



## ORIGINAL ARTICLE

# Validation and responsiveness of the Late-Life Function and Disability Instrument Computerized Adaptive Test in community-dwelling stroke survivors

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## ABSTRACT

**BACKGROUND:** Follow-up of stroke survivors is important to objectify activity limitations and/or participations restrictions. Responsive measurement tools are needed with a low burden for professional and patient.

**AIM:** To examine the concurrent validity, floor and ceiling effects and responsiveness of both domains of the Late-Life Function and Disability Index Computerized Adaptive Test (LLFDI-CAT) in first-ever stroke survivors discharged to their home setting.

**DESIGN:** Longitudinal study.

**SETTING:** Community.

**POPULATION:** First ever stroke survivors.

**METHODS:** Participants were visited within three weeks after discharge and six months later. Stroke Impact Scale (SIS 3.0) and Five-Meter Walk Test (5MWT) outcomes were used to investigate concurrent validity of both domains, activity limitations, and participation restriction, of the LLFDI-CAT. Scores at three weeks and six months were used to examine floor and ceiling effects and change scores were used for responsiveness. Responsiveness was assessed using predefined hypotheses. Hypotheses regarding the correlations with change scores of related measures, unrelated measures, and differences between groups were formulated.

**RESULTS:** The study included 105 participants. Concurrent validity (R) of the LLFDI-CAT activity limitations domain compared with the physical function domain of the SIS 3.0 and with the 5MWT was 0.79 and -0.46 respectively. R of the LLFDI-CAT participation restriction domain compared with the participation domain of the SIS 3.0 and with the 5MWT was 0.79 and -0.41 respectively. A ceiling effect (15%) for the participation restriction domain was found at six months. Both domains, activity limitations and participation restrictions, of the LLFDI-CAT, scored well on responsiveness: 100% (12/12) and 91% (12/11) respectively of the predefined hypotheses were confirmed.

**CONCLUSIONS:** The LLFDI-CAT seems to be a valid instrument and both domains are able to detect change over time. Therefore, the LLFDI-CAT is a promising tool to use both in practice and in research.

**CLINICAL REHABILITATION IMPACT:** The LLFDI-CAT can be used in research and clinical practice.

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**KEY WORDS:** Stroke; Activities of daily living; Survivors.

The majority of people with stroke will return to the home setting after their first-ever stroke.<sup>1</sup> Over forty percent of the population reports limitation in activities of daily living (ADL) and a substantial part of the population reports restrictions in participation compared with life before a stroke.<sup>2</sup> Furthermore, in a substantial part

of people with stroke decline in ADL is observed within the first three years after a first-ever stroke.<sup>3</sup> Less attention has been paid to the long-term burden of stroke and in practice, most stroke patients have no longer contact with healthcare professionals.<sup>4</sup> To provide recommendations for adequate follow-up after a stroke, a measurement tool focusing on ADL and participation that is sensitive to change and with a low burden for patients is needed.

Many instruments have been developed to assess activity limitations and participation restrictions in people with stroke. However, these instruments have several disadvantages. The most used tool to measure activity is the Barthel Index (BI). However, the BI has a large ceiling effect.<sup>5, 6</sup> Another commonly used tool, the modified Rankin Scale (mRS), only gives a global impression of mainly activities.<sup>5</sup> Patient-reported outcomes measures (PROMs) provide additional valuable information.<sup>7</sup> However, PROMs like the Stroke Impact Scale (SIS) and Utrecht Scale for Evaluation of Rehabilitation-Participation, are fixed forms whereas some questions are not applicable for individual patients and time consuming to fill-out for patients and/or professionals.<sup>8, 9</sup> Due to potential cognitive problems and lower energy levels in patients after stroke, it is important to have simple PROMs with low administrative burden.

The limitations mentioned can be overcome by using a Computerized Adaptive Testing (CAT) PROM. CAT instruments have several advantages over conventional instruments.<sup>10</sup> CAT-instruments use the response to an initial question to select the subsequent question. Irrelevant, too easy or too difficult questions for the individual are skipped. Thence, CAT instruments reduce the number of questions needed, maintain measurement precision, and decrease respondent burden.

A promising CAT PROM is the Long-Life Function and Disability Instrument – CAT version (LLFDI-CAT).<sup>11</sup> The LLFDI-CAT was developed and validated within gerontology research<sup>12</sup> and measures two domains, activity limitations and participation restrictions.<sup>11</sup> The terms of the two domains are based on the International Classification of Functioning, Disability, and Health (ICF).<sup>13, 14</sup> The LLFDI-CAT has a database with 137 questions in the activity limitation domain and 55 in the participation domain. Questions are selected based on the answer given to the preceding question. The instrument is completed after reaching a predefined stopping rule. The LLFDI-CAT contains two stopping rules that can be adjusted based on the purpose of use: 1) the number of questions; 2) reaching the predefined standard error of measurement (SEM) of 3.0.<sup>11</sup> Both the English version and Dutch translation showed

promising psychometric results in community-dwelling older persons.<sup>11, 15</sup> Also, the LLFDI-CAT has shown validity in chronic diseases population<sup>16</sup> and seems to be sensitive to measure change.<sup>12</sup>

Due to the wide scope of the LLFDI-CAT on both activity and participation domain, it might be useful for community-dwelling stroke patients. However, before using this PROM in a stroke population both concurrent validity and responsiveness need to be evaluated. Therefore, the purpose of this study was to: 1) investigate the concurrent validity of the activity limitation and the participation restriction domain of the LLFDI-CAT; 2) identify floor and ceiling effects, and 3) examine the responsiveness in community-dwelling stroke patients.<sup>17</sup>

## Materials and methods

### Study population

This study was conducted following the recommendations of the statement Standards for Reporting of Diagnostic Accuracy Studies. Data from the RISE-Study, a two-year hospital cohort study on physical behavior, functional decline and recurrent events in community-dwelling people with stroke, was analyzed. Participants were included between February 2015 and May 2016. Eligible participants were recruited from four participating hospitals in the Netherlands. Inclusion criteria were: 1) having a clinically confirmed first-ever stroke; 2) being discharged from inpatient care (hospital or inpatient rehabilitation) to the home setting; 3) independent in ADL before stroke (BI Score >18);<sup>18</sup> 4) age over eighteen. Exclusion criteria were: 1) scores below four on the Utrecht Communication Assessment;<sup>19</sup> 2) not able to walk without supervision (<3 on the Functional Ambulation Categories);<sup>20</sup> and 3) insufficient Dutch speaking and reading skills.

Eligible patients were asked to participate in the study by their health care professional in the stroke unit. Informed consent was obtained from all individual participants included in the study. Participants gave their written consent to provide contact details, stroke characteristics, and patient characteristics to the researcher. Data collection was performed by participants at home within three weeks and six months later after discharge. Prior to the data collection at the participants' home, participants received a postal questionnaire. The study was approved by the Medical Ethics Committee of the University Medical Center Utrecht, the Netherlands (NL14-076). Informed consent was obtained from all individual participants included in the study.

Assessment of validity

To determine the concurrent validity of the LLFDI-CAT the Stroke impact scale 3.0 (SIS) and five-meter walking test (5MWT) were used.

Assessment of responsiveness

Responsiveness is the ability of an instrument to detect changes over time in the construct to be measured.<sup>17</sup> Hypotheses regarding the correlations with the change scores of related measures (convergent validity), unrelated measures (discriminant validity) and the differences between groups (discriminative validity) were formulated.<sup>17, 21</sup> The SIS 3.0 domains physical functioning and participation were used because these subscales are measuring the same construct according to the International Classification of Functioning, disability, and Health (ICF) as the domains of the LLFDI-CAT. Because the included population was discharged to the community after acute care or after rehabilitation care, this population would mainly have mild to moderate stroke symptoms in the Netherlands.<sup>22</sup> The SIS is able to measure change over time in a mild to moderate stroke population.<sup>23, 24</sup> Additional a measurement tool which was

able to measure both activity limitations as participations restrictions was needed. To limit the burden for the patient only one measurement tool was chosen. Walking speed is associated with both activity limitations and participation restrictions.<sup>15, 25</sup> Because it was not possible to perform the 10 MWT in some residences the 5MWT was chosen. Additional the 5MWT shows the same psychometric proportions compared to the 10 MWT.<sup>26</sup> The Hospital Anxiety and Depression scale, self-efficacy for symptom management scale and checklist individual strength – fatigue are common used, valid and reliable tools and are measuring different constructs according to the ICF as compared with the LLFDI-CAT domains.<sup>14</sup> Although, some of these measurement tools are correlated with activity and participations domains<sup>3</sup> we assumed that the correlation of the changes scores would not exceed 0.3. Therefore, these instruments were used to assess discriminant validity. Three consecutive steps were followed to formulate hypotheses: 1) the principal investigator formulated hypotheses based on literature; 2) a group of five experts was formed and gave individual written feedback on the hypotheses; 3) in case of no consensus a group meeting was planned to reach consensus. Table I presents the formulated hypotheses.

TABLE I.—Predefined hypotheses to assesses the responsiveness of the LLFDI-CAT activity limitations and participation restrictions domain.

Hypotheses LLFDI-CAT activity limitations	Hypotheses LLFDI-CAT participation restrictions
<i>Convergent</i> There is at least a correlation >0.3 between Δ LLFDI activity limitations and: 1. Δ domain physical functioning of the SIS 2. Δ domain participation of the SIS 3. Correlation of physical functioning domain > participation of the SIS 4. Δ domain perceived recovery of the SIS 5. Δ 5MWT	<i>Convergent</i> There is at least a correlation >0.3 between Δ LLFDI participation restrictions and: 1. Δ domain participation of the SIS 2. Δ domain physical functioning of the SIS 3. Correlation of participation domain > physical functioning domain of the SIS 4. Δ domain perceived recovery of the SIS 5. Δ 5MWT
<i>Discriminant</i> There is a correlation ≤0.3 between Δ LLFDI activity limitations and: 6. Δ self-efficacy 7. Δ anxiety 8. Δ depression 9. Δ fatigue	<i>Discriminant</i> There is a correlation ≤0.3 between Δ LLFDI participations restrictions and: 6. Δ self-efficacy 7. Δ anxiety 8. Δ depression 9. Δ fatigue
<i>Discriminative</i> 10. The ability to distinguish patients improved and those who remain stable or improved (AUC≥0.7) 11. We hypothesized that participants who had inpatient rehabilitation in between discharge to the home setting and the hospital showed more change compared with a participant who was discharged directly to the home setting after hospital care 12. We hypothesized that participants who were classified as community walkers showed less change compared with limited community walkers	<i>Discriminative</i> 10. The ability to distinguish patients improved and those who remain stable (AUC≥0.7) 11. We hypothesized that participants who had inpatient rehabilitation in between discharge to the home setting and the hospital showed more change compared with a participant who was discharged directly to the home setting after hospital care 12. We hypothesized that participants who were classified as community walkers showed less change compared with limited community walkers

LLFDI-CAT: Long-Life Function and Disability Instrument-Computer adaptive testing version; SIS: Stroke impact scale 3.0; 5MWT: five-meter Walking Test; AUC: area under the receiver operating characteristics curve.

## Patient and stroke characteristics

Patient characteristics that were collected were age, sex and living alone or together. Stroke characteristics provided information on stroke severity, type (hemorrhage or infarction), hemisphere and location. Stroke severity was assessed using the National Institutes of Health Stroke Scale (NIHSS).<sup>27</sup> The NIHSS measures stroke severity by using eleven items. For each item, a zero score means normal function, a score above zero is indicative for some level of impairment. Scores are summed up with a maximum score of 42 and the minimum score of zero. In this cohort three categories were used 1) no stroke symptoms (0 points); 2) minor stroke (1-4 points); 3) moderate to severe stroke ( $\geq 5$  points).<sup>27</sup> The NIHSS has shown excellent reliability and validity.<sup>28, 29</sup>

## LLFDI-CAT version

The LLFDI-CAT is a PROM consisting a large item bank for both domains. Items were calibrated on a scale ranging from 0 to 100, with a mean of 50.<sup>11</sup> A higher score indicates fewer activity limitations and fewer participation restrictions. The standard question asked within the activity limitation domain is: *“How much difficulty do you currently have doing..?”* supplemented with a particular activity. The participants were allowed to answer *“no difficulty; a little difficulty; a lot of difficulty; unable to do; and does not apply”*. For the participation restriction domain the question: *“Because of your physical or mental health, to what extent do you feel limited in doing..?”* is asked, supplemented with a particular activity. Again five answers can be given: *“not limited at all; a little limited; a lot limited; completely limited; and does not apply”*. Per answer, the software calculates a participant score and an SEM. The final participants' score and level of SEM are calculated after reaching one of the stopping rules. In the present study, the instrument stopped after 10 questions per domain or when the patient-level SEM was less than 3.0.

## Comparative assessment tools

### The Stroke Impact Scale 3.0

The SIS is a PROM designed to measure perceived functional status. Subscales can be evaluated separately. The following subscales of the SIS 3.0 were used: 1) physical (including ADL/iADL, mobility, hand function); 2) participation; and 3) perceived overall recovery. The physical subscale contains twenty-four questions, the participation subscale eight questions. Both subscales show excellent

validity, reliability, and responsiveness.<sup>24</sup> Per subscale, the scores were calculated as a percentage of the total score, in which a higher score indicates better physical ability or higher participation levels. Perceived overall recovery was assessed to measure the patient's perception of stroke recovery. Patients were asked *“how much have you recovered from your stroke?”* with zero representing no recovery and one hundred representing full recovery.

### 5MWT

The 5MWT was used to measure walking speed. Participants were asked to walk three times five meters at a comfortable speed. The average of the three attempts was calculated. The 5MWT is a reliable and valid tool.<sup>26, 30</sup>

### Anxiety and depression

The Hospital anxiety and depression scale (HADS) determines symptoms of anxiety and depression. The HADS consists of fourteen items; seven about anxiety and seven about depression. Each question has a 4-point rating scale (0-3), where higher scores indicate higher levels of anxiety or depression. The HADS is a reliable and valid tool.<sup>31, 32</sup>

### Fatigue

The Checklist individual strength - fatigue (CIS-f) assesses the amount of fatigue. CIS-f consists of eight items. Each item can be rated on a seven-point Likert-Scale (range 8-56). A score of 8 is considered to reflect low amounts of fatigue and 56 reflects high amounts of fatigue. The CIS-f has proven reliability and validity.<sup>33</sup>

### Self-efficacy

Self-efficacy was evaluated with the self-efficacy for symptom management scale (SESx). The SESx consists of 13 items with a range score of 13-130 whereas a high score indicates a higher level of self-efficacy. The SESx is a reliable and valid tool.<sup>34</sup>

## Statistical analysis

Data were analyzed using SPSS 21.0 (SPSS Inc., Chicago, IL, USA). Concurrent validity, floor and ceiling effects, and responsiveness were assessed following the recommendations of the Consensus-based Standards for the selection of health status Measurement Instruments and proposed quality criteria by Terwee *et al.*<sup>17, 35</sup> For this study, a sample of at least fifty participants is needed.<sup>35</sup> Descriptive statistics were used to describe the participants' characteristics.

### Concurrent validity

Concurrent validity of both domains of the LLFDI-CAT was determined by comparing scores with the SIS physical functioning subscale and the participation subscale as well as with the 5MWT respectively. Correlations were calculated. When data were non-normally distributed Spearman's rho was used, otherwise Pearson's r was used. Normality was checked by comparing histograms to a normal probability curve. The convention of Cohen for effect sizes of Pearson's r (<0.10 small, between 0.1 and 0.3 medium and  $\geq 0.5$  large effect size) was used for interpretation.<sup>36</sup>

### Floor and ceiling effects

Floor and ceiling effects were determined of both LLFDI-CAT domains. Floor and ceiling effects were considered to be present if more than fifteen percent of the respondents achieved the lowest or highest possible score.<sup>17, 37</sup>

### Responsiveness

The responsiveness was considered to be adequate when >75% of the predefined hypotheses were confirmed (Table I).<sup>17</sup> The change scores of related and unrelated measures were calculated. All correlations were calculated in the same manner as the concurrent validity. Discriminative validity was calculated using the size of the area under the receiver operating characteristic curve (AUC).<sup>38</sup> The AUC measures the ability of a questionnaire that distinguishes between patients who have changed and who remained stable, according to an external criterion. We considered an AUC of at least 0.70 to be adequate.<sup>17</sup> The AUC was calculated for improvements in the activity and participation domain using the change score of the LLFDI-CAT activity limitations and participation restrictions domain. Since a gold standard for change in both domains is lacking, we used patients' perceived change of overall recovery from the SIS. A change of at least 10 percent was considered to be a clinically important change.<sup>39</sup> Scores were dichotomized to indicate individual improvement vs. participants who remained stable. The dichotomized scores were used in the AUC.

## Results

In total 110 patients participated in the study of which 105 participants (95%) completed both measurements. One participant died before the first measurement, one participant did not return the first questionnaire and three par-

ticipants were lost to follow-up. The majority of the participants were male (71.5%), mean age at onset of stroke was 68.4 (SD 11.2) years. The majority of the population had minor stroke symptoms two days after stroke (56.2%). Twenty percent was first discharged to inpatient rehabilitation before being discharged to the home setting. The majority of the population were classified as community walkers (73.3%). The mean score at baseline was 57.36 (SD 11.54) on the LLFDI-CAT activity limitation scale and 48.38 (SD 11.38) on the LLFDI-CAT participation restriction scale. Other participants characteristics can be found in Table II.

TABLE II.—Participant baseline characteristics.

Characteristics (N.=105)	% or mean $\pm$ SD
Demographic characteristics	
Males	71.45
Age (years) <sup>a</sup>	68.4 $\pm$ 11.2
Living alone <sup>a</sup>	16.2
Stroke characteristics	
Infarction	89.5
Location	
a. cerebri anterior	2.9
b. cerebri media	57.1
c. cerebri posterior	7.6
d. vertebra basilaris	5.7
Brainstem	4.8
Cerebellum	8.6
Lacunar	8.6
Unknown	4.8
Side of stroke	
Left	53.3
Right	41.9
Both	2.9
Unknown	1.9
Stroke severity day 2 after stroke	3.9 $\pm$ 3.6
No symptoms (NIHSS 0)	12.4
Minor stroke symptoms (NIHSS 1 to 4)	56.2
Moderate to severe stroke symptoms (NIHSS $\geq 5$ )	31.4
Destination of discharge from hospital	
Home	80.0
Rehabilitation	11.4
Geriatric rehabilitation	8.6
Cognitive functioning <sup>a</sup>	24.6 $\pm$ 3.7
Impaired cognitive function (MOCA $\leq 25$ ) <sup>a</sup>	38.1
Depressed	19.0
Anxiety	22.9
Walking speed (m/s) <sup>a</sup>	0.97 $\pm$ 0.26
Limited community walker ( $\geq 0.93$ m/s) <sup>a</sup>	26.7
LLFDI-CAT activity limitations <sup>a</sup>	57.36 $\pm$ 11.54
LLFDI-CAT participations restrictions <sup>a</sup>	48.38 $\pm$ 11.38

NIHSS: National Institutes of Health Stroke Scale; MOCA: Montreal Cognitive Assessment; m/s: meters per second; LLFDI-CAT: Long Life Function and Disability Index Computer Adaptive testing.

<sup>a</sup>Assessments were carried out in the home setting of the participant within three weeks after discharge from inpatient care (hospital or inpatient rehabilitation).

### Concurrent validity

A strong correlation was found between the LLFDI-CAT activity limitations domain and SIS physical subscale (0.79) and a medium correlation with 5MWT (-0.46). Likewise, a strong correlation was found between the LLFDI-CAT participations restriction domain and SIS participation subscale (0.79) and a medium correlation with the 5MWT (-0.41).

### Ceiling and floor effects

None of the participants scored the lowest possible score, meaning that no floor effect was found. Also, no ceiling effect was found within the activity limitation domain. A ceiling effect was found regarding the LLFDI-CAT participation restriction domain after six months. In total sixteen participants (15%) scored the maximum amount of points.

### Responsiveness

Table III presents the correlation coefficients between changes in both domains of the LLFDI-CAT and the

change scores on related and unrelated outcome measures. Regarding related outcome measures, all hypotheses were confirmed for the LLFDI-CAT activity limitations domains and four out of five for the participation restrictions domain. The rejected hypothesis was: *there is at least a correlation >0.3 between  $\Delta$  LLFDI participation restrictions and the change score of the 5MWT*. For both domains of the LLFDI-CAT correlations below 0.3 were found with all unrelated constructs. Therefore, hypotheses 6 to 9 were confirmed. Both domains of the LLFDI-CAT showed good ability to distinguish between improved patients and other participants with an AUC of  $\geq 0.7$  (Figure 1) (hypothesis 10). Hypotheses 11 and 12 were confirmed. Participants discharged to rehabilitation and limited community walkers showed in both domains more improvement compared with respectively discharge immediately to the home setting and community walkers (Table IV). All predefined hypotheses regarding the LLFDI-CAT activity limitations domain were confirmed and eleven out of twelve (91.7%) in the participation restrictions domain (Table I).

TABLE III.—Pearson correlation coefficients (*r*; 95%) between changes scores.

	$\Delta$ LLFDI activity limitations	95%CI	P value	$\Delta$ LLFDI participation restrictions	95%CI	P value
$\Delta$ SIS physical functioning	0.569	0.343 to 0.733	>0.001	0.483	0.236 to 0.689	>0.001
$\Delta$ SIS participation	0.407	0.210 to 0.569	>0.001	0.618	0.483 to 0.745	>0.001
$\Delta$ SIS perceived recovery	0.365	0.185 to 0.503	>0.001	0.411	0.261 to 0.549	>0.001
$\Delta$ 5MWT	0.308	0.141 to 0.451	0.001	0.262	0.111 to 0.418	0.007
$\Delta$ SESx	0.210	0.013 to 0.371	0.032	0.146	0.007 to 0.294	0.137
$\Delta$ HADS anxiety	-0.275	-0.464 to -0.090	0.005	-0.124	-0.292 to 0.046	0.207
$\Delta$ HADS depression	-0.240	-0.413 to -0.064	0.14	-0.248	-0.387 to -0.101	0.011
$\Delta$ CIS fatigue	-0.283	-0.45 to -0.097	0.003	-0.221	-0.395 to -0.031	0.024

$\Delta$ : change score; LLFDI: Long Life Function and Disability Index; CI: confidence interval; SIS: Stroke Impact Scale; 5MWT: Five Meter Walk Test; SESx: self-efficacy for symptom management scale; HADS: Hospital Anxiety and Depression Questionnaire; CIS: Checklist individual strength.

TABLE IV.—Scores three weeks after discharge, six months and change scores in total group and subgroups.

Outcome	Within three weeks after discharge mean (SD)	Six months later mean (SD)	Change Score mean (95%CI)
LLFDI activity limitation			
Total (N.=105)	57.36 $\pm$ 11.54	59.16 $\pm$ 9.89	1.80 (0.39 to 3.37)
Discharge to the home setting (N.=84)	58.77 $\pm$ 11.37	60.30 $\pm$ 9.75	1.53 (-0.11 to 3.35)
Discharge to rehabilitation (N.=21)	51.70 $\pm$ 10.68	54.58 $\pm$ 9.30	2.88 (0.86 to 4.77)
Community walkers (N.=77)	61.36 $\pm$ 9.20	62.83 $\pm$ 8.20	1.47 (-0.08 to 3.14)
Limited or no community walkers (N.=28)	46.35 $\pm$ 10.14	49.04 $\pm$ 6.55	2.69 (-0.46 to 5.20)
LLFDI participation restrictions			
Total (N.=105)	48.38 $\pm$ 11.38	51.26 $\pm$ 9.67	2.88 (1.23 to 4.61)
Discharge to the home setting (N.=84)	49.63 $\pm$ 11.54	52.09 $\pm$ 9.54	2.46 (0.62 to 4.62)
Discharge to rehabilitation (N.=21)	43.38 $\pm$ 9.40	47.93 $\pm$ 9.65	4.55 (2.42 to 6.56)
Community walkers (N.=77)	51.21 $\pm$ 9.46	54.07 $\pm$ 8.31	2.86 (0.72 to 4.51)
Limited or no community walkers (N.=28)	40.59 $\pm$ 12.70	43.52 $\pm$ 8.99	2.94 (0.52 to 6.73)

SD: standard deviation; LLFDI: Long Life Function and Disability Index; SIS: Stroke Impact Scale; MWT: Meter Walk Test; SESx: self-efficacy for symptom management scale; HADS: Hospital Anxiety and Depression questionnaire; CIS: Checklist individual strength.

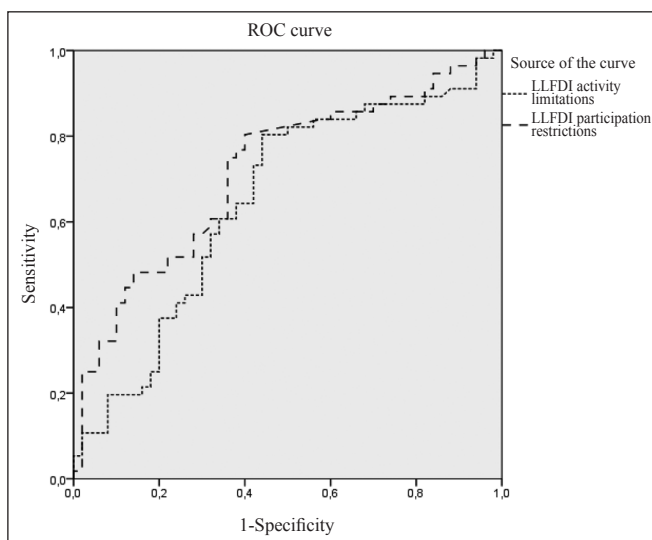


Figure 1.—ROC curve showing the sensitivity and 1- specificity of the activity limitations (0.7) and participation restrictions domain (0.7) of the LLFDI-CAT in patients who improved compared with the other patients.

## Discussion

In this study validity, floor and ceiling effects and responsiveness of the LLFDI-CAT in a community dwelling stroke population were evaluated. The study supports concurrent validity for both domains of the LLFDI-CAT. No ceiling effects were found regarding activity limitations and only a small ceiling effect six months after stroke regarding participation restrictions. The results of this study endorse that both domains of the LLFDI-CAT are able to detect changes over time. This suggests that the LLFDI-CAT is a responsive tool in community dwelling people with stroke.

The results in this study are consistent with previous studies comparing the LLFDI-CAT domains with resembling instruments<sup>15, 16</sup> and with the 5 MWT.<sup>15, 40, 41</sup> However, these studies were conducted on an elderly population. This is the first study on a stroke population. In our study, both domains of the LLFDI-CAT showed a strong correlation with the counter domains of the SIS. Both instruments are based on the same participation domain of the ICF. This could explain the high correlation between both instruments. A moderate correlation was found between the 5MWT and both domains of the LLFDI-CAT. A potential explanation is that the 5MWT only measures the physical part of disability and does not include, for example, cognitive functioning, upper extremity functioning and environmental factors.<sup>42</sup>

In the activity limitations domain, no ceiling effects were found. Only a small ceiling effect was found six months after discharge from inpatient care in the participation restriction domain. Possible explanations could be that the included population in our study had mainly minor to moderate stroke symptoms and contains also young participants. Potentially these scored the highest possible score and reached the participation level as before stroke. Another possible solution to overcome the ceiling effect is to extend the number of questions in the participation restriction domain including higher levels of participation.

Since participation restrictions in people with stroke are common<sup>2</sup> and high on the research priority list<sup>43</sup> the LLFDI-CAT could be suggested to be used in both clinical practice and research. Additionally, the LLFDI-CAT was developed to measure over time. The results indicate the ability to measure change over time in both activity limitations and participation restrictions using the LLFDI-CAT.

## Limitations of the study

In a stroke population with minor to moderate stroke symptoms, the LLFDI-CAT seems a valid instrument and is able to detect change over time. Although, the group discharged to a rehabilitation setting showed more change compared to the group discharged to the home setting (hypothesis 11) more research is needed to find evidence for validity and responsiveness in a stroke population with more severe symptoms. Additionally, patients who had difficulties in speaking or languages were excluded. Aphasia is associated with worse outcome<sup>44</sup> and people with more severe stroke symptoms seem to be at high risk for decline in ADL<sup>3</sup> and potential participation. Therefore, it would be interesting to investigate the agreement between caretakers and stroke survivor using the LLFDI-CAT. Concurrent validity of the LLFDI-CAT was not assessed with the BI or mRS, commonly used instruments in stroke research. It was expected that in this cohort, mainly consisting of people with minor to moderate stroke symptoms, the SIS would be more suitable to use.<sup>23</sup> Moreover, the SIS physical functioning showed fair to good correlations with the BI and mRS.<sup>7, 24</sup> To investigate responsiveness predefined hypotheses were formulated. The hypotheses remain arbitrary because there are no guidelines available. To avoid this, the same cut-off values for correlations were used as in the article of Mahler *et al.*<sup>45</sup> In the future, prescribed rules could give direction to the magnitude and amount of hypotheses to reach consensus. However, overall the results suggest the potential use of the LLFDI-CAT because it is able to measure change in health status of relevance

to the patient. Furthermore, the LLFDI-CAT could be applicable when higher precision or less precision is required because stopping rules can be adjusted if needed. This underlines the potential of the instrument.

## Conclusions

The results demonstrated that the LLFDI-CAT seems to be a valid instrument and is able to detect change over time in both activity limitations and participation domain. Therefore, the LLFDI-CAT is a promising tool to use in community dwelling stroke survivors for clinical and research purposes.

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