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Validation of the tablet-administered Brief Assessment of Cognition (BAC App)



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ARTICLE INFO

Article history: Received 26 April 2016 Received in revised form 3 October 2016 Accepted 5 October 2016 Available online 19 October 2016

Keywords: Schizophrenia Cognition App Cognitive test Tablet assessment BACS

ABSTRACT

Computerized tests benefit from automated scoring procedures and standardized administration instructions. These methods can reduce the potential for rater error. However, especially in patients with severe mental illnesses, the equivalency of traditional and tablet-based tests cannot be assumed. The Brief Assessment of Cognition in Schizophrenia (BACS) is a pen-and-paper cognitive assessment tool that has been used in hundreds of research studies and clinical trials, and has normative data available for generating age- and gender-corrected standardized scores. A tablet-based version of the BACS called the BAC App has been developed. This study compared performance on the BACS and the BAC App in patients with schizophrenia and healthy controls. Test equivalency was assessed, and the applicability of paper-based normative data was evaluated. Results demonstrated the distributions of standardized composite scores for the tablet-based BAC App and the pen-and-paper BACS were indistinguishable, and the between-methods mean differences were not statistically significant. The discrimination between patients and controls was similarly robust. The between-methods correlations for individual measures in patients were r > 0.70 for most subtests. When data from the Token Motor Test was omitted, the between-methods correlation of composite scores was r = 0.88 (df = 48; p < 0.001) in healthy controls and r =0.89 (df = 46; p < 0.001) in patients, consistent with the test-retest reliability of each measure. Taken together, results indicate that the tablet-based BAC App generates results consistent with the traditional pen-and-paper BACS, and support the notion that the BAC App is appropriate for use in clinical trials and clinical practice.

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1. Introduction

Cognitive deficits in schizophrenia can be severe and devastating to patients and their families. People with schizophrenia underperform controls by an estimated one and a half to two standard deviations on multiple aspects of cognitive functioning (Nuechterlein et al., 2008). Cognitive impairment in schizophrenia is an important unmet medical need, and is the target of numerous treatment efforts (Keefe et al., 2011a,b, 2013; Wykes et al., 2011; Goff et al., 2011).

A variety of methods have been used to measure cognition in patients with schizophrenia in clinical practice and clinical trials. Standard neuropsychological tests have been used for decades to measure cognition in patients with schizophrenia. These standard clinical measures

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have the benefit of proven methodologies and patient-rater interaction, which can be flexible based upon the needs of the patient and the clinical situation. In schizophrenia research, these measures have demonstrated sensitivity to impairments and consistent correlations with functional outcomes, which has been one of the key driving forces of interest in cognition as a treatment target.

Compared to traditional pen-and-paper neurocognitive assessments, computerized tests carry the potential to reduce rater error by leveraging automated scoring algorithms and standardized administrator instructions. However, especially in patients with severe mental illnesses and neurologic disorders, computerized tests can be difficult to implement due to the rigidity of their administration procedures and reduced adaptability to individual patient needs and understanding. These limitations have sometimes resulted in increased rates of missing data for computerized tests relative to standard paper methods (Silver et al., 2006; Harvey et al., 2013; Keefe et al., 2007a,b; Iverson et al., 2009). Further, because computerized tests tend to be more abstract

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than paper tests with physical materials, severely impaired populations may struggle to understand test requirements (Iverson et al., 2009).

One potential solution for impaired populations that may combine the strengths of both traditional pen-and-paper and computerized testing platforms is a streamlined tablet-based interface that combines the flexibility and human interaction of standard methods with the consistency and automaticity of computerized methods. Tablet-based versions of other standard cognitive assessment instruments such as the Wechsler Adult and Child Intelligence Scales (Wechsler, 2003, 2008) have been developed and are in use in clinical practice.

The Brief Assessment of Cognition in Schizophrenia (Keefe et al., 2004) was developed as a quick and effective tool for the assessment of cognitive change in schizophrenia. The BACS comprises six tasks for the evaluation of 4 cognitive domains identified as important for clinical trials in schizophrenia by the MATRICS Neurocognition Committee (Nuechterlein et al., 2004), including verbal memory, working memory, processing speed, and reasoning/problem solving. The composite score has high test-retest reliability in patients with schizophrenia and healthy controls (ICCs > 0.80), has been shown to be as sensitive to the cognitive deficits of schizophrenia as a standard 2.5-hour battery (Keefe et al., 2004) and is highly correlated (r = 0.84, p < 0.001) with the composite score derived from the CATIE Neurocognitive Test Battery (Keefe et al., 2007a,b; Hill et al., 2008). The BACS has clear functional relevance, as evidenced by strong correlations between the composite score and functional measures such as independent living skills (r = 0.45), performance-based assessments of performance of everyday living skills (r = 0.56), and interview-based assessments of cognition in patients with schizophrenia (r = 0.48; Keefe et al., 2006). It has also demonstrated sensitivity to treatment (Bowie et al., 2012; Geffen et al., 2012). The original BACS has been adapted for use for indications beyond schizophrenia (Keefe et al., 2014), and in this context is referred to simply as the BAC (Brief Assessment of Cognition). Normative data based upon 400 healthy participants demographically matched to the US Census (Keefe et al., 2008) allow for calculation of standardized domain scores and overall composite scores with correction for age and gender.

The BAC App was developed to allow tablet-based delivery and scoring of all subtests included in the original pen and Paper BAC/BACS instrument, which we will refer to here as the Paper BAC. The test battery can be administered in full or with individual tests to yield subtest and total scores with normative results. Like the original instrument, the BAC App assesses multiple cognitive domains. By ensuring standardized administration of instructions and test stimuli, the BAC App allows for reduction in error variance due to rater inconsistencies, and provides automated scoring. Results can be immediately reviewed on the tablet device, or transferred to a central data repository for later analysis.

The primary aim of the present validation study was to assess the validity of the BAC App as a measure of cognitive function by comparing performance and psychometric characteristics of the BAC App with the original Paper BAC in the same group of participants. In order to assess test equivalency and determine the sensitivity of the BAC App to cognitive deficits in schizophrenia, healthy controls and patients with schizophrenia completed the BAC App and Paper BAC within a single visit.

2. Methods

2.1. Participants

Participants included 48 patients (23 females) with schizophrenia (DSM-IV-TR Criteria) and 50 healthy controls (25 females) recruited from three academic sites including the University of California-San Diego, the University of Miami - Miller School of Medicine, and the University of South Carolina. All participants were screened for alcohol and substance abuse using modules J and K of the MINI International

Neuropsychiatric Interview. Any subject meeting criteria for current alcohol or substance abuse was excluded. All subjects provided signed informed consent prior to completion of study-related activities.

Detailed demographic information is displayed in Table 1. To ensure adequate sampling to support validation of the BAC App across age and sex demographics, enrollment was stratified to include balanced representation of men and women in each of 6 age groups: 18-29, 30-39, 40-49, 50-59, 60-69, 70+. In addition, study investigators made a concerted effort to match patients and controls on age, sex and race. As indicated in Table 2, groups were well matched on each of these variables and on maternal education. Patients and controls differed significantly with respect to years of education attained (p < 0.001).

2.2. Design and procedure

All subjects completed the BAC App and the Paper BAC assessments at a single study visit, with order of administration counterbalanced across subjects. For subtests with multiple forms (Verbal Memory, Tower of London, Symbol Coding), alternate versions were utilized during administration of the tablet and paper-based tests. As such, no word list memoranda, Tower of London item or Symbol Coding configuration was completed more than once for any participant.

Following informed consent procedures, participants completed a brief demographic and medical history questionnaire. Participants were screened for current alcohol and substance abuse to ensure eligibility prior to testing. The BAC App and Paper BAC tests were then administered by trained raters. Following completion of both assessments, subjects completed a brief questionnaire to provide subjective ratings of their experiences with the BAC App. Finally, all subjects were administered two measures of functional capacity, including the Virtual Reality Functional Capacity Assessment Tool (Ruse et al., 2014; Atkins et al., 2015) and the UCSD Performance-based Skills Assessment (Patterson et al., 2001) not discussed here. The study visit lasted approximately 3 h, including screening. Participants received a \$50 gift card as compensation for their time and effort.

2.2.1. BAC App method

Detailed descriptions of the Paper BAC tests can be found in previous publications (e.g. Keefe et al., 2004, 2006, 2008). The BAC app is a tablet-based version of the instrument developed for use on an iPad© tablet. Subtests within the BAC App can be administered in sequence as a full battery, as presented here, or the App can be configured to allow for administration of a smaller selection of tests and/or customized test order. In order to facilitate repeated testing and reduce practice effects, alternate versions are available for several BAC App subtests, including Verbal Memory (7 versions), Symbol Coding (8 versions), and Tower of London (8 versions).

All tests administered within the BAC App are completed under the supervision of a trained rater. Instructions for each subtest are presented by a female narrator within the App, ensuring consistent and accurate administration. The rater can initiate repetition of instructions through the touch screen to ensure adequate understanding by the subject prior to task initiation. The electronic tablet device is passed between the rater and the subject during testing.

Table 1Sample demographics.

Parameter	Patients ($n = 48$)	Healthy controls ($n = 50$)	p value
Age	46.04 ± 13.18	48.26 ± 14.52	ns
Education	12.63 ± 1.65	15.12 ± 2.55	< 0.001
Maternal education	12.47 ± 3.51	13.43 ± 2.64	ns
Sex (% male)	52%	50%	ns
Race (% white)	74%	79%	ns

All table entries are mean \pm SD or %. Continuous variables were compared by independent t-test and the categorical variables were compared by Fisher's exact test. All p-values are non-significant ($\alpha > 0.1$) except for Education (p < 0.001).

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