Bridging the Assessment Gap: Newly Developed Neuropsychiatric Cognitive Assessments on the Cognivue® Platform Show Strong Correlation with Traditional Gold Standard Tests

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KEY TAKEAWAY: Cognitive assessment with the computerized Cognivue *Clarity*® device showed strong correlation with traditional gold-standard cognitive tests and excellent internal consistency and reliability.

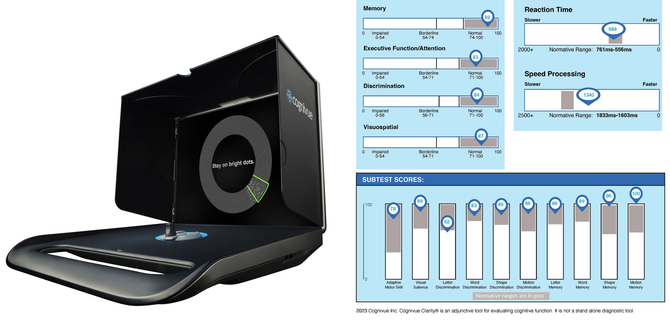
BACKGROUND

Research has shown that structured cognitive assessment tools are more effective in detecting mild cognitive impairment or dementia vs spontaneous detection by primary care providers.[1] However, many tools for assessing decline in cognitive function have limited utility due to issues of accuracy, testing bias, and uptake among clinicians.[2,3] The FDA-cleared Cognivue *Clarity*® and *Thrive*® devices provide computerized cognitive assessment based on modern cognitive neuroscience, allowing clinicians and patients to move beyond the questions and answers approach of traditional cognitive tests.

The automated Cognivue technology utilizes adaptive psychophysics and assesses the patient's motor skills and visual acuity, eliminating biases that can be found in common cognitive testing mechanisms. The Cognivue *Clarity*® device assesses the domains of Visuospatial, Executive Function, Naming, Memory, Delayed Recall, and Abstraction, as well as two speed performance parameters. The Cognivue *Thrive*® test assesses the domains of Memory, Visuospatial, and Executive Function as well as two speed performance parameters. The Cognivue *Clarity*® and Cognivue *Thrive*® devices are the first FDA-cleared tests of cognitive performance based on modern cognitive neuroscience. The Cognivue *Clarity*® device provides a 10-minute comprehensive assessment while the Cognivue *Thrive*® device provides a 5-minute cognitive screen (Figure 1). After assessment, both devices provide immediately accessible results for clinicians in a clinical report and/or in a CSV file (Figure 1).

The Cognivue *Clarity*® and Cognivue *Thrive*® devices are adjunctive tools for evaluating cognitive function and are not stand-alone diagnostics. Clinical contextualization is required.

Figure 1. The Cognivue *Clarity*® device (below) and a page from the report (right).



METHODS

This was a multi-site validity and reliability study that enrolled subjects at 14 study sites throughout the United States. Demographic information, including age, sex, race, ethnicity, and education, was captured and regularly assessed during enrollment to ensure a diverse representation of study subjects.

The study's primary endpoint was confirmation of scoring and normative ranges with the Cognivue *Clarity*® and Cognivue *Thrive*® tests. In addition to testing with Cognivue devices, subjects were randomized for order of testing at each study site to complete six gold-standard neuropsychiatric cognitive tests, including gaiting, reaction time (auditory and visual), digit span (auditory and visual), Stroop (acoustic amplitude and color word), cued visual go-no go, and delayed recall.

Secondary endpoints of the study included stratification of study population by age, sex, education, and ethnicity compared to normative ranges of Cognivue *Clarity*® and Cognivue *Thrive*® tests; determination of the level of training effect; and comparison of test sensitivity between Cognivue *Clarity*® and Cognivue *Thrive*® and the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), a widely used cognitive test.

Collected data were analyzed with regression analyses for agreement and retest reliability; rank linear regression; bivariate correlation analysis; and factor analysis for psychometric comparisons.

RESULTS

The study enrolled 1,575 participants who underwent both the Cognivue assessments and RBANS.

The Cognivue *Clarity*® device exhibited strong internal consistency and test-retest reliability. Investigation of internal consistency across psychometric properties using Cronbach's alpha found a significant consistency score of 0.864 (95% confidence interval [CI]: 0.848-0.879); $p<.001$. The test-retest reliability found a score of 0.85.

After eliminating individuals with exceptionally large swings between measurement occasions (subjects with between measurement differences of 15 or higher) the learning effect for Cognivue *Clarity*® was 2.99 points per measurement, or approximately a 0.20 standard deviation (SD) increase in score.

Scores for 10 factors (motor, visual, letter discrimination, word, shape, motion, letter memory, word memory, shape memory, and motion memory) were plotted into a scree plot to estimate which would yield the best fit for the data (Figure 2). Factors to the left of the "elbow" where values begin to level off in the scree plot are generally considered significant and subjected to further examination. Based on results of the scree plot, it was estimated that a one-, three-, or four-factor model would yield the best fit for the data.

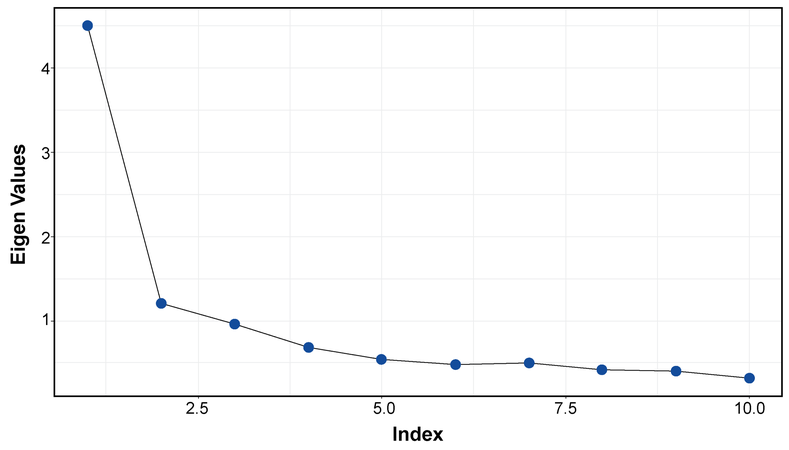


Figure 2. Scree plot of the factor-model analysis for Cognivue *Clarity*®.

The one-factor, three-factor, and four-factor models were examined with the root mean square error of approximation (RMSEA), Chi-Square, and Tucker-Lewis fit indices. For RMSEA, values less than 0.05 are considered good a good fit; the Chi-Square test should be non-significant; and a good Tucker-Lewis index is above 0.95. Results of these fit indices are provided in Table 1. The results suggest that the four factor-model used by Cognivue *Clarity*® yields not only the best fit of the three models; it is also a *good* fit to the data, with all three fit indices falling within the acceptable range.

The factor loadings themselves are depicted in Table 2 along with the sum of squared (SS) loadings, which is used to determine the value of each factor. An SS loading over 1 is generally considered strong. A delayed memory factor was found to be the strongest among those examined, with high loadings from all memory scores and a SS loading of 2.1. A visuospatial factor, comprised of motor adaptive and visual salience scores, was the second strongest, with smaller loadings than that of the memory factor and an SS loading of 1.2. An executive attention factor, composed of the letter and word discrimination scores, and a perceptual factor, comprised of the shape and motion discrimination scores, were not as clearly defined in the analysis (SS loading 0.86 and 0.65, respectively).

	RMSEA (90% CI)	Chi-Square Test	Tucker-Lewis Index
One-factor model	0.142 (0.131, 0.154)	*P*<0.0001	0.75
Three-factor model	0.052 (0.035, 0.07)	*P*<0.0001	0.97
Four-factor model	0.029 (0, 0.055)	*P*<0.11	0.99

Table 1. Factor analyses fit indices using Cognivue *Clarity*® data.

Factor	Memory Domain	Visuospatial Domain	Executive Domain	Perceptual Domain
Letter Memory Score	**0.73**	0.03	-0.08	0.11
Word Memory Score	**0.86**	-0.09	0.01	0.07
Shape Memory Score	**0.72**	0.07	0.09	-0.1
Motion Memory Score	**0.56**	0.22	0.06	-0.12
Motor Score	0.03	**0.78**	-0.09	0.07
Visual Score	-0.01	**0.73**	0.13	0.01
Letter Discrimination Score	0.01	0	**0.74**	0.03
Word Discrimination Score	0.07	0.03	**0.49**	0.18
Shape Discrimination Score	0.05	0.12	0.11	**0.59**
Motion Discrimination Score	0.13	0.12	0.13	**0.46**
SS Loadings	**2.1**	**1.2**	0.86	0.65

Table 2. Factor analysis loadings using Cognivue *Clarity*® data.

An analysis of Cognivue *Clarity*® scores showed good convergence among of correlations. Correlations between the broader factors examined in the factor analysis are depicted in Table 3, with inter-item correlations of psychometric properties shown in Table 4. Good convergence was seen between total scores and subtests, memory tests, and discrimination tests. Scores among the motor and visual adaption tests, which are presented first to participants and used by the Cognivue *Clarity*® device to calibrate subsequent tests, showed weaker correlation with those of other subtests.

In a comparison of the Cognivue *Clarity*® device test results and those of the RBANS test, the global Cognivue Score showed small- to-medium but significant correlations with RBANS test scores, subscores, index scores, and total scores (R range from 0.156-0.318; Figure 3). Individual Cognivue test scores showed small correlations with RBANS test scores, subscores, and index scores; these individual Cognivue test scores also showed small- to-medium but significant correlations with RBANS total score (R range from 0.145-0.347), with memory tests showing stronger correlations than discrimination tests. When Cognivue *Clarity*® scores were residualized on the age variable using a linear regression, correlation with RBANS improved markedly, demonstrating the impact of age norming on Cognivue results (Figure 3).

	Memory Domain	Visuospatial Domain	Executive Domain	Perceptual Domain
Memory Domain	1	0.5	0.45	0.5
Visuospatial Domain	0.5	1	0.44	0.52
Executive Domain	0.45	0.44	1	0.54
Perceptual Domain	0.5	0.52	0.54	1

Table 3. Correlations between factors using Cognivue *Clarity*® data.

	Global	MS	VS	LD	WD	SD	MD	LM	WM	SM	MM
Global Score	**1.000**										
Motor Score (MS)	0.51	**1.00**									
Visual Score (VS)	0.51	0.60	**1.00**								
Letter Discrimination (LD)	0.59	0.32	0.37	**1.00**							
Word Discrimination (WD)	0.63	0.32	0.36	0.50	**1.00**						
Shape Discrimination (SD)	0.69	0.41	0.41	0.40	0.44	**1.00**					
Motion Discrimination (MD)	0.72	0.41	0.42	0.40	0.42	0.55	**1.00**				
Letter Memory (LM)	0.74	0.35	0.31	0.25	0.36	0.39	0.43	**1.00**			
Word Memory (WM)	0.77	0.32	0.30	0.30	0.34	0.43	0.41	0.67	**1.00**		
Shape Memory (SM)	0.75	0.32	0.33	0.31	0.32	0.36	0.40	0.57	0.61	**1.00**	
Motion Memory (MM)	0.70	0.37	0.35	0.28	0.28	0.34	0.35	0.48	0.52	0.51	**1.00**

Table 4. Inter-item correlations between psychometric properties using Cognivue *Clarity*® data.

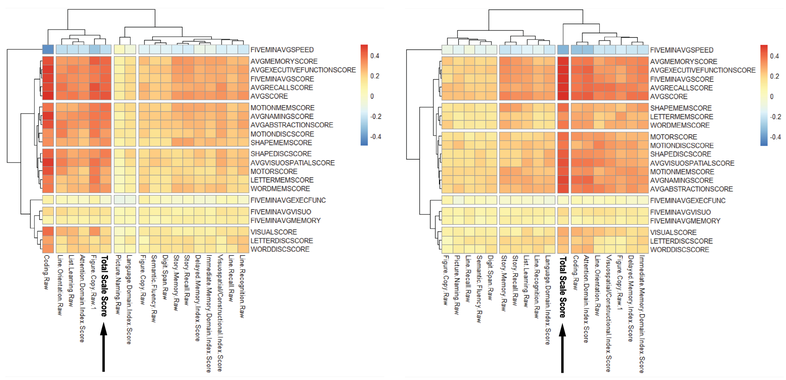


Figure 3. Comparison of Cognivue *Clarity*® and RBANS test, without age norming (left) and with Cognivue *Clarity*® scores residualized on the age variable using a linear regression (right).

CONCLUSIONS

The results of this study revealed a remarkably high correlation between the Cognivue suite of assessments and the traditional gold standard tests. This strong correlation indicates a robust relationship and demonstrates the reliability and validity of the Cognivue platform in measuring cognitive performance. Testing with Cognivue *Clarity*® demonstrated excellent internal consistency and test-retest reliability with a small practice effect. The significant correlations between Cognivue *Clarity*® scores and that of the RBANS test were markedly improved by a linear regression on the age variable, supporting the use of age norming with the Cognivue *Clarity*® device. This study supports the potential use of Cognivue *Clarity*® as a easy-to-use, brief, and valid cognitive assessment that can be used for identifying individuals for clinical research studies.

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