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

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Introduction

In African Sub-Saharan developing countries, current clinical trial psychometric practices rely on a limited number of instruments developed in other countries (i.e., USA), characterised 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 context of use.

The **Zambia Cognitive Ability Assessment Tool** (CAAT) is an instrument to detect mild to moderate cognitive impairment in a school-aged pediatric population in a context of a severely under-resourced healthcare system. The CAAT is designed for use in clinical research settings. The 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 other experts in methodology of cognitive test development.

Methods

Psychometric properties of the CAAT were assessed in a field trial, sponsored by Leoben Research and 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. 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

The 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 fits the data. The hypothesis of uni-dimensionality 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, organised, cognitive behaviour in response to environmental demands. The score range is 0-24, with higher values indicating 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 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 = 0.041), whereas NEU and CPSD groups (p = 0.73) didn't differ. The three medical condition groups did not differ by socio-demographics variables (i.e., age, sex, education level).

Conclusions

The results support the validity of CAAT use to evaluate the effect of different disease conditions on paediatric cognitive functioning. We found that the presence of a neurological condition or prolonged exposure to psychosocial stress and deprivation are associated to lower Knowledge Processing. The results of our study highlight the potential of the CAAT as a viable, reliable, and cost-effective solution for child's cognitive health assessment in Zambia. Future research should characterise CAAT clinical utility and diagnostic accuracy (i.e., sensitivity and specificity) in relation to specific disease conditions. These results also warrant further validation of CAAT use to monitor treatment response in clinical trial settings.

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