

EARLY DETECTION OF AUTISM RISK AMONG CHILDREN AGED 12–16 MONTHS USING THE CONCERN-9 CHECKLIST: A CROSS-SECTIONAL STUDY FROM A PEDIATRIC TERTIARY CARE CENTRE

R.Harish¹, Venmugil Ponnusamy², V.K. Aravinth¹

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Corresponding Author:

Dr. R. Harish,
Email: doctorharish14@gmail.com

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¹Assistant Professor, Department of Pediatrics, Government Pudukkottai medical college and hospital, Tamilnadu, India

²Associate Professor, Department of Pediatrics, Government Pudukkottai medical college and hospital, Tamilnadu, India

ABSTRACT

Background: Early identification is important because developmental interventions initiated during the first years of life may improve language, social and adaptive outcomes in ASD. However, many commonly used autism screening instruments are designed for children older than 16 months. Brief screening instruments suitable for younger children may therefore facilitate earlier identification in routine paediatric practice. The objective is to estimate the proportion of children aged 12–16 months at risk for autism using the Concern-9 checklist and to assess the association of selected socio-demographic, screen-time and prenatal factors with autism-risk screening status. **Materials and Methods:** A hospital-based cross-sectional analytical study was conducted in the Department of Pediatrics, Government Pudukkottai Medical College, Tamil Nadu. A total of 350 children aged 12–16 months attending the paediatric outpatient department for routine health check-ups, immunization or other complaints were enrolled after obtaining informed consent. Autism risk was assessed using the Concern-9 checklist. Data were entered in Microsoft Excel and analysed using Epi Info 7. **Result:** Among 350 children screened, 5 (1.4%) were screen-positive and 345 (98.6%) were screen-negative. All screen-positive children had screen exposure >2 hours/day, showing a statistically significant association with Concern-9 screening status ($p=0.018$). All five screen-positive children belonged to families in which both parents were working, which was also statistically significant ($p=0.006$). **Conclusion:** In this hospital-based cross-sectional study of 350 children aged 12–16 months, 1.4% screened positive for autism risk using the Concern-9 checklist. The study demonstrates the feasibility of conducting autism-risk screening during the early second year of life in a paediatric outpatient setting.

INTRODUCTION

Autism spectrum disorder (ASD) is a heterogeneous neurodevelopmental disorder characterized by persistent difficulties in social communication and social interaction together with restricted or repetitive patterns of behaviour, interests or activities. The clinical presentation varies considerably in severity and functional impact. Symptoms may involve social communication, language, cognition, adaptive functioning and behaviour.^[1–5]

Early identification of ASD is increasingly recognized as an important component of paediatric healthcare. Developmental differences may become apparent during infancy, particularly in domains such as eye contact, social engagement, response to name,

joint attention, babbling and gesture use. Although some children develop apparently normally during infancy, developmental abnormalities may become evident later or may emerge following regression.^[1,6–8]

The first two years of life represent an important period of brain development and neuroplasticity. Identification of developmental concerns during this period can facilitate developmental surveillance, parental counselling and timely referral for intervention. Evidence indicates that early behavioural and developmental interventions can improve language, social communication and adaptive functioning in children with ASD.^[9–11] Despite the importance of early identification, diagnosis frequently occurs considerably later than

the emergence of the earliest behavioural signs. Conventional screening instruments have different age ranges and psychometric characteristics. The Modified Checklist for Autism in Toddlers (M-CHAT), for example, is primarily designed for children aged 16–30 months. Other instruments such as the First-Year Inventory (FYI), Autism Observation Scale for Infants (AOSI) and Early Screening for Autism and Communication Disorders (ESAC) have been developed to facilitate earlier identification.^[12–16]

The Concern-9 checklist represents a brief screening approach focusing on early behavioural and developmental concerns. Its simplicity may be particularly useful in busy paediatric outpatient settings and in healthcare systems where access to developmental specialists is limited. Parent-reported observations can provide valuable information because caregivers frequently recognize developmental differences in naturalistic settings.^[17–20]

The epidemiology of ASD varies between populations, with reported differences related to diagnostic practices, awareness, healthcare access and study methodology. Indian data remain relatively limited, and hospital-based screening studies can contribute important information regarding the feasibility of early identification in routine paediatric practice.^[21–25]

Screen-time exposure has also become an important area of interest in early childhood development. Prolonged exposure may reduce opportunities for direct caregiver-child interaction and has been associated with developmental and communication difficulties in some observational studies. However, the relationship between screen exposure and ASD is complex and should not be interpreted as a direct causal relationship.^[23–25]

The present study was therefore undertaken to assess autism risk among children aged 12–16 months using the Concern-9 checklist and to examine selected socio-demographic, screen-time and prenatal factors associated with screening status.

Objectives

Primary objective

To estimate the proportion of children aged 12–16 months attending the paediatric outpatient department who screen positive for autism risk using the Concern-9 checklist.

Secondary objectives

1. To describe the socio-demographic and clinical characteristics of children screened using the Concern-9 checklist.
2. To assess the association between screen-time exposure and autism-risk screening status.
3. To assess the association of selected parental, family and prenatal factors with autism-risk screening status.
4. To facilitate early referral of children who screen positive for comprehensive developmental assessment.

MATERIALS AND METHODS

Study design and setting: A hospital-based cross-sectional analytical study was conducted in the Department of Pediatrics, Government Pudukottai Medical College, Pudukottai, Tamil Nadu. The source population consisted of children attending the paediatric outpatient department. The study methodology specified recruitment of children aged 12–16 months attending for routine health check-ups, immunization or other complaints.

Study population: Children aged 12–16 months attending the paediatric outpatient department during the study period were eligible for screening.

Inclusion criteria

- Children aged 12–16 months.
- Children attending for routine health assessment, immunization or any paediatric complaint.
- Written informed consent from the parent or legal guardian.
- Children without a previous diagnosis of another condition causing developmental delay.
- Medically stable children able to undergo screening.

Exclusion criteria

- Known global developmental delay or genetic syndromes affecting neurodevelopment.
- Severe visual or hearing impairment preventing valid behavioural assessment.
- Acute illness or hospitalization interfering with participation.
- Parents or guardians unwilling to provide consent.

Sample size: The sample size was calculated using OpenEpi based on an anticipated prevalence of 1%, with an alpha error of 1.1% and 80% power. The calculated sample size was 314; after allowing for a 5% non-response rate, the final sample size was rounded to 350.

Data collection: After obtaining informed consent, demographic and family information was collected from caregivers. Information regarding parental education, working status, socioeconomic status, family type, maternal age at conception, birth spacing, prenatal folic acid intake and first-trimester drug/toxin exposure was obtained using a structured questionnaire. Screen-time exposure was recorded as the reported duration of daily exposure to screen-based electronic devices.

Autism-risk screening: The Concern-9 checklist was administered to children aged 12–16 months. The checklist was used to classify children as screen-positive or screen-negative according to the specified scoring criteria. Children identified as screen-positive were referred for detailed developmental assessment and appropriate early intervention services.

A positive screening result was considered an indication for further developmental assessment and not a definitive diagnosis of ASD.

Statistical analysis: Data were entered into Microsoft Excel and analysed using Epi Info 7. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were expressed as frequencies and percentages. Associations between categorical variables and screening status were assessed using the chi-square test. Continuous variables were compared using the independent t-test. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 350 children aged 12–16 months were included in the study. The mean age was 14.36 ± 1.12 months. Five children (1.4%) screened positive on the Concern-9 checklist, while 345 (98.6%) screened negative.

Table 1: Socio-demographic and clinical characteristics of the study population (n=350)

Variable	Category	n	%
Concern-9 screening	Screen positive	5	1.4
	Screen negative	345	98.6
Sex	Male	204	58.3
	Female	146	41.7
Family type	Nuclear	236	67.4
	Joint	94	26.9
	Other	20	5.7
Mother's education	Primary	12	3.4
	Middle	35	10.0
	High/Higher secondary	121	34.6
	Graduate	123	35.1
Parental working status	Postgraduate	59	16.9
	Both working	148	42.3
	Single parent working	187	53.4
	None working	15	4.3
Socioeconomic status	Upper	4	1.1
	Upper middle	16	4.6
	Lower middle	96	27.4
	Upper lower	122	34.9
	Lower	112	32.0
Screen time	<1 hour/day	78	22.3
	1–2 hours/day	93	26.6
	>2 hours/day	179	51.1

The study population showed a male predominance, with males accounting for 58.3%. Nuclear families constituted 67.4% of the study population. More than

half of the children (51.1%) had reported screen exposure exceeding 2 hours per day.

Table 2: Association of socio-demographic factors with Concern-9 screening status

Variable	Category	Screen positive n (%)	Screen negative n (%)	p-value
Age	Mean $\pm$ SD (months)	14.35 $\pm$ 1.2	14.47 $\pm$ 1.4	0.842
Sex	Male	4 (80.0)	200 (58.0)	0.317
	Female	1 (20.0)	145 (42.0)	
Parental education	Graduate/postgraduate	1 (20.0)	181 (52.5)	0.182
	$\leq$ Higher secondary	4 (80.0)	164 (47.5)	
Parental working status	Both working	5 (100)	143 (41.4)	0.006
	One/both not working	0	202 (58.6)	
Family type	Nuclear	4 (80.0)	232 (67.2)	0.527
	Joint/other	1 (20.0)	113 (32.8)	
Socioeconomic status	Upper	0	20 (5.8)	0.118
	Middle	1 (20.0)	111 (32.2)	
	Lower	4 (80.0)	214 (62.0)	

There was no statistically significant association between child age, sex, parental education, family type or socioeconomic status and Concern-9 screening status. However, parental working status

showed a statistically significant association: all five screen-positive children belonged to families in which both parents were working ($p=0.006$).

Table 3: Association of screen time and selected prenatal factors with Concern-9 screening status

Variable	Category	Screen positive n (%)	Screen negative n (%)	p-value
Screen time	>2 hours/day	5 (100)	174 (50.4)	0.018
	$\leq$ 2 hours/day	0	171 (49.6)	
Maternal age at conception	Mean $\pm$ SD (years)	23.33 $\pm$ 2.1	23.53 $\pm$ 2.4	0.781
Birth spacing	First born	2 (40.0)	141 (40.9)	0.964
	<3 years	2 (40.0)	115 (33.3)	

	>3 years	1 (20.0)	89 (25.8)	
Prenatal folic acid	Yes	5 (100)	333 (96.5)	0.621
	No	0	12 (3.5)	
First-trimester drug/toxin exposure	Yes	0	15 (4.3)	0.587
	No	5 (100)	330 (95.7)	

All five screen-positive children had reported screen exposure exceeding 2 hours/day. The association between screen time and screening status was statistically significant ($p=0.018$). Maternal age, birth spacing, prenatal folic acid intake and first-trimester drug/toxin exposure were not significantly associated with screening status.

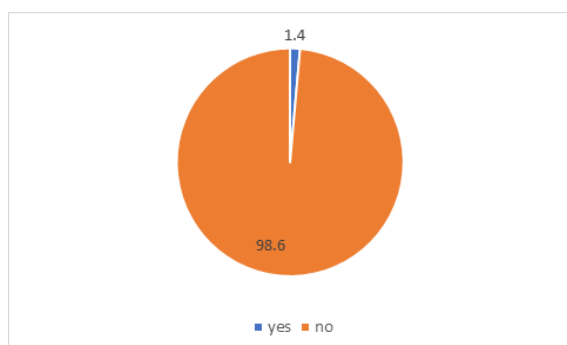


Figure 1: Autism risk prevalence

DISCUSSION

The present study evaluated autism risk among 350 children aged 12–16 months using the Concern-9 checklist. Five children screened positive, giving an autism-risk screening prevalence of 1.4%. The study population had a mean age of 14.36 ± 1.12 months and included a greater proportion of males than females. These findings are broadly consistent with the established epidemiological observation of greater ASD identification among males. However, the association between sex and screening positivity was not statistically significant in the present study. The observed screening positivity of 1.4% is within the range reported in epidemiological studies of ASD and developmental risk. Differences between studies may arise from variation in age at screening, diagnostic criteria, population characteristics, screening instruments and healthcare access. Indian studies have also demonstrated considerable variability in reported prevalence because of differences in methodology and population characteristics.^[21–25]

An important finding was that all five screen-positive children had screen exposure exceeding 2 hours per day, and the association was statistically significant ($p=0.018$). Previous observational research has reported associations between higher early childhood screen exposure and developmental outcomes. Excessive screen exposure may potentially reduce opportunities for direct caregiver-child interaction, communication and play.^[23–25] Nevertheless, the present cross-sectional study cannot establish that screen exposure causes autism or autism-like developmental characteristics. Reverse causation is

also possible, whereby children with early developmental differences may receive more screen exposure because caregivers use digital media to occupy or soothe them.

The study also identified a statistically significant association between parental working status and Concern-9 screening status. All five screen-positive children had both parents working ($p=0.006$). Although reduced caregiver interaction could potentially be one explanation for this observation, parental employment itself cannot be considered an established risk factor for ASD based on these data. Employment status may be acting as a marker for other factors, including childcare arrangements, screen exposure, socioeconomic characteristics and the amount or nature of caregiver-child interaction. The very small number of screen-positive children also means that this finding should be interpreted cautiously.

Parental education was not significantly associated with screening status. Four of the five screen-positive children were from families in which parental education was at or below higher secondary level, but the association was not statistically significant ($p=0.182$). Previous literature suggests that parental education may influence awareness, recognition of developmental concerns and healthcare-seeking behaviour rather than directly determining ASD risk.^[21,22]

Similarly, family type and socioeconomic status were not significantly associated with screening positivity. Although 80% of screen-positive children were from nuclear families, this difference did not reach statistical significance. Four of the five screen-positive children were categorized within the lower socioeconomic group, but the association was also non-significant. These findings should be interpreted in the context of the small number of positive screens and the hospital-based design.

The mean maternal age at conception was similar between screen-positive and screen-negative groups. No statistically significant association was observed between maternal age and screening status ($p=0.781$). Although advanced parental age has been described as an epidemiological risk factor for ASD, the present sample was predominantly composed of mothers in early adulthood, with a mean maternal age of approximately 23 years. The restricted age distribution and small number of positive screens may have limited the ability to identify an association.^[22,23]

Birth spacing was also not significantly associated with Concern-9 status ($p=0.964$). Similarly, prenatal folic acid intake and first-trimester drug/toxin exposure did not demonstrate statistically significant associations. Nearly all mothers (96.6%) reported

prenatal folic acid intake, resulting in limited variation between exposure groups. Only 4.3% reported first-trimester drug/toxin exposure. The small number of exposed participants and the small number of screen-positive children substantially limit interpretation of these findings.

The present study supports the potential utility of early developmental screening during the 12–16-month period. Several studies have demonstrated that behavioural manifestations associated with ASD can become apparent during the second year of life, and repeated screening can increase the opportunity for early identification.^[1,6,7] Screening instruments designed specifically for younger children may complement routine developmental surveillance.

An important practical advantage of a brief checklist such as Concern-9 is its potential integration into routine paediatric outpatient services. The current thesis describes the checklist as simple, rapid and feasible for use in busy clinical settings. However, a positive screening result should always be followed by comprehensive developmental assessment because screening instruments identify children who require further evaluation rather than establishing a definitive diagnosis.

Early identification is clinically important because children identified with developmental concerns can be referred for multidisciplinary evaluation and early intervention. The present study referred all five screen-positive children for further evaluation through an early intervention service. Early intervention may include developmental, behavioural, speech and language and parent-mediated approaches depending on individual developmental needs.^[9–11]

Limitations: Several limitations should be considered. First, this was a single-centre hospital-based cross-sectional study, limiting generalizability to the wider community. Second, Concern-9 is a screening instrument and not a diagnostic assessment; therefore, the 1.4% figure represents screening positivity/autism risk rather than confirmed ASD prevalence.

CONCLUSION

In this hospital-based cross-sectional study of 350 children aged 12–16 months, 1.4% screened positive for autism risk using the Concern-9 checklist. The study demonstrates the feasibility of conducting autism-risk screening during the early second year of life in a paediatric outpatient setting.

Screen exposure exceeding 2 hours per day and having both parents working were significantly associated with Concern-9 screen positivity. However, these findings represent associations and should not be interpreted as evidence that screen exposure or parental employment causes ASD.

The findings support incorporation of early developmental surveillance and autism-risk screening into routine paediatric care. Children who screen positive should undergo comprehensive developmental assessment rather than being labelled as having ASD solely on the basis of a screening result. Early referral can facilitate timely developmental intervention, parental counselling and continued developmental monitoring.

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