Advancing Computerized Cognitive Assessment with Cognivue®: Enhanced Normative Range Data Sets from a Diverse Population Improve Sensitivity and Patient Profiling

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KEY TAKEAWAY: Cognitive assessment with Cognivue *Clarity*® among a diverse population of study participants enhances normative range data sets to improve sensitivity and patient profiling.

BACKGROUND

Clinical trials run in the United States tend to include study cohorts that are disproportionately composed of patients who are older, non-Hispanic White, and highly educated.[1] Though the median age of a US resident is 38.9 years, a survey of US participants in clinical trials found an average age of 60.7.[1,2] Research has also shown racial and ethnic minorities comprise 39% of the US population, but account for roughly 2% to 16% of clinical trial participants by some estimates.[3] A similar gap is seen in education levels; though 63% of US residents have less than a bachelor's degree, research has found that 55.8% of participants in clinical trials had a college or advanced degree.[1,4]

In the field of cognitive research, recruitment of non-diverse study populations risks limiting our understanding of the uneven burden of cognitive impairment.[5] A 2020 paper assessing the cognitive impairment landscape found that though disadvantaged subgroups (i.e. Black and/or those with lower levels of education) have shorter lifespans, they experience a younger age of onset, higher lifetime risk, and more years with cognitive impairment.[5]

The present study sought to recruit historically underserved and underrepresented populations to undergo computerized cognitive assessment with the Cognivue *Clarity*® and Cognivue *Thrive*® devices. The study's aim was to collect additional normative range data that could be used to further enhance sensitivity and improve patient profiling in the field of cognitive assessment.

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 2).

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.

Figure 2. Page 1 of the Cognivue *Clarity*® report.

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 Cognivue *Clarity*® device's 10-minute test and the Cognivue *Thrive*® device's 5-minute test were administered to assess scoring and normative ranges in addition to validation comparison against performance on accepted gold-standard neuropsychological test batteries within the diverse study cohort.

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 from 11 states. Participants had a mean age of 50.2+16.3 years (range 18-89); 59.2% were female; and 51.8% had 12 years or less of education. Importantly, 37% of participants recruited were underrepresented minorities with 28% of subjects identified their race as Black or African American; American Indian or Alaska Native; Asian, Native Hawaiian or Pacific Islander, and 12% reporting Hispanic ethnicity.

Cognivue *Clarity*® detected differences across the ranges among cohorts stratified by age, race, and education level. A strong relationship was seen between Cognivue *Clarity*® mean score and age (Figure 3). Those participants >70 years of age had significantly lower mean scores than those 40 to 69 and those 18 to 39 (both comparisons *P*<0.001). Participants aged 18 to 39 had significantly higher mean scores than those age 40 to 69 (*P*=0.002; Figure 4).

White participants had significantly higher mean scores with Cognivue *Clarity*®in comparison with Black participants (77.8 [SD=13.0] vs 71.9 [SD=16.7], respectively; *P*<0.001; Figure 5).

Significant differences were seen between participants stratified by educational attainment, with the greatest differences occurring between participants with less than a high school diploma (65.4 [SD=16.1]; and those with a Bachelor's degree (80.3 [SD=11.8]) or a Master's degree (79.6 [SD=12.2]; *P*<0.001 for both comparisons with those without a high school diploma; Figure 6). No effect was seen when stratifying participants by gender or by ethnicity.
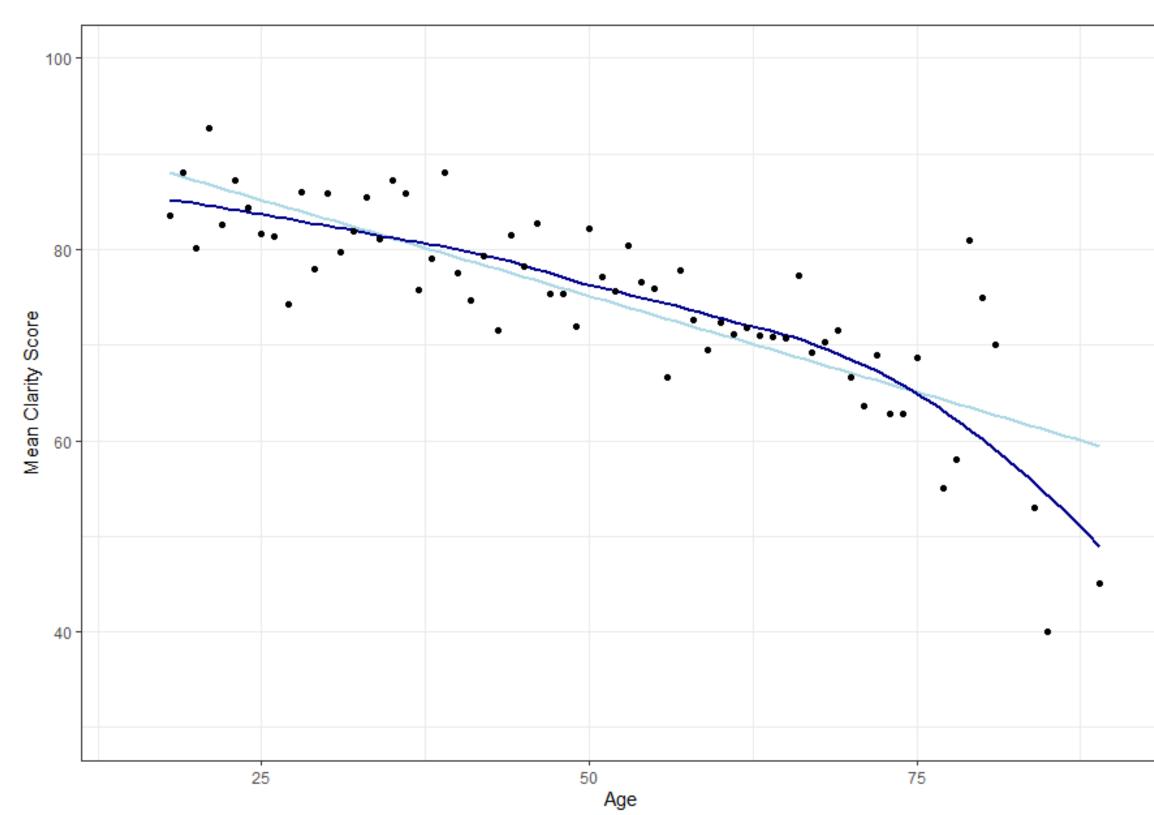

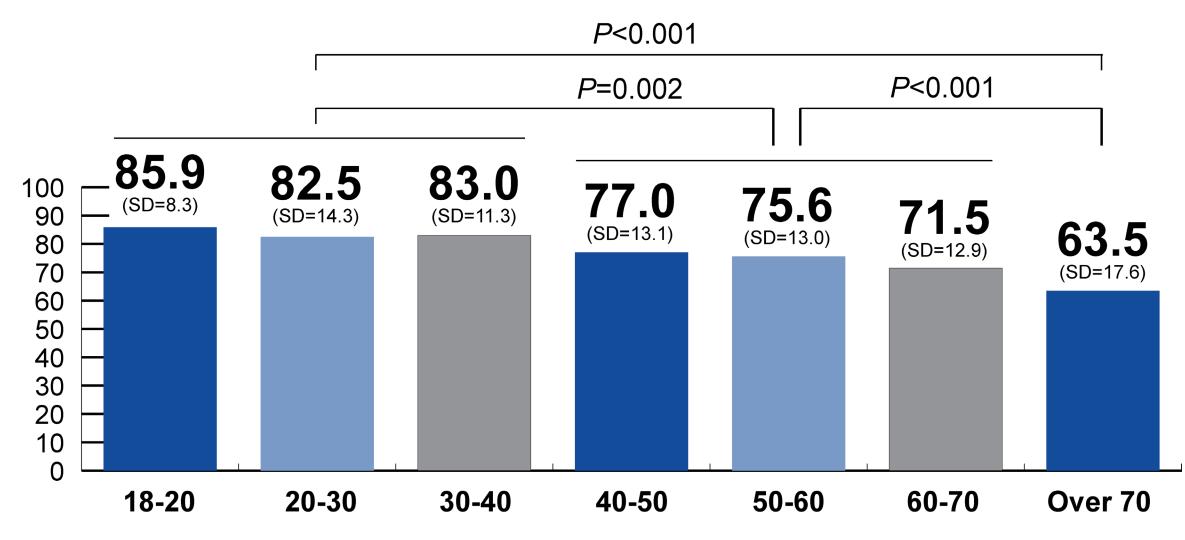**Figure 3. Plot of mean Cognivue *Clarity*® score against age.**

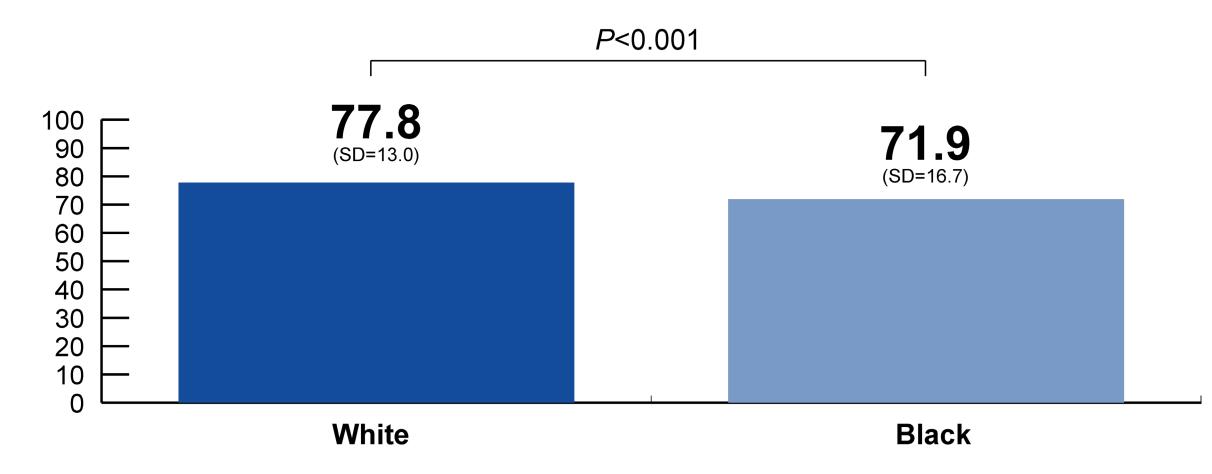**Figure 4. Mean Cognivue *Clarity*® score stratified by age.**

Figure 5. Mean Cognivue *Clarity*® score stratified by race.
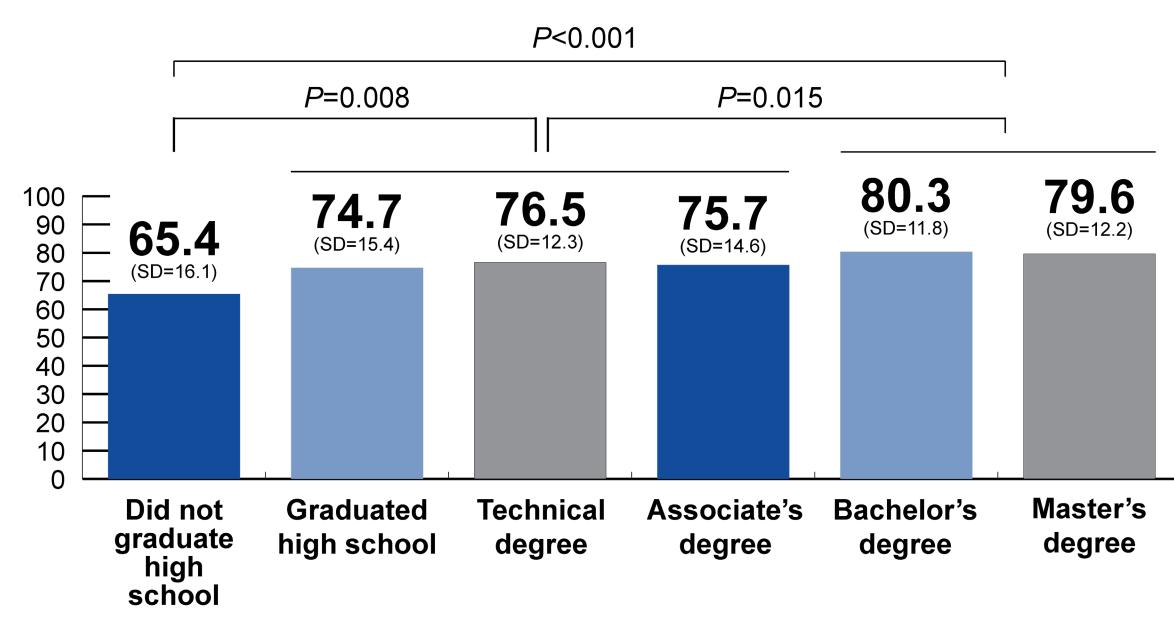

Figure 6. Mean Cognivue *Clarity*® score stratified by educational attainment.

CONCLUSIONS

This study, which recruited a patient population that was diverse in age, race, and level of educational attainment, enhances the normative ranges in the field of cognitive assessment. The refined normative ranges generated in this study will result in a more precise scoring system for future Cognivue research, and offer valuable insights for clinicians, researchers, and practitioners. More diverse normative ranges enable more precise interpretations of testing and test results, enhancing the accuracy of a brief cognitive assessment that can be used both in clinical practice for early detection and in research for clinical trial eligibility. By providing data sets stratified across participants in multiple ways, this study provides a broader perspective, enabling the establishment of more comprehensive and inclusive norms that may contribute to more equitable and effective assessments and treatment strategies. These normative ranges are part of Cognivue's aim to develop a gold standard for cognitive evaluation in diverse populations.

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