

*Locked-in syndrome in Sweden:  
an explorative study of persons who underwent  
rehabilitation*



Master Thesis, Programme in Medicine, University of Gothenburg

Author: Kajsa Svernlind  
Supervisor: Katharina Stibrant Sunnerhagen

*Locked-in syndrome in Sweden: an explorative study  
of persons who underwent rehabilitation*

**Master thesis in Medicine**

Kajsa Svernlng

Supervisor: Katharina Stibrant Sunnerhagen

*Professor of Rehabilitation Medicine, University of Gothenburg*

*Senior Consultant Rehabilitation Medicine, Sahlgrenska University Hospital*

**Institute of Neuroscience and Physiology**

Department of Clinical Neuroscience and Rehabilitation



**UNIVERSITY OF GOTHENBURG**

Programme in Medicine

Gothenburg, Sweden 2015

# Abstract

---

Master Thesis, Programme in Medicine

**Title:** *Locked-in syndrome in Sweden; An explorative study of persons who underwent rehabilitation*

**Author:** Kajsa Svernling, 2015

Institute of Neuroscience and Physiology, Department of Clinical Neuroscience and Rehabilitation

The Sahlgrenska Academy, Gothenburg, Sweden

**Introduction:** Locked-in syndrome (LiS) is a rare condition, characterized by a complete paresis except for vertical eye movements and blinking with cognitive functions intact, commonly caused by ischemia in ventral pons. Previous studies have indicated that persons with LiS can live on for many years and have a good quality of life (QoL). LiS has, to our knowledge, never been studied in Sweden.

**Aim:** To explore LiS in Sweden; describing population characteristics, living situation, mortality/cause of death and health-related quality of life/impact on participation.

**Methods:** Explorative, nation-wide study in two parts. Persons registered in WebRehab during 2007-2014 were eligible. Ten study persons were included in part one, four participated in part two. Data collection; Part one: WebRehab, medical charts and registers. Part two; questionnaires and interviews.

**Results:** Seven out of ten were men, median age at onset was 49 years and the cause of LiS was in all cases stroke, 70% ischemic. Three of the study persons were deceased, median time

of survival 1.9 years. Seven of the study persons were still alive, median time elapsed since onset was 5.8 years. Three participants experienced good quality of life. Information and respect were two areas with unfulfilled needs.

**Conclusion:** This was the first study conducted in Sweden and the characteristics of this population were similar to those studied abroad. With proper care, appropriate technical aids and a supportive environment, it is possible for persons with LiS to have a good quality of life but there is still much room for improvements.

Key words: Locked-in syndrome; Living situation; Quality of Life

## Table of Contents

---

Abbreviations and acronyms .....	5
Introduction .....	6
Definition, etiology and clinic .....	6
Prognosis and consequences.....	7
Participation and health-related quality of life in context of disability .....	8
Locked-in syndrome in Sweden .....	10
Aim and scientific issues .....	11
Method .....	11
Study population.....	11
Procedure .....	12
WebRehab .....	13
Questionnaires .....	14
Statistical methods.....	16
Ethics .....	16
Results .....	17
Population characteristics .....	17
HRQoL and impact on participation .....	19
Case reports .....	22
Discussion .....	27
Methodological considerations.....	31
Limitations and strengths.....	31

Conclusion .....	33
Populärvetenskaplig sammanfattning .....	34
Acknowledgements .....	36
References .....	37
Appendices .....	40

## Abbreviations and acronyms

---

ADL	Activities of Daily Living
DOC	Disorders of Consciousness
EQ-5D	EuroQol-5 dimensions
FIM	Functional Independence Measure
HRQoL	Health-Related Quality of Life
ICD-10-SE	International Statistical Classification of Diseases and Related Health Problems - Tenth Revision – Swedish version
IPA-E	Impact on Participation and Autonomy Questionnaire, Extended version
LiS	Locked-in syndrome
MCS	Minimally Conscious State
QoL	Quality of Life
RAND-36	Modern version of SF-36
SIS v3.0	Stroke Impact Scale Version 3.0
SF-36	The Short Form (36) Health Survey
WHO	World Health Organization

## Introduction

---

Locked-in syndrome (LiS) is a rare condition in which a person is locked in inside his or her own body, unable to move or speak but with intact cognition.

The first known clinical case of LiS was diagnosed in 1947 and was a result of an infarction to the brain stem (1) but the very first time it was described was in 1844 by Alexandre Dumas in “The Count of Monte Cristo” (2) . It has thereafter been described by authors like Èmile Zola (3) and Jean-Dominique Bauby, who himself suffered from LiS and wrote an autobiography by blinking his left eyelid (4).

### ***Definition, etiology and clinic***

LiS was defined in 1966 as a state in which a patient is both quadriplegic and paralyzed to the lower cranial nerves but conscious and with retained control of vertical eye movement and eyelids (5). The condition is in many cases preceded by premonitory symptoms (6) and can be associated with a period of coma (5, 7).

LiS is usually caused by a lesion to the brain stem, most commonly a ventral pontine lesion that interrupts the descending pyramidal tracts (5, 8). The lesion is often a result of an ischemic stroke due to thrombosis in the basilar artery but can also be caused by hemorrhages, trauma, tumors or ischemia due to hypotension (9-11). In rare cases the cause is metabolic or infectious (12).

In 1979, a classification of LiS was introduced based on clinical observations in 12 patients (13). *Classic LiS* is defined as a fully paralyzed patient with intact vertical eye movements and movement in the eyelid (13). *Incomplete LiS* is similar to Classic LiS but with remnants of motor functions beyond those of the classic variant (13). *Total LiS* is defined as total immobility, the use of electroencephalography – EEG is then necessary to ascertain



consciousness (13). In context of duration, LiS can be chronic or transient, in the latter the patient recovers completely (13).

Diagnosis of LiS is often based on clinical observations with the help of neuroimaging techniques, techniques measuring functional activity and/or neurobehavioral criteria. EEG is a technique that measures functional activity of the nervous tissue and can be used to assess level of consciousness in comatose patients or patients with other disorders of consciousness. Another technique is functional magnetic resonance imaging – fMRI, that visualizes structural changes and blood oxygenation of the brain (5, 14, 15) American Congress of Rehabilitation Medicine (ACRM) recommends neurobehavioral criteria to be used when diagnosing LiS (16). The criteria are 1: Eye opening well sustained, 2: Basic cognitive abilities preserved (clinical examination), 3: Severe hypophonia or aphonia on clinical examination, 4: Quadriplegia/Quadriplegia on clinical examination and 5: Communication primarily through eye movements or through blinking (16). An alternative or additional method is assessment of consciousness according to Giacino et al. which is an assessment based on clinical features (17). Standardized diagnostic procedures with angiographic methods for acute onset and MRI for more chronic patients have been suggested (18).

The diagnosis is often triggered by family member noticing awareness (12). Time until diagnosed varies, the mean time elapsed until diagnosed was in one French population 79 days but in some cases it has taken several years (12).

### ***Prognosis and consequences***

The view on prognosis of LiS has shifted a lot through the years. When LiS first became a subject of studies, the opinion was that acute mortality was high (6) with nearly no long-term survivors (19). Since then opinion has shifted, numbers on mortality still varies between

studies but the overall view on survival is more positive. If the patient medically stabilizes and survives the first year, 5-year survival may be 81-86 % (10, 20) and some patients survive for decades (12).

Patients with chronic LiS often remain highly impaired in motor functions even if some improvement is possible (6, 20, 21). Among other things, the impairments lead to them becoming dependent in Activities of Daily Living – ADL (self-care etc). Tetraplegia, along with impairments in breathing patterns, also mean respiratory complications are common (6). Most patients living with LiS learn to communicate in some way (12, 20, 22).

Studies on quality of life – QoL has shown that measured with scales including motor impairment, LiS patients show lower QoL than healthy controls but measured using scales not including motor impairment, it is not significantly altered (23). Mild and moderate depression is more common in LiS patients than healthy controls (23). It is common for patients to be more emotionally sensitive and experience involuntary cries or laughter after onset of LiS, compared to before (12), a known problem after injuries to the brainstem (24).

Early medical stabilization and early rehabilitation improves the prognosis (9, 20) and to minimize suffering and enable proper care, a correct diagnosis early on is essential (11). When caused by an ischemic stroke, early stroke treatment such as anticoagulation and treatment with tissue plasminogen activator – t-PA could enhance the possibilities of a larger recovery (25, 26).

### ***Participation and health-related quality of life in context of disability***

Patients with LiS are, by definition, severely disabled. Disability is defined by the World Health Organization, WHO, as “*an umbrella term for impairments, activity limitations, and participation restrictions, denoting the negative aspects of the interaction between an*

*individual (with a health condition) and that individual's contextual factors*" (27). This means that disability cannot be seen only as an attribute of a person but needs to be seen in a broader perspective including contextual factors and interactions with these. One aspect of disability is how it affects impact on participation, another how it affects health-related quality of life (HRQoL).

The definition of participation is, according to WHO, "*a person's involvement in a life situation, representing the societal perspective of functioning*"(27). Participation is an aspect of disability which is dependent on both personal and environmental factors, shown in the ICF-International Classification of Functioning, Disability and Health (28). A person's impact on participation affects autonomy and quality of life (29, 30), why it becomes an important issue to discuss. Neither autonomy nor participation is static; they are both values that can differ, through life and between different aspects (29) which means it can be reduced in one area but still be high in others. This becomes relevant in the topic of LiS, when the motor functions are low but cognitive functions high. Examples of tools to measure impact on participation are Impact on Participation and Autonomy Questionnaire – Extended version – IPA-E (31), Assessment of Life Habits – LIFE-H (32) and Stroke Impact Scale – SIS (33).

Quality of Life, QoL, describes a person's well-being, including all aspects. Health-related Quality of Life, HRQoL, is a less broad term which only describes the parts of QoL which are directly affected by the person's health situation. There are numerous scales and instruments for assessing HRQoL, for example RAND-36 (34) and EuroQol 5 dimensions – EQ-5D (35).

QoL in severely disabled persons could be assessed by questions to significant others and family members, but these tend to underestimate (36-38). Many severely disabled persons report good QoL despite of their serious conditions, which is called the disability paradox (39). The accuracy of the paradox is often mistrusted but when investigating possible sources

of error, the conclusion was that the disability paradox does exist (40). This emphasizes the importance of caution for physicians and significant others when forced to make important decisions for their patients or next of kin, and not easily assume low life satisfaction.

### ***Locked-in syndrome in Sweden***

The incidence of LiS in Sweden is unknown. The International Statistical Classification of Diseases and Related Health Problems - Tenth Revision – Swedish version – ICD-10-SE is a classification list issued by WHO and can be used to monitor incidence and prevalence of diseases and other health problems (41). Previous of 2015, there has not been an ICD-code for LiS in ICD-10-SE which means The National Board of Health and Welfare has no statistics on the syndrome. LiS is not reported in the national quality register for stroke care, Riksstroke (42). One registry in Sweden, WebRehab, offers the possibility to report level of consciousness and thereby report LiS (43). There is a European Network for LiS patients but Sweden is not represented (44).

To our knowledge, locked-in syndrome has never been researched in Sweden. Previous studies have suggested that rehabilitation in these patients could improve if care was centralized and given by a skilled, interprofessional team (8) and that early, intensive rehabilitation improves the prognosis (20). Further research exploring LiS in Sweden, assessing possibilities and needs, is therefore well needed.

## ***Aim and scientific issues***

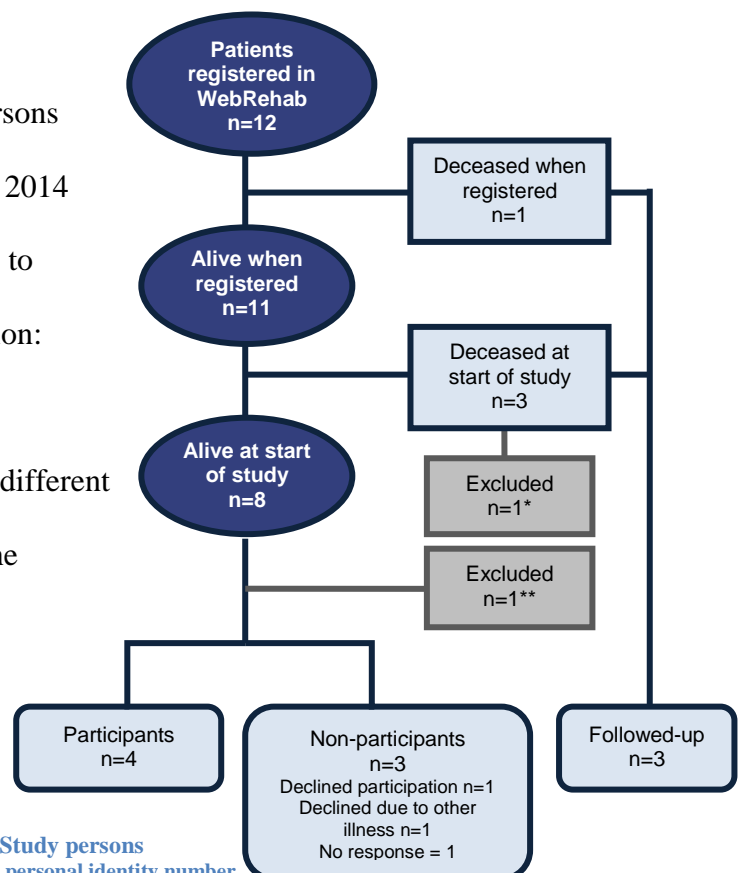
The overall aim of this study is to explore and describe LiS in Sweden with the purpose of gaining a better understanding of the life situation for this group of patients.

To achieve the overall aim, following issues were explored; (a) Population characteristics at onset and during rehabilitation period with focus on diagnosis, prevalence of respiratory complications and ADL, (b) Population characteristic at time of study with forms of residency and living, (c) Mortality and, in affected cases, cause of death and (d) HRQoL and impact on participation. For a deeper understanding, the aim is to use case reports to describe the life situation for the participants.

## **Method**

### ***Study population***

The persons eligible for this study were persons registered in WebRehab between 2007 and 2014 for whom level of consciousness according to Giacino (17) was reported. Inclusion criterion: Diagnosed with Locked-in syndrome. Twelve persons were identified from eight different hospitals. One person was excluded after the validation process due to not meeting the inclusion criteria and one person due to not having a valid personal identity number. For details see fig 1.



**Figure 1 Study persons**  
\* No valid personal identity number  
\*\* Did not meet inclusion criterion

## Procedure

### Part one – Population characteristics.

The identity of the included study persons was obtained from WebRehab's database.

Data collection procedure is described in table 1.

The Functional Independence Measure – FIM – measures level of disability and independence in two scales, one motor scale and one cognitive scale (45) and was analyzed for description of ADL-functions and dependency.

For validation of the data in WebRehab, medical charts were analyzed. To obtain these charts, concerned care units were contacted, first by letters, then reminders were sent by email and attempts was made to reach persons in charge by phone.

Data from the Swedish Tax Agency's population register was collected to investigate how many of the study persons who were still alive and to obtain their addresses and contact information

Data on cause of death and date of death were obtained from The National Board of Health and Welfare's registry on Cause of Death. Both the application and the communication following the application was written and handled by the author.

**Table 1 Procedure, collection of data**

Part one	10 study persons
<b>Onset and admission</b>	
WebRehab and medical charts	
Age at onset	
Sex	
Previous medical history	
Diagnosis	
Classification	
Complications	
Time frames	
<b>Discharge</b>	
WebRehab and medical charts	
Improvement in FIM	
Form of residency - discharged to	
<b>Today</b>	
Population register	
Form of residency - today	
Register on Cause of Death	
Date of death/Survival time	
Cause of death	
Part two	4 participants
<b>Today</b>	
Questionnaires (EQ-5D, IPA-E, SIS-v3.0, RAND-36) and interviews	
HRQoL and participation	
Living situation	

*FIM- Functional Independence Measure, EQ-5D - EuroQol 5 dimensions, IPA-E - Impact on Participation and Autonomy, SIS-v3.0 - Stroke Impact Scale version 3.0 HRQoL - Health-Related Quality of Life*

*Part two – HRQoL and participation.*

An information letter along with the questionnaires was sent to all study persons still alive. If no response, a reminder was sent by letter and thereafter attempts to reach the study persons or proxy by phone was made. If the study persons wanted to participate, they were asked to send in the questionnaires or contact the author.

Study persons who agreed to participate were visited for a personal, structured interview. The interviews were conducted at the participants' home and were recorded and transcribed. All interviews were conducted by the author. During the interviews, some information was told by next of kin or a personal assistant and the rest was told by the participant and translated by next of kin. After the interview, the participant confirmed that the information given was correct, both the information given in the interview and the information given in the questionnaires. One participant was not able to participate in a personal interview but participated through a telephone interview with her trustee.

Data was thereafter extracted and is presented both as case reports and summarized in Appendix A (Table 2)

***WebRehab***

WebRehab is a National Quality Registry in Rehabilitation Medicine. The purpose of a national quality registry is to facilitate improvements and possibilities to follow up patients in specific areas.

WebRehab is owned by Region Västra Götaland and the Swedish Association of Local Authorities and Regions, SALAR, and administrated by Uppsala Clinical Research Center (46). Twenty-three rehabilitation medicine units in Sweden are contributing to the database, representing all 21 counties of Sweden (46). The rehabilitation medicine units reports data

from the rehabilitation period, including admission and discharge, and from a 1-year follow-up (43).

A National quality registry can be certified at 3 different levels depending on level of development and usability (47). WebRehab is certified at level 2 which is the second highest certification level (47).

### ***Questionnaires***

The different questionnaires (in Swedish) can be found in Appendix B.

#### ***SIS-v3.0***

To assess health status a Swedish version of the SIS-v3.0 (33) – was used. The Stroke Impact Scale is validated and reliable for use on stroke patients (48). Stroke Impact Scale measures health status by assessment of eight domains: strength, hand function, ADL/IADL, mobility, communication, emotion, memory and thinking and participation/role functioning and is especially designed for stroke-patients (33). For three questions, the item score is reversed before calculating the domain score (3f, 3h, 3i – Emotion domain). A summative score for each domain was generated using an algorithm, resulting in a value between 0-100 where higher values indicates higher health status in that domain (49). SIS-v3.0 also contains a ranking scale, ranging from 0-100, asking the respondent to rank how recovered they feel after their stroke (49). Zero represents no recovery, 100 represents the respondent feeling fully recovered.

#### ***RAND-36***

RAND-36 is a survey instrument that assesses health-related quality of life. The Swedish version of RAND-36 is a modern translation of The Short form Health Survey – SF-36, but it is similar enough to allow comparisons. It is reliable and valid for measures on HRQoL in



stroke patients (50). The survey is comprised by 36 questions where every answer represents a precoded numeric value. This value is recoded according to a scoring key to a score that represents the percentage of total possible score and is therefore a value between 0-100. The individual scores are thereafter averaged together in eight different areas, resulting in one score for each area (34). A higher score indicates higher HRQoL in that area. The eight areas are: physical functioning, role limitations caused by physical health problems, role limitations caused by emotional problems, social functioning, emotional well-being, energy/fatigue, pain and general health perceptions (34).

### *IPA-E*

IPA-E was used to assess and measure impact on participation and autonomy. The original version of IPA has good validity and reliability (31, 51). IPA-E includes 5 domains, autonomy indoors, family role, autonomy outdoors, social life and relationships and work and education (31). There are five response levels for scoring participation and autonomy, from “very good” to “very poor” coded as 0-4, and three response levels for scoring the extent of the limitations, from “no problems” to “major problems”, coded as 0-2 (52). A median value was then calculated for each domain, the final value is therefore a value between 0-4 where a higher value represents more restrictions in participation and a lower level of autonomy and participation (58).

### *EQ-5D*

To assess health related quality of life a Swedish version of the questionnaire EQ-5D was used. EQ-5D is a standardized, validated health questionnaire developed by the EuroQol Group Association (53). It is intended to be used for self-completion in postal surveys, interviews and clinical practice (53). The EQ-5D is a valid and reliable measure of HRQoL after stroke (54). EQ-5D assesses health in 5 dimensions, mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The version used in this project was EQ-5D-3L, the

“3L” indicating 3 response levels, from no problems to extreme problems, coded as 1 through 3. Depending on the answers, an index score was calculated using a tariff (in Sweden, the tariff for UK is used). The index score varies from 1 to -0.594, 1 indicating full health related quality of life, 0 indicating death and values below 0 indicating conditions worse than death (35). Mean value in a general population in Sweden is 0.84 (55).

The EQ-5D also contains a visual analog scale where the respondent rates their health from “Best imaginable health state” (100) to “Worst imaginable health state” (0). Mean value in a general population in Sweden is 0.85 (when divided with 100) (55).

### ***Statistical methods***

For statistical analyses IBM<sup>®</sup> *SPSS Statistics 21* was used. Mainly descriptive statistics with mean and median values were used. Kaplan-Meier diagrams were used to calculate survival over time after onset of LiS.

### ***Ethics***

This study was approved by the Regional Ethical Review Board in Gothenburg (Application approval number 052-15). The first version of the application was written by the supervisor of this study. Approval was given after completions and revisions made by the author.

In part one, data from medical charts was gathered for validation and quality control of a quality register and according to Swedish law on personal particulars data (SFS 1998:204); no informed consent from the study persons is then needed.

In part two, informed, written consent was obtained from all participants or their fiduciary.

## Results

### *Population characteristics*

The characteristics of the study population are summarized in table 2.

Out of ten study persons, there were three (30%) women and seven (70%) men, ages at onset varying from 22 years to 67 years with a median of 49 years. The cause was in all cases a stroke, 30% were hemorrhagic and 70% ischemic. In six of the cases of ischemic stroke, the underlying cause was a basilar thrombosis. In the seventh case, the underlying cause was a vertebral artery dissection. 60% of the study persons had a history of cardiovascular disease or documented vascular risk factors. The most common vascular risk factor was hypertension.

90% of the study persons experienced respiratory complications during hospitalization.

No change in ADL-dependency in motor scale domains was seen in any of the study persons when measured with FIM at admission and discharge; all study persons were totally dependent in all domains. Improvements in FIM cognitive domains are shown in figure 2 as improvements in total sum of cognitive domains.

For one study person, FIM was not reported.

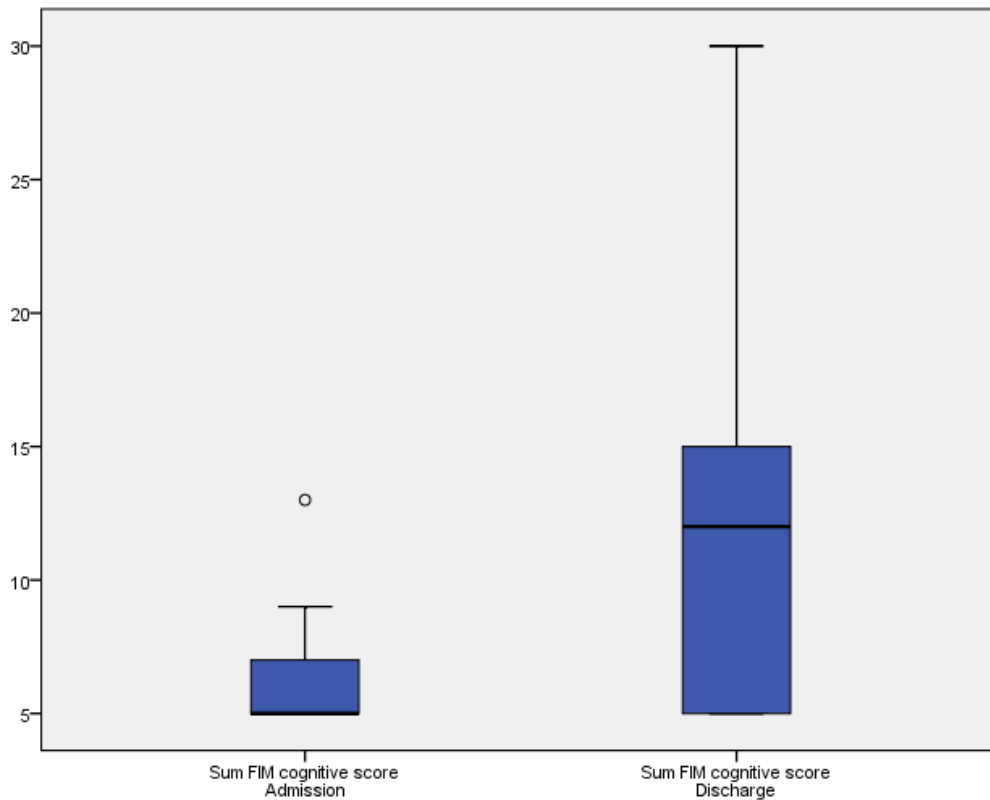
**Table 2 Characteristics of the study population**

Study persons	n=10
<i>Alive at 1.5.2015</i>	7
<i>Deceased</i>	3
Cause of LiS	
<i>Ischemic stroke</i>	7
<i>Hemorrhagic stroke</i>	3
Classification of LiS at onset	
<i>Classic</i>	6
<i>Incomplete</i>	4
Previous CVD/VRF	6
Length of Stay Median (Range)	151 days (63-289)
Age at onset Median (Range)	49 y (22-67)
Survival* Median (Range)	1.9 y (1.5-2.3)
Time since onset** Median (Range)	5.9 y (2.3-8.1)

\* *Deceased study persons included*

\*\* *Alive study persons included*

LiS - Locked-in syndrome, CVD - Cardiovascular disease, VRF - Vascular Risk Factors



**Figure 2 Improvement in Functional Independence Measure – cognitive domain during rehabilitation. Five persons improved, four were stable and none deteriorated. Missing data for one person**

Three of the study persons were discharged to short-term care units, three to nursing home or similar care facilities and three were discharged to independent living with personal assistance. One person was deceased before discharge.

Seven (70%) study persons from the total population (n=10) was still alive at start of study and 3 (30%) study persons were deceased. One person died during rehabilitation and the remaining two after initial rehab period. Time from onset to date of death varied from 1.5 to 2.3 years with a median of 1.9 years. The cause of death was different for each case: pulmonary embolism, acute myocardial infarction and acute vascular disorders of the intestine. In none of the cases the cause of death was reported as being the result of respiratory complication due to LiS.

Survival for all study persons, for the ones still alive calculated as time from onset to 1<sup>st</sup> of May 2015 is showed in figure 3 as a Kaplan-Meier diagram.

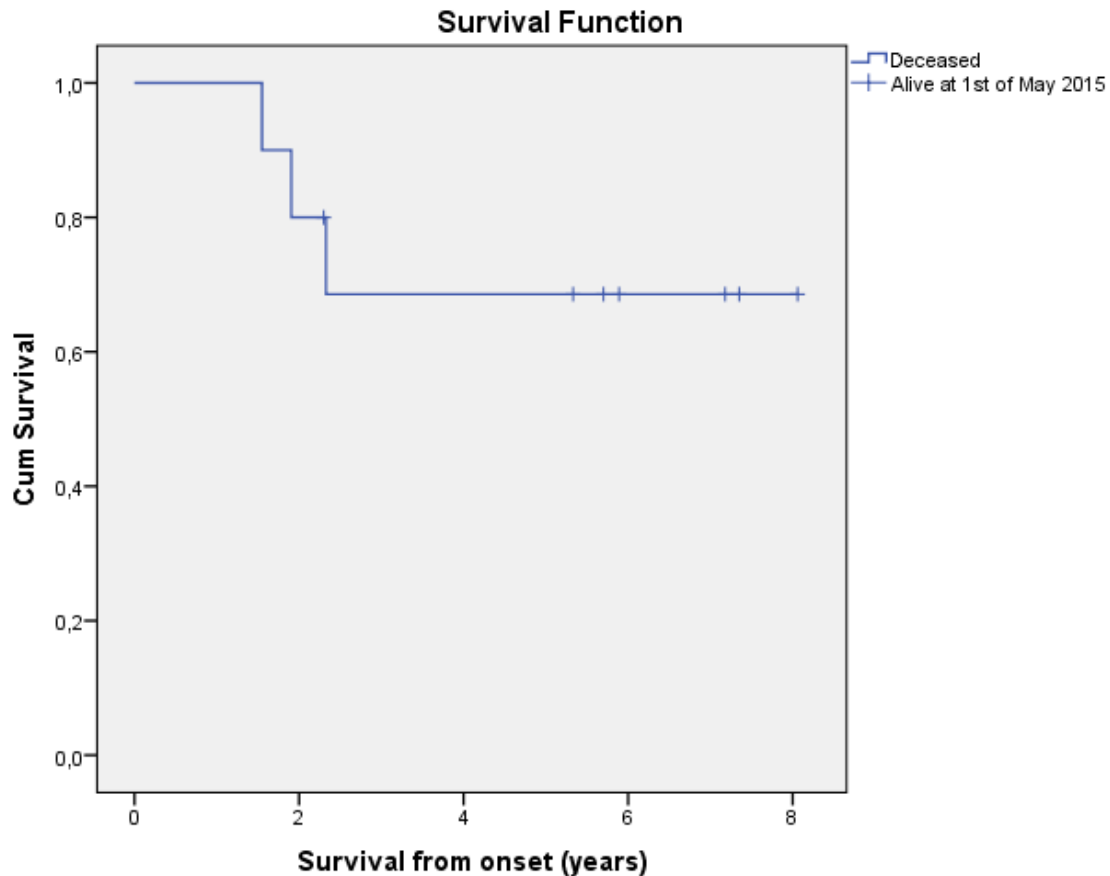


Figure 3 Kaplan-Meier diagram showing survival from onset, all study persons included

Four (57%) of the study persons agreed to participate, one of these was not able to participate in a personal interview but through a phone-interview with her trustee. Three persons declined participation, further details in figure 1.

For details on all study persons and on participants in particular, see appendix A.

### ***HRQoL and impact on participation***

Results on the questionnaires are presented separately for each questionnaire. No mean scores were calculated due to the low number of participants. To put the participants' scores in perspective, values for reference populations are included in the tables.

The main finding from the questionnaires is that, although values vary between participants, higher scores were seen in cognitive and mental domains (e.g. SIS-v3.0 Memory and Emotion

and RAND-36 Mental Health) than in physical domains (e.g. SIS-v3.0 Strength, RAND-36 Physical Functioning and EQ-5D Mobility).

Individual scores on the SIS-v3.0 are presented in table 3, on RAND-36 in table 4, on IPA-E in table 5 and on EQ-5D in table 6.

**Table 3 Results on Stroke Impact Scale.**

Domain	Individual score				Reference* Mean (SD)
	2	4	6	10	
Strength	25	37.5	25	0	71 (26.9)
Hand function	0	0	30	0	81.1 (22.2)
Mobility	0	0	19.4	5.6	77.6 (17.4)
ADL	0	12.5	15	20	85 (21)
Emotion	44.4	94.4	88.9	86.1	75 (28.5)
Memory	100	42.9	100	71.4	75.6 (29.2)
Communication	75	85.7	53.6	14.3	68.9 (34.5)
Social participation	12.5	31.25	78.1	25	70.3 (27.5)
Stroke recovery	20	50	100	10	68.4 (25.5)

\* Swedish stroke population, assessed 12 months after stroke (56)

Domain scores range from 0-100, higher scores indicates better health status in that domain (49).

**Table 4 Results on RAND-36.**

Domain	Individual score				Reference (LiS)* Mean (SD)	Reference (Stroke)** Mean (95% CI)
	2	4	6	10		
Physical functioning	0	0	5	0	0 (0)	51.2 (44.3-58.1)
Role limitations due to physical health	0	0	100	0	59.4 (32.6)	14.7 (3.3-26.1)
Role limitations due to emotional problems	33.3	100	100	100	75.0 (34.5)	18.0 (10.2-25.8)
Vitality/Energy-fatigue	45	55	75	70	64.4 (24.6)	42.9 (37.8-48.0)
Mental health/Emotional well-being	60	76	92	76	68 (19.6)	62.7 (58.2-67.2)
Social functioning	12.5	75	50	87.5	56.3 (34.1)	55.2 (49.2-61.4)
Bodily pain	80	90	100	67.5	82 (26.8)	65.0 (57.9-72.1)
General health	40	30	100	60	63.5 (33.0)	58.2 (52.5-63.9)

\* Belgian Locked-in syndrome – LiS – population, assessed more than 12 months after onset (21)

\*\* Swedish stroke population, assessed 2 years after day hospital rehabilitation for stroke (57).

The score in each domain represents a percentage of the total possible score and ranges from 0-100, higher scores indicates better HRQoL in that domain (34).

**Table 5 Results on Impact on Participation and Autonomy questionnaire**

Domain	Individual score				Reference * Mean (SD)
	2	4	6	10	
Autonomy indoors	4	3	0	2	0.96 (0.6)
Family role	4	4	4	4	1.96 (1.1)
Autonomy outdoors	4	3	2	3	2.35 (0.9)
Social life and relations	3	2	3	3	1.48 (0.7)
Work and education	.1	.1	1	.1	-

<sup>1</sup>Cannot be calculated, participant is not currently employed

\*Iranian stroke population, assessed 5-36 months after their stroke (58)

Domain scores range from 0-4, a higher score represents more restrictions in participation and a lower level of autonomy and participation (58).

**Table 6 Results on EuroQol-5 dimensions**

Domain	Individual score				Reference* Mean (95% CI)
	2	4	6	10	
Mobility	3	3	3	3	-
Self-care	3	3	3	3	-
Usual activities	3	3	1	3	-
Pain/discomfort	3	2	1	2	-
Anxiety/depression	2	2	1	2	-
Index value	-0.429	-0.166	0.122	-0.166	0.44 (0.28-0.42)
VAS	0.02	0.5	1	0.4	0.63 (58.8-66.6)

\*Swedish stroke population, assessed 2 years after day hospital rehabilitation for stroke (57).

Domain scores range from 1-3, 1 indicates no problems and 3 extreme problems in that area. The index value varies from 1 to -0.594, 1 indicating full health related quality of life, 0 indicating death and values below 0 indicating conditions worse than death (35). The Visual analog Scale (VAS) varies from 0-1, 0 represents worst imaginable health state and 1 best imaginable health state (55).

## ***Case reports***

### *Case number 2*

This participant is female, she was a 46 years old when she got her stroke, which is eight years ago. She had no risk factors or relevant previous diseases. The cause of her LiS was a basilar thrombosis. During rehabilitation she learned to communicate by blinking. Since discharged from rehabilitation, she has been living in a nursing home with personal living areas and joint common areas but she will soon move out to her own apartment. She will then have personal assistance around the clock. At the moment, her family situation is complicated but she has recently got a trustee who is now looking after her interest.

In her current residency, she is visited by an occupational therapist and a physiotherapist every second week, no additional training beyond that although she is not satisfied and would like a lot more. Today, several years after her stroke, she is still progressing and improving in motor functions. In terms of technical aids, she has a wheel-chair, an adjusted bed and a lift. She is communicating with help of an alphabet board but has requested to be evaluated for an eye-tracking computer device. She is able to turn her head and has an alarm button which can be placed by her temple; this enables her to attract attention.

Contacts with authorities have worked well but daily interactions and contacts with caregivers have worked less well. She describes a lack of information and that she feels that she is not listened to. Her trustee describes her as a woman who knows what she wants but whose autonomy is being violated on a daily basis because she is treated like she does not understand. She does not have a good quality of life today, she is unhappy with her living situation and she doesn't feel like she can live her life on her own conditions. Her trustee describes her situation as followed; "she is a woman in the prime of her life – she wants more".



#### *Case number 4*

This participant was a 22 year old man at onset and had no previous medical history. The cause of his LiS was an ischemic stroke, a basilar thrombosis. Time elapsed since then is almost seven and a half (7.4) years. At admission he had some movement in his left hand. During rehabilitation he learned to communicate by blinking, head-shaking and with help of an alphabet board. Today he lives in his own apartment with community-based support and personal assistance around the clock. During 1.5 hour per day he has two assistants (a total of 10.5 hours/week). The technical and rehabilitation aid he is using today is a wheel-chair, a tilting table, a hospital bed, a ceiling hoist and a bicycle for passive cycling.

He is communicating with the help of an alphabet board and is currently learning to use an eye-tracking computer device. He has some oral communication including most vowels, some consonants and a few, short words. His motor functions are constantly improving, today he is able to control his jaw and tongue muscles and he has some movement in his fingers. He is able to eat all meals orally.

He was offered support by a counselor which he accepted and was very pleased with.

Contact with authorities has mostly worked well but he would like more hours with two assistants which he thinks would improve his quality of life.

He is pleased with the amount of information he has gotten and he feels that he knows who to contact if he has questions. Regarding respect his experience is that it is quite common that persons who don't know him treat him as if he did not understand.

The assistants together with his mother handle his finances but he is able to control how he spends his money.

He has a good quality of life but with room for improvement. He is able to travel and use his leisure time as he wants. He has studied at the university after the stroke, this has worked very well and he is going back again this fall. He feels that he can live the life he wants.

### *Case number 6*

This is a man who was 29 years old at onset which is almost five years and nine months (5.7) ago. He was previously healthy and got LiS directly after a chiropractic cervical spine manipulation, the cause was an ischemic stroke due to a vertebral artery dissection. The dissection was treated with a stent. During rehabilitation he improved very much and was at discharge able to move all four extremities and had some oral communication. Since he was discharged he has been living in a house with his family. The house is adjusted; there is a ramp and adjusted thresholds and an elevated toilet seat. He has personal assistance daytime and assistance when needed nighttime. In technical aids, he has three wheelchairs, two of them are electrical, an adjusted bed, a walking frame with extra support and a sit-to-stand and transfer device (ReTurn™).

He is mainly communicating orally but has a very dysarthric speech. Because of that, he has an alphabet board he can point at as well as letters tattooed on his arms. He has a keyboard-based, text-to-speech communication aid as well but he doesn't use it since he is able to use ordinary computers and tablets.

He has no active, ongoing rehabilitative training or contact with a physiotherapist but has been to two different intensive rehabilitation camps. He has improved remarkably in motor functions; today he can walk a few steps with support, lift his arms and move his head. He also has some function in his left hand, although he is still completely dependent in ADL.

He is able to eat solid food and has no additional nutritional support.

He has been offered support by counselors, mainly during the rehabilitation camps. Overall he has had a great deal of support and help during short, intensive periods but lacks continuous support, both in physical aspects and psychological.

Contacts with authorities have worked well but have taken a lot of time and energy. His speech problems are the main reason why problems occur since he is not able to answer

questions by phone.

During the acute phase when he was treated at the intensive care unit, his family was satisfied with the amount of information but his experience is that while he has gotten better, information has gotten worse. He feels he does not know who to turn to for information and he would like to meet a specialist but experiences that need not to be heard.

His experience is that some people treat him disrespectfully, mainly by talking over his head with whoever is with him, treating him as a child or speaking very slow and loud and that there is an association between a person's knowledge and how they treat him.

He has a good quality of life and describes his health as excellent. He is able to work a few hours per month and is also able to travel and participate in leisure activities.

#### *Case number 10*

This participant was a 56 year old man with hypertension in his medical history. He suffered from LiS due to a basilar thrombosis and had classic LiS. Time elapsed since then is almost seven years and three months (7.2). During rehabilitation he learned to communicate by blinking. Today he lives with his family in a house. He has personal assistance around the clock, daytime two assistants. The house has had some minor adjustments done, a ramp and a widened door. The technical aid he is using today is an electric wheelchair, a standing wheelchair and a bicycle for passive cycling. He wants a Functional Electric Stimulation/FES-assisted training device but has been denied grants from the municipality for this. He is also part of a customer test-group for a device which combines the eye-tracking technology with an electric wheelchair to enable maneuvering the wheelchair with eye movements.

He is communicating mainly by blinking; he has an eye-tracking device but mostly uses this for reading, listening to music etc. He has an alarm button with a pre-recorded sentence which he can press by turning his head to attract attention. During the last year, he has learnt to shake his head and is currently practicing nodding which, according to his partner, has led

to him being treated with more respect.

Most of his training and rehabilitation he does on his own with the help of personal assistants but he and his family are very pleased with the support they have received from his occupational therapist, physiotherapist and speech therapist.

He was offered support by a counselor but since he was unable to utilize this, it was offered to his partner instead.

The main critic from him and his family was the lack of information in the beginning, they felt they did not get enough information about the condition and the information they got was hard to understand since it was a lot of medical terms. Most of his technical aids they have found on their own. Another thing that was brought up was his wishes to be treated with respect and as the adult he is and not as a child, which in his experience was quite common amongst new assistants etc.

He has a good quality of life and feels that he can live his life on his own conditions. They have chosen to handle many things by themselves, such as home care and transportation, for instance they have bought an adjusted car.

## Discussion

---

The primary purpose of this study was to map the Locked-in syndrome in Sweden. We identified ten persons who had been diagnosed with LiS between 2007 and 2014 and investigated factors at onset, rehabilitation period and discharge. Seven of these persons were still alive at start of study and four of these participated.

In general, our findings on population characteristics with sex, age, underlying causes etc. were consistent with findings in previous studies. The utmost common cause was stroke and most of these were ischemic. One of the study persons had an ischemic stroke after a chiropractic cervical spine manipulation. The association between stroke/cervical artery dissection and cervical spine manipulation is a controversial subject. The American Heart Association along with the American Stroke Association recommends practitioners to inform patients about the association before the procedure (59). This because most studies show an association, even if there is insufficient biomechanical proof of causality (59). In line with previous findings (12, 20, 21), most of the study persons were middle-aged with a median age of 49 years at onset. In this population, the majority (70%) of the study persons was male but due to the small number of persons, no conclusions can be drawn from this.

Since this was a nation-wide study and no selection was done, the number of patients identified might be considered few compared to previous studies abroad with study samples of around 20-30 persons (10, 12, 23). According to WHO, Sweden does not stand out in number of lost DALY's due to stroke compared to western Europe (60) and the US. With stroke being the leading cause of LiS, one hypothesis could be that incidence numbers on LiS in particular truly differs for some reason, another that incidence numbers are similar but we have not been able to identify all persons with LiS. One possible explanation to the latter might be that the study population was identified through a register for rehabilitation medicine

and therefore did not include patients who did not receive rehabilitation, e.g. those who died in intensive care units. Up until the end of 2014, WebRehab was, to our knowledge, the only register in Sweden that had statistics on LiS but as from 1<sup>st</sup> of January 2015, there is an ICD-code in ICD-10-SE (61). What this will mean for the care of LiS-patients is hard to predict but it will at least facilitate further research in the area since reporting LiS will not be dependent on specific quality registers but possible for every care unit. Another possible explanation to the small number of persons identified is that there have been patients with LiS that have not been diagnosed, and is therefore not registered. The importance of maintaining vital functions and that fatality in LiS have declined with improvements in quality of medicine has been discussed in previous studies (11). So has also the fact that LiS can be mistaken for other Disorders of Consciousness - DOC when not assessed properly or thorough enough (18). A missed diagnosis could therefore be due to, e.g., vital functions not being maintained or that the condition was misdiagnosed as another DOC.

According to medical charts, some of the study persons improved in motor function although none improved in independency measured with FIM motor scale. This is consistent with previous knowledge that patients with chronic LiS have slim chances of major improvements in motor function (20). Worth noticing is that all participants are still improving in motor function.

Cognitively, no major deficits are reported in the medical charts. According to FIM, five persons improved in independency in cognitive domains. Expression and problem solving are the two areas with the least improvements which might be explained by the poor communicative skills of this patient group.

Mortality in this population was 30 % and mean survival time for the deceased was 1.9 years. For the study persons still alive, mean time since onset of LiS was 5.9 years. This seems

consistent with previous knowledge that mortality is high during the first years after onset but when stabilized, persons with LiS may live for decades (12). Since onset of LiS for our study population only goes back to 2007, long term survival cannot be commented here.

In none of the cases, the cause of death was reported as a result of respiratory complications or problems with breathing, this in spite of the high prevalence of respiratory complications during hospitalization. This might be explained by good, proper care which has prevented or successfully treated the respiratory problems, but it might also be explained by a fortuity.

The questionnaires used are in many ways similar to each other but all of them include unique aspects compared to each other. EQ-5D is a quite rough instrument and physical functions have a large impact on the final result. The value of using it in this particular study, where physical functions are very low, might therefore be discussed. In the EQ-5D, an index score under 0 is described to indicate a condition worse than death which is a problematic statement, e.g. did three of our participants had an index score under 0, none of them describing their situation as worse than death.

When presenting the results on the questionnaires, values from reference populations are included in the tables. The reason they were included was to put our participants' scores in perspective but due to the low numbers of participants, no further comparisons can be made. The reference populations are all stroke populations, this because all our participants had suffered a stroke and is often included in this patient group. Discussing similarities and differences between a general stroke population and a LiS population is therefore interesting and further comparisons might be an interesting subject for future studies. One reference population is Iranian, this since no other study with appropriate populations was found. Cultural differences may impact results which should be acknowledged but since no further comparisons have been made, this does not impact the result of this particular study.

In many aspects the results on the questionnaires varied between the participants but most of them scored high on domains measuring emotional and cognitive functions and low on physical domains and functions. This is in line with previous knowledge that QoL in persons with LiS can be high in mental domains while low in physical (23).

For each individual participant, the data from the questionnaires were mostly in line with the data from the interview, those who expressed high QoL and high impact on participation and autonomy in the interview, also scored high in domains not affected by motor impairments in the questionnaires.

Factors that were brought up during the interviews to have a positive effect on quality of life and participation were to have appropriate technical aids and support from family and friends. The participants were mostly satisfied with their technical aids but expressed that there is always room for improvements. Three of the participants expressed that they had great support from their families but all participants described that many of their friends from before onset, had disappeared.

From the interviews we could identify areas with unfulfilled needs, information and respect. Out of four participants, three had experienced a lack of information, both in the acute phase and later on. Specific problems like nursing staff using too much medical terms which were hard to understand or not getting enough information about technical and rehabilitation aids were brought up. All four participants had experienced problems with being treated with respect and felt that people all too often treated them as if they didn't understand or talking over their heads. These are problems that have been discussed in context of both disability and aphasia, it affects social participation and with that, quality of life in a negative way (62, 63). Both these issues, a perceived lack of information and a feeling of being treated as if they don't understand, can have a negative effect on a person's mental well-being. It can be



perceived as abasement and according to Swedish law (3 kap. Patientlagen (2014:821)), patients are entitled to appropriate information about their health which means that if caregivers fail to fulfill these needs, it is in fact a violation of Swedish law. Raising awareness about LiS, both among caregivers and the general public is necessary since it might lead to less insecurity and incertitude when meeting a person with LiS and hopefully, therefore treating this person with more respect.

### ***Methodological considerations***

The method chosen for this study was a quantitative, descriptive method containing analysis of register data, medical charts and structured interviews based on questionnaires. The reason we chose this approach instead of a qualitative method with unstructured interviews was the participants' limited possibilities of communication which we believe would mean unstructured interviews would not give more information than structured interviews.

### ***Limitations and strengths***

This study is primarily limited by its small number of patients which means that the results only can be seen as indicative and cannot be generalized. Worth noticing is, though, that compared to other studies on the same subject where a few has studied more than 20 persons but most studies are less than ten or even single cases, this study does not stand out as particularly small. Three persons did not participate; the reasons different for each case. No associations were found between the studied clinical characteristics and participation.

Another limitation is that the only register that contains information on LiS is a register for rehabilitation medicine; patients who did not receive rehabilitation could not be identified.

There is also a possibility that patients wasn't identified because they received rehabilitation

at a unit not reporting to WebRehab, because of misdiagnosis or because incorrect registration in WebRehab.

The study population is the total population of patients with LiS that we were able to identify; this means no selection has been done from our side.

Some data are based on clinical assessments made by clinicians and is interpretation sensitive. The risk of information being interpreted or reported differently by different clinicians should be acknowledged.

All questionnaires used are based on self-assessments and the results should be read accordingly. Differences in scores between the participants may be due to differences in actual differences in their life situation but may also be due to differences in attitudes, either way, the results tells us something about the situation at hand, even if it cannot conclude the reasons.

By combining questionnaires with personal interviews, the participants had a chance to elaborate their answers and opinions while still maintaining a standardized form of assessment with the questionnaires.

Since next of kin or a personal assistant was present and involved in the interviews, there is a risk of misinterpretations in translations or that things did not get told the way the participant intended. All participants were therefore asked if the information told was correct in the end of the interviews.

## ***Conclusion***

Locked-in syndrome is a very rare condition, and seems to be so also in Sweden. To our knowledge, this is the first study on LiS based on a Swedish cohort and the studied population is in clinical characteristics similar to populations throughout the world. Prognosis on cognitive functions is very good, on motor function poorer but there is a chance of improvements, even several years after onset. With proper care, appropriate technical aids and a supportive environment, persons with LiS can have good quality of life and impact on autonomy and participation.

In interviews we identified two main areas of unfulfilled needs. Firstly, the perceived lack of information experienced both by the participants and their significant others. Secondly, the participants' experiences of not being respected as adults, who are fully capable of understanding and processing a normal conversation and does not want to be treated as children or having people talking about them over their heads

Many studies on LiS, including this one, have small study populations which mean most of the results only can be seen as indicative and descriptive. For further research, the possibility of international multi-center studies should be considered. Further research is also well needed in the area of technical aids, which is a fast developing area with a lot of room for improvements.

## Populärvetenskaplig sammanfattning

---

### KARTLÄGGNING AV PERSONER MED LOCKED-IN SYNDROM SOM FÅTT REHABILITERING

Locked-in syndrom (LiS) är ett ovanligt tillstånd, för allmänheten kanske mest känt genom populärvetenskapen. Syndromet innebär att den drabbade förlorar all rörelseförmåga förutom ögonmotoriken. Kognitiva förmågor, som exempelvis medvetande, minne, inläring och förståelse, är dock fortfarande intakta vilket resulterar i ett tillstånd av att vara fången i sin egen kropp – Locked in. Det orsakas oftast av en stroke i hjärnstammen men kan också orsakas av exempelvis trauma eller tumörer.

Det finns ett antal studier gjorda utomlands om LiS men det saknas fortfarande mycket kunskap på området. I Sverige har man inte tidigare studerat syndromet specifikt.

Socialstyrelsen har ingen statistik på hur många drabbade det finns i Sverige, då LiS inte har haft någon diagnoskod. Man kan därför inte veta hur många i Sverige som har drabbats av LiS.

Forskningspersonerna i vår studie är hämtade från det nationella kvalitetsregistret för rehabiliteringsmedicin - *WebRehabs* databas. Initialt inkluderades samtliga tolv personer som registrerats med LiS mellan 2007-2014 i studien. Två personer exkluderades, en av dessa saknade svenskt personnummer och en var felregistrerad. Information kring insjuknande och rehabiliteringsprocess inhämtades från *WebRehab* samt från patientjournaler. De personer som levde då studien startade följdes sedan upp med enkäter som handlade om deltagande, självständighet och hälsorelaterad livskvalitet samt med en personlig intervju. De personer som avlidit följdes upp genom inhämtning av data ur *Dödsorsaksregistret*.

Medianåldern vid insjuknande var 49 år och av 10 forskningspersoner så var tre kvinnor och sju män. I samtliga fall orsakades LiS av en stroke, tre till följd av en blödning och sju till

följd av en blodpropp. Vid studiens start hade tre personer avlidit, mediantiden för överlevnad var 1,9 år. Sju stycken levde fortfarande, fyra av dessa deltog.

Resultaten på enkäterna visade att deltagarna generellt hade en mycket låg fysisk funktion men god kognitiv och mental hälsa. I de delar som mätte livskvalitet och delaktighet utan att räkna in fysisk funktion, hade deltagarna generellt bra resultat.

Intervjuerna bekräftade denna bild. I intervjuerna framkom även två områden där deltagarna upplevde problem. Det första var en brist på information från vården och det andra var att deltagarna ibland upplevde att de inte blev bemötta med respekt utan att personer, oftast då personer de inte kände väl, pratade över huvudet på dem eller behandlade dem som om de vore barn.

Slutsatsen som kan dras av denna studie är att de kliniska karakteristika, i de fall vi har studerat, stämmer med det tidigare forskning visat. Studien visar även att det med god vård, lämpliga hjälpmedel och lämplig rehabilitering samt en stöttande omgivning är möjligt att ha en bra livskvalitet samt goda möjligheter att känna delaktighet. Brist på information samt brister i bemötande tycks vara de områden där deltagarna upplever otillfredsställda behov.

Då denna studie baseras på så få personer kan resultaten endast ses som en indikation. Mer forskning behövs för att kunna utveckla och förbättra vården och omhändertagandet av personer med Locked-in syndrom.

## Acknowledgements

---

First and foremost, I would like to thank the participants and their families for allowing me to visit them and for generously telling me about their situation and experiences.

I would also like to thank my supervisor, prof. Katharina Stibrant Sunnerhagen and her research group at the Department of Clinical Neuroscience and Rehabilitation for all the help and support and for contributing to making this semester an educational and inspiring experience.

And last but not least, I would like to thank friends and family, who has encouraged and supported me during this semester.

## References

---

1. van Eeckhout P. Le Locked-in-Syndrom. *Rééducation Orthophonique*. 1997(35):123-135.
2. Dumas A. *The count of Monte Cristo*. Ware: Wordsworth Editions; 1997.
3. Zola É, Bouleau A. *Thérèse Raquin*. Höganäs: [Bra böcker]; 1985.
4. Bauby J-D, Björkman M. *Fjärilen i glaskupan : [berättelsen som blinkats fram av ett öga]*. Stockholm: Dagens nyheter; 1997.
5. Posner JB, Saper CB, Schiff ND, Plum F. *Plum and Posner's Diagnosis of Stupor and Coma*. 4 ed. New York: Oxford University Press; 2007.
6. Patterson JR, Grabis M. Locked-in syndrome: a review of 139 cases. *Stroke*. Jul-Aug 1986;17(4):758-764.
7. Smith E, Delargy M. Locked-in syndrome. *BMJ*. Feb 19 2005;330(7488):406-409.
8. Schjolberg A, Sunnerhagen KS. Unlocking the locked in; a need for team approach in rehabilitation of survivors with locked-in syndrome. *Acta Neurol Scand*. Mar 2012;125(3):192-198.
9. Doble JE, Haig AJ, Anderson C, Katz R. Impairment, activity, participation, life satisfaction, and survival in persons with locked-in syndrome for over a decade: follow-up on a previously reported cohort. *J Head Trauma Rehabil*. Sep-Oct 2003;18(5):435-444.
10. Katz RT, Haig AJ, Clark BB, DiPaola RJ. Long-term survival, prognosis, and life-care planning for 29 patients with chronic locked-in syndrome. *Arch Phys Med Rehabil*. May 1992;73(5):403-408.
11. Nikic PM, Jovanovic D, Paspalj D, Georgievski-Brkic B, Savic M. Clinical characteristics and outcome in the acute phase of ischemic locked-in syndrome: case series of twenty patients with ischemic LIS. *Eur Neurol*. 2013;69(4):207-212.
12. Leon-Carrion J, van Eeckhout P, Dominguez-Morales Mdel R, Perez-Santamaria FJ. The locked-in syndrome: a syndrome looking for a therapy. *Brain Inj*. Jul 2002;16(7):571-582.
13. Bauer G, Gerstenbrand F, Rimpl E. Varieties of the locked-in syndrome. *J Neurol*. Aug 1979;221(2):77-91.
14. Laureys S, Owen AM, Schiff ND. Brain function in coma, vegetative state, and related disorders. *Lancet Neurology*. 2004;3(9):537-546.
15. Gosseries O, Thibaut A, Boly M, Rosanova M, Massimini M, Laureys S. Assessing consciousness in coma and related states using transcranial magnetic stimulation combined with electroencephalography. *Annales Francaises d'Anesthesie et de Reanimation*. 2014;33(2):65-71.
16. American Congress of Rehabilitation M. Recommendations for use of uniform nomenclature pertinent to patients with severe alterations in consciousness. *Archives of Physical Medicine and Rehabilitation*. 1995;76(2):205-209.
17. Giacino JT, Ashwal S, Childs N, et al. The minimally conscious state: Definition and diagnostic criteria. *Neurology*. 2002;58(3):349-353.
18. Kotchoubey B, Lotze M. Instrumental methods in the diagnostics of locked-in syndrome. *Restor Neurol Neurosci*. 2013;31(1):25-40.
19. Pearce JM. The locked in syndrome. *Br Med J (Clin Res Ed)*. Jan 24 1987;294(6566):198-199.
20. Casanova E, Lazzari RE, Lotta S, Mazzucchi A. Locked-in syndrome: improvement in the prognosis after an early intensive multidisciplinary rehabilitation. *Arch Phys Med Rehabil*. Jun 2003;84(6):862-867.
21. Snoeys L, Vanhoof G, Manders E. Living with locked-in syndrome: an explorative study on health care situation, communication and quality of life. *Disabil Rehabil*. May 2013;35(9):713-718.
22. Soderholm S, Meinander M, Alaranta H. Augmentative and alternative communication methods in locked-in syndrome. *J Rehabil Med*. Sep 2001;33(5):235-239.

23. Rousseau MC, Pietra S, Nadji M, Billette De Villemeur T. Evaluation of quality of life in complete locked-in syndrome patients. *Journal of Palliative Medicine*. 2013;16(11):1455-1458.
24. Parvizi J, Anderson SW, Martin CO, Damasio H, Damasio AR. Pathological laughter and crying: A link to the cerebellum. *Brain*. 2001;124(9):1708-1719.
25. Barbic D, Levine Z, Tampieri D, Teitelbau J. Locked-in syndrome: a critical and time-dependent diagnosis. *CJEM*. Sep 2012;14(5):317-320.
26. Janjua N, Wartenberg KE, Meyers PM, Mayer SA. Reversal of locked-in syndrome with anticoagulation, induced hypertension, and intravenous t-PA. *Neurocrit Care*. 2005;2(3):296-299.
27. World Health Organization. *World Report on Disability 2011*. Malta: World Health Organization, The World Bank; 2011.
28. World Health Organization. *International Classification of Functioning, Disability and Health (ICF)*. Geneva: World Health Organization; 2001.
29. Cardol M, De Jong BA, Ward CD. On autonomy and participation in rehabilitation. *Disability and Rehabilitation*. 2002;24(18):970-974.
30. Yeung P, Towers A. An exploratory study examining the relationships between the personal, environmental and activity participation variables and quality of life among young adults with disabilities. *Disability and Rehabilitation*. 2014;36(1):63-73.
31. Kersten P, Cardol M, George S, Ward C, Sibley A, White B. Validity of the impact on participation and autonomy questionnaire: a comparison between two countries. *Disabil Rehabil*. Oct 15 2007;29(19):1502-1509.
32. Fougereyrollas P, Noreau L, Bergeron H, Cloutier R, Dion SA, St-Michel G. Social consequences of long term impairments and disabilities: Conceptual approach and assessment of handicap. *International Journal of Rehabilitation Research*. 1998;21(2):127-141.
33. Duncan PW, Bode RK, Min Lai S, Perera S. Rasch analysis of a new stroke-specific outcome scale: the Stroke Impact Scale. *Arch Phys Med Rehabil*. Jul 2003;84(7):950-963.
34. Hays RD, Sherbourne CD, Mazel RM. The RAND 36-Item Health Survey 1.0. *Health Econ*. Oct 1993;2(3):217-227.
35. Dolan P. Modeling valuations for EuroQol health states. *Med Care*. Nov 1997;35(11):1095-1108.
36. Kübler A, Winter S, Ludolph AC, Hautzinger M, Birbaumer N. Severity of depressive symptoms and quality of life in patients with amyotrophic lateral sclerosis. *Neurorehabilitation and Neural Repair*. 2005;19(3):182-193.
37. Lulé D, Zickler C, Häcker S, et al. Life can be worth living in locked-in syndrome. *Progress in Brain Research*. Vol 1772009:339-351.
38. Trail M, Nelson ND, Van JN, Appel SH, Lai EC. A study comparing patients with amyotrophic lateral sclerosis and their caregivers on measures of quality of life, depression, and their attitudes toward treatment options. *Journal of the Neurological Sciences*. 2003;209(1-2):79-85.
39. Albrecht GL, Devlieger PJ. The disability paradox: High quality of life against all odds. *Social Science and Medicine*. 1999;48(8):977-988.
40. Ubel PA, Schwarz N, Loewenstein G, Smith D. Misimagining the unimaginable: The disability paradox and health care decision making. *Health Psychology*. 2005;24(4 SUPPL.):S57-S62.
41. WHO. *International Classification of Diseases (ICD)*. [Internet] Geneva 2015 [cited 2015 May 26th]; Available from: <http://www.who.int/classifications/icd/en/>.
42. Asplund K, Hulter Asberg K, Appelros P, et al. The Riks-Stroke story: building a sustainable national register for quality assessment of stroke care. *Int J Stroke*. Apr 2011;6(2):99-108.
43. Sunnerhagen KS, Flansbjer UB, Lannsjö M, Tolli A, Lundgren-Nilsson A. WebRehab: a Swedish database for quality control in rehabilitation. *J Rehabil Med*. Nov 4 2014;46(10):958-962.
44. Association du Locked in Syndrome ALIS. LISEF LIS European Foundation. [Internet] [cited 2015 May 26th]; Available from: <http://www.alis-asso.fr/lisef/>.



45. Grimby G, Gudjonsson G, Rodhe M, Sunnerhagen KS, Sundh V, Ostensson ML. The functional independence measure in Sweden: experience for outcome measurement in rehabilitation medicine. *Scand J Rehabil Med.* May 1996;28(2):51-62.
46. Om WebRehab Sweden. [Internet] Uppsala: WebRehab Sweden; [updated 2014 Apr 3 cited 2015 Feb 2]; Available from: <http://www.ucr.uu.se/webrehab/index.php/om-webrehab-sweden>.
47. Nationella kvalitetsregister, Certifieringsnivåer. [Internet] Stockholm: Sveriges Kommuner och Landsting,; [updated 2014, March 26; cited 2015 Feb 12]; Available from: <http://www.kvalitetsregister.se/registerarbete/certifieringsnivaer>.
48. Duncan PW, Wallace D, Lai SM, Johnson D, Embretson S, Laster LJ. The stroke impact scale version 2.0. Evaluation of reliability, validity, and sensitivity to change. *Stroke.* Oct 1999;30(10):2131-2140.
49. Stroke Engine. Stroke Engine Assess. [Internet]: Stroke Engine; [updated 2015; cited 2015 May 28]; Available from: [http://www.strokeengine.ca/indepth/sis\\_indepth/](http://www.strokeengine.ca/indepth/sis_indepth/).
50. Anderson C, Laubscher S, Burns R. Validation of the Short Form 36 (SF-36) health survey questionnaire among stroke patients. *Stroke.* 1996;27(10):1812-1816.
51. Lund ML, Fisher AG, Lexell J, Bernspang B. Impact on participation and autonomy questionnaire: internal scale validity of the Swedish version for use in people with spinal cord injury. *J Rehabil Med.* Mar 2007;39(2):156-162.
52. Sibley A, Kersten P, Ward CD, White B, Mehta R, George S. Measuring autonomy in disabled people: Validation of a new scale in a UK population. *Clin Rehabil.* Sep 2006;20(9):793-803.
53. EuroQol Research Foundation. [Internet] Rotterdam: EuroQol Research Foundation; 2015 [cited 2015 Feb 6]; Available from: <http://www.euroqol.org/about-eq-5d.html>.
54. Dorman PJ, Waddell F, Slattery J, Dennis M, Sandercock P. Is the EuroQol a valid measure of health-related quality of life after stroke? *Stroke.* Oct 1997;28(10):1876-1882.
55. Burstrom K, Johannesson M, Diderichsen F. Swedish population health-related quality of life results using the EQ-5D. *Qual Life Res.* 2001;10(7):621-635.
56. Guidetti S, Ytterberg C, Ekstam L, Johansson U, Eriksson G. Changes in the impact of stroke between 3 and 12 months post-stroke, assessed with the Stroke Impact Scale. *J Rehabil Med.* Nov 2014;46(10):963-968.
57. Grenthe Olsson B, Sunnerhagen KS. Functional and cognitive capacity and health-related quality of life 2 years after day hospital rehabilitation for stroke: a prospective study. *J Stroke Cerebrovasc Dis.* Sep-Oct 2007;16(5):208-215.
58. Fallahpour M, Tham K, Joghataei MT, Jonsson H. Perceived participation and autonomy: aspects of functioning and contextual factors predicting participation after stroke. *J Rehabil Med.* Apr 2011;43(5):388-397.
59. Biller J, Sacco RL, Albuquerque FC, et al. Cervical arterial dissections and association with cervical manipulative therapy: a statement for healthcare professionals from the american heart association/american stroke association. *Stroke.* Oct 2014;45(10):3155-3174.
60. Mackay J, Mensah GA, Mendis S, Greenlund K. The atlas of heart disease and stroke. Geneva: World Health Organization; 2004.
61. Socialstyrelsen. Ändringar i och tillägg till Internationell statistisk klassifikation av sjukdomar och relaterade hälsoproblem - systematisk förteckning, svensk version 2011 (ICD-10-SE) gällande från den 1 januari 2015 2014-10-03.
62. Dalemans RJ, de Witte L, Wade D, van den Heuvel W. Social participation through the eyes of people with aphasia. *Int J Lang Commun Disord.* Sep-Oct 2010;45(5):537-550.
63. Wagner M. "Does he take sugar?". *World Health Forum.* 1991;12(1):87-89.

## Appendices

---

APPENDIX A	Table 1 Overview All study persons Table 2 Overview participants
APPENDIX B	Questionnaires
APPENDIX C	Guide for interviews
APPENDIX D	STROBE statement for cohort studies

Table 1 – Overview all study persons

	Study persons									
	2	3	4	5	6	7	8	9	10	11
Sex	Female	Female	Male	Female	Male	Male	Male	Male	Male	Male
Age at onset <sup>1</sup>	46 yrs	67 yrs	22 yrs	59 yrs	29 yrs	49 yrs	47 yrs	47 yrs	56 yrs	65 yrs
Etiology	Vascular (I)	Vascular (H)	Vascular (I)	Vascular (I)	Vascular (I)	Vascular (H)	Vascular (I)	Vascular (H)	Vascular (I)	Vascular (I)
Classification at onset	Classic	Classic	Incomplete	Classic	Classic	Incomplete	Incomplete	Incomplete	Classic	Classic
Discharged to	Nursing home	Short-term care	Short-term care	Nursing home	Independent living with personal assistance	Independent living with personal assistance		Independent living with personal assistance	Short-term care	Nursing home
Survival	- <sup>2</sup>	1,9 y	- <sup>2</sup>	2,3 y	- <sup>2</sup>	- <sup>2</sup>	1,6 y	- <sup>2</sup>	- <sup>2</sup>	- <sup>2</sup>
Cause of death (ICD-10-SE)		Pulmonary embolism (I26.9)		Acute vascular disorders of intestine (K55.0)			Acute myocardial infarction (I21.9)			
Present form of residency	Nursing home		Apartment with community-based support		Independent living with personal assistance	Independent living with personal assistance		Independent living with personal assistance	Independent living with personal assistance	Nursing home

<sup>1</sup> Full years, <sup>2</sup> Still alive

Abbreviations: H - Hemorrhagic, I - Ischemic

Table 2 – Living situation today - Participants

	Participant			
	2	4	6	10
Living arrangement	Lives in a nursing home/home with society-based support. Joint common areas.	Lives in an apartment with society-based support. Lives alone.	Lives in a house. Lives with family.	Lives in a house. Lives with family.
Personal assistance	No personal assistants. Gets assistance from staff.	External personal assistants + extra assistance from staff when needed nighttime	External personal assistance + partner as paid assistant	External personal assistance + partner as paid assistant
Amount	Assistance from staff 168h/week	Assistance - 168 h/week Dual staffing - 10.5 h/week Total – 178.5 h/week	Single staffing - 168 h/week.	Assistance - 168 h/week Dual staffing - 80.5 h/week Total – 248.5 h/week
Communication	Alphabet board, blinking	Alphabet board (blinking)	Oral, alphabet board (pointing)	Blinking, eye-tracking device
Nutrition	Percutaneous endoscopic gastrostomy (PEG)	Oral, pureed/semi-solid	Oral, solid diet	PEG, occasional treat by mouth
Locomotion	Electric wheelchair	Electric wheelchair	Electric/manual wheelchair. Can walk a few steps with support	Electric wheelchair

# Skala för bedömning av följder efter stroke

(Swedish version of SIS)

Center on Aging  
University of Kansas Medical Center  
3901 Rainbow Blvd.  
Kansas City, KS 66160-7117  
(913) 588-1468

Development of this instrument has been supported by funds from The United States Department of Veteran Affairs Rehabilitation Research and Development, the University of Kansas Claude D Pepper Older Americans Independence Center (NIA 5 P60 AG 14635-02), the American Heart Association and Glaxo Wellcome Inc.

Copyright 1999 © University of Kansas Medical Center,  
Kansas City  
All Rights Reserved

This instrument was developed by Pamela Duncan, PhD, PT, Dennis Wallace, PhD, Sue Min Lai, PhD, MS, MBA, Stephanie Studenski, MD, MPH, Dallas Johnson, PhD, and Susan Embretson, PhD

Distribution Center: Mapi Research Institute  
27, rue de la Villette, 69003 Lyon, France  
Translation coordinated by Mapi Research Institute

## Skala för bedömning av följder efter stroke

Syftet med dessa frågor är att utvärdera hur din stroke har påverkat din hälsa och ditt liv. Vi vill utifrån **DIN EGEN ÅSIKT** veta vilka följder sjukdomen har haft för dig. Vi kommer att ställa frågor om de begränsningar som orsakats av din stroke, samt hur det har påverkat din livskvalitet. Till sist ber vi dig att bedöma hur du återhämtat dig från din stroke.

Följande frågor handlar om de fysiska (kroppsliga) problem som kan vara en följd av din stroke.

1. Under den senaste veckan, hur skulle du bedöma styrkan...	Mycket styrka	Ganska mycket styrka	En viss styrka	Liten styrka	Ingen styrka alls
a. i den arm som <u>har påverkats mest</u> av din stroke?	5	4	3	2	1
b. i gripförmåga i den hand som <u>har påverkats mest</u> av din stroke?	5	4	3	2	1
c. i det ben som <u>har påverkats mest</u> av din stroke?	5	4	3	2	1
d. i den fot/vrist som <u>har påverkats mest</u> av din stroke?	5	4	3	2	1

Följande frågor handlar om ditt minne och din tankeförmåga.

2. Under den senaste veckan, hur svårt har det varit för dig att...	Inte alls svårt	Lite svårt	Ganska svårt	Mycket svårt	Oerhört svårt
a. komma ihåg saker som folk just sagt till dig?	5	4	3	2	1
b. komma ihåg saker som hände dagen innan?	5	4	3	2	1
c. komma ihåg att göra saker (t.ex. hålla avtalade tider eller ta medicin)?	5	4	3	2	1
d. komma ihåg vilken veckodag det var?	5	4	3	2	1
e. koncentrera dig?	5	4	3	2	1
f. tänka snabbt?	5	4	3	2	1
g. lösa vardagsproblem?	5	4	3	2	1

**Följande frågor handlar om hur du känner dig, om humörförändringar och om din förmåga att kontrollera dina känslor efter din stroke.**

<b>3. Under den senaste veckan, hur ofta...</b>	<b>Aldrig</b>	<b>Sällan</b>	<b>Ibland</b>	<b>Största delen av tiden</b>	<b>Hela tiden</b>
a. har du känt dig ledsen?	5	4	3	2	1
b. har du känt att du inte har någon som står dig nära?	5	4	3	2	1
c. har du känt dig som en börda för andra?	5	4	3	2	1
d. har du känt att du inte har något att se fram emot?	5	4	3	2	1
e. har du anklagat dig själv för missöden och misstag du gjorde?	5	4	3	2	1
f. har du haft det lika trevligt som du alltid haft?	5	4	3	2	1
g. har du känt dig nervös?	5	4	3	2	1
h. har du känt att livet är värt att leva?	5	4	3	2	1
i. har du lett och skrattat minst en gång om dagen?	5	4	3	2	1

**Följande frågor handlar om din förmåga att samtala med andra människor, samt din förmåga att förstå vad du läser och vad du hör i ett samtal.**

<b>4. Under den senaste veckan, hur svårt har det varit att...</b>	<b>Inte alls svårt</b>	<b>Lite svårt</b>	<b>Ganska svårt</b>	<b>Mycket svårt</b>	<b>Oerhört svårt</b>
a. säga namnet på en person du haft framför dig?	5	4	3	2	1
b. förstå vad som sades till dig i ett samtal?	5	4	3	2	1
c. besvara frågor?	5	4	3	2	1
d. namnge saker och ting vid dess rätta namn?	5	4	3	2	1
e. delta i ett samtal med en grupp människor?	5	4	3	2	1
f. samtala i telefon?	5	4	3	2	1
g. ringa upp någon samt välja rätt telefonnummer och slå numret?	5	4	3	2	1

Följande frågor handlar om de aktiviteter du kan tänkas syssla med under en vanlig dag.

5. Under de senaste 2 veckorna, hur svårt har det varit att...	Inte alls svårt	Lite svårt	Ganska svårt	Mycket svårt	Kan inte alls göra detta
a. skära upp din mat med kniv och gaffel?	5	4	3	2	1
b. klä på dig på överkroppen?	5	4	3	2	1
c. tvätta dig (bada, duscha...)?	5	4	3	2	1
d. klippa tånaglarna?	5	4	3	2	1
e. komma snabbt till toaletten?	5	4	3	2	1
f. kontrollera blåsan (så att det inte händer en olycka)?	5	4	3	2	1
g. kontrollera tarmen (så att det inte händer en olycka)?	5	4	3	2	1
h. göra lättare hushållssysslor?	5	4	3	2	1
i. gå och handla?	5	4	3	2	1
j. utföra tyngre hushållssysslor?	5	4	3	2	1



**Följande frågor handlar om din rörelseförmåga i och utanför hemmet.**

<b>6. Under de senaste 2 veckorna, hur svårt har det varit att...</b>	<b>Inte alls svårt</b>	<b>Lite svårt</b>	<b>Ganska svårt</b>	<b>Mycket svårt</b>	<b>Kan inte alls göra detta</b>
a. sitta utan att tappa balansen?	5	4	3	2	1
b. stå utan att tappa balansen?	5	4	3	2	1
c. gå utan att tappa balansen?	5	4	3	2	1
d. förflytta dig från sängen till en stol?	5	4	3	2	1
e. gå hundra meter?	5	4	3	2	1
f. gå snabbt?	5	4	3	2	1
g. gå upp för en trappa?	5	4	3	2	1
h. gå upp för flera trappor?	5	4	3	2	1
i. ta dig in i och ut ur en bil?	5	4	3	2	1

**Följande frågor handlar om din förmåga att använda den hand som har PÅVERKATS MEST av din stroke.**

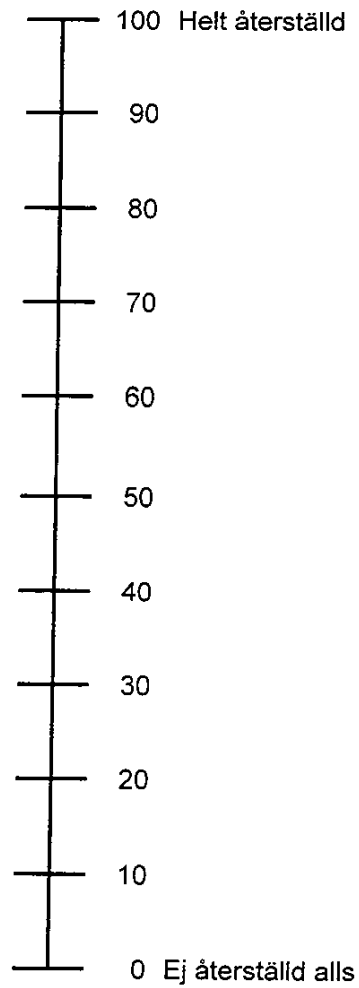
<b>7. Under de senaste 2 veckorna, hur svårt har det varit att använda den hand som har påverkats mest av din stroke för att...</b>	<b>Inte alls svårt</b>	<b>Lite svårt</b>	<b>Ganska svårt</b>	<b>Mycket svårt</b>	<b>Kan inte alls göra detta</b>
a. bära tunga saker?	5	4	3	2	1
b. vrida om nyckeln i ett lås?	5	4	3	2	1
c. öppna en konservburk eller syltburk?	5	4	3	2	1
d. knyta ett skosnöre?	5	4	3	2	1
e. plocka upp ett litet mynt?	5	4	3	2	1

**Följande frågor handlar om hur din stroke har påverkat din förmåga att delta i de aktiviteter som du brukar göra, saker som är viktiga för dig och som hjälper dig att finna livet meningsfullt.**

<b>8. Under de senaste 4 veckorna, hur stor del av tiden har du haft begränsningar när det gäller...</b>	<b>Aldrig</b>	<b>Sällan</b>	<b>Ibland</b>	<b>Största delen av tiden</b>	<b>Hela tiden</b>
a. arbete (betalt, frivilligt eller annat)?	5	4	3	2	1
b. aktiviteter tillsammans med andra?	5	4	3	2	1
c. lugna fritidssysselsättningar?	5	4	3	2	1
d. aktiva fritidssysselsättningar?	5	4	3	2	1
e. din roll som familjemedlem och/eller vän?	5	4	3	2	1
f. ditt deltagande i andliga eller religiösa aktiviteter?	5	4	3	2	1
g. din förmåga att ha kontroll över ditt liv så som du önskar?	5	4	3	2	1
h. din förmåga att hjälpa andra människor?	5	4	3	2	1

**9. Återhämtning efter din stroke**

Ange på nedanstående skala hur mycket du har återhämtat dig från din stroke. På skalan mellan 0 och 100 betyder 100 att du är helt återställd och 0 att du inte återhämtat dig alls.



## RAND-36 Hälsa och livskvalitet

RAND-36 handlar om din hälsa och funktion i vardagen. Välj det svarsalternativ som stämmer bäst för dig på varje fråga.

- |   |                          |                          |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
|   | Utmärkt                  | Mycket god               | God                      | Någorlunda               | Dålig                    |
| 1. I allmänhet, skulle du säga att din hälsa är:                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Mycket bättre            | Något bättre             | Ungefär densamma         | Något sämre              | Mycket sämre             |
| 2. Jämfört med för ett år sedan, hur skulle du bedöma din hälsa nu? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Följande frågor handlar om aktiviteter du kan tänkas ägna dig åt en vanlig dag. **Begränsar din nuvarande hälsa dig i dessa aktiviteter? Om ja, hur mycket?**

- |  |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|
|  | Ja, mycket begränsad     | Ja, lite begränsad       | Nej, inte alls begränsad |
| 3. <b>Fysiskt ansträngande aktiviteter</b> , t.ex. löpning, lyfta tunga föremål, delta i ansträngande idrotter | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. <b>Måttligt ansträngande aktiviteter</b> , t.ex. flytta ett bord, dammsuga, promenera eller cykla           | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Lyfta eller bära matkassar  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Gå upp för <b>flera</b> trappor   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Gå upp för <b>en</b> trappa   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Böja dig eller gå ner på knä  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Gå <b>mer än ett par kilometer</b>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Gå <b>flera kvarter</b> (flera hundra meter)   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Gå <b>ett kvarter</b> (hundra meter)   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Bada/duscha eller klä på dig   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Under de **senaste 4 veckorna**, har du haft något av följande problem med ditt arbete eller andra vanliga dagliga aktiviteter **på grund av din fysiska hälsa?**

- |  |                          |                          |
|--|--------------------------|--------------------------|
|  | Ja                       | Nej                      |
| 13. Dragit ner på <b>tiden</b> du ägnat åt arbete eller andra aktiviteter                            | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. <b>Fått mindre gjort</b> än du skulle vilja  | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Begränsats i <b>vissa</b> arbetsuppgifter eller andra aktiviteter                                | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Haft <b>svårt</b> att utföra arbete eller andra aktiviteter (t.ex. det krävdes mer ansträngning) | <input type="checkbox"/> | <input type="checkbox"/> |

Under de **senaste 4 veckorna**, har du haft något av följande problem med ditt arbete eller andra vanliga dagliga aktiviteter **på grund av känslomässiga problem** (t.ex. att du känt dig nere eller orolig)?

- |   |                          |                          |
|---|--------------------------|--------------------------|
|   | Ja                       | Nej                      |
| 17. Dragit ner på <b>tiden</b> du ägnat åt arbete eller andra aktiviteter   | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. <b>Fått mindre gjort</b> än du skulle vilja                             | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. Utfört arbete eller andra aktiviteter mindre <b>noggrant</b> än vanligt | <input type="checkbox"/> | <input type="checkbox"/> |

- |   |                          |                          |                          |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
|   | Inte alls                | Lite grand               | Måttligt                 | Ganska mycket            | Extremt mycket           |                          |
| 20. Under de <b>senaste 4 veckorna</b> , i vilken omfattning har din fysiska hälsa eller känslomässiga problem stört dina vanliga sociala aktiviteter med familj, släkt, vänner, grannar eller föreningar etc.? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                          |
|   | Ingen                    | Mycket lätt              | Lätt                     | Måttlig                  | Svår                     | Mycket svår              |
| 21. Hur mycket <b>fysisk</b> smärta har du haft under de <b>senaste 4 veckorna</b> ?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Inte alls                | Lite grand               | Måttligt                 | Ganska mycket            | Extremt mycket           |                          |
| 22. Under de <b>senaste 4 veckorna</b> , hur mycket har smärta stört ditt vanliga arbete (gäller både arbete utanför hemmet och hushållsarbete)?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                          |

Följande frågor handlar om hur du känner dig och hur det har varit **under de senaste 4 veckorna**. Ange det svar som stämmer bäst med hur du känt dig.

- |  |                          |                          |                          |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Hur mycket av tiden under de <b>senaste 4 veckorna</b> ...       | Hela tiden               | Största delen av tiden   | En stor del av tiden     | En viss del av tiden     | En liten del av tiden    | Inget av tiden           |
| 23. Har du känt dig pigg?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 24. Har du känt dig mycket nervös?                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 25. Har du känt dig så nere att ingenting kunnat muntra upp dig? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 26. Har du känt dig lugn och harmonisk?                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 27. Har du känt dig energisk?                                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 28. Har du känt dig dystert och ledsen?                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 29. Har du känt dig utsliten?                                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 30. Har du känt dig lycklig?                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 31. Har du känt dig trött?                                       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- |  |                          |                          |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
|  | Hela tiden               | Största delen av tiden   | En viss del av tiden     | En liten del av tiden    | Inget av tiden           |
| 32. Under de <b>senaste 4 veckorna</b> , hur mycket av tiden har din <b>fysiska hälsa eller känslomässiga problem</b> stört dina sociala aktiviteter (som att träffa vänner, släktingar etc.)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Hur väl stämmer följande påståenden in på dig?

- |   |                          |                          |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
|   | Stämmer helt             | Stämmer ganska bra       | Vet inte                 | Stämmer ganska dåligt    | Stämmer inte alls        |
| 33. Jag verkar ha något lättare att bli sjuk än andra människor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 34. Jag är lika frisk som andra jag känner                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 35. Jag tror att min hälsa kommer att försämrans                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 36. Min hälsa är utmärkt  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

IPA-E JL 0505 KSS/0608

# Inverkan på delaktighet och självbestämmande (IPA-E) JL / 0505 KSS/0608

Sibley A, Kersten P, Ward CD, White B, Mehta R, George S. Measuring autonomy in disabled people: Validation of a new scale in a UK population. Clin Rehabil. 2006 Sep;20(9):793-803.

## Inledning:

I detta frågeformulär ställs ett antal frågor om dagliga aktiviteter. Syftet är att få **Din åsikt** om hur Ditt hälsotillstånd är i dag och hur Dina begränsningar **inverkar** på Ditt dagliga liv.

## Allmänna råd:

Tänk på att det handlar om Din åsikt och Dina erfarenheter.  
Inget svar är rätt eller fel.

Du besvarar frågorna genom att sätta ett kryss vid det svar Du väljer. Vid varje fråga kryssar du bara för ett svar. Om du tvekar på svaret, välj då det svar som ligger närmast din åsikt. Det är viktigt att du svarar på alla frågor.

Det tar ungefär 20 minuter att fylla i dessa frågor.

## FRÅGORNA:

### 1. RÖRLIGHET

Först vill vi ställa ett antal frågor om rörlighet, dvs. din möjligheten att förflytta dig dit du vill och vara där du vill. I denna fråga handlar det framförallt om huruvida du själv kan bestämma vart du förflyttar dig och när du gör det.

1a/ Att förflytta mig i min egen bostad **vart/var** jag vill går:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

1b/ Att förflytta mig i min egen bostad **när** jag vill går:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

IPA-E JL 0505 KSS/0608

1c/ Att besöka grannar, vänner och bekanta **när** jag vill gå:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

1d/ : Att göra utflykter eller en (semester)resa **så som** jag vill gå :

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

**1e/ Problemupplevelse**

I vilken utsträckning tycker du att ditt hälsotillstånd eller dina begränsningar är ett problem för din rörlighet inomhus och utomhus?

- inget problem
- i viss mån ett problem
- ett stort problem

(Eventuell) kommentar till svaren på frågorna 1a -1e

## 2. PERSONLIGA BESTYR

Här följer nu några frågor om personliga bestyr. I dessa frågor handlar det om i vilken mån Du kan bestämma själv när du sköter dina bestyr eller får hjälp, och hur detta sker, även om du får hjälp.

2a/ Att tvätta sig, klä på sig och sköta personlig hygien *på det sätt* jag vill gå:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

2b/ Att tvätta sig, klä på sig och sköta personlig hygien *när* jag vill gå:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

IPA-E JL 0505 KSS/0608

2c/ Att lägga sig och att stiga upp *när* jag vill går:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

2d/ Att gå på toaletten *när* jag vill det och tycker det är nödvändigt går:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

2e/ Att bestämma *när* jag vill äta och dricka går:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

**2f/ Problemupplevelse**

I vilken utsträckning tycker du att ditt hälsotillstånd eller dina begränsningar är ett problem för dina personliga bestyr?

- inget problem
- i viss mån ett problem
- ett stort problem

(Eventuell) kommentar till svaren på frågorna 2a -2f

**3. AKTIVITETER HEMMA OCH ROLL I FAMILJEN**

I varje familj har var och en vissa uppgifter och ansvarsområden. Det är vad som avses med roll i familjen.

Följande frågor handlar om Din roll i familjen och inverkan av Ditt hälsotillstånd. Det handlar åter om i vilken utsträckning du kan bestämma när och hur något skall ske även om du inte gör det själv, därför står ordet "låta" i vissa frågor inom parantes.



IPA-E JL 0505 KSS/0608

3a/ Mitt bidrag till hushållsuppgifterna *så som* jag vill är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

3b/ Att (låta) utföra lätt hushållsarbete ( laga mat, kaffe, te) *så som* jag vill går:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

3c/ Att (låta) utföra tyngre hushållsarbete (t.ex. städning) *så som* jag vill går:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

3d/ Att (låta) utföra hushållsuppgifter *när* jag vill går:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

3e/ Att (låta) utföra småarbeteten och underhåll på hus och trädgård *så som* jag vill går:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

IPA-E JL 0505 KSS/0608

3f/ Möjligheten att hemma spela den roll som tillkommer mig är

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

3g/ **Problemupplevelse**

I vilken utsträckning tycker du att ditt hälsotillstånd eller dina begränsningar är ett problem för din roll i familjen eller i hushållet?

- inget problem
- i viss mån ett problem
- ett stort problem

(Eventuell) kommentar till svaren på frågorna 3a -3g

#### 4. EKONOMISK SITUATION.

I denna fråga handlar det om hur ditt hälsotillstånd och dina begränsningar påverkar användandet av din inkomst.

4a/ Möjligheten att använda pengarna *så som* jag vill är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

4b/ **Problemupplevelse**

I vilken utsträckning tycker du att ditt hälsotillstånd eller dina begränsningar är ett problem för din ekonomi?

- inget problem
- i viss mån ett problem
- ett stort problem

(Eventuell) kommentar till svaren på frågorna 4a -4b

IPA-E JL 0505 KSS/0608

## 5. ANVÄNDNING AV TIDEN OCH AVKOPPLING

Om du själv kan bestämma vad du vill göra på din (fri)tid, *när* du vill göra det eller *hur länge* är vad denna fråga handlar om.

5a/ Möjligheten att disponera min (fri)tid **så som jag vill är:**

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

5b/ **Problemupplevelse**

I vilken utsträckning tycker du att ditt hälsotillstånd eller dina begränsningar är ett problem för hur du använder din tid och din fritid?

- inget problem
- i viss mån ett problem
- ett stort problem

(Eventuell) kommentar till svaren på frågorna 5a -5b

## 6. SOCIALA KONTAKTER

Följande frågor handlar om dina sociala kontakter.

Det kan vara så att dina sociala kontakter är annorlunda och förekommer mindre ofta på grund av ditt hälsotillstånd eller din(a) begränsning(ar). I frågorna 6c och 6e talas det om "respekt". Med respekt menas den utsträckning i vilken du behandlas korrekt och hövligt, som du under normala omständigheter har rätt att vänta dig.

6a/ Möjligheten till ett **jämställt** samtal med mina närmaste är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

6b/ Umgänget med mina närmaste är:

IPA-E JL 0505 KSS/0608

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

6c/ Den respekt jag får av mina närmaste är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

6d/ Umgänget med människor jag känner mindre väl är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

6e/ Den respekt som jag får av människor jag känner mindre väl är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

På grund av ditt hälsotillstånd eller dina(a) begränsning(ar) kan fysisk intimitet, eller inledning av intimitet med annan vara förändrad.

6f/ Möjligheten till intimitet som jag vill är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

IPA-E JL 0505 KSS/0608

Det kan vara så att omfattningen med vilken du träffar andra människor förändras på grund av ditt hälsotillstånd eller din(a) begränsning(ar).

6g/ Den omfattningen med vilken jag träffar andra människor är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

6h/ Problemupplevelse

I vilken utsträckning tycker du att ditt hälsotillstånd eller din(a) begränsning(ar) är ett problem för dina sociala kontakter?

- inget problem
- i viss mån ett problem
- ett stort problem

(Eventuell) kommentar till svaren på frågorna 6a -6h

## 7. YRKESVERKSAMHET.

Här följer några frågor om det arbete (betalt eller ofrivilligt arbete) som du nu utför. Om du för närvarande inte har något betalt arbete eller inte något frivilligt arbete, fyll då i "inte tillämpligt" och fortsätt med fråga 8. Om du inte arbetar men ändå har ett arbete ber vi dig ändå fylla i denna fråga.

7a/ Möjligheten att utföra just det arbete jag vill utföra är::

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt
- inte tillämpligt

7b/ Möjligheten att utföra mitt arbete just på det sätt som jag vill det skall utföras är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

7c/ Kontakten med arbetskamrater är:

IPA-E JL 0505 KSS/0608

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

7d/ Möjligheten att nå eller behålla den befattning som jag vill är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

7e/ Möjligheten att byta funktion eller arbetsgivare är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

7f/ **Problemupplevelse**

I vilken utsträckning tycker du att ditt hälsotillstånd eller din(a) begränsning(ar) är ett problem i ditt arbete?

- inget problem
- i viss mån ett problem
- ett stort problem

## 8. UTBILDNING.

Denna fråga handlar om vilket inflytande ditt hälsotillstånd eller din(a) begränsning(ar) har på möjligheterna att (full)följa utbildning eller kurs som du vill. Om du inte vill gå en kurs eller utbildning fyll i "inte tillämpligt". Om du skulle vilja gå n utbildning men ditt hälsotillstånd förhindrar det, ber vi att du svarar i första kolumnen (mycket bra, bra, ganska bra, ganska dåligt, dåligt).

IPA-E JL 0505 KSS/0608

8a/ Möjligheten att (full)följa den utbildning eller kurs som jag vill är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt
- inte tillämpligt

### 8b/ Problemupplevelse

I vilken utsträckning tycker du att ditt hälsotillstånd eller din(a) begränsning(ar) är ett problem när det gäller att genomgå en utbildning?

- inget problem
- i viss mån ett problem
- ett stort problem

## 9. HJÄLPA OCH STÖDJA ANDRA MÄNNISKOR.

9a/ Min möjlighet att hjälpa eller stötta andra människor är:

- mycket bra
- bra
- ganska bra
- ganska dåligt
- dåligt

### 9b/ Problemupplevelse

I vilken utsträckning tycker du att ditt hälsotillstånd eller din(a) begränsning(ar) är ett problem när det gäller att hjälpa och stötta andra personer?

- inget problem
- i viss mån ett problem
- ett stort problem

## Sammanfattande IPA frågor

10. I detta formulär har du fått svara på frågor som har att göra med effekterna av din hälsa eller funktionsnedsättning på ditt liv, såväl personliga som sociala aspekter. Om du tar hänsyn till alla delar, kan du säga om du för det mesta upplever att du har tillräcklig kontroll över ditt liv?

IPA-E JL 0505 KSS/0608

10. Mina möjligheter att leva det liv jag önskar är

- Mycket bra
- Bra
- Hyfsat
- Dåliga
- Mycket dåliga

(Eventuell) kommentar till svaren på frågan om kontroll över ditt liv

11. Vad skulle du säga är de 3 huvudproblemen orsakad av din hälsa eller funktionsnedsättning? (Vi tänker på de olika områdena i frågeformuläret: rörlighet, personliga bestyr, aktiviteter hemma och roll i familjen, ekonomisk situation, användning av tiden och avkoppling, sociala kontakter, yrkesverksamhet, utbildning, hjälpa och stödja andra människor)

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

12. I detta frågeformulär har vi frågat dig många frågor om effekterna på av din hälsa och funktionsnedsättning på ditt liv, såväl personliga som sociala aspekter. Är det andra aspekter som du vill nämna, som vi inte har frågat dig om?

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Det var sista frågan i formuläret. Kanske du har andra saker som är angelägna för dig. Om du har synpunkter kan du skriva dem här nedan eller på baksidan.**

**Tack för din medverkan !**



# **EQ - 5D**

**Hälsokenkät**

**Svensk version**  
*(Swedish version)*

Markera, genom att kryssa i en ruta i varje nedanstående grupp (så här ) , vilket påstående som bäst beskriver Ditt hälsotillstånd i dag.

**Rörlighet**

- Jag går utan svårigheter
- Jag kan gå men med viss svårighet
- Jag är sängliggande

**Hygien**

- Jag behöver ingen hjälp med min dagliga hygien, mat eller påklädning
- Jag har vissa problem att tvätta eller klä mig själv
- Jag kan inte tvätta eller klä mig själv

**Huvudsakliga aktiviteter** (*t ex arbete, studier, hushållssysslor, familje- och fritidsaktiviteter*)

- Jag klarar av mina huvudsakliga aktiviteter
- Jag har vissa problem med att klara av mina huvudsakliga aktiviteter
- Jag klarar inte av mina huvudsakliga aktiviteter

**Smärtor/besvär**

- Jag har varken smärtor eller besvär
- Jag har måttliga smärtor eller besvär
- Jag har svåra smärtor eller besvär

**Oro/nedstämdhet**

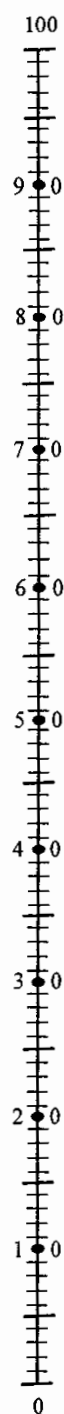
- Jag är inte orolig eller nedstämd
- Jag är orolig eller nedstämd i viss utsträckning
- Jag är i högsta grad orolig eller nedstämd

Till hjälp för att avgöra hur bra eller dåligt ett hälsotillstånd är, finns den termometer-liknande skalan till höger. På denna har Ditt bästa tänkbara hälsotillstånd markerats med 100 och Ditt sämsta tänkbara hälsotillstånd med 0.

Vi vill att Du på denna skala markerar hur bra eller dåligt Ditt hälsotillstånd är, som Du själv bedömer det. Gör detta genom att dra en linje från nedanstående ruta till den punkt på skalan som markerar hur bra eller dåligt Ditt nuvarande hälsotillstånd är.

**Ditt  
nuvarande  
hälsotillstånd**

Bästa  
tänkbara  
tillstånd



Sämsta  
tänkbara  
tillstånd

## Intervjuer

### Övergripande:

*Hur ser din livssituation ut? Boende, familj etc.*

*Hur upplever du din livssituation? Livskvalitet? Delaktighet?*

*Får du tillräckligt med stöd? Från vården? Från övriga myndigheter?*

- **Info – samtycke, studien etc**
- **Gå igenom formulären om inte gjort dem/har frågor**
- **Intervju**

### **BOENDE**

Boendeform?

Assistans? Timmar?

### **REHABILITERING**

Har du några rehabiliteringsinsatser nu?

Vad använder du för kommunikationshjälpmedel? Har du de hjälpmedel du behöver?

Vilka hjälpmedel?

### **KONTAKT, INFORMATION**

Är det något du saknat? Information?

Hur blir du bemött?

Är det lätt att få kontakt med vården när du behöver?

Tycker du att du har fått tillräckligt med hjälp och stöd praktiskt?

Har du blivit erbjuden stöd från kurator el liknande?

### **ALLMÄNT**

Hur tycker du själv att du mår nu?

Tycker du att du har en bra livskvalitet?

Har du familj? Anhöriga?

### **ÖVRIGT (PATIENTFÖRENINGAR, FÖRSÄKRINGSKASSAN MM)**

### **HAR DU NÅGOT MER DU VILL TA UPP? KOMMENTARER? FRÅGOR?**

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	<b>Item No</b>	<b>Recommendation</b>	
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Within the title, front page and title page
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 1-2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 6-10
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 11
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	Page 1, 12-13
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 11-13
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 11-16
		(b) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Table 1
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 12-16
Bias	9	Describe any efforts to address potential sources of bias	Page 13
Study size	10	Explain how the study size was arrived at	N/A
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 16
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 16
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A
		(d) If applicable, explain how loss to follow-up was addressed	Page 11
		(e) Describe any sensitivity analyses	N/A

<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study— e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed	Figure 1
		(b) Give reasons for non-participation at each stage	Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 2 Page 17-18 Appendix A
		(b) Indicate number of participants with missing data for each variable of interest	Page 17 Figure 2
		(c) Summarize follow-up time (e.g., average and total amount)	Table 2
Outcome data	15*	Report numbers of outcome events or summary measures over time	Table 1 Page 18
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 17-26 Table 2-6
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses	N/A
<b>Discussion</b>			
Key results	18	Summarize key results with reference to study objectives	Page 27-31
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 31-32
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 33
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 31
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	N/A