Qr8 HEALTH | Setting the standard in digital cognitive assessment

From Validation to Value:

# Evaluating the Efficacy of Qr8 Cognition Suite in Clinical Settings

**This white paper draws on the work of Stephen M. Rao et al., as detailed in their study, 'Cleveland Clinic Cognitive Battery (C3B): Normative, Reliability, and Validation Studies of a Self-Administered.' Their foundational research has significantly informed the development of this paper.**

## Introduction

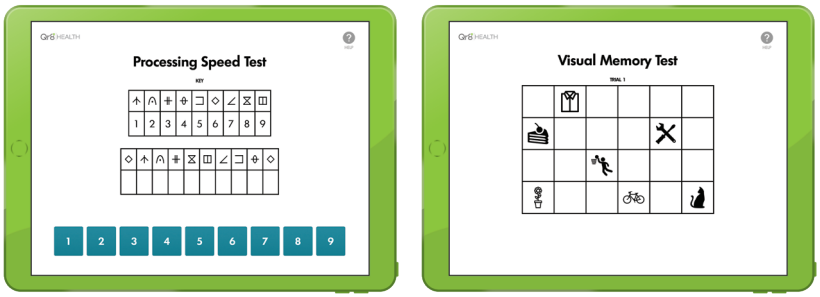
Broad agreement exists among providers that the lack of digital innovation in dementia diagnosis has left a majority of patients undiagnosed and untreated, a critical oversight in modern healthcare where integrating advanced digital tools could dramatically alter outcomes.[1] Estimates suggest that 76% of dementia patients remain undiagnosed. Among those, 30-40% could experience improvement—or even reversal—of symptoms with early detection.[2] While the diagnosis gap is well understood, the underlying cause of this clinical shortcoming in advanced healthcare is not well characterized.

After over a decade of development and rigorous testing, Qr8 Cognition Suite, an innovative digital neuropsychological assessment developed by a team at Cleveland Clinic, is now setting the standard of care for individuals 65 and older. It is a patient self-guided and iPad-based solution that offers an efficient and user-friendly approach to cognitive screening in primary care settings.

**76% of dementia patients remain undiagnosed.**

In the most recent study of Qr8 Cognition Suite published in the Journal of Alzheimer's Disease, researchers focused on the effectiveness and validation of Qr8 Cognition Suite within primary care.[3] The assessment integrates a Processing Speed and Visual Memory test.

- **Processing Speed Test:** Patients pair numbers with symbols using a uniquely generated key to assess information processing speed and working memory.
- **Visual Memory Test:** Patients recall and recreate a unique pattern of icons on a grid to assess spatial and verbal memory.




This overview summarizes the validity study of Qr8 Cognition Suite, highlighting its effectiveness in real-world clinical settings.

The findings confirm that Qr8 Cognition Suite:

- detects early signs of cognitive disease
- enhances cognitive assessment in primary care

# Objectives

The study's objectives were to evaluate the efficacy and validity of Qr8 Cognition Suite as a patient self-guided, in-office assessment tool. Researchers formulated targeted inquiries to gauge its reliability and practical utility, concentrating on:

- performance expectations
- consistency across evaluations
- testing conditions
- patient autonomy
- the earliest clinical signs of cognitive impairment

**Key questions addressed in the study included:**

1. How do we expect someone to perform on these tests given their age, education, etc.?
2. Will someone score about the same on the test if they take it multiple times, and does it matter how many times they've taken it before?
3. Does the patient need to be in a quiet area for the results to be valid?
4. Can the patient be in a busy primary care setting, and do they find the tests to be valuable?
5. Can you really identify patients who are showing early signs of dementia?

# Methodology

Researchers employed various methodologies to gather data and assess the tool's performance. These methodologies included normative data collection, reliability testing, comparative analysis, environmental testing, and practical deployment in real-world settings, specifically primary care and clinical environments. The following details outline each step of the process:

- **Normative Data Collection**: A stratified sample of 428 healthy adults age 18-89 was used to generate regression-based norms.
- **Reliability Testing:** A subset of 30 elderly participants was assessed for test-retest reliability and practice effects over a two-week interval.
- **Comparative Analysis:** 30 patients with MCI and 30 demographically matched controls were assessed to evaluate the tool's discriminative abilities.
- **Environmental Testing:** The tool's performance was tested in both distracting and quiet conditions among 30 healthy adults.
- **Practical Deployment:** The tool was administered to 470 consecutive primary care patients as part of routine clinical care, evaluating its practical integration and user satisfaction.

**Normative Data Collection** | **Reliability Testing** | **Comparative Analysis** | **Environmental Testing** | **Practical Deployment**

# Results

The study yielded significant insights into the performance of Qr8 Cognition Suite. Each research question was thoroughly investigated, revealing important findings that demonstrate the tool's capabilities in various aspects of cognitive assessment. The results provide a comprehensive understanding of how Qr8 Cognition Suite performs in healthcare settings, offering valuable information for clinicians seeking an easy-to-implement assessment solution.

**1. How do we expect someone to perform on these tests, given their age, education, etc.?**

To address the question of expected performance on the cognitive tests based on demographic variables such as age, education, sex, and race effectively, researchers developed regression-based models using data from a normative sample. This sample was comprised of 428 healthy individuals at four diverse centers, ensuring a broad demographic range that reflects the general population.

Age significantly predicts performance. The Processing Speed Test and Visual Memory Test within Qr8 Cognition Suite effectively predict demographics, showcasing age-related influences on cognitive performance.


Indirect correlation between demographic prediction (age) and cognitive ability on test performance.

## Processing Speed Test:

- **Description:** Observes a decline in the number of correct responses as age increases, which is typical as younger individuals generally perform tasks more quickly than older individuals.
- **Interpretation:** The regression line on the graph models expected performance declines as age increases, aiding in setting realistic benchmarks for speed-related cognitive tasks.

## Visual Memory Test:

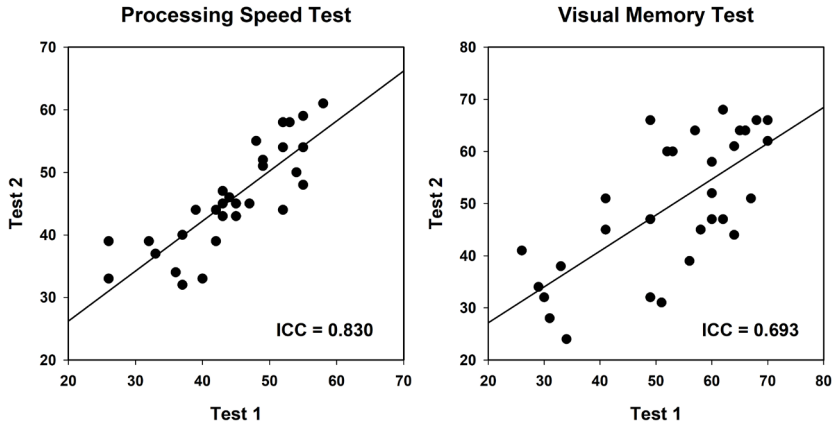
- **Description:** Like the processing speed graph, this shows a decline in performance with age.
- **Interpretation:** The regression line indicates a decrease in visual memory capability as age increases, a common trend in cognitive aging.

In addition to age alone, race, sex, and education were also significant predictors and incorporated into the model. A linear regression model was developed to analyze correlations between test performance and each demographic factor, enabling researchers to establish expected relationships. These insights facilitate precise demographic corrections and deliver individualized results, enabling physicians to assess whether a patient's performance aligns with their cohort's norms.

## 2. Will someone score about the same on the test if they take it multiple times, and does it matter how many times they've taken it before?

To evaluate the test-retest reliability and assess the impact of practice effects in Qr8 Cognition Suite, researchers conducted a study with 30 healthy older patients. Each participant completed both the Processing Speed Test and the Visual Memory Test twice, with a two-week interval between sessions.

The results, illustrated through scatter plots, reveal high reliability for both tests. The Processing Speed Test showed an Intraclass Correlation Coefficient (ICC) of 0.830, indicating strong consistency in test scores across time. Similarly, the Visual Memory Test demonstrated good reliability with an ICC of 0.693. These findings indicate that scores on these cognitive tests exhibit stability over time, showing minimal susceptibility to variations from repeated testing. This confirms the tests' reliability for consistent use in clinical assessments.




High reliability on both Processing Speed Test and Visual Memory Test across time.

**Integrated Demographic Variables and Significant Predictors**

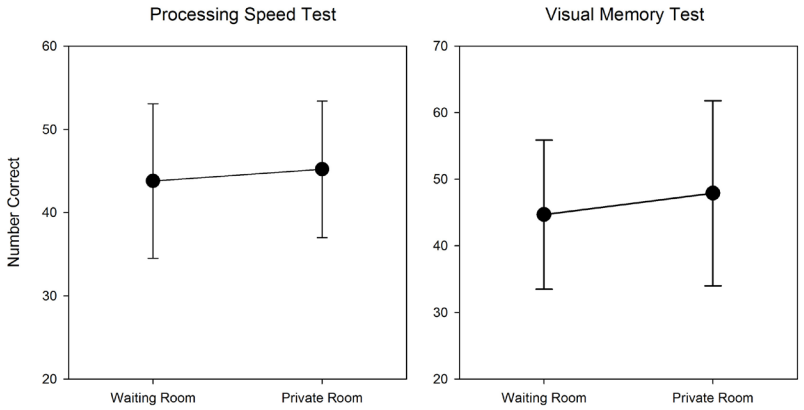
## Age, Race, Sex, Education

Linear regression assessed the validity of the test by analyzing and adjusting scores for correlated demographic factors such as age, education, race, and sex, highlighting the tool's sensitivity to these variables.

### 3. Does the patient need to be in a quiet area for the results to be valid?

To assess the validity of cognitive screening in varying environmental conditions, a study was conducted with 29 healthy older patients who performed both the Processing Speed Test and the Visual Memory Test in two different settings: a private room and a waiting room. The tests were administered one hour apart in a random order of locations to mitigate any order effects.

The findings revealed minimal difference in performance across the two environments for the Processing Speed Test and 0.09 for the Visual Memory Test. These results suggest that both tests can yield reliable results even in potentially distracting environments, supporting their use in diverse clinical settings without the strict requirement for a controlled, quiet space. This flexibility in testing conditions enhances the practicality and adaptability of Qr8 Cognition Suite for real-world clinical applications.




> Validated reliability in test results in distracting environments and clinical settings.

### 4. Can patients complete this on their own, and do they find the tests to be valuable?

In a comprehensive evaluation involving over 500 patients age 65 years and older, Qr8 Cognition Suite's usability and value were rigorously assessed within a primary care setting. The results were highly positive.

These findings affirm that Qr8 Cognition Suite not only meets the practical needs of elderly patients but also serves as a crucial tool for physicians dedicated to identifying and supporting patients with dementia. The high rates of usability and clear instructions enhance patient engagement, while the strong affirmation of the assessment's importance reflects a proactive attitude towards cognitive health among older adults. This combination of ease of use and perceived value supports the integration of Qr8 Cognition Suite into routine clinical practice, ensuring that cognitive assessments are both accessible and impactful.

| MEASURE | RESULT |
|---|---|
| **Usability** | **93.2%** of those who completed the tests encountered no frustrations or usability issues, demonstrating the user-friendliness of Cognition Suite |
| **Clarity of Instructions** | **98.4%** of participants found the test instructions to be clear, ranging from somewhat to very clear, indicating that the suite's guidance is effectively communicated to its users. |
| **Perceived Importance** | **93.9%** of the patients believed it was somewhat to very important for their doctor to test their memory and thinking abilities, highlighting the value they place on cognitive assessments. |
| **Perceived Value of Routine Testing** | **82%** of the participants thought it was somewhat to very important that their memory and thinking be assessed every time they visit their doctor, underscoring the need for regular cognitive health monitoring. |

### 5. Can you really identify patients who are showing early signs of dementia?

The critical question of whether early signs of dementia can be accurately identified is addressed through a comparative analysis of Qr8 Cognition Suite's testing modalities against the commonly used Mini-Cog test. This comparison reveals significant differences in their ability to discern Mild Cognitive Impairment (MCI) from healthy cognitive aging.

**16-19% of patients age 65 and above are afflicated with dementia.[4]**


1. **Usability 92%**
2. **Clarity of Instruction 98.4%**
3. **Perceived Importance 93.9%**
4. **Perceived Value of Routine Screening 82%**

## Comparative Analysis of Diagnostic Accuracy

Thirty healthy controls (HC) and 30 patients with diagnosed MCI were tested using both the Mini-Cog and Qr8 Cognition Suite (PST and VMT).

The charts below show how the evaluations compared in predicting these participant groups. A perfect score would show 30 in both green boxes and correspond to a Youden Index of 100%.

| Mini-Cog | | Diagnosed | |
|---|---|---|---|
| | | MCI | HC |
| Predicted | MCI | 13 | 0 |
| | HC | 17 | 30 |

Sensitivity: 45%
Specificity: 100%
Youden Index: 45%

| PST & VMT | | Diagnosed | |
|---|---|---|---|
| | | MCI | HC |
| Predicted | MCI | 27 | 5 |
| | HC | 3 | 25 |

Sensitivity: 90%
Specificity: 83%
Youden Index: 73%

**Sensitivity and Youden Index comparison**

## Results Summary

| MINI-COG | MINI-COG | COGNITION SUITE (PST & VMT) |
|---|---|---|
| **Effectiveness** | The Mini-Cog test correctly identified 13 MCI patients but failed to recognize 17, showing a sensitivity of 45%.<br><br>It correctly identified all 30 healthy controls (specificity of 100%) but misclassified 17 MCI patients as healthy. This suggests that while the Mini-Cog is highly specific, it lacks the sensitivity needed to detect early, subtle cognitive declines, risking progression of MCI before it is caught. | Qr8 Cognition Suite correctly identified 27 MCI patients and misclassified only five (5) healthy controls, reflecting a sensitivity of 90%.<br><br>It accurately identified 25 healthy controls and misclassified only 3 MCI patients as healthy, showing a specificity of 83%. |
| **Metrics** | The Mini-Cog demonstrated a Youden Index of 45%, indicating moderate effectiveness in distinguishing between MCI and healthy controls. However, its low sensitivity limits its utility as an early diagnostic tool. | With a Youden Index of 73%, Qr8 Cognition Suite proved significantly more effective in detecting early signs of dementia, confirming its superiority over the Mini-Cog in early dementia screening. |

This comparative data underscores Qr8 Cognition Suite's enhanced ability to detect MCI, crucial for initiating early and potentially more effective interventions. In contrast, the Mini-Cog's lower sensitivity indicates a risk of missing early-stage MCI, suggesting the need for more refined screening tools—like those provided by Qr8 Cognition Suite—in primary care settings.

# Summary: Findings and Benefits

This study reinforces previous research on the effectiveness of Qr8 Cognition Suite in assessing cognitive impairment.

- **Accuracy and Efficiency**:
  Qr8 Cognition Suite provides reliable, demographic-corrected cognitive assessments that are critical for personalizing patient care.

- **Usability and Patient Satisfaction**
  With its patient self-guided format and minimal need for professional oversight, Qr8 Cognition Suite promotes greater patient independence and integration into busy clinical settings. Feedback from users has highlighted the ease of use and non-intrusive nature of the test, factors vital for patient compliance and satisfaction.

- **Adaptability**
  Qr8 Cognition Suite's robust performance in various environments, including noisy settings such as waiting rooms, ensuring its versatility and adaptability and making it a suitable option for diverse real-world clinical scenarios.

**Qr8 offers a dependable, scientifically validated, and user-friendly approach to cognitive assessment.**

# Conclusion

Qr8 Cognition Suite represents a pioneering digital solution for early detection of cognitive impairment in primary care. Tailored to meet the practical requirements of healthcare providers and patients alike, it offers a dependable, scientifically validated, and user-friendly approach to cognitive assessment. By enabling timely diagnosis and intervention for conditions such as MCI and Alzheimer's Disease, Qr8 Cognition Suite:

- **facilitates early detection and personalized interventions** to mitigate risk factors and improve cognitive health outcomes.
- **integrates advanced algorithms and user-friendly interfaces** to advance cognitive assessment technology, enhancing diagnostic accuracy in clinical settings.
- **represents a proactive shift** towards personalized and preventive healthcare strategies, emphasizing tailored patient management plans aimed at improving long-term health outcomes.

In doing so, Qr8 Cognition Suite stands at the forefront of transforming cognitive healthcare delivery, fostering early intervention and personalized care pathways to enhance overall patient well-being.

**Footnotes**

1 Based on internal data compiled from multiple internal sources and studies

2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7392084/?trk=public_post_comment-text

3 Stephen M. Rao et al., "Cleveland Clinic Cognitive Battery (C3B): Normative, Reliability, and Validation Studies of a Self-Administered Computerized Tool for Screening Cognitive Dysfunction in Primary Care," Journal of Alzheimer's Disease 92 (Pre-press February 20, 2023): 1051-1066.

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Qr8 HEALTH

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**About Qr8 Health**

Qr8 Health is a digital health company pioneering the use of patient self-administered, clinically-validated digital outcome assessment tools for the measurement of neurological and motor function. Our vision is to enable transformational improvement in patient care by providing digital health tools for collecting highly standardized clinical data in any medical or home setting where it has not been possible or practical before.

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