

# Multicenter Randomized Controlled Trial of an Outreach Nursing Support Program for Recently Discharged Stroke Patients

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**Background and Purpose**—Many stroke patients and informal carers experience a decreased quality of life after discharge home and are dissatisfied with the care received. We assessed the effectiveness of an outreach nursing care program.

**Methods**—In a multicenter trial, 536 stroke patients were randomized at discharge to standard care (n=273) or standard care plus outreach care (n=263). The outreach care consisted of 3 telephone calls and 1 home visit within 5 months after discharge by 1 of 13 stroke nurses. Patients were masked for the trial objectives. Six months after discharge, they assessed the 2 primary outcomes: quality of life (Short Form 36 [SF-36]) and dissatisfaction with care. Secondary measures of outcome were disability, handicap, depression, anxiety, and use of health care services and secondary prevention drugs. Informal carers assessed strain, and social support. Analysis was by intention to treat.

**Results**—Twelve patients died before follow-up, 38 declined outcome assessment, and 486 completed the primary outcome assessments. Outreach care patients had better scores on the SF-36 domain “Role Emotional” than controls (mean difference 7.9 [95% confidence limit, 0.1 to 15.7]). No statistically significant differences were found on the other primary outcome measures. For secondary outcomes, no statistically significant differences were found, except that intervention patients used fewer rehabilitation services (relative risk, 0.66 [0.44 to 1.00]) and had lower anxiety scores (median difference 1 [0.19 to 2.79]).

**Conclusions**—This outreach nursing stroke care was not effective in improving quality of life and dissatisfaction with care of recently discharged patients. (*Stroke*. 2004;35:2867-2872.)

**Key Words:** cerebrovascular disorders ■ quality of life ■ randomized controlled trials ■ rehabilitation

Patients who return home after being admitted after a stroke experience reductions in quality of life 6 to 12 months after discharge.<sup>1</sup> Although the use of care in these patients is high, one-third perceive unmet needs<sup>1</sup> and half are dissatisfied with at least 1 aspect of outpatient care.<sup>2,3</sup> For informal carers, caregiving for stroke patients has a major impact on their well-being.<sup>4</sup> Several extra care programs addressing the well-being of home-dwelling stroke patients or their carers have been assessed for effectiveness.<sup>5-12</sup> The lack of consistent, statistically significant results might be explained by the small numbers of patients included in most of these trials,<sup>6-12</sup> but there are 2 other methodological concerns. First, the generalizability of the improvements found is limited when only 1 center participated in the trial or 1 caregiver provided the service.<sup>5,8,10-12</sup> Second, in some trials, patients who assessed outcomes knew that an extra service was assessed for effectiveness.<sup>8,9</sup> The knowledge that other patients had received extra care may bias the results toward a less favorable outcome in controls. Conversely, in patients who had received the extra service, this knowledge may introduce a more favorable assessment because of loyalty to

the staff applying the program. We assessed in a multicenter randomized controlled trial the effectiveness of an outreach care program applied by a substantial group of nurses on dissatisfaction with care and quality of life among a large number of stroke patients who were recently discharged home. To avoid the above-mentioned bias, patients were masked for the trial objectives.

## Methods

### Setting and Participants

Patients were recruited in 2 university hospitals and 10 general hospitals (including 2 nonacademic teaching hospitals) in the districts of Amsterdam and Utrecht, the Netherlands. Dutch-speaking patients were eligible if they met the following criteria: (1)  $\geq 18$  years of age; (2) first admission for a stroke (transient ischemic attack [TIA] or ischemic stroke, primary intracerebral hemorrhage, or subarachnoid hemorrhage [SAH]); (3) hospitalization within 72 hours after onset of symptoms; (4) life expectancy of  $>1$  year; (5) independent or partly dependent on discharge (Rankin grade 0 to 3);<sup>13</sup> (6) discharged home; and (7) residence within 40 km of the catchment areas served by the hospitals.

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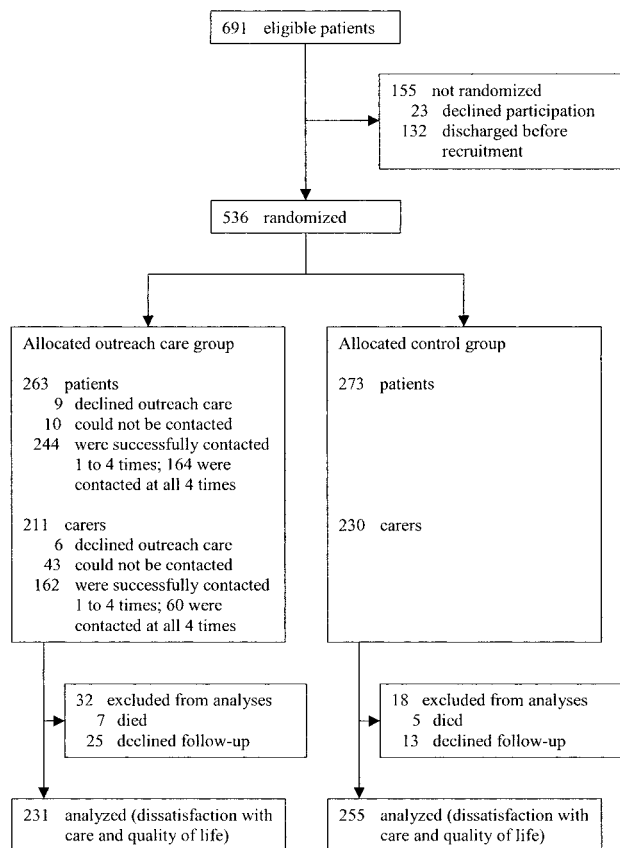


Figure 1. Trial profile.

## Recruitment and Randomization

Before discharge, patients were included according to the postponed informed consent procedure.<sup>14</sup> In short, patients were asked for a telephone interview and a postal questionnaire 6 months after discharge, and they were told that they would be informed about an additional research question only after follow-up because informing during recruitment would affect the results. The ethics committees of the participating centers approved the procedures followed. After written consent was obtained, patients were randomized to the control group (standard care only) or the intervention group (standard care and outreach care program; Figure 1). Allocation was done by means of a central telephone service. A minimization procedure was performed to reduce imbalance in the distributions of treatment numbers within the levels of each individual possible prognostic factor.<sup>15</sup> The minimization factors were “center,” “ability to perform activities of daily living on recruitment” (Barthel Index with cut-off point at 20), and “type of stroke” (SAH versus other strokes). After randomization, we offered patients and carers in the intervention group the outreach care program and informed them about its purpose, content, and timing but not that it was evaluated for effectiveness.

## Study Stroke Nurses and Intervention

Thirteen experienced and comprehensively trained stroke nurses applied the outreach care program that consisted of 3 nurse-initiated telephone contacts (1 to 4; 4 to 8; and 18 to 24 weeks after discharge) and a visit to the patients in their homes (10 to 14 weeks after discharge).<sup>16</sup> This number of contacts was based on a previous trial on extra care.<sup>5</sup> During all contacts, the nurses used a standardized checklist on risk factors for stroke, consequences of stroke, and unmet needs for stroke services.<sup>16</sup> We developed for carers a similar checklist, with special attention to the consequences the stroke had on the carers’ well-being. Nurses supported patients and carers according to their individual needs (eg, by giving information or

reassurance) or, when the presented problem required additional care or exceeded the nurses’ expertise, advised patients or carers to contact the general practitioner. Brochures on stroke or informal care were discussed and distributed when appropriate. Instead of actively solving problems, which may induce a passive attitude and lead to depression and poor social adjustment,<sup>5</sup> the nurses aimed to support patients and carers and advised how to solve the problems themselves or cope with them. On the checklist, the nurses kept a detailed record of all contacts, which allowed referring to previously raised needs, and applied interventions.

## Outcome Assessment

Primary outcome measures were dissatisfaction with stroke care (Satisfaction-With-Stroke-Care questionnaire [SASC-19])<sup>17</sup> and quality of life (Short Form 36 [SF-36])<sup>18,19</sup> 6 months after discharge by means of a postal questionnaire. Secondary outcome measures were anxiety and depression (Hospital Anxiety and Depression Scale [HADS])<sup>20</sup> and readmission since discharge. Additional secondary outcome measures were assessed by telephone interview, also 6 months after discharge: (1) ability to perform ADL (Barthel Index; scale 0 to 20),<sup>21</sup> (2) overall degree of independence (modified Rankin Scale), (3) use of health care services since discharge (eg, general practitioner and therapy), and (4) use of secondary prevention drugs since discharge. Those who declined to be interviewed were asked whether this was because they were dissatisfied with the care received. The assessment by telephone was performed in a blinded fashion. Outcome measures for carers were strain (Caregiver Strain Index [CSI])<sup>22</sup> and Sense of Competence Questionnaire [SCQ])<sup>23</sup> and discrepancies in social support measured by the subscales problem-oriented emotional support and social companionship (Social Support List–Discrepancies [SSL-D]).<sup>24</sup>

## Sample Size Determination

We assumed a degree of patient dissatisfaction of 50%<sup>3</sup> and considered a 25% relative reduction of this proportion as realistic and clinically relevant. For the SF-36, we used “effect sizes” (the difference between the mean scores of the experimental and the control group divided by the SD of the control group) as benchmark for assessing the relative magnitude of differences between both strategies. Although an effect size of 0.20 can be defined as small,<sup>25</sup> such a difference in mean quality of life scores may be clinically important. Therefore, we considered it necessary to detect this small difference in mean SF-36 domain scores between both strategies. Both calculations yielded a total sample size of 524 patients (262 patients per strategy) based on 2-tailed tests ( $\alpha=5\%$ ) and a power of 80%.

## Data Analysis

We analyzed baseline characteristics of patients and carers with descriptive statistics. Before calculating sum scores per respondent, missing responses on the SASC-19, SF-36, HADS, CSI, SCQ, and SSL-D were replaced by respondents’ mean scores for completed items of the same (sub)scale when at least half of the (sub)scale responses were valid.<sup>18</sup> Proportional differences were expressed in relative risks with corresponding 95% confidence limits (CLs). The 95% CLs of the difference between medians were obtained by performing a bootstrap. In this approach, we computed a sampling distribution of median difference scores based on 500 bootstrap samples. Subsequently, we sorted this sampling distribution from low to high and calculated the 2.5th and 97.5th percentile, which reflects the upper and lower cutoffs for the 95% CLs. All comparisons between groups were performed according to the intention-to-treat principle. An independent data-monitoring committee performed an interim analysis after the outcome assessment of 200 patients and advised us to continue the study.

## Results

### Patients

Between February 1999 and May 2002, nurses identified 691 eligible patients (Figure 1). Of these patients, 132 were

**TABLE 1. Baseline Characteristics of Patients**

	Intervention (n=263)	Control (n=273)
Sociodemographic characteristics		
Median age (IQR)	66 (52 to 76)	63 (51 to 74)
Women	133 (51%)	143 (52%)
Living alone	80 (30%)	70 (26%)
Patients identifying carer	211 (80%)	230 (84%)
Education level		
Primary school or less	64 (24%)	74 (27%)
Secondary school	157 (60%)	157 (58%)
Higher education or university	39 (15%)	41 (15%)
Unknown	3 (1%)	1 (<1%)
Type of stroke		
Ischemic stroke†	187 (71%)	195 (71%)
Hemorrhagic stroke	25 (10%)	25 (9%)
SAH	51 (19%)	53 (19%)
Health status on recruitment		
Rankin grade		
0	47 (18%)	45 (16%)
1	92 (35%)	87 (32%)
2	83 (32%)	98 (36%)
3	41 (16%)	43 (16%)
Median Barthel Index (IQR)	20 (19 to 20)	20 (19 to 20)
Median hospital depression subscale (IQR)	4 (1 to 7)	4 (2 to 7)
Median hospital anxiety subscale (IQR)	5 (2 to 8)	5 (2 to 8)
Hospitalization		
Median total length of stay in days (IQR)	13 (8 to 20)	13 (7 to 19)
Median length of stay since randomization in days (IQR)	2 (1 to 4)	2 (1 to 4)

IQR indicates interquartile range.

†Includes TIA (23 outreach care patients and 22 controls).

discharged before recruitment and 23 declined participation. Thus, we randomized 536 patients: 263 (with 211 carers) to standard care plus outreach care and 273 (with 230 carers) to standard care only. The groups were well matched (Table 1). Seven outreach care patients and 5 controls died before follow-up; 231 (90%) of the 256 outreach care patients and 255 (95%) of the 268 controls completed primary outcomes. Among nonrespondents, 2 (1 control) declined to respond because they were dissatisfied with the care received.

**Primary Outcomes: Dissatisfaction With Care and Quality of Life**

In both groups, one-fifth of the patients were dissatisfied with care received in the hospital, and half were dissatisfied with care received after discharge (Table 2). Apart from better scores in outreach care patients on the domain “role limitations due to emotional health” (mean 60.1 [SD 43.2] versus 52.3 [43.8] in controls; mean difference 7.9; 95% CL, 0.1 to 15.7), there were no other statistically significant differences (Figure 2).

**Secondary Outcomes**

Intervention patients had less use of rehabilitation services and lower anxiety scores than controls, but on other out-

comes, no statistically significant differences were found (Tables 2 and 3). For carers, we found no statistically significant differences between the 2 groups (Table 4).

In analyses with complete observations only for the SASC-19, HADS, CSI, SCQ, and SSL-D, results were essentially the same as in the main analysis.

**Discussion**

Except for a small effect on 1 of the domains of quality of life (SF-36) in favor of the outreach care patients, we found no other statistically significant differences in quality of life or dissatisfaction with care. For the secondary outcome measures, only statistically significant but small differences were found for anxiety and the use of rehabilitation services.

This study has some advantages when compared with previous studies. First, because the use of the conventional informed consent procedure might have induced biased results in this study, we modified the procedure to mask respondents. Second, the generalizability of the results was improved by the use of 12 participating centers and 13 stroke nurses who applied the service.

Nevertheless, some weaknesses remain. First, we missed a substantial group of eligible patients who were discharged

**TABLE 2. Comparison of Proportions of Patients Who Were Dissatisfied With the Care Received (SASC-19), Used Health Care Services, or Secondary Prevention Drugs According to Allocated Treatment**

	Intervention*	Control*	Relative Risk (95% CL)
Dissatisfaction with care			
Hospital subscale†	50/230 (22%)	47/254 (19%)	1.17 (0.82 to 1.68)
Home subscale‡	115/223 (52%)	119/247 (48%)	1.07 (0.89 to 1.28)
Health care services			
General practitioner	174/236 (74%)	181/250 (72%)	1.02 (0.91 to 1.13)
Readmission§	35/215 (16%)	28/243 (12%)	1.41 (0.89 to 2.24)
Therapy	109/237 (46%)	126/250 (50%)	0.91 (0.76 to 1.10)
(I)ADL care¶	73/234 (31%)	68/252 (27%)	1.16 (0.88 to 1.53)
Rehabilitation**	32/236 (14%)	51/250 (20%)	0.66 (0.44 to 1.00)
Aids††	72/235 (31%)	77/250 (31%)	0.99 (0.76 to 1.30)
Secondary prevention drugs‡‡	152/164 (93%)	167/176 (95%)	0.98 (0.92 to 1.03)

\*Denominators fluctuate due to differences in response.

†Theoretical scores range from 0 to 24 (8 items); arbitrarily, a score <16 is considered to indicate dissatisfaction with inpatient stroke care.<sup>17</sup>

‡Theoretical scores range from 0 to 33 (11 items); arbitrarily, a score <22 is considered to indicate dissatisfaction with stroke care after discharge.<sup>17</sup>

§Readmission to hospital or other care institute.

||Physiotherapy, speech therapy, or occupational therapy.

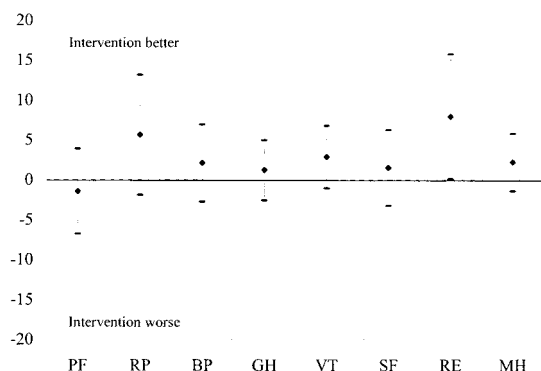
¶(Instrumental) activities of daily living: home nursing, home help, or meals on wheels.

\*\*Day care or social care.

††Home adaptation; (non)body-adapted aids, or outdoor mobility.

‡‡Excluding patients with hemorrhagic stroke or SAH.

before recruitment. We do not feel that this affected the results because these patients probably needed less care after discharge than enrolled patients did. Second, although we enrolled more patients than indicated by the power analysis, the final number of patients who eventually completed the outcome questionnaires was slightly lower than planned. Consequently, we lost some power (from 80% to 77%) to statistically detect our intended treatment goals. Third, there was a lower response rate among outreach care patients than in controls. Perhaps some outreach care patients felt there was no need to complete the questionnaire because they had already discussed their well-being with the nurse. Although these patients might have responded differently on the primary outcome measures than responding outreach care patients, we did not explore this possible effect because of the neutral results of the trial.



**Figure 2.** Mean differences of 8 domains of quality of life (SF-36) between treatment groups (bars are 95% CLs).

The recruitment of a large proportion of patients with an SAH, who were mostly of younger age, is not a major concern because post hoc analyses showed comparable response patterns between this subgroup and the total group. Additionally, patients with a maximum score on the Barthel Index or TIA were not excluded because these patients have room for further improvement on their quality of life scores, and disability is not related to dissatisfaction with care.<sup>2,26</sup> Finally, because usually only independent or partly dependent patients (Rankin grade 0 to 3) are discharged home, we decided to exclude those few patients who were dependent (Rankin grade 4 or 5) and discharged home.

Several reasons may explain why the program was not effective. First, components with proven efficacy for the program were not available when it was developed (eg, in terms of content, timing, or type of nursing interventions for specific problems). Furthermore, we used a generic instrument to assess patients' quality of life (SF-36) because an appropriate stroke-specific instrument was not available at the start of the study. Finally, patients' dissatisfaction with care and decreased quality of life may have resulted mainly from their grieving over lost abilities after their stroke. Apparently, the program could not improve this.

Our results on patients' dissatisfaction with care and quality of life are comparable to those of previous studies.<sup>5-12</sup> In 2 studies, the proportions of dissatisfaction with care were decreased for 3 to 5 of 20 different aspects of care.<sup>5,10</sup> Because scores were analyzed on item level, these results are prone to type I error. Three studies presented 1 to 2 scores for dissatisfaction with care;<sup>8,9,12</sup> only 1 study on a brief program of domiciliary occupational therapy showed a significant

**TABLE 3. Comparison of Median Scores on Patients' Health Status According to Allocated Treatment (Interquartile Range)**

	Intervention		Control		Differences Between Medians (95% CL)†
	No.*	Median	No.*	Median	
Barthel Index	236	20 (20 to 20)	252	20 (19 to 20)	0 (0 to 0)
Rankin	237	1 (1 to 2)	253	1 (1 to 2)	0 (−0.32 to 0.39)
Hospital depression subscale	217	3 (1 to 7)	244	4 (2 to 8)	1 (−0.52 to 2.98)
Hospital anxiety subscale	217	4 (2 to 8)	244	5 (2 to 8)	1 (0.19 to 2.79)

\*No. of patients.

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

decrease of dissatisfaction with care received after discharge.<sup>8</sup> All these trials assessed effects on (domains of) patients' quality of life.<sup>5–12</sup> Only 2 trials found statistically significant effects: 1 study on education and counseling for carers found a positive effect on patient adjustment, and another study on services from a stroke family care worker found an adverse effect on social adjustment.<sup>5,11</sup>

Our study confirmed the previously found large proportion of 50% for dissatisfaction with care received after discharge and also for reduction in quality of life among recently discharged stroke patients when compared with a national sample.<sup>19</sup> Although there was enough room for improvement, we conclude that the present results, those of previous studies, and the costs of the program (in terms of finance and the employment of scarce stroke nurses) do not warrant implementation of such outreach stroke care programs in clinical practice. Before developing new programs, further research is needed on the predictors of dissatisfaction with care and quality of life and the development of tools to identify patients at risk. Such tools might include emotional symptoms because many stroke patients feel depressed or anxious, and these outcomes are related to dissatisfaction with care.<sup>2,17</sup> A stroke-specific quality of life instrument should be used to assess the effectiveness of these programs.

## Appendix

### HESTIA (Home Evaluation of STroke Induced Aid) Study Group

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#### Independent Data Monitoring Committee

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**TABLE 4. Comparison of Median Scores on Carers' Strain and Social Support According to Allocated Treatment (Interquartile Range)**

	Intervention		Control		Differences Between Medians (95% CL)†
	No.*	Median	No.*	Median	
Strain‡					
CSI	158	3 (0 to 5)	191	3 (1 to 6)	0 (−1.01 to 1.53)
SCQ	157	40 (35 to 47)	191	41 (35 to 50)	1 (−1.58 to 3.44)
Discrepancies in social support§					
Problem-oriented subscale	142	8 (8 to 12)	181	8 (8 to 12)	0 (−1.20 to 1.20)
Social companionship subscale	141	5 (5 to 7)	178	5 (5 to 7)	0 (−0.59 to 0.61)

\*No. of carers.

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

‡CSI (range 0–13; higher scores indicate higher burden) and SCQ (range 27–108; higher scores indicate higher burden).

§Problem-oriented emotional support (range 8–24; higher scores indicate less social support) and social companionship (range 5–15; higher scores indicate less social support).

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