Implementing neurocognitive testing in clinical trials: facilitating rater administration with an iPad-based App

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OBJECTIVE

To facilitate rater administration of neurocognitive testing in clinical trials, we developed an iPad-based application (the BAC App) of a widely-used pen-and-paper battery, the Brief Assessment of Cognition (BAC). The purpose of the BAC App is to reduce administration burden on site raters by automating and standardizing the testing procedures and scoring, while maintaining the importance of the rater-patient interaction. Ensuring full understanding of the task at hand, motivation to try their best, and providing general encouragement to complete the testing is critical to obtaining meaningful data in impaired or behaviorally-challenging patient populations such as Alzheimer’s Disease, depression, ADHD and schizophrenia.

The objective of this study was to determine the utility and psychometric validity of the iPad-based BAC App compared to the established pen-and-paper neurocognitive test battery, in a patient population and healthy controls.

RESULTS

The BAC App demonstrated equivalent sensitivity to cognitive deficits in schizophrenia: Cohen’s d=1.34 for the BAC App, d=1.25 for the pen-and-paper BAC. Patients performed an average of 1.2 SD below the demographically corrected normative mean on each BAC App subset.

Methods

48 patients (23 female) with schizophrenia and 50 healthy controls (25 female) were recruited from 3 US academic sites, stratified by age bands. Participants were assessed with both the BAC App and pen-and-paper version at the same visit, in a counterbalanced order. Where applicable, alternate versions of the subtests were used to prevent learning effects.

In both groups, the distributions of standardized composite scores for the BAC App and pen-and-paper BAC were indistinguishable, and the between-methods means were not significantly different. The between-methods correlations for individual measures in patients were r=.70 except Token Motor (r=.43) and Tower of London (r=.61). In patients, performance between the test methods was not significantly different on any test, except the Token Motor Test, where the mode of performance is qualitatively different. When data from the Token Motor Test were excluded, the correlation of composite scores improved to r=.88 (p<.001) in healthy controls and r=.89 (p<.001) in patients, consistent with the test-retest reliability of each measure.

CONCLUSIONS

This validation study confirms the equivalence of the mode of administration between the pen-and-paper BAC and BAC App for all subtests, except the Token Motor task. The applicability of the established normative data is also confirmed. Therefore, tablet-assisted rater administration using the BAC App is a viable option for use in future clinical trials to reduce site burden while maintaining the validity of the neurocognitive outcomes.

DISCLOSURE

Brian K. Saxby is a fulltime employee of NeuroCog Trials, provider of clinical trial services to pharmaceutical clients, including licensing of the BAC and BAC App neurocognitive assessment tools referenced in this poster.

Presented at DIA 2016, June 26-30, Philadelphia, PA.