

# Cognitive assessment at bedside for iPad: A preliminary validation of a novel cognitive test for stroke patients

Lasse Willer<sup>1</sup>, Palle Møller Pedersen<sup>2,3</sup>, Hysse B Forchhammer<sup>2</sup> and Hanne Christensen<sup>1</sup>

## Abstract

**Introduction:** Cognitive impairments are frequent in stroke. Cognitive testing is important for research, prognostication and planning in sub-acute stroke, but poses difficulties due to aphasia, hemineglect, hemiplegia and fatigue. We present the first steps towards a validation of a novel iPad-based test battery: Cognitive Assessment at Bedside for iPad (CABPad).

**Patients and methods:** Stroke patients and age matched healthy controls were tested with CABPad including tests for aphasia, neglect, episodic memory, attention span, executive function, working memory, mental speed, anosognosia, motor speed and depression. A re-test was performed after 1 month. Furthermore, a group of stroke patients was tested with CABPad and traditional neuropsychological tests.

**Results:** Fifty-four patients and 48 healthy controls were included in the first phase. Fifty-three patients (98%) were able to complete at least one test and 50 (92%) all tests at the first test point. Mean test duration in patients was 39 min (range 30–60). We found significant differences in test results at baseline between the two groups. Episodic memory mean difference: 8.5 (95% confidence interval: 4.3, 12.7). Symbol Digit Coding mean difference: 16.3 (95% confidence interval: 10.8, 21.7). The second phase included 16 patients. We found adequate to excellent correlation in the majority of the tests. The CABPad Speech Comprehension test and the Auditory Word Recognition subtest of the Western Aphasia Battery correlated with  $r = 0.82$ ,  $p < 0.001$ .

**Conclusion:** CABPad is useful for cognitive testing in stroke patients. It is easy to use for the examiner and patients alike. Immobile patients can be tested at bedside, irrespectively of upper extremity paresis, and the assessment can be performed in a relatively short timespan.

## Keywords

Stroke, neuropsychological test, cognitive symptoms, aphasia, episodic memory, hemispatial neglect

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## Introduction

Disturbances of cognitive and language functions are frequent after stroke.<sup>1,2</sup> Reduction in the ability to perform complex tasks may have serious implications for Activities of Daily Living (ADL) and Independency in Daily Life Functions (IADL),<sup>3</sup> quality of life<sup>4</sup> and return to work.<sup>5</sup> These non-motor deficits are often a large burden to patients and relatives and screening of dysfunctions in language and cognition is, therefore, important for planning of rehabilitation and determination of whether the patient may be discharged to own home and need for support in ADL.

Research into the time-course of cognitive symptoms in stroke as well as planning of rehabilitation is

dependent on reliable and sensitive cognitive testing. Moreover, cognitive testing of stroke patients poses specific challenges as symptoms like aphasia, hemineglect and hemiplegia that may exclude many patients from performing a number of traditionally employed test methods. Patients may also be bedridden which

<sup>1</sup>Department of Neurology, Bispebjerg University Hospital, Denmark

<sup>2</sup>Department of Neurology, Rigshospitalet-Glostrup University Hospital, Denmark

<sup>3</sup>Cognisoft ApS

### Corresponding author:

Lasse Willer, Department of Neurology, Bispebjerg Hospital, Copenhagen, Denmark.

Email: Lasse.Willer@regionh.dk

necessitates a setup that is applicable at bedside. Finally, the battery has to be performed in a short time-span because many patients are easily fatigued.

Research in cognitive and language symptoms in stroke has usually used either short dementia screening instruments or more extended neuropsychological assessments. Short dementia screening instruments like the Mini-Mental State Examination (MMSE) and The Montreal Cognitive Assessment (MoCa) do not cover all relevant symptoms in stroke.<sup>6</sup> An existing short cognitive screening battery, which can be administered within half an hour, is The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS).<sup>7</sup> The RBANS battery has good psychometric properties.<sup>8</sup> It is, however, not designed specifically for assessment of stroke patients, which limits its relevance. Thus, the memory tests included requires the ability to speak or to copy a complex design, excluding a large number of patients with either aphasia, visuo-constructional abilities or weakness of the dominant upper extremity. Extended neuropsychological assessment cannot be performed at the bedside and there are usually not resources to offer it to all stroke patients.

In this article, we present our validation of a novel cognitive test battery: Cognitive Assessment at Bedside for iPad (CABPad). It includes nonverbal memory, attention and executive tests to allow for aphasic patients to cooperate. Furthermore, the iPad reads aloud the instructions to enhance standardization and to reduce the demands for psychometric skills of the assessor.

## Method

Validation of CABPad was divided into two phases. In phase 1, stroke patients and age matched healthy controls were tested twice with a 1-month interval. In phase 2, stroke patients were tested with CABPad and traditional neuropsychological tests in a single session.

CABPad was developed by neuropsychologist Palle M. Pedersen, Cognisoft ApS. It has now been made available in the Apple App Store. For more information, visit <http://www.cognisoft.info/>

## Included tests in CABPad

Rating of Anosognosia, Motor Speed for Hands, Speech Comprehension (aphasia), Picture Naming (aphasia), Verbal Fluency (phonemic and semantic), Timed Neglect Test, The Baking Tray Test (hemineglect), Attention Span (for symbols), Working Memory (for symbols), Arrow Stroop (executive attentional control), Episodic Memory (Memory for Pattern Locations), Symbol Digit Coding (mental and

visuo-motor speed) and Geriatric Depression Scale, Short Form (GDS).<sup>9</sup> Attention Span and Working Memory are combined into a Working Memory Index. All cognitive test scores (excluding Motor Speed for Hands and GDS) are also combined into a weighted Total Cognitive Index (for a comprehensive description, see the supplementary material available online with this article, <http://eso.sagepub.com>).

## Phase 1

Stroke patients were included from two large stroke centres in the Capital Region of Denmark. Inclusion criteria were a stroke within the last 3 months, age 18 years or older, capable of understanding oral or written information and giving informed consent, and speaking Danish. Only patients with a confirmed stroke (ischaemic or haemorrhagic) requiring rehabilitation were included. They were tested in the sub-acute phase and re-tested after 1 month. Healthy controls were recruited by asking brain-healthy spouses to participate and by advertising through a local elderly organisation. This was done to recruit controls in the same age category of 45 and older that we expected to find our patients in.

All participants were tested with an examiner present, beside the participant, controlling the CABPad app. To reduce inter-examiner variability, all instructions were read aloud by the iPad app. For the majority of the tests, the examiner starts the test. The participant then solves the test according to instructions read aloud by the App. For tests for anosognosia, naming, verbal fluency and GDS, the examiner enters the response from the participant in predefined categories.

## Phase 2

**Patients.** Stroke patients were assessed during hospital stay at one of the stroke units at Glostrup Hospital, Denmark. Patients were tested at the ward. These patients were not a part of phase 1, as not all sub-test were included.

**Assessments.** All assessments were carried out by the same neuropsychologist (PMP) in a single session, typically lasting about 1½ hour. The order of CABPad testing and testing with the traditional neuropsychological tests were carried out pseudo-randomized by a fixed, predetermined schedule. To reduce fatigue effects, the test battery was made as small as possible. Only iPad subtests relevant for comparison with traditional tests were included. Anosognosia Rating and Motor Speed for the Hands were not included, as they have no obvious traditional counterparts. The Verbal Fluency Test was excluded, as we believe the iPad version to be very similar to the traditional version of the test.

The following traditional tests were employed: Western Aphasia Battery (WAB) part II b: Auditory Word Recognition and IV a: Object Naming;<sup>10</sup> Behavioural Inattention Test (BIT): Line cancellation, Star Cancellation and Letter Cancellation;<sup>11</sup> WAIS-IV: Digit Span and Coding;<sup>12</sup> WMS-IV: Symbol Span and Designs I;<sup>13</sup> DKEFS: Colour-Word Interference Test.<sup>14</sup>

### Statistics

Statistics were done using IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp. Comparison of patients and healthy controls were done using independent t-test and Mann-Whitney test, and comparison of test to re-test in both healthy controls and patients were done with paired t-test and Wilcoxon signed-rank test. Effect size calculated as Cohen's d when normal distribution is assumed and otherwise Pearson's correlation coefficient r. All results with a p-value of 0.05 or lower were considered significant. Educational level was computed as years of school (primary- and high-school) + a score of 1–5 depending on type of further education (no further education; semi-skilled worker; skilled blue- and white-collar worker; a longer, non-academic theoretical education; academic education) with a maximum score of 17.

## Results

### Phase 1

Fifty-four patients and 48 healthy controls were included. There was no significant difference in age and education level between the groups (Table 1). Fifty-three patients (98%) were able to complete at least one test and 50 (92%) were able to complete all tests at first test point. Mean test time duration in sub-acute stroke patients was 39 min (range 30–60).

Table 2 shows the test results in controls and patients at first test point. A comparison of means between controls and patients showed a significant difference in all tests except for the Baking Tray Test. Cohen's d was calculated to estimate an effect size and is high in all tests except for the two neglect tests. Patients with neglect and aphasia were then analysed separately and compared with healthy controls (Tables 3 and 4). In the eight patients with neglect, we found a significant difference in the Timed Neglect Test: Mean difference 1.79 (0.96, 2.61),  $p=0.001$ ; Cohen's  $d=3.75$ ; but no significant difference in the Baking Tray Test: Mean difference 97.96 (–73.9, 269.8),  $p=0.22$ , Cohen's  $d=0.987$ . In the 15 patients with aphasia, we found significant differences in Picture Naming, Semantic Verbal Fluency, Phonemic Verbal Fluency and Speech Comprehension.

Thirty (55%) patients and 11 (23%) controls were re-tested, and a comparison of difference in mean change between the two groups showed a significant difference in Speech Comprehension, Picture Naming, Semantic Verbal Fluency, Working Memory Index, Arrow Stroop and Symbol Digit Coding. Cohen's d is moderate to large in all tests except for the two neglect tests (Table 5).

We calculated a Cognitive index and found a significant difference in controls and patients: 26.0 (17.7, 34.3),  $p < 0.001$  with Cohen's  $d=1.458$ . In the comparison of difference in mean change, the two groups were significantly different: 13.6 (2.2, 24.1),  $p=0.05$  with Cohen's  $d=1.307$ . The control group had a lower mean change than the patient group.

### Phase 2

Sixteen patients with stroke completed the assessment (11 male; mean age 67.3 (11.1), range 44–86; mean education 11.1 (2.8), range 8–17; 13 ischaemic,

**Table 1.** Demographics and patient characteristic, phase 1.

	Patients (N = 54)	Controls (N = 48)	Mean diff. (95% CI)
Mean age (range)	63.8 (30–90)	67.5 (49–86)	3.7 (–0.6, 8.1) $p=0.093$
Female sex % (N)	37% (20)	54% (26)	$p=0.083$
Mean education (range) <sup>a</sup>	12.8 (7–17)	13.8 (8–17)	1.0 (–0.1, 2.1) $p=0.073$
Handedness right/left/ambidexter	39(75%)/9/3 (3 missing values)	45(93%)/2/1	$p=0.081$
Median NIHSS on admission (range)	7 (1–21)		
Mean days from admission to first test	17 (1–78)		
Ischaemic stroke/ICH/SAH	51/2/1		
Prior stroke	11 (20.4%)		

<sup>a</sup>Years of school (primary and high-school) + 1–5 depending on type of further education (see explanation in the text).

**Table 2.** Results of first test.

	Controls, mean (SD)	Patients, mean (SD)	Mean diff. (95% CI)	Cohen's d/Pearson's r
Cognitive index	97.5 (15.0)	71.5 (24.8)	26.0 (17.7;34.3), p < 0.001	d = 1.458
Motor speed for hands, right hand, total responses	65.6 (16.1)	41.8 (26.4)	23.8 (15.3;32.4), p < 0.001	d = 1.184
Motor speed for hands, left hand, total responses	72.5 (16.2)	47.8 (29.2)	24.7 (15.5, 33.9), p < 0.001	d = 1.170
Speech comprehension, total correct	34.2 (1)	31.6 (6.5)	2.6 (0.8, 4.4), p = 0.001	r = 0.319
Picture Naming, total correct	19 (1.1)	15.9 (5.3)	3.1 (1.6, 4.6), p < 0.001	r = 0.466
Verbal fluency (phonemic), total correct	45.4 (15)	28.9 (14.2)	16.5 (10.6, 22.4), p < 0.001	d = 1.145
Verbal fluency (semantic), total correct	45.2 (8.9)	29 (13.3)	16.2 (11.7, 20.7), p < 0.001	d = 1.529
Working memory index, total correct	8.1 (2.5)	4.5 (2.9)	3.6 (2.5, 4.7), p < 0.001	d = 1.334
Episodic memory, total correct	22.2 (9.4)	13.7 (11.8)	8.5 (4.3, 12.7), p < 0.001	d = 0.819
Symbol digit coding, total correct	46.9 (93)	30.6 (17.3)	16.3 (10.8, 21.7), p < 0.001	d = 1.332
Arrow stroop, total correct	101.9 (17.5)	79.8 (27.8)	22.1 (12.9, 31.4), p < 0.001	d = 1.036
Timed Neglect Test, neglect index	0.059 (0.35)	0.35 (0.85)	-0.29 (-0.6, -0.03), p = 0.024	d = 0.546
Baking tray, mean deviance	10.1 (76.2)	31.2 (214.9)	-21.1 (-84.1, 41.8), p = 0.5	d = 0.165
GDS, total score	1.2 (1.9)	2.9 (2.6)	-1.7 (-2.6, -0.75), p = 0.001	d = 0.770

Comparisons by t-test and Mann–Whitney test. Effect size calculated as Cohen's d and Pearson's correlation coefficient r.

**Table 3.** Neglect test scores in patients with neglect and in healthy controls.

	Controls (SD) (N = 48)	Patients with neglect (SD) (N = 8)	Mean difference (95% CI)	Cohen's d
Timed Neglect Test, neglect index	0.059 (0.35)	1.85 (0.99)	1.79 (0.96, 2.61), p = 0.001	d = 3.75
Baking Tray Test, mean deviance	10.1 (76.2)	-87.88 (205.1)	97.96 (-73.9, 269.8), p = 0.22	d = 0.987

2 intracerebral haemorrhage (ICH), 1 subarachnoid haemorrhage (SAH); 15 first-ever stroke; 8 right hemisphere, 6 left hemisphere, 2 infratentorial; mean days from admission to assessment 48.4 (48), range 18–186). Two more patients were unable to cooperate due to very severe Wernicke aphasia and fatigue.

Correlations between CABPad subtests and traditional subtests are shown in Table 6. Correlations among the traditional BIT subtests may be used as a

reference for expected sizes for correlations among neuropsychological subtests assessing the same functional domain. None of these were significant (Line cancellation – Star Cancellation:  $r = 0.41$ , NS; Line cancellation – Letter cancellation:  $r = 0.41$ , NS; Star cancellation – Letter cancellation:  $r = 0.47$ , NS).

It may be noted that both neglect subtests from CABPad have higher correlations with BIT Line Cancellation and BIT Star Cancellation than either

**Table 4.** Aphasia test scores in patients with aphasia and healthy controls.

	Controls (SD) (N = 48)	Patients with aphasia (SD) (N = 15)	Mean difference (95% CI)	Cohen's d/ Pearson's r
Speech comprehension, total correct	34.2 (1)	28.2 (11.1)	6.0 (0.143, 12.2), p = 0.002	r = 0.391
Picture Naming, total correct	19 (1.1)	11.5 (8.1)	7.5 (2.8, 12.1), p < 0.001	r = 0.496
Verbal fluency (phonemic), total correct	45.4 (15)	20.2 (14.4)	25.2 (15.3, 35.1), p < 0.001	d = 2.567
Verbal fluency (semantic), total correct	45.2 (8.9)	20.7 (13.5)	24.6 (15.7, 33.4), p < 0.001	d = 3.251

**Table 5.** Mean change from first to second test.

	Mean change first to second test, controls (SD) (N = 11)	Mean change first to second test, patients (SD) (N = 30)	Mean diff. (95% CI)	Cohen's d/ Pearson's r
Cognitive index	0.7 (10.5)	13.0 (15.0)	13.6 (2.2;24.1), p = 0.005	d = 1.307
Motor speed for hands, right hand, total responses	1.73 (12.68)	10.67 (20.38)	8.94 (-1.9, 19.8), p = 0.1	d = 0.623
Motor speed for hands, left hand, total responses	0.45 (13.02)	9.47 (20.48)	9.01 (-2.1, 20.1), p = 0.1	d = 0.625
Speech comprehension, total correct	-0.36 (0.50)	0.73 (2.01)	1.1 (0.3, 1.9), p = 0.043	r = 0.317
Picture Naming, total correct	0.36 (0.81)	1.43 (2.74)	1.1 (-0.05, 2.2), p = 0.148	r = 0.226
Verbal fluency (phonemic), total correct	2.09 (8.92)	6.54 (10.21)	4.4 (-2.4, 11.3), p = 0.19	d = 0.587
Verbal fluency (semantic), total correct	-0.45 (5.72)	5.50 (9.23)	5.95 (0.9, 10.9), p = 0.02	d = 0.894
Working Memory Index	-0.09 (1.76)	2.66 (3.12)	2.7 (1.1, 4.3), p = 0.001	d = 1.238
Episodic memory, total correct	-1.27 (10.07)	3.67 (10.54)	4.9 (-2.6, 12.5), p = 0.18	d = 0.637
Symbol digit coding, total correct	-0.64 (4.52)	7.27 (8.85)	7.9 (3.6, 12.2), p = 0.001	d = 1.274
Arrow Stroop, total correct	3.27 (7.27)	13.14 (15.39)	9.9 (2.6, 17.2), p = 0.01	d = 0.914
Timed Neglect Test, neglect index	-0.03 (0.35)	0.02 (0.86)	0.05 (-0.33, 0.43), p = 0.79	d = 0.087
Baking Tray Test, mean deviance	-33.82 (64.95)	-31.43 (116.28)	2.4 (-56.44, 61.2), p = 0.93	d = 0.029

of these tests have with each other and with BIT Letter Cancellation. The indices from CABPad Timed Neglect Test and Baking Tray Tests also correlates significantly ( $r = 0.88$ ,  $p < 0.001$ ) and more strongly than the correlations among the BIT subtests.

The correlation among the two CABPad aphasia subtests was high ( $N = 16$ ,  $r = 0.85$ ,  $p < 0.001$ ), and at the same level as the correlation among the two traditional aphasia subtests from WAB ( $N = 16$ ,  $r = 0.89$ ,  $p < 0.001$ ).

**Table 6.** Correlations among iPad subtests and traditional tests (phase 2).

CABPad (iPad) test	Traditional test	N	Correlation
Speech comprehension	WAB II b	16	$r = 0.82, p < 0.001$
Picture Naming	WAB IV a	16	$r = 0.83, p < 0.001$
Timed Neglect Test	BIT Line Cancellation	15	$r = 0.84, p < 0.001$
Timed Neglect Test	BIT Star Cancellation	14	$r = 0.81, p < 0.001$
Timed Neglect Test	BIT Letter Cancellation	14	$r = 0.44, NS$
Baking Tray Test	BIT Line Cancellation	15	$r = 0.87, p < 0.001$
Baking Tray Test	BIT Star Cancellation	13	$r = 0.74, p = 0.002$
Baking Tray Test	BIT Letter Cancellation	14	$r = 0.30, NS$
Working Memory Index	WAIS-IV Digit Span	14	$r = 0.66, p = 0.01$
Working Memory Index	WMS-IV Symbol Span	14	$r = 0.61, p = 0.02$
Arrow Stroop, Total Correct	DKEFS Colour-Word Interference Test, Total time	9	$r = 0.47, NS$
Arrow Stroop, Error %	DKEFS Colour-Word Interference Test, total errors	9	$r = 0.48, NS$
Arrow Stroop, Congruent/ Incong. time diff.	DKEFS Colour-Word Interference Test, Inhibition score	9	$r = 0.15, NS$
Episodic memory	WMS-IV Designs I, raw score	13	$r = 0.49, NS$
Symbol digit coding	WAIS-IV Coding, scale score	13	$r = 0.91, p < 0.001$

It may be noted that the correlation among the CABPad Working Memory Index and WAIS-IV Digit Span, and among CABPad Working Memory Index and WMS-IV Symbol Span was at the same level as among WAIS-IV Digit Span and WMS-IV Symbol Span ( $r = 0.67, p = 0.009, N = 14$ ).

## Discussion

We aimed to develop an easy to apply neuropsychological test battery specifically for stroke patients, covering most common domains affected by stroke. Time is of obvious importance in sub-acute and immobilised patients who tire easily. In this validation, we demonstrate that most of the patients were able to use the test (98% at least one and 92% all tests) and that mean time of testing was 39 min, which is acceptable even for patients who are easily fatigued. We furthermore demonstrated that the test battery discriminates patients with stroke from matched controls. Stroke patients performed significantly worse than healthy controls in all tests except for one of the neglect tests. Looking at the patients with neglect and comparing them alone to the healthy controls, we found a significant difference in the Timed Neglect test but not in the Baking Tray Test. Neglect is a very specific symptom affecting a minority of the stroke patients, which reduces the statistical power to find a true difference between groups. Stroke patients improved more than controls in all tests, but the differences in the size of the

improvements were not significant in all tests. This could be due to the small number of retested healthy controls. The Cohen's  $d$  was moderate to large, which could indicate an effect despite the low significance levels and that the improvement in stroke patients over time is not just an expression of a learning effect. We computed an overall Cognitive Index that proved to be sensitive to stroke as well as to remission. We do not believe this index to be of importance for clinical decisions for the individual patient, but it constitutes a relevant indicator in research projects with comparisons of outcome or treatment effect. The specificity and sensitivity of this index remains to be determined in a larger study.

The adequate to excellent correlations of the majority of the CABPad subtests with traditional neuropsychological subtests demonstrates the general feasibility of the iPad for neuropsychological screening of stroke patients. The Symbol Digit Coding test has a remarkably high correlation with the WAIS-IV Coding subtests. This is important, as the WAIS Coding has repeatedly been shown to be very sensitive to even mild cognitive decline in a wide range of etiologies.<sup>12,15,16</sup>

Very good correlations were found with traditional tests for the two aphasia tests as well as for the two neglect tests. The two CABPad neglect tests have higher correlations with each other and with two out of three traditional tests than the traditional tests have among each other. This strongly suggests that the neglect tests in the CABPad battery are both valid and have satisfactory sensitivities in spite of the

non-significant findings in the comparisons with healthy controls.

Working memory had satisfactory correlations with traditional verbal and a nonverbal working memory tests, and at the same level as the correlations among the two traditional tests. The two CABPad Working Memory subtests uses pictogram symbols, and may be approached with verbal as well as non-verbal working memory strategies, which can explain the similar correlations found. This lends further support to the feasibility of the iPad for neuropsychological testing in stroke.

For the Arrow Stroop, it was not possible to find a similar non-verbal test among well standardized traditional tests, and the verbal nature of the chosen DKEFS Colour Word Interference Test can explain a low and non-significant correlation exuberated by some aphasic patients unable to cooperate with the DKEFS Colour Word Interference Test, reducing the N. It is necessary to find other ways to validate the Arrow Stroop. One possibility would be to correlate test results with lesion localizations in stroke patients.

Concerning the low and non-significant correlation between the two tests for episodic memory (CABPad Episodic Memory and WAIS-IV Designs I), it may have been caused by some patients having problems understanding the instructions for Episodic Memory. In addition, some patients may have had visual attention and neglect problems with the large number of design cards to choose from in WAIS-IV Designs I. Possibly, the CABPad Episodic Memory test may be improved by a video instruction, which is considered for future versions of the test battery. As mentioned in the supplementary material, the episodic memory test was developed as a non-verbal test to take the high number of aphasic patients into account. This, on the other hand, made it difficult to find a similar test to validate against. This is a limitation of this study, but we believe such a test is necessary in cognitive testing of stroke patients and further validation is needed.

In this study, we included the GDS short form to test for symptoms of depression, but we did not evaluate the level of anxiety, fatigue or apathy. This is a limitation to our study as those symptoms may also affect the cognitive test results in stroke patients. However, our aim was to develop a test that is both comprehensive and at the same time is as short as possible due to the known fatigue in many stroke patients.

This validation was done on a rather limited number of patients and healthy controls. Therefore, the results of this validation should be considered as preliminary.

## Conclusion

We find that CABPad is a useful tool for cognitive testing in stroke patients. It is easy to use for the

examiner and patients alike. Immobile patients can be tested at bedside and irrespectively of upper extremity paresis. Our cognitive test-battery can be performed in a relatively short timespan.

We developed this test to use in our research, as we wanted a test battery developed specifically for stroke patients that took their specific deficits, as neglect and aphasia, into account. Furthermore, we see this as a useful test to stratify patients to further testing and training in the clinical daily routine.

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The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: CABPad was developed and is sold by neuropsychologist Palle Møller Pedersen, Cognisoft Aps.

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## Ethical approval

Validation and method development of the CABPad neuropsychological test: it is not notifiable according to Danish law. The Validation could be completed as planned and stated by The Scientific Ethics Committee of the Capitol Region Denmark, decision: H-1-2012-147.

## Informed consent

Verbal informed consent was obtained from all subjects before the study.

## Guarantor

LW.

## Contributorship

LW, HC and PMP researched literature and conceived the study. LW, HC and HBF were involved in protocol development, gaining ethical approval and patient recruitment. LW, HC and PMP were involved in data analysis. LW wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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