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Abstract	in detecting autism spectrum sample, which consisted of 11 between 16 and 24 months of 2); 57 children had ASD and yielded an optimal combination	y examined the utility of the screening tool for autism in 2-year-olds (STAT) disorder (ASD) in toddlers who are less than 24 months of age. The study 9 toddlers with developmental problems, were assessed when they were age (Time 1) and after a period of 18 months to finalize the diagnosis (Time 62 children had developmental delays. A cutoff score of 2.5 on the STAT on of high sensitivity and specificity. The STAT demonstrated adequate g ASD in Taiwanese toddlers who are less than 24 months of age.
Keywords (separated by '-')	Autism spectrum disorder - T	oddler - Screening - Sensitivity - Specificity
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ORIGINAL PAPER



² The Utility of the Screening Tool for Autism in 2-Year-Olds in Detecting

Autism in Taiwanese Toddlers Who are Less than 24 Months of Age:
 A Longitudinal Study

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Abstract

¹⁰ The present longitudinal study examined the utility of the screening tool for autism in 2-year-olds (STAT) in detecting ¹¹ autism spectrum disorder (ASD) in toddlers who are less than 24 months of age. The study sample, which consisted of 119 ¹² toddlers with developmental problems, were assessed when they were between 16 and 24 months of age (Time 1) and after ¹³ a period of 18 months to finalize the diagnosis (Time 2); 57 children had ASD and 62 children had developmental delays. A ¹⁴ cutoff score of 2.5 on the STAT yielded an optimal combination of high sensitivity and specificity. The STAT demonstrated ¹⁵ adequate predictive validity in detecting ASD in Taiwanese toddlers who are less than 24 months of age. <u>AQI</u>

¹⁶ Keywords Autism spectrum disorder \cdot Toddler \cdot Screening \cdot Sensitivity \cdot Specificity

17 Autism spectrum disorder (ASD) is a neurodevelopmental 18 disorder that emerges during early childhood. It is defined 19 by impairments in social and communication skills, repeti-20 tive behavior patterns, and a restricted range of interests 21 (American Psychiatric Association 2013). There are con-22 siderable individual differences in the behavioral, language, 23 and intellectual capabilities of individuals with ASD. Past 24 studies have shown that children with ASD who begin 25 receiving early intervention services between the ages of 2 26 and 5 exhibit improved outcomes and prognosis (Dawson 27 et al. 2010; Pickles et al. 2016). The effectiveness of early 28

intervention highlights the importance of early diagnosis.	
On average, parents develop concerns about their children	29
with ASD and seek professional help for the first time when	30
their children are 19 and 24 months of age, respectively	31
(Becerra-Culqui et al. 2018; De Giacomo and Fombonne	32
1998; Sacrey et al. 2015). There are a few factors (e.g., sex,	33
degree of impairment that is associated with ASD) that delay	34
the diagnosis of ASD and consequently adversely impact	35
child and family outcomes (Wiggins et al. 2006).	36

The prevalence of ASD among children has increased dramatically in recent years. Indeed, estimates suggest that

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1 in 59 children in the United States (Baio et al. 2018), 1.2 in 39 100 children in the United Kingdom (Baird et al. 2006), and 40 1 in 106 children in Australia (Veness et al. 2012) have ASD. 41 The increasing prevalence of ASD and the effectiveness of 42 early interventions highlight the need for and importance of 43 early diagnosis. However, the prevalence of ASD is lower in 44 Taiwan than in Western countries (Lai et al. 2012; Sun et al. 45 2013), and this difference can be attributed to factors such as 46 the stigma that is associated with psychological diagnoses in 47 Chinese culture (Pang et al. 2018), government policies (Lai 48 et al. 2012), and the inadequacy of tools that can be used to 49 screen for ASD among young children (Lai et al. 2011). The 50 lower prevalence may be associated with delayed diagnoses, 51 which in turn may cause parents to experience high levels of 52 anxiety and frustration. Thus, it is necessary to facilitate the 53 early diagnosis of ASD in Taiwan, especially in community-54 based clinical settings, such as district hospitals.

55 The best-estimate clinical diagnosis (BECD) is formu-56 57 lated based on the information that is yielded by a multidisciplinary assessment process, which includes the child's 58 developmental history, parental concerns, and the measure-59 60 ment of cognitive and language abilities, adaptive functioning, and the diagnostic criteria for autism (Le Couteur et al. 61 2008). The Autism Diagnostic Interview-Revised (ADI-62 R; Le Couteur et al. 2003), autism diagnostic observation 63 schedule (ADOS; Lord et al. 1999), and the ADOS-2 (Lord 64 et al. 2012b) are valid measures that can be used to make 65 diagnostic decisions about autism; in particular, a combi-66 nation of the ADI-R and ADOS(-2) yields valid diagno-67 ses. Both the BECD protocol and the combinatorial use of 68 69 measurements that aid in the diagnosis of autism are timeconsuming procedures. In Taiwan, only child and adolescent 70 psychiatrists are eligible to issue documents that certify a 71 child with a diagnosis of ASD. Child and adolescent psy-72 chiatrists typically shoulder a heavy workload, and they typi-73 cally treat more than 30-40 children within a 3-4-h clinic 74 session. They may refer the child to clinical psychologists 75 for further assessments that could aid the diagnostic deci-76 sion-making process. However, it is difficult for Taiwanese 77 child and adolescent psychiatrists or clinical psychologists to 78 execute the BECD protocol or administer a combination of 79 measurements that assess the diagnostic criteria for autism. 80 81 Therefore, it is important to use an affordable and easy-toadminister screening tool to facilitate the early identification 82 and diagnosis of ASD among children in Taiwan, particu-83 84 larly in clinical settings.

The existing screening tools for ASD can be divided into 85 two levels (Barton et al. 2012; Filipek et al. 1999). Level 1 86 screening tools are designed for use with the general popu-87 lation, whereas level 2 screening tools are designed for use 88 with those who are at a high risk for ASD or with clini-89 cal samples. In Taiwan, a majority of infants and toddlers 90 undergo physical and developmental screening in primary 91

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care settings (e.g., community clinics, health centers) when they are vaccinated. This process allows healthcare providers to examine the socioemotional functioning (e.g., response to one's name) of infants and toddlers, and identify high-risk cases that require further clinical diagnosis. One of main following referring settings is the department of child psychiatry at regional hospitals in Taiwan. Clinical psychologists are one of the key collaborative professionals for these psychiatrists to make formal diagnosis. Thus, a level 2 (rather 100 than a level 1) screening tool that is used for differentiating 101 between children with ASD and those with other develop-102 mental problems is urgently needed because all high-risk 103 infants and toddlers were referred from primary care settings 104 in Taiwan. 105

The American Academy of Pediatrics recommends that 106 all toddlers who are between the ages of 18 and 24 months 107 should be screened using an ASD-specific tool (Johnson 108 and Myers 2007). However, there are only a few interactive 109 screening measures for ASD that are suitable for use with 110 toddlers who are below 24 months of age; these assessments 111 include the screening tool for autism in 2-year-olds (STAT; 112 Stone et al. 2004), Autism Detection in Early childhood 113 (ADEC; Nah et al. 2014), and Rapid Interactive Screening 114 Test for Autism in Toddlers (RITA-T; Choueiri and Wagner 115 2015). Among these three interactive screening measures, 116 only the STAT and ADEC have been validated and tested 117 using high-risk samples. The STAT consists of 12 activity-118 based items that measure four domains: play, requesting, 119 directing attention (i.e., joint attention), and imitation. It 120 was originally designed for use with young children who 121 are between the ages of 24 and 35 months. Khowaja et al. 122 (2012) found that a cutoff score of 2.25 on the STAT had a 123 sensitivity and specificity of 0.75 for a sample of 24 tod-124 dlers who were less than 24 months old. On the other hand, 125 the ADEC consists of 16 items that are suitable for use 126 with young children who are between the ages of 12 and 127 36 months. A cutoff score of 11 on the ADEC yielded a 128 sensitivity of 1 and specificity of 0.77 for 70 young children 129 with autism ($M_{age} = 29.4$ months) and 57 young children 130 with other developmental disorders ($M_{age} = 24.1$ months). 131 The ADEC demonstrated better sensitivity and specificity 132 than the STAT (Nah et al. 2014). 133

Correct identification of children with ASD (i.e., high 134 sensitivity and positive predictive value) allows both the 135 children and their families to receive early intervention. 136 However, false positives (i.e., low specificity and negative 137 predictive value) can adversely affect the misdiagnosed chil-138 dren and their families. Therefore, it is important to establish 139 the predictive validity of ASD screening tools and the tem-140 poral stability of diagnostic assessment. A few recent studies 141 have suggested that the BECD is a reliable and stable assess-142 ment that can be used to diagnose ASD in toddlers who are 143 less than 24 months of age (Barbaro and Dissanayake 2017; 144 Guthrie et al. 2013; Kim et al. 2016). However, few studies have examined the predictive validity of ASD screening tools.

In order to validate the STAT, Stone et al. (2008) 148 recruited 71 toddlers who were between the ages of 12 and 149 23 months ($M_{age} = 16.4$ months). Of these, 59 toddlers had 150 an older sibling with ASD and 12 toddlers were referred 151 for an assessment of ASD. All the participants (including 152 the 19 children with ASD and 52 children without ASD) 153 were retested when they were between the ages of 24 and 154 42 months ($M_{age} = 31.3$ months). A cutoff score of 2.75 155 on the STAT yielded a predictive sensitivity of 0.95 and 156 specificity of 0.73 for toddlers who were less than 24 months 157 old. However, their findings entailed a high number of false 158 positives for toddlers who were less than 13 months of age. 159 Dix et al. (2015) assessed 53 toddlers who were between 160 the ages of 18 and 47 months ($M_{age} = 32.2$ months). Of 161 these, 32 children received a diagnosis of ASD ($M_{age} =$ 162 41.2 months, range = 22-65 months), and all the partici-163 pants were retested when they were between the ages of 48 164 and 97 months ($M_{age} = 74.5$ months). A cutoff score of 11 165 on the ADEC yielded a predictive sensitivity of 0.88 and 166 specificity of 0.62 for 2-year-old toddlers. Contrary to the 167 concurrent validity results of the two assessments, the STAT 168 demonstrated better predictive validity than the ADEC. 169

The sensitivity of the STAT and T-STAT (i.e., the Tai-170 wanese version of the STAT) was tested using a hospital-171 based clinical sample of 24-36-month-old children with 172 ASD and developmental delays (DD: Chiang et al. 2012. 173 2013). A cutoff score of 2 on the T-STAT yielded acceptable 174 sensitivity (0.94–0.97) and specificity indices (0.82–0.93). 175 Additionally, a study that examined the validity of the STAT 176 in ascertaining the risk of ASD among 2-year-old children in 177 Taiwan yielded promising results. However, there is a need 178 to examine the predictive validity of the STAT using samples 179 of toddlers who are older than 24 months. Thus, the primary 180 purpose of the present study was to examine the predictive 181 validity of the STAT as a screening tool for ASD using a 182 hospital-based clinical sample. Specifically, we examined 183 the utility of the STAT in detecting ASD in toddlers who are 184 less than 24 months of age (Time 1). Additionally, we exam-185 ined the predictive validity of the STAT by readministering 186 it to the participants after a period of 18 months (Time 2). 187

188 Methods

189 Participants

The present study was approved by the Ditmanson Medical Foundation Chia-Yi Christian Hospital Research Ethics Committee (CYCH-IRB101022; CYCH-IRB102045). All parents provided informed consent prior to the administration of the assessment. A total of 139 toddlers 194 who were between the ages of 16 and 24 months (Time 1) 195 participated in the study, and they were all recruited from a 196 teaching hospital in the Chia-Yi area. After 18 months had 197 passed, the participants were invited for a reassessment. 198 A total of 119 children who were between the ages of 35 199 and 46 months (Time 2) underwent follow-up assessment; 200 the remaining 20 children did not attend the follow-up 201 assessment. None of the participants had sensory or motor 202 impairments, or previously diagnosed genetic disorders. 203 The average period of time that had elapsed between 204 the initial and follow-up assessments was 18.64 months 205 (SD = 1.09).206

All participants were diagnosed with either ASD or DD 207 in accordance with the Diagnostic and Statistical Manual of 208 Mental Disorders, Fifth edition (DSM-5; APA 2013) criteria 209 and the results of the follow-up assessment. According to the 210 DSM-5 criteria for ASD, a child must exhibit a minimum of 211 three deficits in social communication/interaction skills and 212 two restricted/repetitive behaviors. However, previous stud-213 ies (e.g., Frazier et al. 2012) have shown that these DSM-5 214 criteria have a lower sensitivity than those of the Diagnostic 215 and Statistical Manual of Mental Disorders, Fourth edition, 216 Text Revision (DSM-IV-TR; APA 2000). Thus, partici-217 pants that did not meet the criteria for ASD according to 218 the DSM-5 still had significant impairments related to the 219 core symptoms of ASD. Participants that no longer met the 220 DSM-5 criteria for ASD may not be classifiable into DD 221 groups. Using the strict diagnostic criteria of the DSM-5 222 may impede early intervention for children with ASD and 223 family services. Thus, to increase sensitivity, Frazier et al. 224 (2012) have proposed a set of less stringent criteria based on 225 which a child may be considered to meet the DSM-5 criteria 226 for ASD. Accordingly, the following criteria were used in 227 the present study: (1) three deficits in social communication/ 228 interaction skills and one restricted/repetitive behaviors, and 229 (2) two deficits in social communication/interaction skills 230 and two restricted/repetitive behaviors. All participants with 231 ASD were assessed and diagnosed based on their devel-232 opmental history, the current concerns of the parents, the 233 results of tests that measure cognitive and adaptive func-234 tioning, clinical observations of the child, and the results 235 of ADOS (Lord et al. 1999) by a multidisciplinary team 236 that included two senior clinical child psychologists with 237 doctoral degrees and two senior child and adolescent psy-238 chiatrists constituted the diagnostic team. The participants 239 who failed to reach a total score of 85 on the Mullen Scales 240 of Early Learning (MSEL; Mullen 1995) or a T-score of 35 241 on any of the four cognitive scales (i.e., visual reception, fine 242 motor, receptive language, and expressive language) were 243 considered to have DD. Finally, there were 57 children who 244 had ASD and 62 children who had DD. Of the 57 children 245 who had ASD, 43 children met the strict DSM-5 criteria 246

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whereas the others met the less stringent DSM-5 criteria that have been suggested by Frazier et al. (2012).

All the study participants were assessed using the MSEL 249 (Mullen 1995), which measures the four domains of devel-250 opmental abilities. The mental age was computed by averag-251 ing the age equivalents across the four domains. The results 252 of an independent-samples t-tests showed that the ASD and 253 DD groups were of comparable chronological age at both 254 Time 1 and Time 2. In addition, the *t*-tests showed that chil-255 dren with DD had a higher mental age than those with ASD 256 at both Time 1 and Time 2. The results of the *t*-tests also 257 showed that children with ASD obtained higher scores than 258 children with DD on ADOS at both Time 1 and Time 2. 259 260 The results of a chi-squared test showed that there was no significant difference in the gender ratios of the two groups. 261 The demographic characteristics of the sample that were 262 included in the present study are presented in Table 1. 263

264 **Procedures and Measures**

During the initial and follow-up assessments, all the participants were subjected to the STAT (Stone et al. 2008), MSEL (Mullen 1995), and ADOS (Lord et al. 1999). The examiners who administered the STAT were agnostic to the diagnostic information of the participants as well as to the concerns of the caregivers prior to administration. In addition, the examiners who administered the ADOS were not provided with any information about the STAT prior to the administration procedure. For each child, a different examiner administered the STAT during the initial and follow-up assessments.

Table 1 Demographic characteristics of the participants

Variable	ASD group $(n = 57)$	DD group $(n=62)$	р
Time 1			
Mean (SD): CA ^a	21.37 (1.97)	21.21 (1.93)	0.658
Mean (SD): MA ^a	13.96 (3.32)	16.23 (2.96)	0.000
Mean (SD): composite score of ADOS	16.04 (4.90)	5.26 (3.98)	0.000
Time 2			
Mean (SD): CA ^a	39.93 (2.23)	39.92 (1.89)	0.978
Mean (SD): MA ^a	31.11 (9.74)	35.92 (6.88)	0.002
Mean (SD): composite score of the ADOS	14.30 (3.74)	2.76 (2.21)	0.000
Gender ratio			
Male: female	47:10	44:18	0.140

CA chronological age, *MA* mental age, *ADOS* autism diagnostic observation schedule, *ASD* autism spectrum disorder, *DD* developmental delays

^aIn months

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However, due to a limited number of research staff, a major-
ity of the ADOS administrations were undertaken by the first
and second authors who had received research training and
certification in Taiwan (i.e., by Dr. Catherine Rice's team at
Pingtung county). The authors did not review participants'
ADOS scores at Time 1 before administering and scoring
the ADOS at Time 2.275
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The STAT was administered by examiners who were 282 graduate students (i.e., Master of Science) in the discipline 283 of clinical psychology and had received prior training on 284 the administration and scoring of the assessment. The clear 285 operationalization of each item and provision of examples 286 that aid the scoring process minimize the subjective inter-287 pretations of the examiner (Nah et al. 2014). Prior to the 288 administration of the assessments, an 8-h training course was 289 conducted for the examiners who were required to adminis-290 ter the STAT. The examiners were trained with the objective 291 of familiarizing them with the standardized test administra-292 tion protocol; interrater reliability between these examiners 293 and the first author who had been trained in the administra-294 tion and scoring of the STAT was high (i.e., 0.90). In order 295 to enhance interrater reliability, the examiners periodically 296 discussed the manner in which they scored the STAT and 297 ADOS. 298

Mullen Scales of Early Learning (MSEL; Mullen 1995)

The MSEL is a standardized comprehensive developmen-300 tal test that was designed for use with preschool children 301 whose ages range from 0 to 68 months. It consists of four 302 cognitive scales: visual reception, fine motor, receptive lan-303 guage, and expressive language. The four cognitive scales 304 yield T-scores, which have a mean of 50. The four subscale 305 scores can be used to compute a composite score, which is 306 an indicator of early learning and has a mean of 100. The 307 MSEL has demonstrated concurrent validity against other 308 well-known developmental tests of language and cognitive 309 development (e.g., Bayley Scales of Infant Development; 310 Bayley 1969). In addition, it has demonstrated acceptable 311 internal consistency and test-retest reliability. 312

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Screening Tool for Autism in 2-Year-Olds (STAT; Stone et al. 313 2004, 2008) 314

The STAT is an interactive measurement instrument that 315 was originally designed to screen for autism in children 316 who are between the ages of 24 and 35 months. The STAT 317 is an individually administered assessment that consists of 318 12 activity-based items and takes approximately 20 min 319 to complete. It measures four early social-communicative 320 skills: play (two items), requesting (two items), joint atten-321 tion (four items), and imitation (four items). All of the items 322 are scored as either a "pass" or a "fail." The failed items of 323

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each domain are converted into scores. The scores of the 324 two-item domains can be 0, 0.5, or 1, whereas the scores for 325 the four-item domains can be 0, 0.25, 0.50, 0.75, or 1. Thus, 326 the scores for each domain of the STAT can range from 0 327 to 1. In addition, the total STAT score can be computed by 328 summing the four domain scores. Therefore, the composite 329 score can range from 0 to 4; higher scores are indicative of 330 greater levels of impairment. The STAT has demonstrated a 331 good level of accuracy in identifying autism and DD in chil-332 dren who are between the ages of 24 and 35 months. Item 333 descriptions and the scoring procedure have been provided 334 by Stone et al. (2004). 335

Autism Diagnostic Observation Scale (ADOS; Lord et al. 336 1999) 337

The ADOS is a semi-structured play-based and observational assessment that is divided into four modules. Each module is selected based on the age and expressive language of the respondent. The ADOS is considered to be the best diagnostic tool for ASD because it serves as a standardized means by which language and communication skills, reciprocal social and stereotypic behaviors, and restricted interests can be observed and scored. Each module provides an algorithm that entails cutoffs that can be used to assign respondents to one of the following three categories: autism, 347 autism spectrum (i.e., pervasive developmental disorder-not 348 otherwise specified; PDD-NOS), or non-ASD. In the present study, both autism and PDD-NOS were merged into one category, namely, ASD. Due to the relatively young age of the children who participated in the present study, Module 1 was administered at Time 1 and either Module 1 or 2 was 353 administered at Time 2. A modified version of the ADOS, 354 namely, the ADOS-2: Toddler Module (Lord et al. 2012a), 355 is commonly used with toddlers who are between the ages 356 of 12 and 30 months. However, this assessment was not used 357

in the present study due to constraints that were related to 358 cultural adaptation and validation. Thus, we used Module 359 1 of the ADOS to diagnose ASD in 24-month-old toddlers. 360

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Analysis

Statistical Package for the Social Sciences (SPSS) was used 362 to conduct the statistical analyses that were used in the pre-363 sent study. Independent-samples t-tests were used to com-364 pare children with ASD and DD on the STAT scores across 365 Time 1 and Time 2. To avoid alpha inflation, only results 366 that corresponded to *p*-values that were less than 0.01 (i.e., 367 (0.05/5) were considered to be statistically significant. In 368 addition, the screening properties of the STAT were exam-369 ined using receiver operating characteristics (ROC). The 370 ROC was examined to select the optimal range of cutoff 371 scores and consequently examine the sensitivity and speci-372 ficity of the STAT. Finally, we tested the diagnostic accuracy 373 of the STAT by examining the area under the curve (AUC), 374 as per the specifications that have been provided by Cic-375 chetti et al. (1995). Specifically, values that are less than 376 0.70, between 0.70 and 0.79, between 0.80 and 0.89, and 377 above 0.90 are indicative of poor, fair, good, and excellent 378 sensitivity and specificity, respectively. 379

Results

The performances of the two groups on the STAT are shown 381 in Table 2. The results revealed significant group differences 382 in the four subscale scores (i.e., play, requesting, joint atten-383 tion, and imitation domain) as well as the composite STAT 384 score at Time 1. Further, when mental age (MA) at Time 1 385 was controlled for, significant group differences emerged for 386 three subscale scores (i.e., play, requesting, and joint atten-387 tion) and the composite STAT score at Time 1. However, 388

Table 2 Significance of the difference in performance on	Variable	ASD (<i>n</i> =57)	DD (<i>n</i> =62)	р	Cohen's d
the STAT between the ASD and	Time 1				
DD groups	Mean (SD): play	0.75 (0.33)	0.40 (0.34)	0.000	1.045
	Mean (SD): requesting	0.79 (0.34)	0.33 (0.39)	0.000	1.257
	Mean (SD): joint attention	0.85 (0.21)	0.52 (0.29)	0.000	1.303
	Mean (SD): imitation	0.69 (0.25)	0.52 (0.25)	0.001	0.680
	Mean (SD): total score	3.08 (0.84)	1.76 (0.75)	0.000	1.658
	Time 2				
	Mean (SD): play	0.30 (0.41)	0.07 (0.18)	0.000	0.726
	Mean (SD): requesting	0.56 (0.44)	0.22 (0.37)	0.000	0.836
	Mean (SD): joint attention	0.78 (0.24)	0.37 (0.29)	0.000	1.540
	Mean (SD): imitation	0.32 (0.28)	0.26 (0.25)	0.175	0.226
	Mean (SD): total score	1.96 (0.92)	0.92 (0.71)	0.000	1.266

ASD autism spectrum disorder, DD developmental delays

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there was a marginally significant group difference in imita-389 tion subscale scores (p=0.024) at Time 1. Similarly, there 390 were significant group differences in three subscale scores 391 (i.e., play, requesting, and joint attention domain) and the 392 composite STAT score at Time 2. There was no significant 393 group difference in imitation subscale scores at Time 2. 394 Further, when MA at Time 2 was controlled for, signifi-395 cant group differences emerged for two subscale scores (i.e., 396 requesting and joint attention) and the composite STAT 397 score at Time 2. Additionally, group differences were mar-398 ginally significant for play subscale scores (p=0.011) and 399 nonsignificant for imitation subscale scores at Time 2. 400

An examination of the ROC revealed that 2.25-2.75 was the optimal range based on which cutoff scores for the STAT should be derived for Time 1 (see Table 3). The sensitivity and specificity of the total STAT scores at Time 1 are presented in Table 4. For a cutoff score of 2.25, the positive predictive value (PPV) was 74.6%, and the negative predictive value (NPV) was 86.5%. For a cutoff score of 2.50, the PPV was 80.3%, and the NPV was 86.2%. For a cutoff score of 2.75, the PPV was 85.7%, and the NPV was 78.6%. The AUC was 0.87 at Time 1. The predictive validity of Module 1 of the ADOS at Time 1 was examined by comparing the resultant classification with the participants' clinical diagnoses (see Table 4). The PPV was 84.4%, the NPV was 94.5%, and the AUC was 0.93.

An examination of the ROC revealed that 1.25-1.50 was the optimal range based on which the cutoff scores for the STAT should be derived for Time 2 (see Table 3). The

Table 3 The sensitivity and specificity of different STAT Cutoff Scores

Cutoff ^a	Sensitivity	Specificity
Time 1		
1.50	0.93	0.34
1.75	0.90	0.50
2.00	0.90	0.63
2.25	0.88	0.73
2.50	0.86	0.81
2.75	0.74	0.89
3.00	0.67	0.90
Time 2		
0.25	1	0.07
0.50	0.98	0.24
0.75	0.97	0.39
1.00	0.91	0.61
1.25	0.86	0.71
1.50	0.70	0.79
1.75	0.58	0.81

^aA score that is greater than or equal to the cutoff score is indicative of a risk for autism spectrum disorder (ASD)

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Table 4 The predictive validity of the STAT and ADOS category (Time 1) with regard to clinical diagnosis (Time 2)

STAT risk category	Clinical diagnosis			
	$\overline{\text{ASD}(n=57)}$	DD (<i>n</i> =62)		
Cutoff=2.25				
High risk	50 (87.7%)	17 (27.4%)		
Low risk	7 (12.3%)	45 (72.6%)		
Cutoff = 2.50				
High risk	49 (86.0%)	12 (19.4%)		
Low risk	8 (14.0%)	50 (80.6%)		
Cutoff=2.75				
High risk	42 (73.7%)	7 (11.3%)		
Low risk	15 (26.3%)	55 (88.7%)		
ADOS				
ASD	54 (94.7%)	10 (16.1%)		
Non-ASD	3 (5.3%)	52 (83.9%)		

STAT screening tool for autism in 2-year-olds, ADOS autism diagnostic observation schedule, ASD autism spectrum disorder, DD developmental delays

sensitivity and specificity of the total STAT scores at Time 418 2 are presented in Table 5. For a cutoff score of 1.25, the 419 PPV was 73.1%, and the NPV was 84.6%. For a cutoff score 420 of 1.50, the PPV was 75.5%, the NPV was 74.2%, and the 421 AUC was 0.82 at Time 2. 422

Discussion

The purpose of the present study was to examine whether 424 the STAT is suitable for use with toddlers who are less than 425 24 months of age. If this is indeed the case, then the STAT 426 can be used to promote early screening for ASD in toddlers 427 in clinical settings in Taiwan. 428

In accordance with past findings (e.g., Stone et al. 2008; 429 Watson et al. 2007), toddlers with ASD who participated in 430

 Table 5
 The concurrent validity of the STAT risk categories (Time 2)
 with regard to clinical diagnosis (Time 2)

STAT risk category	Clinical diagnosis	
	ASD $(n=57)$	DD(n=62)
Cutoff=1.25		
High risk	49 (86.0%)	18 (29.0%)
Low risk	8 (14.0%)	44 (71.0%)
Cutoff = 1.50		
High risk	40 (70.2%)	13 (21.0%)
Low risk	17 (29.8%)	49 (79.0%)

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the present study demonstrated early social-communicative 431 impairments at 24 months of age. Even after controlling for 432 mental age, early social-communicative impairments were 433 evident in toddlers with ASD. The emergent effect size sug-434 gests that toddlers with ASD experience substantial joint 435 attention deficits. The findings also suggest that requesting 436 capabilities are also a second challenge for toddlers with 437 ASD and that integrations of multiple nonverbal commu-438 nication skills (e.g., coordinated eye contact and gesture, 439 vocalization) can be used to differentiate toddlers with ASD 440 and DD who are less than 24 months of age. At Time 2, chil-441 dren with ASD demonstrated significantly higher levels of 442 social-communicative impairments than children with DD; 443 the one exception to this finding pertained to the imitation 444 subscale. Again, joint attention domain and requesting capa-445 bilities were better discriminators of the two groups. These 446 findings underscore the temporal stability of impairments in 447 the integration of multiple nonverbal communication skills 448 in children with ASD. Previous studies have shown that 449 children with ASD do not exhibit significant impairments 450 on tasks that require the imitation of meaningful actions 451 that involve objects (e.g., Hepburn and Stone 2006; Wu and 452 Chiang 2014). Accordingly, given that the imitation sub-453 scale of the STAT has three items that necessitate imitation 454 of meaningful actions that involve objects, the 3-year-old 455 children with ASD may not have demonstrated significantly 456 greater impairments than their counterparts with DD. In 457 addition, the findings suggested that significant changes in 458 social-communicative development across follow up time 459 in children with ASD, except for domain of Joint Attention. 460 These findings support the contention that joint attention 461 deficits are the most important indicators of ASD during 462 the early years. 463

Consistent with past findings (Stone et al. 2008), the pre-464 sent study showed that the STAT has high sensitivity, speci-465 ficity, PPV, and NPV in differentiating between toddlers with 466 ASD and DD who are less than 24 months of age. A cutoff 467 score of 2.50 yielded good predictive sensitivity (86%) and 468 specificity (80.6%) indices. Further, a cutoff score of 2.25 469 demonstrated good predictive sensitivity (87.7%) and fair 470 predictive specificity (72.6%). On the other hand, a cutoff 471 score of 2.75 yielded fair predictive sensitivity (73.7%) and 472 good predictive specificity (88.7%) indices. Additionally, an 473 examination of the AUC revealed that the STAT can reliably 474 identify toddlers with ASD who are less than 24 months of 475 age. In contradistinction to Stone et al.'s (2008) use of 2.75 476 as the cutoff score, the present findings suggest that a score 477 of 2.50 yields better differentiation. One of the possible 478 explanations for this difference may pertain to the character-479 istics of the samples that were used in the two studies. First, 480 Stone et al. (2008) used a sample of toddlers whose ages 481 ranged from 12 to 23 months; on the other hand, the sam-482 ple that was used in the present study consisted of toddlers 483

whose ages were between 16 and 24 months. Stone et al. 484 (2008) has suggested that the rate of failure on scale items 485 may be higher for younger toddlers. Second, the non-ASD 486 sample that was used in Stone et al.'s (2008) study consisted 487 of those who exhibited a broad autism phenotype (BAP); in 488 contrast, our control sample consisted of only toddlers with 489 DD. Third, a majority of the participants in Stone et al.'s 490 (2008) study were high-risk siblings. On the other hand, our 491 sample consisted of children whose parents brought them to 492 clinical facilities due to concerns about their developmental 493 problems. 494

Module 1 of the ADOS yielded either good or excellent 495 predictive sensitivity (0.95), specificity (0.84), PPV (84.4%), 496 and NPV (94.5%) at Time 2. In addition, the AUC (0.93) 497 was also excellent. These findings suggest that module 1 of 498 the ADOS can be used to diagnose ASD in toddlers who 490 are less than 24 months of age. This is a significant finding 500 because the ADOS-2: Toddler Module was unavailable in 501 Taiwan during the time period of the present study. Module 502 1 of the ADOS was more accurate in short-term predictive 503 classification (e.g., sensitivity, specificity) than the STAT. 504 The ADOS is a diagnostic tool, and it can be mapped in 505 accordance with the DSM-5 diagnostic criteria for ASD. 506 In addition, whereas the ADOS is a comprehensive diag-507 nostic assessment, the STAT is a time-effective screening 508 instrument. Thus, it is reasonable that the accuracy of the 509 ADOS was higher than that of the STAT. Despite the lower 510 accuracy, the STAT must be used to screen for ASD in tod-511 dlers who are less than 24 months of age because it is a less 512 time-consuming screening tool that one can easily be trained 513 to use; further, its validity is only marginally lower than that 514 of the ADOS. 515

Past studies have shown that a cutoff score of 2 on the 516 STAT can be used to reliably identify young children with 517 autism who are between the ages of 24 and 35 months (Stone 518 et al. 2004). In the present study, a cutoff score of 1.25 on 519 the STAT exhibited good current sensitivity (0.86) and NPV 520 (84.6%), and fair current specificity (0.71) and PPV (73.1%) 521 in differentiating between children with ASD and DD who 522 are older than 3 years. In addition, an examination of the 523 AUC revealed that the STAT can reliably identify children 524 with ASD who are between the ages of 36 and 48 months. 525 The results of the present study suggest that, in order to be 526 effective, different cutoff scores must be used for children 527 with ASD who are between the age of 16 and 24, and 35 528 and 46 months. 529

In the present study, 43 and 14 children with ASD met the strict and relaxed DSM-5 criteria for ASD, respectively. At Time 1, a cutoff score of 2.50 reliably identified 39 (90.7%) and 10 (71.4%) children with ASD who met the strict and relaxed DSM-5 criteria for ASD, respectively. In addition, at Time 2, a cutoff score of 1.25 reliably detected 38 (88.4%) and 11 (78.6%) children with ASD who met the strict and 536

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relaxed criteria for DSM-5, respectively. Children with 537 ASD who met the relaxed DSM-5 criteria for ASD dem-538 onstrated higher mental ages at Time 1 (15.50 months vs 539 13.46 months, p < .05) and lower total score of the ADOS 540 at both Time 1 (11.64 vs 17.47, *p* < .001) and Time 2 (11.78 541 vs 15.12, p < .001). In accordance with past studies that 542 have used the STAT to detect autism in children who are 543 between the ages of 25 and 35 months (e.g., Stone et al. 544 2004), the present findings suggest that the STAT can be 545 used to reliably detect severe rather than mild symptoms 546 of ASD across two different time points. However, future 547 studies must recruit larger samples of children with ASD 548 who meet the relaxed DSM-5 criteria in order to ascertain 549 the cutoff scores and examine the sensitivity and specificity 550 of the assessment. 551

The present study sought to investigate the utility, concur-552 rent validity, and predictive validity (i.e., at follow-up) of 553 the STAT using a Taiwanese sample. The first assessment 554 (Time 1) was administered to a sample of toddlers who were 555 less than 24 months of age and the second assessment (Time 556 2) was administered after a year and a half to finalize the 557 diagnosis. The present findings suggest that the STAT can 558 reliably detect high-risk children with ASD who are situated 559 within the developmental period that ranges from toddler-560 hood to preschool age. The healthcare providers referred 561 infants and toddlers suspected to have developmental prob-562 lems to child psychiatrists at local or metropolitan general 563 hospitals for clinical diagnosis. However, the diagnostic 564 decision-making process may require diagnostic recommen-565 dations from other professionals, mainly by clinical psychol-566 ogists. The STAT which is level 2 screening tool takes only 567 20 min to complete, and it is easy to administer; therefore, 568 its use must be promoted among practitioners (e.g., clinical 560 psychologists) who work at district or regional hospitals, aid 570 in differentiating toddlers with ASD from those with other 571 developmental problems, and collaborate mainly with the 572 child psychiatrists for making formal diagnosis of ASD and 573 following evidence-based treatments. 574

575 Limitations and Future Directions

In conclusion, the present study used the STAT as a Level 2 576 screener for ASD among young at-risk toddlers. The results 577 suggest that STAT has a high level of predictive and concur-578 rent validity and can therefore be used as an autism-specific 579 screening tool for children who are situated within the devel-580 opmental period that ranges from toddlerhood to preschool 581 age. However, the present study has a few limitations. First, 582 the present study was conducted in only one clinical setting, 583 and the sample size was not large; therefore, future research 584 studies should validate the STAT using a larger sample that 585 is recruited from diverse hospital-based clinical settings. 586

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Second, the ADI-R was not used in the present study, and 587 this may adversely influence the accuracy of the clinical 588 diagnosis. Third, children with ASD who met the relaxed 589 DSM-5 criteria for ASD demonstrated higher mental ages 590 and mild autistic symptoms. Future studies should recruit 591 more participants for a distinct category for examining the 592 cutoff of the STAT. Fourth, contrary to previous studies 593 (e.g., Stone et al. 2004), the sample was not large enough 594 and we could not conduct a scoring algorithm and valida-595 tion data split to generate or test the potential cut-offs. Thus, 596 again, future research should include a higher number of 597 participants to validate the cutoffs. 598

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Ethical Approval In the present study, all the procedures that involved
human participants were conducted in accordance with the ethical
standards of the institutional and/or national research committee as
well as the 1964 Helsinki declaration and its later amendments or com-
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