

Clinical Validation of Cognivue® - A Computerized Alternative to the Montreal Cognitive Assessment Test

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Abstract

Aims: To determine the utility of Cognivue® compared to the MoCA for reliably assessing cognitive impairment (CI).

Methods: Adults ≥55y completed two testing sessions 1-2 weeks apart during which both Cognivue® and MoCA were conducted. Correlation analyses were performed for overall scores on each neuropsychological test and retest reliability was assessed via regression analyses.

Results: 100 participants completed the testing sessions. A statistically significant positive correlation between overall scores on Cognivue® and MoCA was found ($r = 0.38$; $p < 0.001$). Test-retest reliability was greater for Cognivue® than MoCA for participants initially classified as having no CI (87.3% vs. 73.1%). Regression analyses of test-retest reliability revealed a tighter and more linear pattern for Cognivue® than MoCA, however a statistically significant regression fit for both was demonstrated (Cognivue®: $R^2 = 0.439$, $r = 0.663$; MoCA: $R^2 = 0.378$, $r = 0.615$).

Conclusions: Cognivue® demonstrated comparable reliability to MoCA, thus providing an efficient, easy-to-use alternative for assessing CI.

Keywords: Cognitive Assessment; Dementia; Memory; Motor Control; Cognivue; MoCA

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Introduction

Current estimates of cognitive impairment (CI) prevalence vary from 5-8% for dementia [1] to as high as 42% for mild cognitive impairment (MCI) [2,3]. In late 2020, the World Health Organization (WHO) released updated global health estimates of cause-specific mortality with “Alzheimer’s disease and other dementias” ranked as the 7th leading cause of death globally [4]. In the US specifically, it is now the 2nd leading cause of death overall with an incidence of 87.3 per 100,000 people [4].

Though age is the strongest risk factor [3], several other issues have also been associated with an increased incidence of CI and include, but are not limited to, traumatic brain injury (TBI) [5,6], repetitive head impacts [5], post-traumatic stress disorder (PTSD) [7], major depressive disorder (MDD) [8,9], and hearing issues [10].

Different risk factors for CI have been associated with impairments to different cognitive domains. For example, repetitive head injury is associated with deficits in working memory [5], patients with depressive symptoms show reductions in information processing speed [11], and PTSD is associated with impairments to learning and memory [12], information processing [13], and executive function [13].

Early identification and routine assessment of CI can facilitate discussion between the patient and clinician regarding potential interventions (eg, specific attention to modifiable risk factors for CI progression), providing greater opportunity to improve patient outcomes. Additionally, increasing system-wide use of a faster yet more objective method of multi-domain cognitive assessment would enhance the efficiency of neurocognitive testing in clinical practice and be of particular value in large healthcare systems such as the Veteran’s Health Administration (VHA) where a 2017 survey among clinicians (n=123) revealed that 215 different instruments had been used in a single month [14].

The more traditional cognitive assessment methods relying on paper-and-pencil and/or face-to-face interaction have become less suitable for current practice. In addition to the numerous and well-documented downsides to instruments like the Montreal Cognitive Assessment (MoCA), the St. Louis University Mental Status (SLUMS) examination, and the Mini-Mental Status Examination (MMSE) such as time required for administration [3,15, and 16], mediocre sensitivity and retest reliability [17-19], subjective scoring [20,21], and various bias issues [22,23], these tools fall short in meeting the current moment where a shorter duration of direct contact between the clinician and patient might be preferable. Furthermore, the effort to improve access



to care has created a substantial need for alternative methods to assess cognition in patients, however many of the current adaptive solutions for remote testing, either via video-link, telephone, or other means, introduce additional challenges-the most concerning being an inability to fully assess certain cognitive domains [24-27].

Cognivue® is an easy-to-use, automated platform for evaluating and tracking CI. It provides both the patient and clinician with specific feedback for multiple cognitive domains within 10 minutes. Initial research for Cognivue® assessed neural mechanisms of different functional impairments and established a foundation for subsequent pivotal trials examining its psychometric properties and utility as a tool for assessing degree of CI. The reliability of Cognivue® has been established and the agreement between Cognivue® and SLUMS scoring relative to CI impairment classifications has been validated [21], leading to Cognivue® being granted FDA-clearance in 2015 for use as an adjunctive tool to assist in assessing for CI [28].

While trials directly comparing Cognivue® and the MoCA have not been previously published, studies demonstrating good agreement between both Cognivue® and SLUMS scores [21] as well as between SLUMS and MoCA scores [29] are available and provide a reasonable extrapolation of the relationship between Cognivue® and MoCA scoring.

The objective of the current study was to clinically validate Cognivue® via comparison of overall scoring relative to the MoCA test. Additionally, this study sought to assess differences in overall cognitive assessment to determine the test-retest reliability between Cognivue® and the MoCA.

Methods

Study Participants

Adults 55 years of age or older were recruited from assisted- and independent-living facilities and invited via posters and email notifications to enroll in the study. Those who provided informed consent and met the following criteria were enrolled: useful vision in ≥1 eye, conversational hearing in ≥1 ear, useful manual control ≥1 hand, able to comfortably sit upright for ≥30 minutes, and English language conversational competency and basic reading skills.

Study Design

Two testing sessions of 45-60 minutes in duration were conducted approximately one to two weeks apart. The sessions were procedurally identical with various demographic characteristics being recorded followed by the administration of two neuropsychological tests: the standard Cognivue® assessment and the MoCA. All testing was conducted in small private rooms to limit distractions and took place at either the Cognivue, Inc. offices or on-site at one of the independent or assisted living facilities.

Neuropsychological Tests

Cognivue®: Detailed description of Cognivue® and its components has been previously published [21]. Briefly, Cognivue® includes 10 separately scored sub-tests overall, with two assessing visuospatial functioning, four assessing perceptual processing, and four assessing memories. Each of the 10 sub-tests is approximately one minute in duration with the three sub-batteries proceeding in an automated 10-minute sequence. Cognivue® has received FDA-clearance for use as an adjunctive tool to assist in assessing for CI in individuals between 55 and 95 years of age [28]. The classification ranges for Cognivue® are as follows: no CI (≥75), low-mild CI (51-74), and moderate-severe CI (≤50).

Montreal Cognitive Assessment (MoCA): The MoCA is a widely used neuropsychological assessment tool designed to detect MCI. It consists of 12 sub-tasks covering a total of eight cognitive domains and can be administered in 10 minutes [30]. The classification ranges for the MoCA are as follows: no CI (26-30), mild CI (18-25), and moderate-severe CI (0-17).

Statistical Analyses

To better determine clinical validity, correlation analyses were performed for overall scores from visits one and two for each of the neuropsychological tests, as well as between mean overall scores (both visits) on Cognivue® and the MoCA. Additionally, assessment of the test-retest reliability of both neuropsychological tests was performed by regression analysis.

Results

A total of 100 participants were included in the study with both Cognivue® and the MoCA tests being completed in a single testing session. Repeat administration of both tests was conducted approximately two weeks later. All participants completed the MoCA twice, however one participant did not complete Cognivue® during either session and another did not complete Cognivue® during the second session.

Among the overall study population, 78% were classified as having no CI, 22% as having low-mild CI, and none as having moderate-severe CI according to the first administration of the MoCA. Whereas upon initial administration of Cognivue®, a greater proportion of participants were classified as having low-mild CI (30%) or moderate-severe CI (5%) (Table 1). This pattern was reversed at visit 2 where a greater proportion of participants were classified as having no CI and a lesser proportion classified as having low-mild CI according to Cognivue® compared with the MoCA.

A statistically significant positive correlation between overall scores on Cognivue® and the MoCA was demonstrated ($r = 0.38$; $p < 0.001$).

The percent-agreement between visit 1 and visit 2 administrations of the MoCA among participants initially classified as having no CI was 73.1%, whereas retesting of Cognivue® demonstrated an 87.3% agreement (Table 2).

Table 1: Classifications of impairment according to neuropsychological test.

Test	No CI, n (%)	Low-mild CI, n (%)	Moderate-severe CI, n (%)
Visit 1			
MoCA	78 (78)	22 (22)	0 (0)
Cognivue®*	64 (65)	30 (30)	5 (5)
Visit 2			
MoCA	62 (62)	38 (38)	0 (0)
Cognivue®*	77 (79)	21 (21)	0 (0)

*1 participant failed to take Cognivue® at visits 1 and 2, and another did not take Cognivue® at visit 2 CI: cognitive impairment; MoCA: Montreal Cognitive Assessment.

Table 2: Test-retest reliability as measured by percent agreement.

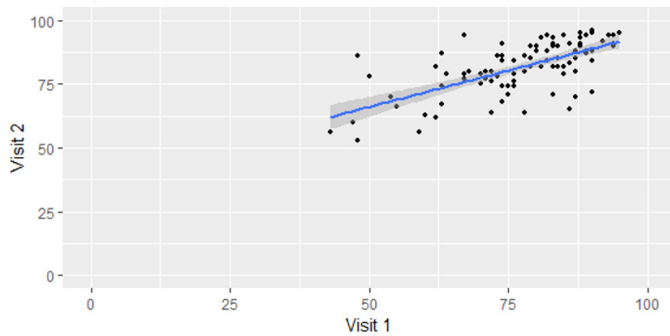
Visit 1	Visit 2		% -agreement
	CI present	No CI	
MoCA	CI present	5	77.3
	No CI	57	73.1
Cognivue®	CI present	22	37.1
	No CI	55	87.3

CI: cognitive impairment; MoCA: Montreal Cognitive Assessment

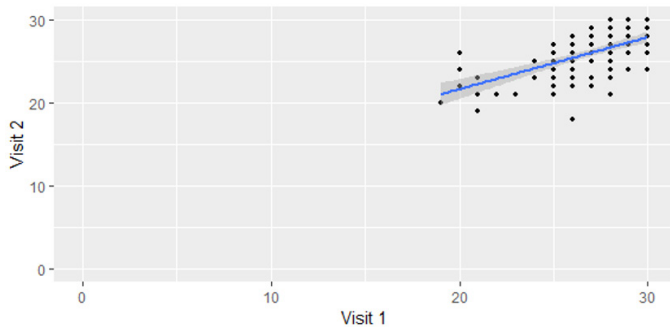


Regression analyses of the test-retest reliability of both neuropsychological tests showed similar scores upon repeat testing for each (Figure 1). A statistically significant regression fit was found for Cognivue® ($R^2 = 0.439$; $r = 0.663$) and the MoCA ($R^2 = 0.378$; $r = 0.615$) (both $p < 0.001$).

A: Cognivue®.



B: MoCA.



MoCA: Montreal Cognitive Assessment

Figure 1: Regression analyses of test-retest reliability.

Discussion

The primary aim of the present study was to clinically validate Cognivue® compared with the MoCA. This study also assessed the test-retest reliability of Cognivue® to ascertain its utility and potential for deployment to large clinical settings where replacement of outmoded neuropsychological instruments might be warranted. To that end, this study provides data collected from 100 participants ≥ 55 years of age from assisted- and independent-living facilities who completed Cognivue® and the MoCA twice.

Overall scores on Cognivue® demonstrated statistically significant positive correlations with MoCA overall scores. Test-retest reliability was higher with Cognivue® compared with the MoCA for participants without CI. And overall, while results of regression analyses of test-retest reliability were statistically significant for each of the tests, findings for Cognivue® revealed a tighter and more linear pattern than observed for the MoCA (Figure 1). These findings align with prior studies establishing the validity and psychometric properties of Cognivue® [21] and demonstrate its utility relative to the MoCA for detecting multi-domain CI.

There is substantial need for a more objective and comprehensive means of efficiently and accurately detecting-and subsequently monitoring-CI in clinical practice. This is especially true for patients with suspected CI from trauma-related causes (eg, TBI), as early identification is integral to minimizing disability potential and

achieving functional recovery.

Certain patient populations are at greater risk for CI. Older patients are at risk for age-related cognitive decline [3], Alzheimer's disease and other dementias are more common among females [31], and service members and veterans are more likely to experience issues which commonly precipitate CI such as concussion and TBI [32-34]. Veterans are also more likely to report multiple TBIs, PTSD, and MDD-all of which are associated with significantly elevated risk of CI [32-35].

The limitations of traditional paper-and-pencil methods of assessing cognitive function have been extensively detailed elsewhere. Such tools often suffer from numerous bias issues [22,23], a high degree of subjectivity in scoring [20,21], weak sensitivity and retest reliability [17-19,36, and 37], and impractical administration times [15,16].

A variety of issues specifically pertaining to the MoCA have also been noted. There is some disagreement as to the most appropriate MoCA cut-off scores, with multiple studies suggesting that a lower cut-off score (eg, 23/30) than the typically used 26/30 would be more accurate for classification of CI [38,39]. The MoCA has consistently demonstrated poor sensitivity for detecting MCI [17,18, and 36], with rates as low as 25% being reported in a 2018 study comparing computerized cognitive assessment to the standard MoCA [40]. Modified versions have fared no better. Pragmatic diagnostic accuracy studies of a short version of the MoCA revealed extremely poor specificity for dementia and only moderate sensitivity and specificity for MCI [41].

Perhaps the most conspicuous issue that has recently emerged is that the MoCA is no longer freely accessible. It has become a proprietary tool which mandates clinicians undergo specific training, become certified, pay a licensing fee, and re-certify every two years [42]. This shift to privatization is similar to other cognitive assessment tools such as the MMSE and Telephone Interview for Cognitive Status (TICS), both of which have declined in use.

Several approaches to better facilitate implementation of routine cognitive assessment into clinical care-especially within the context of a pandemic-have been proposed. However, adaptive methods for assessing cognitive status can present other challenges, such as difficulty in accurately assessing certain cognitive domains [24,25] and being poorly suited to patients with communication or cognitive difficulties [26].

Although the assessment of visuo-perceptual function and visual motor skills is possible via video (ie, telemedicine), such a method can be difficult and lead to lower scores [43], in addition to being dependent on access, connectivity speed, and the patient being prepared with their own materials [25].

Another adaptive approach has been to use existing tools but omit the components unable to be administered by telephone, however impaired patient hearing and loss of visual cues are but a few of the issues potentially inhibiting an accurate assessment of cognition with this approach [25]. Beyond the inherent issues with cognitive assessment via telephone, this mode of delivery may simply not be as effective. Studies comparing face-to-face and telephone versions of the MoCA have shown the latter to be markedly deficient in its ability to assess visuo-executive and complex language subdomains [24]. The issue of hearing impairment may also be of particular relevance for some sites, such as a VHA facility, where there is a high prevalence of service-connected auditory disabilities [14]. Further, telephone versions of assessment tools in particular may be less than ideal as



evidenced by a 2020 survey which measured patient satisfaction and reported 68% of respondents preferred in-person assessment [27].

An electronic version of the MoCA (eMoCA) has been developed and compared to the standard paper-and-pencil version in clinical validation studies [44,45]. Although validity of the eMoCA was determined to be adequate, approximately 1 in 4 study participants had a 3-to-5-point variance in total scores between tests [44]. This effect may also be more pronounced in specific cognitive domains, as a statistically significant difference in visuospatial/executive subscore was shown between the two modalities [45].

It is important to note that although the eMoCA offers automated overall scoring, a clinician specifically trained in its use (and now certified and licensed [42]) is still necessary for administering it since actual patient use of the tablet is only for a small portion of the test. This approach effectively fails to eliminate the inherent subjectivity and potential for bias common in older paper-and-pencil methods. Additionally, because a clinician is still needed for the eMoCA, it results in considerable cost per administration simply by requiring a greater than necessary amount of the clinician's valuable time and attention. Indeed, one of the first studies comparing an electronic version of the MoCA to the paper-and-pencil version found a statistically significant increase in mean administration time, with the electronic version taking 50% longer to complete than the standard version (15.45 minutes vs. 10.27 minutes; $p=0.00001$) [46]. While such results illustrate the inefficiency of the eMoCA, that the mean administration time of the paper-and-pencil version also exceeded 10 minutes further highlights the room for improvement-improvement that another option such as Cognivue® can provide as it is self-administered by the patient after being initiated by clinic support staff and is completed within 10 minutes.

Direct comparison between the MoCA and Cognivue® for identifying and classifying degree of impairment had not been done previously. However, SLUMS cut-off scores and corresponding impairment classifications relative to Cognivue® have been established [21], as they have for the SLUMS and MoCA [29]. And while not explicitly comparable, validation analyses of Cognivue® scores corresponding to established classifications of impairment relative to SLUMS scores demonstrated a positive percent agreement of 56% and negative percent agreement of 95% [21], whereas the MoCA demonstrated a positive predictive value of 52% and a negative predictive value of 88% when compared to the MMSE for detecting CI among a cohort of VHA outpatients referred for neuropsychological testing [47]. The results of the current study underscore the accuracy of such a transitive-based hypothesis.

We recognize that clinicians who routinely assess and monitor cognitive function, but who may be better served with a more robust and objective tool for doing so, may require an even greater rationale than increased comprehensiveness and objectivity for transitioning away from conventional methods such as the MoCA. Frequently, that greater rationale is simply time, as the necessity of maximizing efficiency in a clinical setting is often a key concern. Cognivue® offers a means of assisting in that endeavor. Unlike most traditional methods of neuropsychological testing which require specific competency and must be administered by the provider, computerized instruments can allow other members of the healthcare team to initiate cognitive testing, thus providing a direct benefit to clinicians by allowing for a greater flexibility in their workload [15]. The more timely and efficient assessment and monitoring of potential impairment is likely to be of

substantial benefit to patients as well, providing more opportunity for earlier interventions to address cognitive issues.

Although the current study is limited by its modest sample size, Cognivue® offers a means of assessing for CI that is as effective as the MoCA, while also offering additional features that may confer a positive impact upon the uptake and routine use of cognitive assessments in clinical practice. Specifically, given the significant correlation of overall scores and similar levels of test-retest reliability between Cognivue® and the MoCA, the results of this study support the use of Cognivue® to increase clinical efficiency in detecting and monitoring CI.

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