

Comparison of the Cognivue[®] quantitative assessment tool and SLUMS to classify the risk of cognitive impairment

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ABSTRACT

Background: Cognivue[®] was developed based on clinical experience and NIH funded laboratory research into the neural mechanisms of functional impairment in aging and dementia. The computerized testing tool provides an automated brain functional assessment tool not tied to traditional question & answer testing. Cognivue[®] consists of 3 sub-batteries of 10 separately scored sub-tests presented in a 10 minute automated sequence. These include basic motor & visual ability (visuo-motor and visual salience), perceptual processing (letter, word, shape, and motion discrimination), and memory processing (letter, word, shape, and motion memory).

Objective: To determine the Cognivue[®] cut-off scores corresponding to the St. Louis University Mental Status (SLUMS) 3-level classification for risk of cognitive impairment.

Methods: Adults (age 55–95 y) at risk for age-related cognitive decline or dementia were invited via posters and email to complete the SLUMS and Cognivue[®] tests. Optimization analyses by positive percent agreement (PPA) and negative percent agreement (NPA), as well as by accuracy and error bias were conducted.

Results: 92 subjects, at 5 sites, completed SLUMS (reference standard) and Cognivue[®] tests. Based on SLUMS score, 50% were not impaired (>26), 38% were intermediate (26–21), and 12% were impaired (<21). Analyses using 2 measures of objective function (inaccuracy and error bias), showed that a SLUMS cut-off score of <21 (impairment) corresponded to a Cognivue[®] score of 54.5 (NPA = 0.92; PPA = 0.64). The SLUMS cut-off score of >26 (no impairment) corresponded to a Cognivue[®] score of 78.5 (NPA = 0.5; PPA = 0.79). Based on the results of 2 separate analysis techniques, results showed that Cognivue[®] scores between 55–64 corresponded to SLUMS scores for impairment, and Cognivue[®] scores between 74–79 corresponded to SLUMS scores for no impairment.

Conclusions: Cognivue[®] scores ≤50 provide a conservative standard consistent with cognitive impairment that will avoid misclassification of an individual that is impaired. Cognivue[®] scores ≥75 provide a conservative cut-off consistent with no impairment that will avoid misclassification of an individual that is not impaired.

BACKGROUND

- Many tools for assessing cognitive function decline are limited by issues of measurement efficacy, testing bias, or lack of uptake by clinicians
- Cognivue[®] was developed based on clinical experience and NIH-funded laboratory research into neural mechanisms of functional impairment in aging & dementia
- Cognivue[®] is a computerized testing tool that provides an automated brain functional assessment tool not tied to traditional question & answer testing. It only takes 10 minutes to complete
- Cognivue[®] is FDA-cleared for use as an adjunctive tool to aid in assessing cognitive impairment risk in those 55–95 years of age
 - Not intended to be used alone for diagnostic purposes
- Basic research (neurophysiological studies) created the scientific foundation for Cognivue[®] technology:
 - Learning & memory in development & aging
 - Cortical information processing
 - Influences of multi-stimulus interactions on cortical signal processing (focus on attentional & task effects on cortical neurons)
- Clinical research on aging & dementia contributed to the experimental foundations of Cognivue[®] technology:
 - 21 published studies, conducted predominantly at University of Rochester Medical Center with NIH funding or at the company (Cognivue, Inc.)

METHODS

Purpose: Compare Cognivue[®] quantitative assessment tool & SLUMS to determine cut-off scores to classify risk of cognitive impairment

Subjects: Adults (55–95 y) from assisted & independent-living communities, at risk for age-related cognitive decline or dementia, invited via posters and email to complete SLUMS and Cognivue[®] tests

Tests:

- Cognivue[®] quantitative assessment tool includes (Table 1):
 - 3 sub-batteries (visuo-motor ability, perceptual processing, & memory processing) presented in automated sequence over 10 minutes

METHODS (CONT.)

Tests (cont.):

- SLUMS (reference standard)
 - 11-item questionnaire with scores ranging from 0 to 30
 - Designed to measure orientation, memory, attention, & executive functions
- Stratification: >26 = unimpaired; 26–21 = mild cognitive impairment; <21 = impaired

Analyses: 2 different optimization methods used to determine cut-off values for Cognivue[®] scores corresponding to SLUMS classifications for risk of impairment

- 1st analysis used minimization algorithm to optimize PPA & NPA between Cognivue[®] & SLUMS scores in the objective function:
 - NPA = (true negative [TN]/false positive [FP] + TN) x 100%
 - PPA = (true positive [TP]/false negative [FN] + TP) x 100%
- 2nd minimization algorithm used accuracy & error bias measures in the objective function:
 - Inaccuracy = 1 - (TP + TN/total)
 - Error bias = contrast ratio (difference/sum) of FPs & FNs

Table 1. Components of Cognivue[®] quantitative assessment tool

Sub-battery & Sub-test	Description of assessment
Basic motor & visual ability	
Adaptive motor control test	<ul style="list-style-type: none"> Visuo-motor responsiveness using speed & accuracy measures Ability to control rotatory movement of CogniWheel[™] in response to rotational visual stimuli
Visual salience test	<ul style="list-style-type: none"> Basic visual processing functions Ability to identify wedge filled by random pattern of black & white dots shown on neutral (gray) background
Perceptual processing	
Letter Discrimination	<ul style="list-style-type: none"> Measures perceptual processing of different forms, despite addition of increasing amounts of clutter Discriminate real English letters from variety of non-letter, letter-like shapes
Word Discrimination	<ul style="list-style-type: none"> As above Discriminate real 3-letter words from 3-letter non-words
Shape Discrimination	<ul style="list-style-type: none"> As above Discriminate a circle filled with a common shape from rest of display filled with other common shapes
Motion Discrimination	<ul style="list-style-type: none"> As above Discriminate a circle filled with 1 direction of dot motion from rest of display filled with another direction of dot motion
Memory processing	
Letter memory	<ul style="list-style-type: none"> Memory using specialized sets of visual stimuli Ability to recall which letter presented as pre-cue, and then select that letter from display of alternative items, despite addition of increasing amounts of clutter Select correct letter of English alphabet
Word memory	<ul style="list-style-type: none"> As above Select correct 3-letter word
Shape memory	<ul style="list-style-type: none"> As above Select correct shape
Motion memory	<ul style="list-style-type: none"> As above Select correct direction of motion

RESULTS

- 92 subjects total, at 5 sites, completed both SLUMS & Cognivue[®] tests
- Scores for participants shown in Figure 1, and based on SLUMS score:
 - 50% not impaired (>26)
 - 38% intermediate (26–21)
 - 12% impaired (<21)

1st analysis

- SLUMS impairment cut-off score (<21) minimized to 0.297 at Cognivue[®] cut-off score of 63.5 (NPA = 0.80; PPA = 0.79)
- SLUMS unimpaired cut-off score (>26) minimized to 0.324 at Cognivue[®] cut-off score of 73.5 (NPA = 0.68; PPA = 0.67)

RESULTS (CONT.)

Figure 1. Scatterplot of SLUMS & Cognivue[®] scores for 92 study participants

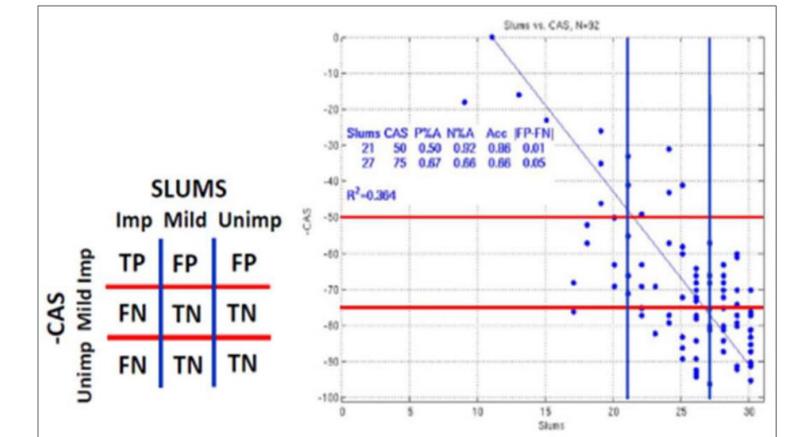


Table to left of scatter plot provides key for relating plot to participant classifications. Above upper horizontal red line shows Cognivue[®] scores <50, to left of the left vertical blue line shows SLUMS scores <21 denoting high risk of impairment. Below bottom horizontal red line shows Cognivue[®] scores >75, to right of the right vertical blue line shows SLUMS >27 denoting low risk of impairment. Classification analyses results included in table enclosed in scatter plot. ACC: accuracy; CAS: Cognivue[®] assessment system; FN: false negative; FP: false positive; N%A: negative percent agreement; P%A: positive percent agreement; SLUMS: St. Louis University Mental Status; TN: true negative; TP: true positive

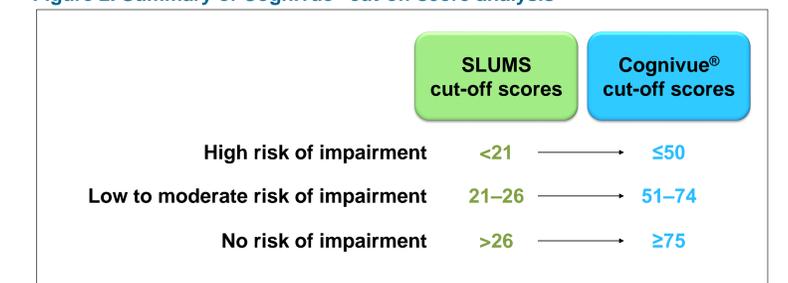
2nd analysis

- SLUMS cut-off score <21 (impairment) = Cognivue[®] score 54.5 (NPA = 0.92; PPA = 0.64)
- SLUMS cut-off score >26 (no impairment) = Cognivue[®] score 78.5 (NPA = 0.5; PPA = 0.79)

Combined findings

- Based on 2 separate analysis techniques, it was determined that:
 - Cognivue[®] scores of 55–64 = SLUMS scores for impairment (0–20)
 - Cognivue[®] scores of 74–79 = SLUMS scores for no impairment (27–30)
- Cognivue[®] cut-off scores (Figure 2) of:
 - ≤50 provide a conservative standard consistent with cognitive impairment that will avoid misclassification of an individual that is impaired
 - ≥75 provide a conservative cut-off consistent with no impairment that will avoid misclassification of an individual that is not impaired
- Cognivue[®] scores between ranges classifying impairment & unimpairment = SLUMS scores of 21–26

Figure 2. Summary of Cognivue[®] cut-off score analysis



CONCLUSIONS

- Cognivue[®] scores ≤50 and ≥75 consistent with conservative standards for impairment and no impairment, respectively
- Cognivue[®] is an easy to use, computerized cognitive assessment aid, which provides a useful adjunctive part of a full medical work-up for cognitive impairment

INDICATIONS FOR USE: Cognivue[®] testing is indicated as an adjunctive tool for evaluating perceptual and memory function in individuals aged 55–95 y. It is not intended to be used as a stand-alone device to identify the presence or absence of clinical diagnoses. Cognivue[®] is intended to be used by medical professionals qualified to interpret the results of a cognitive assessment examination. This study was supported by Cognivue, Inc.