Development of a Cognitive Ability Assessment Tool (CAAT) for use in pediatric clinical trials in Sub-Saharan countries.

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SUBMISSION DETAILS

What is the Methodological Question Being Addressed? In Sub-Saharan developing countries, current clinical trial psychometric practices rely on a limited number of instruments developed in other countries (i.e., USA), characterized by irreconcilable cultural, environmental, and socio-economic backgrounds. Sequential issues of trans-cultural validity pose serious methodological concerns on the use of most of these cognitive measurements. Therefore, there is a compelling need for culturally appropriate assessment tools which are sensitive to the local (i.e., Sub-Saharan) context of use.

Introduction CAAT is a clinical method to detect mild to moderate cognitive impairment in a school-aged pediatric population in a context of a severely under-resourced healthcare system. CAAT is designed for use in clinical research settings. CAAT includes eight items (Orientation Place and Time; Number Sequencing, Forward and Backward; Command Execution; Reading Comprehension; Writing; Copy Design). The selection of cognitive tasks was based on consensus reached by expert review. The panel of experts included Zambian healthcare professionals (three pediatricians, two psychologists, a pediatric neurologist) and two experts in methodology of cognitive test development.

Methods CAAT psychometric properties were assessed in a field trial, approved by Zambian Regulatory Authorities. Participants (446 children, aged 5-17 years-old) were recruited at multiple clinical facilities and schools in Zambia. Methods and techniques based on Item Response Theory and on Structural Equation Modelling (i.e., Confirmatory Factor Analysis) were applied for item analysis and selection as well as for reliability and validity assessments. Clinical utility was evaluated by comparing three clinical sub-groups - neurological (NEU), medical non-neurological (MED), chronic psychosocial stress and deprivation (CPSD) - to Healthy Controls (HC).

Results CAAT provides a summary measure of cognitive ability, Knowledge Processing (Cronbach's α: 0.85). The Confirmatory Factor Analysis demonstrated that a single-factor model could fit the data. The hypothesis of unidimensionality could not be rejected as good-fit indices satisfied cut-offs criteria (CFI = 0.99; TLI = 0.98; RMSEA = 0.041; SRMSR = 0.025). Knowledge Processing is defined as the ability to immediately exert a multi-element, organized, cognitive behavior in response to environmental demands. The score range is 0-24, with higher values indicate higher ability. Knowledge Processing increases over age (simple regression model, $R^2 = 0.44$). A one-way ANOVA showed a significant effect of the type of chronic health condition on Knowledge Processing at the $p < .05$ level, $F_{(3, 185)} = 10.34$, $p = 0.000$. Post-hoc pairwise comparisons (Bonferroni's post-criterion test) indicated that HC mean score ($n = 80$, $M = 17.9$, $SD = 3.8$) was significantly different from two of the three the disease conditions: NEU ($n = 31$, $M = 13.2$, $SD = 5.8$) and CPSD ($n = 48$, $M = 14.5$,

SD = 5.0). HC did not differ from MED (n = 30, M = 16.4, SD = 4.0, p = 0.07). There was a significant difference between NEU and MED groups (p = 0.41), whereas NEU and CPSD groups (p = 0.73) didn't differ.

Conclusion Study results provide initial demonstration of reliability and validity of use of CAAT in a pediatric Zambian population and warrant further validation of CAAT use in clinical trial settings.

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Keywords

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Guidelines I have read and understand the Poster Guidelines

Disclosures if applicable Leoben Research is the sponsor of the study.

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