

# The Virtual Reality Functional Capacity Assessment Tool (VRFCAT): A Normative and Standardization Study

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**What is the Methodological Question Being Addressed?** How the interpretability of individual- and group-level scores on an objective, performance-based functional capacity task can be enhanced by establishing population-based norms.

**Introduction** Treatment developers, regulators, and payers have increasingly viewed improvement in the capacity to function independently as an important outcome for many psychiatric and neurological conditions. The VRFCAT is a tablet-based measure that simulates real-world situations using immersive, interactive gaming technology. It offers many practical and scientific advantages over traditional functional capacity measures for global clinical trials in schizophrenia and other conditions. A challenge to date for all functional capacity measures has been the lack of normative information. To facilitate interpretation of performance-based functional capacity assessment, normative data were obtained from a representative American community sample.

**Methods** 650 healthy individuals from the general community were evaluated. Recruitment was stratified by age in decades ranging from 20 to 80+, sex, race, and education. We sampled most of our participants from ages relevant for studies of schizophrenia and early-onset challenges in aging, recruiting twice as many participants in age ranges of 40-50 and 50-60 as younger and older participants. Diagnostic, cognitive, and functional capacity assessments were administered in a single session. Three sets of analyses were conducted. First, for Total Adjusted Time, the primary outcome variable, and for secondary outcome variables, age, sex, race, and education effects on performance were examined. Second, regression-based norms were developed. Third, these normative standards were evaluated in an existing sample of 166 schizophrenia patients to evaluate patient-control differences across the life span.

**Results** Within each decade, there were approximately equal proportions of males and females, educational attainment levels (60% or more having at least high school education), and race subgroups (30% African American). For Total Adjusted Time, we found effects of age,  $F(6,596)=30.84$ ,  $p<.001$ , educational attainment,  $F(1,601)=4.63$ ,  $p=.032$ , and race ( $1, 601$ )= $15.90$ ,  $p<.001$ . There was no significant effect of sex,  $F(1,601)=0.46$ ,  $p=.50$ , or 2- or 3-way interactions. Participants in their 20's and 30's performed significantly faster ( $p<.05$ ) than those in their 40's and older; from age 60 on, each successive decade was associated with significantly ( $p<.05$ ) slower performance. Standardized scores were derived from multivariate regression models, allowing an

individual's score to be adjusted for demographic characteristics, and a program was developed to compute T-scores. When normative T-scores were examined in the schizophrenia sample, patients showed a relative impairment of 1.9 to 2.4 SD for each decade from 20-69 years after demographic (education, race) adjustments.

**Conclusion** In a large, representative sample of healthy adults, performance-based functional capacity measurement was sensitive to age effects and other demographics. We developed regression-based norms to generate demographically-adjusted T-scores, which can be applied to ages ranging from 20-80+. When applied to schizophrenia, patients showed equivalently impaired performance across the age span. The availability of functional capacity norms adds clinical meaningfulness to study results and makes it easier to communicate findings across settings, which are key benefits for global clinical trials. This functional capacity assessment approach was designed to be amenable to cross-cultural use to increase the accessibility of standardized functional capacity measurement. Through rigorous translation and cultural adaptation methods, it has been adapted into over 25 languages and it is currently being used in 32 countries as part of a phase 3 schizophrenia program.

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Dr. Keefe is the owner of VeraSci, a company that has been paid to provide various services over the past 3 years for over 100 entities, most of which are pharmaceutical companies. VeraSci is the copyright holder of the VRFCAT and the Brief Assessment of Cognition (BAC). He has served as a consultant or Ad Board member for Merck, Akili, Avanir, GE Health, GW Pharma, Karuna, SK Life Sciences, Boehringer-Ingelheim, Jazz Pharma, Acadia, Biogen.

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