

# Protocol of the Sunnaas International (SIN) Stroke Project an International Multicenter Study of Specialized Rehabilitation for Stroke Patients

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## Abstract

**Rationale:** Stroke is leading cause of serious, long-term disability in adults. Consequently, many individuals with stroke are in need of specialized rehabilitation. However, the content of specialized rehabilitation may vary.

**Aims:** To describe the content of specialized stroke rehabilitation, and possible influence on the physical and social functioning after specialized rehabilitation, in nine rehabilitation institutions representing seven different countries.

**Design:** The design is a prospective, descriptive study of the specialized rehabilitation of stroke patients in rehabilitation institutions in Norway, PR China, the United States, Russia, Israel, Palestine and Sweden. Patients with a primary diagnosis of stroke consecutively attending an institution for specialized rehabilitation will be invited to enroll in the study.

**Study Outcomes:** General descriptive data of the rehabilitation centers, the content of their programs for specialized rehabilitation for stroke patients, and descriptive data of enrolled patients will be registered. Primary outcome measures are the Barthel Index (BI), alternatively, the Functional Independence Measure (FIM), which reflect performance of the activities of daily living. Secondary outcome measures are the Life Satisfaction Scale (LISAT-11), the Modified Rankin Scale (MRS), the National Institutes of Health Stroke Scale (NIHSS) and a semi-structured questionnaire with focus on the social situation. Tests will be performed on admission to rehabilitation, 18-22 days into rehabilitation, at discharge, six and twelve months after discharge.

**Discussion:** The study will contribute to the knowledge about the content of specialized stroke rehabilitation with examples from nine clinics in seven different countries. The study will highlight how the different models of specialized rehabilitation may influence patients' outcomes. Data from all sites will target what physical and psychosocial situations persons with stroke face in different settings. The international aspects of specialized stroke rehabilitation may serve as background for the discussion on the optimal rehabilitation services for stroke patients.

**Keywords:** Multidisciplinary; Physical; Psychological; Rehabilitation; Social support; Stroke; Quality of life

## Introduction

It is estimated that 15 million people worldwide survive stroke each year, and approximately one third of these survivors will have a remaining disability after stroke. Additionally, six million people worldwide will die of stroke each year [1-2].

Stroke is a disease associated with the highest odds of reporting severe disability and might be considered to be the most common cause of complex disability in the adult population [3,4]. Consequently, many individuals with stroke are in need of rehabilitation, some also of specialized rehabilitation. Specialized rehabilitation has been defined by the British Society of Rehabilitation Medicine (BSRM) as “services that support patients with complex disability, whose rehabilitation needs are beyond the scope of their local rehabilitation services” [5-7]. Furthermore, specialized rehabilitation activities described as “high cost, low volume and unpredictable” [6].

“High cost” in terms of a prolonged, complex rehabilitation to the more severely disabled stroke patients involving highly qualified personnel, specialized equipment and an environmental context encouraging to independence and activity. “Low volume” refers to the concentration of specialized staff and facilities in relatively few centers. “Unpredictable» indicates that the referral system may serve as “gate keeper” that is screening patients with special needs [6]. For the individual this may seem unpredictable since the criteria for referral is dependent upon factors out of control for the individual person in need of specialized rehabilitation [8-10].

In the United Kingdom’s (UK) Department of Health’s guidance for commissioning specialized services, it is stated that certain elements of neurological services are designated as “specialized”. These include neurology, neurosurgery, rehabilitation for adults with brain injury and complex disability [11].

This is further developed in the National Services Framework, UK [12] for Long Term neurological Conditions which:

Recognizes the need for specialist services for people with more complex needs and therefore recommends that rehabilitation services are planned and delivered through coordinated networks in which specialist neuro-rehabilitation services work both in hospital and the community to support local rehabilitation and care support teams

Specialized rehabilitation services consist of a combination of individual and group based interventions with the goal of stimulating social interaction, communication, life and work skills [13-14]. The services are usually offered as in-patient/residential programs, but may also be as day-patient/community programs.

The content of rehabilitation may be very different both within countries and across national borders, efforts have been made to unlock the black-box of rehabilitation in other studies [15-19]. The content of specialized rehabilitation, on the other hand, has neither been standardized, described nor compared between institutions.

There are reasons to believe that cultural context such as social, educational, religious and linguistically diversities may influence how rehabilitation services are provided [20].

A study comparing specialized rehabilitation for stroke patients in different rehabilitation institutions in various countries would gain insight into what is interpreted as specialized rehabilitation, what is considered as prerequisite of services and how these services are provided?

Furthermore, the requirements for referral and inclusion in specialized rehabilitation programs are often somewhat elusive, and may differ between regions and countries [8-10]. Neither the evaluation of rehabilitation outcomes nor what is considered ‘optimal rehabilitation’ is standardized within countries or between countries. In addition, funding of health services in general and specialized rehabilitation in particular differs between countries. In some areas, the specialized rehabilitation is part of the general health care insurance, in other countries it is mainly private or a mixed public/private model [21]. These different models may influence the accessibility and use of what is essentially the same services.

A major stroke has severe consequences for the individual, both in a physical and a psychological sense. Many people will find themselves in a difficult economic situation after a major stroke. Many cannot go back to work [22-25]. This has implications both for the individuals and for their families. These problems will probably vary among stroke

patients in different countries, but comparable data are scarce. There are few, if any, comparable studies on stroke patients and their social situation after stroke. Thus, more knowledge is required about what specialized rehabilitation is today, and then discussion about how these services might be further developed for stroke patients. We found that such studies should preferably be undertaken in a cross-cultural setting, so that the findings could be compared between different countries, and thereby enable the discussion of optimal services in each country, and between units with different levels of experience of having participated in a clinical research trial. The present study is registered in Clinical trials Gov.; NCT01732679.

## Aim of the study

The primary aim is to describe the content of in-patient specialized stroke rehabilitation in nine institutions from seven countries. Secondary aims are to describe how specialized rehabilitation influences physical outcomes as well as quality of life in stroke patients in the same institutions. Lastly, to investigate the physical and social challenges affecting patients after discharge from the specialized in-patient rehabilitation units, in seven different countries.

The hypothesis is that there are differences in the content of specialized rehabilitation between the clinics in different countries and that the different models of rehabilitation will influence physical outcomes but will have less impact on psychosocial factors.

## Methods

### Design

The design is a prospective, descriptive study of the specialized rehabilitation of stroke patients in rehabilitation institutions in Norway, PR China, the United States, Russia, Israel, Palestine, and Sweden. Patients with a primary diagnosis of stroke consecutively attending one of these institutions for specialized rehabilitation will be invited to participate in the study.

First, the characteristics of the specialized rehabilitation units in the different countries, the therapies provided and the respective principles for admission and discharge are to be described and provide an overview of current practice of specialized stroke rehabilitation in the participating countries. A specific questionnaire will be developed to gather information from the rehabilitation staff. The contact person in each hospital is key person for collecting the data together with the hospital administrators.

In addition, descriptive data will be recorded in regard of the patients’ age, gender, occupation, civil status, stroke incidence, treatment, medication and length of stay in the institution by a test-person not involved in the rehabilitation. Secondly, the same test person, to evaluate the possible change in dependence, motor function and quality of life, will test patients regularly, providing information as to how the different specialized rehabilitation models may influence outcomes.

### Settings

Clinics participating in the study will provide descriptive data of the clinics, content of specialized rehabilitation, rehabilitation services for stroke patients and the outcomes of rehabilitation. The nine clinics providing data are: Sunnaas Rehabilitation Hospital, Norway; China Rehabilitation and Research Center (CRRC), Beijing, PR China; Baiy

Rehabilitation Center, Chengdu, PR China; Rusk Rehabilitation Institute, New York, USA; Policlinica nr 2, Petrozavodsk, Karelian Republic, Russian Federation; Sheba Medical Center, Israel; Bethlehem Arab Society Rehabilitation (BASR), Palestine; El Wafa Hospital, Gaza, Palestine; and Högsbo Hospital, Gothenburg University, Sweden.

## Subjects

Patients with a primary diagnosis of stroke as defined by the World Health Organization [26], irrespective of age and gender, will be invited to enroll in the study, as they consecutively attend one of the nine institutions for specialized rehabilitation. Inclusion criteria are persons with stroke admitted to specialized rehabilitation and willing to participate. Exclusion criteria are sub-arachnoid hemorrhage, tumor, or another severe medical condition in combination with stroke. The patients have to be able to cooperate in performing the planned assessments. Information to participants is given, both in writing and verbally, in accordance with the Helsinki Declaration [27]. Patients may withdraw from the study at any time during the study.

## Sample size

A priori, the power of the study was calculated with respect to the activities of daily living. A sample size of 30 patients in each center would allow us to detect a change in score of mean 15% on the Barthel Index (BI) or the Functional Independence Measure (FIM) total score. This is considered a meaningful clinical change, with a power of 90% and  $p < 0.05$ .

## Outcome measures

General descriptive data of the collaborating centers (capacity, admission criteria, services provided for patients, determinants for length of stay, having performed clinical research earlier) and descriptive data of patients participating in the study (gender, age, residential condition, occupational situation, and formal education) will be recorded. Description of therapies provided to patients will be registered in terms of frequency, intensity, time and type. The primary outcome measure for the patients is the Barthel Index (BI) or the Functional Independence Measure (FIM) to assess the performance of the activities of daily living. Secondary outcome measures are the Life Satisfaction Scale (LISAT-11), the Modified Rankin Scale (mRS), and the National Institutes of Health Stroke Scale (NIHSS) for measuring the degree of disability or dependence, and a structured questionnaire focusing on the patient's social situation performed as an interview. Tests are being performed at baseline on admission to rehabilitation, 18-22 days into rehabilitation (BI/FIM), at discharge, six and 12 months after discharge.

Data will continuously be reported to the Project Investigator (PI) through regular physical meetings. One copy will be stored at the centers involved; the other copy will be stored with the PI.

## Statistical analysis

The content of specialized rehabilitation will be described and compared to a standard; The British Society of medical rehabilitations (BSMR) in a qualitative manner [5].

Patients' quantitative data will be analyzed with descriptive and analytical statistics; mean, standard deviation, student t-test, Mann Whitney U-test for comparisons of performance at baseline, discharge, six months and twelve months post discharge [28]. The semi-

structured questionnaire performed as an interview will be analyzed as categorical data, and presented in frequencies, percentages and associations from cross tabular calculations [28-29].

## Ethics

Approval of the local ethical committees has been obtained in all the participating clinics and from the Regional Ethical Committee of Health in South-East Norway (2012/768). Patients included in the study have been informed both verbally and in written form about the aim of the study, and forms for written consent will be provided for all participants in all clinics by the test person.

## Study organization and funding

Sunnaas International Network's study administration and project group is funded by Sunnaas Rehabilitation Center and supported by the Research Council of Norway, Ministry of Health and Care Services and by the participating clinics locally.

## Summary and Conclusion

A multinational research project with focus on the content of specialized stroke rehabilitation and the consequences of stroke during and after specialized rehabilitation in seven different countries is presented. The comparative design will contribute to knowledge about the content and organization of specialized rehabilitation services in different countries, in order to enhance discussion about how to optimize services in the different institutions and countries. The explorative design targets how stroke patients are treated after the acute incident, and what physical and psycho-social circumstances the patients meet in different settings. These international aspects of specialized stroke rehabilitation have not, to our knowledge, been the focus of any previous studies, and will bring new knowledge and basis for the discussion on optimal specialized stroke rehabilitation.

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