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Development of the Childhood Autism Rating Scale-Brief Form for early detection of autism spectrum disorder in toddlers under three

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ABSTRACT

Background: Early diagnosis and intervention could improve the prognosis of autism spectrum disorder (ASD). This study aimed to investigate the validity of the Childhood Autism Rating Scale (CARS) in toddlers with ASD under 3 years and develop an efficient abbreviated version for early diagnosis of ASD.
Methods: Two studies were conducted to evaluate the validity of the CARS for detecting ASD. Study 1 examined the differences between 30 toddlers with ASD and 30 toddlers with developmental delays (DD) and analyzed the area under the receiver operating characteristic (ROC) curve. Critical items were selected as the CARS-Brief Form (CARS-BF) and cutoff scores were determined. Study 2 involved 206 toddlers, including 115 with ASD, 34 with mild-ASD, and 57 with DD, to validate the utility of the CARS-BF.
Results: Study 1 identified 7 items for the CARS-BF and found the optimal cutoff scores to be 12.5 and 13. Study 2 confirmed the optimal cutoff score of 12.5 and 13 for the CARS-BF and demonstrated good accuracy. Besides, the cutoff score of 13 exhibited high sensitivity (88.7 %) and specificity (84.2 %).
Conclusion: The CARS-BF demonstrated a high level of accuracy. It can be utilized as an effective tool for identifying toddlers with ASD in clinical settings.

Introduction

Autism spectrum disorder (ASD) is a neurodevelopmental condition clinically characterized by deficits in social communication and restricted, repetitive patterns of behavior and interests (American Psychiatric Association, 2013). Recent studies report a rising prevalence of ASD, now estimated at around 2 % in the United States (Christensen et al., 2018; Maenner et al., 2023). This increase underscores the need for accurate diagnosis and early intervention. The age at which young children received an ASD diagnosis varies

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widely, ranging from 12 months (Pierce et al., 2019; Pierce et al., 2021) to 48 months (Shaw et al., 2020). Early identification is crucial, as demonstrated by Gabbay-Dizdar et al. (2022), who found that identification before 2.5 years significantly improved social-communication behaviors.

In Taiwan, a recent meta-analysis of epidemiological studies also indicated an increasing trend in ASD diagnoses (Qiu et al., 2020). Lai et al. (2012) reported that the prevalence of ASD among preschool children was approximately 2 per 1000. Their study also found higher ASD rates in children of more highly educated parents. Additionally, greater ASD prevalences were observed in more urbanized areas with fewer barriers to healthcare access. Under these conditions, the prevalence of ASD in Taiwan was estimated to be around 1 % (Chen et al., 2020; Hsu et al., 2023). Over the past decade, the prevalence of ASD has continued to increase. However, according to Wu et al. (2021), the low rate of early childhood ASD diagnosis in Taiwan can be attributed to the lack of valid assessment tools for toddlers and parents' unawareness of the signs in their children. Furthermore, as reported by Ward et al. (2016), clinicians in Taiwan may face challenges in screening and diagnosing children with ASD under the age of 3 given their inexperience or restricted knowledge of ASD. This may lead to extended observation periods, potentially delaying early intervention. Therefore, developing more efficient tools for detecting ASD in toddlers is necessary.

Common ASD diagnostic tools include the Autism Diagnostic Observation Schedule, Second Edition (ADOS-2; Lord et al., 2012) and the Autism Diagnostic Interview—Revised (ADI-R; Rutter et al., 2003). However, these tools can be time-consuming in clinical settings. To improve efficiency, researchers have categorized ASD screening tools into two levels (Filipek et al., 2000). Level 1 tools screen children at a heightened likelihood of developmental delays (DD) in the community. Level 2 tools, administered by experienced experts, differentiate children with ASD from those with DD. For example, the Childhood Autism Rating Scale (CARS; Schopler et al., 1988) or its updated version, the CARS2-Standard Version (CARS2-ST; Schopler et al., 2010), is a widely used and well-studied Level 2 tool. However, recent research has supported its utility as a diagnostic tool due to its strong diagnostic accuracy (Alotaibi & Alotaibi, 2021).

The CARS/CARS2-ST, is an observational instrument that has demonstrated good internal consistency and inter-rater agreement. Past studies reported good sensitivity and specificity for the CARS with a cutoff point of 30 (Eaves & Milner, 1993; Mayes et al., 2009; Nordin et al., 1998; Rellini et al., 2004; Schopler et al., 1988). However, these studies may have limitations, such as small sample sizes, overly wide age ranges of the samples (Nordin et al., 1998; Rellini et al., 2004), or variations in IQ levels (Mayes et al., 2009). Research indicates that age-specific cutoff scores may more accurately identify children with ASD. Perry et al. (2005) and Chlebowski et al. (2010) emphasized the importance of age-specific cutoff scores, particularly for preschool-aged children whose developmental characteristics differ from older children under the DSM-IV-TR criteria. These findings highlight the need for adjusted CARS cutoff scores to ensure accurate classification across age groups.

In Asia, studies have adapted the CARS to local contexts. In Japan, Tachimori et al. (2003) found high sensitivity (86 %) and specificity (83 %) with lower cutoff scores (25.5–26) in the CARS-Tokyo version. In Korea, Shin and Kim (1998) explored the K-CARS and achieved a correct classification rate of 73 % for ASD with a cutoff score of 28. Kwon et al. (2017) further validated the K-CARS and reported a sensitivity of.81 and specificity of.66. These studies suggest that adjusting cutoff points for different cultural contexts may improve classification accuracy of the CARS.

Focusing on Chinese samples, Wu et al. (2014) studied the use of the CARS for detecting ASD in toddlers aged 24–36 months. Their findings showed that cutoff scores between 28.5 and 29 yielded high sensitivity (92 %) and specificity (88 %) in Taiwan. Additionally, Chu et al. (2020) recommended a higher cutoff score of 34 for a broader age range (1.6–14 years), demonstrating fair sensitivity (79 %) and specificity (76 %) in mainland China. The variation in findings between Asian and Western studies led Stevanovic et al. (2021) to propose that the CARS might not offer cross-culturally valid assessments of ASD, emphasizing the need for culturally specific research.

While the original CARS offers a quicker assessment compared to tools like the ADOS, it still requires substantial time for comprehensive evaluations in clinical practice (Nah et al., 2014). Given the limited number of child psychiatrists and resource disparities in Taiwan (National Health Research Institutes [NHRI], 2019), there is a growing need for a more efficient tool to improve early ASD diagnosis. To enhance efficiency, some studies have employed signal detection theory (SDT) to streamline the items of the CARS. Constantino et al. (2012) developed the CARS2-Observation (CARS2-Obs), a modified version that includes the first eight items of the original CARS for detecting ASD in children aged 3–16 years. Their findings revealed that using a cutoff score of 16 for the CARS2-Obs yielded a specificity of.95 and a sensitivity of.62. In contrast, Wu et al. (2014), working with a smaller sample, identified nine key items (items 1, 2, 3, 5, 7, 8, 11, 12, and 15), showing a specificity of.86 and a sensitivity of.93. While Constantino et al.'s (2012) study covered a broader age range (3–16 years), Wu et al.'s study focused on a narrower age range (24–36 months). Previous studies have rarely focused on brief versions adapted to specific age ranges. Since the CARS can be adapted to different cultural contexts, developing a shorter, age-specific version could enhance its effectiveness in clinical settings. A streamlined CARS would allow for more efficient assessments, particularly in resource-limited environments. Furthermore, such a version could potentially improve early detection rates for ASD, especially in younger children.

Wu et al. (2014) collected their sample using the DSM-IV-TR criteria, while Dawkins et al. (2016) found that the CARS2-ST maintained high diagnostic consistency with the DSM-5 criteria. Despite the efforts that have been made to determine appropriate cutoff scores for the CARS for different age groups, research on preschool-aged children remains limited. With the updated DSM-5 criteria, it is crucial to validate the CARS accordingly. Recognizing the importance of early identification and the need for more efficient and culturally adjusted diagnostic tools, this research undertook two studies to develop the CARS-Brief Form (CARS-BF) for toddlers under 3 years old in Taiwan. Study 1 used receiver operating characteristic (ROC) analysis to select key items from the CARS to establish the CARS-BF and determine optimal cutoff scores. Study 2 aimed to validate these cutoff scores and assess the efficacy of the CARS-BF for detecting ASD in toddlers under 36 months.

Study 1

Methods

Participants

This study received approval from the Institutional Review Board of Ditmanson Medical Foundation Chia-Yi Christian Hospital. All participants were recruited from a teaching hospital located in the Southwest area of Taiwan and provided informed consent prior to their involvement. The sample consisted of 30 participants with ASD as well as 30 participants with DD. Toddlers with ASD met the criteria outlined in the DSM-5 (American Psychiatric Association, 2013), which include the presence of three deficits in the social-communicative/interaction skills domain and at least two of the four types of restricted/repetitive behaviors. DD stands for developmental delays, referring to instances where a child lags behind in reaching developmental milestones compared to other children of the same age (Choo et al., 2019). Children with DD in this study had at least one T-score below 35 in any of the four cognitive scales of the Mullen Scales of Early Learning (MSEL; Mullen, 1995) or total score of 85 on the MSEL. Furthermore, they did not meet the diagnostic criteria for ASD as outlined in the DSM-5. Children with sensory or motor impairments, as well as those with previously diagnosed genetic disorders, were excluded from the study. Only participants who were below 36 months of age and met the eligibility criteria were included.

Materials and Procedure

Evaluations were conducted by a research team. Two psychiatrists independently used the CARS to evaluate ASD symptoms through behavioral observation and semi-structured clinical interviews. They received the CARS training and followed Wu et al.'s (2014) approach for consistent rating. Inter-rater reliability was ensured by setting a criterion based on Nordin et al.'s (1998) guidelines: Scores were considered consistent if the difference between raters for each item did not exceed.50. The inter-rater reliability was.87. Compared to Wu et al.'s (2014) study, this research recruited younger participants (18–36 months). An independent clinical psychologist, unaware of the CARS results, evaluated children based on the DSM-5 criteria. This methodology aimed to provide a comprehensive and unbiased assessment of the effectiveness of the CARS in younger children. Participants were individually assessed with the MSEL (Mullen, 1995) and the ADOS (Lord et al., 1999) prior to the diagnostic decisions were made.

The Mullen Scales of Early Learning (MSEL) is designed to assess cognitive abilities in preschool children aged 0 to 68 months, focusing on four cognitive subscales: visual reception, fine motor skills, receptive language, and expressive language. In this study, the gross motor scale was excluded. Each subscale provides T-scores (mean = 50), which can be combined into a composite score reflecting overall early learning abilities (mean = 100). Additionally, age-equivalent scores were calculated to assess developmental levels relative to chronological age (CA). Cheong et al. (2022) has demonstrated the reliability (α = .84–.93) and validity of the Taiwanese version of the MSEL in evaluating cognitive abilities in toddlers with ASD, developmental delays, and typical development.

The Autism Diagnostic Observation Schedule (ADOS; Lord et al., 1999) and its second edition (ADOS-2; Lord et al., 2012) are semi-structured diagnostic tools to assess social interaction, communication, play, and stereotyped behaviors in people who are suspected to be ASD. The ADOS includes three domain scores: communication, social interaction, and a combined score for both. People are categorized into autism, PDD-NOS, or non-autism based on these scores. The ADOS-2 introduced the Toddler Module for children aged 12–30 months, with revised scoring that includes social affect and repetitive behavior domains. In Study 1, 60 participants were assessed using the ADOS, while in Study 2, 12 participants were evaluated with the ADOS-2. The ADOS-2 demonstrated high diagnostic sensitivity (.83 −.96) in a sample in Taiwan (Chen et al., 2023).

Childhood Autism Rating Scale (CARS; Schopler et al., 1980) and Childhood Autism Rating Scale–Second Edition (CARS-2; Schopler et al., 2010). The CARS is a clinician-rated scale developed to distinguish between children with ASD and typically developing

Table 1
Demographics of the Study 1 sample.

Variables	ASD (N = 30)	DD (N = 30)	*p*
Gender (% boys)	93 %	77 %	.071
CA (months), mean (*SD*)	28.67 (2.70)	28.30 (3.90)	.673
MA (months), mean (*SD*)	19.93 (3.08)	20.02 (3.68)	.917
ADOS total score, mean (*SD*)	16.97 (3.00)	3.5 (2.23)	.000
Parent education level			
Mother			
Senior high or lower	13	13	.833
College or higher	15	16	
Father			
Senior high or lower	13	13	.833
College or higher	16	15	

Note. CA= chronological age; MAs = mental ages; ADOS = Autism Diagnostic Observation Schedule; ASD = autism spectrum disorder; DD = developmental delays.

children aged 2 and older. It consists of 15 items that describe various behaviors associated with ASD. Each item is rated on a 7-point scale, with scores ranging from 1 to 4 in half-point increments (1, 1.5, 2, 2.5, 3, 3.5, 4). A total score below 30 indicates non-autism. The CARS has a high internal reliability of.93 and demonstrates strong agreement with clinical diagnosis (Schopler et al., 1988). The CARS2-ST maintain the same item content and scoring criteria as the original CARS (Schopler et al., 1988, 2010). For clarity, throughout the subsequent text, when we use the term "CARS", we are specifically referring to the CARS2-ST.

Statistical Analysis

The independent-samples t-tests were employed to compare various factors between the ASD and DD groups, including the ADOS scores, parents' years of education, MA, and chronological ages (CA) of the participants. The findings revealed no significant differences between the ASD and DD groups in terms of parents' years of education, MA, and CA. However, there was a notable distinction in the ADOS scores, with participants in the ASD group displaying significantly higher scores compared to those in the DD group. Table 1 presents an overview of the demographic characteristics of the participants. The analysis revealed no significant differences in these variables, except for the ADOS score, which displayed a notable distinction between the groups.

Results

We conducted a thorough analysis to determine the most suitable cutoff score for the 15-item version of the CARS in a group of children aged under 3 years. Our findings revealed that the optimal cutoff score for the CARS total score fell within the range of 27.75 to 29.00, as depicted in the comprehensive data presented in Table 2. The cutoff scores of 27.5, 28 and 28.5 correctly classified 93.3 % of children with ASD (n = 28) and 90 % of children with DD (n = 27). This contrasts with the cutoff score of 30 suggested by Schopler et al. (1980), which accurately classified 83.3 % of children with ASD (n = 25) and 96.7 % of children with DD (n = 29). The positive predictive value (PPV) and negative predictive value (NPV) were.90 and.93, respectively.

To select suitable items for the CARS-BF, a two-step process was followed. In the first step, independent t-tests were used to compare the scores of each item between the ASD and DD groups in the CARS. Items with a p value > .000 were excluded, and in the second step, ROC analysis was conducted to determine the optimal cutoff scores, sensitivity, specificity, and area under the ROC curve (AUC) for each item. Items with an AUC below.80 were also excluded based on the criteria outlined by Douglas et al. (2008). The remaining items that met both criteria were selected to develop the CARS-BF.

Data from a sample of 60 matched pairs of participants were analyzed using independent t-tests to examine the differences in the total scores for the 15 original CARS items between the matched pairs. The results indicated that there were no significant differences in Items 4, 10, 11, 13, and 14 (p > .000), and therefore, these items were removed from the analysis. The remaining 10 items showed significant differences and were retained for further analysis. Following established research criteria (Douglas et al., 2008), we considered an AUC > .80 as an acceptable measure of overall predictive validity, which guided our item selection process. Based on this criterion, we excluded Items 4, 5, 6, 9, 10, 11, 13, and 14. Ultimately, we selected Items 1, 2, 3, 7, 8, 12, and 15 to create a simplified version of the questionnaire, referred to as CARS-BF. Detailed results can be found in Table 3.

Following the identification of the seven crucial items for the CARS-BF, we proceeded to evaluate the appropriate cutoff score in the matched sample. When applying cutoff scores of 12.5 and 13 in the sample, 90 % of individuals with DD were correctly identified. Notably, a cutoff point of 12.5 demonstrated a higher rate of accurate categorization of children with ASD compared to a cutoff point of 13, as indicated in Table 4. The PPV and NPV were.90–.91 and.93–.96, respectively.

Discussion

The ROC analysis indicated that 27.5, 28 and 28.5 were the most appropriate cutoff scores when using the original CARS for a sample under 3 years old, demonstrating excellent sensitivity and specificity. Based on the AUC values and item differences, seven

Table 2
Sensitivity, specificity, PPV and NPV of different CARS cutoff scores in the Study 1 sample.

Cutoff	Sensitivity	Specificity	PPV	NPV
25.00	.96	.60	.71	.94
25.50	.96	.63	.72	.94
26.00	.96	.70	.76	.95
26.50	.93	.84	.85	.92
27.00	.93	.86	.87	.92
27.50	.93	.90	.90	.93
28.00	.93	.90	.90	.93
28.50	.93	.90	.90	.93
29.00	.90	.90	.90	.90
29.50	.86	.93	.92	.87
30.00	.83	.96	.95	.85
30.50	.83	.96	.95	.85
31.00	.83	.96	.95	.85
31.50	.80	.96	.95	.83

Note: PPV: Positive Predictive Value; NPV: Negative Predictive Value

Table 3
Matched participants' score for each CARS item.

CARS item	ASD (n = 30)	DD (n = 30)	p	AUC
1. Relating to people	2.63(.52)	1.56(.39)	.000	.945
2. Imitation	2.32(.65)	1.47(.45)	.000	.842
3. Emotional response	2.50(.54)	1.52(.50)	.000	.886
4. Body use	2.00(.73)	1.82(.65)	.309	.569
5. Objects use	2.45(.71)	1.68(.62)	.000	.784
6. Adaption to change	2.38(.70)	1.77(.54)	.000	.761
7. Visual response	2.33(.50)	1.13(.29)	.000	.842
8. Listening response	2.42(.64)	1.55(.59)	.000	.828
9. Taste, smell, touch response and use	2.42(.76)	1.62(.69)	.000	.769
10. Fear or nervousness	2.18(.71)	1.82(.64)	.040	.648
11. Verbal communication	2.60(.59)	2.28(.43)	.021	.671
12. Nonverbal communication	2.43(.47)	1.55(.50)	.000	.873
13. Activity level	1.82(.78)	1.45(.65)	.053	.630
14. Level and consistency of intellectual response	2.45(.51)	2.05(.42)	.002	.714
15. General impression	2.30(.53)	1.28(.28)	.000	.963

Note. ASD = autism spectrum disorder; DD = developmental delays; AUC = area under the curve.

Table 4
Sensitivity, specificity, positive predictive value and negative predictive value of different CARS cutoff scores in the Study 1 sample.

Cutoff	Sensitivity	Specificity	PPV	NPV
11.50	1.00	.80	.83	1.00
12.00	1.00	.86	.88	1.00
12.50	.96	.90	.91	.96
13.00	.93	.90	.90	.93
13.50	.83	.96	.95	.85
14.00	.83	1.00	1.00	.85

Note: PPV: Positive Predictive Value; NPV: Negative Predictive Value

items were selected to create the CARS-BF. Subsequently, a favorable cutoff score for the CARS-BF was determined to fall within the range of 12.5 to 13. Ultimately, cutoff scores of 12.5 and 13 were chosen and utilized in Study 2 as they showed good sensitivity and specificity in this study.

Study2

Methods

Participants

In Study 2, participants were also recruited from a teaching hospital in the Southwest region of Taiwan and categorized into three groups based on different diagnostic criteria compared to Study 1. The diagnostic criteria for ASD have undergone changes over time to better capture the actual characteristics of individuals with ASD (Rosen et al., 2021). DSM-5 introduced two core domains for

Table 5
Demographics of the Study 2 Sample.

Variables	ASD (N = 115)	Mild-ASD (N = 34)	DD (N = 57)	F or χ^2	p
Gender (% boys)	88.7 %	64.7 %	57.9 %	22.919	.000
CA (months), mean (*SD*)	28.90 (3.85)	28.18 (3.78)	29.72 (4.31)	1.707	.184
MA (months), mean (*SD*)	16.52 (5.08)	17.33 (5.79)	22.37 (4.67)	25.963	.000
ADOS total score, mean (*SD*)	17.67 (2.94)	16.42 (3.39)	3.91 (3.69)	358.416	.000
Parent education level					
Mother					
Senior high or lower	39	15	24	2.000	.368
College or higher	76	18	33		
Father					
Senior high or lower	46	13	30	2.734	.255
College or higher	69	20	27		

Note. CA= chronological age; MAs = mental ages; ADOS = Autism Diagnostic Observation Schedule; ASD = autism spectrum disorder; DD = developmental delays.

diagnosing ASD, which improved specificity and reduced misdiagnosis rates. However, this more stringent criterion also resulted in decreased sensitivity. Frazier et al. (2012) discovered that using more relaxed criteria can enhance sensitivity with minimal impact on specificity.

Following Wu et al.'s (2021) criteria, the study included three groups: ASD, mild-ASD, and DD. Toddlers with milder ASD symptoms were identified based on the presence of either (1) three deficits in social communication/interaction and one restricted/repetitive behavior, or (2) two deficits in social communication/interaction and two restricted/repetitive behaviors. The final sample included 115 toddlers with ASD, 34 with mild-ASD, and 57 with DD. Detailed demographic information is presented in Table 5. To examine potential significant differences in demographic characteristics across the three groups, a one-way analysis of variance (ANOVA) was conducted. The results indicated significant differences in gender, MA, and ADOS score among the groups.

Materials and Procedure

Following the same evaluation process with same assessment tools employed in Study 1, participants in Study 2 were allocated to one of three groups using the categorization criteria established by Frazier et al. (2012). The participants' ASD symptoms were assessed by psychiatrists using the CARS and DSM-5 criteria, with a specific emphasis on maintaining consistency above 80 %. Additionally, the cutoff score identified in Study 1 was applied to the Study 2 sample to validate its effectiveness.

Results

In Study 2, a larger sample size was utilized to validate the initial cutoff score obtained for the CARS-BF from Study 1. The original CARS(CARS2-ST) recommended the cutoff scores of 27.5, 28 and 28.5 as appropriate. Applying these cutoff scores to the Study 2 sample, the findings indicated that the cutoff scores of 28 and 28.5 classified 129 out of 149 children with ASD (or children with mild-ASD) and 46 out of 57 children with DD. The cutoff score of 27.5 classified 131 out of 149 children with ASD (or children with mild-ASD) and 45 out of 57 children with DD and exhibited the highest sensitivity comparing with the other two cutoff scores (see Table 6). Moreover, toddlers with ASD and those with mild-ASD were combined into a single group for comparison with the DD group. The PPV and NPV were summarized in Table 7.

The agreement between the CARS-BF and clinical diagnosis was assessed by comparing the diagnosis category determined by the CARS-BF, as presented in Table 8. With a cutoff score of 12.5, 135 out of 149 children with ASD (or children with mild-ASD) and 44 out of 57 children with DD were correctly classified. Similarly, with a cutoff score of 13, 129 out of 149 children with ASD (or children with mild-ASD) and 48 out of 57 children with DD were accurately classified based on their clinical diagnosis. The cutoff score of 12.5 demonstrated higher sensitivity in detecting toddlers with an increased likelihood of an ASD diagnosis s, with a sensitivity of.90 and a specificity of.77 for distinguishing between ASD and DD. Likewise, for the cutoff scores of the CARS-BF, toddlers with ASD and those with mild-ASD were also grouped together and compared against the DD group. The PPV and NPV were presented in Table 9.

General Discussion

This study aimed to evaluate the validity of the CARS, a diagnostic instrument developed by Schopler et al. (1980), in a sample of children aged under 3 years. While the CARS is widely utilized in clinical settings as a Level 2 tool for distinguishing between ASD and DD, limited research has focused on its application for detecting ASD in young children. Research has highlighted the importance of identifying infants at elevated likelihood for ASD and the subsequent provision of early intervention resources, as this can significantly improve their symptoms. Furthermore, considering the time constraints often faced in clinical assessments, there is a need for a shortened version of the CARS that maintains consistency with clinical diagnosis. The development and validation of the brief version of the CARS in this study provide a valuable contribution to enhance the efficiency of early diagnostic processes for ASD. The findings support the utility of the CARS as a valuable tool for diagnosing ASD in children under 3 years old, with the potential to improve early intervention strategies and ultimately enhance outcomes for these children.

The original version of the CARS employed a cutoff range of 30 to 36.5 to classify children with ASD based on different levels of challenges. However, studies conducted in Western populations, such as the research by Perry et al. (2005), have suggested a cutoff score of 30. Although a cutoff point of 30 is commonly applied to distinguish children with ASD from those without ASD children,

Table 6
Agreement of the CARS adjusted cutoff score with clinical diagnosis classification.

	Clinical diagnosis					
	ASD (n = 115)		Mild-ASD (n = 34)		DD (n = 57)	
CARS risk category						
Cutoff 27.5						
High risk		103 (89.6 %)	28 (82.4 %)			12 (21.1 %)
Low risk		12 (10.4 %)	6 (17.6 %)			45 (78.9 %)
Cutoff 28、28.5						
High risk	102 (88.7 %)		27 (79.4 %)		11 (19.3 %)	
Low risk	13 (11.3 %)		7 (20.6 %)		46 (80.7 %)	

Note. ASD = autism spectrum disorder; DD = developmental delays.

Table 7
PPV and NPV of different CARS cutoff scores in the Study 2 sample.

Cutoff	Sensitivity	Specificity	PPV	NPV
Cutoff 27.5	.88	.79	.92	.71
Cutoff 28	.87	.81	.92	.70
Cutoff 28.5	.87	.81	.92	.70

Note: PPV: Positive Predictive Value; NPV: Negative Predictive Value

Table 8
Agreement of the CARS-BF category with clinical diagnosis classification.

	Clinical diagnosis		
	ASD (n = 115)	Mild-ASD (n = 34)	DD (n = 57)
CARS-BF risk category			
Cutoff 12.5			
High risk	106 (92.2 %)	29 (85.3 %)	13 (22.8 %)
Low risk	9 (7.8 %)	5 (14.7 %)	44 (77.2 %)
Cutoff 13			
High risk	102 (88.7 %)	27 (79.4 %)	9 (15.8 %)
Low risk	13 (11.3 %)	7 (20.6 %)	48 (84.2 %)

Note. ASD = autism spectrum disorder; DD = developmental delays.

Table 9
PPV and NPV of different CARS-BF cutoff scores in the Study 2 sample.

Cutoff	Sensitivity	Specificity	PPV	NPV
Cutoff 12.5	.91	.77	.91	.76
Cutoff 13	.87	.84	.93	.71

Note: PPV: Positive Predictive Value; NPV: Negative Predictive Value

previous studies have shown that when the CARS is applied to different cultural samples, varying optimal cutoff scores are often found, leading to improved sensitivity and specificity. Interestingly, research conducted in Asian populations, including studies by Tachimori et al. (2003) and Kwon et al. (2017), have consistently indicated that a lower cutoff score is more appropriate. These cultural differences suggest that the cutoff scores may need adjustment to better reflect the unique behavioral and developmental characteristics of children in different regions. Our findings align with these Asian studies, further highlighting the need for a lower cutoff score in Asian populations for accurate classification of children with ASD using the CARS.

While it is important to consider different perspectives, such as the study conducted by Chu et al. (2020) in China suggesting an increased cutoff score, it is essential to note the limitations of their study, particularly the wide age range of their participants, which may affect the generalizability of the proposed score across all age groups. Furthermore, Stevanovic et al. (2021) highlighted those variations in training methods and cultural factors related to the manifestation of ASD symptoms can impact the cross-cultural validity of the CARS in assessing ASD. Therefore, adjusting the cutoff score based on specific cultural and contextual considerations becomes necessary to ensure accurate and appropriate classification of children with ASD using the CARS.

In Study 1, we determined optimal cutoff scores of 27.5, 28, and 28.5 for distinguishing between ASD and DD in toddlers. The diagnostic validity results were highly promising. By utilizing these cutoff scores, we achieved a high classification accuracy, correctly identifying 93.3 % of toddlers with ASD and 90 % of toddlers with DD. These findings demonstrate the effectiveness of the chosen cutoff scores in accurately differentiating between ASD and DD in young children. To validate the newly determined cutoff scores, we utilized a separate sample in Study 2. This study followed the approach of Frazier et al. (2012) by using both strict and lenient DSM-5 criteria to include toddlers with ASD or those with mild-ASD. Following the categorization method proposed by Wu et al. (2021), we divided the Study 2 sample into three groups based on the diagnostic criteria. First, in original CARS, using the chosen cutoff scores (e.g., 27.5, 28 and 28.5), we achieved a classification accuracy over 80 % for toddlers with ASD. While cognitive ability was not specifically controlled for, the sensitivity and specificity of the cutoff score remained above the recommended threshold of.80. Among these cutoff scores, 27.5 exhibited the highest sensitivity in Study 2. These findings align with previous studies highlight the significance of early diagnosis and the utility of using a cutoff score of 27.5 in diagnosing children with increased likelihood of ASD in the preschool age range.

Following item selection, we identified cutoff scores of 12.5 and 13 as optimal for distinguishing between ASD and DD using the CARS-BF. When classifying children with ASD using the CARS-BF, cutoff scores of 12.5 and 13 demonstrated strong agreement with clinical diagnoses. These findings suggest that the optimal cutoff range for the CARS-BF lies between 12.5 and 13, and that it demonstrates diagnostic accuracy comparable to that of the original CARS. However, it is crucial to acknowledge that if compared to international studies, the sample size in this study was relatively small, primarily consisting of participants from southern Taiwan. To

enhance the generalizability of these findings, future research should strive to validate these results with larger and more diverse samples. Furthermore, when the cutoff scores of 12.5 and 13 were applied to the Study 2 sample, they successfully identified approximately 80 % of cases with mild ASD. This underscores the significance of continuous monitoring and tracking the development of toddlers exhibiting milder ASD symptoms. These findings are consistent with previous research conducted by Wu et al. (2021), which also reported a detection rate of around 70 % to 80 % for mild ASD cases. These findings indicate that toddlers with mild ASD are indeed considered to be at an elevated likelihood for ASD.

In previous diagnostic classifications, individuals with mild-ASD were commonly categorized as pervasive developmental disorder not otherwise specified (PDD-NOS) within the DSM-IV-TR (APA, 2000). However, the heterogeneity in clinical characteristics and the varying severity of symptoms have posed significant challenges in classifying individuals with PDD-NOS as a homogeneous group (Buitelaar et al., 1999; Luteijn et al., 2000; Stone et al., 2004). As a result, early identification and diagnosis of children with mild-ASD have become increasingly challenging. In our study, the inclusion of toddlers with mild-ASD may have had implications for the validity of the results. It is important for future research to specifically focus on this subgroup, as they are often at risk of being misclassified as having DD. Further investigation into the characteristics of toddlers with mild-ASD is crucial to prevent misdiagnosis and ensure timely access to appropriate early intervention and educational support for these toddlers.

After determining the cutoff score for the original version of the CARS, seven items were selected from the original CARS instrument, resulting in the development of the CARS-BF, based on their strong validity in our sample. To ensure effectiveness, we used a significance criterion of $p < .001$ to compare scores in the Study 1 sample. This rigorous approach aimed to enhance the discriminatory power of the selected items for improved accuracy of the CARS-BF as a diagnostic tool. In our selection process, we also considered the standard set by Douglas et al. (2008), which recommends choosing items with an AUC greater than.80 for discrimination. The CARS-BF, comprising the items Relating to people (1), Imitation (2), Emotional response (3), Visual response (7), Listening response (8), Nonverbal communication (12), and General impression (15), showed enhanced validity in our sample. Certain items, namely Objects use, Adaptation to change, Taste, smell, touch response and use (9), Fear or nervousness (10), Verbal communication (11), and Activity level (13), were excluded from the CARS-BF based on the analysis conducted in this study. The purpose was to create a more streamlined and efficient diagnostic tool for ASD.

In contrast to previous abbreviated studies (Sanchez & Constantino, 2020; Wu et al., 2014), our study applied stricter criteria for item exclusion, resulting in a reduced number of items in the CARS-BF. However, the selected items (1, 2, 3, 7, 8) in our study were found to be consistent across various factor analysis studies (DiLalla & Rogers, 1994; Magyar & Pandolfi, 2007; Moulton et al., 2019). These items specifically assess social interaction and communication, which are considered essential domains in the evaluation of ASD. While Sanchez and Constantino (2020) excluded Items 9–15 in their study, our findings, along with previous research, indicate the importance of including Item 12, related to communication in the DSM-5 (American Psychiatric Association, 2013), and Item 15, which reflects the assessor's impression of toddlers. These two items, capturing the assessors' impression, can provide valuable discriminative information. Therefore, we recommend including Items 12 and 15 in the CARS-BF for enhanced validity.

In the process of developing the CARS-BF, we excluded 8 items (4, 5, 6, 9, 10, 11, 13, 14) from the original CARS. Notably, Items 6 and 9 specifically address restricted and repetitive behaviors (RRBs). RRBs can be classified into two categories: Lower-order RRBs and higher-order RRBs, as described in research by Uljarević et al. (2017). Higher-order RRBs, such as adaptation to change, typically manifest and become more apparent in later childhood, which may explain the exclusion of Item 6 in our study focusing on children under 3 years old (Song et al., 2022). On the other hand, Item 9 falls into the category of lower-order RRBs, which encompasses repetitive sensorimotor behaviors more commonly observed in young children (Coulter et al., 2021). Considering the developmental differences in RRBs, the exclusion of Item 6 and Item 9 in our study aligns with the goal of capturing early social communication difficulties in young children with ASD. Given that our sample consisted of children under 3 years old, it is possible that Item 9 could be observed frequently in both toddlers with ASD and those with DD.

In our study, Item 10 (fear or nervousness), 11 (verbal communication) and 14 (Level and consistency of intellectual response) did not reach the significance level ($p < .001$) and were therefore excluded from the CARS-BF. However, it is worth noting that if a less stringent significance level of $p < .05$ was used, these items still showed significant differences between the ASD and DD groups. For example, toddlers with ASD exhibited more nervousness and anxiety (Item 10) compared to toddlers with DD. Nevertheless, nervousness and anxiety are common in children of this age group, particularly in unfamiliar environments, limiting Item 10's ability to accurately differentiate between the two groups.

Similarly, regarding the exclusion of Item 11 and 14, it's important to consider the cultural context. In Taiwan, it is common for parents to seek early intervention for their children who experience language delay or intellectual impairment. Our study indeed observed that participants exhibited poor verbal abilities, which were closely related to their intellectual functioning. Consequently, Item 11 and 14 may not effectively distinguish between the two groups.

While these items were excluded due to statistical considerations, further analysis of other items revealed additional insights into the challenges of differentiating between ASD and DD in young children. For example, toddlers with weaker verbal skills regardless of their diagnoses often rely more on body language to express their intentions, which could explain why Item 4 (Body use) may not have good discriminatory power. Additionally, toddlers with developmental disabilities (e.g., ASD, DD), often struggle with rule-following and may display high levels of activity. As a result, Item 13 may not demonstrate significant differences in these toddlers. These factors present significant challenges for early diagnosis, and it is possible that these items may not effectively differentiate between ASD and DD.

In summary, this study highlights the need for adjusting the cutoff score of the original CARS when assessing toddlers, particularly in Asian populations. To address this, the CARS-BF was developed, consisting of 7 items, which has the potential to significantly reduce the time needed for identifying toddlers at elevated likelihood for ASD. The study aimed to establish an appropriate cutoff score for the

CARS-BF and validate its effectiveness in accordance with clinical diagnosis. The findings align with prior research and emphasize the importance of utilizing items that assess social interaction and communication difficulties to differentiate between toddlers with ASD and those with DD.

Conclusion

This study sought to assess the diagnostic validity of the CARS in a group of children under 3 years old diagnosed with ASD and DD. The findings revealed high sensitivity and specificity when utilizing a lower cutoff score. Furthermore, the study evaluated the efficacy of the CARS-BF, a shorter version of the scale, in a larger validation sample, employing a cutoff score of 13. This study has provided a more efficient tool for early clinical assessments through the development of CARS-BF and the determination of optimal cutoff values. By deriving a shortened version from the original CARS, future research can directly validate the efficacy of the brief version.

The study's findings indicated favorable validity of the CARS-BF for detecting ASD in toddlers. However, it is crucial to acknowledge some limitations of the study. Firstly, the sample size employed in the research was relatively small, particularly when considering toddlers with mild-ASD, in comparison to previous studies conducted in the field. The possibility of misidentifying these individuals as toddlers with DD at an early stage is a valid concern that warrants recognition. Secondly, it is worth noting that the study's sample was predominantly recruited from a rural area in Taiwan, which may limit the generalizability of the findings to other populations. Recent research by Hsu et al. (2023) has highlighted the potential variations in ASD prevalence between urban and rural areas in Taiwan. To overcome this limitation, future studies should strive to include participants from diverse sources and geographical locations.

CRediT authorship contribution statement

Yuh-Ming Hou: Methodology, Investigation. **Pei-Ci Chuang:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Chin-Chin Wu:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Conceptualization. **Lai-Sang Iao:** Writing – review & editing, Writing – original draft.

Informed consent

Informed consent was obtained from all individual participants included in this study.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the Ditmanson Medical Foundation Chia-Yi Christian Hospital Research Ethics Committee (CYCH-IRB102045).

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The data that has been used is confidential.

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