Hild Fjærtoft

Extended stroke unit service and early supported discharge
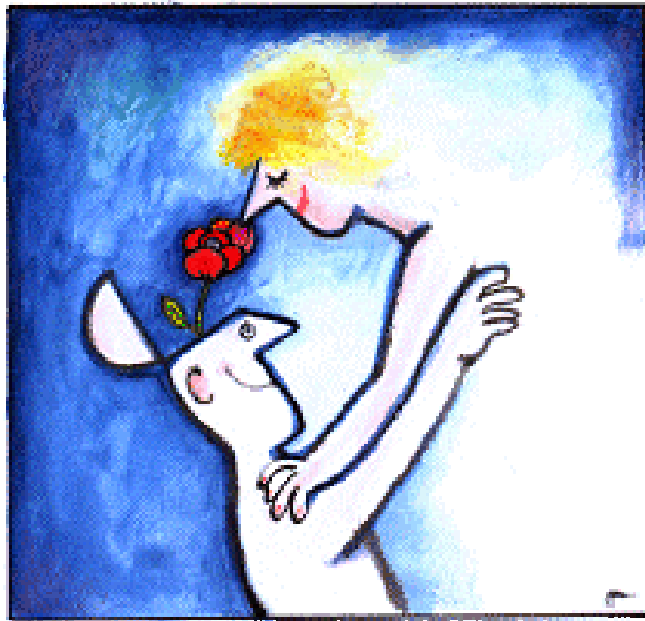
Short and long-term effects

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"Advances in clinical research in the hospital and the primary health care service are beginning to merge and show that the human brain is capable of significant recovery in the longer term after stroke, provided that the appropriate treatments and stimuli are applied in adequate amounts, at the right time and in the right surroundings."

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Background and purpose

Stroke imposes a considerable burden for patients, their caregivers and the society worldwide. It is a challenge to organise the healthcare service that can provide effective management of patients who have suffered from stroke. Several trials have shown that stroke unit care improves the outcome for stroke patients. More limited information exists about the most effective way to organise the follow-up care after the acute care in a stroke unit. Stroke patients conventionally receive a substantial part of their rehabilitation in hospital or in other institutions that offer 24 hours-stay.

The primary aim of this thesis was to increase knowledge about the organising of follow-up care for stroke patients after the acute care in a stroke unit. To achieve this we performed a trial to evaluate the short and long-term effects of an extended stroke unit service (ESUS), with early supported discharge from hospital, co-operation with the primary health care, and more emphasize on rehabilitation at home as essential elements.

Methods

We performed a randomized controlled trial in which 320 acute stroke patients admitted to the Stroke Unit at St. Olavs Hospital, Trondheim University Hospital were included and allocated either to ordinary stroke unit care (OSUS) (160 patients) with further in-patient rehabilitation or follow-up from the primary healthcare service, or to stroke unit care with early supported discharge (160 patients). The ESUS consisted of a mobile team which co-ordinate early supported discharge and further rehabilitation.

Included in this thesis are 4 papers based on data from this study population of acute stroke patients followed in one year after the onset of stroke. We wanted to compare the groups in relation to independency, quality of life (QoL) and resource use and costs.

- Functional outcome were measured as the proportion of patients who were independent as assessed by modified Rankin Scale (RS)(RS$\leq$2 =global independence) and Barthel Index (BI)(BI$\geq$95 = independent in ADL) at 26 weeks and 52 weeks, the differences in final residence and analyses to identify patients who benefited most of an early supported discharge service *(paper I and II)*. All assessments were blinded.

- The outcome of QoL was measured by the Nottingham Health Profile (NHP) at 52 weeks. Other outcomes measured at 52 weeks were differences between the groups according to social activity, depression, cognitive function and the burden for carers'. *(paper III)*.

- The use of all health services during the first 52 weeks was recorded prospectively in both groups; its costs were measured as service costs and represent a combination of calculated average costs and tariffs. Hospital expenses were measured as costs per inpatient day. The secondary objectives were to explore differences in costs between the groups with respect to different types of services, time of service delivery and stroke severity *(paper IV)*.

Results

- Extended stroke unit service with early supported discharge and co-ordination by a mobile team improves functional outcome 6 months and 12 months after stroke. The Odds Ratio for independence at one year was 1.56 (95% C.I, 1.01-

to 2.44). It was most beneficial for patients with moderate stroke *(papers I and II).*

- Extended stroke unit service with early supported discharge can improve long-term quality of life measured by global NHP. The ESUS group had a significant better QoL after one year than the OSUS group (p = 0.048). There were no significant differences between the groups in the secondary outcomes social activity, depression and cognitive function. The caregivers who got their patients early at home did not report an increased burden compared to caregivers whose patients became ordinary stroke unit care *(paper III).*

- The length of initial institutional stay (hospital and rehab.clinic) were reduced with 40 % for the patients offered extended stroke unit service (18.6 days in the ESUS versus 31.1 days in the OSUS) (p=0.032). There was also a reduction in average number of total inpatient days during the first year in favour of the ESD group (p = 0.012) *(paper IV).*

- The total health services costs for ESUS was equal or less than costs for ordinary care during the first year after stroke. There was a non-significant reduction in total mean service costs in the ESUS group (EUR 18937 / EUR 21824). The service seemed to be most cost effective for patients with moderate severity of stroke (23% lower mean costs compared to OSUS). The important cost savings caused by reduced length of institutional stay did not lead to an increase in costs for home-based rehabilitation *(paper IV).*

Conclusion
An extended stroke unit service with early supported discharge improved functional outcome and reduced the length of stay in institutions compared to traditional stroke

unit care. It also seems that this service can improve long-term quality of life. The costs are equal or less than costs for ordinary care.

An early, well organised discharge from hospital co-ordinated by a mobile team seems to be an important contribution in the treatment of stroke patients and should be considered, in addition to organised in-patient stroke unit care, as a part of a comprehensive stroke care.

Acknowledgements:

List of papers:

This thesis is based on the following papers:

1. Indredavik B, Fjærtoft H, Ekeberg G, Løge A, Mørch B: Benefit of an extended stroke unit service with early supported discharge: A randomized, controlled trial. Stroke 2000; 31:2989-94.

2. Fjærtoft H, Indredavik B, Lydersen S: Stroke Unit Care combined with Early Supported Discharge. Long Term follow-up of a Randomized Controlled Trial: Stroke 2003; 34:2687-2692.

3. Fjærtoft H, Indredavik B, Johnsen R, Lydersen S: Acute stroke unit care combined with early supported discharge. Long-term effects on quality of life. A randomized controlled trial. Clinical Rehabilitation 2004; 18:580-586.

4. Fjærtoft H, Indredavik B, Magnussen J, Johnsen R: Early Supported Discharge for Stroke Patients Improves Clinical Outcome. Does It Also Reduce Use of Health Services and Costs? One year follow-up of a randomised controlled trial. Cerebrovasc Dis 2005;19:376-383.

Abbreviations:

ADL: Activities of daily living

BI: Barthel Index

CI: Confidence Interval (i.e. 95% Confidence interval)

CSI: Caregivers Strain Index

DRG: Diagnoses related system

ESD: Early Supported Discharge

ESDT: Early supported discharge trialists

ESUS: Extended Stroke Unit Service

EUR: Euro

FAI: Frenchay Activities Index

MADRS: Montgomery - Åsberg Depression Scale

MMSE: Mini-mental State Examination

mRS: Modified Rankin Scale

MT: Mobile Team

NHP: Nottingham Health Profile

NNT: Number needed to treat

NOK: Norwegian "kroner"

OR: Odds ratio

OSUS: Ordinary Stroke Unit Service

PHCS: Primary Health Care Service

QoL: Quality of Life

RCT: Randomised controlled trial

RS: Rankin Scale

SD: Standard Deviation

SSS: Scandinavian Stroke Scale

S.U: Stroke unit

SUTC: Stroke Unit Trialists collaboration

TIA: Transient ischaemic attack

W: Weeks

WHO: World Health Organization

1.0 Introduction:

1.1. Stroke Disease

Stroke is one of the major causes of death and disability in western countries (1-2). It consumes about 5% of total health service resources (3), and in addition to the loss of function for the patients and the burden for their families, it imposes a considerable economic burden on the individuals as well as society worldwide (4-6).

During the past decade, the interest for and the focus on stroke research and development of more effective treatment methods have increased. The question about the importance of organizing of stroke care was addressed for the first time in the 1950's (7), and as early as in 1962 the first randomised trial on stroke unit care was published (8). During the next decades several randomised trials on stroke unit care were performed (9). Hospital organisation seems to play an important role, and there is strong evidence today that treatment in dedicated stroke units in the acute phase has been shown to be clearly superior to treatment in a general ward for several important outcomes, e.g. mortality, functional dependency and need for institutional long-term care (9-19). There is consensus that Stroke Unit treatment should be the first link in the chain of care (20).

However, the question about the optimal organisation of post-discharge stroke rehabilitation has arisen during the recent years, and the answers are still not well documented. A few randomised trials of early supported hospital discharge (ESD) and further rehabilitation at home have documented benefits, mostly in reduced length of hospital stay (21). However, the organisation of the multidisciplinary team and the selection of patients in these trials are varying, and there are great differences. There

exists today no single recommendation in relation to how to do the follow-up rehabilitation in the most effective way.

The present thesis is based on methods and results from a randomised controlled trial of early supported discharge service for patients at the Stroke Unit at St. Olavs Hospital, Trondheim University Hospital. We have compared Extended Stroke Unit Service (ESUS) with more traditional post stroke treatment on short and long-term mortality and disability *(papers I and II)*, quality of life *(paper III)* and resource use and costs *(paper IV)* during the first year following a stroke. We have also explored the association between stroke severity and an eventually benefit of ESUS versus Ordinary Stroke Unit Care (OSUS) *(paper I, II, IV)*.

1.2. Epidemiology

The first population-based stroke register in Norway (22) indicates that we would expect about 10000 first ever stroke and 3400 recurrent stroke to occur every year in Norway. The incidence of stroke increased exponentially by age, and about 65% of the stroke victims were 75 years and older (22). In the future we will expect change in the age distribution of the population in Norway and a projected increase in the population older than 70 years, caused by the increase in childbirths after the Second World War. This will have a major implication for future understanding of the epidemiology of stroke, with an expected increase to about 1 million aged 67 and older by 2050 (23). In 2001 the population older than 70 years was about 520 000 (23). A comparison between Norway and other West-European countries did not indicate major regional variations in stroke incidence (24), but the MONICA project has reported a higher incidence of stroke among populations in eastern Europe than in western Europe (25).

The prevalence of stroke is difficult to measure, and the estimates reported in the literature vary a lot (26,27). But two well-designed population-based studies measuring prevalence in the 90's agreed well (28,29), with estimates of the prevalence rate on 960 per 100 000 in the population aged $\geq$ 20 years when standardized to the entire European population (30). Like the incidence the prevalence increases rapidly with age, with an estimated increase from about 1% at age 50 to about 10% in the age group over 80 years.

The mortality rate of stroke per year in Norway based on the national cause of death register is approximately 5500 (31), which are 12% of all deaths and the third leading cause of death in our country.

1.3. Definition of stroke:

Stroke is defined according to the World Health Organisation criteria as "Rapid developed clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than of vascular origin (32).

1.4. Definition of a stroke unit

There exist different definitions and descriptions of what a stroke unit is, but the organisation of care for the stroke patients in hospital are common for all of them. The Stroke Unit Trialist's Collaboration (SUTC) defines "stroke unit" as **"Organised specialists in-patient stroke care"**, and divide the way of treatment in 3 different categories as *a)* dedicated stroke units, *b)* mixed assessment/rehabilitation unit and *c)* stroke team (9). See further description in chapter 2.3.

1.5. Definition of early supported discharge:

The history of the early supported discharge service is short, and the concept seems to hold different types of treatment. The services have variously been termed "early supported discharge schemes, "accelerated discharge schemes" and "post discharge support service". One of the subgroups in the Cochrane collaboration is the Early supported discharge trialists' (ESDT) (21), set up to compile all information on clinical trials according to ESD. They define this system of care as an Early Supported Discharge services that try to develop a service that aims to accelerate the discharge home of patients already admitted to hospital. The term "Extended Stroke Unit Service" used in this thesis has much in common with the definition of ESD-service, but our stroke team found this term more adequate to use because not all the patients in this trial were discharged directly to home. Some of them were discharged to other institutions, but they got follow-up service as well.

1.6. Definition of inpatient rehabilitation

In-patient rehabilitation in this thesis is defined as rehabilitation that took place when the patient stayed in an institution 24 hours a day, i.e. rehabilitation clinic and residential institution.

1.7. Definition of outpatient rehabilitation

Outpatient rehabilitation is in this thesis defined as rehabilitation that took place when the patient had their base at home. It represent a group of different out-patient services including rehabilitation in a day clinic or adult day care, visits by home nursing service, visit to general practitioner, visit to physiotherapist, visit to occupational therapist, and visit to speech therapist.

2.0 Background

2.1 Generally

The effectiveness of treatment in stroke units for acute stroke patients is well documented and recommended for all stroke patients in our country (31). The first stroke unit (SU) in Norway was established at Aker Hospital, Oslo, during 1983 (33). The first stroke unit trial to show statistically significant effects on several outcomes was published in Trondheim in 1991 (19). This unit was a combined comprehensive stroke unit that offered both acute care and rehabilitation (see chapter 2.3.) However, the long-term consequences after stroke and the challenges in which the subsequent care should be organised, was insufficiently described in the literature worldwide when we started planning our trial in 1995. Some trials had focused on the opposite alternatives to in-patient care by preventing stroke patients from being admitted to hospital by having an alternative "hospital at home" service. This treatment did not show benefits (34). Some trials had compared rehabilitation in day clinics or in 24-hour institutions with rehabilitation at home (35-39), but only one of them documented a significant positive effect of rehabilitation at home (35). Since the last part of the 90's one approach has been to develop services that could accelerate the discharge of patients already admitted to hospital. This is the kind of service that has been described with different terms, as "post discharge support services", "early supported discharge schemes", and "accelerated discharge schemes" (21).

2.2. Background for the Extended Stroke Unit Service trial in Trondheim:

At St. Olavs Hospital, Trondheim University Hospital we already had an evidence based stroke unit treatment based on a combined approach focusing both on acute care

and on early rehabilitation (19) when we started planning our extended stroke unit

service trial in 1995. This stroke unit is defined to be one of the units that have

showed the most convincing results (40) in acute stroke care. Hence, we might be

allowed to classify the acute treatment as the "gold standard" acute care. However, we

also knew that the follow-up treatment after discharge from the stroke unit had several

weaknesses. Searching in the literature about evidence-based management in the

follow-up of stroke patients showed that further research was necessary. We designed

a trial at our stroke unit with the objective to organise the post acute stroke care in a

better way to improve the patient's outcome without increasing the use of health

resources. The extended stroke unit service we established, greatly emphasized the

post-discharge service, and can be regarded as a further development of stroke unit

care as illustrated in **figure 1**.

Stroke –The chain of care

Stroke unit **Follow-up**

Acute stroke   **Active life**

Diagnosis
Observation
Acute treatment
Acute rehabilitation

Further rehabilitation
Further support
Secondary prophylaxis
Cooperation:
Mobile team
Specialist care
Primary health care

Trondheim: Stroke unit trial   **The extended stroke unit trial**

2.3. The stroke unit at St. Olavs Hospital.

SUTC categorised such a unit as: "*a dedicated combined acute / rehabilitation stroke unit which accepts patients acutely for acute treatment combined with early rehabilitation for a period of at least 1-2 weeks*" (9).

The aim of these combined units is to offer a systematic non-intensive acute care, together with an early quite intensive rehabilitation care. In the stroke unit at St. Olavs Hospital there is a program for diagnostic evaluation, systematic observation, acute treatment and acute rehabilitation. The aim is: "identifying, reducing or solving existing problems; discovering the patients' resources; enhancing recovery; and preventing the occurrence of potential problems at different stages of their illness" (41). The unit aim to have a holistic evaluation of the patient, and not only focus on the focal lesion in the brain. They also have an observation program with repeated assessments of neurological deficits and vital signs to receive information about eventually changes continuously. The nursing staff works in close co-operation with the physiotherapist and the physicians and the staff is educated to carry out the acute treatment and rehabilitation plan 24 hours a day.

Recommendation from "The Stroke Unit Trialist's in Trondheim" (41)**:**

"Acute stroke patients need acute care and acute rehabilitation, and they need both elements simultaneously during the first few hours/days. Hence, a combined SU model may be the most appropriate model for effective management of stroke patients. The model of a combined unit which is developed in Trondheim has produced some of the most favourable results of SU care, and is one of the models which have described the treatment and rehabilitation program in most details. This model of SU care may

therefore be a possible guideline for other hospitals which are going to establish

stroke units."

The Program for diagnostic evaluation, observation, acute treatment, and acute

rehabilitation in the stroke unit are shown in **table 1**.

TABLE 1. Program for diagnostic evaluation, observation, acute treatment, and acute rehabilitation in the stroke unit.

Time	Diagnosis	Observation	Acute treatment	Acute rehabilitation
0-72 hours	Clin exam.	BP	I.V.saline solution	Stimulation
	CT scan	Heart rate	Oxygen	Mobilisation
	ECG	Temp	Antipyretics	Sitting, out of bed
	Clin Chemistry	SSS		
	Ultrasound	BP	Sec.prophylaxis	Mobilisation
	Carotid arteries*	Heart rate	Early treatment of complications	Training, sitting, walking
	Heart*	Temp		
	Others*	SSS	I.V.fluid*	Training in ADL
	Clin.Chemistry			
Day 3 – Discharge	Further investigations when necessary	Exam complications SSS and BI Day 7 and discharge	Further treatment Sec. prophylaxis Treatment of complications	Further task oriented training Discharge planning

*Selected patients
BP indicate blood pressure; CT, computer tomography; SSS, Scandinavian Stroke Scale; ADL, activities of daily living; Sec, secondary; Exam, examination; d, day and I.V., intravenous; BI, Barthel Index.

Adapted and modified after Indredavik B. Thesis 156. Faculty of Medicine, NTNU. TAPIR 1999.

2.4. The prepatation of the extended stroke unit service trial

In 1994 a delegation with clinicians from the stroke unit at St. Olavs Hospital travelled to Norrköping in Sweden to see how they treated their stroke patients after the acute stage, during transfer from stroke unit to short-term rehabilitation unit or day clinic at the same hospital or discharge to home (42,43).

The stroke research group organised a steering committee and a planning committee with representatives from our collaborating partners in the primary health care service (PHCS) and the different institutions. We established a net of "contact persons" in the primary health care system, which were invited to practice at the SU for a period of 14 days and were "educated" in the holistic way of thinking during seminars. We also had a skills upgrading of the personnel in the SU to secure the communication lines and the multidisciplinary teamwork. A lot of information and education meetings in the municipality and in the institutions at different levels were also a part of the preparation and accomplishment in the trial together with an information and status book about the trial, which was updated every month during the entire project period. The communication between the different health care levels in the "stroke line" were emphasised to be of great importance in the trial.

2.5. User survey and pilot study:

Before the start of the trial, we performed a user survey with stroke patients and relatives who was and has been admitted to the stroke unit at St. Olavs Hospital. The survey implemented 20 patients, evaluated by structured interview and standardised schemes.

The aims were*:*

 - To explore the patients satisfaction with the health care service.

- To identify eventually change in quality of life after stroke

- To assess the need for help and support for the patients

- To use the information to construct an extended stroke unit service for stroke

  patients.

Results:

- 80% of the patients reported reduced QoL after stroke

- 70% of the patients requested more follow-up from the hospital after discharge

- 60% of the patients and 70% of their relatives described the transfer from hospital to
the primary health care service, and in particularly the first time after discharge, as the
most difficult period.

- 75% of the patients and their relatives requested more information about their illness
and the consequences.

We also carried out a pilot study with 24 patients followed in one month after
discharge from hospital. In this study the communication program with the PHCS and
the different evaluation tools were tried out.

*We concluded that the follow-up program for stroke patients living in Trondheim had
some defects, especially in the difficult transfer from the hospital to the home
environment, and the survey gave valuable information about important attempts in a
new chain of care.*

3.0. Objectives and hypothesis:

3.1. The main aims of this thesis were:

1. To construct a stroke service system in co-operation between the Hospital and the Primary Health Care Service.

2. To perform a trial to evaluate the short and long- term effects of an extended stroke unit service co-ordinated by a stroke team compared to traditional stroke care in terms of functional disability and Quality of Life. *(paper I, II, III)*

3. To assess the resource use and costs of the ESUS compared to the OSUS during the first year post-stroke. *(paper IV)*

5. To be able to make guidelines about effective organisation of follow-up stroke care after discharge from hospital.

3.2. Hypothesis:

The trial was designed to test the following hypothesis:

1. Early supported discharge from hospital coordinated by a mobile stroke team, with focus on home-based rehabilitation and co-operation with the Primary Health Care Service System, improve functional outcome for stroke patients.

2. Rehabilitation and training at home or in day clinics are more effective for stroke patients than 24-hour inpatient rehabilitation in a clinic, if the patient does not need continuous care and support 24 hours a day.

4.0. Patients and methods:

4.1. Study population

During the period February 1995 to July 1997, 468 patients from the city of Trondheim, aged 60 years or older with acute stroke admitted to the Stroke Unit at St. Olavs Hospital in Trondheim were screened for inclusion in the trial. The inclusions were stopped two months during summer each year. Hence, the total time of inclusion was 24 months. Most of the patients below 60 years (that represent about 10% of the stroke patients) were admitted to another department at our hospital and were not available for inclusion in this trial.

The criteria for inclusion were chosen with the main aim to investigate an as unselected population as possible, and all patients with sign and symptoms of acute stroke according to the WHO definition (32) were screened for inclusion.

The reasons for exclusion (148 patients) were: SSS < 2 or SSS>57 (105 patients); onset of symptoms more than 7 days before the screening for inclusion (14 patients); admission to the unit more than 72 hours before the screening for inclusion (3 patients); included in other trials (12 patients); admitted from nursing homes (4 patients); no informed consent (10 patients).

Unconscious patients could not be included because we needed informed consent, and patients living in nursing homes were not included because one of the main objectives in this trial was to find the proportion of patients able to return to their own homes after their stroke. Inclusion criteria and reasons for exclusion are also shown in **figure 2.**

Fig 2

The original randomised design was the base for meeting the aims and testing the hypothesis. The 320 patients included in the trial, were all included in the "intention to treat analyses" (described in chapter 4.4.3.1) (paper I, II, IV). The 258 patients with measures on QoL after 52 weeks were included in the "on treatment analyses" (*paper III*). The baseline characteristics are shown in **table 2,** and the proportion of patients in different treatment groups by severity in **table 3**.

TABLE 2. Baseline characteristics[1] of the patients allocated to the Extended Stroke Unit Service (ESUS) and to the Ordinary Stroke Unit Service (OSUS).

Characteristic	ESUS (*n* =160)	OSUS (*n* =160)
Age,y (mean/median)	74.0/74.5	73.8/74.0
Sex (% female)	46	56
Living alone (%)	41	43
Diagnoses (%)		
Nonembolic infarction	68.8	65.0
Embolic infarction	22.5	23.1
Hemorrhage	7.5	10.0
Other	1.2	1.9
Medical History (%)		
TIA	13	14
Stroke	12	16
Hypertension	33	35
Myocardial infarction	19	16
Atrial fibrillation	17	15
Diabetes	15	12
Functional state		
SSS*(mean/median)	43.6 / 48.0	43.2 / 47.0
BI† (mean/median)	60.4 / 65.0	58.5 / 60.0
RS‡ (mean/median)	3.3 / 4.0	3.4 / 4.0

* SSS = Scandinavian Stroke Scale was assessed at inclusion before randomization
† BI = Barthel Index was assessed within 24 hours after randomization
‡ RS = Rankin Scale was assessed within 24 hours after randomization
[1] No significant differences between the groups in baseline characteristics

TABLE 3. Proportion of patients in the two treatment groups by severity of stroke at baseline[1].

	ESUS (%) n=160	OSUS (%) n=160
Mild Baseline SSS 53-58	39 (24.4)	38 (23.6)
Moderate Baseline SSS 40-52	81 (50.6)	74 (46.4)
Severe Baseline SSS <40	40 (25.0)	48 (30.0)

SSS indicates Scandinavian Stroke Scale
[1] No significant differences between the groups

4.2. Study design and randomisation procedures

We wanted in this trial to evaluate the short-term and long-term effects of acute stroke unit care combined with early supported discharge in a scientific way. The design was strict experimental and had a prospective randomised controlled design (44-46) as illustrated in **figure 2**. After consent, randomisation was restricted in permuted blocks with random numbers tables provide in sealed opaque envelopes. The size of the blocks was 6, 8 and10 and the sequences of the different blocks where unknown to all the trialists. Another department at the St. Olav's University Hospital in Trondheim organised the entire randomisation and inclusion procedure. They generated the allocation sequences and assigned the participants to their groups. No stratification was used. Independent and blinded assessors specially trained in the use of all the outcome measures performed the assessments at 6 weeks, 26 weeks and 52 weeks.

4.3. The mobile ESD team

The mobile team (MT) in the present trial was specially designed to organise the follow up, cooperate with the PHCS and to offer support during the first period after discharge from the stroke unit. They were responsible for making an as "seamless transfer" as possible between the different stages in the health care service. The team was hospital-based and was defined as a coordinated multidisciplinary ESD team (21). They were represented in all stages in the chain of care **(figure 3),** either the patient was discharge to home, rehabilitation clinic or nursing home, and were responsible to establish a service and support system that allowed the patient to live at home as soon as possible, if possible. Most of the service after discharge was offered by trained staff in the community healthcare system, coordinated by the mobile team. For some patients with more extensive needs, the team offered training and support in addition to service from other agencies. The team consisted of a nurse, an occupational therapist, a physiotherapist and part time service of a physician. They also had access to speech therapy. One of the therapists acted as a key worker (case-manager) and was responsible for the patient and in between the team they used each other's qualifications to solve current problems and challenges. The main points in the ESUS and the duty assignment for the mobile team are shown in **figure 4** and further described in paper I and II.

4.4. The organisation of care for ESUS and OSUS in the stroke unit.

All patients in both groups were offered the "gold-standard" treatment in the Stroke Unit (19). When the patient arrived, the different members of the stroke team in the unit did the diagnostic and functional evaluation immediately. The acute team was a

Figure 3. The mobile ESD team in the chain of care.
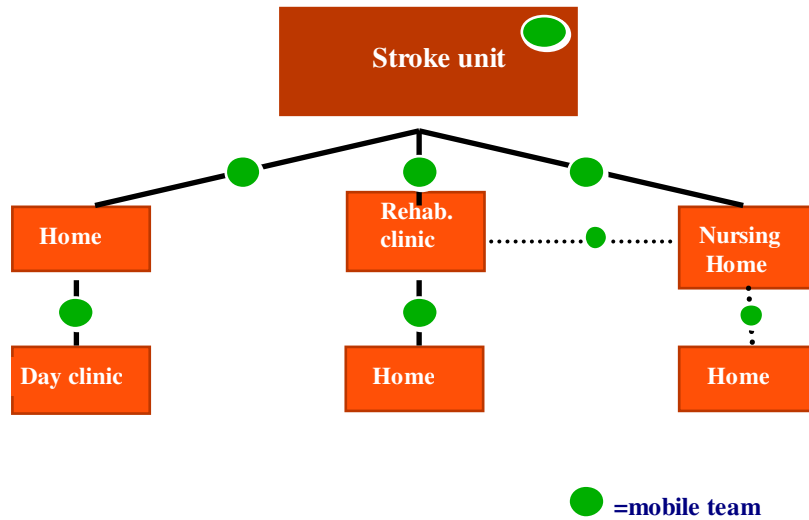
Figure 4: The intervention line for the Extended stroke unit service (ESUS)
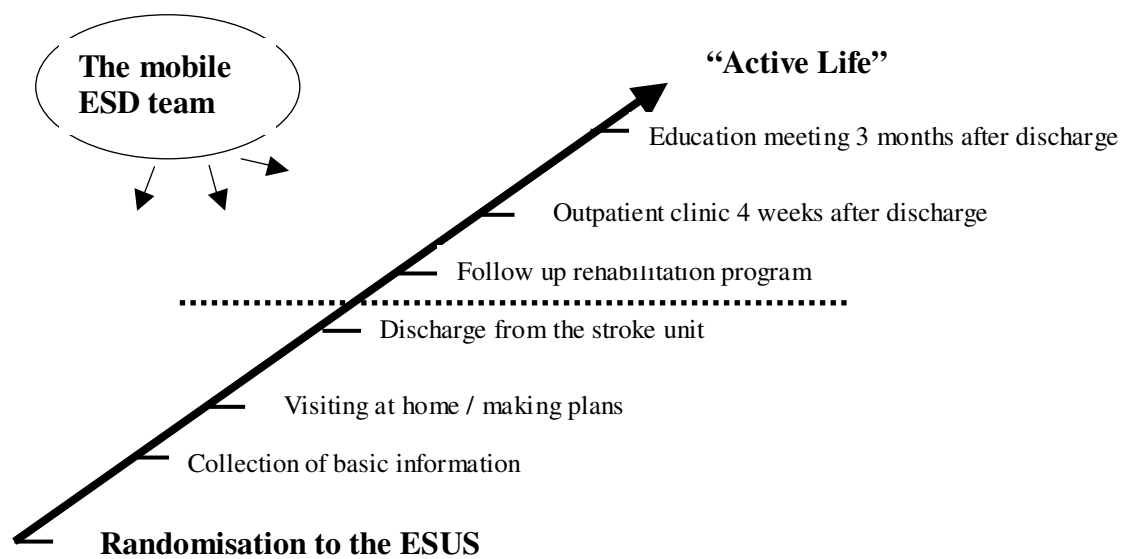
small one consisting of a stroke nurse, a physiotherapist responsible for the mobilisation / training program and a physician. The team had the first day an "acute – meeting" to plan the initial treatment. A multidisciplinary "planning-meeting" took place once a week, to decide the further treatment and rehabilitation program for the patients and the level of service needed. A discharge meeting with patients and their relatives was arranged before they left the stroke unit. The initial treatment was the same for both groups, as previously described. However, some differences existed because the MT started their work as soon as the patient was included in the trial. This contact in the stroke unit consisted of collecting basic information from the patient and their relatives, explaining their role to the patients, organizing contact with the PHCS and starting to plan the further follow-up as early as possible.

4.5. Treatment program for the OSUS

The patients in the OSUS group were offered the standardized treatment for stroke patients in our stroke unit, which has shown to be very beneficial, compared to treatment in general medical ward (19,47-50). OSUS could be defined as acute stroke treatment according to evidence-based recommendation (9). After discharge from the stroke unit, the PHCS were responsible for all the further follow-up. The communication between the Hospital and the PHCS varied a lot, from satisfactorily in some situations to insufficient in other. Traditionally the patients were discharged either to further in-patient rehabilitation or to their homes, with a relative great importance to in-patient rehabilitation. They got the follow-up, which until then had been the standard way of treatment after discharge from SU in our municipality as well as in other Norwegian municipalities. The differences between the follow-up for the ESUS and OSUS are illustrated in **figure 5.**

Figure 5: Study Design II for the Extended stroke unit service (ESUS) and the Ordinary stroke unit service (OSUS).
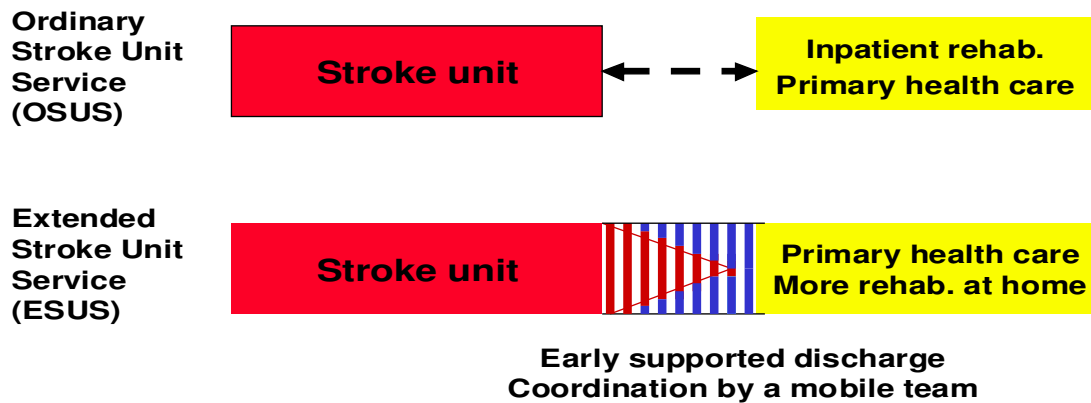
4.6. Treatment program for the ESUS

The patients in the ESUS were offered the same standardised stroke unit treatment as the patients in the OSUS in the acute stage. As described in chapter 4.4, the team started their work as soon as possible after the inclusion. Concrete communication lines and follow-up schemes with control routines were developed, with the intention to optimise recovery, shorten the need for institutional care and reset the patient to an active life at home as soon as possible. An organised planning together with the patient, relatives, staff in the stroke unit and the PHCS made the basis for the further follow-up. The aim was to get a possibility to "manage" the resources and offers to the patients who needed it most at the time when they needed it. The idea was that to give priority in the initial phase would give patients and relatives a substantial secure platform and less need for help later.

At least one home-visit during the first week was a part of the intervention for most of the patients (80%). For a few patients with the most severe stroke, it was not possible to perform a home-visit during the first acute stage. They had to wait until the patients were medically stabilised.

The intention with this early visit was to get a picture of the scope of the necessary rehabilitation process, to be able to put the aims in concrete terms, and to motivate patients and relatives to see the possibilities in an enriched environment.

A "seamless transfer" between different areas in the health care service was emphasised to aspire to a more continued rehabilitation process. The patient never left the Hospital or Rehabilitation clinic without a companying person (the key worker) from the MT, which could bring the necessary medical information and aims for the further action program directly to the personal at the next step in the chain of care. One month after discharge from Hospital or Rehabilitation clinic we try to phase out the close relationship between the patient and their key worker in the MT, among other factors to avoid an addiction problem. We also emphasised for the patient and their relatives the importance to return to the daily routine and being a "person" rather than a "patient" after a period. Further details of the intervention are described in paper I.

4.7. Assessments of outcome

The International Classification of Impairments, Disabilities and Handicaps (ICIDH) was published in 1980 (51) as a model of systematic classification of illness and functioning in order to classify and categorize the data that may be collected, and measure the results. This system has recently been revised, and the overall objective is

to provide a standardised vocabulary for the description and for research of health outcomes in terms of body, person, or social function (52). The ICIDH offers an important theoretical perspective to research, although it has been said to have weaknesses, especially to the concept of quality of life (53). The term "functional outcome" which is often used in this thesis is not described by the ICIDH. We have used the term according to ADL (Barthel Index) and Rankin scale, as a term of disability.

In general there has been little consistency and no consensus to how the outcome of stroke should be measured (3), even though it is developed a number of stroke scales for use in clinical trials (54). That complicates the interpretation of the results and the comparison between studies. The main issue is, however, to choose instruments in accordance with the research question and consistent with the aims of the intervention or treatment to be evaluated. Consistency in the use of appropriate measures of outcome, the methods of analyses and the timing of measurements would have many benefits for the stroke research (55). Continued use of several of instruments that may not be specific or sensitive enough may result in more questions than answers, and may easily become an obstacle to further research.

When we started the trial and decided which outcomes that were relevant to choose, we did not have many references in this field, because the history of ESD research was short. However, we had experience from a randomised controlled trial (RCT) for stroke patients (41) and wanted a continuance, if possible, of some of the scales measurements that already were chosen and well known at the stroke unit. Some guidelines are essential when choosing outcomes tests and scales. The evidence of reliability and validity is vital for all outcome measures, to ensure confidence in their scientific robustness (56). The reliability of the tests is a measure of to what degree

the data are identical if they are sampled repeatedly under the same conditions (57), and should be emphasized. The validity is the degree to which the measure reflects what it is intended to measure (3), and important in this kind of trials. The validity of this thesis will be further described in chapter 6.2. The power, which refers to the ability to identify differences between the groups, (3) is also important. The fact that the tests had to be easy to complete for the patients was essential in our trial, and the practical usefulness for the clinician was also something we had in mind.

Measures like mortality, morbidity, recurrence, length of stay in hospital and measures of activity in different forms are frequently used in stroke research (58,59). The methods used for evaluation and the point in time for the different assessments are shown in **table 4**.

According to primary and secondary outcome scales in this thesis, our use of primary outcome in the different papers may lead to some confusion. The main primary outcome of the trial was modified Rankin Scale (mRS) (60) and Barthel Index (BI) (61) at 26 weeks *(paper I)*, which means that the power calculation was based upon this primary outcome. We have used the modified Rankin Scale at 52 weeks as the primary functional outcome in the long-term analyses *(paper II)*. The Nottingham Health Profile (NHP) (62) was the primary outcome of long-term Quality of Life *(paper III)*.

For the modified Rankin Scale and the Nottingham Health Profile at 52 weeks we made no power calculations and we are aware that the use of the term "primary outcome" in these follow-up analyses might be questioned. We wanted a hierarchical structure of the analysis also in the follow-up analysis, and that is why we have used the term "primary outcome". All the analyses at 26 and 52 weeks were pre-defined

Table 4

and described in the protocol, except the sub-group analysis at 26 weeks for patients

with moderate and severe stroke at baseline (SSS >2 and $\leq$ 52).

4.7.1. Primary outcomes scales

Barthel Index (BI) was developed in 1965 (61), and later modified as a scoring

technique that measures the patient's performance in ten activities of daily living (63).

It is the most commonly selected measure of basic activities of daily living in stroke

research today (3,64,65). BI is an ordinal scale with maximum score of 100, and it is

considered to have good reliability and validity (56,64,66). The reliability is known to

be high even when data are collected by indirect observation (67). The score

associates to many other measures such as stroke severity, social activities and

mortality, so the index also has predictive and concurrent validity (68). The index is

not very precise, but quite sensitive to detect improvement. A problem with this scale

is the insensitivity to small changes in functional status, and its significant ceiling-

effects (65,69). That may represent a problem in long-term follow up trials (as in

paper II in this thesis) and in measurements of patients with mild stroke. Although the

BI is the most common measure, the cut-off scores used to differentiate outcomes are

recorded to be defined in 7 different ways (55,70,71). However, according to Duncan

et al (55), the cut off point $\geq$95 (as used in *paper I and II)* is together with cut off

point $\geq$ 60 the most frequently used in stroke studies. The BI is used as primary

outcome measure in paper I and as secondary outcome measure in paper II.

Rankin Scale (RS) (60) is another of the most frequently used scale to assess

functional outcome and disability in clinical stroke trials. Initially, the scale consists

of 5 grades, from 1 to 5, with 1 corresponding to no symptoms and 5 corresponding to

severe disability. The scale has the two great virtues of simplicity and reliability making it ideal for many trials (72,73). It is also validated (55). The criticism about this scale is that it is inherently insensitive, it mixes objective and subjective items and it spans impairment, disability and handicap (64,69). The modified version of the RS is called mRS and consists of 6 grades including a class for "death". The modified Rankin Scale (mRS) is widely used to assess global outcome after stroke. Dichotomising scales as in this thesis with mRS $\leq$ 2 defined as favourable outcome are commonly used and have many advantages, but is also criticised for reducing the outcome information and may limit the ability to detect a significant shift in disability (55,74). The inter-rater reliability of the mRS is not shown to be substantial (75). The mRS is used as primary outcome measure in paper I and paper II.

Quality of Life

QoL has been defined by the World Health Organization Quality of Life Group (WHOQOL) as "individuals' perceptions of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations, standards and concerns" (76). In stroke research, assessment of quality of life is becoming increasingly common the recent years, and there has been focused on the necessity of using QoL assessments to get a clear and comprehensive evaluation of efficacy in different stroke trials (69,77,78).

It has been difficult to agree on a uniform way to measure Quality of Life for stroke patients, and no single measurement scale is developed. The lack of general agreement for standardized methods for QoL assessment in stroke patients is a difficult challenge. The concept of QoL is not clearly defined (65). Some define QoL as the patients' own perception, satisfaction and well being (79,80), and other has a

more health related approach (81). Hence, it seems that a multidimensional approach comprising 3 broad domains (physical, mental and social) is important (48,82-84). The evidence of validity and reliability should be the first considerations, together with appropriateness and comprehensiveness (78).

The Nottingham Health Profile scale (NHP) (62) was used to assess quality of life at one year in this thesis. The NHP measures emotional, social and physical distress. It quantifies health status and has been used for the general evaluation of health or health-related QoL. It emphasizes subjective aspects of health assessment. NHP part 1 contains 38 items in six sections: pain, emotional reactions, sleep, physical mobility, social isolation and energy level. Each item reflects departures from normal and the items are weighted to reflect their importance. Part I of the NHP forms a profile of six scores corresponding to the different sections of the questionnaire, and there is no single summary index. Each component is weighted to give a score 0-100 (85). Part II of the Profile relates to seven areas of task performance most affected by health. This section has no weights but a summary statistic. These data are of more limited use. We have also used a global NHP score (86). The use of this total summary score can be discussed (3), but it may give some important information about the total life situation for the patient.

When we started planning this trial in the 90's, this scale was the most frequently used in stroke trials. Today, more systematic reviews and knowledge have been published according to the different qualities of different outcomes scales (57,78,84) and we might would have considered choosing another scale. The NHP was used as primary outcome measure in paper III and the advantages and disadvantages with the NHP are discussed in this paper.

4.7.2. Secondary outcomes scales.

Proportion of patients at Home, in Institution and Diseased.

The differences between the groups in the proportion of patients at Home, in Institution and Diseased after 26 weeks *(paper I)* and after 52 weeks *(paper II)* were used as secondary outcomes together with the differences in length of stay in institutions *(paper I)*. Indirectly, it says something about the patient's disability, but we preferred to use the BI and mRS as a more directly measures on functional ability and activities of daily living as the primary outcomes.

The length of stay in institutions were measured as length of inpatient stay before discharge to final residence, which means that at the day when a patient for example were decided to live permanently in a Nursing Home, we ended the registration. The length of "institutional stay" presented in papers I and II, included the initial hospital stay and initial stay in rehabilitation clinic. The "discharge day" from hospital was not included in the initial hospital length of stay. In the "length of inpatient rehabilitation" presented in paper IV the residential institution and readmissions in rehabilitation clinic were supplemented. The registration started at the day of admission to hospital, and not at the day of inclusion in the trial. The date of transfer from one "care level" to another was recorded at the place the patient was discharged from *(paper IV)*. The data on length of stay in hospital and other institutions were recorded during data registration program at the hospital and monthly reports from the other institutions. The deaths were recorded during a monthly death reports from the municipality Registry Office.

The Frenchay Activity Index (FAI) (87) has been developed specifically for stroke patients, and according to the ICIDH-2 (50,51), the FAI reflects aspects of activities

(disability) and also of participation (handicap). It measures more complex physical activities and social functioning with a score for each of the 15 items (max score 60). It exhibits reliability and validity and has been shown to be responsive to change (78). It can be both self-and interviewer-administrated, and also the inter-rater reliability between patients and relatives has been evaluated as good (88-90). The scale has also been used to measure QoL for stroke patients, and it is a stroke-specific measure that can be used to successfully assess QoL with proxy respondents (78). The FAI is used as secondary outcome in paper III.

The Montgomery - Åsberg Depression Scale (MADRS) (91) is a rating scale for mood disorders. It consists of 10 items (0-6) and avoids emphasis on somatic symptomatology. The scale has the considerable advantage of brevity and ease of administration (92). The scale exhibited construct and concurrent validity (93). The MADRS was used as secondary outcome in paper III.

The Mini Mental State Examination (MMSE) (94) is a simplified scored form of the cognitive mental status examination and includes eleven questions and a sum score of 30. The domains including orientation, registration of words, attention, calculation, recall, language and visual construction. The test is widely used for screening, but is criticised for may misclassify patients with aphasia (95). The test is provided to be reliable and valid. It is useful in quantitatively estimating the severity of cognitive impairment, in serially documenting cognitive changes. The MMSE was used as secondary outcome in paper III.

The Caregivers Strain Index (CSI) (96) is a validated 13 items strain index developed to measure the burden of the patient's illness on the caregiver. High score indicated a low level of burden, and the score ranges from 13 to 26. CSI is a brief, easily administrated instrument that identifies strain of informal care providers. The CSI was used as secondary outcome in paper III.

The Scandinavian Stroke Scale (97) was used to quantify neurological dysfunction in this trial. The scale are frequently used in stroke trials to assess the primarily body function or impairment, to quantify neurological deficits, to measure recovery, predicting outcome and to compare stroke severity of patient groups at baseline (97,98). The SSS contents of 2 parts, a prognostic score and a long-term score. We used the total score, which included the items from both the prognostic score and the long-term score and consist of 9 items and a maximum score of 58 (99). SSS is simple to use and the validation and reliability are quite high. (54,70,97,98,100). The scale was used to assess the severity of stroke at baseline in our secondary analyses *(paper I and II)*.

4.7.3. Assessments of resource use and costs

The resource implication and costs of the ESD-service are important in relation to how relevant the service is to take into use. Stroke imposes a considerable economic burden on the society and the costs are of vital importance for making decision about use of different treatment methods.

Resource use:

We recorded all the different types of inpatient and outpatient health services the patients in this trial received in the period from inclusion to one year after inclusion. The different services recorded are listed in paper III (table 1). The type, frequency and number of services were recorded during **"health service registration cards"** given to the patients, their family and their health workers each month **(appendix 2).** They had the responsibility to filled them out exact each time they were offered some of the services. The study group developed these registration cards, because we could not find this type of prospective registration system used in other stroke trials. As a security system we used the data registration system in the primary health care system (GERIX) (101) when available. The length of institutional stay was recorded as described in chapter 4.7.2.

Costs

An independent research institution in Norway, SINTEF Health Research, calculated the costs of all types of health services recorded in the trial. The work was complicated because the different institution did not have exact information about the unit costs and for some health services they had to find national costs estimates. We chose to use estimates of average costs per service type, a so-called "gross-costing" (102) rather than a detailed micro costing of services. Costs were measured as service costs, which mean a combination of tariffs and calculated average costs. The cost is presented as total mean services costs for all 320 patients.

We categorized the different types of the 15 health services into six groups as follows:

1) Acute care costs represent the costs for the initial stay in the stroke unit. It was measured as cost per inpatient day, and adjusted for the patients Diagnoses Related Group (DRG). A Diagnosis Related Groups specific cost is available in Norway, and these DRG's are used as the basis for hospital financing. This cost is thus a national average cost. (Our stroke unit has been one of the departments where these national DRG cost estimations have been performed.)

2) Acute care readmissions costs represent all readmissions to hospital (independent of reason) during the first year post stroke, and were measured in the same way as the acute care costs.

3) Inpatient rehabilitation costs represent the costs for inpatient care in rehabilitation clinic or in residential institution. Detailed cost data for this service were available.

4) Home-based rehabilitation costs represent a group of different outpatient services including rehabilitation in a day clinic or adult day care, visits by home nursing service, use of general practitioner, physiotherapist, occupational therapist, speech therapist and use of automatic warning aid. Tariffs were used for some of these services, when detailed costs were not available.

5) Permanent institutionalisation costs represent the costs for the group of patients who were discharged to a nursing home or another form of "assisted living". The costs calculated for a nursing home were detailed costs while the other was tariff cost.

6) The mobile team costs.

The estimated total costs of the mobile team are defined and recorded as wage costs per year for the four members of the team.

The mobile team costs in the analyses are overall costs measured as a total sum for each patient during the first year in the ESUS group, and are the same for each

patient, regardless of whether they have had more or less service from the mobile team. We do not have good enough information to select the costs for each patient, but these costs represent a small proportion of the total costs, and we do not think it will have any important influence of the results. In the sub-analyses of costs stratified in time periods *(paper IV)* we have entered the mobile team costs in the first 6 weeks based on the most intensive intervention period.

4.8. Statistical analysis.

For the preparation and accomplishment of this trial we have received statistical guidance from the Life Insurance Medical Statistic Institute at Ullevål Hospital in Oslo. For the preparation of paper II and paper III, we have got statistical guidance from Unit for Applied Clinical Research, Faculty of Medicine, the Norwegian University of Science and Technology.

4.8.1 Sample size estimation

The Rankin Scale and Barthel Index 26 weeks after the onset of stroke was the main primary outcome in this trial, and the basis for the sample size calculation. With an estimated rate of success of 15% (differences between the groups), power 80%, and significance level 0.05, we estimated a sample size of 320 patients (45,103). This was also the upper size for our ability to run this trial in our centre, because we had some limitations on time, funds and admission of patients. When we planned this trial we did not have results from other trials, and therefore we had to make our own decision about the projected effect of this intervention based on a clinically pragmatic approach. Our calculation was partly based on results from the previous acute stroke unit care trial (19).

4.8.2. Statistics of the baseline data

The statistical software program used was SPSS 10-7 (SPSS Inc., Chicago, IL).

Group homogeneity was analysed with the Persons X^2 test for category data like

medical history, sex, distribution of diagnoses and living condition.

Mann-Whitney U test (non-parametric test) was used to compare the groups for

variables not normally distributed, as age and severity of stroke according to the SSS-

score at baseline and the differences in BI and RS assessed within 24 hours after

randomisation (61). The significance level for all the analyses in this trial was set to

0,05.

4.8.3. Statistical evaluation of outcomes

4.8.3.1. Intention to treat analyses

The intention to treat (103) population was used in all the main analyses on the

categorized BI and mRS *(paper I-II)*. If a patient had a missing last value on BI or

mRS we used all other available information to calculate their functional level or we

carried forward their baseline values. All patients had participated in at least 2

assessments, and with the results from the last assessment, sometimes combined with

telephone interview and information from readmissions, it was possible to categorise

quite precisely their functional level.

Regarding the effect of ESUS compared to OSUS related to long-term QoL, intention

to treat analyses was not feasible, because the NHP we used as a measure of QoL

require a minimum of communication with the patients (3,62,104). Hence, for our

QoL analyses we had to select patients with the ability to speak and to understand.

(paper III).

There were no significant differences in the number of patients excluded and the missing documentation between the groups.

4.8.3.2. Multiple regression analyses

We used multivariable regression methods to adjust for differences in baseline characteristics between the groups and to analyse the odds ratio (OR) for independence. The type of the regression model depends on the distribution of the dependent variable (y). The multivariable regression modelling gives the opportunity to include and control for variables with potential confounding effects. A confounder is a variable that is both associated with the exposure and, independent of that, is associated with disease (105). In our analyses confounding is associated with outcome, and we have adjusted for confounders because it may influence the outcome. Logistic regression is commonly used when the independent variables include both numerical and nominal measures and the dependent variable is dichotomized (binary) as in our trial.

In this trial logistic regression were carried out to obtain a more precise estimate of the primary outcome mRS at 52 weeks (RS$\leq$ 2 as dependent variable) *(paper II)*, adjusted for potential confounders (106). As independent variables we chose age, sex, severity of stroke and cohabiting status because these variables are known to be strong predictors of outcome after stroke (107).

We also used the fitted logistic regression model when we analysed the relation between the severity of stroke and the Number needed to treat (NNT) (108) to achieve one more independent patient in the ESUS group versus the OSUS group *(paper II).*

4.8.3.3. Cost analyses

Health economy as a discipline represents a complex area and requires qualification beyond what is necessary to plan and complete a clinical trial for stroke patients. The economic analyses are not a primary outcome in this thesis *(paper IV),* but an important contribution to give a more complete picture of the early supported discharge service carried out in this trial. The data on resource use were collected prospectively and accurate, and to the calculation of unit costs and the preparation of the paper we had contribution from a health economist.

We have calculated the costs for each patient up to one year or to time of death, and then shared the total costs to estimate total average total costs for the patients in each group. There was no significant difference in mortality between the groups in this trial, and the results of the trial will not be influenced by how we have analysed the patients who died.

4.8.3.4. Paper I-IV.

Paper I-II.

To investigate any differences between the groups in the primary outcomes mRS and BI, we used the Pearsons X^2 test because the variables were dichotomized. To investigate any differences in the secondary outcomes proportion of patients independent, at home, in institution and diseased we also used the Pearsons X^2 test (109).

To express the relative benefit of the intervention according to independence we also calculated the Odds Ratio (OR), which here is defined as the odds for good outcome defined by mRS<2 in the active treatment group divided by the odds for good outcome in the control group (103). The measure has several statistical advantages

and is used extensively in epidemiology, but is perhaps not very helpful in clinical decision making (108).

Number needed to treat (NNT) is another measure we used to estimate the effect of the intervention. It describes in our trial how many patients that were needed to treat in the intervention group to achieve one more independent patient. NNT is becoming widely used as a tool for therapeutic decision making the recent years and is calculated on the inverse of the absolute risk reduction. It conveys both statistical and clinical significance to the health workers (108). The figure 2 in paper II is an example of the estimated NNT which may can give information to the clinician in relation to predict outcome related to severity of stroke at baseline, or may give information about which patients should be given priority from a mobile team. For the Logistic regression used, see chapter 4.8.3.2.

Paper III.

For ordinal scales like NHP, FAI, MADRS, CSI and MMSE, we used the non-parametric Mann Whitney U test to compare the differences between the groups. In the presentation of results on NHP we found it suitable to present the mean values in addition to the median values because some of the median values were zero and give little information.

There was no significant difference in mortality between the groups at 52 weeks and the drop-outs in both groups were below 5% (6 in the ESUS and 9 in the OSUS), so we do not think that will influence any results. Some considerations about the use of the " intention to treatment population" in these analyses are described in chapter 4.8.3.1.

Paper IV

In the analyses, we used the Mann-Whitney U test to investigate any differences in costs between the groups. The cost data were right skewed, which means they were not normally distributed (103). A large number of patients had zero cost values, because they did not receive all the different health services recorded in the trial. Because of the skewed distribution we found it suitable to present the mean values instead of the median levels, as described and recommended of Heyse et al. (110). We also used simple sensitivity analyses of the most expensive cost components by decrease and increase the costs by 25%.

4.9 Funding

5. Results

5.1 Review of paper I:

Benefit of an extended stroke unit service with early supported discharge:

A randomized, controlled trial.

Indredavik B, Fjærtoft H, Ekeberg G, Løge A, Mørch B.

Background and purpose: Several trials have shown that stroke unit care improves the outcome for stroke patients. The aim of the present trial was to evaluate the effects of an extended stroke unit service (ESUS), with early supported discharge, co-operation with the primary health care, and more emphasize on rehabilitation at home as essential elements.

Patients and Methods: In a randomized controlled trial 160 patients with acute stroke were allocated to the ESUS and 160 to the ordinary stroke unit service (OSUS). The primary outcome was the proportion of patients being independent assessed by the modified Rankin Scale (RS)(RS$\leq$2 =global independence), and independent in activities of daily living (ADL) assessed by Barthel Index (BI)(BI$\geq$95 = independent in ADL) after 26 weeks (w). Secondary outcomes were RS and BI after 6w, the proportion of patients at home, in institutions and deceased after 6 and 26 w and the length of stay in institutions.

Results: After 26 w 65.0% in the ESUS versus 51.9% in the OSUS group showed a global independence (RS$\leq$ 2) (P=0,017), while 60.0% in the ESUS versus 49.4% in the OSUS were independent in ADL (BI$\geq$95) (P=0.056). The odds ratio (OR) for independence (ESUS versus OSUS) were for RS: 1.72 (95%CI:1.10-2.70), and for BI: 1.54 (95%CI:0.99-2.39). At 6 w 54.4% of the ESUS and 45.6% of the OSUS group were independent according to RS (P=0.118), and 56.3% versus 48.8% independent

according to BI (P=0.179). The proportion of patients at home after 6w were 74.4% (ESUS) and 55.6%(OSUS) (P=0.0004), and in institutions 23.1% versus 40.0% (P=0.001). After 26 w 78.8% in the ESUS group versus 73.1% in the OSUS were at home (P=0.239), while 13.1% versus 17.5% were in institutions (P=0.277). The mortality in the two groups did not differ. Average lengths of stay in institution were 18.6 days in the ESUS and 31.1 days in the OSUS group (P=0.0324).

Conclusion: An extended stroke unit service with early supported discharge improves functional outcome, and reduces the length of stay in institutions compared to traditional stroke unit care.

5.2 Review of paper II:

Stroke Unit Care combined with Early Supported Discharge. Long Term follow-up of a Randomized Controlled Trial.

Fjærtoft H, Indredavik B, Lydersen S.

Background and Purpose: Early supported discharge from a stroke unit reduces the length of hospital-stay. Evidence of a benefit for the patients is still unknown. The aim of this trial was to evaluate the long-term effects of an extended stroke unit service (ESUS), characterised by early supported discharge.

Methods: A randomised controlled trial where 320 acute stroke patients were allocated either to ordinary stroke unit care (OSUS) (160 patients) or stroke unit care with early supported discharge (160 patients). The ESUS consists of a mobile team which co-ordinates early supported discharge and further rehabilitation.

Primary outcome was the proportion of patients who were independent as assessed by modified Rankin Scale (RS)(RS$\leq$2 =global independence). Secondary outcome measured at 52 weeks was Barthel Index (BI)(BI$\geq$95 = independent in ADL), the differences in final residence and analyses to identify patients who benefited most of an early supported discharge service. All assessments were blinded.

Results: 56.3% of the patients in the ESUS versus 45.0% in the OSUS were independent (RS$\leq$ 2) (p=0.045). NNT to achieve one independent patient in ESUS versus OSUS was 9. The odds ratio (OR) for independence was 1.56 (95%CI: 1.01-2.44). There were no significant differences in BI and final residence. Patients with moderate to severe stroke benefited most from the ESUS.

Conclusion: Stroke service based on treatment in a stroke unit combined with early supported discharge improves the long-term clinical outcome measured by modified Rankin Scale compared to ordinary stroke unit care. Patients with moderate to severe stroke benefit most.

5.3 Review of paper III:

Acute stroke unit care combined with early supported discharge. Long-term effects on quality of life. A randomized controlled trial.

Fjærtoft H, Indredavik B, Johnsen R, Lydersen S:

Objectives: The aim of the present trial was to compare the effects of an extended stroke unit service (ESUS) with the effects of an ordinary stroke unit service (OSUS) on long-term Quality of Life (QoL).

Design: One-year follow-up of a randomized controlled trial with 320 acute stroke patients allocated either to OSUS (160 patients) or ESUS (160 patients) with early supported discharge and follow-up by a mobile team. The intervention was a mobile team and close co-operation with the primary health care service. All assessments were blinded.

Main outcome measure: Primary outcome of QoL in this paper was measured by the Nottingham Health Profile (NHP) at 52 weeks. Secondary outcomes measured at 52 weeks were differences between the groups measured by the Frenchay Activity Index, Montgomery-Åsberg Depression Scale, Minimental State Score and the Caregivers Strain Index.

Results: The ESUS group had a significant better QoL (mean score 78.9) assessed by global NHP after one year than the OSUS group (mean score 75.2) (p = 0.048). There were no significant differences between the groups in the secondary outcomes, but a trend in favor of ESUS. Caregivers Strain Index showed a mean score of 23.3 in the ESUS group and 22.6 in the OSUS group (p= 0.089).

Conclusion: It seems that stroke unit treatment combined with early supported discharge in addition to reducing the length of hospital stay, also can improve long-term QoL. However, other similar trials are necessary to confirm the benefit of this type of service.

5.4 Review of paper IV:

Early Supported Discharge for Stroke Patients Improves Clinical Outcome.

Does It Also Reduce Use of Health Services and Costs? One year

follow-up of a randomised controlled trial.

Fjærtoft H, Indredavik B, Magnussen J, Johnsen R.

Background: An early supported discharge service (ESD) appears to be a promising alternative to conventional care. The aim of this trial was to compare the use of health services and costs with traditionally stroke care during a one-year follow-up.

Methods: 320 patients were randomly allocated either to ordinary stroke unit care (OSUS) or stroke unit care combined with ESD that was coordinated by a mobile team. The use of all health services was recorded prospectively; its costs were measured as service costs and represent a combination of calculated average costs and tariffs. Hospital expenses were measured as costs per inpatient day and adjusted for the DRG.

Results: There was a reduction in average number of inpatient days at 52 weeks in favour of the ESD group (p = 0.012), and a non-significant reduction in total mean service costs in the ESD group (EUR 18937 / EUR 21824). ESD-service seems to be most cost effective for patients with a moderate stroke.

Conclusion: Acute stroke unit care combined with an ESD-program reduces the length of institutional stay without increasing the costs of outpatient rehabilitation compared to traditional stroke care.

6.0 General discussion

6.1. Methodological considerations

In this trial we have tried to follow the procedures according to good clinical practice and ethical principles for medical research described in the Declaration of Helsinki (111). Randomised controlled trials are usually taken as the "gold standard" against which to judge the quality of the design of a trial (103). The randomisation is a method of eliminating bias in the way that treatments are allocated to patients, and the key of a successful clinical trial is to avoid any biases in the comparison of the groups. Random allocation is crucial to ensure comparability among groups and provide reliable answers. The randomisation deals with possible bias at the treatment allocation, but bias can also creep in while the study is being run. Therefore a blinded evaluation is also necessary (103). In our trial neutral assessors (physiotherapists) specially trained in the use of the outcome measures performed all the assessments. The blinding procedure is not simple in this kind of trials, but the evaluation was blinded as far as possible. The strength of the blinded evaluation procedure is unclear, and we have not performed any evaluation of the efficacy of this blinding procedure. However, this trial has been mentioned from the leader of the SUTC (112-comment) to have high methodological quality.

Randomly allocation does not guarantee that the characteristics of the different groups are similar, but in our trial there were no significant differences between the groups in baseline characteristics **(table 2).** There was a trend towards sex differences between the groups at baseline with a pre-dominance of men in the ESUS group (54% against 44%), which could have caused a bias. A Swedish study recently has shown women

to have a worse post stroke condition than men (113) while other trials has shown that sex has no influence on outcome (114). However, since differences at baseline between the groups were not significant, we did not find it necessary to take that into account.

The distribution of the severity of stroke was the same in both groups at baseline **(table 3),** and **table 5** shows that there were no significant differences between the groups at discharge from hospital although the destination were different. But there was a reduction in both groups according to the number of patients with severe stroke (16% in ESUS, 19% in OSUS) at the time of discharge. Most of the other ESD trials included the patients about the time of discharge from hospital, and excluded patients that were not able to transfer independently or by resident carer (115), had moderate disability (116) or intact cognition (37). The meta-analysis from Langhorne et al (117) showed a median proportion of patients eligible for ESD services of 41% (range 13-68). We included 68 % in our trial, and had a quite more unselected population than the other trials in the field.

TABLE 5. Proportion of patients in the two treatment groups by severity of stroke[1] at discharge from Stroke Unit

	ESUS (%) n=156	OSUS (%) n=155
Mild SSS 53-58	70 (44.9)	69 (44.5)
Moderate SSS 40-52	61 (39.1)	57 (36.8)
Severe SSS <40	25 (16.0)	29 (18.7)

SSS indicates Scandinavian Stroke Scale
[1] no significant differences.

A limitation with this kind of methodology used in our trial, is that we do not know exactly why the present service system works so well. It may be different factors that plays important role, and to identify the most important components might be a challenge for the future. Enriched environment is shown to be important for better outcome in animal studies (118), and rehabilitation at home may have a lot of gains (115,119). Physical and psychosocial elements of the environment influence the patients' ability to perform desired activities and attain targeted levels of participation during rehabilitation (120,121).

A couple of studies from rehabilitation in institution have shown that not much of the time was occupied by training (122,123). It also may be an explanation that training in institution has a low degree of transmission to functioning at home (124).

The description and discussion about the test instruments we used for the primary and secondary outcomes are described in chapter 4.7, and will not be repeated here.

From a methodological point of view it is a challenge to compare trials measuring resource use and costs for stroke patients *(paper IV)*. There are big differences in how each component of health care are valued, how and when the costs are measured, which costs items are included and how costs are estimated and concerning the time period in which the resource use is recorded.

In this trial the use of "health service registration cards" which were checked by a coordinator each month is a strength, and should be able to give a reliable estimate. It is also an advantage that a third party calculated the unit costs.

In this trial we also have at least three shortcomings. First, we did not have the opportunity to include capital costs, and thus underestimate the costs of hospitalisation, rehabilitation and nursing homes. Second, although we believe that

the costs give an accurate picture of actual treatment costs, deviations from optimal efficiency levels may distort them from efficient societal costs.

Third, we do not include travel costs, losses in productivity or intangible costs related to the decreased quality of life, or informal costs. It has been estimated that informal costs for stroke patients and their relatives are considerable (125,126) and should be taken into account. However, most of the limitations are equal to both treatment groups and, therefore, should not influence the comparisons.

6.2. Validity

The validity (lack of systematic errors) of a study is often called internal validity.

The internal validity is defined as the degree to which the results are representative for the particular population being studied (127). Randomised controlled trials are in general defined as trials with the highest internal validity (64). In this trial the conformity between the groups in the baseline data indicated that there was no selection bias. Blinded assessors accomplished all the tests, which should avoid some detection bias. A lack in the internal validity in this trial could be the use of the same tests several times, because the patients may be familiar with the tests, and may score higher on repeated measures.

External validity deals with whether the results are applicable in other populations and the extent to which the results can be generalised (127). Despite the fact that this trial was defined to have high methodological quality and promising results, we should be careful to generalise. This trial was a single-centre trial carried out in the setting of a Norwegian community, were the ESD-team also was able to access high quality of rehabilitation service in the primary care. The history of ESD-trials is short, but a meta-analysis, which used the Cochrane review methods, recently, showed

accordance between different trials (117). However, most of the trials included only a part (median 41%) of stroke patients admitted to urban hospitals. Therefore the results of these trials may only be relevant to a proportion of patients living in a relatively local area and have moderate or mild stroke. In our trial we included a more unselected population (68%), and 22% of the excluded patients did either not have any functional deficit or they were unconscious (SSS<2 or >57). So we think it is right to say that this trial has external validity. In comparison, thrombolytic treatment is applicable for about 5 % of the unselected stroke population.

An ESD trial (128) with the same design as in our trial, carried out in 3 rural municipalities showed no benefit for the ESUS group, but due to a small sample size the trial had a lack of statistical power, and an increased risk of uneven distribution of confounders. It may also be a reason that differences in the organisation of the primary health care system in the different municipalities play an important role for the benefit of an ESD intervention.

Some considerations about validity and reliability are also described in chapter 4.7.

6.3 Ethical considerations

A clinical trial is an experiment on human beings, so there may be several important ethical issues relating to a clinical trial. The participants in this trial were informed about the nature of the trial, and signed a personal content at the time of inclusion **(appendix 1)**. The informed consent might be controversial, because it is likely that many patients do not really understand what they are told (103). In this trial the patients and relatives together became the information and the participants had the right to withdraw from the trial and refuse any of their data at any time during the year if they wanted. We had some concerns about the early discharge to home in case it

would not be successfully. The patients in the intervention group had the right to return to hospital if they did not find the early discharge to home as the right decision, but no one did.

The regional Ethical Committee for Medical Research evaluated the study protocol and approved the trial. The Norwegian Data Inspectorate approved the collecting of data.

6.4. Evaluation of the results

Paper I and II.

For the first time it has been shown that Stroke patients that were offered early supported discharge service as a further development of stroke unit care, achieved improved short-term (26 weeks) and long-term (52 weeks) functional outcome compared with patients who were offered traditional stroke care. The patients were more likely to be independent and to be living at home. The improvement was large, and is in fact similar in size to the effect of thrombolytic treatment with alteplase within 3 hours (129), in addition to that it can be applied to almost all stroke patients. Similar to other ESD-trials (21), the length of institutional stay was also significantly reduced in our trial (40%). Other trials (37,115,116,130-133) have evaluated the benefits of ESD-service organised by multidisciplinary team in different ways with regard to functional outcome. None of them found differences in functional outcome after one year, and only one found a short-term significant benefit for the ESD group (116). The first long-term follow-up 5 years after stroke was recently published by Thorsén et al (134) which concluded that ESD service has a beneficial effect on extended ADL 5 years after stroke for patients with mild or moderate stroke.

There are many differences between the various trials that make the comparison difficult. Our design with early randomisation (within 72 hours after onset of stroke), initial stroke unit care for all patients in the trial and a quite unselected stroke population are probably strengthened for the trial. In most of the other trials patients with severe stroke were not included because only patients who were able to transfer independently from the hospital and had a carer at home were included. These patients probably had a relatively high functional level at baseline.

Because we included a relative unselected stroke population, this trial give us the opportunity to analyse which patients that benefit most.

We have therefore created a model to calculate the benefit of ESUS for the different levels of stroke severity in this trial. The results, which showed most benefit for patients with a baseline score between 35 and 54, can give some information about which patients might be given priority for such a follow-up treatment, although we should be very careful to generalise the results.

Paper III

The results of this paper indicate that patients who received initial stroke unit care combined with early supported discharge and follow-up by a mobile team report a better quality of life measured by global NHP at one year than patients receiving ordinary stroke service. Two other ESD-trials have reported the same effects, but just as short-term benefit (116,132). Other trials with long-term follow-up have not shown any differences in QoL (37,115,131). We did not find any significant difference in depression between the groups, although the association between depression and QoL are reported in earlier stroke trials (135). Nor was there any difference in social activity index or cognitive function between the groups, but a trend towards reduced

burden for the caregivers in the ESUS group. The fact that the patients in our ESUS group also achieved a better functional outcome (*paper I and II*), may contribute to perceive better QoL and lesser burden for the caregivers. A Swedish trial recently (136) showed that the caregiver's most important determinants of QoL were their own age and the patients' functional status. It has been estimated that at least 2/3 of the home care of the elderly is informal (125,137), so the impact the stroke has on the whole family is an important aspect.

The reasons for our favourable results in the measure of QoL compared to the other trials remain unclear. Some of the reasons might be the fact that we had established more "links" and flexibility in our chain of care, which may have given a more complete service system and a better "safety" for the patients and their carers. There were no significant differences between the groups in number of contacts with the out-patient service, except of more use of day clinic and fewer visits from home nursing care in the ESUS group versus the OSUS group.

Paper IV

This trial has shown that the total health services costs for an ESD service with early supported discharge and follow-up by a mobile team, are equal or less than costs for ordinary stroke unit care during the first year after stroke. We achieved a significant reduction of total in-patient days, which did not lead to an increase in costs for home-based rehabilitation or readmissions to hospital. Some other trials have examined the economic consequences of ESD by comparing it with traditional care (137-142), and most of them found lower average costs for the ESD group. Seemingly, one of these trials correspond to our results (142) while some other of these trials showed lower average costs for both groups after one year than our trial (137,138). We have to take

into account the fact that the patients in these trials had a higher functional level at baseline, and because of that may have reduced costs compared to our patients. There was an increased use of outpatient rehabilitation clinic as expected, but an unexpected trend towards reduced use of home nursing care during the first year after stroke. Some other trials have measured the costs of home nursing care for stroke patients with opposite results (137,138). One of the reasons for the difference in results might be the increased functional outcome for our patients during the first year after stroke.

Time is an important factor since stroke-induced disability improves or worsens with time. Our findings with a cost reduction for both groups over time are supported by results from previous descriptive studies, which concluded that the first time is the most expensive (143,144). The increase in cost differences in the last period from 26 to 52 weeks (23%) are interesting, and it may indicates long-term effects on resource use and costs in favour of the ESD service.

Our findings of resource use and costs according to functional outcome are important, but not well documented in ESD trials. The ESD- program seems to be most effective for patients with moderate stroke (RS 2-3 at baseline) and more expensive than ordinary care for patients with highest functional level (RS 0-1 at baseline). The reason for the fact that the costs for treating patients with mild and moderate stroke in our trial (*table 5, paper IV*) is the same, needs further investigations to be explained.

6.5. Early supported discharge trialists

The Cochrane collaboration is set up to compile all information on clinical trials, mainly randomized trials, within every field of medicine. One of the work groups according to stroke within the Cochrane stroke module is the Stroke unit trialist

collaboration, which consists of researches from most of the randomised stroke unit trials (10). Another group is the early supported discharge trialists group, co-ordinated by Peter Langhorne. Their first Cochrane review was published in the Cochrane Library in 1999 (21), and later updated. The last version was published in April 2005 (117,145) with a meta-analysis on outcome data from 11 ESD-trials (published and unpublished data).

This meta-analysis of individual patient data is an important contribution to the ESD-research. The generalisability increases by systematic review compared to single centre trials (146), and meta-analyses seems to have a high degree of evidence if the different trials used has high quality. Langhorne et al (117,145) showed a significant reduction in length of hospital stay equivalent to approximately 8 days for this selected group of elderly stroke patients with moderate disability (p< 0.0001). A reduction in death and dependency (OR 0.79, 95% CI 0.64 to 0.97) was also found in addition to improvement in patients' satisfaction with services and in extended activities of daily living score. This corresponds to our results with 12.5 days reduction in institutional stay (p=0.032) and odds ratio for death or dependency 0.65 (95% CI 0.42 – 1.01) **(Figure 6).** They documented the greatest benefit in trials evaluating a co-ordinated ESD-team (see chapter 6.6 in this thesis), and for patients with mild to moderate stroke.

This meta-analysis concluded that ESD service seems to offer a promising contribution and effective service in addition to organised inpatient stroke unit care for a selected group of stroke patients with mild and moderate stroke.

Fig 6

6.6. Different ESD models.

As previous described, there are big differences between the trials according to the organising and use of the ESD teams. It seems clear that patients who were early discharge from Hospital need some sort of support in the follow-up phase. It appears that early discharge from hospital without enhanced stroke service may lead to an increase in morbidity (147).

But the different trials in this field have used different ways to organize their early supported discharge service. Most of them are based on a multidisciplinary team comprising physiotherapy and occupational therapy staff with variable amounts of medical, nursing, and speech therapy input (112-comment). Other differences lies in weather they coordinate and deliver the treatment or they planned and supervised the treatment which been handed over to the community-based staff (117). There exist also differences in whether the teams have seat in the hospital (hospital based) or in the primary health care system (community based).

There is a spectrum of approaches that have in common in different ways to plan and /or provide early post-discharge rehabilitation, co-ordinate discharge and / or hands over care to community services.

The Early supported discharge trialists have made following classification of the ESD:

- ESD team co-ordination and delivery: co-ordinated multidisciplinary ESD team co-ordinated and provided post-discharge care (37,115,116,130,131,133)

- ESD team co-ordination: co-ordinated multidisciplinary ESD team co-ordinated supervised discharge and immediate post-discharge care but then handed over to other services (132,148)

- No ESD team: post-discharge services were not provided by co-ordinated multidisciplinary ESD team (147).

There exists no simple way to classify the different teams, which our trial exemplifies. Our team can be defined as a co-ordination team, which handed over care to community service after the early post-discharge co-ordination and organisation. However, for patients with more extensive needs they offered training and support in addition to the service from other agencies and could be categorized as a co-ordination and delivery team.

There exists no direct comparison between the different team models and it is in present not possible to conclude which team model that should be preferred. The organisation of the local health care service might be important for the model choosing.

Table 6 shows an overview of the mobile team's work in our trial and the frequency of contacts with the patients and different health service agencies.

TABLE 6: Mobile team. Frequencies of contacts with patients and health service agencies (n=158).

	Mean Contacts (n)	Patients (n)	(%)	Total number of contacts
Contacts with:				
Patient in S.U.	8.7	159	(99%)	1379
Relatives	7.5	141	(89%)	1053
Rehabilitation clinic	6.3	62	(39%)	388
Home nursing care	5.5	118	(75%)	644
Nursing Home	3.9	21	(13%)	82
Out-patient clinic	1.2	145	(91%)	171
Number of:				
Home visits	5.7	126	(80%)	712
Telephone contact	5.3	130	(82%)	692
Follow by transfer	1.4	94	(59%)	128
Discharge meeting	1.1	134	(85%)	146
Other contacts	3.1	53	(34%)	165
Total	35	159	(99%)	5560

7.0 Conclusion

Stroke rehabilitation has received increased attention in the past decade. When we started our planning in 1995, research on stroke service was concentrated about stroke units, and no published randomised trials existed on the follow-up research. Today new alternatives, as early supported discharge from hospital followed by home-based rehabilitation, have arisen and been carried out in several randomised trials published the last years. And even if this specific field so far has a short history, we begin to see the outlines of a more effective way to organise and accomplish the stroke rehabilitation after the first period of acute stroke unit care.

This thesis with scientific methods used, will hopefully be a contribution to more knowledge about the benefit and effectiveness of early supported discharge service and organising of the follow-up after initial stroke unit care.

In this thesis we have

- constructed a stroke service system with early supported discharge in co-operation between the hospital and the primary health care service.

- evaluated the short and long-term effects of this extended stroke unit service co-ordinated by a mobile stroke team compared to traditional stroke care in terms of functional disability and Quality of Life.

The results of this evaluation showed that the constructed follow-up service were beneficial. For the first time it was shown that stroke patients who were offered extended stroke unit service combined with early supported discharge, had a better functional outcome after 6 and 12 months of follow-up than patients offered ordinary stroke unit care. Subgroup analyses indicated that ESD-service were most beneficial

for patients with moderate severity of stroke. For the first time it was also shown that ESD-service also might improve the global quality of life for stroke patients compared to traditional stroke care. Finally, our ESD-service has like some other trials documented a significant reduction in length of hospital stay and length of total institutional stay during the first year post-stroke.

We assessed the resource use and costs of the ESUS compared to the OSUS during the first year post-stroke. Our findings stating that the total costs were equal or less than costs for ordinary stroke unit care. The cost analyses also showed that patients with moderate severity of stroke had the most saving on costs, and that the difference in costs between the groups increased over time during the first year in favour of the ESUS group.

In spite of the fact that little is known about the effect of the various components of the treatment provided in our trial and in other ESD trials, the importance of early, well organised discharge from hospital co-ordinated by a mobile team seems to be an important contribution in the treatment of stroke patients in addition to the initial stroke unit care. But we still need research in some areas to conclude for which stroke patients that home-based rehabilitation is preferable to hospital-based rehabilitation.

Extended stroke unit service combined with early supported discharge improve functional outcome and improve quality of life compared to traditional stroke care. The costs are equal or less than costs for ordinary care. Hence, it should be considered, in addition to organised in-patient stroke unit care, as a part of a comprehensive stroke care.

8. What does this thesis add:

- Extended stroke unit service with early supported discharge and co-ordination by a mobile team improves functional outcome 6 months and 12 months after stroke. It was most beneficial for patients with moderate stroke.

- Extended stroke unit service with early supported discharge can improve long-term quality of life measured by global NHP, if stroke unit care is the initial treatment and the follow-up is co-ordinated by a mobile team.

- It seems that an ESD service does not influence areas concerning the patients' cognitive function, social activities and any depression.

- The caregivers who got their patients early at home did not report an increased burden compared to caregivers whose patients became ordinary stroke unit care.

- This trial showed that early supported discharge reduced the length of hospital stay with 40 %, and did also reduce the total length of institutional stay during the first 12 months significantly. The reduction in institutional stay did not lead to an increase in use of outpatient health care resources.

- The total health services costs for an ESD service are equal or less than costs for ordinary care during the first year after stroke. The important cost savings caused by reduced length of institutional stay did not lead to an increased in costs for home-based rehabilitation. The ESD-programme seems to be most cost-effective for patients with moderate stroke and seems to be an expensive alternative for patients with mild stroke. The difference in costs increases over time during the first year.

9. Suggestions for further research

- Different models concerning ESD service is established so far. Several characteristics of the ESD service are identified, but we still do not know which components are most important. We need more research to obtain a common agreement of the contents of this kind of service.
The suggestion that particular patient groups benefit more than others also requires further exploration.

- It seems that the co-ordinating ESD team which co-ordinate discharge and handed over the responsibility to other services and ESD teams that emphasize co-ordination and provide post-discharge care both might be effective. More research is needed to concretise the most suitable function for an ESD team, their degree of responsibility and the extent of their work.

- Optimal length of follow-up for an evaluation of the efficacy of post-stroke rehabilitation is not known. To accumulate more evidence, future analyses should include long-term follow-ups.

- All the randomised trials researching ESD service so far, except of one, has been carried out in urban communities. The effectiveness of ESD service in more dispersed rural municipalities has not been adequately tested. The information so far is limited and further research is necessary to make a final conclusion

- Various countries and various communities organise their health care services in very different ways. How can variation in the clinical practice and organisation of the health services in the primary health care system affect the outcome following stroke?

- Stroke imposes a great economic burden for the society and the patients. So far just a couple of trials (4-5) have analysed the resource use and costs following an ESD service. We need more research to conclude if this is a cost-saving alternative or not. The registration of the costs of informal care that probably is considerable should be taken into consideration.

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11. Appendix

Enclosure 1: Patient information and informed consent

Enclosure 2: Health registration service card with information

Appendix 1

Pasientinformasjon.

"Slagbehandlingskjeden-Trondheim" er betegnelsen på et prosjekt som støttes av Helse- og Sosialdepartementet. Formålet er å utvikle en behandlingskjede for slagpasienter i Trondheim. Vi har etter hvert utviklet relativt gode metoder for akuttbehandling av slagpasienter, men helsetjenestens oppfølging etter den akutte fase, oppleves av mange som mangelfull. Vi har derfor nå laget et opplegg for oppfølging av pasienter som har hatt hjerneslag, og skal prøve ut om dette fungerer bedre enn eksisterende tilbud.

Hva betyr dette for deg som pasient?
Pasienter fra Trondheim som er innlagt med akutt hjerneslag, blir spurt om å delta i prosjektet. Alle pasienter vil få det vanlige behandlingstilbudet i Slagenheten, samt en grundig undersøkelse etter en uke.

Etter utskriving vil en gruppe pasienter få den standardoppfølging som gis i dag, men med et tillegg i form av en undersøkelse og spørreskjemaer etter seks uker, seks måneder og 12 måneder.

En annen gruppe vil følges opp med ytterligere noen kontroller.

Det vil så bli sammenlignet hvilke av disse opplegg som fungerer best, og som deltaker vil du også bli spurt om hvordan du har opplevd det tilbud som er gitt deg. På den måten kan du være med å gi oss kunnskap om hvilken oppfølging pasienter med hjerneslag trenger.

Felles for alle som er med i dette prosjektet, er at ingen får et dårligere tilbud enn det som eksisterer i dag.

Frivillig deltagelse.
Deltagelse i dette prosjekt er frivillig, og sier du nei takk til å delta, vil du få den vanlige behandling som vi ellers gir til pasienter med akutt hjerneslag, men ingen spesiell oppfølging eller tilleggsundersøkelser etter utreise. Du vil når som helst i oppfølgingsperioden også kunne trekke deg fra deltagelse i prosjektet hvis du skulle ønske det.

Pasientopplysninger.
I forbindelse med et slikt prosjekt, må en del medisinske opplysninger samles og databehandles, men alle som har tilgang til opplysningene har taushetplikt.

Prosjekt " Enhet for helhetlig slagbehandling" Slagenheten, Medisinsk avdeling, RiT

Pasientnavn:_____	Prosjektlp.nr.:
inklusjon:_____	Dato for
Fødselsdato:	
inkludert:_____	Hvem har

Jeg har fått informasjon og er villig til å delta i studien :

Sted:_____   Dato:_____

Navn:_____

_____
pasientens underskrift

Jeg bekrefter at pasienten har mottatt informasjon og gitt muntlig samtykke til å delta i studien:1

Sted:_____   Dato:_____

Navn:_____
pårørende/vitne*

_____
underskrift pårørende/vitne*

Pasientens medisinske tilstand er slik at samtykke etter min vurdering ikke kan innhentes. Jeg har lest informasjonen og er enig i at pasienten deltar i studien:2 Pasienten vil senere bli forespurt om videre deltakelse.

Sted:_____   Dato:_____

Navn:_____
pårørende/ vitne*

_____
underskrift pårørende/vitne*

Jeg bekrefter med dette at pasienten/pårørende/vitne* egenhendig har underskrevet på denne pasientinformasjonen:3

Sted:_____   Dato:_____

Lege:_____

underskrift av den lege som inkluderer pasienten
----
*stryk det som ikke passer.
1) dette felt undertegnes bare hvis pasienten gir muntlig samtykke, men ikke selv kan undertegnes.
2) dette felt undertegnes bare når pasienten ikke selv er i stand til å gi skriftlig eller muntlig samtykke.

Prosjekt "Enhet for helhetlig slagbehandling" Slagenheten, Medisinsk avdeling, Regionsykehuset i Trondheim.

<div align="center">

"Slagbehandlingskjeden - Trondheim"
PASIENTINFORMASJON

</div>

Det er bestemt at du skal reise hjem etter dette oppholdet i Slagenheten.
Som deltaker i prosjekt " Slagbehandlingskjeden - Trondheim" vil du få et ekstra tilbud fra helsevesenets side.

I Slagenheten.
Under oppholdet her vil du få kontakt med et såkalt "ambulerende team" før utreise.Dette teamet vil ha oppgaver både i Slagenheten og utenfor sykehuset,og vil sammen med deg og dine pårørende være med på å planlegge hjemreisen. Dagen før du reiser hjem vil du få en utskrivingssamtale med lege . Der vil du kunne ha med deg dine pårørende om du ønsker det.
Vi ønsker også i dette prosjektet å se hvor ofte du har kontakt med andre deler av helsevesenet, f.eks. legebesøk.Du vil få med deg et skjema hjem som du skal fylle ut.Dette vil du få innføring i.

Etter utskrivning fra Slagenheten.
Etter en uke vil du bli oppringt hjemme av en som kjenner deg fra Slagenheten .
Hvis det skulle vise seg at ting ikke fungerer som forventet etter utskrivning fra sykehuset,at planlagte tiltak ikke blir fulgt opp eller at nye problemer har dukket opp,så vil det ambulerende team følge opp dette.Det er også mulig for deg å ta direkte kontakt med det ambulerende team.

Poliklinikk.
Etter 1 mnd. vil du bli innkalt til en kontroll på poliklinikken her på sykehuset. Der vil du treffe legen fra avdelingen og den fra det ambulerende teamet som du hadde mest kontakt med i Slagenheten eller etter hjemreise.

6 uker, 6 mnd. og 12 mnd. etter at du ble akutt syk.
Nå får du besøk av helsepersonell hjemme som kommer til å gjøre enkelte undersøkelser av deg og stille deg spørsmål fra en del skjema.

Pasientopplysninger.
I forbindelse med et slikt prosjekt må en del medisinske opplysninger om deg samles og databehandles,men alle som har tilgang på opplysninger har taushetsplikt.

Mer informasjon ?
Vi står alltid åpne for spørsmål både for deg som pasient,og for dine nærmeste.

Prosjektkontor   **Prosjektleder**
Telefonnr.: 73 99 87 60.   Bent Indredavik,

Appendix 2

Prosjekt "Slagbehandlingskjeden – Trondheim"

Slagenheten, medisinsk avdeling, Regionsykehuset i Trondheim

Til ....

I følge våre papirer på Slagenheten, Med. avd., Regionsykehuset i Trondheim, ble du utskrevet fra avdelingen .... Under sykehusoppholdet ble du forespurt om å være med i et prosjekt angående hjerneslagpasienter. Dette svarte du ja til.

På Slagenheten fikk du utdelt et informasjonsskriv om dette prosjektet, hvor det bl.a. sto at vi skal registrere forbruket av helsetjenester hos pasienter etter hjemkomst fra sykehuset.Til dette har vi utarbeidet egne **blå kort,** som dere skal benytte.

Helseregistreringskortet skal fylles ut hver gang du mottar helsetjenester i form av f.eks. hjemmesykepleie, bruker trygghetsalarm, eller hver gang du er hos din primærlege eller fysioterapeut. Dette registreres ved at du skriver dato øverst på kortet, og setter en strek for den aktuelle tjeneste på helseregistreringskortet.

I informasjonsskrivet står det at du vil bli oppsøkt av oss 6 uker og 6 måneder og ett år etter at du var innlagt i Slagenheten, bl.a. for at vi skal undersøke din motoriske funksjon og spørre deg litt om hvordan du har det i hverdagen din. De som kommer til deg vil kunne hjelpe deg med helseregistreringsskjemaet hvis du skulle ha behov for det . De vil også ta med kortene tilbake til oss etterhvert som de er utfyllt.

Vi takker på forhånd for at du vil være med i dette helsetjenesteforskningsprosjektet, og med at du hjelper oss å registrere forbruk av helsetjenester. **Dette er svært viktig for oss,** for at vi skal kunne undersøke om slagpasienter får et tilfredsstillende tilbud også etter utskrivelse fra sykehuset, eller om dette må bli bedre. Den eneste måten vi kan få informasjon på, er at dere registrerer hva dere mottar.

Skulle du ha problemer med registreringskortene, kan du ringe prosjektkontoret tlf.
73 99 87 60.

Med vennlig hilsen
Hild Fjærtoft
 prosjektkoordinator

Registreringsskjema for helsetjenester

Tilbudene registreres med en strek pr gang

DATO	MAN	TIR	ONS	TOR	FRE	LØR	SØN	MAN	TIR	ONS	TOR	FRE	LØR	SØN	MAN	TIR	ONS	TOR	FRE	LØR	SØN	MAN	TIR	ONS	TOR	FRE	LØR	SØN
HJEMMESYKEPL.																												
KORTTIDSOPPHOLD I SYKEHJEM																												
TRYGGHETSALARM																												
DAGTILBUD																												
DAGREABILITERING																												
FYSIOTERAPI																												
ERGOTERAPI																												
LOGOPED																												
LEGEBESØK																												
POLIKLINIKK																												