification for health authorities to purchase the FSO service. In particular, because a stated aim of the service is to provide emotional support, there is little evidence that the service improved mood, although patients and caregivers were more satisfied with their knowledge of how to obtain emotional support.

Patients and caregivers who received more support from the FSO may have benefited from receiving the service, but this effect could have been masked by the results of the whole sample. For example, the mean number of contacts was 6, with a very wide range. Therefore, some people had only 1 contact. No statistical analysis was made of the amount of contact in relation to outcome because neither time nor number of contacts was considered an accurate reflection of the amount of work done. The intervention was provided for only 9 months. For most patients and caregivers, this length of time was sufficient to achieve the aims of the intervention, but a few people may have benefited more if the involvement had been longer. Most of the benefits of the service occurred during the first 4 months and did not change between 4 and 9 months. Therefore, it seems unlikely that a longer follow-up would have detected additional benefits of the service.

The inclusion of patients and caregivers who did not want to receive the FSO service diluted the effects of the intervention. In particular, the contrast between this evaluation and that of Mant et al¹³ suggests that the lack of effect on caregivers in our own study may have been a result of our policy of involving the FSO as a member of the multidisciplinary team. Other members of the multidisciplinary team may have been more aware of those not allocated to the FSO and unintentionally compensated by giving those in the control group increased attention and support. However, it is not possible to check this possibility formally because no records were kept of interventions provided to the control group.



Trial profile. NH indicates nursing home; BI, Barthel Index.

The provision of the FSO service to all those admitted to hospital with stroke is consistent with the policies of the Stroke Association’s FSO service. Most patients and caregivers were provided information early after stroke. However, when the service was originally developed, professionals referred people to the FSO service, and the FSO worked almost exclusively with families after hospital discharge. The

broadening of the service to encompass early intervention in hospital and later intervention at home may have reduced its effectiveness. However, such neutral effects on patients’ and caregivers’ psychological health are not specific to the Stroke Association’s FSO service. It appears from studies done outside the United Kingdom that the enduring psychological effects of stroke are also not adequately addressed in other

TABLE 2. Comparison of Patient Outcomes

Outcome Measures	Intervention (4 mo)			Control (4 mo)			Comparison <i>P</i>	Intervention (9 mo)			Control (9 mo)			Comparison <i>P</i>
	<i>n</i>	Median	IQR	<i>n</i>	Median	IQR		<i>n</i>	Median	IQR	<i>n</i>	Median	IQR	
GHQ-12	105	16	10–12	103	19	12–25	0.11	94	16	11–21	90	16	10–21	0.97
Barthel Index	104	14	10–18	105	16	12–18	0.29	95	15	10–18	92	16	12–18	0.28
EADL	106	17	9–38	106	21	9–37	0.89	94	19	9–35	92	22	12–38	0.32
Knowledge of														
Stroke	105	3	2–3	105	1	0–2	0.001*	95	2	1–3	89	1	1–2	0.001*
Reducing the risk	104	2	1–3	105	1	0–2	0.001*	94	2	1–3	89	1	0–2	0.01*
Benefits	105	2	1–3	105	2	0–3	0.31	94	2	1–3	89	2	1–3	0.20
Practical help	105	2	1–3	104	2	0–3	0.01*	94	3	1–3	89	2	1–3	0.21
Community services	104	3	2–3	104	2	1–3	0.01*	94	3	2–3	89	2	1–3	0.04*
Emotional support	105	2	1–3	105	1	0–2	0.001*	94	2	1–3	89	1	0–2	0.001*
Satisfaction with information on														
Stroke	105	2	2–3	105	2	1–3	0.01*	95	2	2–3	90	2	2–3	0.55
Recovery	105	2	1–3	105	2	1–3	0.07	94	2	1–3	90	2	1–3	0.72
Benefits	105	3	2–4	104	2	2–4	0.67	95	3	2–4	89	3	2–4	0.09
Reducing the risk	105	3	2–4	105	2	2–3	0.001*	95	3	2–4	89	2	2–4	0.07
Community services	102	3	2–4	104	3	2–4	0.13	94	3	3–4	89	3	2–4	0.02*
Practical help	105	3	2–4	105	3	2–4	0.33	95	3	2–4	89	3	2–4	0.74
Emotional support	103	3	2–4	104	3	2–4	0.001*	94	3	2–4	89	2	2–3	0.006*
Overall satisfaction with services received	105	2	2–3	105	2	2–4	0.21	95	2	2–3	90	2	2–3	0.20

*Significant difference favors intervention group.

TABLE 3. Comparison of Carer Outcomes

Outcome Measures	Intervention (4 mo)			Control (4 mo)			Comparison <i>P</i>	Intervention (9 mo)			Control (9 mo)			Comparison <i>P</i>
	n	Median	IQR	n	Median	IQR		n	Median	IQR	n	Median	IQR	
GHQ-12	81	14	10–18	77	14	9–19	0.81	75	13	10–18	70	12	9–18	0.99
Carer Strain Index	81	16	8–24	76	15	9–24	0.92	75	15	8–25	69	15.5	7–21	0.75
EADL	Q	Q	Q	Q	Q	Q	Q	67	59	47–66	64	58	51–64	0.86
Knowledge of														
Stroke	82	2	1–3	77	2	1–3	0.04*	75	3	1–3	70	1	1–2	0.001*
Reducing the risk	82	2	1–3	77	1	0–3	0.02*	76	3	1–3	70	2	1–3	0.007*
Benefits	82	2	1–3	76	2	1–3	0.41	76	2	1–3	70	2	1–3	0.62
Practical help	82	2	1–3	77	2	1–3	0.14	76	2	1–3	70	2	1–3	0.08
Community services	81	3	2–3	77	2	1–3	0.04*	76	2.5	1–3	70	2	1–3	0.06
Emotional support	80	2	1–3	77	1	0–2	0.001*	76	2	1–3	70	1	0–2	0.001*
Satisfaction with information on														
Stroke	82	2	2–3	77	2	2–3	0.62	76	3	2–3	70	3	2–3	0.21
Recovery	80	2	2–3	76	2	1–3	0.11	76	2	2–3	70	2	2–3	0.95
Benefits	81	3	2–4	77	2	2–4	0.11	76	3	2–4	68	3	2–4	0.49
Reducing the risk	82	3	2–4	77	2	2–3	0.001*	76	4	2–4	68	3	2–4	0.06
Community services	81	3	2–4	77	3	2–4	0.11	76	4	3–4	67	3	2–4	0.07
Practical help	82	4	2–4	77	3	2–4	0.03*	74	4	2–4	68	3	2–4	0.03*
Emotional support	81	3	2–4	76	2	2–3	0.001*	75	3	2–4	68	2	2–3	0.001*
Overall satisfaction	82	2	2–3	77	2	1–3	0.06	76	2	2–3	70	2	2–3	0.18

*Significant difference favors intervention group.

Q indicates questionnaire not administered.

stroke support services,¹¹ suggesting that the effectiveness of the FSO service is representative of other relatively short-term, early stroke interventions.

In response to observations in previous UK trials, this research was carried out in a relatively underdeveloped stroke service. In light of our findings, however, we would suggest that it is not the location but rather the timing of when the service is provided and to whom that matter. For example, a stated aim of the service is to make contact as soon as possible after the stroke (the critical period). However, many are still receiving conventional care from the hospital team, so potential problems might have already have been predicted and managed by the hospital team. This seems likely to have occurred because a qualitative study undertaken in addition to this main trial found that patients and caregivers in the control group reported that most of the necessary support was found through professionals in the hospital team who provided poststroke care.²⁰

Future research needs to further define the role of the FSO to avoid duplicating the support offered elsewhere. We also recommend that less time and fewer resources be spent approaching every patient at such an early stage after stroke but that referrals be made to the FSO service when patients and caregivers need the specific help of the FSO. Furthermore, from the qualitative data,²⁰ it would appear that patients and caregivers are reluctant to seek help; thus, even when the most help is needed, very little is actually being provided.

In summary, this trial has suggested the FSO service we provided had little effect on mood, independence, or a reduction in caregiver strain but improved knowledge and

satisfaction with information and services. The results are based on 1 FSO who may not be representative of all. However, her training was based on that of other FSOs. Furthermore, the sample was small relative to the heterogeneity of the population. It is therefore possible that a significant effect has been missed. These results suggest, however, that the policies and training procedures of such services need to be evaluated to ensure that a cost-effective service is being provided to stroke patients and their caregivers.

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