Specialist nurse support for patients with stroke in the community: a randomised controlled trial

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Abstract

Objective—To evaluate whether specialist nurse visits enhance the social integration and perceived health of patients with stroke or alleviate stress in carers in longer term stroke care.

Design—Stratified randomised controlled trial; both groups assessed at time of recruitment and at 3, 6, and 12 months.

Setting—Patients with disability related to new stroke who lived in their own homes in the Bradford Metropolitan District.

Subjects—240 patients aged 60 years or over, randomly allocated to control group (n = 120) or intervention group (n = 120).

Intervention—Visits by specialist outreach nurses over 12 months to provide information, advice, and support; minimum of six visits during the first six months. The control group received no visits.

Main outcome measures—The Barthel index (functional ability), the Frenchay activities index (social activity), the Nottingham health profile (perceived health status). Stress among carers was indicated by the general health questionnaire-28 (28 items). The nurses recorded their interventions in trial diaries.

Results—There were no significant differences in perceived health, social activities, or stress among carers between the treatment and control groups at any of the assessments points. A subgroup of mildly disabled patients with stroke (Barthel index 15-19) had an improved social outcome at six months (Frenchay activities index, median difference 3 (95% confidence interval 0 to 6; P = 0.03)) and for the full 12 months of follow up (analysis of covariance P = 0.01) compared with the control group.

Conclusions—The specialist nurse intervention resulted in a small improvement in social activities only for the mildly disabled patients. No proved strategy yet exists that can be recommended to address the psychosocial difficulties of patients with stroke and their families.

Introduction

The *Health of the Nation* prompted health authorities to examine service provision for patients with stroke and their families.¹ Planning for the acute treatment of such patients has been aided by an overview analysis showing the effectiveness of care given by stroke units.² Any strategy for treatment, however, must consider a longer term perspective, as several studies have highlighted the poor emotional and social consequences of stroke for patients and their families that may persist for several years after the onset of stroke.^{3, 4}

The practical difficulties for patients with stroke include lack of information about their condition,⁵ poor knowledge of the services and benefits available,^{6, 7} and fragmented community services.⁸ A survey of patients six months after onset of stroke found that two thirds had some residual disability but less than half were receiving help of any kind.⁹ Social activities may be restricted despite apparently good physical recovery.^{7, 10}

To address these problems we devised an intervention that was based on regular visits by specialist outreach nurses to provide advice, information, and support to patients with stroke and their families. We aimed to help the patients to adjust to the new way of life associated with their stroke—to move from the postulated “treatment” stage towards a final stage of “adjustment.”^{11, 12}

We chose specialist nurse visits deliberately as a move away from an emphasis on the medical or therapy model of stroke care towards a counselling and enabling model, which may better address psychosocial factors.¹³ The two hypotheses that we tested were, firstly, that the intervention of the specialist nurses would result in improvement in perceived health and social integration for the patients with stroke, and, secondly, that the main carers would make better emotional adjustment. We evaluated the intervention using a randomised controlled trial with both quantitative and qualitative methodologies and present the quantitative results here.

Method

ENTRY CRITERIA

Patients were eligible if they were aged 60 years or over with a principal diagnosis of acute stroke, had a disability related to stroke, and gave informed consent. We excluded patients if they had multi-infarct dementia, had a concurrent medical condition associated with a poor prognosis, or lived in residential care.

RECRUITMENT

We identified potential trial subjects by several overlapping methods: visits twice a week to relevant hospital wards, monthly inspection of the register of the speech therapy department, and regular liaison with community physiotherapists. We gave a supply of “notification cards” to the district nurses, to be completed and returned when a patient with a new stroke was referred. The information department of Bradford Community Health Trust provided a monthly register of all new patients seen by the district nurses. Patients were screened by AF for eligibility to the trial either before discharge from hospital or within six weeks of the acute stroke if not admitted to hospital.

Once recruited, the patients were stratified by whether they had been admitted to hospital or stayed at home, by level of social activities before their stroke (Frenchay activities index,¹⁴ categories 0-10, 11-30, 31-45), and by functional ability (the Barthel index,¹⁵ categories 0-9, 10-14, 15-19, 20). This stratification was to optimise the baseline matching between groups and to allow separate subgroup analysis to identify groups of patients or carers who might particularly benefit. An assistant in our department who was otherwise unconnected with the study randomised the patients by four length random permuted blocks¹⁶ to the control group or the intervention group (the patients receiving visits by the specialist nurses). The patients in both groups received the usual treatment and services arranged for them by hospital or community staff, but only the patients randomised to the intervention group received the additional intervention.

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Timing and nature of minimum specialist nurse visits required

Visit 1 (within one week of recruitment)

Introduction

Identification of the other community staff involved in patient's care

Identification of immediate problems

Provision of information booklets

Visit 2 (one week later)

Follow up of early problems

Review of patient's need for aids—for example, adapted toilet seats, high seat chairs

Advice on benefits

Review of patient's or carer's previous week's experience

Visit 3 (one month later)

Goal setting with emphasis on maximising social activities and relief for carer

Visit 4 (two months later)

Information, advice, and active support to improve patient's socialisation and relief for carer

Visit 5 (three months later)

As for visit 4

Visit 6 (six months later)

Information and advice about holidays

Advice about driving (as needed)

Visit 7 (12 months later)

Review of progress

SPECIALIST NURSES AND INTERVENTION

The specialist nurses were five G grade nurses with a role in our department as outreach staff assessing patients in the community. They were experienced in assessing disability in elderly people and in problem solving approaches using community based services.

Before the trial the nurses attended a two day training programme designed to enhance their counselling and listening skills. We held focus groups with local patients with stroke and carers to identify the information and advice that they would have appreciated in the first year after stroke. Using this knowledge, we devised an outline programme of minimum mandatory visits for the specialist nurses that included goal setting, problem solving, and advice on specific issues (box). We compiled information packs containing detailed lists of locally available services, booklets published by the Stroke Association, and information on benefits. The specialist nurses could give these packs to patients and their families and discuss the contents. The nurses kept a detailed account of all visits and telephone calls, time spent, and action taken in diaries specially produced for the trial.

ASSESSMENTS

We used the Barthel index and the functional ambulatory categories¹⁷ to assess functional ability, the Frenchay activities index to assess social activities, the Nottingham health profile (excluding the physical mobility section)¹⁸ to assess perceived health, and the general health questionnaire-28 (28 items)¹⁹ to assess stress on the resident main carer. A single researcher (AF) did the assessments at the time of recruitment (the assessments included a Frenchay activities index for abilities before stroke, an abbreviated mental test,²⁰ and the Frenchay aphasia screening test²¹) and three, six, and 12 months later. She assessed inpatients before discharge; all other assessments were carried out in the patients' homes.

SAMPLE SIZE

The main trial outcome was social activities determined by the Frenchay activities index. A similar

cohort of patients in a previous study had a mean Frenchay activities index of 22 before stroke and of 9 (that is, 40% of activity possible before stroke) six months after stroke.²² An empirical decision was taken to improve this score by four points and aim for a return to 60% of the activity that was possible before stroke over 12 months. An improvement of four points would, for example, describe a patient who previously rarely went out in three months but who now went out at least weekly and did some housework. A sample size of 160 to 220 at 90% power and 0.05 and 0.01 significance respectively was calculated.²³

ANALYSIS

Analysis was performed with the social sciences statistics package SPSS and Minitab. An "intention to treat" analysis was performed by including all available data for each patient. Differences within the groups were examined by Wilcoxon's signed rank test and those between the groups by the Mann-Whitney U test and χ^2 test. The between group differences were also examined with repeated measures analysis of covariance.²⁴ The dependent variables were the main outcome measurements: the Frenchay activities index for the patients and general health questionnaire for carers. These dependent variables had a skewed distribution, but square root transformation produced an acceptable normal distribution. The significant covariates were first determined by a multiple regression analysis. This procedure identified the Frenchay activities index before stroke and the Barthel index at each assessment point as significant covariates for the activity index outcome and the Nottingham health profile and sex for the general health questionnaire outcome.

Results

In all, 694 patients aged 60 years or over with a new stroke were screened for trial eligibility between January 1992 and September 1993. Of these, 194 patients had no residual disability, 125 were discharged to a residential or nursing home, 48 had been in residential care before their stroke, 31 had a diagnosis of multi-infarct dementia, 22 already lived or had moved out of the area, 16 had severe concurrent illnesses, and 18 refused consent. The remaining 240 patients were recruited to the trial, with 120 patients randomised to each group.

Table 1—Clinical features of patients in intervention group and control group. Values are numbers (percentages) of patients unless stated otherwise

	Specialist nurse group (n = 120)	Control group (n = 120)
Men	66 (55)	61 (51)
Women	54 (45)	59 (49)
Type of stroke:		
Right hemiplegia	61 (51)	68 (57)
Left hemiplegia	52 (43)	48 (40)
Other	7 (6)	4 (3)
Previous stroke	18 (15)	15 (13)
Lives alone	42 (35)	42 (35)
Median (range) age (years)	73 (60-94)	73 (60-90)
Abbreviated mental test score $\leq 7^*$	20 (22)	20 (20)
Median Barthel index at recruitment (range)	17 (1-20)	16 (1-20)
Frenchay aphasia screening test failed	19 (16)	17 (14)
Median (range) Frenchay activities index before stroke	27 (0-41)	26 (0-37)
No or little English spoken	3 (3)	5 (4)

*27 Patients in the specialist nurse group and 22 patients in the control group had comprehension difficulties because of stroke and could not complete the mental test.

PATIENTS

The two groups of patients were well matched (table 1). In the year after recruitment 32 patients died (17 in the intervention group, 15 in the control group), seven patients in each group moved into residential care, two patients in the intervention group moved out of the area, and one patient in the intervention group refused follow up assessments. All survivors except the patient who refused follow ups were reassessed.

SOCIAL ACTIVITIES

Patients in both groups showed significant improvement in Frenchay activities index between the three and

Table 2—Median (interquartile range) Frenchay activities indices for patients in intervention group and control group at the four assessment points

	Before stroke	3 Months	6 Months	12 Months
Specialist nurse group:				
No of patients	120	111	109	102
Index	27 (20-31)	8 (3-13)	13 (5-20)	12 (6-19)
Control group:				
No of patients	120	116	115	105
Index	26 (20-31)	6 (3-12)	10 (4-17)	10 (5-20)

Table 3—Median (interquartile range) Frenchay activities indices for patients in intervention group and control group from Barthel index stratification cell of 15 to 19

	Before stroke	3 Months	6 Months	12 Months
Specialist nurse group:				
No of patients	71	68	67	65
Index	28 (23-31)	9 (6-15)	15 (9-21)	15 (9-21)
Control group:				
No of patients	69	67	66	62
Index	27 (21-31)	8 (3-12)	10 (6-18)	13 (6-21)
Median of difference (95% confidence interval)		2 (0 to 4)†	3 (0 to 6)‡	2 (-1 to 5)§

*Analysis of covariance adjusted difference 0.59 (95% confidence interval 0.14 to 1.05); P = 0.01.

†P = 0.04, Mann-Whitney U test. ‡P = 0.03, Mann-Whitney U test. §P = 0.21, Mann-Whitney U test.

Table 4—Median (interquartile range) for Barthel indices and Nottingham health profile scores for patients in intervention group and control group at four assessment points and for general health questionnaire completed by resident main carers of patients

	Recruitment	3 Months	6 Months	12 Months
Barthel index				
Specialist nurse group:				
No of patients	120	111	110	102
Index	17 (12-19)	17 (14-19)	18 (13-20)	18 (14-19)
Control group:				
No of patients	120	116	115	105
Index	16 (12-18)	17 (14-19)	17 (13-19)	17 (13-19)
Nottingham health profile				
Specialist nurse group:				
No of patients	95*	95	95	88
Score	93 (38-152)	96 (24-171)	96 (25-169)	97 (24-184)
Control group:				
No of patients	95*	98	95	89
Score	70 (24-181)	78 (24-196)	84 (29-175)	80 (26-172)
General health questionnaire				
Specialist nurse group:				
No of carers	71†	67	62	56
Score	4 (1-8)	3 (1-7)	1 (0-7)	2 (0-6)
Control group:				
No of carers	68‡	66	62	55
Score	4 (1-10)	3 (0-8)	2 (0-8)	2 (0-7)

*25 Patients had comprehension difficulties because of stroke and therefore could not complete the profile.

†7 Carers could not read English and therefore could not complete the questionnaire.

‡10 Carers could not read English and therefore could not complete the questionnaire.

12 month assessments (table 2), but no significant difference was found between the two groups at three, six, or 12 months.

A further analysis showed that the treated patients undertaking the most social activities were the mildly disabled patients (randomisation Barthel index stratification cell of 15-19) who had a significantly higher activity index at three months (intervention group, median score = 9; control group, median score = 8; median of the difference 2 (95% confidence interval 0 to 4); P = 0.04) and at six months (15; 10; 3 (0 to 6); P = 0.03) (table 3) and a significant treatment effect with multiple analysis of covariance over the full 12 months of the study (adjusted difference 0.59 (0.14 to 1.05), P = 0.01).

PERCEIVED WELLBEING

No significant difference either within or between the groups was found for the Nottingham health profile (table 4). The percentage of patients in both groups who scored 30 or more (indicating depressed mood²⁵) remained similar over the 12 months (at recruitment, intervention group 26% (25/95), control group 29% (28/95); at 12 months, 33% (29/88) and 30% (27/89) respectively).

PHYSICAL ABILITIES

Patients in both the intervention and the control group showed an improved Barthel index from recruitment to reassessment 12 months later (Wilcoxon's signed rank test, P<0.05), but no differences between groups were found (table 4). Analysis of the scores for the functional ambulatory categories showed no differences, with 45% (46/102 intervention group, 48/105 control group) of patients in both groups able to walk independently at 12 months.

STRESS IN CARERS

The total and subsection scores for the general health questionnaire provided by the resident carers showed no significant difference between the two groups at 12 months or in analysis of covariance (table 4). The proportion of carers with stress (score ≥ 5 ¹⁹) decreased in both groups from about a half at the time of recruitment to about a third at 12 months (intervention group 33/71 v 18/56; control group 31/68 v 18/55).

SPECIALIST NURSE VISITS

Inspection of the trial diaries kept by the specialist nurses showed that the nurses had adhered to the framework programme (box). Most patients received more visits than the mandatory minimum. In the first six months of the trial the 120 patients received an average of eight visits each, with two patients receiving a maximum 19 visits. Visits were reduced in the second six months, with the 101 patients available being visited an average of four times (maximum 10). In addition to visiting the patients and carers at home, the specialist nurses maintained telephone contact with the families and other community staff, and they undertook specific tasks such as introducing the patient and carers to stroke clubs (21 patients) and day centres (37), facilitating home care provision (56), and completing attendance allowance forms (62). Five patients were helped to move to more suitable accommodation, and one severely disabled man was given extensive help to fulfil his ambition to visit his family in India.

Discussion

Physical recovery has become a dominant short term outcome measure after stroke on which the timing of hospital discharge and provision of community services is based. Yet patients with stroke and their carers would like a more comprehensive rehabilitation package to

help them come to terms with the changes in their life. When interviewed three years after stroke, patients and their carers expressed a need for better post-discharge support and counselling and more information rather than more rehabilitation.⁷ Our study was designed to address these issues.

The results are disappointing in that they did not show improvement in social activities for the patients or improvement in carers' wellbeing for the group of patients who received visits from the specialist nurses. A small treatment effect was observed in a subgroup of mildly disabled patients with stroke (randomisation Barthel index 15-19). This observation needs clarification in future studies; the patients with a Barthel index of <15 might have been too disabled to participate in a programme to increase social activities.

PREVIOUS STUDIES

It is difficult to design an intervention appropriate to a heterogeneous condition such as stroke that can effectively address complex psychosocial problems. The Leeds family placement scheme was designed to support patients through the potentially difficult time of hospital discharge.²⁶ Suitable patients spent time in the care of volunteer families who facilitated eventual resettlement in their own home. In a small non-randomised study the scheme had an impact on physical improvement but no effect on social activities. A preliminary study of "leisure therapy" carried out by an occupational therapist has been encouraging.²⁷ A randomised trial in Canada showed no benefit from a special programme of social support in which the focus was on improving the social network of the patient rather than directly enhancing social activities.²⁸ The Stroke Association has developed a family support service—a visiting service that offers information, literature, and emotional support for patients with stroke and their families. Although this is a popular and established service, it has not yet been evaluated by a clinical trial. No previous randomised controlled trial similar to ours has therefore been run.

DESIGN OF TRIAL

This was a pragmatic randomised trial²⁹ with a heterogeneous population including patients with aphasia, cognitive impairment, and diverse ethnic backgrounds. The study needed widespread local support, and therefore knowledge of the trial's objectives may have raised other community staff's awareness of psychosocial problems related to stroke. Moreover, intermittent professional contact with the specialist nurses will have further emphasised this effect. Inevitably there will have been contact between the two groups of patients with stroke at day centres, stroke clubs, or local community gatherings. All these potential confounding factors would have been in the direction of reducing the measured effectiveness of the trial. Lastly, during the 12 months, other significant life events—such as new physical illness or bereavement—took place and are likely to have influenced the psychological state and social functioning of the patients; we found no evidence, however, that such adverse events were more frequent in one or other group.

SAMPLE SIZE

The main outcome of the trial was to improve the social activities of the patients, as quantified by the Frenchay activities index. We calculated that 160 to 220 patients would be needed to show a clinically meaningful four point increase in the index. A calculation after the trial based on the actual indices obtained showed that 230 to 310 patients would have been needed to show this predetermined effect with a trial power of 90% and significance levels of 0.05 and 0.01

Key messages

- Many patients with stroke make good early physical recovery, but later psychosocial recovery and adjustment to stroke related disability has been disappointing
- This randomised controlled trial using specialist nurses in an intervention strategy found that no significant differences were seen at one year follow up between the two groups of patients in wellbeing or social activities and no reduction in stress among carers
- A significant but small increase in social activities was reported by a subgroup of mildly disabled patients with stroke
- No proved strategy yet exists to address the psychosocial difficulties of patients with stroke and their families

respectively. This shortfall in sample size has been a common problem with single centre, pragmatic stroke trials, which has been overcome by using combined centre analyses³⁰ but which emphasises the need for multicentre studies.

TRIAL INTERVENTION

The intervention addressed issues identified in the literature on stroke and arising from our focus groups before we started the trial. We used an approach similar to one successfully adopted for patients with major depressive illness.³¹ The intervention was provided by five nurses, which enhances external validity of the study by testing the concept of the intervention rather than the expertise of a single worker. The intervention was readily accepted by the patients and carers: all the allocated patients accepted the specialist nurses' visits. Any specific intervention, however, needs general support, and despite the specialist nurses' best efforts some problems remained intractable, particularly the provision of home adaptations—some patients were still waiting for housing alterations at the end of the study. Also, the greatest intensity of nurse visits took place in the first six months of the trial. The pattern of frequent visiting may not have been sustained for long enough to address some of the deep rooted problems imposed by stroke.³² There are special difficulties with "community working" in creating effective teamwork, and the specialist nurses may not have been sufficiently integrated into the community infrastructure—for example, an appreciable number of depressed patients and carers were not given antidepressants.

CONCLUSION

Specialist nurse visits that were aimed at improving the psychosocial outcome for patients with stroke and their carers and that were evaluated in a randomised controlled trial by using relevant quantitative assessments did not result in a better outcome for the intervention group. At best, the specialist nurses' visits had a small effect in improving social activities in the subgroup of more mildly disabled patients with stroke.

The extent to which the service was valued by the patients and carers and its influence on the perception of recovery from stroke are not addressed by the quantitative outcome measurements. The parallel qualitative inquiry should inform these other important patient centred outcomes.

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Hormone replacement therapy and tumour grade in breast cancer: prospective study in screening unit

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Several studies report an increased incidence of breast cancer in women taking hormone replacement therapy (apparently a duration dependent phenomenon)¹⁻³; however, a decreased mortality from breast cancer has been reported in women using the treatment.¹ We assessed the prognostic factors for breast cancers detected by screening at one unit to determine if cancers developing in women who used hormone replacement therapy have a better prognosis.

Patients, methods, and results

All postmenopausal women (>12 months since last menstrual period or women over 50 who had had a hysterectomy) with invasive breast cancer detected at our screening unit between 1989 and 1994 were identified. Prognostic factors and history of use of hormone replacement therapy were recorded. Women taking hormone replacement therapy for more than three months within the year before their breast cancer diagnosis were considered "users." After definitive surgery, pathological tumour size, grade, axillary node metastases, and steroid receptor status were compared between users of hormone replacement therapy and non-users.

Of the 433 postmenopausal women with screen detected cancer, fewer women diagnosed in the prevalence round than in the incident (second) screen were using hormone replacement therapy (74/325 (23%) v 34/108 (32%); $\chi^2 = 3.3$; $P > 0.05$). Median duration of use was 24 (range 3-264) months.

Well differentiated grade I cancers occurred more often in users of hormone replacement therapy than non-users (45% v 20%; $P < 0.001$; table 1); 15% (16) of users compared with 45% (146) of non-users had grade

Table 1—Tumour grade of breast cancers in users and non-users of hormone replacement therapy

Hormone replacement therapy	Grade I tumour	Grade II tumour	Grade III tumour
Users (n=108)	49 (45)	48 (44)	11 (10)
Non-users (n=325)	65 (20)	208 (64)	52 (16)

I, well differentiated tumours ($P < 0.001$). The likelihood of cancers detected in the users being well differentiated increased from the prevalence screen (relative risk 2.19; 95% confidence interval 1.54 to 3.12) to the incident screen (2.49; 1.38 to 4.49). Tumour size and steroid receptor status (analysed by immunocytochemical assay) were similar in the groups. The excess of grade I tumours was seen equally in the 72 women using oestrogen only and the 36 using a combined preparation.

In women undergoing axillary surgery, node positivity occurred in 23 (26%) of users and 68 (28%) of non-users (difference -2.6%; -14% to 8.5%). In the total group, positivity was 21% in users and non-users (69/325 v 23/108).

A total of 28 women developed recurrent cancer after a median follow up of 45 (range 12-96) months. Recurrence was similar in users and non-users (8 (7%) v 20 (6%); $P = 0.99$, log rank test).

Comment

Although an increased breast cancer risk (up to two-fold) has been linked with long term use of hormone replacement therapy, a large British cohort study has

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