A STUDY OF AUTISM-DEVELOPING
AND VALIDATING A DIAGNOSTIC CLINICAL TOOL

Abstract

Autism which was first described by Leo Kanner way back in 1943, is a chronic Neuro-developmental disorder characterized by social and language impairments and stereotyped, repetitive patterns of behaviour. Symptoms manifest before the age of 3 years, and affected children often require constant care from family members and professionals. Early detection is critical for providing early stimulation in an effort to reduce the symptoms and for possible cure. In the clinical setting, professionals usually make the diagnosis by administering the Childhood Autism Rating Scale (CARS), the commonly used scale for diagnosis and measuring the severity of autism and the same has been validated against DSM-IV-TR criteria. CARS is still the best available reference standard used for diagnosing Autism in India, however it is a copy righted measure and requires advanced training in using and interpreting the scores. It was in this context that this study was conducted to develop and validate a simple tool for diagnosis of autism among children between 2 and 6 years of age.

Primary Objectives

- To develop a culturally appropriate tool for diagnosis of autism among children between 2 and 6 years of age.
- To validate the tool against the reference standard Childhood Autism Rating Scale (CARS).

Secondary Objective

- To study the modifiable risk factors for autism among children between 2 and 6 years of age.
Methods

The study was conducted at Child Development Centre Kerala, a research, training and teaching tertiary care centre in Thiruvananthapuram district, State of Kerala in Southern India.

**Study design: Mixed** study designs including qualitative and quantitative methods were followed for the conduct of the study.

- Descriptive - cross sectional study, which included a theory driven, psychometric approach for development and validation of the tool.
- Case control design to identify the modifiable risk factors of autism.

**Study Population:** The children between 2 and 6 years were recruited into the study from the autism clinic of CDC Kerala, if inclusion and exclusion criteria were satisfied. The inclusion criteria were; (i) children between 2 and 6 years of age, (ii) referred with suspected deviation in communication, socialization and with restricted interest or repetitive behaviour, all suggestive of autism and (iii) primary care giver has a working knowledge of Malayalam, Hindi or English. The exclusion criteria were children, with severe disabilities, acute illnesses or those whose primary care giver was not available or unwilling to participate.

**Sample size:** For development and validation of the new tool 200 samples based on the calculation of 5 samples for each item of the tool and for risk factor assessment 200 cases and 200 normal children.

**Study Procedure:** The standard guidelines for the development of neurodevelopmental / psychological test were adopted for the tool development which included; Step 1: Forming the expert panel for the technical advice of developing tool, Step 2: Agreeing on the measure and conceptualization of construct, Step 3: Decision on the nature of the measure, Step 4: Item development, Step 5: Item wording and sequencing, Step 6: Formatting, endorsement and scoring pattern, Step 7: Translation and back translation, Step 8: Pretesting, Step 9: Pilot study, Step 10: Final Administration of the tool on
study sample, and finally a tool having 39 items were developed for further validation, which included reliability analysis, validity analysis. Risk factor analysis was done after entering and cleaning the data, statistical analysis was done using SPSS version 19.0.

Results

Among 200 children recruited in the project with suspected impairment in personal social development, language development and abnormal behavioural development, only 143 was diagnosed as autism by administering Childhood Autism Rating Scale (CARS) and 57 had no autism and were excluded from the risk factor analysis. Among children having autism 83.3% were males and 16.8% were females and the male – female ratio was 5:1.

The test-retest reliability of the new tool “Childhood Autism Tool – Trivandrum (CAT-T)” using intra-class correlation coefficient (ICC) to assess the reproducibility was 0.867 and the inter-observer reliability of CAT-T using ICC to assess degree of agreement among raters was 0.898. The results show that the test-retest reliability and inter-rater reliability was high and the new tool has good reliability. The internal consistency of CAT-T, calculated using Cronbach's alpha coefficient was 0.864, which means that the tool has good stability and items are homogenous.

It was observed that the new tool the CAT-T has adequate face and content validity established by consensus among clinicians and other stakeholders. The convergent validity of the new tool with CARS and VSMS calculated using Pearson's correlation coefficient, was moderately acceptable ($r=0.4326$, $P=0.001$) & ($r=0.264$, $P=0.009$), which means that the tool correlates with other tools that measures diseases having theoretically similar constructs. Divergent validity of CAT-T with DDST showed non-significant associations ($r=-0.159$; $P=0.099$) demonstrating that the new tool can discriminate other diseases having theoretically dissimilar constructs, like gross motor delay.
An Exploratory Factor Analysis (EFA) was done to assess the construct validity of CAT-T. The Kaiser-Meyer-Olkin (KMO) measure was 0.853, which indicated that there was appropriate sample size to undertake factor analysis. Bartlett's Test of Sphericity was significant (Chi-Square=2141.7; P-value=0.001), which showed factorability of the variables.

The 39 items of the CAT-T were subjected to Principal Components Analysis (PCA) with varimax rotation to investigate the underlying structure of the tool. The Kaiser criterion, to select those factors that have an Eigen value of \( \geq 1.00 \) and scree plot analysis to extract factors that lie before the point at which Eigen values begin to drop was utilized to determine the number of factors to be retained.

Among various factor solutions extracted after item reduction seven factor solution was deemed to be most statistically and conceptually appropriate for the new tool. The 39 items in the tool were reduced to 24 items. The 7 factor structure was derived using the following statistical principles; (i) communalities of all 24 latent items after extraction was high, i.e. 0.4 or above, which indicated that the components represents the variables well, (ii) a factor loading above 0.4 as the cutoff point for identifying factors, (iii) there were at least 2 items in a factor, (iv) all factors had an Eigen value of \( \geq 1.00 \), (v) there was 7 factor support from scree plot test, (vi) the total variance was 66.22%, (vii) there were no cross loadings of values more than 0.4.

The final tool which has 7 factors includes the following; **Factor 1**: “Personal-Social” items, which accounted for 30.95% of total variance. This factor includes 8 items and reflects information about the social development of the child with highest factor loading item of 0.933 and lowest of 0.403; **Factor 2**: “Communication” items, which accounted for 9.06% of total variance. This factor includes 4 items and reflects information about the language development of the child with highest loading item of 0.967 and lowest of 0.671; **Factor 3**: “Behaviour - sameness” items, which accounted for 6.88% of total variance. This factor includes 3 items and reflects information about the language development.
of the child with highest loading item of 0.741 and lowest of 0.642; **Factor 4:** “Behaviour - hyperactivity” items, which accounted for 5.65% total variance. This factor includes 2 items and reflects information about the behaviour development of the child with highest loading item of 0.904 and lowest of 0.868; **Factor 5:** “Behaviour - preoccupation” items, which accounted for 4.88% total variance. This factor includes 3 items and reflects information about the behaviour development of the child with highest loading item of 0.839 and lowest of 0.489; **Factor 6** “Behaviour - repetitive, sensory dysfunction (auditory)” items, which accounted for 4.60% total variance. This factor includes 2 items and reflects information about the sensory development of the child with highest loading item of 0.836 and lowest of 0.624; **Factor 7** “Behaviour - sensory dysfunction (gustatory)”items, which accounted for 4.20% total variance. This factor includes 2 items and reflects information about the sensory development of the child with highest loading item of 0.811 and lowest of 0.756.

**Diagnostic accuracy:** Various parameters of diagnostic accuracy for different cut-off points of the CAT-T, were tested against the reference standard CARS. A score of 17 and above in the CAT-T achieved a sensitivity of 71.33% (95% CI=63.2 - 78.6), a specificity of 84.21(95% CI=72.1 - 92.5)), a positive likelihood ratio of 4.52 (95% CI=2.5 – 8.3), a negative likelihood ratio of 0.34 (95% CI=0.3 - 0.5), a positive predictive value of 91.9%,(95% CI=85.2 – 96.2)and a negative predictive value of 53.9%;(95% CI=43.0 -64.6). The area under curve (AUC) in the ROC for the CAT-T was 0.812 (95% CI=0.751-0.864) P=0.0001. The diagnostic accuracy of the tool is 75 and the diagnostic odds is 11.33. Thus it was established that CAT-T score of 17 and above can be used for the identification of autism among children between 2 and 6 years. The final tool the ‘Childhood Autism Tool-Trivandrum (CAT-T)’ having 24 items to be rated on a Likert scale of 0 to 3 (no problems = 0; occasionally = 1; frequently = 2; always = 3) with equal weightage for all items has good psychometric properties.
**Significant risk factors for autism**

Logistic regression model using items based on the results obtained on univariate analysis involving socio-demographic factors, antenatal, natal & neonatal and early child care practices were derived. It was observed that the following six factors were associated with a statistically significant increased risk of autism.

Undesirable early child care practices  P-value- <0.001 (OR 27.94, 95%CI 12.31-63.39)
Respiratory infection P-value- 0.013 (OR 13.42, 95%CI 1.743-103.29)
Excessive foetal movement P-value- 0.010 (OR 10.25, 95%CI 1.76-59.61)
Socio economic status – upper P-value- 0.001 (OR 7.40, 95%CI 2.36-23.25)
Delayed cry P-value- 0.025 (OR 6.12, 95%CI 1.26-29.74)
Gender - Male P-value- < 0.001 (OR 4.62, 95%CI 2.01-10.62)

**Policy Implications**

The new Indian tool CAT-T would give an impetus for the National programme Rashtriya Bal Swastya Karyakram (RBSK) for early detection of delays, deviations and disabilities including autism, because of the following reasons;

(i) have good psychometric properties
(ii) high positive predictive value of 91.3% against the reference standard tool the CARS.
(iii) easily usable in clinical settings by clinicians, speech therapists and clinical psychologists to identify autism among children between 2 and 6 years at minimal cost and training enabling early intervention services.

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