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TITLE PAGE

Early prediction of physical activity level one year after stroke, a longitudinal cohort study.

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ABSTRACT

Objective: To investigate which pre-stroke and early predictors those have impact on the level of physical activity one year post stroke.

Design: Prospective longitudinal cohort with logistic regression analysis.

Setting: Stroke Unit at Sahlgrenska University Hospital, Gothenburg, Sweden.

Participants: 117 patients admitted to the Stroke Unit during a period of 18 months in 2009-2010 were consecutively recruited. The inclusion criteria were: first-time stroke, impaired upper-extremity function, admitted to the Stroke Unit within 3 days since onset, local residency, ≥18 years old. The exclusion criteria were: upper extremity condition or severe multi-impairment prior to stroke, short life-expectancy, non-Swedish speaking. 77 patients were followed-up at one year post stroke.

Primary outcome: Physical activity level one year after stroke was assessed using a 6-level scale, which was first dichotomized into mostly inactive or mostly active, and secondly into low or moderate/high level of physical activity.

Results: Being mostly inactive one year after stroke could be predicted by age at stroke onset (OR 1.07, 95% CI 1.00-1.13, p=0.041), functional dependency at discharge (OR 7.01, 95% CI 1.73-28.43, p=0.006) and pre-stroke physical activity (OR 7.46, 95% CI 1.51-36.82, p=0.014). Having a low level of physical activity one year after stroke could be predicted by age at stroke onset (OR 1.13, 95% CI 1.06-1.21, p<0.001) and functional dependency at discharge (OR 3.62, 95% CI 1.09-12.04, p=0.036).

Conclusions: Previous low level of physical activity, older age and functional dependency all provide value in predicting low physical activity one year after stroke. These results show that age and simple clinical evaluations early after stroke may help clinicians to identify patients at risk of being insufficiently active after stroke and target specific interventions to improve physical activity in this group.

Clinical trial registration: Clinical Trial Registration-URL: http://www.clinicaltrials.gov. Unique identifier: NCT01115348

Strengths and limitations of the study

- Clinically important parameters prior to, and early after stroke were included
- Longitudinal consecutively recruited cohort study with one year follow-up time
- Clinically relevant dichotomization of physical activity levels produced interpretable data
- Despite relatively large cohort, the number of included predictors was limited due to small number of cases for some variables
- Patients with minor stroke showing no upper-extremity impairment early after stroke were not included

INTRODUCTION

Low physical activity (PA) has shown to be an independent risk factor for stroke[1-3] and PA is a part of primary[1] as well as secondary prevention in most of the stroke guidelines[4]. The World Health Organization (WHO) has identified physical inactivity to be the fourth leading risk factor for overall global mortality[5]. The definition of PA according to WHO is ”any bodily movement produced by skeletal muscles that requires energy expenditure – including activities undertaken while working, playing, carrying out household chores, travelling, and engaging in recreational pursuits”[6]. Higher PA level pre-stroke may predict a less severe stroke[7, 8], decrease the overall risk for death from first time stroke[9] and is associated with a better functional status post stroke[7, 10, 11].

It is a complex question to answer why some people are physically active after having a stroke and others are not? PA in healthy populations has shown to be influenced by factors such as age, gender, motivation, previous PA, self-efficacy and health status[12, 13]. Being physically active post-stroke is associated with a better quality of life and have a positive correlation to functional ability[14]. The PA level among stroke-survivors has been shown to be significantly lower than in a healthy reference-population[15-19] and correlate to walking ability, balance and physical fitness[15], but cannot be explained by motor disability alone[16, 20]. Barriers to PA reported by stroke survivors include lack of motivation, fear of falling, inaccessibility to training centers and physical impairments[21, 22]. It is, however, not clear to what extent factors connected to the pre-stroke lifestyle and medical status may be associated with the PA level among stroke survivors. Identifying patients at risk of being inadequately active post stroke may help to target specific interventions for this group at an early stage. The purpose of this study is to investigate possible pre-stroke and early predictor variables that may impact the PA level one year after first time stroke.

MATERIALS AND METHODS

Population and data collection

This longitudinal study is a part of the Stroke Arm Longitudinal study at the University of Gothenburg (SALGOT)[23], with the original purpose to describe upper extremity functioning after stroke. Over a period of eighteen months, in 2009-2010, patients were included to the SALGOT-study from one of the largest out of three Stroke Units at the Sahlgrenska University Hospital, Gothenburg, with the following inclusion criteria: 1) first-time stroke according to International Classification of Diseases codes I61 intracerebral hemorrhage or I63 ischemic stroke; 2) impaired upper-extremity function, defined as not achieving the maximal points at the Action Research Arm Test (ARAT)[24] three days post-stroke; 3) admitted to the Stroke Unit within three days since stroke onset; 4) residency in the Gothenburg urban area, within 35km from the hospital; 5) ≥18 years of age. The exclusion criteria were: 1) an upper extremity injury/condition prior to stroke; 2) severe multi-impairments or diminished physical condition prior to stroke; 3) short life-expectancy; 4) non-Swedish speaking. Three experienced physiotherapists performed all clinical assessments at hospital or in the patient's home according to a standardized protocol[23]. From a total cohort of 763 patients, 117 patients were included in the SALGOT study, and 77 still remained in the study at one year post stroke (fig.1). The main reason for not being assessed at one year was that the patients had died (n=14) (fig 1). The study was approved by The Regional Ethical Review Board in Gothenburg (225-08). All participants or their next of kin gave written informed consent. The STROBE-guidelines for reporting observational data were followed[25].

Potential predictor variables

Potential predictors prior and close to the stroke onset, theorized to have impact on PA, were considered for model building. Prior stroke predictor variables included in the analyses were: smoking, living alone, TIA, diabetes, atrial fibrillation, treatment for high blood pressure and PA level. Other predictors included were: age, gender, type of stroke, stroke severity, upper extremity functioning three days post stroke and functional dependency at discharge (table 1).

Table 1. Demographics, clinical characteristics and considered predictor variables.

Demographic and clinical characteristics n=77	
Age at stroke onset, mean (SD)	67.2 (11.9)
Men, n (%)	46 (59.7)
Hemorrhagic stroke, n (%)	11 (14.3)
Smoking[1], n (%), n=76	18 (23.7)
Living alone[1], n (%)	31 (40.3)
TIA/Amaurosis Fugax[1], n (%), n=76	4 (5.3)
Diabetes[1], n (%)	10 (13)
Atrial Fibrillation[1], n (%), n=76	11 (14.5)
Treatment for high blood pressure[1], n (%), n=76	26 (34.2)
NIHSS at admission, median (q1-q3)	7 (3-12.5)
ARAT at three days, median (q1-q3), n=74	7 (0-47)
mRS at discharge from Stroke Unit, n (%).	
independent walkers (grade 0-3)	37 (48.1)
unable to walk independently (grade 4-6)	40 (51.9)
Pre-stroke PA, n (%), n=73	
mostly inactive (grade 1-2),	19 (26.0)
low (grade 1-3)	43 (58.9)

[1] = prior to stroke.

Abbreviations: SD= Standard Deviation, y/n=yes/no, TIA=Transient Ischemic Attack, NIHSS=National Institute of Stroke Scale, ARAT=Action Research Arm Test, mRS=modified Rankin Scale, PA=Physical Activity, q1-q3=1st to 3rd quartile.

Information of history of smoking, whether the patient shared livings with another adult and medical history prior to stroke were acquired by the national Swedish Stroke Register[26] or medical charts. The stroke severity at admission to the hospital was assessed using the National Institute of Health Stroke Scale (NIHSS)[27]. The upper extremity functioning was assessed using the ARAT, which includes 19 items scored on a 4-grade ordinal scale, with a total score varying from 0-57 points, where a higher score indicates less limitation[24]. The functional dependency at discharge from the Stroke Unit (mean time 13 days, SD=7,4 range 1-42) was assessed using the modified Rankin Scale (mRS)[28]. The mRS is an ordinal scale ranging from 0 to 6 where lower numbers indicates less dependency[28]. The mRS was dichotomized between the grade 3 and 4 creating one group that contained patients able to walk without assistance (no/slight/moderate disability) and one group who could not (moderately severe to severe disability). The self-reported PA level was recorded using a 6-level scale for classification of physical activity level (including leisure-time, occupational and household activities) (appendix A), originally developed from the 4 graded Saltin-Grimby scale[29, 30]. The participants' PA level was scored through an interview within three days and at one year post stroke considering the PA level during the previous six months. In the statistical analyses, the PA was dichotomized in two different ways. First, to mostly inactive (grade 1-2) or mostly active (grade 3-6) and; secondly, to low (grade 1-3) or moderate/high activity level (4-6). The first dichotomization was selected to match the original 4-level scale based upon prevention of cardiovascular disease[31]. The second dichotomization was selected to match the level of physical activity (of 30 minutes of activity, 5 days per week) recommended by the WHO in order to prevent morbidity[6]. Within each prediction model, the same dichotomization of PA level was used for outcome and for predictor variable.

Statistics

Differences between groups were investigated with Fishers exact test, Mann-Whitney U test or t-test depending on data level. Demographic data was presented with medians and percentiles or means and standard deviation (SD). The statistically significant level was set to $p<0.05$ unless stated otherwise. A multivariate logistic regression was used to investigate which predictor variables may impact on the PA level one year after stroke. Two separate models were built, one for each dichotomization of the outcome variable. As first step in selection of potential predictor variables for the regression models, the cross tabulation was used to identify and exclude predictor variables with less than 5 observations in any subgroup. Collinearity between predictor variables was checked for using Spearman's rank correlation test for ordinal variables or Likelihood Ratio test for binary variables. Variables with correlation above 0.7 were considered for collinearity. A series of univariate logistic regression analysis was performed in order to identify significant variables for further analyzes (significance level $p<0.25$, tested with Wald's test). The multivariate models were then built on the enter method in which all predictor variables not reaching the significance level of 0.05 were ruled out. Individuals with missing data on any of the variables included in the final multivariate models were excluded for analysis. All the previously ruled out variables were then re-inserted in the final model one by one to check for possible significant effect in the model ($p<0.05$, Likelihood Ratio test). The final models were analyzed with the Likelihood Ratio test, percent of correct classification, Nagelkerke R^2 and the Hosmer and Lemeshow goodness of fit test. Results are presented as Odds-Ratio (OR) with 95% confidence interval (CI). Data was analyzed using the Statistical Package for Social Sciences (SPSS) software (IBM SPSS Statistics for Mac, Version 23.0. Armonk, NY: IBM Corp.)

RESULTS

Clinical characteristics

The group of non-participants not assessed at one year from the SALGOT cohort (n=40) was older (mean difference 6.23 years, p=0.01), had a higher incidence of atrial fibrillation (p=0.04) and were less active prior to their stroke (p=0.03). No other statistical significant differences were found between the groups. Demographic and clinical characteristics are presented in table 1. Prior to stroke, 74% (n=54) of the patients with stroke were considered to be mostly active, in contrast to 61% (n= 47) at one year post stroke. Similarly, 41% (n=30) of the patients with stroke had a moderate to high activity level prior to stroke in contrast to 34% (n=26) one year later.

Selection of predictor variables

The type of stroke along with smoking, TIA, diabetes and atrial fibrillation prior to stroke contained too few individuals in subgroups and were therefore not included into further analysis. Strong significant collinearity was found between the predictor variables: mRS and ARAT (-0.74). These two variables were therefore entered into separate models and their impact to respective model compared. Likelihood Ratio Test showed a significant correlation between gender and pre-stroke PA (p=0.02) and between treatment for high blood pressure prior to stroke and pre-stroke PA (p=0.01). The results from the univariate analysis are presented in an online supplementary table (appendix B). None of the variables that were re-inserted in the final step for the multivariate analysis was significant (p>0.05).

Predicting being mostly inactive

The final model for predicting being mostly inactive post stroke included three significant predictor variables: age, functional dependency (mRS) and pre-stroke PA (table 2a).

Table 2. Logistic Regression models for predicting physical activity level one year post stroke; a) dependent variable of mostly inactive (n=73); b) dependent variable of low level of physical activity (n=77).

2a						
Coefficient	**B**	**S.E**	**Wald's**	**df**	**P**	**OR (95% CI)**
Constant	-6.52	2.15	9.17	1	0.002	0.001
Age	0.06	0.03	4.18	1	0.041	1.07 (1.00-1.13)
mRS at discharge	1.95	0.71	7.43	1	0.006	7.01 (1.73-28.43)
Pre-stroke PA (mostly inactive)	2.01	0.81	6.10	1	0.014	7.46 (1.51-36.82)
Test			**chi^2**	**df**	**P**	
Likelihood Ratio Test			32.59	3	<0.001	
Hosmer and Lemeshow			9.66	8	0.290	
2b						
Constant	-8.12	2.25	13.03	1	<0.001	<0.001
Age	0.13	0.03	13.52	1	<0.001	1.13 (1.06-1.21)
mRS at discharge	1.29	0.61	4.41	1	0.036	3.62 (1.09-12.04)
Test			**chi^2**	**df**	**P**	
Likelihood Ratio Test			30.47	2	<0.001	
Hosmer and Lemeshow			3.28	7	0.858	

Dependent variable coded as a) mostly active=0, mostly inactive=1; b) moderate/high PA=0, low PA=1; Cox & Snell R^2 a) = 0.360; b)= 0.327 Nagelkerke R^2 a) = 0.489; b)= 0.453 Abbreviations: OR=Odds Ratio, S.E=Standard Error, df=Degrees of freedom PA=Physical Activity, mRS=modified Rankin Scale

The percentage of total correctly classified for the model was 78.1 with sensitivity 75.0% and specificity of 79.5%. The odds for being mostly inactive one year after stroke, increased by 7% for every year of increasing age. The odds for being inactive also increased by 6 times if the patient was not able to walk independently at discharge and by 6.5 times if the patient was already mostly inactive pre-stroke. Predicted probabilities for this model are presented in Figure 2. A separate model including the three significant predictor variables, age, ARAT (instead of mRS) and pre-stroke PA demonstrated comparable level of correct classification (78.6%).

Predicting low physical activity

The final model for predicting low PA level included two significant predictor variables: age and functional dependency (mRS) at discharge from Stroke Unit (table 2b).

The percentage of total correctly classified for the model was 74.0 with sensitivity 77.2% and specificity of 65.0%. The odds of having a low PA level one year after stroke increased with 13% for every year of increasing age. The odds of having a low PA level also increased, by 2.6 times if the patient was not able to walk independently at discharge. Predicted probabilities for this model are presented in Figure 3. A separate model including the two significant predictor variables, age and ARAT (instead of mRS) demonstrated comparable level of correct classification (75.7%).

DISCUSSION

Higher age, functional dependency at discharge from stroke unit and being physically inactive prior to stroke all contributed to increase the probability of being physically inactive one year after stroke. The probability of having a low PA level after stroke increased with older age and functional dependency at discharge from stroke unit. Findings from this study provide new insights on what factors obtained early after stroke may impact on the PA level at later stages among stroke survivors. This information would allow an early identification of patients at risk for inactivity or low PA level, so that targeted intervention could be offered as part of secondary prevention.

When comparing levels of physical activity two different dichotomizations of data (two models), based on different recommendations on physical activity was used[6, 29]. The first model aimed to address inactivity as important cut-off for prevention of cardiovascular disease[31] and the second to address PA at lower than the recommended level required for prevention of morbidity[6]. Age was found to be a significant predictor in both models, but it had a greater impact on the model for identifying those with low PA level. This finding is in concurrence with an earlier study in older adults, where the age was inversely correlated with the amount of moderate-intensity PA, but not with the amount of low-intensity PA[32]. Functional dependency including ability to walk independently or not, was also found as a significant predictor for physical activity after stroke in both models, which is in concurrence with previous studies[15, 21]. These findings suggest that, similarly to older adults, age may have a greater impact on the intensity of PA after stroke, but also that the disability level expressed as dependence in walking and daily activities influence the PA level at later stages post stroke. The upper extremity functioning (ARAT) early after stroke was found to have similar effect on the later post stroke PA, as the functional dependency (mRS) at discharge. This indicates that other measures of activity limitations might also be suitable for prediction of PA. Being mostly inactive pre-stroke had a significant effect when predicting inactivity at later stage post-stroke. However, the level of PA pre-stroke, low or moderate/high, did not have a significant effect in the model predicting post stroke PA level, which indicate that the level of PA post stroke may to larger degree be affected by other factors, such as the disability level and age.

There has been little interest in investigating which early predictors might influence PA among stroke-survivors and most studies on PA look at cross-sectional correlations. A previous longitudinal study[33] investigating physical inactivity after stroke, found significant correlation between time spent upright and degree of independence in activities of daily living and walking at the first weeks after stroke, as well as at 1, 2 and 3 years post stroke. Although these findings reflect merely cross-sectional correlations, they indicate that independence in daily activities and ambulation are important for PA among stroke-survivors. In a review comprising people after stroke with ability to walk,[15] walking ability, balance and physical fitness were positively associated with PA level. Walking ability in the form of walking speed has further been found to explain some of the variation of PA level among stroke-survivors[16]. Studies on what stroke-survivors experience as barriers to PA have identified physical impairment as one of the main barriers to PA[21, 22], yet motor impairment have been found to correlate mainly with walking capacity and energy cost for walking and not with PA level in stroke patients[17]. In another study physical capacity, measured by a test for fitness, was found to have a moderate correlation to self-assessed PA[34]. In our study the mRS-scale addressing disability rather than impairment was used[28] and although disability and impairment are correlated, impairment does not fully explain disability among stroke patients[20]. Previous studies have not shown significant correlation between age and PA after stroke[15, 33]. Age has, however, been found to be inversely correlated to PA in healthy populations[12, 35], although not as a clear determinant compared to health status or previous PA habits[12]. The decline in PA with increasing age does not seem to be linear but exponential in older adults[35] and functional outcome has been found to drop steeply in the older ages among stroke patients[36], yet most work on PA among stroke-survivors have been made in patients aged 65 to 75 years[15]. The present study had no upper limit of age and so was able to include some of the elderly patients, yet the group of patients in this study were somewhat younger than the average stroke-population in Sweden[26], therefore, the effect of age on PA level in stroke-survivors might be slightly underestimated.

Pre-stroke PA has been found to have a significant impact on functional outcome at acute phase[11], 3 months[10, 19], one year[11] and two years after stroke[7]. A longitudinal study[11] showed that the main differences for functional outcome were found when comparing a subgroup with relatively low PA level, measured as people who walked less than 30 minutes per day with groups walking for more than 30 minutes a day. The group with low amount of walking time was more dependent as measured by the mRS-scale and the Barthel Index and had a slower walking speed. These differences were not seen when comparing one group that walked for 30-60 minutes per day with another group who walked for more than 60 minutes per day[11]. These results are in line with the findings in our study showing that being mostly active, as analyzed in the first model, was important for staying active, whilst a higher PA level made no further contribution in predicting a higher PA level post stroke. Pre-stroke habits of PA may also possibly mean having some knowledge about PA and its beneficial health effects, while lack of knowledge and disbeliefs related to PA have been reported as barriers to PA by stroke-survivors[21, 22] and could be a part of the explanation of our finding that pre-stroke PA level is important for being active after stroke.

The strength of this study was that many clinically important parameters that can be obtained early post stroke were considered as potential predictors for long-term outcome of PA level. It is of clinical importance to identify patients at risk of becoming inactive at an early stage, since PA after stroke may help in preventing secondary complications[4]. Furthermore the dichotomizations for PA level used in the study are clinically relevant and concurrent with recommendations for prevention of morbidity. There are, however, several limitations to this study, including a low number of cases in some subgroups that did not allow inclusion of all potential predictor variables into the regression models. The main outcome variable for PA was an interview based questionnaire[29, 30]. This type of scale presents with some problems including being at an ordinal level of data and the risk for recall bias[37]. There is only a limited number of studies investigating validity of the 6-graded scale used in this study[38]. The dichotomization used in the first model between grade 2 and 3 may, however, be directly translated into the original 4-grade Saltin-Grimby scale[29, 30], which has been widely used and shown to have a good concurrent validity[38]. Self-assessed PA has also been shown to have good predictor value for cardiovascular risk profiles[39] as well as for functional outcome after stroke[19]. The alternative option for reporting PA is direct measurement, e.g. through using accelerometers[37]. This option would not have been possible for establishing PA level prior to stroke, but could have been for outcome. There are several other variables, such as mood, balance scales[40], fear of falling[20] lack of motivation and environmental factors[21] that may influence PA after stroke that were not taken into account in the current study. Furthermore, our study included patients with an impaired upper extremity function only, leading to risk of selection bias by indirectly excluding patients with minor stroke.

The present study aimed to predict patients that have a higher risk in becoming inactive after their stroke. The problem of inactivity amongst patients with stroke is well established and recent recommendations have highlighted the challenges in increasing the physical activity amongst these patients[4]. By identifying which patients that have an increased risk of becoming inactive clinicians may be able to identify these patients earlier and help prevent them from falling into a vicious circle of inactivity and secondary complications[4].

CONCLUSION

Physical inactivity among stroke survivors is a major clinical problem. The present study showed that patients with a higher age, higher degree of functional dependency early after stroke and a history of inactivity prior to stroke are at increased risk of being insufficiently active at one year post stroke. By these findings, clinicians may be able to identify patients in need of targeted interventions for reaching an adequate amount of PA. The list of predictor variables identified in this study contribute, but cannot explain all of the variation of PA level among stroke-survivors and other predictors need to be further explored.

Online supplements:

Appendix A: Scale for physical activity

Appendix B: Supplementary table of univariate logistic regression

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Contributors: OAO, HCP, MAM, KSS contributed to the design of the study concept, in analysis and interpretation of results and in drafting/revising the manuscript for content. All authors have read and approved the final manuscript. In addition to this HCP and MAM performed the acquisition of data, HCP, MAM and KSS obtained funding, OAO performed the statistical analysis and KSS supervised the SALGOT-study.

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Competing interest: The authors declare that they have no competing interests.

Data Sharing: Interested researchers may submit requests for data to the authors (contact ks.sunnerhagen@neuro.gu.se). According to the Swedish regulation (http://www.epn.se/en/start/regulations/) the permission to use data is only for what has been applied for and then approved by the Ethical board.

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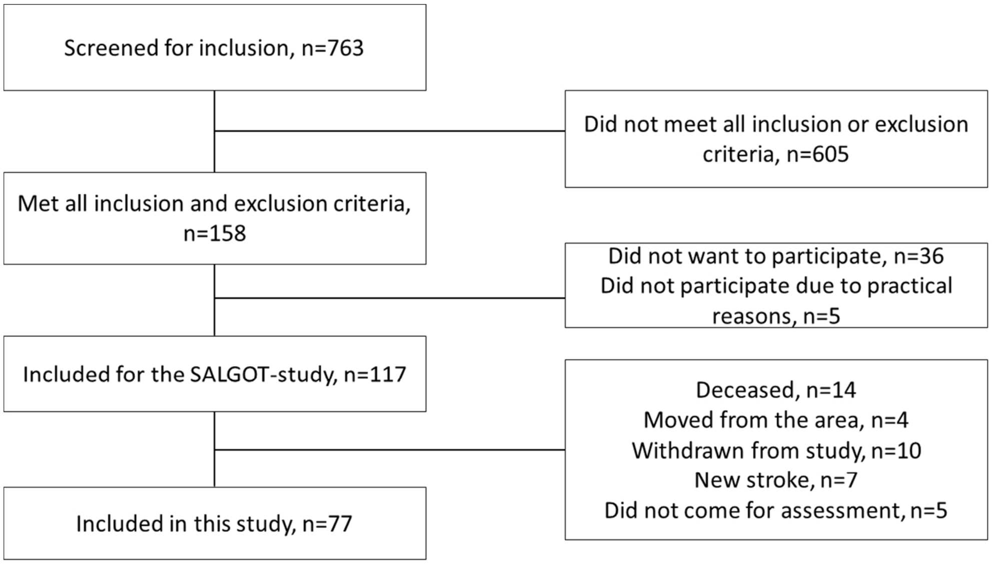
Figure legends

Fig 1. Flowchart for inclusion of the study participants

Fig 2. Predicted probabilities of being mostly inactive one year after stroke. The predicted probability increases with higher age, higher degree of functional dependency and being physically inactive pre-stroke.

Fig.3 Predicted probability for having low PA one year after stroke. The predicted probability increases with higher age and higher degree of functional dependency.



Flowchart for inclusion of the study participants

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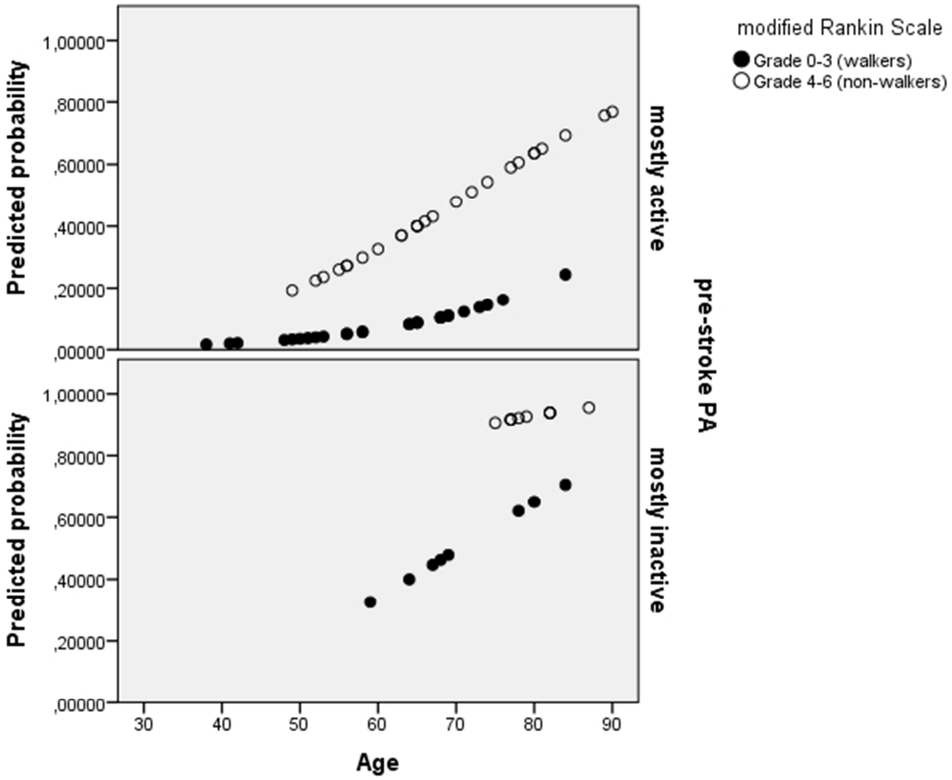

Predicted probabilities of being mostly inactive one year after stroke. The predicted probability increases with higher age, higher degree of functional dependency and being physically inactive pre-stroke.

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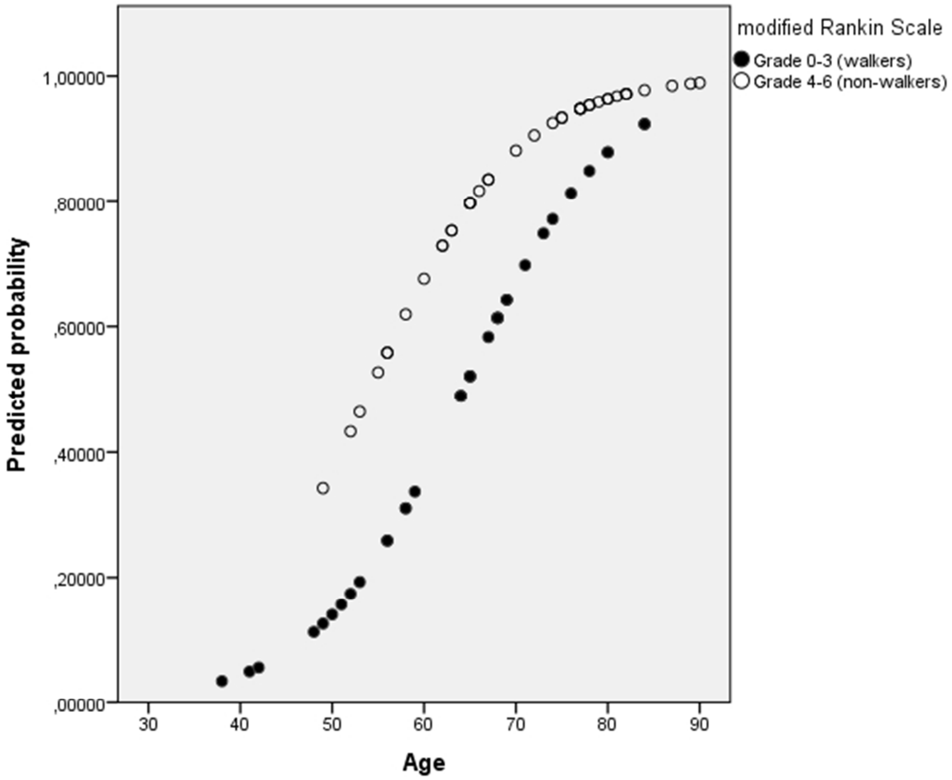

Predicted probability for having low PA one year after stroke. The predicted probability increases with higher age and higher degree of functional dependency.

53x42mm (300 x 300 DPI)

Appendix A

6-level scale for physical activity

1. Hardly no physical activity
2. Mostly sitting, sometimes a walk, easy gardening or similar tasks, sometimes light household activities such as heating up food, dusting, or “clearing away”
3. Light physical exercise for about 2-4 hours a week, e.g. walks, fishing, dancing, ordinary gardening etc., including walks to and from shops. Main responsibility for light domestic work such as cooking, dusting, “clearing away”, and making beds. Performs or takes part in weekly cleaning
4. Moderate exercise 1-2 hours a week, e.g. jogging, swimming, gymnastics, heavier gardening, home repair or easier physical activities more than 4 hours a week. Responsible for all domestic activities, easy as well as heavy. Weekly cleaning with vacuum cleaning, washing floors and window-cleaning
5. Moderate exercise at least 3 hours a week, e.g. tennis, swimming, jogging etc.
6. Hard or very hard exercise regularly and several times a week, during which physical exertion is great, e.g. jogging, skiing

Appendix B

Supplementary table. Univariate logistic regression analysis between predictors and outcome variable of physical activity level one year after stroke

	Mostly inactive (grade 1-2)		**Low PA (grade 1-3)**	
Predictor variables	**Wald**	**p-value**	**Wald**	**p-value**
Age	14.018	<0.001	16.483	<0.001
Gender	0.001	0.970	0.518	0.472
Ischemic/hemorrhagic	1.274	0.259	1)	1)
Smoking	1)	1)	1.083	0.298
Shared living	1.918	0.166	4.597	0.032
Treatment for high blood pressure	1.487	0.223	1)	1)
NIHSS	3.946	0.061	1.588	0.208
ARAT	9.545	0.002	10.023	0.002
mRS	11.902	0.001	9.512	0.002
Pre-stroke PA	11.755	0.001	6.669	0.010

1)= not applicable due to too small subgroups for analysis.

P-Value for significance set for 0.25

Abbreviations: NIHSS=National Institute of Health Stroke Scale, mRS=modified Rankin Scale, ARAT=Action Research Arm Test, PA=Physical Activity.

Alt Murphy *et al. BMC Neurology* 2011, **11**:56
http://www.biomedcentral.com/1471-2377/11/56

BMC Neurology

STUDY PROTOCOL Open Access

SALGOT - Stroke Arm Longitudinal study at the University of Gothenburg, prospective cohort study protocol

Margit Alt Murphy*, Hanna C Persson, Anna Danielsson, Jurgen Broeren, Åsa Lundgren-Nilsson and Katharina S Sunnerhagen

Abstract

Background: Recovery patterns of upper extremity motor function have been described in several longitudinal studies, but most of these studies have had selected samples, short follow up times or insufficient outcomes on motor function. The general understanding is that improvements in upper extremity occur mainly during the first month after the stroke incident and little if any, significant recovery can be gained after 3-6 months. The purpose of this study is to describe the recovery of upper extremity function longitudinally in a non-selected sample initially admitted to a stroke unit with first ever stroke, living in Gothenburg urban area.

Methods/Design: A sample of 120 participants with a first-ever stroke and impaired upper extremity function will be consecutively included from an acute stroke unit and followed longitudinally for one year. Assessments are performed at eight occasions: at day 3 and 10, week 3, 4 and 6, month 3, 6 and 12 after onset of stroke. The primary clinical outcome measures are Action Research Arm Test and Fugl-Meyer Assessment for Upper Extremity. As additional measures, two new computer based objective methods with kinematic analysis of arm movements are used. The ABILHAND questionnaire of manual ability, Stroke Impact Scale, grip strength, spasticity, pain, passive range of motion and cognitive function will be assessed as well. At one year follow up, two patient reported outcomes, Impact on Participation and Autonomy and EuroQol Quality of Life Scale, will be added to cover the status of participation and aspects of health related quality of life.

Discussion: This study comprises a non-selected population with first ever stroke and impaired arm function. Measurements are performed both using traditional clinical assessments as well as computer based measurement systems providing objective kinematic data. The ICF classification of functioning, disability and health is used as framework for the selection of assessment measures. The study design with several repeated measurements on motor function will give us more confident information about the recovery patterns after stroke. This knowledge is essential both for optimizing rehabilitation planning as well as providing important information to the patient about the recovery perspectives.

Trial registration: ClinicalTrials.gov: NCT01115348

Keywords: stroke, upper extremity, recovery of function, kinematics, longitudinal study

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Background

Stroke is defined by the World Health Organization (WHO) as rapidly developing clinical signs of focal or global disturbance of cerebral function, with symptoms lasting more than 24 hours or leading to death and with no apparent non-vascular cause. The incidence of stroke in Sweden is 300 cases per 100 000 inhabitants in a year of whom 200 suffer a first incidence of stroke leading to a total of 18 000 new stroke victims. About 25000 - 30000 persons yearly suffer from acute stroke each year in Sweden. Of these, about 20% will die within the first month and about 1/3 of the survivors will remain significantly disabled after 6-12 months [1].

The upper extremity function is impaired after stroke in approximately 70-80% of patients in acute phase and in 40% in chronic phase [2-4]. This impairment limits the voluntary, well coordinated, and effective movements as well as a person's level of activity [5] and participation in their social and physical environment [2]. This longstanding disability might also influence the quality of life [6].

Recovery of motor skills after stroke depends both on spontaneous reparative process as well as reorganization of neural mechanisms, influenced by inputs and demands given to the motor control system. The current perspective on motor learning focuses on active task-oriented training and how feedback and other basic training principals such as regularity, intensity and specificity affects the long-term recovery [7,8]. In order to detect meaningful improvements in motor function, appropriate outcome measures should be used. Beside the requirements on reliability, validity and sensitivity, the issues of functionality and objectivity must be considered while selecting the appropriate measures. Assessment methods with continuous variables are recommended to be included into evaluation batteries since they might have higher power to detect the important improvements in motor recovery [9-11].

Improved understanding of the recovery patterns after stroke is essential for planning and execution of optimal rehabilitation. Recovery patterns of upper extremity function have been described for selected stroke populations in several longitudinal studies. The general idea is that improvements in the upper extremity occur mainly during the first month after onset of the stroke and that little, if any, significant recovery can be gained after 3-6 months [3,12-14]. Several studies, conducted in selected populations at rehabilitation facilities have shown that, in some patients, the improvements also continued for a longer time [2,4,15]. There are only a few studies with non-selected community based populations describing the recovery patterns in the upper extremity. These studies report a similar recovery pattern with little or no significant recovery beyond 2-3 months [3,16-18]. Whether this is correct is not clear for the non-selected studies, since in some reports the sample sizes were small [14,15], the follow up times were short [3,4] or the information on the motor assessments was not satisfactory [3,18].

Kinematic measurement - drinking task

Kinematics describes movements of the body through space and time, including linear and angular displacements, velocities and accelerations, but without reference to the forces involved. Kinematic data can be achieved by optoelectronic systems where multiple high-speed cameras send out infra red light signals and detect the reflection from the markers placed on the body. Kinematic variables provide objective, precise and detailed measures of movement performance and quality.

Kinematic movement analysis has become a useful assessment tool within rehabilitation and is employed routinely for gait analyses. Few studies have used kinematic movement analysis to examine the upper extremity in a longitudinal design. In one of these studies the kinematic data was obtained from an isolated fast elbow extension [15,19] and in the other a targeting fast reaching movement [20]. In order to better understand the situation of a person with impaired upper extremity function, information is needed regarding activities of daily living. It is known that the motor activity of the upper extremity is dependent on the meaning of the task and on the shape and placement of the object [21]. Thus, it is meaningful to study natural purposeful movements with real-life objects. In an earlier study we have developed a test protocol and a program for data analyses of the kinematic variables for the activity of drinking from a glass, which has been applied in a control setting [22] and in stroke subjects [23].

Kinematic measurement - Virtual reality test

Virtual reality (VR) can be described as the world perceived in a computer. VR systems that include a haptic device can provide tactile feedback to the user through the force feedback. If the system detects a collision between the device and virtual objects, it transmits a reaction to the user's hand, which interacts with perception of the test or training situation [24]. In the real world, objects are usually perceived in the same location whether the sense involved is vision or touch (haptic). In the virtual world, the precise co-location of haptics is technically harder to achieve, but when the co-location is accurate the realism of the manipulation is very high and the user's performance is improved [25]. The knowledge about effects of using VR in assessments and training after stroke is still limited, but sufficiently encouraging to justify additional clinical trials in this population [26-31].

Theoretical background

WHO approved in May 2001 the model on International Classification of Functioning, Disability and Health (ICF) [32] to assess the consequences of a disorder or a disease on the individual person. The ICF model provides a multi-perspective approach to the classification of functioning and disability as an interactive and evolutionary process. In the model an individual's functions in a specific domain is an interaction or complex relationship between the health conditions (physical or mental) and contextual factors (social and physical environment as well as personal factors). The components of ICF can be used to indicate problems (e.g. impairments, activity limitations or participation restrictions summarized under the umbrella term disability) in different areas. This approach forces health professionals to look wider than the usual perspective, which has traditionally lain in the domain of body function and structures. The model boosts the traditional rehabilitation ideology where the focus has not been on the organ but on the person and thereby requiring different treatments depending on that person's goal. In order to assess the consequences of a disease we need to look at different components of the ICF.

Longitudinal studies are difficult to perform. Sweden has a unique situation since people are quite easy to trace through the civic system and moving from one region to another is not so frequent. In addition, the representativeness for the disease is good since all patients within a catchment area are usually referred to the same hospital as private alternatives are scarce and thereby the possibilities to generalize the results are good.

The purpose of this study is to describe the recovery of upper extremity function longitudinally in a non-selected sample with first ever clinical stroke admitted to a stroke unit.

The specific objectives of the present study are to:

A. Follow recovery of upper extremity by using clinical measures of body function (motor function, spasticity), activity (use of the arm and hand) and participation (impact of limitations) after stroke
B. Follow functional recovery by using objective, new IT technology (kinematic movement analysis and VR-test with sensory feedback) after stroke
C. To gather the assessments of participants self-perceived upper extremity function over the first year after stroke
D. To predict function at 12 months by analysis of data gathered at first week after onset of stroke

Methods/Design

A sample of 120 persons with a first occurrence of stroke will be included and followed longitudinally for one year after the stroke. The group will consist of consecutively included persons recruited from the stroke unit at Sahlgrenska University Hospital, Gothenburg, Sweden. The Stroke unit at Sahlgrenska University Hospital serves the larger Gothenburg urban area, thus all persons from this catchment area are randomly referred to the Sahlgrenska University Hospital. The project is approved by the Regional Ethical Review Board and the Helsinki declaration is followed. Written informed consent will be obtained from the participants or from their closest relative. The SALGOT study is registered on ClinicalTrials.gov (NCT01115348).

Inclusion criteria are:

- Diagnosed first ever clinical stroke, based on WHO criteria (ischemic infarct, haemorrhagic and subarachnoidal bleeding)
- Impaired upper extremity function. This is defined in two steps. On the first or second day after stroke onset the upper extremity function is assessed with Modified Motor Assessment Scale (M-MAS UAS-95) [33] (this is performed as standard clinical assessment by physiotherapists working at the stroke unit). All persons, who do not obtain the maximum score on the subtests of arm function, hand movements and fine motor function due to hemiparesis, will be informed about the study and retested at day three after stroke with Action Research Arm Test (ARAT) [34]. All persons who do not achieve the maximum score for ARAT (score 57) will be included.
- Admitted to the stroke unit within three days after stroke onset
- Living in the Gothenburg urban area (maximal 35 km from the Sahlgrenska University Hospital)
- Age 18 or older

Exclusion criteria are:

- Upper-extremity injury or condition prior to the stroke that limits the functional use of the affected arm and hand
- Severe multi-impairment or diminished physical condition before the stroke that will affect the arm function
- Life expectancy less than 12 months due to other illness (cardiac disease, malignancy) or severity of stroke injury
- Not Swedish speaking prior to the stroke incident

Design and procedure

This study will evaluate the recovery patterns after first ever stroke without any intervention except standard rehabilitation planning and procedures. All included

participants will be assessed eight times during the first year after stroke. Assessments are performed at day 3 and 10, week 3, 4 and 6, month 3, 6 and 12 after onset of stroke. Tests are administrated in block randomized manner in order to minimize the systematic testing bias. The test order and the reason for missed or unsuccessful test results will be recorded in a protocol. All tests are performed by three experienced physical therapists, undergoing a training period together for the assessment battery prior to the study start. ICF classification of functioning, disability and health is used as framework for the selection of assessment measures (Figure 1).

Outcome measures

Demographic data will be collected during the first assessment. Stroke subtype will be confirmed by CT and/or MRI scans. Ischemic strokes will be classified for subtype and site for lesion by using TOAST [35] and Bamford classifications [36]. Treatments of thrombolysis or thromboectomy will be registered. Additional data will be extracted from the national quality register for stroke - Swedish Stroke Register [1]. The Self-Administrated Comorbidity Questionnaire (SCQ) will be used to collect additional information on relevant medical conditions and problems [37]. Cognitive function is evaluated at every test occasion using Barrow Neurological Institute Screen for Higher Cerebral Functions (BNIS) [38]. The three prescreen items scoring the level of consciousness/alertness, cooperation and basic communication skills and the item of auditory comprehension will be assessed. The level of physical activity is recorded by a 6-grade scale of Physical Activity Classification [39,40]. This instrument is valid, short and suitable for longitudinal studies and takes account the activity level both during domestic and fitness activities [40]. Exact time points for all assessments are listed in Table 1.

Clinical outcome measures of function and activity

The upper extremity motor function will be assessed using the Fugl-Meyer Assessment for Upper Extremity (FMA-UE) [41], and a maximum score of 66 corresponds to normal motor function. The psychometric properties of Fugl-Meyer Assessment have shown excellent reliability and validity [41-43]. The non-motor domains of FMA-UE, sensation, passive range of motion and pain during passive joint motions will be completed as well.

Action research Arm Test (ARAT) is a performance test for upper extremity function and dexterity [44]. The ARAT uses ordinal scoring on 19 items divided into four hierarchical subtests: grasp, grip, pinch and gross movement. Each upper extremity is evaluated individually and the test can be completed in 5-15 minutes [44,45]. ARAT has been shown to have good validity, sensitivity to spontaneous and therapy-related gains after stroke both in acute and chronic phase [44,46]. The ARAT has shown good responsiveness [47] and excellent inter-rater and intra-rater reliability [44,48].

Spasticity will be assessed with the Modified Ashworth Scale (MAS). The muscle groups of elbow flexors and

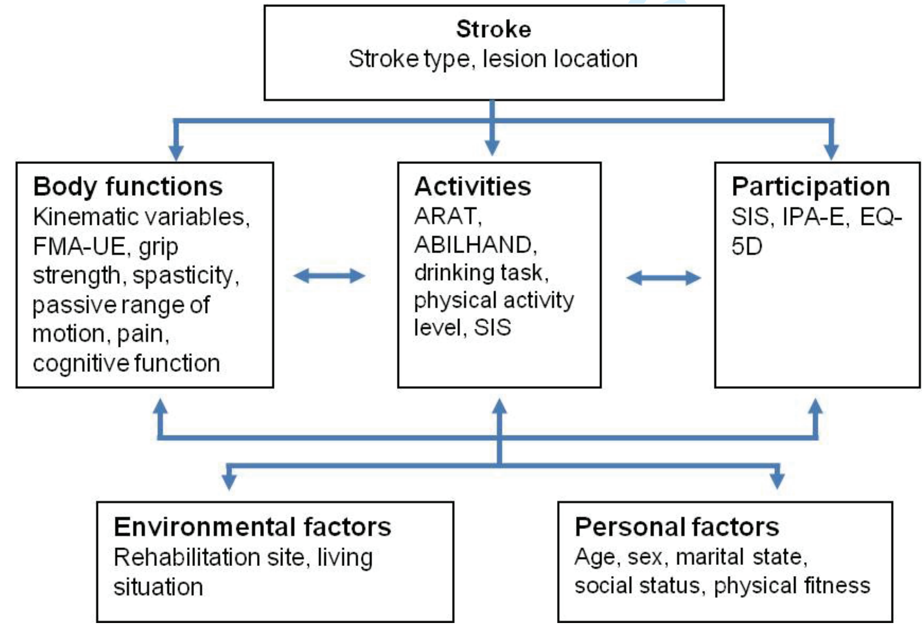

Figure 1 Outcome measures used in SALGOT study according to ICF classification.

Table 1 Scheme over the assessments and time-points for test occasions

Assessments	Test occasion (d=day, w=week, m=month)								
	d1	d3	d10	w3	w4	w6	m3	m6	m12
M-MAS UAS -95	x								
NIHSS	x								
BNIS		x	x	x	x	x	x	x	x
Physical activity scale		x						x	x
FMA-UE		x	x	x	x	x	x	x	x
Action Research Arm Test		x	x	x	x	x	x	x	x
ABILHAND		x	x	x	x	x	x	x	x
Grip strength		x	x	x	x	x	x	x	x
Modified Ashworth Scale	x	x	x	x	x	x	x	x	x
Kinematic - drinking task		x	x		x		x	x	x
Kinematic - VR-test		x	x	x	x	x	x	x	x
Stroke Impact Scale			x		x		x	x	x
IPA-E									x
EQ-5D									x

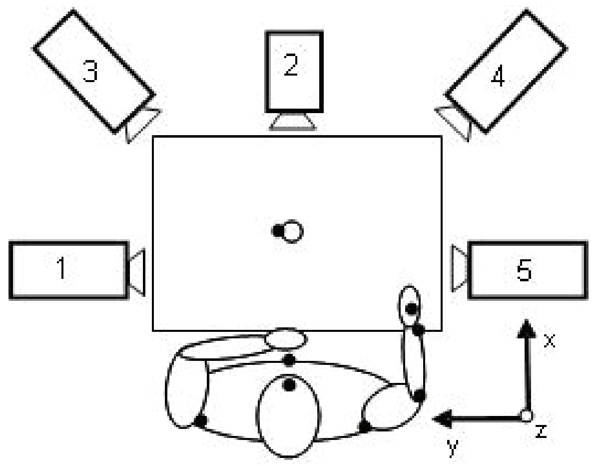

Figure 2 Setup of kinematic 5-camera motion capture system for the drinking task. Participant is presented with the right arm in initial position, and marker sites are shown as black dots.

extensors, wrist flexors and extensors will be evaluated. The MAS is the best alternative for spasticity assessment in clinical setting available and has been shown to have fair reliability for these joints [49,50].

The grip strength will be measured using the Jamar Hand Dynamometer. Standardized positioning and instructions are followed and the average of three trials is used as test outcome [51]. Reliability for the grip strength measure is very high [52].

Kinematic measurements - objective outcomes of performance

Three-dimensional motion analysis of upper extremity during drinking task will be performed with a 5-camera optoelectronic ProReflex Motion Capture System (MCU240 Hz, Qualisys AB, Sweden). The tracing of the three-dimensional coordinate positions of the markers is completed automatically by Qualisys Track Manager, 2.0. The capture data is then transferred to MATLAB (The MathWorks Inc) software for custom-made analysis. A standardized drinking task with stable test-retest reliability will be used [53]. The participant is sitting in front of the table with tested hand resting on the edge of the table (Figure 2). A drinking glass, filled with 100 mL water is placed 30 cm from the table edge in the midline of the body. The drinking task includes reaching, grasping, and lifting the glass from the table and taking a drink (one sip); placing the glass back on the table behind a marked line; and returning to the initial position. Participants are instructed to sit against the chair back during the whole task, but the sitting position is not restrained, and compensatory movements are allowed. All participants perform the drinking task at a comfortable self-paced speed, starting with their non-affected arm, after practicing a few times. The mean of the three middle trials of total five will be used for statistical calculations. A total of 9 spherical 12-mm retro-reflective markers are placed on the third metacarpophalangeal joint of hand, styloid process of ulna on wrist, lateral epicondyle of elbow, middle part of acromion on right and left shoulder, upper part of sternum, forehead and on the upper and lower edge of the glass. The procedure has been described in more detail previously [53,54].

In the VR test [55], the participant reaches into a virtual space and interacts with 3D objects. The VR equipment consists of a semi-immersive workbench with haptic device and stereoscopic glasses. In our set-up, the haptic equipment looks like a stylus shaped instrument attached to a lever system and it is freely movable in all directions (Figure 3). During the test, the position of the stylus is tracked, and resistive force is applied to the stylus when it comes into contact with the virtual object, providing force feedback. In addition to the visual perception, the haptic device creates an illusion of manipulation and sensation of the virtual objects. The participant moves the stylus in a realistic environment, experiencing the sense of moving inside the computer screen. The precise co-location of haptics is achieved by projecting the virtual image onto the same location as the user's hand through the mirror setup. The VR-test, developed by our group, is a precise quantitative kinematic measurement tool for arm and hand movements

Figure 3 Participant is performing the VR-test. The VR equipment consists of a semi-immersive workbench with haptic device and stereoscopic glasses.

and has been shown to have a good test retest reliability [31,56,57]. During the test the participant has to move the haptic stylus to 32 different targets in the virtual environment (VE) generated by the computer. The targets appear one after the other and disappear when touched. Each target consists of a whole circle (diameter 3.0 cm viewing angle). The 32 target placements in the VE are random to the subject but are actually set according to a pre-set kinematic scheme for evaluation purposes. In each test occasion the participant have one or two training trails before the measurements starts. Both dominant and non-dominant hand is measured, starting with the non-dominant hand. The participant performs the test as fast as possible.

Self-perceived outcomes

ABILHAND [58,59] is a questionnaire aiming to assess manual ability in persons with chronic stroke. It is interview based and focused on perceived difficulties in everyday activities. A Swedish version has been validated [60]. ABILHAND is a Rasch-based assessment; it is unidimensional and can be used as linear measure [58,59].

Stroke Impact Scale (SIS) [61] is a questionnaire on different aspects of the stroke recovery where the person replies on their perception regarding their life after the stroke. The 59 questions are divided into 8 domains; strength, memory, emotion, communication, activities of daily living, mobility, hand function and social participation. Items within the domain are ordered hierarchically based on clinical perspective and Rasch analysis [62]. Only the first four sections are used for the test occasion at day 10.

Impact on Participation and Autonomy (IPA-E) is a generic outcome measure for adults with chronic conditions where the person estimates perceived limitations in participation and autonomy related to dependency in the current living surrounding [63-65]. The subscales include autonomy indoors, family role, autonomy outdoors, social life and relationships, work and education. Additionally, IPA-E identifies the extent to which limitations in life are experienced as problematic in areas of mobility, self care, activities, economy issues, social life, work and education. IPA-E is valid, reliable and sensitive to change after stroke [63-65].

EuroQol Quality of Life Scale (EQ-5D) will be used to measure the health status related to the quality of life. It is a widely used generic measure and includes five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression [66,67].

Data analysis

The kinematic data in the drinking task is filtered with a 6-Hz second-order Butterworth filter, resulting in zero-phase distortion and fourth-order filtering. The drinking task is broken down into five logical phases: reaching for the glass, forward transport of the glass to the mouth, drinking, back transport of the glass to the table, and returning the hand to the initial position. The selection of kinematic variables and data analysis calculations will be based on our earlier studies [53,54]. Movement onset is defined as the time when the tangential velocity of the hand marker exceeds 2% of the maximum velocity in the reaching phase. Movement offset is detected when the velocity of the hand is less than 2% of the maximum velocity in the returning phase. Start of forward transport phase is defined as the time when the tangential velocity of the glass exceeds 15 mm/s. The drinking phase is identified by a 15% increase or decrease of the steady-state distance between the face and glass marker. The start of the returning phase is defined as the time when the tangential velocity of the glass is less than 10 mm/s. Movement times are calculated for the whole movement and separately for each phase. Peak tangential velocity and angular velocity of the elbow joint are computed for the reaching phase. Smoothness of movement is quantified by computing the number of movement units during the reaching and forward transport phases [53]. Angular joint motions are computed from the 3D position data for elbow flexion/extension, shoulder flexion/extension in the sagittal plane, and abduction/adduction in the frontal plane [53]. Compensatory trunk movement is computed for the entire drinking task as the maximal displacement of the thorax marker from the initial position [53]. Inter-joint coordination between the shoulder and elbow joint angles for reaching phase is computed using cross-correlation analysis of zero time lag [53].

In the VR-test hand position data (haptic stylus endpoint) will be gathered. The position of the stylus is

tracked and resistive force is applied to it when it comes into contact with the virtual model, providing force feedback. All measurements generate time-stamped motion data (x, y, z) at 1000 Hz. Different parameters such as reaction- and movement time, velocity, acceleration and deceleration times are calculated. To obtain the movement quality of the hand trajectory, a hand path ratio, corresponding to the length of the pathway is calculated. The selection of kinematic variables and data analysis calculations will be based on our earlier study [30].

The raw scores from the ABILHAND questionnaire are analyzed using a Rasch analysis computer program and expressed as logistically transformed probability measures, logits [68]. In the Rasch model the raw scores are used to estimate the linear ability for each subject and linear difficulty for each item of measurement around a unidimensional continuum. Thus, the Rasch model converts the ordinal score of subject's manual ability into an equal interval linear measure.

Group size/power analysis

Prior longitudinal studies stroke cohorts at Sahlgrenska University Hospital have had a dropout rate of 30%. With a power (1-β) at 0.8 and a significance level (α) at 0.05, we need a sample of 88 patients (two-sided test) to determine a medium effect of 6 points change (10%) on ARAT. Therefore, we aim to include 120 persons.

Discussion

The SALGOT study is a longitudinal prospective study with a non-selected sample from Gothenburg urban area. A sample of 120 persons with first ever clinical stroke admitted to a stroke unit will be consecutively recruited from Sahlgrenska University Hospital. The study is non-interventional and the main goal is to describe the recovery of upper extremity function after first ever clinical stroke and to follow the improvements and consequences of stroke during the first year in these persons life. Measurements are performed both using traditional clinical assessments as well as computer based measurement systems that provide objective kinematic data. The person's perspective of recovery is captured both with stroke specific as well as generic self-perceived outcome measures.

In this study, the participants are assessed at eight occasions during the first year after stroke. This design gives an opportunity to study which persons will recover, when and in which areas the recovery occurs. From earlier studies it is known that the improvement of function is mostly gained during the first months after stroke. But the majority of these reports have been conducted on selected populations and in many studies the selection of outcome measures on motor function has not been sufficient. Additionally, new technologies obtaining objective kinematic measures on motor function and performance have been scarcely used in longitudinal studies.

The gained knowledge of recovery patterns is necessary both for the healthcare system and for the individual who has suffered a stroke. Since the rehabilitation resources are limited, there is a need to know the optimal time point for interventions and have guidelines for rehabilitation planning. The more detailed information about the recovery patterns of upper extremity is needed in order to offer individualized assessment and treatment, to inform the patient sufficiently about the recovery perspectives and to enhance the patient's motivation for the rehabilitation period.

Abbreviations

ARAT: Action research Arm Test; BNIS: Barrow Neurological Institute Screen for Higher Cerebral Functions; EQ-5D: EuroQol Quality of Life Scale; FMA-UE: Fugl-Meyer Assessment for Upper Extremity; IPA-E: Impact on Participation and Autonomy; M-MAS UAS-95: Modified Motor Assessment Scale accordingly Uppsala Akademiska Sjukhus 95; NIHSS: National Institutes of Health Stroke Scale; SIS: Stroke Impact Scale; TOAST: Trail of Org 10172 in Acute Treatment; VR: Virtual reality; VE: Virtual Environment.

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Authors' contributions

MAM and HCP participated in the conception and design, planning, managing the process and are responsible for day-to-day management of the study. KSS initiated the study, participated in the conception and design, managed the process and drafted the initial manuscript. All authors contributed to the study planning, drafting the manuscript and have approved the final manuscript.

Competing interests

The authors declare no competing interests.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-8
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	7,8
Bias	9	Describe any efforts to address potential sources of bias	16, study protocol
Study size	10	Explain how the study size was arrived at	5, figure 1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8,9
		(*b*) Describe any methods used to examine subgroups and interactions	8,9
		(*c*) Explain how missing data were addressed	9
		(*d*) If applicable, explain how loss to follow-up was addressed	5
		(*e*) Describe any sensitivity analyses	9
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	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	7
		(b) Indicate number of participants with missing data for each variable of interest	7
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	11
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	11
		(*b*) Report category boundaries when continuous variables were categorized	7,8
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	13,16,17
Other information			
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	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Early prediction of physical activity level one year after stroke, a longitudinal cohort study.

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TITLE PAGE

Early prediction of physical activity level one year after stroke, a longitudinal cohort study.

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Key words: Stroke, Physical activity, Motor activity, Prognosis, Outcome Assessment

Number of words: 3820 including tables

ABSTRACT

Objective: To investigate which variables present prior and early after stroke may have an impact on the level of physical activity one-year post stroke.

Design: Prospective longitudinal cohort and logistic regression analysis.

Setting: Stroke Unit at Sahlgrenska University Hospital, Gothenburg, Sweden.

Participants: 117 individuals part of the Stroke Arm Longitudinal study (SALGOT) admitted to the stroke unit during a period of 18 months (2009-2010) were consecutively recruited. The inclusion criteria were: first-time stroke, impaired upper-extremity function, admitted to the stroke unit within 3 days since onset, local residency, ≥18 years old. The exclusion criteria were: upper extremity condition or severe multi-impairment prior to stroke, short life-expectancy, non-Swedish speaking. 77 participants were followed-up at one year post stroke.

Primary outcome: Physical activity level one year after stroke was assessed using a 6-level Saltin-Grimby scale, which was first dichotomized into mostly inactive or mostly active, and secondly into low or moderate/high level of physical activity.

Results: Being mostly inactive one year after stroke could be predicted by age at stroke onset (OR 1.07, 95% CI 1.00-1.13, p=0.041), functional dependency at discharge (OR 7.01, 95% CI 1.73-28.43, p=0.006) and pre-stroke physical activity (OR 7.46, 95% CI 1.51-36.82, p=0.014). Having a low level of physical activity one year after stroke could be predicted by age at stroke onset (OR 1.13, 95% CI 1.06-1.21, p<0.001) and functional dependency at discharge (OR 3.62, 95% CI 1.09-12.04, p=0.036).

Conclusions: Previous low level of physical activity, older age and functional dependency all provided value in predicting low physical activity one year after stroke. These results indicate that age and simple clinical evaluations early after stroke may be useful to help clinicians identify persons at risk of being insufficiently active after stroke. Further research is needed to clarify if these findings may apply to the large population of stroke-survivors.

Clinical trial registration: Clinical Trial Registration-URL: http://www.clinicaltrials.gov. Unique identifier: NCT01115348

Strengths and limitations of the study

- Clinically important parameters prior to, and early after stroke were included
- Longitudinal consecutively recruited cohort study with one year follow-up time
- Clinically relevant dichotomization of physical activity levels produced interpretable data
- Despite relatively large cohort, the number of included predictors was limited due to small number of cases for some variables
- Persons with minor stroke showing no upper-extremity impairment early after stroke were not included

INTRODUCTION

Low physical activity (PA) has shown to be an independent risk factor for stroke[1-3] and PA is a part of primary[1] as well as secondary prevention in most of the stroke guidelines[4]. The World Health Organization (WHO) has identified physical inactivity to be the fourth leading risk factor for overall global mortality[5]. The definition of PA according to WHO is ”any bodily movement produced by skeletal muscles that requires energy expenditure – including activities undertaken while working, playing, carrying out household chores, travelling, and engaging in recreational pursuits”[6]. Higher PA level pre-stroke may predict a less severe stroke[7 8], decrease the overall risk for death from first time stroke[9] and is associated with a better functional status post stroke[7 10 11].

It is a complex question to answer why some people are physically active after having a stroke and others are not. PA in healthy populations has shown to be influenced by factors such as age, gender, motivation, previous PA, self-efficacy and health status[12 13]. Being physically active post-stroke is associated with a better quality of life and has a positive correlation to functional ability[14]. The PA level among stroke-survivors has been shown to be significantly lower than in a healthy reference-population[15-19] and correlates with walking ability, balance and physical fitness[15], but cannot be explained by motor disability alone[16 20]. Barriers to PA reported by stroke survivors include lack of motivation, fear of falling, inaccessibility to training centers and physical impairments[21 22]. It is, however, not clear to what extent factors connected to the pre-stroke lifestyle and medical status may be associated with the PA level among stroke survivors. Identifying persons at risk of being inadequately active post stroke may help to target specific interventions for this group at an early stage. The purpose of this study was to investigate possible pre-stroke and early predictor variables that may impact the level of PA one year after the first time stroke.

MATERIALS AND METHODS

Population and data collection

This longitudinal study is a part of the Stroke Arm Longitudinal study at the University of Gothenburg (SALGOT)[23], with the original purpose to describe upper extremity functioning after stroke. Over a period of eighteen months, in 2009-2010, consecutively, every person who met the criteria was included to the SALGOT-study from one of the largest out of three comprehensive Stroke Units at the Sahlgrenska University Hospital, Gothenburg. The following inclusion criteria were used: 1) first-time stroke according to International Classification of Diseases codes I61 intracerebral hemorrhage or I63 ischemic stroke; 2) impaired upper-extremity function, defined as not achieving the maximal points at the Action Research Arm Test (ARAT)[24] three days post-stroke; 3) admitted to the Stroke Unit within three days since stroke onset; 4) residency in the Gothenburg urban area, within 35km from the hospital; 5) ≥18 years of age. The exclusion criteria were: 1) an upper extremity injury/condition prior to stroke; 2) severe multi-impairments or diminished physical condition prior to stroke; 3) short life-expectancy; 4) non-Swedish speaking. Three experienced physiotherapists performed all clinical assessments according to a standardized protocol[23]. Most assessments were performed at the hospital and only at persons' home or nursing home when the participant was unable to travel. Prior power analysis for SALGOT to determine a minimum of 6 points change on ARAT (statistical power of 0.8, α 0.05) and considering a 30% dropout rate indicated that a sample size of 114 was needed. From a total cohort of 763 persons, 117 were included in the SALGOT study, and 77 still remained in the study at one year post stroke (fig.1). The main reason for not being assessed at one year was death (n=14) (fig 1). The study was approved by The Regional Ethical Review Board in Gothenburg (225-08). All participants or their next of kin gave written informed consent. The STROBE-guidelines for reporting observational data were followed[25].

Potential predictor variables

Potential predictors prior and close to the stroke onset, theorized to have impact on PA, were considered for model building. Prior stroke predictor variables included in the analyses were: smoking, living alone, TIA, diabetes, atrial fibrillation, treatment for high blood pressure and PA level. Other predictors included were: age, gender, type of stroke, stroke severity, upper extremity functioning three days post stroke and functional dependency at discharge (table 1).

Table 1. Demographics, clinical characteristics and considered predictor variables.

Demographic and clinical characteristics n=77	
Age at stroke onset, mean (SD)	67.2 (11.9)
Men, n (%)	46 (59.7)
Hemorrhagic stroke, n (%)	11 (14.3)
Smoking[1], n (%), n=76	18 (23.7)
Living alone[1], n (%)	31 (40.3)
TIA/Amaurosis Fugax[1], n (%), n=76	4 (5.3)
Diabetes[1], n (%)	10 (13)
Atrial Fibrillation[1], n (%), n=76	11 (14.5)
Treatment for high blood pressure[1], n (%), n=76	26 (34.2)
NIHSS at admission, median (q1-q3)	7 (3-12.5)
ARAT at three days, median (q1-q3), n=74	7 (0-47)
mRS at discharge from Stroke Unit, n (%).	
independent walkers (grade 0-3)	37 (48.1)
unable to walk independently (grade 4-5)	40 (51.9)
Pre-stroke PA, n (%), n=73	

mostly inactive (grade 1-2)	19 (26.0)
low (grade 1-3)	43 (58.9)
Acute hospital stay, days mean (SD)	12.6 (7.1)
Discharge to post acute hospital stay, n (%)	
Ordinary home	27 (35)
In-hospital rehabilitation unit	46 (60)
Nursing home	4 (5)

[1] = prior to stroke.

Abbreviations: SD= Standard Deviation, y/n=yes/no, TIA=Transient Ischemic Attack, NIHSS=National Institute of Stroke Scale, ARAT=Action Research Arm Test, mRS=modified Rankin Scale, PA=Physical Activity, q1-q3=1st to 3rd quartile.

Information of history of smoking, whether the participant shared livings with another adult and medical history prior to stroke were acquired by the national Swedish Stroke Register[26] or medical charts. The stroke severity at admission to the hospital was assessed using the National Institute of Health Stroke Scale (NIHSS)[27]. The upper extremity functioning was assessed using the ARAT, which includes 19 items scored on a 4-grade ordinal scale, with a total score varying from 0-57 points, where a higher score indicates less limitation[24]. The functional dependency at discharge from the stroke u(mean time 13 days, SD=7,4 range 1-42) was assessed using the modified Rankin Scale (mRS)[28]. The mRS is an ordinal scale ranging from 0 to 6 where lower numbers indicates less dependency[28]. The mRS was dichotomized between the grade 3 and 4 creating one group that contained persons able to walk without assistance (no/slight/moderate disability, grades 1-3) and one group who could not (moderately severe to severe disability, grades 4-5). The self-reported PA level was recorded using a 6-level scale for classification of physical activity level (including leisure-time, occupational and household activities) (appendix A), originally developed from the 4 graded Saltin-Grimby scale[29 30]. The participants' PA level was scored through an interview within three days and at one year post stroke considering the PA level during the previous six months. In the statistical analyses, the PA was dichotomized in two different ways. First, to mostly inactive (grade 1-2) or mostly active (grade 3-5) and; secondly, to low (grade 1-3) or moderate/high activity level (4-5). The first dichotomization was selected to match the original 4-level scale based upon prevention of cardiovascular disease[31]. The second dichotomization was selected to match the level of physical activity (of 30 minutes of activity, 5 days per week) recommended by the WHO in order to prevent morbidity[6]. Within each prediction model, the same dichotomization of PA level was used for outcome and for predictor variable.

Statistics

Differences between groups were investigated with Fishers exact test, Mann-Whitney U test or t-test depending on data level. Demographic data was presented with medians and percentiles or means and standard deviation (SD). The statistically significant level was set to $p<0.05$ unless stated otherwise. A multivariate logistic regression was used to investigate which predictor variables may impact on the PA level one year after stroke. Two separate models were built, one for each dichotomization of the outcome variable. As first step in selection of potential predictor variables for the regression models, the cross tabulation was used to identify and exclude predictor variables with less than 5 observations in any subgroup. Collinearity between predictor variables was checked for using Spearman's rank correlation test for ordinal variables or Likelihood Ratio test for binary variables. Variables with correlation above 0.7 were considered for collinearity. Second step was a series of univariate logistic regression analysis was performed on all variables not excluded by the crosstabulation in order to identify significant variables for further analyzes (significance level $p<0.25$, tested with Wald's test). Third, the variables that were significant in the univariate step was put in multivariate models, built on the enter method in which all predictor variables not reaching the significance level of 0.05 were ruled out. Individuals with missing data on any of the variables included in the final multivariate models were excluded for analysis. Fourth, all of the previously ruled out variables were then re-inserted in the final model one by one to check for possible significant effect in the model ($p<0.05$, Likelihood Ratio test). Finally, the models were analyzed with the Likelihood Ratio test, percent of correct classification, Nagelkerke R^2 and the Hosmer and Lemeshow goodness of fit test. Results are presented as Odds-Ratio (OR) with 95% confidence interval (CI). Data was analyzed using the Statistical Package for Social Sciences (SPSS) software (IBM SPSS Statistics for Mac, Version 23.0. Armonk, NY: IBM Corp.)

RESULTS

Clinical characteristics

The group of non-participants not assessed at one year from the SALGOT cohort (n=40) was older (mean difference 6.23 years, p=0.01), had a higher incidence of atrial fibrillation (p=0.04) and were less active prior to their stroke (p=0.03). No other statistical significant differences were found between the groups. Demographic and clinical characteristics are presented in table 1. Prior to stroke, 74% (n=54) of the participants were considered to be mostly active, in contrast to 61% (n= 47) at one year post stroke. Similarly, 41% (n=30) of the participants had a moderate to high activity level prior to stroke in contrast to 34% (n=26) one year later.

Selection of predictor variables

The type of stroke along with smoking, TIA, diabetes and atrial fibrillation prior to stroke contained too few individuals in subgroups and were therefore not included into further analysis. Strong significant collinearity was found between the predictor variables: mRS and ARAT (-0.74). These two variables were therefore entered into separate models and their impact to respective model compared. Likelihood Ratio Test showed a significant correlation between gender and pre-stroke PA (LRT=5.910, p=0.02 and between treatment for high blood pressure prior to stroke and pre-stroke PA (LRT= 10.358, p=0.01). The results from the univariate analysis are presented in an online supplementary table (appendix B). None of the variables that were re-inserted in the final step for the multivariate analysis were significant (p>0.05).

Predicting being mostly inactive

The final model for predicting being mostly inactive post stroke included three significant predictor variables: age, functional dependency (mRS) and pre-stroke PA (table 2a).

Table 2. Logistic Regression models for predicting physical activity level one year post stroke; a) dependent variable of mostly inactive (n=73); b) dependent variable of low level of physical activity (n=77).

2a						
Coefficient	**B**	**S.E**	**Wald's**	**df**	**P**	**OR (95% CI)**
Constant	-6.52	2.15	9.17	1	0.002	0.001
Age	0.06	0.03	4.18	1	0.041	1.07 (1.00-1.13)
mRS at discharge	1.95	0.71	7.43	1	0.006	7.01 (1.73-28.43)
Pre-stroke PA (mostly inactive)	2.01	0.81	6.10	1	0.014	7.46 (1.51-36.82)
Test			**chi^2**	**df**	**P**	
Likelihood Ratio Test			32.59	3	<0.001	
Hosmer and Lemeshow			9.66	8	0.290	
2b						
Constant	-8.12	2.25	13.03	1	<0.001	<0.001
Age	0.13	0.03	13.52	1	<0.001	1.13 (1.06-1.21)
mRS at discharge	1.29	0.61	4.41	1	0.036	3.62 (1.09-12.04)
Test			**chi^2**	**df**	**P**	
Likelihood Ratio Test			30.47	2	<0.001	
Hosmer and Lemeshow			3.28	7	0.858	

Dependent variable coded as a) mostly active=0, mostly inactive=1; b) moderate/high PA=0, low PA=1; Cox & Snell R^2 a) = 0.360; b)= 0.327 Nagelkerke R^2 a) = 0.489; b)= 0.453 Abbreviations: OR=Odds Ratio, S.E=Standard Error, df=Degrees of freedom PA=Physical Activity, mRS=modified Rankin Scale

The percentage of total correctly classified for the model was 78.1 with sensitivity 75.0% and specificity of 79.5%. The odds for being mostly inactive one year after stroke, increased by 7% for every year of increasing age. The odds for being inactive also increased by 6 times if the participant was not able to walk independently at discharge and by 6.5 times if the participant was already mostly inactive pre-stroke. Predicted probabilities for this model are presented in Figure 2. A separate model including the three significant predictor variables, age, ARAT (instead of mRS) and pre-stroke PA demonstrated comparable level of correct classification (78.6%).

Predicting low physical activity

The final model for predicting low PA level included two significant predictor variables: age and functional dependency (mRS) at discharge from Stroke Unit (table 2b).

The percentage of total correctly classified for the model was 74.0 with sensitivity 77.2% and specificity of 65.0%. The odds of having a low PA level one year after stroke increased with 13% for every year of increasing age. The odds of having a low PA level also increased, by 2.6 times if the participant was not able to walk independently at discharge. Predicted probabilities for this model are presented in Figure 3. A separate model including the two significant predictor variables, age and ARAT (instead of mRS) demonstrated comparable level of correct classification (75.7%).

DISCUSSION

Higher age, functional dependency at discharge from stroke unit and being physically inactive prior to stroke all contributed to increase the probability of being physically inactive one year after stroke. The probability of having a low PA level after stroke increased with older age and functional dependency at discharge from stroke unit. Findings from this study provide new insights on what factors obtained early after stroke may impact on the PA level at later stages among stroke survivors. This knowledge could be used to identify patients at risk for inactivity or low PA level early after stroke, so that targeted intervention could be offered as part of secondary prevention.

When comparing levels of physical activity two different dichotomizations of data (two models), based on different recommendations on physical activity was used[6 29]. The first model aimed to address inactivity as important cut-off for prevention of cardiovascular disease[31] and the second to address PA at lower than the recommended level required for prevention of morbidity[6]. Age was found to be a significant predictor in both models, but it had a greater impact on the model for identifying those with low PA level. This finding is in concurrence with an earlier study in older adults, where the age was inversely correlated with the amount of moderate-intensity PA, but not with the amount of low-intensity PA[32]. Functional dependency including ability to walk independently or not, was also found as a significant predictor for physical activity after stroke in both models, which is in concurrence with previous studies[15 21]. These findings suggest that, similarly to older adults, age may have an impact on the intensity of PA after stroke, but also that the disability level expressed as dependence in walking and daily activities influence the PA level at later stages post stroke. The upper extremity functioning (ARAT) early after stroke was found to have similar effect on the later post stroke PA, as the functional dependency (mRS) at discharge. Functional dependency at discharge and limitation in the upper extremity use early after stroke may both be associated with to the stroke severity, but these factors may also mean that the limited function itself after stroke may impact the PA level negatively[15-19]. Being mostly inactive pre-stroke had a significant effect when predicting inactivity at later stage post-stroke. However, the level of PA pre-stroke, low or moderate/high, did not have a significant effect in the model predicting post stroke PA level, which indicates that the level of PA post stroke may to larger degree be affected by other factors, such as the disability level, age and co-morbidities.

There has been little interest in investigating which early predictors might influence PA among stroke-survivors and most studies on PA look at cross-sectional correlations. A previous longitudinal study[33] investigating physical inactivity after stroke, found significant correlation between time spent upright and degree of independence in activities of daily living and walking at the first weeks after stroke, as well as at 1, 2 and 3 years post stroke. Although these findings reflect merely cross-sectional correlations, they indicate that independence in daily activities and ambulation are important for PA among stroke-survivors. In a review comprising people after stroke with ability to walk,[15] walking ability, balance and physical fitness were positively associated with PA level. Walking ability in the form of walking speed has further been found to explain some of the variation of PA level among stroke-survivors[16]. Studies on what stroke-survivors experience as barriers to PA have identified physical impairment as one of the main barriers to PA[21 22], yet motor impairment have been found to correlate mainly with walking capacity and energy cost for walking and not with PA level[17]. In another study physical capacity, measured by a test for fitness, was found to have a moderate correlation to self-assessed PA[34]. In our study the mRS-scale addressing disability rather than impairment was used[28] and although functional disability and motor impairment are correlated, impairment does not fully explain disability among people with stroke[20]. Previous studies have not shown significant correlation between age and PA after stroke[15 33]. Age has, however, been found to be inversely correlated to PA in healthy populations[12 35], although not as a clear determinant compared to health status or previous PA habits[12]. The decline in PA with increasing age does not seem to be linear but exponential in older adults[35] and functional outcome has been found to drop steeply in the older ages among people that has had with stroke[36], yet most work on PA among stroke-survivors have been made in persons aged 65 to 75 years[15]. The present study had no upper limit of age, yet the participants in the study were somewhat younger than the average stroke-population in Sweden[26], therefore, the effect of age on PA level in stroke-survivors might be slightly underestimated. Pre-stroke PA has been found to have a significant impact on functional outcome at acute phase[11], 3 months[10 19], one year[11] and two years after stroke[7]. A longitudinal study[11] showed that the main differences for functional outcome were found when comparing a subgroup with relatively low PA level, measured as people who walked less than 30 minutes per day with groups walking for more than 30 minutes a day. The group with low amount of walking time was more dependent as measured by the mRS-scale and the Barthel Index and had a slower walking speed. These differences were not seen when comparing one group that walked for 30-60 minutes per day with another group who walked for more than 60 minutes per day[11]. These results are in line with the findings in our study showing that being mostly active, as analyzed in the first model, was important for staying active, whilst a higher PA level made no further contribution in predicting a higher PA level post stroke. Pre-stroke habits of PA may also possibly mean having some knowledge about PA and its beneficial health effects, while lack of knowledge and disbeliefs related to PA have been reported as barriers to PA by stroke-survivors[21 22] and could be a part of the explanation of our finding that pre-stroke PA level is important for being active after stroke.

The strength of this study was that many clinically important parameters that can be obtained early post stroke were considered as potential predictors for long-term outcome of PA level. It is of clinical importance to identify persons at risk of becoming inactive at an early stage, since PA after stroke may help in preventing secondary complications[4]. Furthermore the dichotomizations for PA level used in the study are clinically relevant and concurrent with recommendations for prevention of morbidity. There are, however, several limitations to this study, including a low number of cases in some subgroups that did not allow inclusion of all potential predictor variables into the regression models. The main outcome variable for PA was an interview based questionnaire[29 30]. This type of scale presents with some problems including being at an ordinal level of data and the risk for recall bias[37]. There is only a limited number of studies investigating validity of the 6-graded scale used in this study[38]. The dichotomization used in the first model between grade 2 and 3 may, however, be directly translated into the original 4-grade Saltin-Grimby scale[29 30], which has been widely used and shown to have a good concurrent validity[38]. Self-assessed PA has also been shown to have good predictor value for cardiovascular risk profiles[39] as well as for functional outcome after stroke[19]. The alternative option for reporting PA is direct measurement, e.g. through using accelerometers[37]. This option would not have been possible for establishing PA level prior to stroke, but could have been for outcome.

There are several other variables, such as mood, balance scales[40], fear of falling[20] lack of motivation and environmental factors[21] that may influence PA after stroke that were not taken into account in the current study. Furthermore, our study based on the SALGOT cohort included only persons with an impaired upper extremity function three days post stroke, which need to be considered. Persons without impaired upper extremity might experience other obstacles for being physically active than people with upper limb impairment. Thus the results from the current study can only be applied to persons showing at least some impairment of the upper extremity early after stroke and other studies are needed to see if the findings in our study may also apply to persons without upper extremity impairment early after stroke.

The present study aimed to identify persons that have a higher risk in becoming inactive after their stroke. The problem of inactivity amongst people with stroke is well established and recent recommendations have highlighted the challenges in increasing the physical activity amongst this group[4]. By identifying which individuals that have an increased risk of becoming inactive after their stroke, allows clinicians to identify these persons earlier and so that targeted intervention could be offered as part of secondary prevention[4].

CONCLUSION

Physical inactivity among stroke survivors is a major clinical problem. The present study indicates that persons with a higher age, higher degree of functional dependency early after stroke and a history of inactivity prior to stroke may have an increased risk of being insufficiently active at one year post stroke. These results may help to guide clinicians in identifying individuals in need of targeted interventions for reaching an adequate amount of PA, however, these findings need to be validated by other studies to show if the results may be applicable for other groups of stroke-survivors. The list of predictor variables identified in this study contribute, but cannot explain all of the variation of PA level among stroke-survivors and other predictors need to be further explored.

Online supplements:

Appendix A: Scale for physical activity

Appendix B: Supplementary table of univariate logistic regression

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Contributors: OAO, HCP, MAM, KSS contributed to the design of the study concept, in analysis and interpretation of results and in drafting/revising the manuscript for content. All authors have read and approved the final manuscript. In addition to this HCP and MAM performed the acquisition of data, HCP, MAM and KSS obtained funding, OAO performed the statistical analysis and KSS supervised the SALGOT-study.

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Competing interest: The authors declare that they have no competing interests.

Data Sharing: Interested researchers may submit requests for data to the authors (contact ks.sunnerhagen@neuro.gu.se). According to the Swedish regulation (http://www.epn.se/en/start/regulations/) the permission to use data is only for what has been applied for and then approved by the Ethical board.

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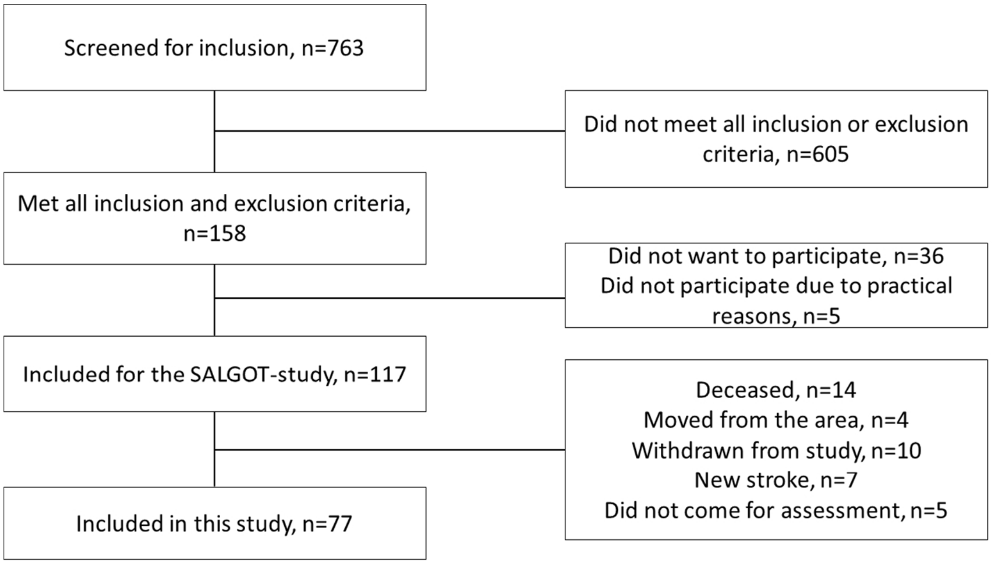
Figure legends

Fig 1. Flowchart for inclusion of the study participants

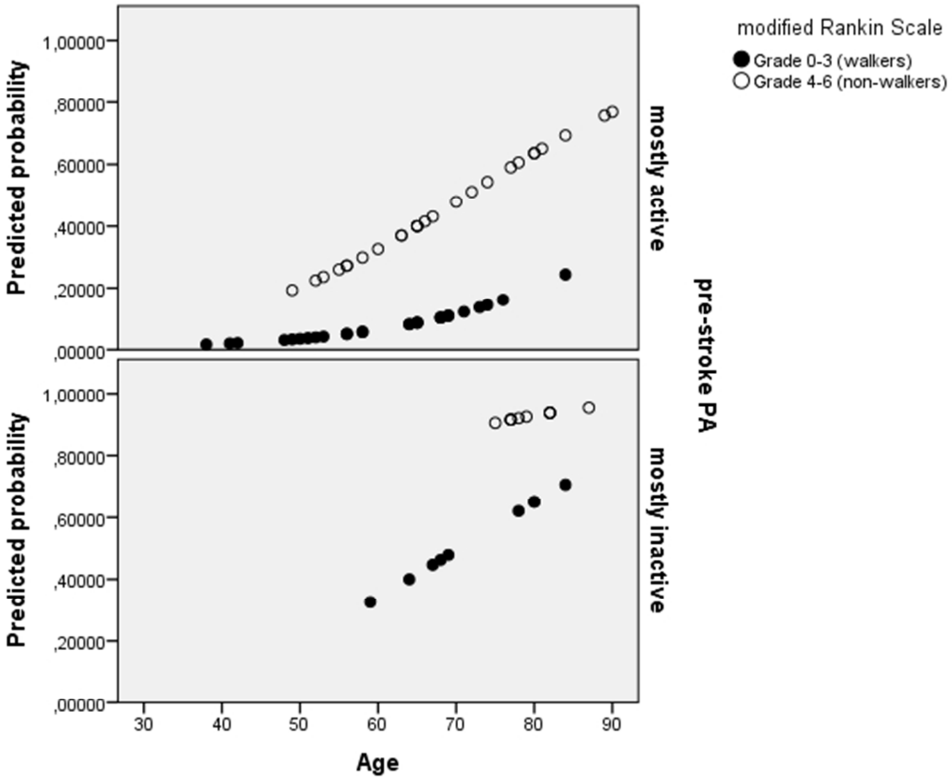
Fig 2. Predicted probabilities of being mostly inactive one year after stroke. The predicted probability increases with higher age, higher degree of functional dependency and being physically inactive pre-stroke.

Fig.3 Predicted probability for having low PA one year after stroke. The predicted probability increases with higher age and higher degree of functional dependency.



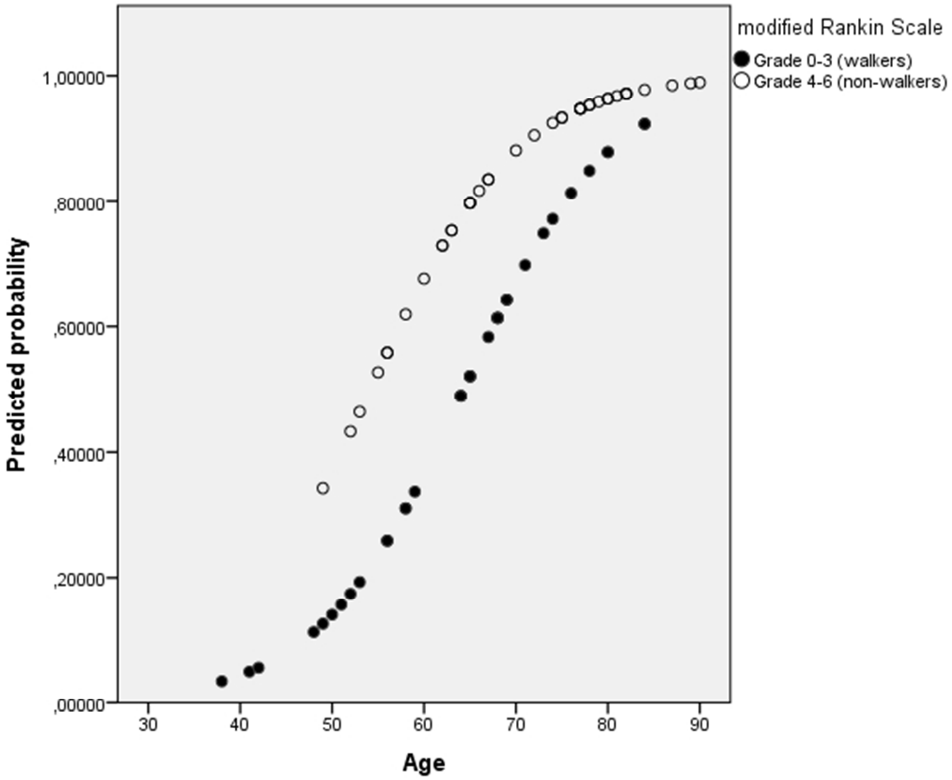
Flowchart for inclusion of the study participants

108x60mm (300 x 300 DPI)



Predicted probabilities of being mostly inactive one year after stroke. The predicted probability increases with higher age, higher degree of functional dependency and being physically inactive pre-stroke.

53x42mm (300 x 300 DPI)



Predicted probability for having low PA one year after stroke. The predicted probability increases with higher age and higher degree of functional dependency.

53x42mm (300 x 300 DPI)

Appendix A

6-level scale for physical activity

1. Hardly no physical activity
2. Mostly sitting, sometimes a walk, easy gardening or similar tasks, sometimes light household activities such as heating up food, dusting, or “clearing away”
3. Light physical exercise for about 2-4 hours a week, e.g. walks, fishing, dancing, ordinary gardening etc., including walks to and from shops. Main responsibility for light domestic work such as cooking, dusting, “clearing away”, and making beds. Performs or takes part in weekly cleaning
4. Moderate exercise 1-2 hours a week, e.g. jogging, swimming, gymnastics, heavier gardening, home repair or easier physical activities more than 4 hours a week. Responsible for all domestic activities, easy as well as heavy. Weekly cleaning with vacuum cleaning, washing floors and window-cleaning
5. Moderate exercise at least 3 hours a week, e.g. tennis, swimming, jogging etc.
6. Hard or very hard exercise regularly and several times a week, during which physical exertion is great, e.g. jogging, skiing

Appendix B

Supplementary table. Univariate logistic regression analysis between predictors and outcome variable of physical activity level one year after stroke

	Mostly inactive (grade 1-2)		Low PA (grade 1-3)	
Predictor variables	**Wald**	**p-value**	**Wald**	**p-value**
Age	14.018	<0.001	16.483	<0.001
Gender	0.001	0.970	0.518	0.472
Ischemic/hemorrhagic	1.274	0.259	1)	1)
Smoking	1)	1)	1.083	0.298
Shared living	1.918	0.166	4.597	0.032
Treatment for high blood pressure	1.487	0.223	1)	1)
NIHSS	3.946	0.061	1.588	0.208
ARAT	9.545	0.002	10.023	0.002
mRS	11.902	0.001	9.512	0.002
Pre-stroke PA	11.755	0.001	6.669	0.010

1)= not applicable due to too small subgroups for analysis.

P-Value for significance set for 0.25

Abbreviations: NIHSS=National Institute of Health Stroke Scale, mRS=modified Rankin Scale, ARAT=Action Research Arm Test, PA=Physical Activity.

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	**Item #**	**Recommendation**	**Reported on page #**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-8
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	7,8
Bias	9	Describe any efforts to address potential sources of bias	16, study protocol
Study size	10	Explain how the study size was arrived at	5, figure 1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8,9
		(*b*) Describe any methods used to examine subgroups and interactions	8,9
		(*c*) Explain how missing data were addressed	9
		(*d*) If applicable, explain how loss to follow-up was addressed	5
		(*e*) Describe any sensitivity analyses	9
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	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	7
		(b) Indicate number of participants with missing data for each variable of interest	7
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	11
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	11
		(*b*) Report category boundaries when continuous variables were categorized	7,8
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	13,16,17
Other information			
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	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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BMC Neurology

STUDY PROTOCOL

Open Access

SALGOT - Stroke Arm Longitudinal study at the University of Gothenburg, prospective cohort study protocol

Margit Alt Murphy*, Hanna C Persson, Anna Danielsson, Jurgen Broeren, Åsa Lundgren-Nilsson and Katharina S Sunnerhagen

Abstract

Background: Recovery patterns of upper extremity motor function have been described in several longitudinal studies, but most of these studies have had selected samples, short follow up times or insufficient outcomes on motor function. The general understanding is that improvements in upper extremity occur mainly during the first month after the stroke incident and little if any, significant recovery can be gained after 3-6 months. The purpose of this study is to describe the recovery of upper extremity function longitudinally in a non-selected sample initially admitted to a stroke unit with first ever stroke, living in Gothenburg urban area.

Methods/Design: A sample of 120 participants with a first-ever stroke and impaired upper extremity function will be consecutively included from an acute stroke unit and followed longitudinally for one year. Assessments are performed at eight occasions: at day 3 and 10, week 3, 4 and 6, month 3, 6 and 12 after onset of stroke. The primary clinical outcome measures are Action Research Arm Test and Fugl-Meyer Assessment for Upper Extremity. As additional measures, two new computer based objective methods with kinematic analysis of arm movements are used. The ABILHAND questionnaire of manual ability, Stroke Impact Scale, grip strength, spasticity, pain, passive range of motion and cognitive function will be assessed as well. At one year follow up, two patient reported outcomes, Impact on Participation and Autonomy and EuroQol Quality of Life Scale, will be added to cover the status of participation and aspects of health related quality of life.

Discussion: This study comprises a non-selected population with first ever stroke and impaired arm function. Measurements are performed both using traditional clinical assessments as well as computer based measurement systems providing objective kinematic data. The ICF classification of functioning, disability and health is used as framework for the selection of assessment measures. The study design with several repeated measurements on motor function will give us more confident information about the recovery patterns after stroke. This knowledge is essential both for optimizing rehabilitation planning as well as providing important information to the patient about the recovery perspectives.

Trial registration: ClinicalTrials.gov: NCT01115348

Keywords: stroke, upper extremity, recovery of function, kinematics, longitudinal study

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Background

Stroke is defined by the World Health Organization (WHO) as rapidly developing clinical signs of focal or global disturbance of cerebral function, with symptoms lasting more than 24 hours or leading to death and with no apparent non-vascular cause. The incidence of stroke in Sweden is 300 cases per 100 000 inhabitants in a year of whom 200 suffer a first incidence of stroke leading to a total of 18 000 new stroke victims. About 25000 - 30000 persons yearly suffer from acute stroke each year in Sweden. Of these, about 20% will die within the first month and about 1/3 of the survivors will remain significantly disabled after 6-12 months [1].

The upper extremity function is impaired after stroke in approximately 70-80% of patients in acute phase and in 40% in chronic phase [2-4]. This impairment limits the voluntary, well coordinated, and effective movements as well as a person's level of activity [5] and participation in their social and physical environment [2]. This longstanding disability might also influence the quality of life [6].

Recovery of motor skills after stroke depends both on spontaneous reparative process as well as reorganization of neural mechanisms, influenced by inputs and demands given to the motor control system. The current perspective on motor learning focuses on active task-oriented training and how feedback and other basic training principals such as regularity, intensity and specificity affects the long-term recovery [7,8]. In order to detect meaningful improvements in motor function, appropriate outcome measures should be used. Beside the requirements on reliability, validity and sensitivity, the issues of functionality and objectivity must be considered while selecting the appropriate measures. Assessment methods with continuous variables are recommended to be included into evaluation batteries since they might have higher power to detect the important improvements in motor recovery [9-11].

Improved understanding of the recovery patterns after stroke is essential for planning and execution of optimal rehabilitation. Recovery patterns of upper extremity function have been described for selected stroke populations in several longitudinal studies. The general idea is that improvements in the upper extremity occur mainly during the first month after onset of the stroke and that little, if any, significant recovery can be gained after 3-6 months [3,12-14]. Several studies, conducted in selected populations at rehabilitation facilities have shown that, in some patients, the improvements also continued for a longer time [2,4,15]. There are only a few studies with non-selected community based populations describing the recovery patterns in the upper extremity. These studies report a similar recovery pattern with little or no significant recovery beyond 2-3 months [3,16-18]. Whether this is correct is not clear for the non-selected studies, since in some reports the sample sizes were small [14,15], the follow up times were short [3,4] or the information on the motor assessments was not satisfactory [3,18].

Kinematic measurement - drinking task

Kinematics describes movements of the body through space and time, including linear and angular displacements, velocities and accelerations, but without reference to the forces involved. Kinematic data can be achieved by optoelectronic systems where multiple high-speed cameras send out infra red light signals and detect the reflection from the markers placed on the body. Kinematic variables provide objective, precise and detailed measures of movement performance and quality.

Kinematic movement analysis has become a useful assessment tool within rehabilitation and is employed routinely for gait analyses. Few studies have used kinematic movement analysis to examine the upper extremity in a longitudinal design. In one of these studies the kinematic data was obtained from an isolated fast elbow extension [15,19] and in the other a targeting fast reaching movement [20]. In order to better understand the situation of a person with impaired upper extremity function, information is needed regarding activities of daily living. It is known that the motor activity of the upper extremity is dependent on the meaning of the task and on the shape and placement of the object [21]. Thus, it is meaningful to study natural purposeful movements with real-life objects. In an earlier study we have developed a test protocol and a program for data analyses of the kinematic variables for the activity of drinking from a glass, which has been applied in a control setting [22] and in stroke subjects [23].

Kinematic measurement - Virtual reality test

Virtual reality (VR) can be described as the world perceived in a computer. VR systems that include a haptic device can provide tactile feedback to the user through the force feedback. If the system detects a collision between the device and virtual objects, it transmits a reaction to the user's hand, which interacts with perception of the test or training situation [24]. In the real world, objects are usually perceived in the same location whether the sense involved is vision or touch (haptic). In the virtual world, the precise co-location of haptics is technically harder to achieve, but when the co-location is accurate the realism of the manipulation is very high and the user's performance is improved [25]. The knowledge about effects of using VR in assessments and training after stroke is still limited, but sufficiently encouraging to justify additional clinical trials in this population [26-31].

Theoretical background

WHO approved in May 2001 the model on International Classification of Functioning, Disability and Health (ICF) [32] to assess the consequences of a disorder or a disease on the individual person. The ICF model provides a multi-perspective approach to the classification of functioning and disability as an interactive and evolutionary process. In the model an individual's functions in a specific domain is an interaction or complex relationship between the health conditions (physical or mental) and contextual factors (social and physical environment as well as personal factors). The components of ICF can be used to indicate problems (e.g. impairments, activity limitations or participation restrictions summarized under the umbrella term disability) in different areas. This approach forces health professionals to look wider than the usual perspective, which has traditionally lain in the domain of body function and structures. The model boosts the traditional rehabilitation ideology where the focus has not been on the organ but on the person and thereby requiring different treatments depending on that person's goal. In order to assess the consequences of a disease we need to look at different components of the ICF.

Longitudinal studies are difficult to perform. Sweden has a unique situation since people are quite easy to trace through the civic system and moving from one region to another is not so frequent. In addition, the representativeness for the disease is good since all patients within a catchment area are usually referred to the same hospital as private alternatives are scarce and thereby the possibilities to generalize the results are good.

The purpose of this study is to describe the recovery of upper extremity function longitudinally in a non-selected sample with first ever clinical stroke admitted to a stroke unit.

The specific objectives of the present study are to:

A. Follow recovery of upper extremity by using clinical measures of body function (motor function, spasticity), activity (use of the arm and hand) and participation (impact of limitations) after stroke
B. Follow functional recovery by using objective, new IT technology (kinematic movement analysis and VR-test with sensory feedback) after stroke
C. To gather the assessments of participants self-perceived upper extremity function over the first year after stroke
D. To predict function at 12 months by analysis of data gathered at first week after onset of stroke

Methods/Design

A sample of 120 persons with a first occurrence of stroke will be included and followed longitudinally for one year after the stroke. The group will consist of consecutively included persons recruited from the stroke unit at Sahlgrenska University Hospital, Gothenburg, Sweden. The Stroke unit at Sahlgrenska University Hospital serves the larger Gothenburg urban area, thus all persons from this catchment area are randomly referred to the Sahlgrenska University Hospital. The project is approved by the Regional Ethical Review Board and the Helsinki declaration is followed. Written informed consent will be obtained from the participants or from their closest relative. The SALGOT study is registered on ClinicalTrials.gov (NCT01115348).

Inclusion criteria are:

- Diagnosed first ever clinical stroke, based on WHO criteria (ischemic infarct, haemorrhagic and subarachnoidal bleeding)
- Impaired upper extremity function. This is defined in two steps. On the first or second day after stroke onset the upper extremity function is assessed with Modified Motor Assessment Scale (M-MAS UAS-95) [33] (this is performed as standard clinical assessment by physiotherapists working at the stroke unit). All persons, who do not obtain the maximum score on the subtests of arm function, hand movements and fine motor function due to hemiparesis, will be informed about the study and retested at day three after stroke with Action Research Arm Test (ARAT) [34]. All persons who do not achieve the maximum score for ARAT (score 57) will be included.
- Admitted to the stroke unit within three days after stroke onset
- Living in the Gothenburg urban area (maximal 35 km from the Sahlgrenska University Hospital)
- Age 18 or older

Exclusion criteria are:

- Upper-extremity injury or condition prior to the stroke that limits the functional use of the affected arm and hand
- Severe multi-impairment or diminished physical condition before the stroke that will affect the arm function
- Life expectancy less than 12 months due to other illness (cardiac disease, malignancy) or severity of stroke injury
- Not Swedish speaking prior to the stroke incident

Design and procedure

This study will evaluate the recovery patterns after first ever stroke without any intervention except standard rehabilitation planning and procedures. All included

participants will be assessed eight times during the first year after stroke. Assessments are performed at day 3 and 10, week 3, 4 and 6, month 3, 6 and 12 after onset of stroke. Tests are administrated in block randomized manner in order to minimize the systematic testing bias. The test order and the reason for missed or unsuccessful test results will be recorded in a protocol. All tests are performed by three experienced physical therapists, undergoing a training period together for the assessment battery prior to the study start. ICF classification of functioning, disability and health is used as framework for the selection of assessment measures (Figure 1).

Outcome measures

Demographic data will be collected during the first assessment. Stroke subtype will be confirmed by CT and/or MRI scans. Ischemic strokes will be classified for subtype and site for lesion by using TOAST [35] and Bamford classifications [36]. Treatments of thrombolysis or thromboectomy will be registered. Additional data will be extracted from the national quality register for stroke - Swedish Stroke Register [1]. The Self-Administrated Comorbidity Questionnaire (SCQ) will be used to collect additional information on relevant medical conditions and problems [37]. Cognitive function is evaluated at every test occasion using Barrow Neurological Institute Screen for Higher Cerebral Functions (BNIS) [38]. The three prescreen items scoring the level of consciousness/alertness, cooperation and basic communication skills and the item of auditory comprehension will be assessed. The level of physical activity is recorded by a 6-grade scale of Physical Activity Classification [39,40]. This instrument is valid, short and suitable for longitudinal studies and takes account the activity level both during domestic and fitness activities [40]. Exact time points for all assessments are listed in Table 1.

Clinical outcome measures of function and activity

The upper extremity motor function will be assessed using the Fugl-Meyer Assessment for Upper Extremity (FMA-UE) [41], and a maximum score of 66 corresponds to normal motor function. The psychometric properties of Fugl-Meyer Assessment have shown excellent reliability and validity [41-43]. The non-motor domains of FMA-UE, sensation, passive range of motion and pain during passive joint motions will be completed as well.

Action research Arm Test (ARAT) is a performance test for upper extremity function and dexterity [44]. The ARAT uses ordinal scoring on 19 items divided into four hierarchical subtests: grasp, grip, pinch and gross movement. Each upper extremity is evaluated individually and the test can be completed in 5-15 minutes [44,45]. ARAT has been shown to have good validity, sensitivity to spontaneous and therapy-related gains after stroke both in acute and chronic phase [44,46]. The ARAT has shown good responsiveness [47] and excellent inter-rater and intra-rater reliability [44,48].

Spasticity will be assessed with the Modified Ashworth Scale (MAS). The muscle groups of elbow flexors and

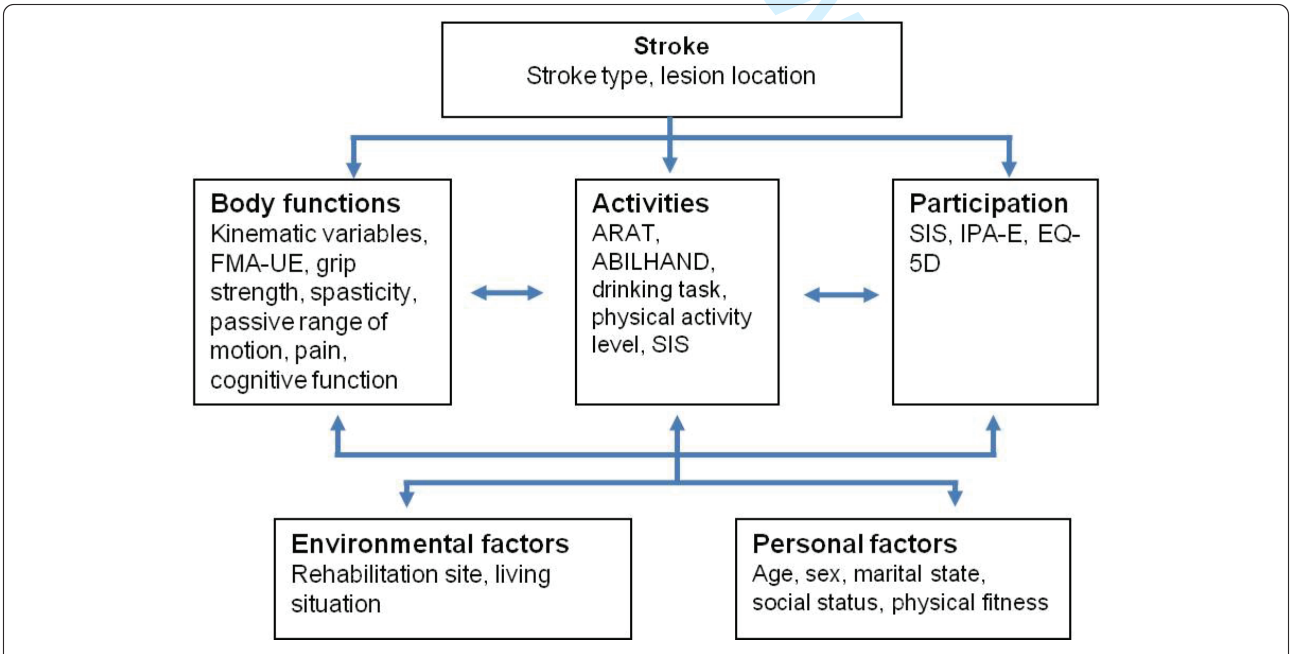

Figure 1 Outcome measures used in SALGOT study according to ICF classification.

Table 1 Scheme over the assessments and time-points for test occasions

Assessments	Test occasion (d=day, w=week, m=month)								
	d1	d3	d10	w3	w4	w6	m3	m6	m12
M-MAS UAS -95	x								
NIHSS	x								
BNIS		x	x	x	x	x	x	x	x
Physical activity scale		x						x	x
FMA-UE		x	x	x	x	x	x	x	x
Action Research Arm Test		x	x	x	x	x	x	x	x
ABILHAND		x	x	x	x	x	x	x	x
Grip strength		x	x	x	x	x	x	x	x
Modified Ashworth Scale	x	x	x	x	x	x	x	x	x
Kinematic - drinking task		x	x		x		x	x	x
Kinematic - VR-test		x	x	x	x	x	x	x	x
Stroke Impact Scale			x		x		x	x	x
IPA-E									x
EQ-5D									x

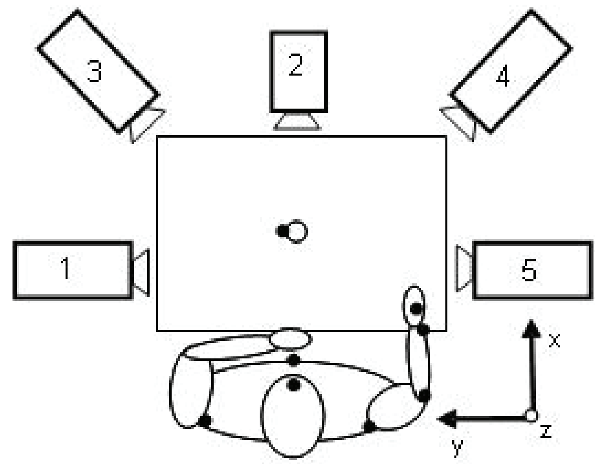

Figure 2 Setup of kinematic 5-camera motion capture system for the drinking task. Participant is presented with the right arm in initial position, and marker sites are shown as black dots.

extensors, wrist flexors and extensors will be evaluated. The MAS is the best alternative for spasticity assessment in clinical setting available and has been shown to have fair reliability for these joints [49,50].

The grip strength will be measured using the Jamar Hand Dynamometer. Standardized positioning and instructions are followed and the average of three trials is used as test outcome [51]. Reliability for the grip strength measure is very high [52].

Kinematic measurements - objective outcomes of performance

Three-dimensional motion analysis of upper extremity during drinking task will be performed with a 5-camera optoelectronic ProReflex Motion Capture System (MCU240 Hz, Qualisys AB, Sweden). The tracing of the three-dimensional coordinate positions of the markers is completed automatically by Qualisys Track Manager, 2.0. The capture data is then transferred to MATLAB (The MathWorks Inc) software for custom-made analysis. A standardized drinking task with stable test-retest reliability will be used [53]. The participant is sitting in front of the table with tested hand resting on the edge of the table (Figure 2). A drinking glass, filled with 100 mL water is placed 30 cm from the table edge in the midline of the body. The drinking task includes reaching, grasping, and lifting the glass from the table and taking a drink (one sip); placing the glass back on the table behind a marked line; and returning to the initial position. Participants are instructed to sit against the chair back during the whole task, but the sitting position is not restrained, and compensatory movements are allowed. All participants perform the drinking task at a comfortable self-paced speed, starting with their non-affected arm, after practicing a few times. The mean of the three middle trials of total five will be used for statistical calculations. A total of 9 spherical 12-mm retro-reflective markers are placed on the third metacarpophalangeal joint of hand, styloid process of ulna on wrist, lateral epicondyle of elbow, middle part of acromion on right and left shoulder, upper part of sternum, forehead and on the upper and lower edge of the glass. The procedure has been described in more detail previously [53,54].

In the VR test [55], the participant reaches into a virtual space and interacts with 3D objects. The VR equipment consists of a semi-immersive workbench with haptic device and stereoscopic glasses. In our set-up, the haptic equipment looks like a stylus shaped instrument attached to a lever system and it is freely movable in all directions (Figure 3). During the test, the position of the stylus is tracked, and resistive force is applied to the stylus when it comes into contact with the virtual object, providing force feedback. In addition to the visual perception, the haptic device creates an illusion of manipulation and sensation of the virtual objects. The participant moves the stylus in a realistic environment, experiencing the sense of moving inside the computer screen. The precise co-location of haptics is achieved by projecting the virtual image onto the same location as the user's hand through the mirror setup. The VR-test, developed by our group, is a precise quantitative kinematic measurement tool for arm and hand movements

Figure 3 Participant is performing the VR-test. The VR equipment consists of a semi-immersive workbench with haptic device and stereoscopic glasses.

and has been shown to have a good test retest reliability [31,56,57]. During the test the participant has to move the haptic stylus to 32 different targets in the virtual environment (VE) generated by the computer. The targets appear one after the other and disappear when touched. Each target consists of a whole circle (diameter 3.0 cm viewing angle). The 32 target placements in the VE are random to the subject but are actually set according to a pre-set kinematic scheme for evaluation purposes. In each test occasion the participant have one or two training trails before the measurements starts. Both dominant and non-dominant hand is measured, starting with the non-dominant hand. The participant performs the test as fast as possible.

Self-perceived outcomes

ABILHAND [58,59] is a questionnaire aiming to assess manual ability in persons with chronic stroke. It is interview based and focused on perceived difficulties in everyday activities. A Swedish version has been validated [60]. ABILHAND is a Rasch-based assessment; it is unidimensional and can be used as linear measure [58,59].

Stroke Impact Scale (SIS) [61] is a questionnaire on different aspects of the stroke recovery where the person replies on their perception regarding their life after the stroke. The 59 questions are divided into 8 domains; strength, memory, emotion, communication, activities of daily living, mobility, hand function and social participation. Items within the domain are ordered hierarchically based on clinical perspective and Rasch analysis [62]. Only the first four sections are used for the test occasion at day 10.

Impact on Participation and Autonomy (IPA-E) is a generic outcome measure for adults with chronic conditions where the person estimates perceived limitations in participation and autonomy related to dependency in the current living surrounding [63-65]. The subscales include autonomy indoors, family role, autonomy outdoors, social life and relationships, work and education. Additionally, IPA-E identifies the extent to which limitations in life are experienced as problematic in areas of mobility, self care, activities, economy issues, social life, work and education. IPA-E is valid, reliable and sensitive to change after stroke [63-65].

EuroQol Quality of Life Scale (EQ-5D) will be used to measure the health status related to the quality of life. It is a widely used generic measure and includes five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression [66,67].

Data analysis

The kinematic data in the drinking task is filtered with a 6-Hz second-order Butterworth filter, resulting in zero-phase distortion and fourth-order filtering. The drinking task is broken down into five logical phases: reaching for the glass, forward transport of the glass to the mouth, drinking, back transport of the glass to the table, and returning the hand to the initial position. The selection of kinematic variables and data analysis calculations will be based on our earlier studies [53,54]. Movement onset is defined as the time when the tangential velocity of the hand marker exceeds 2% of the maximum velocity in the reaching phase. Movement offset is detected when the velocity of the hand is less than 2% of the maximum velocity in the returning phase. Start of forward transport phase is defined as the time when the tangential velocity of the glass exceeds 15 mm/s. The drinking phase is identified by a 15% increase or decrease of the steady-state distance between the face and glass marker. The start of the returning phase is defined as the time when the tangential velocity of the glass is less than 10 mm/s. Movement times are calculated for the whole movement and separately for each phase. Peak tangential velocity and angular velocity of the elbow joint are computed for the reaching phase. Smoothness of movement is quantified by computing the number of movement units during the reaching and forward transport phases [53]. Angular joint motions are computed from the 3D position data for elbow flexion/extension, shoulder flexion/extension in the sagittal plane, and abduction/adduction in the frontal plane [53]. Compensatory trunk movement is computed for the entire drinking task as the maximal displacement of the thorax marker from the initial position [53]. Interjoint coordination between the shoulder and elbow joint angles for reaching phase is computed using cross-correlation analysis of zero time lag [53].

In the VR-test hand position data (haptic stylus endpoint) will be gathered. The position of the stylus is

tracked and resistive force is applied to it when it comes into contact with the virtual model, providing force feedback. All measurements generate time-stamped motion data (x, y, z) at 1000 Hz. Different parameters such as reaction- and movement time, velocity, acceleration and deceleration times are calculated. To obtain the movement quality of the hand trajectory, a hand path ratio, corresponding to the length of the pathway is calculated. The selection of kinematic variables and data analysis calculations will be based on our earlier study [30].

The raw scores from the ABILHAND questionnaire are analyzed using a Rasch analysis computer program and expressed as logistically transformed probability measures, logits [68]. In the Rasch model the raw scores are used to estimate the linear ability for each subject and linear difficulty for each item of measurement around a unidimensional continuum. Thus, the Rasch model converts the ordinal score of subject's manual ability into an equal interval linear measure.

Group size/power analysis

Prior longitudinal studies stroke cohorts at Sahlgrenska University Hospital have had a dropout rate of 30%. With a power (1-β) at 0.8 and a significance level (α) at 0.05, we need a sample of 88 patients (two-sided test) to determine a medium effect of 6 points change (10%) on ARAT. Therefore, we aim to include 120 persons.

Discussion

The SALGOT study is a longitudinal prospective study with a non-selected sample from Gothenburg urban area. A sample of 120 persons with first ever clinical stroke admitted to a stroke unit will be consecutively recruited from Sahlgrenska University Hospital. The study is non-interventional and the main goal is to describe the recovery of upper extremity function after first ever clinical stroke and to follow the improvements and consequences of stroke during the first year in these persons life. Measurements are performed both using traditional clinical assessments as well as computer based measurement systems that provide objective kinematic data. The person's perspective of recovery is captured both with stroke specific as well as generic self-perceived outcome measures.

In this study, the participants are assessed at eight occasions during the first year after stroke. This design gives an opportunity to study which persons will recover, when and in which areas the recovery occurs. From earlier studies it is known that the improvement of function is mostly gained during the first months after stroke. But the majority of these reports have been conducted on selected populations and in many studies the selection of outcome measures on motor function has not been sufficient. Additionally, new technologies obtaining objective kinematic measures on motor function and performance have been scarcely used in longitudinal studies.

The gained knowledge of recovery patterns is necessary both for the healthcare system and for the individual who has suffered a stroke. Since the rehabilitation resources are limited, there is a need to know the optimal time point for interventions and have guidelines for rehabilitation planning. The more detailed information about the recovery patterns of upper extremity is needed in order to offer individualized assessment and treatment, to inform the patient sufficiently about the recovery perspectives and to enhance the patient's motivation for the rehabilitation period.

Abbreviations

ARAT: Action research Arm Test; BNIS: Barrow Neurological Institute Screen for Higher Cerebral Functions; EQ-5D: EuroQol Quality of Life Scale; FMA-UE: Fugl-Meyer Assessment for Upper Extremity; IPA-E: Impact on Participation and Autonomy; M-MAS UAS-95: Modified Motor Assessment Scale accordingly Uppsala Akademiska Sjukhus 95; NIHSS: National Institutes of Health Stroke Scale; SIS: Stroke Impact Scale; TOAST: Trail of Org 10172 in Acute Treatment; VR: Virtual reality; VE: Virtual Environment.

Acknowledgements and Funding

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Authors' contributions

MAM and HCP participated in the conception and design, planning, managing the process and are responsible for day-to-day management of the study. KSS initiated the study, participated in the conception and design, managed the process and drafted the initial manuscript. All authors contributed to the study planning, drafting the manuscript and have approved the final manuscript.

Competing interests

The authors declare no competing interests.

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Early prediction of physical activity level one year after stroke, a longitudinal cohort study.

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TITLE PAGE

Early prediction of physical activity level one year after stroke, a longitudinal cohort study.

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ABSTRACT

Objective: To investigate which variables present prior and early after stroke may have an impact on the level of physical activity one-year post stroke.

Design: Prospective longitudinal cohort and logistic regression analysis.

Setting: Stroke Unit at Sahlgrenska University Hospital, Gothenburg, Sweden.

Participants: 117 individuals as part of the Stroke Arm Longitudinal study (SALGOT) admitted to the stroke unit during a period of 18 months were consecutively recruited. The inclusion criteria were: first-time stroke, impaired upper-extremity function, admitted to the stroke unit within 3 days since onset, local residency, ≥18 years old. The exclusion criteria were: upper extremity condition or severe multi-impairment prior to stroke, short life-expectancy, non-Swedish speaking. 77 participants followed-up at one year post stroke were included in the analysis.

Primary outcome: Physical activity level one year after stroke was assessed using a 6-level Saltin-Grimby scale, which was first dichotomized into mostly inactive or mostly active, and secondly into low or moderate/high level of physical activity.

Results: Being mostly inactive one year after stroke could be predicted by age at stroke onset (OR 1.07, 95% CI 1.00-1.13, p=0.041), functional dependency at discharge (OR 7.01, 95% CI 1.73-28.43, p=0.006) and pre-stroke physical activity (OR 7.46, 95% CI 1.51-36.82, p=0.014). Having a low level of physical activity one year after stroke could be predicted by age at stroke onset (OR 1.13, 95% CI 1.06-1.21, p<0.001) and functional dependency at discharge (OR 3.62, 95% CI 1.09-12.04, p=0.036).

Conclusions: Previous low level of physical activity, older age and functional dependency all provided value in predicting low physical activity one year after stroke. These results indicate that age and simple clinical evaluations early after stroke may be useful to help clinicians identify persons at risk of being insufficiently active after stroke. Further research is needed to clarify if these findings may apply to the large population of stroke-survivors.

Clinical trial registration: Clinical Trial Registration-URL: http://www.clinicaltrials.gov. Unique identifier: NCT01115348

Strengths and limitations of the study

- Clinically important parameters prior to, and early after stroke were included
- Longitudinal consecutively recruited cohort study with one year follow-up time
- Clinically relevant dichotomization of physical activity levels produced interpretable data
- Despite relatively large cohort, the number of included predictors was limited due to small number of cases for some variables
- Persons with minor stroke showing no upper-extremity impairment early after stroke were not included

INTRODUCTION

Low physical activity (PA) has shown to be an independent risk factor for stroke[1-3] and PA is a part of primary[1] as well as secondary prevention in most of the stroke guidelines[4]. The World Health Organization (WHO) has identified physical inactivity to be the fourth leading risk factor for overall global mortality[5]. The definition of PA according to WHO is ”any bodily movement produced by skeletal muscles that requires energy expenditure – including activities undertaken while working, playing, carrying out household chores, travelling, and engaging in recreational pursuits”[6]. Higher PA level pre-stroke may predict a less severe stroke[7 8], decrease the overall risk for death from first time stroke[9] and is associated with a better functional status post stroke[7 10 11].

It is a complex question to answer why some people are physically active after having a stroke and others are not. PA in healthy populations has shown to be influenced by factors such as age, gender, motivation, previous PA, self-efficacy and health status[12 13]. Being physically active post-stroke is associated with a better quality of life and has a positive correlation to functional ability[14]. The PA level among stroke-survivors has been shown to be significantly lower than in a healthy reference-population[15-19] and correlates with walking ability, balance and physical fitness[15], but cannot be explained by motor disability alone[16 20]. Barriers to PA reported by stroke survivors include lack of motivation, fear of falling, inaccessibility to training centers and physical impairments[21 22]. It is, however, not clear to what extent factors connected to the pre-stroke lifestyle and medical status may be associated with the PA level among stroke survivors. Identifying persons at risk of being inadequately active post stroke may help to target specific interventions for this group at an early stage. The purpose of this study was to investigate which possible pre-stroke and early predictor variables may impact the level of PA one year after the first time stroke.

MATERIALS AND METHODS

Population and data collection

This longitudinal study is a part of the Stroke Arm Longitudinal study at the University of Gothenburg (SALGOT)[23], with the original purpose to describe upper extremity functioning after stroke. Over a period of eighteen months, in 2009-2010, consecutively, every person who met the criteria was included to the SALGOT-study from one of the largest out of three comprehensive Stroke Units at the Sahlgrenska University Hospital, Gothenburg. The following inclusion criteria were used: 1) first-time stroke according to International Classification of Diseases codes I61 intracerebral hemorrhage or I63 ischemic stroke; 2) impaired upper-extremity function, defined as not achieving the maximal points at the Action Research Arm Test (ARAT)[24] three days post-stroke; 3) admitted to the Stroke Unit within three days since stroke onset; 4) residency in the Gothenburg urban area, within 35km from the hospital; 5) ≥18 years of age. The exclusion criteria were: 1) an upper extremity injury/condition prior to stroke; 2) severe multi-impairments or diminished physical condition prior to stroke; 3) short life-expectancy; 4) non-Swedish speaking. Three experienced physiotherapists performed all clinical assessments according to a standardized protocol[23]. In SALGOT, the patients were assessed at admission and discharge as well as at 3 and 10 days, at 3, 4, and 6 weeks; and at 3, 6 and 12 months poststroke. In the current study, data from admission, discharge, 3 days and 12 months were used. Most assessments were performed at the hospital and only at persons' home or nursing home when the participant was unable to travel. Prior power analysis for SALGOT to determine a minimum of 6 points change on ARAT (statistical power of 0.8, α 0.05) and considering a 30% dropout rate indicated that a sample size of 114 was needed. From a total cohort of 763 persons, 117 were included in the SALGOT study, and 77 still remained in the study at one year post stroke (fig.1). The main reason for not being assessed at one year was death (n=14) (fig 1). The study was approved by The Regional Ethical Review Board in Gothenburg (225-08). All participants or their next of kin gave written informed consent. The STROBE-guidelines for reporting observational data were followed[25].

Potential predictor variables

Potential predictors prior and close to the stroke onset, theorized to have impact on PA, were considered for model building[12 13 15]. Prior stroke predictor variables included in the analyses were: smoking, living alone, TIA, diabetes, atrial fibrillation, treatment for high blood pressure and PA level. Other predictors included were: age, gender, type of stroke, stroke severity, upper extremity functioning three days post stroke and functional dependency at discharge (mRS), shown in Table 1.

Table 1. Demographics, clinical characteristics and considered predictor variables.

Demographic and clinical characteristics n=77	
Age at stroke onset, years, mean (SD)	67.2 (11.9)
Men, n (%)	46 (59.7)
Hemorrhagic stroke[2], n (%)	11 (14.3)
Smoking[1, 2], n (%), n=76	18 (23.7)
Living alone[1], n (%)	31 (40.3)
TIA/Amaurosis Fugax[1, 2], n (%), n=76	4 (5.3)
Diabetes[1, 2], n (%)	10 (13)
Atrial Fibrillation[1, 2], n (%), n=76	11 (14.5)
Treatment for high blood pressure[1], n (%), n=76	26 (34.2)
NIHSS at admission, median (q1-q3)	7 (3-12.5)
ARAT at three days, median (q1-q3), n=74	7 (0-47)
mRS at discharge from Stroke Unit, n (%).	
independent walkers (grade 0-3)	37 (48.1)
unable to walk independently (grade 4-5)	40 (51.9)
Pre-stroke PA, n (%), n=73	
mostly inactive (grade 1-2)	19 (26.0)
low (grade 1-3)	43 (58.9)
Acute hospital stay, days, mean (SD)	12.6 (7.1)
Discharge to post-acute hospital stay, days, n (%)	
Ordinary home	27 (35)
In-hospital rehabilitation unit	46 (60)
Nursing home	4 (5)

[1] = prior to stroke, [2] = not included in the prediction models due to too few observations

Abbreviations: SD= Standard Deviation, y/n=yes/no, TIA=Transient Ischemic Attack, NIHSS=National Institute of Stroke Scale, ARAT=Action Research Arm Test, mRS=modified Rankin Scale, PA=Physical Activity, q1-q3=1st to 3rd quartile.

Information of history of smoking, whether the participant shared livings with another adult and medical history prior to stroke were acquired by the national Swedish Stroke Register[26] or medical charts. The stroke severity at admission to the hospital was assessed using the National Institute of Health Stroke Scale (NIHSS)[27]. The upper extremity functioning was assessed using the ARAT, which includes 19 items scored on a 4-grade ordinal scale, with a total score varying from 0-57 points, where a higher score indicates less limitation[24]. The functional dependency at discharge from the stroke u(mean time 13 days, SD=7,4 range 1-42) was assessed using the modified Rankin Scale (mRS)[28]. The mRS is an ordinal scale ranging from 0 to 6 where lower numbers indicates less dependency[28]. The mRS was dichotomized between the grade 3 and 4 creating one group that contained persons able to walk without assistance (no/slight/moderate disability, grades 1-3) and one group who could not (moderately severe to severe disability, grades 4-5). The self-reported PA level was recorded using a 6-level scale for classification of physical activity level (including leisure-time, occupational and household activities) (appendix A), originally developed from the 4 graded Saltin-Grimby scale[29 30]. The participants' PA level was scored through an interview within three days and at one year post stroke considering the PA level during the previous six months. In the statistical analyses, the PA was dichotomized in two different ways. First, to mostly inactive (grade 1-2) or mostly active (grade 3-5) and; secondly, to low (grade 1-3) or moderate/high activity level (4-5). The first dichotomization was selected to match the original 4-level scale based upon prevention of cardiovascular disease[31]. The second dichotomization was selected to match the level of physical activity (of 30 minutes of activity, 5 days per week) recommended by the WHO in order to prevent morbidity[6]. Within each prediction model, the same dichotomization of PA level was used for outcome and for predictor variable.

Statistics

Differences between groups were investigated with Fishers exact test, Mann-Whitney U test or t-test depending on data level. Demographic data was presented with medians and percentiles or means and standard deviation (SD). The statistically significant level was set to $p<0.05$ unless stated otherwise. A multivariate logistic regression was used to investigate which predictor variables may impact on the PA level one year after stroke. Two separate models were built, one for each dichotomization of the outcome variable. As first step in selection of potential predictor variables for the regression models, the cross tabulation was used to identify and exclude predictor variables with less than 5 observations in any subgroup. Collinearity between predictor variables was checked for using Spearman's rank correlation test for ordinal variables or Likelihood Ratio test for binary variables. Variables with correlation above 0.7 were considered for collinearity. Second step was a series of univariate logistic regression analysis was performed on all variables not excluded by the crosstabulation in order to identify significant variables for further analyzes (significance level $p<0.25$, tested with Wald's test). Third, the variables that were significant in the univariate step was put in multivariate models, built on the enter method in which all predictor variables not reaching the significance level of 0.05 were ruled out. Individuals with missing data on any of the variables included in the final multivariate models were excluded for analysis (Table 1). Fourth, all of the previously ruled out variables were then re-inserted in the final model one by one to check for possible significant effect in the model ($p<0.05$, Likelihood Ratio test). Finally, the models were analyzed with the Likelihood Ratio test, percent of correct classification, Nagelkerke R^2 and the Hosmer and Lemeshow goodness of fit test. Results are presented as Odds-Ratio (OR) with 95% confidence interval (CI). Data was analyzed using the Statistical Package for Social Sciences (SPSS) software (IBM SPSS Statistics for Mac, Version 23.0. Armonk, NY: IBM Corp.)

RESULTS

Clinical characteristics

The group of non-participants not assessed at one year from the SALGOT cohort (n=40) was older (mean difference 6.23 years, p=0.01), had a higher incidence of atrial fibrillation (p=0.04) and were less active prior to their stroke (p=0.03). No other statistical significant differences were found between the groups. Demographic and clinical characteristics are presented in table 1. Prior to stroke, 74% (n=54) of the participants were considered to be mostly active, in contrast to 61% (n= 47) at one year post stroke. Similarly, 41% (n=30) of the participants had a moderate to high activity level prior to stroke in contrast to 34% (n=26) one year later.

Selection of predictor variables

The type of stroke along with smoking, TIA, diabetes and atrial fibrillation prior to stroke contained too few individuals in subgroups and were therefore not included into further analysis. Strong significant collinearity was found between the predictor variables: mRS and ARAT (-0.74). These two variables were therefore entered into separate models and their impact to respective model compared. Thus, seven possible predictor variables were considered to be entered in the multivariate models in this second step. Likelihood Ratio Test showed a significant correlation between gender and pre-stroke PA (LRT=5.910, p=0.02 and between treatment for high blood pressure prior to stroke and pre-stroke PA (LRT= 10.358, p=0.01). The results from the univariate analysis are presented in an online supplementary table (appendix B). None of the variables that were re-inserted in the final step for the multivariate analysis were significant (p>0.05).

Predicting being mostly inactive

The final model for predicting being mostly inactive post stroke included three significant predictor variables: age, functional dependency (mRS) and pre-stroke PA (table 2a).

Table 2. Logistic Regression models for predicting physical activity level one year post stroke; a) dependent variable of mostly inactive (n=73); b) dependent variable of low level of physical activity (n=77).

2a						
Coefficient	**B**	**S.E**	**Wald's**	**df**	**P**	**OR (95% CI)**
Constant	-6.52	2.15	9.17	1	0.002	0.001
Age	0.06	0.03	4.18	1	0.041	1.07 (1.00-1.13)
mRS at discharge	1.95	0.71	7.43	1	0.006	7.01 (1.73-28.43)
Pre-stroke PA (mostly inactive)	2.01	0.81	6.10	1	0.014	7.46 (1.51-36.82)
Test			**chi^2**	**df**	**P**	
Likelihood Ratio Test			32.59	3	<0.001	
Hosmer and Lemeshow			9.66	8	0.290	
2b						
Constant	-8.12	2.25	13.03	1	<0.001	<0.001
Age	0.13	0.03	13.52	1	<0.001	1.13 (1.06-1.21)
mRS at discharge	1.29	0.61	4.41	1	0.036	3.62 (1.09-12.04)
Test			**chi^2**	**df**	**P**	
Likelihood Ratio Test			30.47	2	<0.001	

Hosmer and Lemeshow	3.28	7	0.858

Dependent variable coded as a) mostly active=0, mostly inactive=1; b) moderate/high PA=0, low PA=1; Cox & Snell R^2 *a) = 0.360; b)= 0.327 Nagelkerke* R^2 *a) = 0.489; b)= 0.453 Abbreviations: OR=Odds Ratio, S.E=Standard Error, df=Degrees of freedom PA=Physical Activity, mRS=modified Rankin Scale*

The percentage of total correctly classified for the model was 78.1 with sensitivity 75.0% and specificity of 79.5%. The odds for being mostly inactive one year after stroke, increased by 7% for every year of increasing age. The odds for being inactive also increased by 6 times if the participant was not able to walk independently at discharge and by 6.5 times if the participant was already mostly inactive pre-stroke. Predicted probabilities for this model are presented in Figure 2. As seen in Figure 2, there were no observations on mostly inactive non-walkers below age 70, which means that the predicted probabilities are extrapolated below this age. A separate model including the three significant predictor variables, age, ARAT (instead of mRS) and pre-stroke PA demonstrated comparable level of correct classification (78.6%).

Predicting low physical activity

The final model for predicting low PA level included two significant predictor variables: age and functional dependency (mRS) at discharge from Stroke Unit (table 2b).

The percentage of total correctly classified for the model was 74.0 with sensitivity 77.2% and specificity of 65.0%. The odds of having a low PA level one year after stroke increased with 13% for every year of increasing age. The odds of having a low PA level also increased, by 2.6 times if the participant was not able to walk independently at discharge. Predicted probabilities for this model are presented in Figure 3. A separate model including the two significant predictor variables, age and ARAT (instead of mRS) demonstrated comparable level of correct classification (75.7%).

DISCUSSION

Higher age, functional dependency at discharge from stroke unit and being physically inactive prior to stroke all contributed to increase the probability of being physically inactive one year after stroke. The probability of having a low PA level after stroke increased with older age and functional dependency at discharge from stroke unit. Findings from this study provide new insights on what factors obtained early after stroke may impact on the PA level at later stages among stroke survivors. This knowledge could be used to identify patients at risk for inactivity or low PA level early after stroke, so that targeted intervention could be offered as part of secondary prevention.

When comparing levels of physical activity two different dichotomizations of data (two models), based on different recommendations on physical activity was used[6 29]. The first model aimed to address inactivity as important cut-off for prevention of cardiovascular disease[31] and the second to address PA at lower than the recommended level required for prevention of morbidity[6]. Age was found to be a significant predictor in both models, but it had a greater impact on the model for identifying those with low PA level. This finding is in concurrence with an earlier study in older adults, where the age was inversely correlated with the amount of moderate-intensity PA, but not with the amount of low-intensity PA[32]. Functional dependency including ability to walk independently or not, was also found as a significant predictor for physical activity after stroke in both models, which is in concurrence with previous studies[15 21]. These findings suggest that, similarly to older adults, age may have an impact on the intensity of PA after stroke, but also that the disability level expressed as dependence in walking and daily activities influence the PA level at later stages post stroke. The upper extremity functioning (ARAT) early after stroke was found to have similar effect on the later post stroke PA, as the functional dependency (mRS) at discharge. Functional dependency at discharge and limitation in the upper extremity use early after stroke may both be associated with to the stroke severity, but these factors may also mean that the limited function itself after stroke may impact the PA level negatively[15-19]. Being mostly inactive pre-stroke had a significant effect when predicting inactivity at later stage post-stroke. However, the level of PA pre-stroke, low or moderate/high, did not have a significant effect in the model predicting post stroke PA level, which indicates that the level of PA post stroke may to larger degree be affected by other factors, such as the disability level, age and co-morbidities.

There has been little interest in investigating which early predictors might influence PA among stroke-survivors and most studies on PA look at cross-sectional correlations. A previous longitudinal study[33] investigating physical inactivity after stroke, found significant correlation between time spent upright and degree of independence in activities of daily living and walking at the first weeks after stroke, as well as at 1, 2 and 3 years post stroke. Although these findings reflect merely cross-sectional correlations, they indicate that independence in daily activities and ambulation are important for PA among stroke-survivors. In a review comprising people after stroke with ability to walk,[15] walking ability, balance and physical fitness were positively associated with PA level. Walking ability in the form of walking speed has further been found to explain some of the variation of PA level among stroke-survivors[16]. Studies on what stroke-survivors experience as barriers to PA have identified physical impairment as one of the main barriers to PA[21 22], yet motor impairment have been found to correlate mainly with walking capacity and energy cost for walking and not with PA level[17]. In another study physical capacity, measured by a test for fitness, was found to have a moderate correlation to self-assessed PA[34]. In our study the mRS-scale addressing disability rather than impairment was used[28] and although functional disability and motor impairment are correlated, impairment does not fully explain disability among people with stroke[20]. Previous studies have not shown significant correlation between age and PA after stroke[15 33]. Age has, however, been found to be inversely correlated to PA in healthy populations[12 35], although not as a clear determinant compared to health status or previous PA habits[12]. The decline in PA with increasing age does not seem to be linear but exponential in older adults[35] and functional outcome has been found to drop steeply in the older ages among people that has had with stroke[36], yet most work on PA among stroke-survivors have been made in persons aged 65 to 75 years[15]. The present study had no upper limit of age, yet the participants in the study were somewhat younger than the average stroke-population in Sweden[26], therefore, the effect of age on PA level in stroke-survivors might be slightly underestimated. Pre-stroke PA has been found to have a significant impact on functional outcome at acute phase[11], 3 months[10 19], one year[11] and two years after stroke[7]. A longitudinal study[11] showed that the main differences for functional outcome were found when comparing a subgroup with relatively low PA level, measured as people who walked less than 30 minutes per day with groups walking for more than 30 minutes a day. The group with low amount of walking time was more dependent as measured by the mRS-scale and the Barthel Index and had a slower walking speed. These differences were not seen when comparing one group that walked for 30-60 minutes per day with another group who walked for more than 60 minutes per day[11]. These results are in line with the findings in our study showing that being mostly active, as analyzed in the first model, was important for staying active, whilst a higher PA level made no further contribution in predicting a higher PA level post stroke. Pre-stroke habits of PA may also possibly mean having some knowledge about PA and its beneficial health effects, while lack of knowledge and disbeliefs related to PA have been reported as barriers to PA by stroke-survivors[21 22] and could be a part of the explanation of our finding that pre-stroke PA level is important for being active after stroke.

The strength of this study was that many clinically important parameters that can be obtained early post stroke were considered as potential predictors for long-term outcome of PA level. It is of clinical importance to identify persons at risk of becoming inactive at an early stage, since PA after stroke may help in preventing secondary complications[4]. Furthermore the dichotomizations for PA level used in the study are clinically relevant and concurrent with recommendations for prevention of morbidity. There are, however, several limitations to this study, including a low number of cases in some subgroups that did not allow inclusion of all potential predictor variables into the regression models. The main outcome variable for PA was an interview based questionnaire[29 30]. This type of scale presents with some problems including being at an ordinal level of data and the risk for recall bias[37]. There is only a limited number of studies investigating validity of the 6-graded scale used in this study[38]. The dichotomization used in the first model between grade 2 and 3 may, however, be directly translated into the original 4-grade Saltin-Grimby scale[29 30], which has been widely used and shown to have a good concurrent validity[38]. Self-assessed PA has also been shown to have good predictor value for cardiovascular risk profiles[39] as well as for functional outcome after stroke[19]. The alternative option for reporting PA is direct measurement, e.g. through using accelerometers[37]. This option would not have been possible for establishing PA level prior to stroke, but could have been for outcome.

There are several other variables, such as mood, balance scales[40], fear of falling[20] lack of motivation and environmental factors[21] that may influence PA after stroke that were not taken into account in the current study. Furthermore, our study based on the SALGOT cohort included only persons with an impaired upper extremity function three days post stroke, and the results apply only to those who were followed-up at one year.. Persons without impaired upper extremity might experience other obstacles for being physically active than people with upper limb impairment. Thus the results from the current study can only be applied to persons showing at least some impairment of the upper extremity early after stroke and other studies are needed to see if the findings in our study may also apply to persons without upper extremity impairment early after stroke.

The present study aimed to identify persons that have a higher risk in becoming inactive after their stroke. The problem of inactivity amongst people with stroke is well established and recent recommendations have highlighted the challenges in increasing the physical activity amongst this group[4]. By identifying which individuals that have an increased risk of becoming inactive after their stroke, allows clinicians to identify these persons earlier and so that targeted intervention could be offered as part of secondary prevention[4].

CONCLUSION

Physical inactivity among stroke survivors is a major clinical problem. The present study indicates that persons with a higher age, higher degree of functional dependency early after stroke and a history of inactivity prior to stroke may have an increased risk of being insufficiently active at one year post stroke. These results may help to guide clinicians in identifying individuals in need of targeted interventions for reaching an adequate amount of PA, however, these findings need to be validated by other studies to show if the results may be applicable for other groups of stroke-survivors. The list of predictor variables identified in this study contribute, but cannot explain all of the variation of PA level among stroke-survivors and other predictors need to be further explored.

Online supplements:

Appendix A: Scale for physical activity

Appendix B: Supplementary table of univariate logistic regression

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Contributors: OAO, HCP, MAM, KSS contributed to the design of the study concept, in analysis and interpretation of results and in drafting/revising the manuscript for content. All authors have read and approved the final manuscript. In addition to this HCP and MAM performed the acquisition of data, HCP, MAM and KSS obtained funding, OAO performed the statistical analysis and KSS supervised the SALGOT-study.

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Competing interest: The authors declare that they have no competing interests.

Data Sharing: Interested researchers may submit requests for data to the authors (contact ks.sunnerhagen@neuro.gu.se). According to the Swedish regulation (http://www.epn.se/en/start/regulations/) the permission to use data is only for what has been applied for and then approved by the Ethical board.

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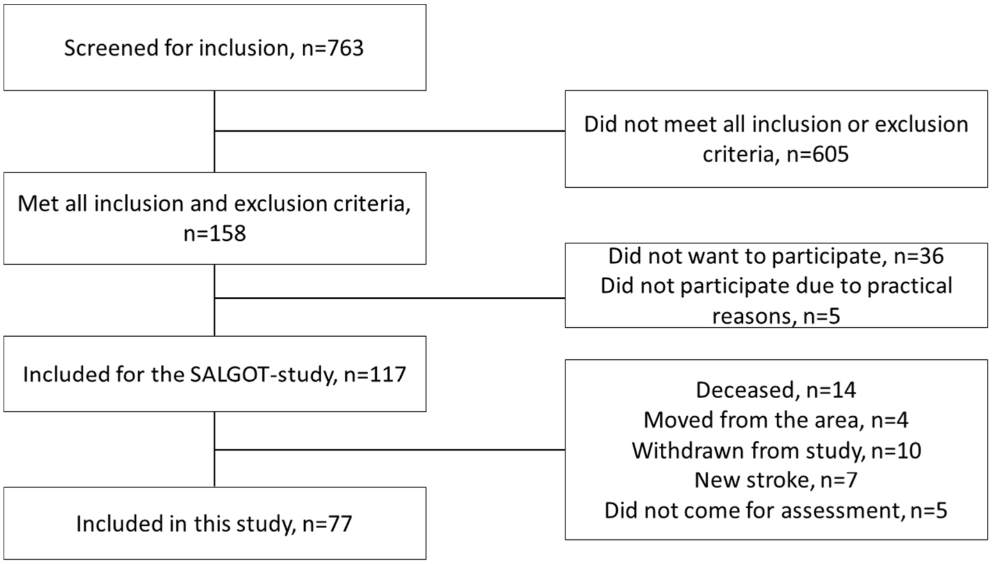
Figure legends

Fig 1. Flowchart for inclusion of the study participants

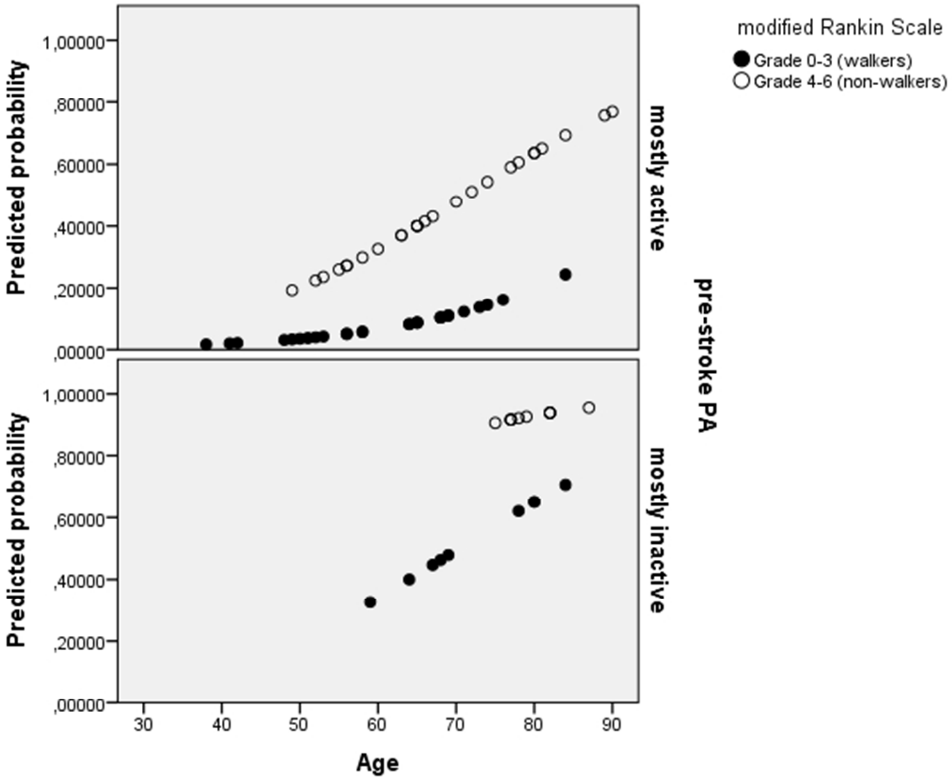
Fig 2. Predicted probabilities of being mostly inactive one year after stroke. The predicted probability increases with higher age, higher degree of functional dependency and being physically inactive pre-stroke.

Fig.3 Predicted probability for having low PA one year after stroke. The predicted probability increases with higher age and higher degree of functional dependency.



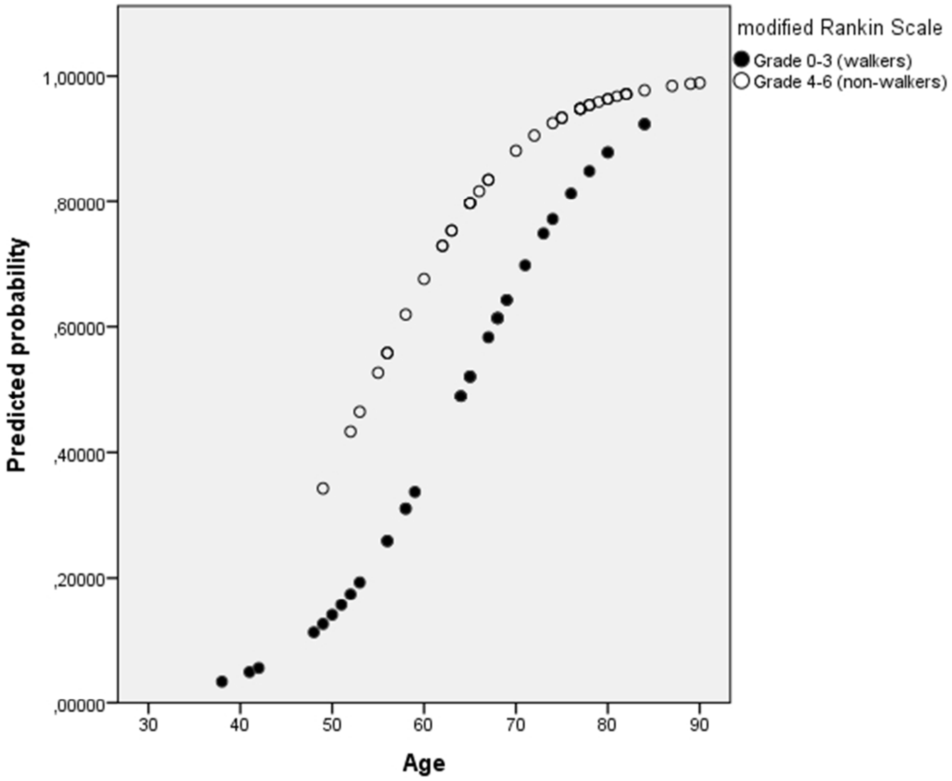
Flowchart for inclusion of the study participants

108x60mm (300 x 300 DPI)



Predicted probabilities of being mostly inactive one year after stroke. The predicted probability increases with higher age, higher degree of functional dependency and being physically inactive pre-stroke.

53x42mm (300 x 300 DPI)



Predicted probability for having low PA one year after stroke. The predicted probability increases with higher age and higher degree of functional dependency.

53x42mm (300 x 300 DPI)

Appendix A

6-level scale for physical activity

1. Hardly no physical activity
2. Mostly sitting, sometimes a walk, easy gardening or similar tasks, sometimes light household activities such as heating up food, dusting, or “clearing away”
3. Light physical exercise for about 2-4 hours a week, e.g. walks, fishing, dancing, ordinary gardening etc., including walks to and from shops. Main responsibility for light domestic work such as cooking, dusting, “clearing away”, and making beds. Performs or takes part in weekly cleaning
4. Moderate exercise 1-2 hours a week, e.g. jogging, swimming, gymnastics, heavier gardening, home repair or easier physical activities more than 4 hours a week. Responsible for all domestic activities, easy as well as heavy. Weekly cleaning with vacuum cleaning, washing floors and window-cleaning
5. Moderate exercise at least 3 hours a week, e.g. tennis, swimming, jogging etc.
6. Hard or very hard exercise regularly and several times a week, during which physical exertion is great, e.g. jogging, skiing

Appendix B

Supplementary table. Univariate logistic regression analysis between predictors and outcome variable of physical activity level one year after stroke

	Mostly inactive (grade 1-2)		Low PA (grade 1-3)	
Predictor variables	**Wald**	**p-value**	**Wald**	**p-value**
Age	14.018	<0.001	16.483	<0.001
Gender	0.001	0.970	0.518	0.472
Ischemic/hemorrhagic	1.274	0.259	1)	1)
Smoking	1)	1)	1.083	0.298
Shared living	1.918	0.166	4.597	0.032
Treatment for high blood pressure	1.487	0.223	1)	1)
NIHSS	3.946	0.061	1.588	0.208
ARAT	9.545	0.002	10.023	0.002
mRS	11.902	0.001	9.512	0.002
Pre-stroke PA	11.755	0.001	6.669	0.010

1)= not applicable due to too small subgroups for analysis.

P-Value for significance set for 0.25

Abbreviations: NIHSS=National Institute of Health Stroke Scale, mRS=modified Rankin Scale, ARAT=Action Research Arm Test, PA=Physical Activity.

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http://www.biomedcentral.com/1471-2377/11/56

BMC Neurology

STUDY PROTOCOL Open Access

SALGOT - Stroke Arm Longitudinal study at the University of Gothenburg, prospective cohort study protocol

Margit Alt Murphy*, Hanna C Persson, Anna Danielsson, Jurgen Broeren, Åsa Lundgren-Nilsson and Katharina S Sunnerhagen

Abstract

Background: Recovery patterns of upper extremity motor function have been described in several longitudinal studies, but most of these studies have had selected samples, short follow up times or insufficient outcomes on motor function. The general understanding is that improvements in upper extremity occur mainly during the first month after the stroke incident and little if any, significant recovery can be gained after 3-6 months. The purpose of this study is to describe the recovery of upper extremity function longitudinally in a non-selected sample initially admitted to a stroke unit with first ever stroke, living in Gothenburg urban area.

Methods/Design: A sample of 120 participants with a first-ever stroke and impaired upper extremity function will be consecutively included from an acute stroke unit and followed longitudinally for one year. Assessments are performed at eight occasions: at day 3 and 10, week 3, 4 and 6, month 3, 6 and 12 after onset of stroke. The primary clinical outcome measures are Action Research Arm Test and Fugl-Meyer Assessment for Upper Extremity. As additional measures, two new computer based objective methods with kinematic analysis of arm movements are used. The ABILHAND questionnaire of manual ability, Stroke Impact Scale, grip strength, spasticity, pain, passive range of motion and cognitive function will be assessed as well. At one year follow up, two patient reported outcomes, Impact on Participation and Autonomy and EuroQol Quality of Life Scale, will be added to cover the status of participation and aspects of health related quality of life.

Discussion: This study comprises a non-selected population with first ever stroke and impaired arm function. Measurements are performed both using traditional clinical assessments as well as computer based measurement systems providing objective kinematic data. The ICF classification of functioning, disability and health is used as framework for the selection of assessment measures. The study design with several repeated measurements on motor function will give us more confident information about the recovery patterns after stroke. This knowledge is essential both for optimizing rehabilitation planning as well as providing important information to the patient about the recovery perspectives.

Trial registration: ClinicalTrials.gov: NCT01115348

Keywords: stroke, upper extremity, recovery of function, kinematics, longitudinal study

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Background

Stroke is defined by the World Health Organization (WHO) as rapidly developing clinical signs of focal or global disturbance of cerebral function, with symptoms lasting more than 24 hours or leading to death and with no apparent non-vascular cause. The incidence of stroke in Sweden is 300 cases per 100 000 inhabitants in a year of whom 200 suffer a first incidence of stroke leading to a total of 18 000 new stroke victims. About 25000 - 30000 persons yearly suffer from acute stroke each year in Sweden. Of these, about 20% will die within the first month and about 1/3 of the survivors will remain significantly disabled after 6-12 months [1].

The upper extremity function is impaired after stroke in approximately 70-80% of patients in acute phase and in 40% in chronic phase [2-4]. This impairment limits the voluntary, well coordinated, and effective movements as well as a person's level of activity [5] and participation in their social and physical environment [2]. This longstanding disability might also influence the quality of life [6].

Recovery of motor skills after stroke depends both on spontaneous reparative process as well as reorganization of neural mechanisms, influenced by inputs and demands given to the motor control system. The current perspective on motor learning focuses on active task-oriented training and how feedback and other basic training principals such as regularity, intensity and specificity affects the long-term recovery [7,8]. In order to detect meaningful improvements in motor function, appropriate outcome measures should be used. Beside the requirements on reliability, validity and sensitivity, the issues of functionality and objectivity must be considered while selecting the appropriate measures. Assessment methods with continuous variables are recommended to be included into evaluation batteries since they might have higher power to detect the important improvements in motor recovery [9-11].

Improved understanding of the recovery patterns after stroke is essential for planning and execution of optimal rehabilitation. Recovery patterns of upper extremity function have been described for selected stroke populations in several longitudinal studies. The general idea is that improvements in the upper extremity occur mainly during the first month after onset of the stroke and that little, if any, significant recovery can be gained after 3-6 months [3,12-14]. Several studies, conducted in selected populations at rehabilitation facilities have shown that, in some patients, the improvements also continued for a longer time [2,4,15]. There are only a few studies with non-selected community based populations describing the recovery patterns in the upper extremity. These studies report a similar recovery pattern with little or no significant recovery beyond 2-3 months [3,16-18]. Whether this is correct is not clear for the non-selected studies, since in some reports the sample sizes were small [14,15], the follow up times were short [3,4] or the information on the motor assessments was not satisfactory [3,18].

Kinematic measurement - drinking task

Kinematics describes movements of the body through space and time, including linear and angular displacements, velocities and accelerations, but without reference to the forces involved. Kinematic data can be achieved by optoelectronic systems where multiple high-speed cameras send out infra red light signals and detect the reflection from the markers placed on the body. Kinematic variables provide objective, precise and detailed measures of movement performance and quality.

Kinematic movement analysis has become a useful assessment tool within rehabilitation and is employed routinely for gait analyses. Few studies have used kinematic movement analysis to examine the upper extremity in a longitudinal design. In one of these studies the kinematic data was obtained from an isolated fast elbow extension [15,19] and in the other a targeting fast reaching movement [20]. In order to better understand the situation of a person with impaired upper extremity function, information is needed regarding activities of daily living. It is known that the motor activity of the upper extremity is dependent on the meaning of the task and on the shape and placement of the object [21]. Thus, it is meaningful to study natural purposeful movements with real-life objects. In an earlier study we have developed a test protocol and a program for data analyses of the kinematic variables for the activity of drinking from a glass, which has been applied in a control setting [22] and in stroke subjects [23].

Kinematic measurement - Virtual reality test

Virtual reality (VR) can be described as the world perceived in a computer. VR systems that include a haptic device can provide tactile feedback to the user through the force feedback. If the system detects a collision between the device and virtual objects, it transmits a reaction to the user's hand, which interacts with perception of the test or training situation [24]. In the real world, objects are usually perceived in the same location whether the sense involved is vision or touch (haptic). In the virtual world, the precise co-location of haptics is technically harder to achieve, but when the co-location is accurate the realism of the manipulation is very high and the user's performance is improved [25]. The knowledge about effects of using VR in assessments and training after stroke is still limited, but sufficiently encouraging to justify additional clinical trials in this population [26-31].

Theoretical background

WHO approved in May 2001 the model on International Classification of Functioning, Disability and Health (ICF) [32] to assess the consequences of a disorder or a disease on the individual person. The ICF model provides a multi-perspective approach to the classification of functioning and disability as an interactive and evolutionary process. In the model an individual's functions in a specific domain is an interaction or complex relationship between the health conditions (physical or mental) and contextual factors (social and physical environment as well as personal factors). The components of ICF can be used to indicate problems (e.g. impairments, activity limitations or participation restrictions summarized under the umbrella term disability) in different areas. This approach forces health professionals to look wider than the usual perspective, which has traditionally lain in the domain of body function and structures. The model boosts the traditional rehabilitation ideology where the focus has not been on the organ but on the person and thereby requiring different treatments depending on that person's goal. In order to assess the consequences of a disease we need to look at different components of the ICF.

Longitudinal studies are difficult to perform. Sweden has a unique situation since people are quite easy to trace through the civic system and moving from one region to another is not so frequent. In addition, the representativeness for the disease is good since all patients within a catchment area are usually referred to the same hospital as private alternatives are scarce and thereby the possibilities to generalize the results are good.

The purpose of this study is to describe the recovery of upper extremity function longitudinally in a non-selected sample with first ever clinical stroke admitted to a stroke unit.

The specific objectives of the present study are to:

A. Follow recovery of upper extremity by using clinical measures of body function (motor function, spasticity), activity (use of the arm and hand) and participation (impact of limitations) after stroke
B. Follow functional recovery by using objective, new IT technology (kinematic movement analysis and VR-test with sensory feedback) after stroke
C. To gather the assessments of participants self-perceived upper extremity function over the first year after stroke
D. To predict function at 12 months by analysis of data gathered at first week after onset of stroke

Methods/Design

A sample of 120 persons with a first occurrence of stroke will be included and followed longitudinally for one year after the stroke. The group will consist of consecutively included persons recruited from the stroke unit at Sahlgrenska University Hospital, Gothenburg, Sweden. The Stroke unit at Sahlgrenska University Hospital serves the larger Gothenburg urban area, thus all persons from this catchment area are randomly referred to the Sahlgrenska University Hospital. The project is approved by the Regional Ethical Review Board and the Helsinki declaration is followed. Written informed consent will be obtained from the participants or from their closest relative. The SALGOT study is registered on ClinicalTrials.gov (NCT01115348).

Inclusion criteria are:

- Diagnosed first ever clinical stroke, based on WHO criteria (ischemic infarct, haemorrhagic and subarachnoidal bleeding)
- Impaired upper extremity function. This is defined in two steps. On the first or second day after stroke onset the upper extremity function is assessed with Modified Motor Assessment Scale (M-MAS UAS-95) [33] (this is performed as standard clinical assessment by physiotherapists working at the stroke unit). All persons, who do not obtain the maximum score on the subtests of arm function, hand movements and fine motor function due to hemiparesis, will be informed about the study and retested at day three after stroke with Action Research Arm Test (ARAT) [34]. All persons who do not achieve the maximum score for ARAT (score 57) will be included.
- Admitted to the stroke unit within three days after stroke onset
- Living in the Gothenburg urban area (maximal 35 km from the Sahlgrenska University Hospital)
- Age 18 or older

Exclusion criteria are:

- Upper-extremity injury or condition prior to the stroke that limits the functional use of the affected arm and hand
- Severe multi-impairment or diminished physical condition before the stroke that will affect the arm function
- Life expectancy less than 12 months due to other illness (cardiac disease, malignancy) or severity of stroke injury
- Not Swedish speaking prior to the stroke incident

Design and procedure

This study will evaluate the recovery patterns after first ever stroke without any intervention except standard rehabilitation planning and procedures. All included

participants will be assessed eight times during the first year after stroke. Assessments are performed at day 3 and 10, week 3, 4 and 6, month 3, 6 and 12 after onset of stroke. Tests are administrated in block randomized manner in order to minimize the systematic testing bias. The test order and the reason for missed or unsuccessful test results will be recorded in a protocol. All tests are performed by three experienced physical therapists, undergoing a training period together for the assessment battery prior to the study start. ICF classification of functioning, disability and health is used as framework for the selection of assessment measures (Figure 1).

Outcome measures

Demographic data will be collected during the first assessment. Stroke subtype will be confirmed by CT and/or MRI scans. Ischemic strokes will be classified for subtype and site for lesion by using TOAST [35] and Bamford classifications [36]. Treatments of thrombolysis or thromboectomy will be registered. Additional data will be extracted from the national quality register for stroke - Swedish Stroke Register [1]. The Self-Administrated Comorbidity Questionnaire (SCQ) will be used to collect additional information on relevant medical conditions and problems [37]. Cognitive function is evaluated at every test occasion using Barrow Neurological Institute Screen for Higher Cerebral Functions (BNIS) [38]. The three prescreen items scoring the level of consciousness/alertness, cooperation and basic communication skills and the item of auditory comprehension will be assessed. The level of physical activity is recorded by a 6-grade scale of Physical Activity Classification [39,40]. This instrument is valid, short and suitable for longitudinal studies and takes account the activity level both during domestic and fitness activities [40]. Exact time points for all assessments are listed in Table 1.

Clinical outcome measures of function and activity

The upper extremity motor function will be assessed using the Fugl-Meyer Assessment for Upper Extremity (FMA-UE) [41], and a maximum score of 66 corresponds to normal motor function. The psychometric properties of Fugl-Meyer Assessment have shown excellent reliability and validity [41-43]. The non-motor domains of FMA-UE, sensation, passive range of motion and pain during passive joint motions will be completed as well.

Action research Arm Test (ARAT) is a performance test for upper extremity function and dexterity [44]. The ARAT uses ordinal scoring on 19 items divided into four hierarchical subtests: grasp, grip, pinch and gross movement. Each upper extremity is evaluated individually and the test can be completed in 5-15 minutes [44,45]. ARAT has been shown to have good validity, sensitivity to spontaneous and therapy-related gains after stroke both in acute and chronic phase [44,46]. The ARAT has shown good responsiveness [47] and excellent inter-rater and intra-rater reliability [44,48].

Spasticity will be assessed with the Modified Ashworth Scale (MAS). The muscle groups of elbow flexors and

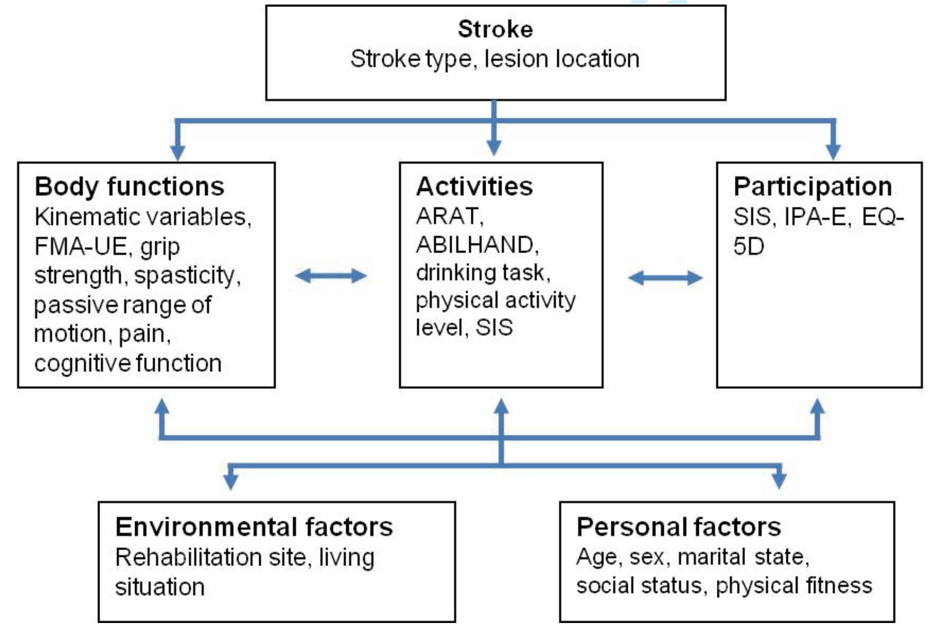

Figure 1 Outcome measures used in SALGOT study according to ICF classification.

Table 1 Scheme over the assessments and time-points for test occasions

Assessments	Test occasion (d=day, w=week, m=month)								
	d1	d3	d10	w3	w4	w6	m3	m6	m12
M-MAS UAS -95	x								
NIHSS	x								
BNIS		x	x	x	x	x	x	x	x
Physical activity scale		x						x	x
FMA-UE		x	x	x	x	x	x	x	x
Action Research Arm Test		x	x	x	x	x	x	x	x
ABILHAND		x	x	x	x	x	x	x	x
Grip strength		x	x	x	x	x	x	x	x
Modified Ashworth Scale	x	x	x	x	x	x	x	x	x
Kinematic - drinking task		x	x		x		x	x	x
Kinematic - VR-test		x	x	x	x	x	x	x	x
Stroke Impact Scale			x		x		x	x	x
IPA-E									x
EQ-5D									x

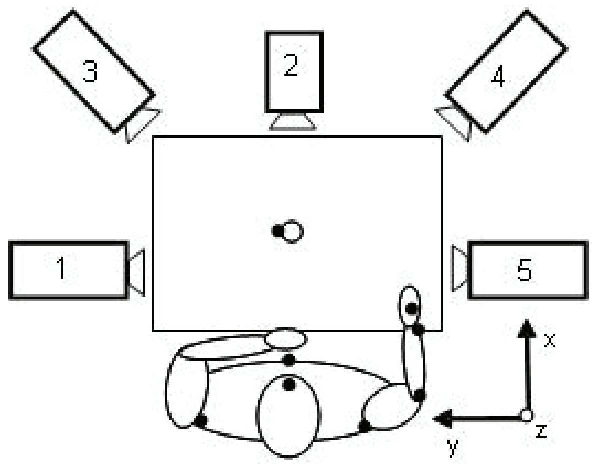

Figure 2 Setup of kinematic 5-camera motion capture system for the drinking task. Participant is presented with the right arm in initial position, and marker sites are shown as black dots.

extensors, wrist flexors and extensors will be evaluated. The MAS is the best alternative for spasticity assessment in clinical setting available and has been shown to have fair reliability for these joints [49,50].

The grip strength will be measured using the Jamar Hand Dynamometer. Standardized positioning and instructions are followed and the average of three trials is used as test outcome [51]. Reliability for the grip strength measure is very high [52].

Kinematic measurements - objective outcomes of performance

Three-dimensional motion analysis of upper extremity during drinking task will be performed with a 5-camera optoelectronic ProReflex Motion Capture System (MCU240 Hz, Qualisys AB, Sweden). The tracing of the three-dimensional coordinate positions of the markers is completed automatically by Qualisys Track Manager, 2.0. The capture data is then transferred to MATLAB (The MathWorks Inc) software for custom-made analysis. A standardized drinking task with stable test-retest reliability will be used [53]. The participant is sitting in front of the table with tested hand resting on the edge of the table (Figure 2). A drinking glass, filled with 100 mL water is placed 30 cm from the table edge in the midline of the body. The drinking task includes reaching, grasping, and lifting the glass from the table and taking a drink (one sip); placing the glass back on the table behind a marked line; and returning to the initial position. Participants are instructed to sit against the chair back during the whole task, but the sitting position is not restrained, and compensatory movements are allowed. All participants perform the drinking task at a comfortable self-paced speed, starting with their non-affected arm, after practicing a few times. The mean of the three middle trials of total five will be used for statistical calculations. A total of 9 spherical 12-mm retro-reflective markers are placed on the third metacarpophalangeal joint of hand, styloid process of ulna on wrist, lateral epicondyle of elbow, middle part of acromion on right and left shoulder, upper part of sternum, forehead and on the upper and lower edge of the glass. The procedure has been described in more detail previously [53,54].

In the VR test [55], the participant reaches into a virtual space and interacts with 3D objects. The VR equipment consists of a semi-immersive workbench with haptic device and stereoscopic glasses. In our set-up, the haptic equipment looks like a stylus shaped instrument attached to a lever system and it is freely movable in all directions (Figure 3). During the test, the position of the stylus is tracked, and resistive force is applied to the stylus when it comes into contact with the virtual object, providing force feedback. In addition to the visual perception, the haptic device creates an illusion of manipulation and sensation of the virtual objects. The participant moves the stylus in a realistic environment, experiencing the sense of moving inside the computer screen. The precise co-location of haptics is achieved by projecting the virtual image onto the same location as the user's hand through the mirror setup. The VR-test, developed by our group, is a precise quantitative kinematic measurement tool for arm and hand movements

Figure 3 Participant is performing the VR-test. The VR equipment consists of a semi-immersive workbench with haptic device and stereoscopic glasses.

and has been shown to have a good test retest reliability [31,56,57]. During the test the participant has to move the haptic stylus to 32 different targets in the virtual environment (VE) generated by the computer. The targets appear one after the other and disappear when touched. Each target consists of a whole circle (diameter 3.0 cm viewing angle). The 32 target placements in the VE are random to the subject but are actually set according to a pre-set kinematic scheme for evaluation purposes. In each test occasion the participant have one or two training trails before the measurements starts. Both dominant and non-dominant hand is measured, starting with the non-dominant hand. The participant performs the test as fast as possible.

Self-perceived outcomes

ABILHAND [58,59] is a questionnaire aiming to assess manual ability in persons with chronic stroke. It is interview based and focused on perceived difficulties in everyday activities. A Swedish version has been validated [60]. ABILHAND is a Rasch-based assessment; it is unidimensional and can be used as linear measure [58,59].

Stroke Impact Scale (SIS) [61] is a questionnaire on different aspects of the stroke recovery where the person replies on their perception regarding their life after the stroke. The 59 questions are divided into 8 domains; strength, memory, emotion, communication, activities of daily living, mobility, hand function and social participation. Items within the domain are ordered hierarchically based on clinical perspective and Rasch analysis [62]. Only the first four sections are used for the test occasion at day 10.

Impact on Participation and Autonomy (IPA-E) is a generic outcome measure for adults with chronic conditions where the person estimates perceived limitations in participation and autonomy related to dependency in the current living surrounding [63-65]. The subscales include autonomy indoors, family role, autonomy outdoors, social life and relationships, work and education. Additionally, IPA-E identifies the extent to which limitations in life are experienced as problematic in areas of mobility, self care, activities, economy issues, social life, work and education. IPA-E is valid, reliable and sensitive to change after stroke [63-65].

EuroQol Quality of Life Scale (EQ-5D) will be used to measure the health status related to the quality of life. It is a widely used generic measure and includes five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression [66,67].

Data analysis

The kinematic data in the drinking task is filtered with a 6-Hz second-order Butterworth filter, resulting in zero-phase distortion and fourth-order filtering. The drinking task is broken down into five logical phases: reaching for the glass, forward transport of the glass to the mouth, drinking, back transport of the glass to the table, and returning the hand to the initial position. The selection of kinematic variables and data analysis calculations will be based on our earlier studies [53,54]. Movement onset is defined as the time when the tangential velocity of the hand marker exceeds 2% of the maximum velocity in the reaching phase. Movement offset is detected when the velocity of the hand is less than 2% of the maximum velocity in the returning phase. Start of forward transport phase is defined as the time when the tangential velocity of the glass exceeds 15 mm/s. The drinking phase is identified by a 15% increase or decrease of the steady-state distance between the face and glass marker. The start of the returning phase is defined as the time when the tangential velocity of the glass is less than 10 mm/s. Movement times are calculated for the whole movement and separately for each phase. Peak tangential velocity and angular velocity of the elbow joint are computed for the reaching phase. Smoothness of movement is quantified by computing the number of movement units during the reaching and forward transport phases [53]. Angular joint motions are computed from the 3D position data for elbow flexion/extension, shoulder flexion/extension in the sagittal plane, and abduction/adduction in the frontal plane [53]. Compensatory trunk movement is computed for the entire drinking task as the maximal displacement of the thorax marker from the initial position [53]. Interjoint coordination between the shoulder and elbow joint angles for reaching phase is computed using cross-correlation analysis of zero time lag [53].

In the VR-test hand position data (haptic stylus endpoint) will be gathered. The position of the stylus is

tracked and resistive force is applied to it when it comes into contact with the virtual model, providing force feedback. All measurements generate time-stamped motion data (x, y, z) at 1000 Hz. Different parameters such as reaction- and movement time, velocity, acceleration and deceleration times are calculated. To obtain the movement quality of the hand trajectory, a hand path ratio, corresponding to the length of the pathway is calculated. The selection of kinematic variables and data analysis calculations will be based on our earlier study [30].

The raw scores from the ABILHAND questionnaire are analyzed using a Rasch analysis computer program and expressed as logistically transformed probability measures, logits [68]. In the Rasch model the raw scores are used to estimate the linear ability for each subject and linear difficulty for each item of measurement around a unidimensional continuum. Thus, the Rasch model converts the ordinal score of subject's manual ability into an equal interval linear measure.

Group size/power analysis

Prior longitudinal studies stroke cohorts at Sahlgrenska University Hospital have had a dropout rate of 30%. With a power (1-β) at 0.8 and a significance level (α) at 0.05, we need a sample of 88 patients (two-sided test) to determine a medium effect of 6 points change (10%) on ARAT. Therefore, we aim to include 120 persons.

Discussion

The SALGOT study is a longitudinal prospective study with a non-selected sample from Gothenburg urban area. A sample of 120 persons with first ever clinical stroke admitted to a stroke unit will be consecutively recruited from Sahlgrenska University Hospital. The study is non-interventional and the main goal is to describe the recovery of upper extremity function after first ever clinical stroke and to follow the improvements and consequences of stroke during the first year in these persons life. Measurements are performed both using traditional clinical assessments as well as computer based measurement systems that provide objective kinematic data. The person's perspective of recovery is captured both with stroke specific as well as generic self-perceived outcome measures.

In this study, the participants are assessed at eight occasions during the first year after stroke. This design gives an opportunity to study which persons will recover, when and in which areas the recovery occurs. From earlier studies it is known that the improvement of function is mostly gained during the first months after stroke. But the majority of these reports have been conducted on selected populations and in many studies the selection of outcome measures on motor function has not been sufficient. Additionally, new technologies obtaining objective kinematic measures on motor function and performance have been scarcely used in longitudinal studies.

The gained knowledge of recovery patterns is necessary both for the healthcare system and for the individual who has suffered a stroke. Since the rehabilitation resources are limited, there is a need to know the optimal time point for interventions and have guidelines for rehabilitation planning. The more detailed information about the recovery patterns of upper extremity is needed in order to offer individualized assessment and treatment, to inform the patient sufficiently about the recovery perspectives and to enhance the patient's motivation for the rehabilitation period.

Abbreviations

ARAT: Action research Arm Test; BNIS: Barrow Neurological Institute Screen for Higher Cerebral Functions; EQ-5D: EuroQol Quality of Life Scale; FMA-UE: Fugl-Meyer Assessment for Upper Extremity; IPA-E: Impact on Participation and Autonomy; M-MAS UAS-95: Modified Motor Assessment Scale accordingly Uppsala Akademiska Sjukhus 95; NIHSS: National Institutes of Health Stroke Scale; SIS: Stroke Impact Scale; TOAST: Trail of Org 10172 in Acute Treatment; VR: Virtual reality; VE: Virtual Environment.

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Authors' contributions

MAM and HCP participated in the conception and design, planning, managing the process and are responsible for day-to-day management of the study. KSS initiated the study, participated in the conception and design, managed the process and drafted the initial manuscript. All authors contributed to the study planning, drafting the manuscript and have approved the final manuscript.

Competing interests

The authors declare no competing interests.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	**Item #**	**Recommendation**	**Reported on page #**
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-8
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	7,8
Bias	9	Describe any efforts to address potential sources of bias	16, study protocol
Study size	10	Explain how the study size was arrived at	5, figure 1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8,9
		(*b*) Describe any methods used to examine subgroups and interactions	8,9
		(*c*) Explain how missing data were addressed	9
		(*d*) If applicable, explain how loss to follow-up was addressed	5
		(*e*) Describe any sensitivity analyses	9
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	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	7
		(b) Indicate number of participants with missing data for each variable of interest	7
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	11
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	11
		(*b*) Report category boundaries when continuous variables were categorized	7,8
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	13,16,17
Other information			
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	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.