

# ESD Stroke Bergen – an RCT comparing two different schemes of early supported discharge after stroke with ordinary treatment: results from 3 months follow-up

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## Background

As a result of demographic changes with a presumed rapidly increasing number of older people during the coming decades, a strong increase in the incidence and prevalence of stroke should be expected. Efficient and cost-effective treatment strategies are therefore needed. Early Supported Discharge (ESD) implies that the patients are discharged to their homes as soon as feasible and that rehabilitative treatment is offered after the discharge, with the patients being home-dwelling. This has proved beneficial in previous studies.

## Aims

The main objective of this study is to explore the important components of ESD treatment by comparing the rehabilitation results of two different ESD schemes with conventional stroke rehabilitation. These ESD schemes comprise intensive rehabilitation treatment given by a multidisciplinary team in a day unit or the same treatment given in the patients' homes.

## Study design

The study is conducted as a single blind RCT with three arms: two different forms of ESD and a control arm with conventional treatment (Figure 1). 306 patients with acute stroke living in the Municipality of Bergen were included from Dec. 2008 through Dec. 2011. The study is registered in *ClinicalTrials.gov* registration#NCT00771771.

## Outcomes

Primary outcome is modified Rankin Scale (mRS) six months after inclusion. Secondary outcomes include Barthel ADL Index and National Institute of Health Stroke Scale at several points in time after inclusion, as well as many other schemes, questionnaires and physical tests. This is summarized in Table 1.

## ESD Principles in this study

1. The patients are discharged to home as early as possible
2. They are followed by a multidisciplinary coordinating team through the hospital and rehabilitation periods
3. Intensive rehabilitation is offered in the patients' municipality after discharge to home
4. Outpatient follow-up is offered 3 and 6 months after the stroke

**Group A:** Rehabilitation in a day unit

**Group B:** Rehabilitation in the patients' homes

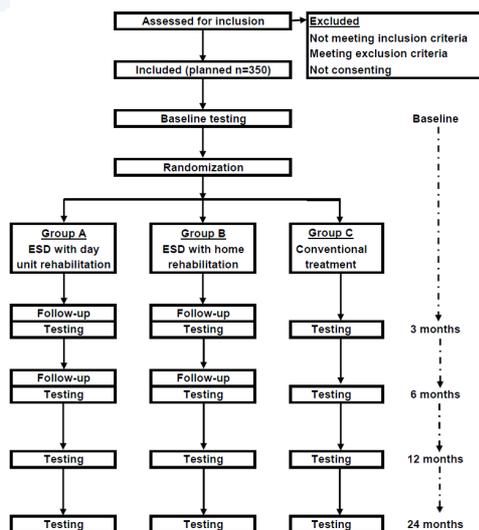


Figure 1. Overview of the study and patient flow

Table 1. Primary and secondary outcomes

Time	Registrations and questionnaires
Before or at inclusion	E-stroke, NIHSS
Soon after inclusion	AMPS, TIS, PASS, TUG, FAC, NRS, MMSE Standardized 5 meter walking test Evaluation by speech therapist
7 days after inclusion or earlier if discharged from the stroke unit	NIHSS, MRS, BI Comorbidity questionnaires (SCQ, SHC)
3 months after inclusion	NIHSS, MRS, BI, Patient satisfaction AMPS, TIS, PASS, TUG, FAC, NRS Standardized 5 meter walking test Evaluation by speech therapist
6 months after inclusion	NIHSS, MRS, BI, Patient satisfaction AMPS, TIS, PASS, TUG, FAC, NRS Standardized 5 meter walking test
12 months after inclusion	NIHSS, MRS, BI, SIS, RSS, PGIC, SF-36, Patient satisfaction Cognitive/neuropsychological evaluation Evaluation by speech therapist
24 months after inclusion	MRS, BI, PGIC, SF-36

## Preliminary results

### Baseline characteristics of the patients

Table 2. Baseline characteristics of included patients

	TOTAL	GROUP A	GROUP B	GROUP C
number of patients	306	103	104	99
males	169	56	61	52
females	137	47	43	47
age all patients (mean)	72.39	70.61	71.99	74.65
age males (mean)	69.82	69.28	69.41	70.90
age females (mean)	75.55	72.21	75.65	78.79
days in Stroke Unit (mean)	11.40	11.30	11.26	11.64
mRS at day 7 (mean)	2.59	2.52	2.59	2.66
Barthel Index at day 7 (mean)	77.32	76.72	79.76	75.36
initial NIHSS score (mean)	5.31	5.98	4.91	5.01

### Logistic regression predicting mRS at 3 months

Table 3.

### Logistic regression predicting mRS 0-2 vs. 3-6 at three months

	B	S.E.	Wald	df	p	OR	95% CI for OR
Sex (M vs. F)	.63	.31	4.02	1	0.045	1.87	1.01-3.45
Age	.10	0.02	40.31	1	0.000	1.10	1.07-1.14
Group			3.26	2	0.196		
Group (A vs. C)	.323	.40	.79	1	0.406	1.38	0.88-2.96
Group (B vs. C)	.679	.38	3.22	1	0.073	1.97	0.94-4.15
Constant	-6.97	1.14	37.74	1	0.000	0.00	

## Comments

In this study two different ESD schemes are compared with treatment as usual in an RCT comprising 306 acute stroke patients. Baseline parameters are comparable in the three groups, but there are more males than females (55.2% vs. 44.8%) and the males are on average six years younger. There is no significant difference between the improvement in the three groups, but for mRS there is a trend towards more improvement with home rehabilitation.

In most previous studies ESD has been superior, but most of them were conducted more than 10 years ago. Today both acute treatment and secondary prevention are greatly improved, and the strokes by themselves generally are less severe. This may possibly explain why the outcome is favourable irrespective of treatment group. The results further support the discharge of acute stroke patients to their homes as early as possible after acute stroke.