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## **Randomized controlled trial of rehabilitation at home after stroke: one-year follow-up of patient outcome, resource use and cost**

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### **Record Status**

This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

### **Health technology**

The health intervention examined in the study was a programme of rehabilitation at home after early discharge for patients after stroke. The programme was adapted to each patient's needs by a team of occupational, physical, and speech-and-language therapists. The early discharge was scheduled when the patient attained independence in toileting. The programme lasted up to 4 months after hospital discharge.

### **Type of intervention**

Rehabilitation.

### **Economic study type**

Cost-effectiveness analysis.

### **Study population**

The study population comprised patients admitted to the stroke unit. Further detailed inclusion criteria were not reported.

### **Setting**

The setting was community. The economic study was carried at the Huddinge University Hospital, Stockholm, Sweden.

### **Dates to which data relate**

Effectiveness evidence and data on resource use were gathered from September 1993 to April 1996. No price year was reported.

### **Source of effectiveness data**

The effectiveness evidence was derived from a single study.

### **Link between effectiveness and cost data**

The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

### **Study sample**

Power calculations were performed in the planning phase: a power of 80% required a sample of 90 patients to detect an odds ratio of 4 in patient outcome, although the outcome in question was not explicitly stated. Patients admitted to the study hospital from September 1993 to April 1996 were included in the study. A final sample of 83 patients (mean age: 72 years; 55% men) was enrolled: 42 subjects were included in the home-rehabilitation group (HRG) and 41

subjects in the routine-rehabilitation group (RRG).

### Study design

The study was a blind, randomised controlled trial carried out in a single centre (the Huddinge University Hospital in Stockholm). The method of randomisation was not reported. A blind assessment was carried out, as the assessors were blind to group assignment and study organisation. Patients were followed for one year and loss to follow-up was one patient in both groups at 3 months, one patient in the HRG and two in the RRG at 6 months, and only one patient in the HRG at 1 year. Therefore, the final sample consisted of 39 patients in the HRG and 38 patients in the RRG.

### Analysis of effectiveness

Patients lost to follow-up were not included in the analysis; therefore the analysis of the clinical study was based on treatment completers only. Several outcome measures were assessed in the analysis: presence of aphasia, Reinvang aphasia test (range: 0 - 100), Lindmark motor capacity (range: 0 - 153), nine hole peg test, time to walk 10 m, Barthel ADL, Katz extended, Frenchay activities index (FAI) (range: 0 - 45), sickness impact profile (SIP) (range: 0 - 100), patients reporting falls and total number of falls, injurious falls. Adverse outcomes (number of deaths or dependencies) were also measured. The effect of rehabilitation at home after 12 months was assessed using a multivariate analysis: the odds ratios (ORs), adjusted for confounding factors such as age, sex, civil status, FAI, etc., were calculated. Spouses' SIP was also measured to assess quality of life of patients' partners. The two study groups were comparable in terms of age, gender, civil status and level of independence, but differed statistically in terms of more diagnosed associated diseases prior to stroke in the HRG ( $p=0.046$ ), better coping capacity ( $p=0.031$ ) in the RRG, side of the lesion (left hemisphere lesion in the HRG: 22, RRG: 13;  $p=0.041$ ), presence of dysphasia (HRG: 10, RRG: 5), and severity of dysphasia (HRG: 4 severe, 4 moderate, 2 mild; RRG: 1 severe, 4 mild,  $p=0.065$ ).

### Effectiveness results

The effectiveness results were as follows:

The differences between the two groups were not statistically significant in terms of any of the health outcomes assessed.

Adverse outcome was 10% in HRG and 44% in RRG, ( $p=0.074$ ).

Adjusted ORs were 1.93 (95% CI: 0.60 - 6.19) for high motor capacity, 2.98 (95% CI: 0.74 - 12.05) for food manual dexterity, 2.48 (95% CI: 0.73 - 8.50) for fast walking ability, 2.75 (95% CI: 0.77 - 9.77) for independence in Barthel, 2.76 (95% CI: 0.82 - 9.27) for independence in Katz Extended ADL, 1.29 (95% CI: 0.36 - 4.61) for high frequency of social activities, 1.00 (95% CI: 0.34 - 2.92) for low sickness impact profile, and 3.17 (95% CI: 0.91 - 11.04) for favourable outcome (independence/dependency or death).

The authors stated that spouses' quality of life measures displayed a median dysfunction of less than 1% of both groups.

### Clinical conclusions

The effectiveness analysis favoured home rehabilitation in most measures of patient outcome that did not reach the statistical significance at the 0.05 level.

### Measure of benefits used in the economic analysis

Health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis, therefore a cost-consequences analysis was carried out.

### Direct costs

Discounting was not relevant since the time horizon of the study was one year. Quantities of resources used were comprehensively reported, but unit costs were not. The cost/quantity boundary adopted was not clearly stated. The cost items included in the analysis were hospitalisation, hospital outpatient therapist visits, home rehabilitation, private caregivers, and visits in primary care setting. Resources used for community based services and informal care were also estimated but were not included in the cost analysis. The estimation of costs was based on actual average cost data derived from the official Stockholm County Council and official statistics of The National (Swedish) Social Insurance Board. The estimation of resource use was based on actual data derived from the trial and measured from September 1993 to April 1996. No price year was reported.

### **Statistical analysis of costs**

Statistical analyses on total costs were conducted to test for statistical significance of the results. In the planning phase of the study it was also estimated that a sample of 24 patients would have been required to detect a difference in cost of Sek 15,000.

### **Indirect Costs**

Indirect costs were not included in the analysis.

### **Currency**

Swedish kroner (Sek).

### **Sensitivity analysis**

Sensitivity analyses were not carried out.

### **Estimated benefits used in the economic analysis**

See effectiveness results above.

### **Cost results**

The cost results were as follows:

Mean hospitalisation costs: HRG (Sek 1,716,495); RRG (Sek 2,658,816), (p=0.002).

Mean nursing costs in primary care were: HRG (Sek 69,160); RRG (Sek 48,880), (p=0.03).

Generally, costs incurred in primary care and rehabilitation were higher in HRG, while costs incurred in hospital and private practice were higher in RRG.

Per patient costs of health care and rehabilitation amounted to Sek 71,959 in HRG and Sek 91,453, with a difference of Sek 19,494 (approximately Euros 2,300) in favour of home rehabilitation (no results of any statistical test were given).

### **Synthesis of costs and benefits**

Not relevant.

### **Authors' conclusions**

The authors concluded that a programme based on early discharge and home rehabilitation for stroke patients was as effective as routine rehabilitation, and overall costs and resource use were lower for the new programme.

### **CRD COMMENTARY - Selection of comparators**

The rationale for the choice of the comparator was clear. Routine rehabilitation was selected as it represented the standard programme for stroke patients. You, as a user of this database, should assess whether it is a widely used programme in your own setting.

### **Validity of estimate of measure of effectiveness**

The analysis of the effectiveness was based on a blind randomised controlled trial, which appeared appropriate for the study question. Loss to follow-up was limited and the basis of the analysis of the clinical study appears to have been treatment completers only. The authors noted that the study had relatively low power to detect small differences between the study groups in terms of health outcomes, which were generally not significantly different. In addition, study groups were not perfectly comparable at baseline, but adjustment was made for confounding.

### **Validity of estimate of measure of benefit**

No summary benefit measure was used in the economic analysis and health outcomes were left disaggregated. However, since the disease assessed has a strong impact on quality of life of patients (and caregivers), it would have been interesting to have used a summary benefit measure reflecting patients' (and caregivers') preferences for the interventions.

### **Validity of estimate of costs**

The perspective of the study was not clearly stated and cost items from different sources were used. However, the cost analysis was limited to direct costs, although the inclusion of indirect costs would have been crucial in the case of the disease considered in the analysis. No price year or unit costs were reported. Statistical analyses of costs and quantities of resources used were conducted, and the resources appear to have been listed comprehensively. The authors pointed out that the cost analysis was not meant to be part of a full economic evaluation, but was conducted for comparative purposes only and therefore not all the resources used in the 12-month period were actually included in the analysis.

### **Other issues**

The authors made few comparisons of their findings with those from other studies. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not carried out. Results were reported fully, except, as acknowledged by the authors, that not all resources were accounted for. The authors' conclusions should be viewed in the light of the relatively select group of patients.

### **Implications of the study**

Further research, as recommended by the authors, should provide reliable information on assessment of quality of life of patients and caregivers as well as other important outcome measures not assessed in the present study, such as timing and content of the rehabilitation programme.

### **Source of funding**

None stated.

### **Bibliographic details**

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