RCT stroke

Evaluation of a stroke family care worker: results of a randomised controlled trial

Martin Dennis, Suzanne O'Rourke, Jim Slattery, Trish Staniforth, Charles Warlow

Abstract

Objective: To examine the effect of contact with a stroke family care worker on the physical, social, and psychological status of stroke patients and their carers.
Design: Randomised controlled trial with broad entry criteria and blinded outcome assessment six months after randomisation.
Setting: A well organised stroke service in an Edinburgh teaching hospital
Subjects: 417 patients with an acute stroke in the previous 30 days randomly allocated to be contacted by a stroke family care worker (210) or to receive standard care (207). The patients represented 67% of all stroke patients assessed at the hospital during the study period.
Main outcome measures: Patient completed Barthel index, Frenchay activities index, general health questionnaire, hospital anxiety and depression scale, social adjustment scale, mental adjustment to stroke scale, and patient satisfaction questionnaire; carer completed Frenchay activities index, general health questionnaire, hospital anxiety and depression scale, social adjustment scale, caregiving hassles scale, and carer satisfaction questionnaire.
Results: The groups were balanced for all important baseline variables. There were no significant differences in physical outcomes in patients or carers, though patients in the treatment group were possibly more helpless, less well adjusted socially, and more depressed, whereas carers in the treatment group were possibly less hassled and anxious. However, both patients and carers in the group contacted by the stroke family care worker expressed significantly greater satisfaction with certain aspects of their care, in particular those related to communication and support.
Conclusions: The introduction of a stroke family care worker improved patients' and their carers' satisfaction with services and may have had some effect on psychological and social outcomes but did not improve measures of patients' physical wellbeing.

Introduction

Stroke has long been recognised as common, frequently fatal, and disabling. In recent years there has been increasing awareness of the psychosocial problems experienced by stroke patients and their carers.[1-3] Though the traditional medical model of care, including hospital based rehabilitation in stroke units, may reduce case fatality and institutionalisation,[4] it often fails to identify or adequately address these psychosocial problems. In 1992 we established a "stroke family care worker." As we were uncertain of the effectiveness of this post and which patients and carers might gain most we evaluated the service in a randomised controlled trial.

Patients and methods

All patients who attended our hospital as an inpatient or outpatient with a diagnosis of recent possible stroke (first and recurrent) were seen and assessed by a stroke physician. Details of patients in whom the diagnosis was confirmed according to World Health Organisation criteria[5] were entered into our stroke register. Patients with subarachnoid haemorrhage were excluded. Baseline data were collected before randomisation and as part of the routine registration of patients in our register.

Because we were uncertain about which patients and carers might gain most from intervention by a stroke family care worker we set broad eligibility criteria. Any patient with a confirmed stroke within the past 30 days could be randomised unless (*a*) they were very likely to die within a few days, (*b*) they lived more than 25 miles (40 km) from the hospital, or (*c*) the stroke occurred on a background of another major illness which was likely to dominate the pattern of care—for example, advanced cancer or renal failure.

Randomisation

Randomisation was balanced in blocks of six within strata defined by age, sex, living alone before the stroke, and stroke severity. Those responsible for randomising patients were unaware of the block size. Stroke severity depended on the prediction by the stroke physician at the time of assessment. Patients with severe strokes were defined as those expected to score >2 on the Oxford handicap scale one year after the stroke. A table with random patient allocation was stored on a personal computer so that nobody concerned in randomising patients could discover to which intervention the next patient would be allocated.

See editorial by Smith and pp 1077, 1107, 1111, 1134

Department of Clinical Neurosciences, University of Edinburgh, Western General Hospital, Edinburgh EH4 2XU
Martin Dennis, *Senior lecturer in stroke medicine*
Suzanne O'Rourke, *Research assistant*
Jim Slattery, *Senior statistician*
Trish Staniforth, *Stroke family care worker*
Charles Warlow, *Professor of medical neurology*
Correspondence to: Dr Dennis.

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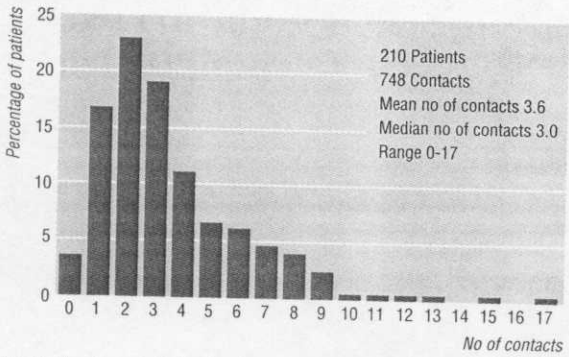

Fig 1 Number of stroke family care worker contacts per patient (or family) in first six months after randomisation. Data include face to face and telephone contacts

Setting and consent

The intervention was tested in the setting of a large teaching hospital with a well organised stroke service. Patients were not required to consent to randomisation but consented to follow up. This approach was approved by our local ethics committee.

Intervention

The stroke family care worker (TS) came from a social work background and had considerable experience in working with voluntary agencies for disabled people. Patients or carers, or both, who were randomised to active intervention were contacted by the stroke family care worker within a week of randomisation. She tried to identify unmet needs and aimed at fulfilling these using any available resources. She would access health services, social services, and voluntary agencies as well as offering some counselling herself. Figure 1 shows the considerable variation in number of contacts she had with patients in the first six months after randomisation. We did not prescribe how many contacts she would have with families; this was left for her to decide and depended on her assessment of their needs. Patients randomised to the control group had no contact with the stroke family care worker for six months, until after our final follow up assessment had been completed.

Follow up

We aimed at following up all patients six months after randomisation. A research psychologist (SO'R), who was blind to the treatment allocation, asked the patients to identify a carer and arrange for him or her to be present at the follow up visit. We followed up only informal carers—that is, spouse or family members—and not, for example, nursing home staff or home helps. Patients and carers were told that we wished to know how they had fared. No reference was made to any assessment of the stroke family care worker.

Follow up comprised several questionnaires aimed at measuring outcome in various domains. The psychologist helped patients complete the Barthel index,[6] Oxford handicap scale,[7] Frenchay activities index,[8] general health questionnaire (30 item),[9] and social adjustment scale[10] during the follow up visit. Meanwhile any carer was asked to complete independently the Frenchay activities index, general health questionnaire, social adjustment scale (on the carer's behalf rather than the patient's), and caregiving hassles scale.[11] Patient and carer were then each left a further questionnaire to return to the psychologist by post. The patient's questionnaire comprised several measures, including the hospital anxiety and depression scale,[12] the mental adjustment to stroke scale,[13] and a patient satisfaction scale.[14] The carer's questionnaire comprised the hospital anxiety and depression scale and a carer satisfaction questionnaire. We modified the mental adjustment to cancer scale[13] for use in stroke patients simply by substituting the word stroke for cancer. In addition, we added further questions to a standard questionnaire to determine the patients' satisfaction[14] with aspects of their care which we thought might be influenced by input from the stroke family care worker. We adjusted the wording of this questionnaire slightly for use with carers (see fig 4).

When patients had cognitive or communication problems which prevented them completing the follow up questionnaires their cognitive status was assessed with the Hodkinson abbreviated mental test[15] and as much information as possible gathered from carers. At the end of the follow up visit the research psychologist guessed which treatment group the patient was in to test the efficacy of our efforts to blind her to the treatment allocation.

Analyses

Results were analysed on an intention to treat basis—that is, the patient or carer was assessed depending on the intervention to which each was randomised even if he or she had no direct contact with the stroke family care worker. Dichotomous variables at baseline and follow up were compared by means of risk ratios with 95% confidence intervals and the χ^2 test. Continuous variables were compared by Student's t test. When comparing outcomes measured on ordinal scales we calculated 95% confidence intervals for the difference between medians.

Results

Between 1 October 1992 and 30 September 1994 we randomised 417 patients, 210 to receive intervention by the stroke family care worker and 207 to receive standard care (controls). The patients represented 67% of all stroke patients assessed at the hospital. The main reason for non-randomisation was that patients lived more than 25 miles (40 km) away. There were few statistically significant differences between randomised and non-randomised patients with respect to baseline variables. Randomised patients were slightly older (mean age 67.8 years *v* 64.6 years; P=0.006) and more likely to be living alone (relative risk 1.54; 95% confidence interval 1.14 to 2.08).

There were no substantial or significant differences between patients randomised to the two intervention groups in terms of lesion location, stroke severity, and pre-stroke function as well as those variables shown in figure 2. The mean age of the treatment group was 67.1 years and that of the controls 68.4 years (P=0.33).

Outcomes

All randomised patients were accounted for at the end of the study. Nineteen (9.0%) patients randomised to the stroke family care worker and 22 (10.6%) controls died before follow up (risk ratio 0.85; 95% confidence interval 0.48 to 1.53). In four survivors in the treatment

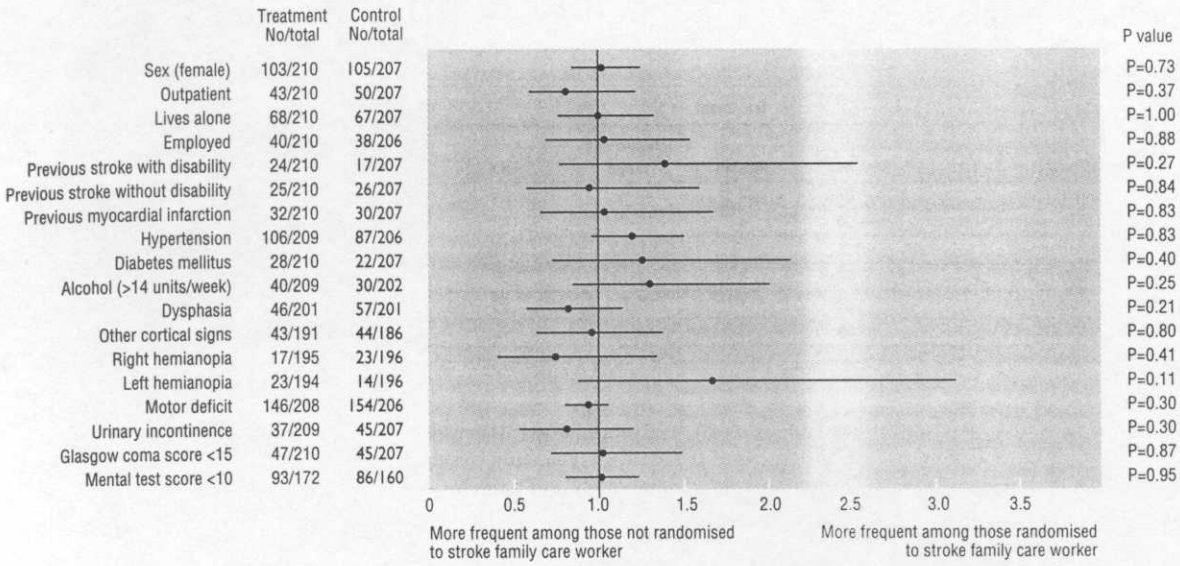

Fig 2 Comparison of baseline characteristics (for dichotomised variables) in patients randomised to treatment and control groups. Points are point estimates of relative risk of characteristic occurring in treatment group compared with control group. Bars are 95% confidence intervals. Denominators vary because some variables were not assessable in a few patientsfor example, hemianopia in unconscious patients

group no further follow up was possible. One patient had emigrated, another had a brain tumour and was too ill to be followed up, and two patients refused.

Of the patients successfully followed up (187 in the treatment group, 185 controls), 29 (15.5%) in the treatment group and 31 (16.8%) controls had cognitive or communication problems which prevented them completing any questionnaire apart from the Barthel index, Oxford handicap scale, and Hodkinson abbreviated mental test score. Of the 158 patients in the treatment group given the second questionnaire, 145 (91.8%) returned them; and of the 154 patients in the control group given the second questionnaire, 147 (95.5%) returned them. On most measures controls tended to have better outcomes, though the difference was significant only for social adjustment and was of borderline significance with respect to helplessness and depression (table 1). Despite this, however, patients in the treatment group were more satisfied with certain aspects of their post-hospital care (fig 3).

We identified 246 carers. Of these, 119 (48.4%) were carers of patients randomised to the stroke family care worker. Six carers in the treatment group and seven in the control group refused follow up and two carers in the control group were not assessable. The remaining 231 (93.9%) carers completed the first questionnaire and 102 (90.3%) in the treatment group and 110 (93.2%) in the control group returned the second questionnaire. Carers of patients in the treatment group tended to have better outcomes than those in the control group. Differences were significant for mood symptoms and of borderline significance for anxiety and hassles (table 2). Carers of patients in the treatment group were also more satisfied with several aspects of their care (fig 4).

Length of hospital stay was slightly shorter in the treatment group than in the control group (mean 34.7 *v* 38.9 days; median 12 *v* 19 days (P=0.1)). There were no significant differences between the groups in the patients' placement after discharge.

Blinding

After each of 312 consecutive follow up assessments the research psychologist was asked to guess whether

Table 1 Comparison of outcomes based on completed questionnaires in patients randomised to treatment and control groups

	Treatment			Control			
Measure	No	Median	Interquartile range	No	Median	Interquartile range	Difference between medians (95% confidence interval)†
Frenchay activities index	164	37	29-42	164	38	26-45	−1 (−4.0 to 3.0)
General health questionnaire	156	7	2.3-11.8	154	5.5	1-12	−1.5 (−3.0 to 1.0)
Social adjustment scale	164	1.7	1.5-2	160	1.6	1.4-1.8	−0.1 (−0.07 to −0.1)
Hospital depression subscale	128	4.5	3-8	124	3	2-7	−1.5 (−2.0 to 0.0)
Hospital anxiety subscale	128	5	2-8.8	124	5	1.3-7.8	0.0 (−1.0 to 2.0)
Barthel index	187	19	16-20	183	19	15-20	0.0 (−1.0 to 1.0)
Oxford handicap scale	184	3	2-4	184	3	2-4	0.0 (−1.0 to 1.0)
Mental adjustment to stroke scale	113			120			
Fighting spirit—helplessness		60	53-63		57	48-62	−3.0 (−5.0 to 0.0)
Anxious preoccupation		53	48-58		56	48-58	3.0 (−1.3 to 3.0)
Fatalism		54	48-59		54	48-59	0.0 (−5.0 to 0.0)

†Positive value for difference between medians indicates better outcome in treatment group; negative value indicates better outcome in control group.

Table 2 Comparison of outcomes based on completed questionnaires in carers of patients randomised to treatment and control groups

Measure	Treatment			Control			Difference between medians (95% confidence interval)†
	No	Median	Interquartile range	No	Median	Interquartile range	
Frenchay activities index	87	47	42-52	84	48	44-50	−1.0 (−2.4 to 2.0)
General health questionnaire	94	4	0-11	92	7.5	1-13	3.5 (0.7 to 7.0)
Social adjustment scale	112	1.7	1.4-2	116	1.7	1.5-2	0.0 (−0.01 to 0.10)
Caregiving hassles scale	70	4	1-13	69	8	1-21	4.0 (0.0 to 9.0)
Hospital depression subscale	89	4	1-7	96	4.5	1-7	0.5 (−1.0 to 2.0)
Hospital anxiety subscale	89	7	3-10	96	7.5	4.3-11	0.5 (0.0 to 3.0)

† Positive value for difference between medians indicates better outcome in treatment group; negative value indicates better outcome in control group.

the patient had been randomised to be seen by the stroke family care worker or not. She guessed correctly in 183 (58.7%) cases, which was more than should have occurred by chance alone (P=0.002), indicating that she was unblinded to some extent. However, the size of any observer bias resulting from this degree of unblinding in a follow up assessment based mainly on self report questionnaires was probably small. This is especially so with respect to the carer questionnaires, which were not completed in the presence of the psychologist.

Discussion

Our stroke family care worker and other similar posts were set up with the expectation that they would help patients and their families. However, there is very little evidence from previous randomised trials on which to base this assumption.[16-20] Most of these trials included few patients and were thus prone to type II error, and no systematic review of these trials has been published. We aimed at overcoming this problem by conducting a large trial with greater statistical power and at least partially blinded outcome measurement.

Though we successfully randomised reasonably large numbers of patients, we found few statistically significant differences in outcome between the treatment and control groups. Clearly, it is possible that some bias may have been introduced by patients or carers failing to complete a questionnaire. Theoretically, failure to complete all questions may have been related to the treatment allocation. However, the most common explanations for missing data were patients' cognitive and communication problems and simple omissions—for example, as a result of turning two pages over at once. Similar numbers in each treatment group encountered these sorts of difficulties. Thus significant bias seems unlikely.

The most convincing evidence of benefit of the stroke family care worker was in improving both patients' and carers' satisfaction in respect of various aspects of communication. Intriguingly, patients in the treatment group tended to be more helpless, less well adjusted socially, and possibly more depressed. We

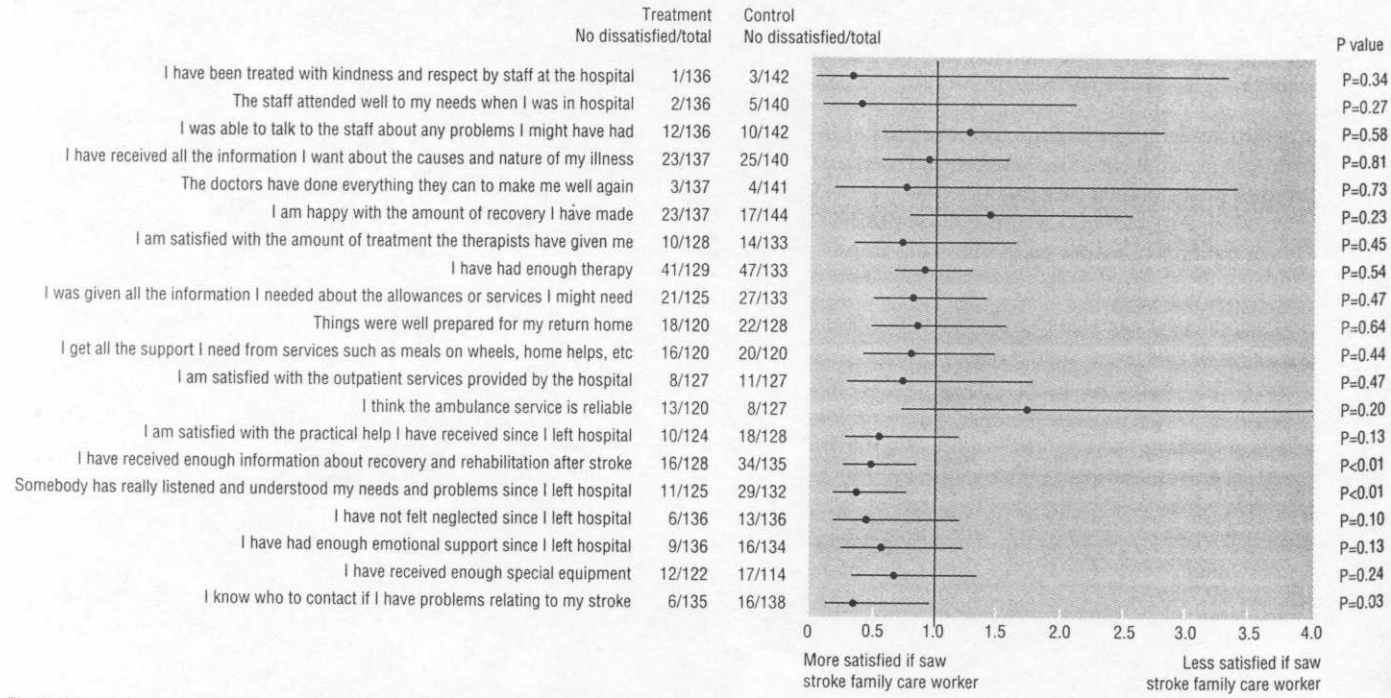

Fig 3 Comparison of responses to individual questions in patient satisfaction questionnaire in treatment and control groups. Points are point estimates of relative risk of patients expressing satisfaction in treatment group compared with control group. Bars are 95% confidence intervals. Difference is significant where confidence interval does not overlap vertical line (relative risk 1.0). Denominators vary because responses were missing in some questionnaires

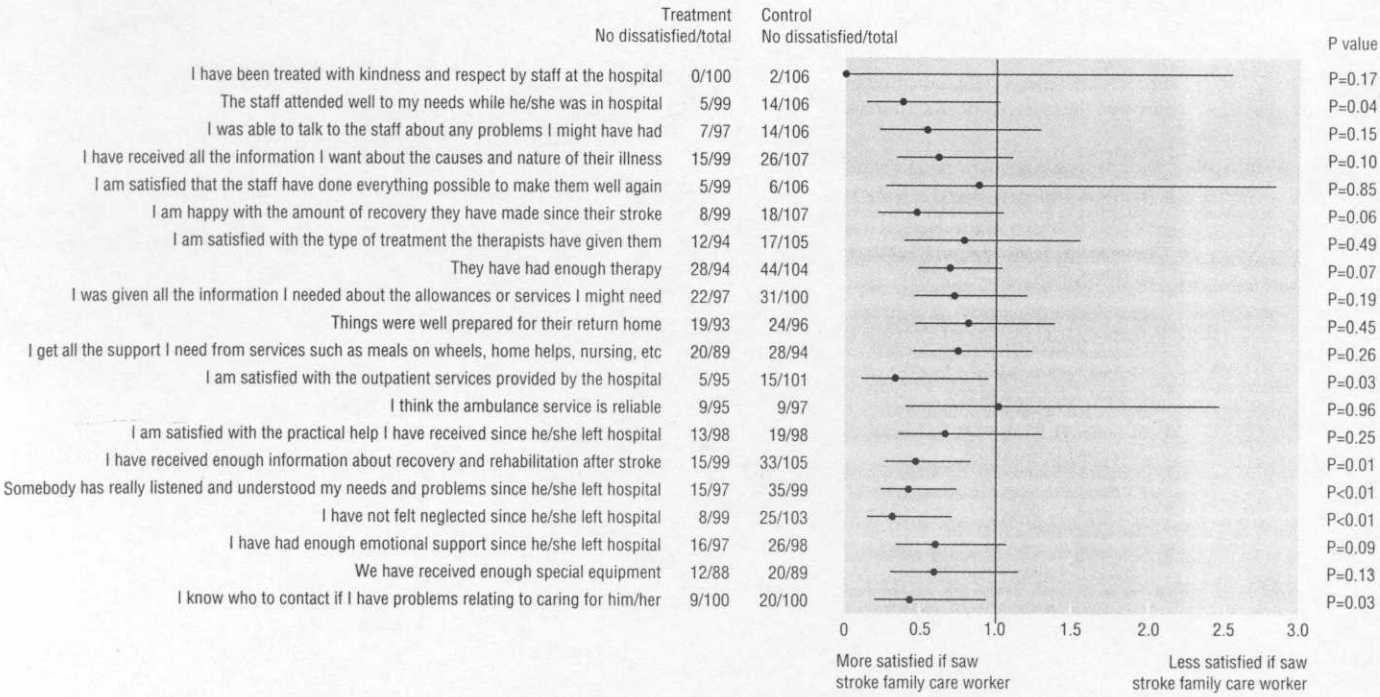

Fig 4 Comparison of responses to individual questions in carer satisfaction questionnaire in treatment and control groups. Points are point estimates of relative risk of patients expressing satisfaction in treatment group compared with control group. Bars are 95% confidence intervals. Difference significant where confidence interval does not overlap vertical line (relative risk 1.0). Denominators vary because responses were missing in some questionnaires

could postulate that intervention by the stroke family care worker, by providing support rather than improving patients' coping skills, induced a passive response to their illness which led to depression and poor social adjustment. Also there was an encouraging trend for carers in the treatment group to be less hassled and to have fewer mood symptoms, especially anxiety, than those in the control group. These moderate effects may, if real, accurately reflect the effectiveness of our stroke family care worker. There are, however, several possible explanations.

Firstly, the post was set up in the context of a well organised stroke service with excellent social work support, and many potential problems for patients and carers were already predicted and averted or managed by the hospital based team. The post might have had a greater effect in a less well organised service. Secondly, we were concerned that follow up at six months might be too early to show the real benefits of the post. Patients and carers may still be adjusting to the stroke and major problems may not yet have developed. At this stage many will still be receiving conventional input from hospital and primary care. Thirdly, we may have used measures of outcome which either were not measuring outcomes which might be influenced by our intervention or were insufficiently sensitive to any differences due to the intervention. Fourthly, our trial was pragmatic and included 67% of stroke patients. Possibly a subgroup of patients did benefit from the input of the stroke family care worker. Fifthly, the stroke family care worker responded to families' needs and wishes and may therefore sometimes have provided too little input to affect outcome.

Though our trial results may be of limited generalisability because we evaluated only a single worker, they suggest that any gain was mainly in satisfaction with aspects of communication and support after hospital discharge, certainly in the setting of a well organised stroke service. Future studies should examine these outcomes as well as psychological ones. Whether purchasers will be willing to fund interventions such as this will depend on the value that they and patients place on such outcomes. Perhaps we need to establish how important patients and their carers regard such outcomes before making any judgments. Pound *et al* identified being "cared for" and "cared about" as of value to patients, and they regarded them as important advantages of hospital admission after stroke.[21] We are currently planning a systematic review of previous and ongoing trials of similar interventions which may go some way in establishing whether stroke family care workers from different backgrounds—that is, working with different intensities for greater durations in different settings—might be more effective.

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Key messages

- A stroke family care worker in the context of a well organised hospital based stroke service has no definite beneficial effect on the physical, social, or psychological outcome of patients or their carers
- A stroke family care worker may reduce carers' hassles and anxiety but render patients more helpless, less well socially adjusted, and more depressed
- A stroke family care worker may improve patients' and their carers' satisfaction with those aspects of stroke services relating to communication and support
- Purchasers of health care need to decide the value they and their patients place on satisfaction with health care

trial was funded by the Scottish Office Home and Health Department.

Conflict of interest: Continued funding of the stroke family care worker relied on the outcome of this trial. As a result of the outcome the post has been terminated.

1 Holbrook M. Stroke: social and emotional outcome. *J R Coll Physicians Lond* 1982;16:100-4.
2 House A, Dennis M, Mogridge L, Warlow C, Hawton K, Jones L. Mood disorders in the first year after first stroke. *Br J Psychiatry* 1991;158:83-92.
3 Anderson CS, Linto J, Stewart-Wynne EG. A population-based assessment of the impact and burden of caregiving for long-term stroke survivors. *Stroke* 1995;26:843-9.
4 Stroke Unit Trialists' Collaboration. A systematic overview of specialist multidisciplinary team (stroke unit) care for stroke inpatients. Revised 27 February 1995. In: Warlow C, Van Gijn J, Sandercock P, eds. *Stroke module. Cochrane database of systematic reviews. Cochrane Collaboration. Issue 2.* Oxford: Update Software, 1995. (Database on disk and CD-ROM.)
5 Hatano S. Experience from a multicentre stroke register: a preliminary report. *Bull World Health Organ* 1976;54:541-53.
6 Mahoney FI, Barthel DW. Functional evaluation: the Barthel index. *Md State Med J* 1965;14:62-5.
7 Bamford J, Sandercock P, Warlow C, Slattery J. Inter observer agreement for the assessment of handicap in stroke patients. *Stroke* 1989;20:828.
8 Holbrook M, Skilbeck C. An activities index for use with stroke patients. *Age Ageing* 1983;12:166-70.
9 Goldberg D. *The detection of psychiatric illness by questionnaire.* Oxford: Oxford University Press, 1972.
10 Weissman MM, Bothwell S. Assessment of social adjustment by patient self-report. *Arch Gen Psychiatry* 1976;33:1111-5.
11 Kinney JM, Stephens MAP. Caregiving hassles scale: assessing the daily hassles of caring for a family member with dementia. *Gerontologist* 1989;29:328-32.
12 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361-70.
13 Watson M, Greer S, Young J, Inayat Q, Burgess C, Robertson B. Development of a questionnaire measure of adjustment to cancer: the MAC scale. *Psychol Med* 1988;18:203-9.
14 Pound P, Gompertz P, Ebrahim S. Patients' satisfaction with stroke services. *Clin Rehabil* 1994;8:7-17.
15 Hodkinson H. Evaluation of a mental test score for the assessment of mental impairment in the elderly. *Age Ageing* 1972;1:233-8.
16 Christie D, Weigall D. Social work effectiveness in two-year stroke survivors: a randomised controlled trial. *Community Health Stud* 1984;8:26-32.
17 Towle D, Lincoln NB, Mayfield LM. Service provision and functional independence in depressed stroke patients and the effect of social intervention on these. *J Neurol Neurosurg Psychiatry* 1989;52:519-22.
18 Evans RL, Matlock AL, Bishop DS, Stranahan S, Pederson C. Family intervention after stroke: does counseling or education help. *Stroke* 1988;19:1243-9.
19 Friedland JF, McColl M. Social support intervention after stroke: results of a randomised trial. *Arch Phys Med Rehabil* 1992;73:573-81.
20 Forster A, Young J. A randomised trial of specialist nurse support for community stroke patients. *BMJ* 1996;313:1642-6.
21 Pound P, Bury M, Gompertz P, Ebrahim S. Stroke patients' views on their admission to hospital. *BMJ* 1995;311:18-22.

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Commentary: No consent means not treating the patient with respect

Sheila McLean

School of Law, Stair Building, University of Glasgow, Glasgow G12 8QQ
Sheila McLean, *professor of law and ethics in medicine*

It is presumably often difficult for researchers to commit themselves wholeheartedly to the notion that before consent (or refusal) is obtained for research it is necessary that the person concerned should be given the fullest information about the project for which his or her agreement is wanted. The concerns expressed by the researchers—not least the possibility of biasing results—are intelligible. However, they are also insufficient to justify deviation from the general rule.

Researchers in many topics face the same problems about possibly influencing results and seek to minimise the possible impact this may have. Many kinds of research—clinical and non-clinical—must and do tackle similar problems while still turning out high quality work. However, this and the other rationales cited by Dennis *et al* disguise a deeper problem. The researchers claim they did not think that failure to provide the fullest possible information would harm their patients. Though this is probably true in a physical sense, it omits to consider the underlying rationale for providing full information—namely, that good research should not only be scientifically sound but it must also at all times respect the subject. Any failure to offer this respect is in itself a harm, even if its consequences are not physical. Indeed, it could plausibly be argued that omitting any substantial factor in the research protocol is enough to render the research unethical, no matter how important the postulated outcome. This is particularly true given that no researcher can know in advance that his or her results will be important.

Everyone starting a project believes that there is value in knowing the answer to the question being asked. But it is only when the answer is found that the truth or falsehood of that assumption can be known. Thus there is an inbuilt intellectual bias in any project which presumes that the answer is important enough to ignore a fundamental tenet of research method and respect for people.

We must also accept that had people been asked and then regretted their decision this would be unfortunate. It is difficult, however, to see how this differs from other projects. Moreover, that the person in question was rendered vulnerable by the nature of the condition argues for more rather than less information. There are always concerns about including in studies people whose condition is precarious. That this research was not directly physical does not remove those concerns or minimise obligations. In addition, I am puzzled by the argument that, as patients and their families would be included, it was "unclear" who might give consent. The answer is clear: anyone who is to be studied must be given the fullest possible information.

We can agree that the conclusions of the study are of considerable interest and that no physical harm was done to patients whose agreement to participate was based on partial rather than full information. It is, however, also dangerous to believe that this is enough. Nor are possible feelings of disappointment on the part of those who might not have agreed to randomisation different from findings in other research settings.

In sum, the arguments against providing full information are frankly unconvincing, however well intentioned. If certain research cannot be undertaken to the maximum standards of scientific inquiry the question is not how much information can be withheld, it is whether the research should be done in the first place. Otherwise we embark on a slippery slope away from one of our most fundamental ethical principles. In the long run the critical issue is not the consequential one; what matters is that people have not been treated with enough respect.