Evaluations of variables in Riksstroke, the Swedish Stroke Register. Short version in English

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Preface

During the years 2012-2013, Riksstroke (The Swedish Stroke Register) performed extensive validations of several dimensions of the register. The present report is a summary of the most important observations. A series of more comprehensive reports will be soon available in Swedish at the Riksstroke website soon.

Anna Söderholm, MSc, coordinated and performed most of the data collection and analyses and wrote a series of reports. Susanne Palmcrantz MD contributed to the analyses. Magnus von Arbin MD (head), Disa Sommerfeld MD, Carina Hortans, OT, Susanne Palmcrantz MD, and Lena Henricson, speech therapist, constituted a Steering Group for part of the project. Professor Bo Norrving was lead in the work on content validity. The staff of the Riksstroke secretariat and the Riksstroke Steering Committee contributed considerably to the work. Kjell Asplund, MD, had the overall responsibility for the project and complied this condensed English version of the work.

Part of this work was supported by a grant from Nationella Kvalitetsregister.

Coverage

Riksstroke covers all hospitals in the country admitting acute stroke patients (72 hospitals in 2012 and 2013).

When compared with patients discharged with a diagnosis of acute stroke routine in administrative registers, 88.2% of were recorded in Riksstroke in 2012. Allowing for the estimated 6% false positive diagnosis of acute stroke in Swedish routine administrative registers [1], the actual coverage of the register is estimated to be 94%.

The Riksstroke follow-up procedures include follow-up questionnaires to surviving patients 3 and 12 months after stroke. In 2012, the response rate the 3-months questionnaire was 88 % and to the 12-months questionnaire 74 %.

Content validity – comparison between Riksstroke and other European stroke audits and registers

Content validity is how well an instrument covers the area that it intends to measure. To assess content validity in an international perspective, we compared the Riksstroke variables with those in other European stroke audits and registers included in the EU-supported European Implementation Score (EIS) Collaboration.

In addition to Riksstroke, EIS includes the German Register study group (ADSR), the Scottish Stroke Care Audit (SSCA), the National Sentinel Audit of Stroke, England/Wales/Northern Ireland; the Quality Register of Flemish Hospital Network of the K.U. Leuven, Belgium and the Catalan Stroke Audit, Spain.

The indicators used by the 6 EIS registers were highly heterogeneous. There were 15 variables that were used in at least 2 of the registers. Riksstroke included 11 of them (Table 1).

Table 1. Quality indicators used by at least 2 of 7 European stroke registers

Included in Riksstroke	Not included in Riksstroke
Stroke unit care	ECG recording
Brain imaging	Early administration of aspirin
Carotid artery imaging	Early mobilization
Test of swallowing	Assessment of depression
Thrombolysis	
Assessment of need for rehab (physiotherapeut, occupational therapist)	
Statins at discharge	
Antiplatelet drugs at discharge	
Anticoagulant at discharge after embolic stroke	
Antihypertensive drugs at discharge	
Deceased during hospital stay	

The EIS project has also identified a core set of 21 indicators in 6 domains that is proposed to be ideal to compare quality of care between different countries and regions. In addition, 6 background variables to be used in case-mix adjustments were identified. Table 2 shows to what extent Riksstroke covers this ideal set of indicators.

Table 2. *Ideal set of variables to be used in stroke quality assessments as identified by EIS.*

Included in Riksstroke or possible to calculate from Riksstroke data	Not included in Riksstroke
Coordination of care:	*Initiation of secondary prevention:*
Stroke unit care	Antiplatelet drugs within 48 h
Length of stroke unit stay	Time to imaging of carotid arteries
Diagnostic procedures:	*Survival and functional outcome:*
Brain imaging in stroke	Dead or dependent at 30 days
Time to first brain imaging in stroke	
Carotid artery imaging in ischemic stroke	
Carotid artery imaging in TIA	
Assessment by physiotherapist/ occupational therapist	
ECG	
Preservation of neuronal tissue:	
Thrombolysis	
Door-to-needle time in thrombolysis	
Prevention of complications:	
Test of swallowing	
Initiation of secondary prevention:	
Antiplatelet drugs at discharge	
Anticoagulants after embolic stroke at discharge	
Statins in ischemic stroke at discharge	
Antihypertensive agents at discharge	
Information on smoking cessation	
Survival and functional outcome:	
Deceased within 30 days	
Symptomatic brain hemorrhage after thrombolysis	
Background information:	
Age	
Sex	
Type of stroke	
Destination at discharge	
Level of consciousness	
NIHSS	

Face validity and readability

Face validity is the extent to which a test is subjectively viewed as covering the concept it purports to measure. A test can be said to have good face validity if it "looks like" it is going to measure what it is supposed to measure. Readability is the ease with which text can be read and understood.

Face validity and readability of the Riksstroke 3-month and 12-month questionnaires were assessed by interviews with patients and stroke care staff. Twenty-five patients in three cities took part in the assessment of the 3-month questionnaire and 22 patients in three cities in the assessment of the 12-month questionnaire. Interviews were performed individually.

Assessment of face validity and readability by stroke care staff was performed by group interviews. Eighteen individuals in two cities participated. They represented a wide range of professions (number in parenthesis): Physicians (2), nurses (4), physiotherapists (3), occupational therapists (4), speech therapists (3), social worker (1) and psychologist (1).

The evaluation groups suggested changes in items covered by the questions and in wordings of the questions (based on readability assessments). Changes of wording are not shown in this summary but is available at the Riksstroke website in Swedish. In a first round, the changes suggested by patients and staff were included in a new version of the questionnaires. This was then presented to the interviewees in a second round and the results of supplementary comments were included in a final version.

Neither patients nor stroke care staff suggested any of the present questions to be deleted. Table 3 summarises the items that were proposed to be added. The suggested additions were closely similar as to the 3-month and 12-month questionnaires. For the sake of simplicity, Table 3 covers both questionnaires together.

Comment. The Riksstroke Steering Committee revises the forms and questionnaires annually. The present evaluations of face validity and readability (and others evaluations included in this report) provide a basis for future revisions. A general approach of Riksstroke is to focus on a limited number of indicators that clearly reflect the quality of care. Items that are purely descriptive and provide limited ´marginal information on the quality of stroke care to the items already present in the questionnaires are avoided.

Table 3. Items suggested to be added to Riksstroke' s 3-month and 12-month questionnaires.

Domains	Suggested additions
Rehabilitation	Number of occasions
Symptoms, additional items	Vision Hearing Understanding speech Counting Concentration Balancing Continence Falls
Functional outcome, additional items	Life satisfaction Need of help with personal hygiene Need of help drinking and eating Speaking/making herself understood Physical activity Need of help with personal economy Use of public transport Return to previous activities and previous life
Examinations	Vision
Other	Information on driving

Variation by means of responding

Fig. 1 shows the distribution of modes of responding to the Riksstroke 3-months follow-up questionnaire.

We tested to what extent the responses were influenced by the way of responding among patients who responded without any help. Depending on the routines of each hospital, patients can respond to the Riksstroke 3-months or 12-months follow-up questionnaires in writing, by a telephone interview or at an interview performed during a visit to the hospital outpatient clinic. Supplementary telephone interviews are sometimes used when the patient has not responded in writing.

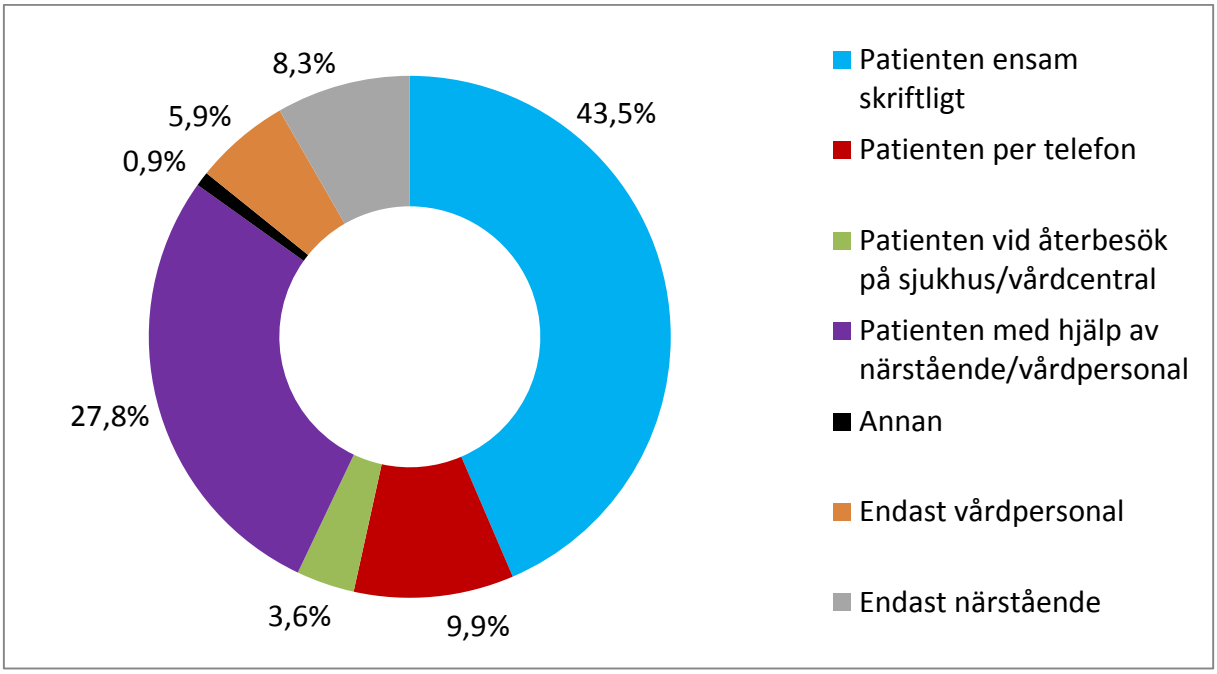

Figure 1. Distribution of modes of responding to the Riksstroke 3-month questionnaire 2009-2012. n=71 264. Patienten ensam = patient alone, vid återbesök = at outpatient visit, hjälp av närstående/personal = help from next-of-kin or staff, annan = other, endast vårdpersonal = staff only, endast närstående = next-of-kin only.

In Table 4, we report three representative examples of how the responses are distributed by the modes of responding. There were no major differences between the three groups.

Table 4. Responses by modes of responding to the 3-months follow-up questionnaire. n=40623.

	Patient alone in writing	Patient per telephone	Patient at outpatient visit in hospital or primary care
Needs of help and support fulfilled:			
Yes, entirely of partly	90.6%	93.1%	92.0%
No	5.9%	3.9%	4.2%
Do not know	3.5%	3.0%	3.8%
Self-assessed general health:			
Very good/fairly good	86.7%	86.3%	85.7%
Very poor/fairly poor	11.4%	12.3%	11.6%
Do not know	1.9%	1.3%	2.7%
Tiredness:			
Never/almost never	68,5%a	69,6%a	69.3%
Often/constantly	31.3%	30.2%	30.3%
Do not know	0.2%	0.3%	0.4%

Most patients who had help by others (next-of-kins or staff) to respond to the 3-month follow-up questionnaire had severe functional impairments. Their responses as to PROMs (patient-reported outcome measurements) was very different from the responses by patients who responded themselves. No meaningful analyses of how mode of responding influenced response patterns could be performed.

Reliability

In psychometrics, reliability is the overall consistency of a measure. A measure is said to have a high reliability if it produces similar results under consistent conditions. In the Riksstroke validation process, we have analysed two components of reliability, inter-rater reliability and test-retest reliability.

Inter-rater reliability

This assesses the degree of agreement between two or more raters in their appraisals.

We tested this by distributing 5 test cases, taken from routine medical records, to the hospitals participating in Riksstroke, asking them to code the cases by their regular routines for acute stroke care. The purpose was (a) to identify variables with high or low inter-rater reliability and (b) to identify hospitals with a high proportion of deviant responses. 67 of 72 hospitals participated in the inter-rater assessment.

Fig. 2 shows the distribution of responses by the frequency of disagreement in 81 variables in the Riksstroke acute care register. For the great majority of variables (67 of 81 variables), the hospitals coded the variables identically or near-identically. For 4 variables, there was more than 15% disagreement. These were (a) test of swallowing, (b) day of stroke onset, (c) CT angiography or MR angiography performed, and (d) delay from onset to arrival in hospital.

There were no major differences between hospitals in the proportion of incorrect codings (ranging from 0% to 7%).

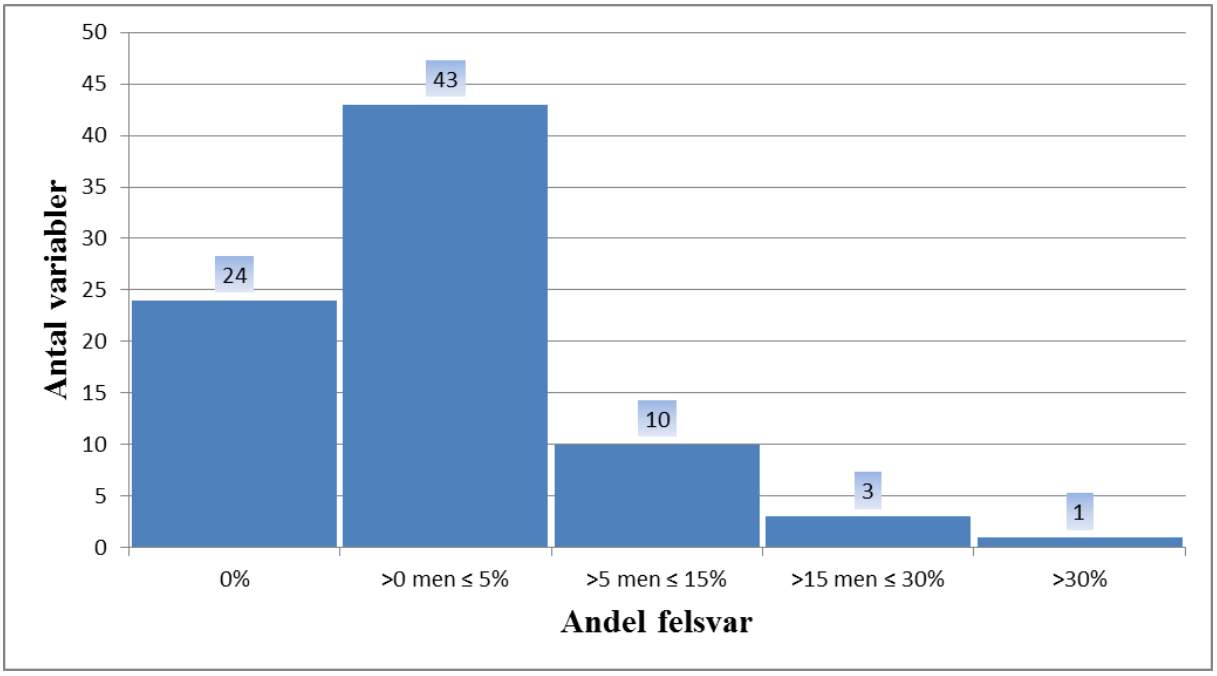

Figure 2. Distribution of variables with different proportions of deviant codings (67 hospitals).

Test-retest reliability

This is often also called repeatability and assesses the degree to which test scores are consistent from one test administration to the next.

Responses in Riksstroke's routine 3-month follow-up questionnaire to surviving patients were compared with a retest using the identical form 2 weeks later. There were 55 responders with a mean age of 73 years. 68% were men, 77% were living at home without community support and 23% had community support or were living in an institution. 41% were single and 11% were dependent in their primary ADL functions. The Riksstroke questionnaire was filled in by the patient himself/herself in 75% of the cases, whereas assistance by a family member was needed in 25%.

In the medical literature, Cronbach's alfa and kappa statistics are the most commonly used measures of reliability. How they usually are interpreted is shown in Tables 5 and 6.

Table 5. Interpretation of Cronbach's alfa.

Cronbach's alpha	Reliability (internal consistency)
$\alpha \geq 0.9$	Excellent
$0.7 \leq \alpha < 0.9$	Good
$0.6 \leq \alpha < 0.7$	Acceptable
$0.5 \leq \alpha < 0.6$	Poor
$\alpha < 0.5$	Unacceptable

Table 6. Interpretation of kappa statistics

Kappa value	Agreement
0.81-0.99	Almost perfect agreement
0.61-0.80	Substantial agreement
0.41-0.60	Moderate agreement
0.21-0.40	Fair agreement
0.01-0.20	Slight agreement

Table 7 shows the main results of the test-retest assessment.

Table 7. *Test-retest reliability of items in Riksstroke's 3-month questionnaire to patients.*

Variable (number of response alternatives)	Cronbach's Alpha	Intraclass Correlation Coefficient	Kappa coefficient (including do not know responses)
1. Where are you living currently? (5)	0.81	0.68	0.81
2. Do you live alone? (2)	1	1	1
3. How is your mobility now? (3)	0.92	0.86	0.83
4. Do you need help from someone else to go to the toilet? (2)	1	1	1
5. Do you need help getting dressed and undressed? (2)	0.94	0.88	0.88
6. After your hospital stay, have you been to see a doctor or been given an appointment to see the doctor again? (6)*	0.83-0.88	0.71-0.83	0.72-0.83
7. After your hospital stay, have you been to see a nurse or been given an appointment to see the nurse again? (6)*	0.58-0.75	0.41-0.60	0.41-0.60
8. What type of support or assistance have you had from the healthcare services or the municipality after your stay in hospital? (8)*			

a. Daytime rehab	0.32	0.19	0.19
b. Rehab in your home	0.54	0.37	0.37
c. Community support at home	0.76	0.62	0.61
d. Alarm	0.85	0.73	0.73
9. Do you think that your need for support or assistance from the health service or municipality has been met? (5)	0.22	0.13	0.52
10. Are you currently dependent on support or assistance from relatives/friends? (4)	0.77	0.63	0.33
11. Do you have difficulty in ....?			
a. speaking (2)	0.72	0.26	0.56
b. reading (2)	0.85	0.74	0.73
c. writing (2)	0.77	0.63	0.62
d. swallowing (2)	0.78	0.64	0.64
e. none of the above (2)	0.73	0.58	0.56
12. Have you seen a speech therapist for assessment or treatment of your ability to speak, swallow or write? (3)	0.90	0.81	0.76
13. Do you smoke? (3)	0.88	0.79	0.78
14. Do you feel depressed? (5))	0.79	0.66	0.58
15. Are you taking any medication for depression? (3)	0.96	0.92	0.93
16. Are you taking any medication for high blood pressure? (3)	0,97	0,95	0,90
17. How would you assess your general health? (5)	0.80	0.67	0.52
18. Do you feel tired? (5)	0.95	0.91	0.81

19. Do you have any pain? (5)	0.79	0.67	0.54
20. Do you have difficulty remembering things? (5)	0.82	0.70	0.52
21. How satisfied or dissatisfied are you with the care you received during your stay in hospital? (5)	0.79	0.66	0.56
22. How satisfied or dissatisfied are you with the way staff dealt with you during your stay in hospital? (5)	0.79	0.65	0.63
23. How satisfied or dissatisfied are you with face-to-face consultations with doctors during your stay in hospital? (6)	0.77	0.63	0.48
24. How satisfied or dissatisfied are you with the stroke information provided? (6)	0,83	0,71	0,58
25. Do you know where to turn to if you need support or assistance after your stay in hospital? (3)	0.72	0.56	0.37
26. How satisfied or dissatisfied are you with the rehabilitation or training during your stay in hospital? (7)	0.81	0.68	0.57
27. How satisfied or dissatisfied are you with the rehabilitation or training after your stay in hospital? (7)	0.80	0.66	0.49
28 Are you undergoing rehabilitation/training right now? (4)	0.84	0.72	0.55
28 Who answered this questionnaire? (7)	1.00	1.00	1.00

* Possible to give multiple alternatives; test-retest results varying by type of alternative.

Special evaluation of questions on early rehabilitation

In 2013, Riksstroke's acute care form included 4 questions on early rehabilitation. With input from experienced physiotherapists (PT) and occupational therapists (OT), we have struggled with the wordings of the question, the response alternatives and detailed instructions. These have undergone yearly revisions without reaching complete satisfaction by the rehabilitation staff in the participating hospitals.

The present four questions are:

- *Has a physiotherapist assessed the patient after arrival in the hospital ward?* The response alternatives are: yes ≤ 24 h/yes >24 h but ≤48 h/yes >48 h/no/unknown
- *Has the patient received physiotherapy based on assessed needs?* The response alternatives are: yes mean **>=**45 min per day/yes mean <45 min per day/no but there has been a need/no need/unknown
- *Has an occupational therapist assessed the patient after arrival in the hospital ward?* The response alternatives are: yes ≤24/yes >24 h but ≤48 h/yes >48 h/no/unknown
- *Has the patient received occupational therapy based on assessed needs?* The response alternatives are: yes mean **>=**45 min per day/yes mean <45 min per day/no but there has been a need/no need/unknown

Detailed information on how to fill in the forms is provided. In our evaluation, we interviewed 15 physiotherapists and 15 occupational therapists in 18 hospitals. 40% of the PTs and 53% of the OCs found the instructions difficult to understand. A specific difficult item concerned how to estimate mean duration of therapy. The respondents suggested a large number of improvements.

Riksstroke will continue its work to improve the questions and instructions on early rehabilitation so that they will meet the needs to function as quality indicators without being too resource-consuming to respond to.

Validation of Patient-Reported Outcome Measurements (PROMs)

The Riksstroke questions on PROMs are selected to be simple and possible for most patients to answer, even those with severe impairments and tiredness. This means that a single question has often been constructed to measure what in research settings is measured by comprehensive instruments. We have thus evaluated some of the Riksstroke questions against conventional research instruments.

These validations were carried out in the patients' homes (including institutions) by experienced stroke nurses.

ADL performance – comparison with Barthel's Index (BI)

Three questions in the Riksstroke questionnaire are used to assess primary ADL functions. These are:

- *How is your mobility now?* Three response alternatives are given: I can get around by myself both in- and outdoors/I can get around by myself indoors, but not outdoors/I get help from someone else to move around.
- *Do you need help from somebody else to visit the toilet?* The two response

alternatives are: I can manage to visit the toilet by myself/I need help to visit the toilet

- *Do you need help getting dressed and undressed?* The two response alternatives are: I can manage to get dressed and undressed by myself/I need help to get dressed and undressed.

A validation of the simplified Riksstroke assessment of ADL performance 3 months after stroke has previously been performed [2]. When compared with the modified Rankin Scale (mRS), the Riksstroke questions classified 76% of the patients to the correct mRS grade. The correlation between Riks-Stroke and mRS was 0.82 and Cohen's kappa (weighted) was 0.85.

In the present round of validations, we compared the responses to the Riksstroke questions to Barthel's Index [3] at Riksstroke's 12-month follow-up. The kappa value was 0.80 (indicating substantial agreement) and Spearman´s rank correlation was high at 0.90.

Instrumental ADL – comparison with Instrumental Activity Measure (IAM)

Using 3 questions, Riksstroke assesses instrumental ADL (secondary ADL) 12 months after stroke. The questions are:

- *Do you get help buying food?* The 3 response alternatives are: I manage to buy food all by myself/I get help buying food/Not applicable, I live in an institution
- *Do you get help to clean?* The 3 response alternatives are: I manage to clean all by myself/I get help to clean/Not applicable, I live in an institution
- *Do you get help with your laundry?* The 3 response alternatives are: I manage my laundry all by myself/I get help to do my laundry/Not applicable, I live in an institution

The sensitivity, specificity and positive predictive values were tested with the Instrumental Activity Measure [4] as the standard. The results are shown in table 8.

Table 8. *Riksstroke's questions on instrumental ADL as compared with the Instrumental Activity Measure*

	Buying food	Cleaning	Laundry
Sensitivity	96%	88%	87%
Specificity	90%	81%	73%
PPV	93%	81%	84%
Kappa	0.88	0.69	0.74

Self-assessed general health – comparison SF-12

The Riks-Stroke question is identical to that used by Statistics Sweden in their Levnadsnivåundersökningar [5] and reads: ”How would you assess your general health?” Five response alternatives are provided: Very good/Quite good/Quite poor/Very poor/Don't know

The responses to the Riksstroke question have usually been dichotomised into (very good + quite good) vs. (quite poor + very poor). We have compared these two response categories with the scoring in the SF-12 health survey form [6] on mental health (SF12-MCF; Fig. 3) and physical health (Fig. 4).

When using our dichotomisation and a cut-off at 50 points in SF-12, the sensitivity of the Riksstroke question as to mental health was 24%, whereas both specificity and positive predictive value were 100%. For physical health the sensitivity was 23%, specificity 100% and positive predictive value 100%.

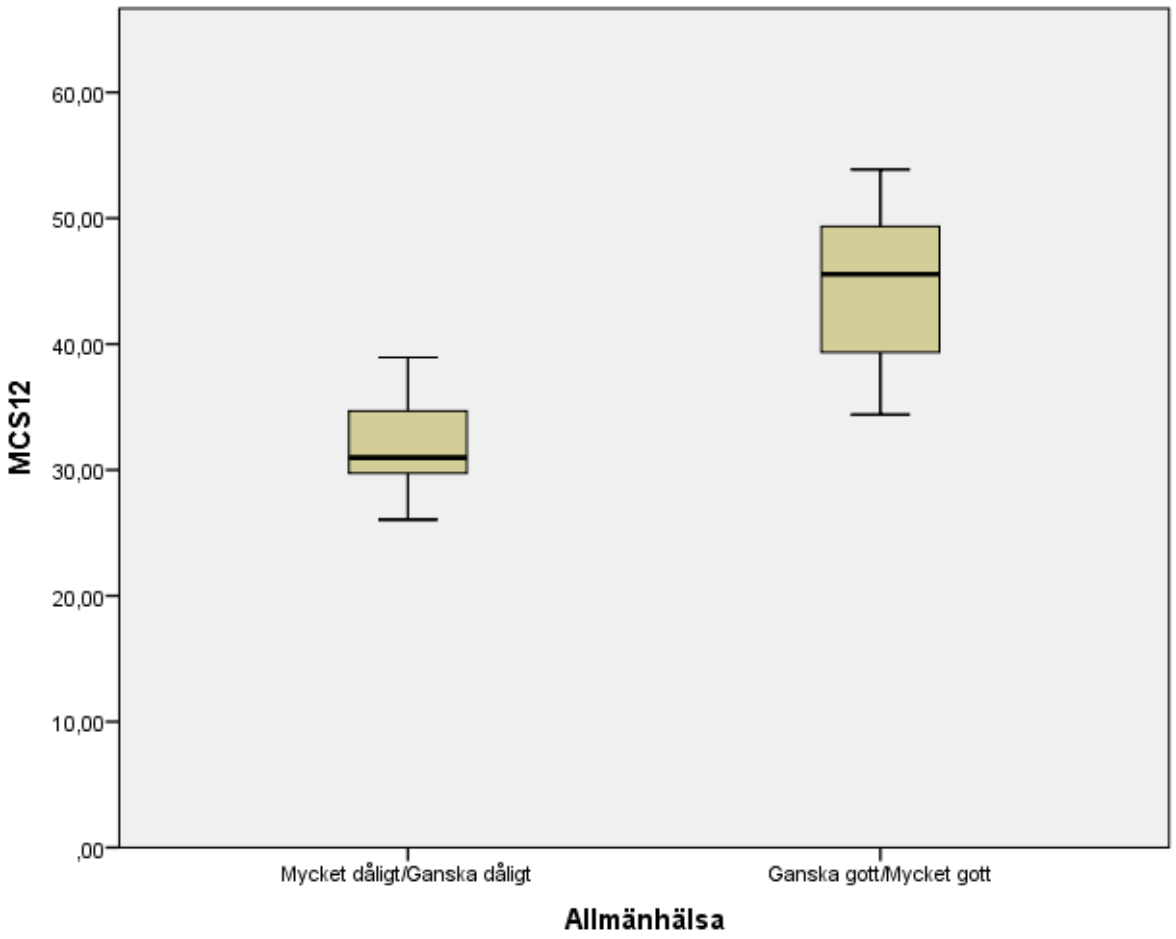

Figure 3. Score in the mental health part of SF-12 in relation to the two categories (very good + quite good; n=55) vs. (quite poor + very poor: n=14).

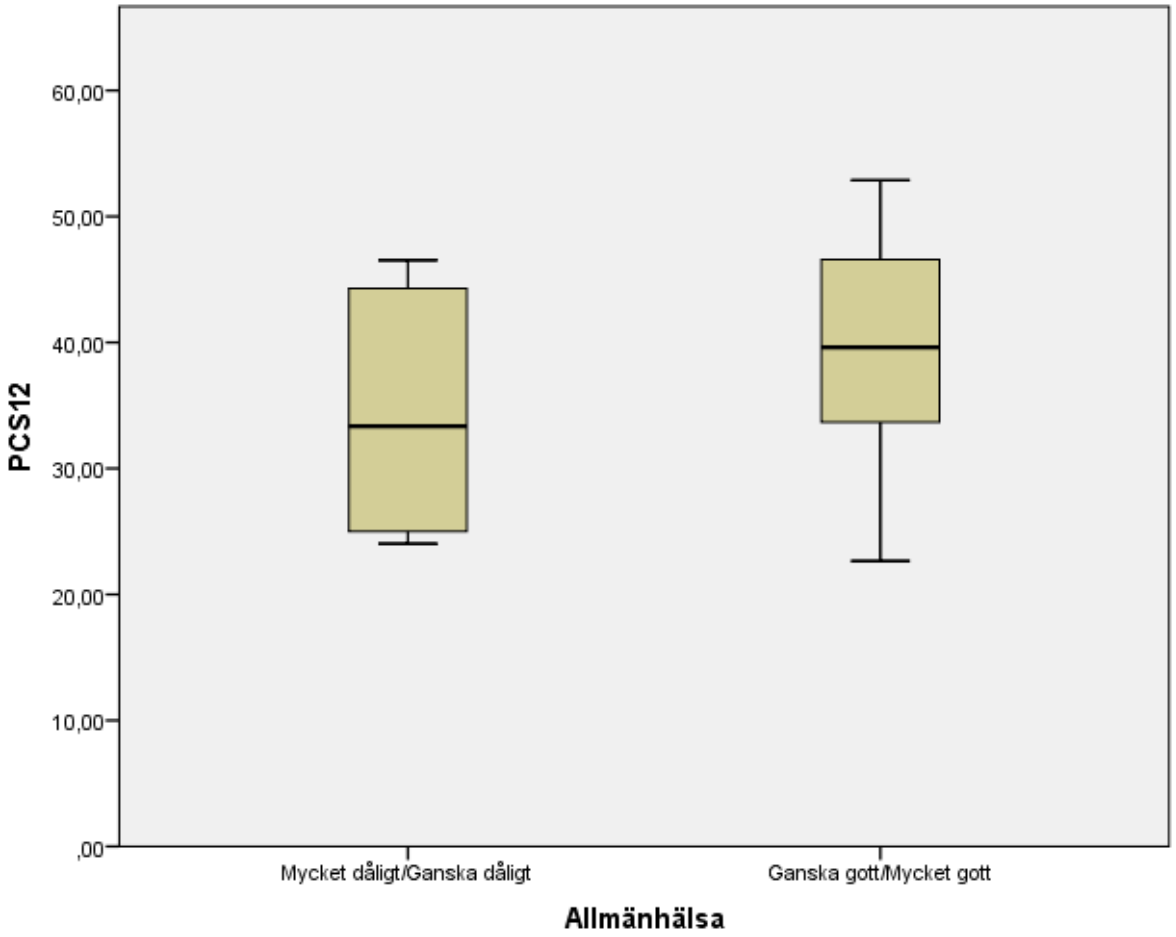

Figure 4. Score in the physical health part of SF-12 in relation to the two categories (very good + quite good) vs. (quite poor + very poor).

Low mood – comparison with the Beck Depression Inventory (BDI-II)

Riksstroke's question on mood is: "Do you feel depressed?" Five response alternatives are given: Never or almost never/Sometimes/Often/Constantly/Don't know.

In our reports, we have usually dichotomized the responses into (never or almost never + sometimes) vs. (often + constantly). Fig. 5 shows the dichotomized responses relate to the results of the BDI-II instrument [7].

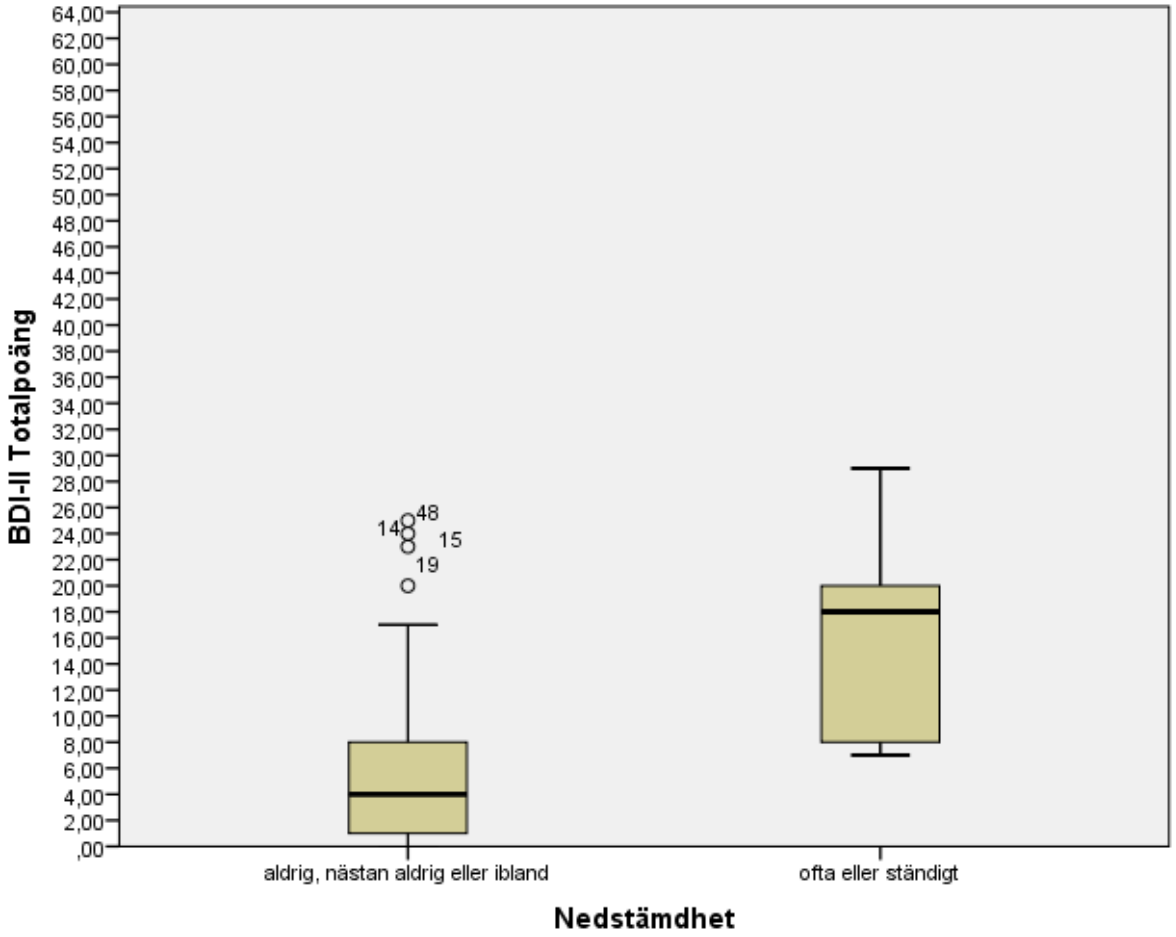

Figure 5. BMI-II points in relation to the two categories (never or almost never + sometimes) and (often + constantly) of low mood. 49 responders.

When the cut-off was set at (never or almost never) vs. (sometimes + often + constantly) there was a very considerable overlap between the BMI-II scores (data not shown in this summary). The number of patients with moderate and severe post-stroke depression was too low to permit meaningful calculations of specificity and sensitivity.

A previous, more extensive evaluation using the Prime-MD criteria on depression showed that the Riksstroke question on mood had a 100% specificity but only a 38% sensitivity to identify patients with depression [8].

Fatigue – comparison with the Fatigue Symptom Inventory (FSI)

The Riksstroke question on mood reads: “Do you feel tired?” Five response alternatives are given: Never or almost never/Sometimes/Often/Constantly/Don't know.

In our reports, we have often dichotomized the responses into (never or almost never) vs. (sometimes + often + constantly). Fig. 6 shows the dichotomized responses relate to the results of the FSI instrument [9]. With an FSI cut-off at 0.3 points, the Riksstroke question on tiredness had a sensitivity of 98%, a specificity of 75% and a positive predictive value of 96%.

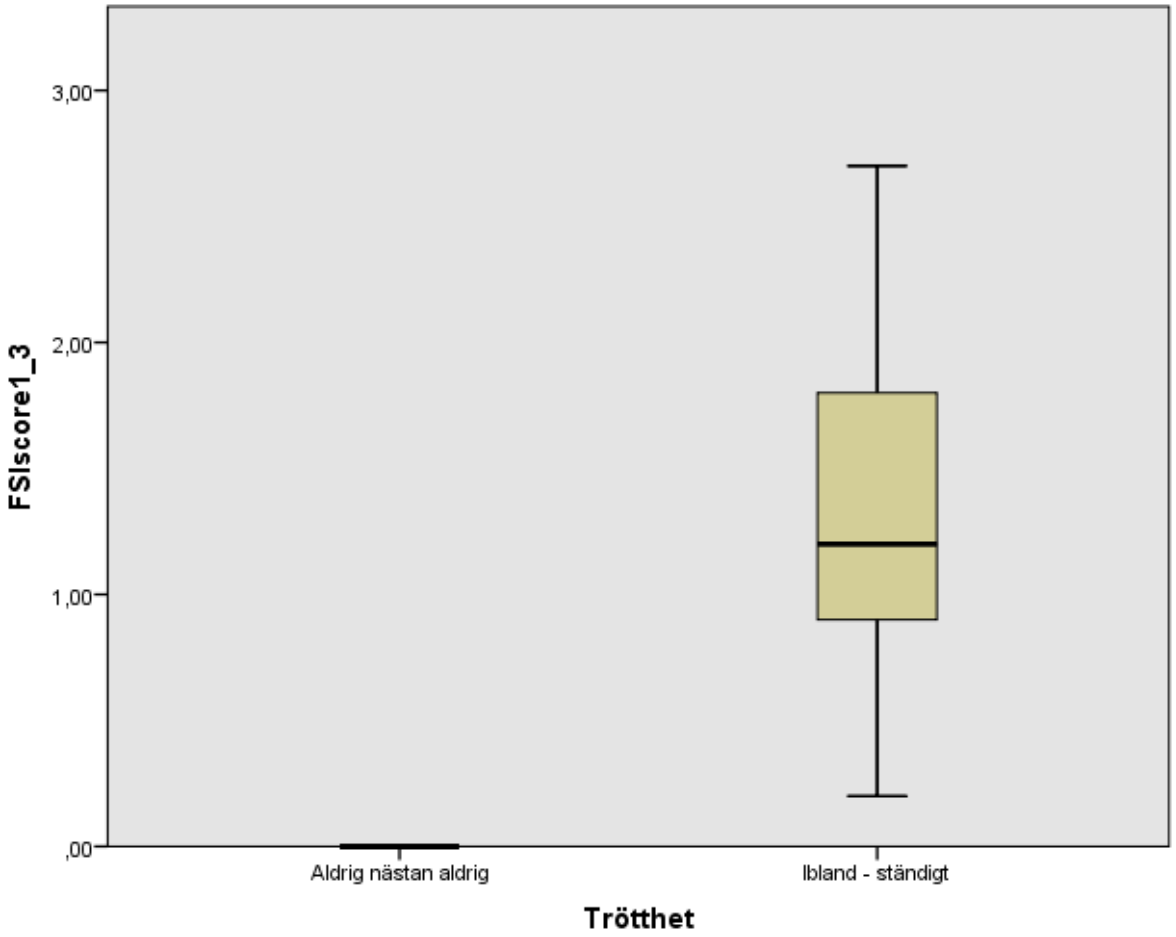

Figure 6. FSI scores in relation to the two categories (never or almost never) and (sometimes + often + constantly) of tiredness. 61 responders.

Impaired memory – comparison with the Mini Mental State Examination (MMSE)

The Riksstroke question on memory reads: "Do you have difficulty remembering things?". Five response alternatives are given: Never or almost never/Sometimes/Often/Constantly/Don't know.

We tested three different cut-offs in the Riksstroke question on memory. The best, although not very satisfactory, agreement was when the responses were dichotomized into (never + sometimes + often) vs. (constantly) (Fig. 7). With a MMSE cuf-off at 25, the sensitivity was 43%, the specificity 87% and the positive predictive value 33%. By kappa statistics, the agreement was fair at 0,27.

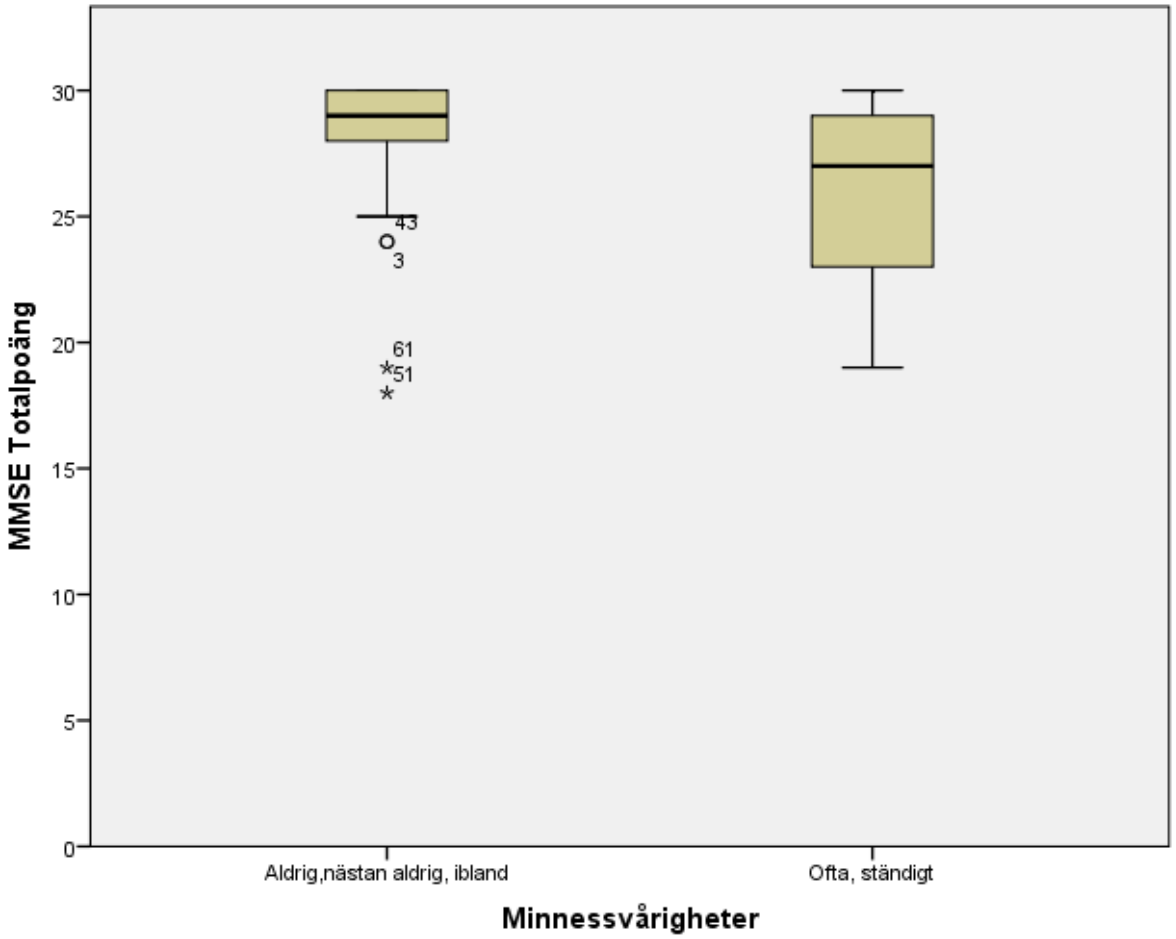

Figure 7. MMSI scores in relation to the two categories (never or almost never + sometimes + often) vs. (constantly) of responses to the Riksstroke question on memory deficits. 54 responders.

Impaired speech– comparison with the Boston Naming Test (BNT)

The Riksstroke question on speech reads: "Do you have difficulties to speak?" Only two alternatives are given, ticking or not ticking the Yes box.

The agreement between Riksstroke speech question and the BNT [10] was poor was kappa value of 0.17 (detailed data not shown here).

Pain – comparison with the Brief Pain Inventory Short From (BPI-SF)

The Riksstroke question on pain reads: "Do you have any pain?" Five response alternatives are given: Never or almost never/Sometimes/Often/Constantly/Don't know.

Figure 8 shows BPI-SF [11] scores by three of the response categories in Riksstroke (sometimes, often and constantly). There was good agreement with a sensitivity of 95%, specificity 83% and a positive predictive value of 74% for the Riksstroke question on pain. The kappa value was 0.73.

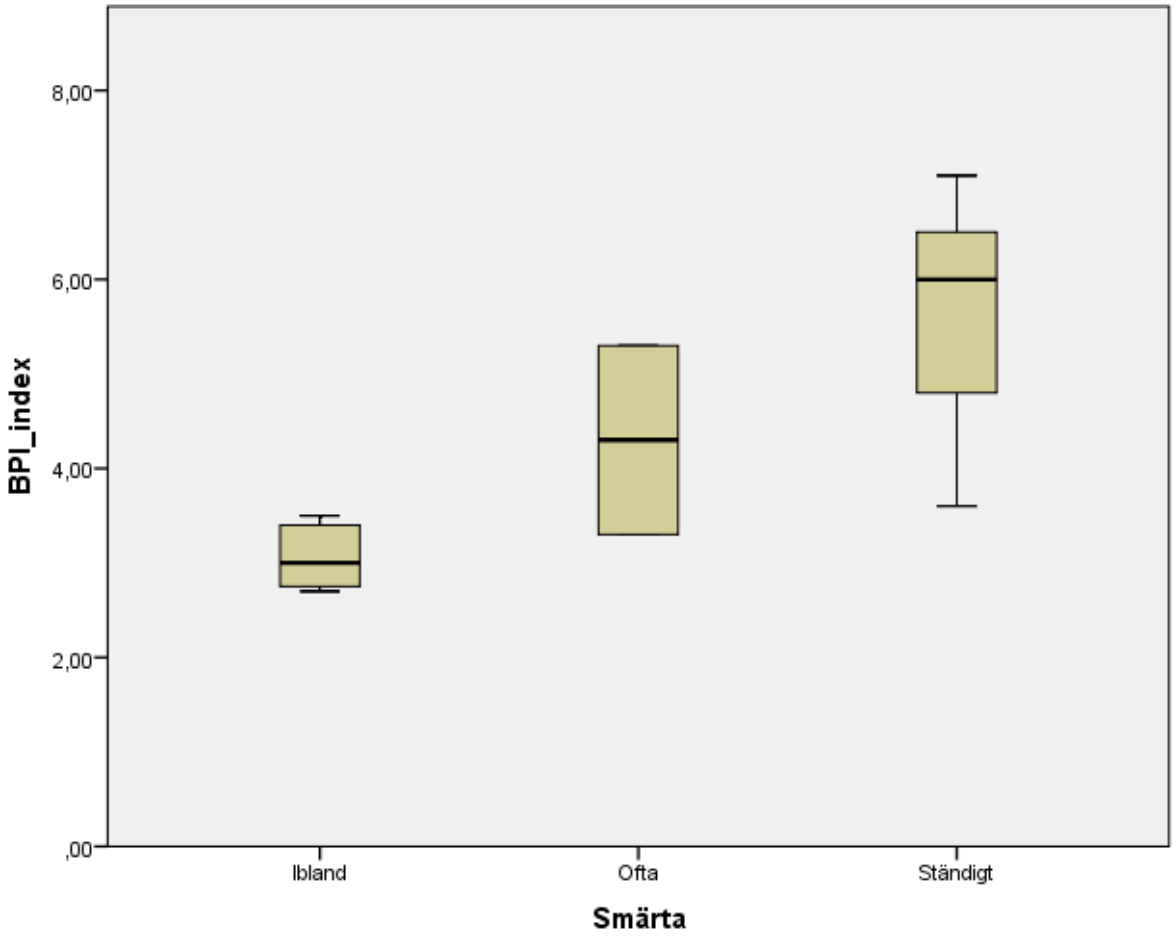

Figure 8. BPI-SF scores by the three response alternatives sometimes, often and constantly) to the Riksstroke question on pain. 27 responders. Answers by 36 patients who responded that they never had pain are not shown.

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