Standardisation and cross validation study of Cogtest - an automated neurocognitive battery for use in clinical trials

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Background: Paper and pencil tests are increasing being replaced by computerized batteries for cognitive testing in clinical trials. We sought to standardize and cross-validate Cogtest, an automated neurocognitive battery with electronic data capturing ability. 200 cognitively healthy individuals took part in two studies, one aimed at assessing concurrent validity with respect to paper-pencil measures and another to establish norms for individual Cogtest endpoints that comprise a Neurocognitive Global Score (NGS) for use in clinical trials.

Methods: The overall design of the first study (N=75) involved parallel, counterbalanced administration of both the Cogtest computerised test battery and a battery of paper-and-pencil (P&P) tests (selected to approximate the testing done in current clinical trials). There were two test sessions, and both sets of instruments were presented in counterbalanced order at both sessions, with testing at 0 and 4 weeks (±3 days) controlling for time of day. Four alternate forms of the Cogtest battery were counterbalanced so that each subject experienced two different forms. The 75 subjects were stratified by age over 4 decades from age 20 to 60. Age 20 subjects, equally distributed across age group and sex. The second study (N=120) involved two baseline sessions and one follow-up session, similar counterbalancing of alternate forms, and 20 participants (10 men and 10 women) in each of 6 age bands from age 13 to 69.

Results: The first study revealed sex differences with men generally faster and more accurate on spatial processing but women more accurate in face recognition memory, paralleling prior research. Correlations of Cogtest measures with analogous P&P tests revealed correlations in the range of r=0.3 to r=0.7. The second study revealed a "classic" curvilinear age effect on NGS and individual domains with lower scores in the 13 to 19 year age group, highest scores in the 20-29 year group, and then monotonically decreasing scores through the 6th decade. Both studies revealed that test-retest stability over up to 4 weeks was in keeping with published results for the paper-pencil tests, with typical test-retest reliability coefficients in the range of ~0.4 to ~0.9.

Conclusion: This study shows that the Cogtest computerized testing battery has similar psychometric properties to paper and pencil tests that have been used in clinical trials and offer the added advantage of computerization, millisecond accuracy electronic data capture and audit trail.