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# RESEARCH ARTICLE

# Early measurement of autism risk constructs in the general population: A new factor structure of the First Years Inventory (FYIv3.1) for ages 6–16 months

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## Abstract

Early detection of autism risk in the community is critical to increasing families' access to early intervention, yet few measures have been developed and tested for the general population of infants <16 months to tap a broader range of autism risk constructs. This study aimed to (a) examine the factor structure of the First Years Inventory, version 3.1 (FYIv3.1), with a sample of 6454 infants 6-16 months, and (b) determine the ability of the resulting factors to discriminate clinical outcome groups at 3 years of age. The FYIv3.1 is a parent-report tool designed to detect early behavioral risk signs that may be associated with a later diagnosis of ASD and related neurodevelopmental conditions. Factor analytic models were used to determine the number of constructs and inter-factor correlations. Findings supported a seven-factor structure: communication, imitation and play (CIP); social attention and affective engagement (SAE); sensory hyperresponsiveness (HYPER); sensory hyporesponsiveness (HYPO); self-regulation in daily routines (SREG); sensory interests, repetitions, and seeking behaviors (SIRS); motor coordination and milestones (MCM). Mean comparisons on these factors demonstrated significant discrimination of the three outcome groups at age 3 years including those classified as having an ASD diagnosis and/or high autism symptoms, those classified as having other developmental disorders/conditions/concerns, and those classified with no known conditions/concerns. These findings support the validity and multidimensionality of early ASD risk constructs, as well as the potential use of the FYIv3.1 for phenotypic subtyping in the general population, and early detection in a broader age range of 6-16 months in future clinical studies.

## Lay Summary

The FYIv3.1 is a 69-item parent-report questionnaire about infant behaviors that may indicate an elevated likelihood for later neurodevelopmental conditions such as autism. Analyses of responses from 6454 parents of infants 6–16 months indicated that items could be grouped reliably into seven categories. Compared to children with or without other developmental conditions, children in the outcome group with autism spectrum disorder and/or high autism symptoms at age three showed more behavioral risk signs in social-communication, sensory, and motor domains during infancy.

#### **KEYWORDS**

autism spectrum disorder, community sample, developmental delay, early identification, infant development, neurodevelopmental risk

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# INTRODUCTION

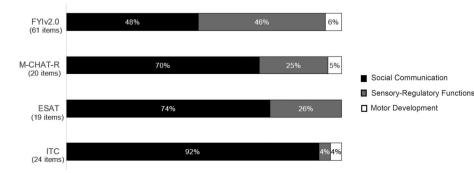
Over approximately the past two decades, a considerable amount of effort has been made to identify early behavioral risk signs among infants and toddlers who may be at elevated likelihood for a later neurodevelopmental condition such as autism spectrum disorder (ASD). Retrospective analyses of home videos and parent reports of infants later diagnosed with ASD (e.g., Baranek, 1999; Dawson et al., 2000) as well as prospective studies of high-risk infant siblings (e.g., Ozonoff et al., 2010; Zwaigenbaum et al., 2005) and infants from community samples (e.g., Barbaro & Dissanayake, 2010; Turner-Brown et al., 2013) have shown that various behavioral atypicalities were observed by at least 12 months.

Importantly, these early behavioral risk markers were noted most in the social-communication domain (e.g., reduced imitation, early pretend play, response to joint attention, gestures, or eye contact) (Colgan et al., 2006; Osterling et al., 2002), but also included atypical patterns of visual attention (Bhat et al., 2010; Zwaigenbaum et al., 2005), repetitive motor behaviors (Baranek, 1999; Osterling et al., 2002), unusual sensory exploration of objects (Baranek, 1999), under- or overreactivity to sensory stimuli (Baranek, 1999; Grzadzinski et al., 2020; Wolff et al., 2019), difficult temperament related to irritability and distress (Bryson et al., 2007; Del Rosario et al., 2014; Zwaigenbaum et al., 2005), sleep and feeding difficulties (Emond et al., 2010; Kozlowski et al., 2012; Turner-Brown et al., 2013), and motor challenges (Arabameri & Sotoodeh, 2015; Harris, 2017; Iverson et al., 2019).

Specifically, in studies of early screening, the utility of behaviors tapping difficult temperament in predicting a later diagnosis of ASD has been demonstrated in infant siblings below 18 months (Brian et al., 2008; Feldman et al., 2012). Additionally, Turner-Brown et al. (2013) as well as Ben-Sasson and Carter (2013) reported that the inclusion of items tapping sensory reactivity and regulation led to higher specificity and thus better predictive accuracy in community samples of infants screened at the age of 12 months. Sacrey et al. (2015) prospectively followed up both low-risk and high-risk infant siblings to examine the predictive utility of parental concerns between 6 and 24 months for an ASD diagnosis at age 3. They found that concerns related to sensory and motor behaviors predicted a later ASD diagnosis as early as 6 months, while the social communication and repetitive behaviors were not useful predictors until after 12 months.

Such findings might be underscored by a recent systematic review (Canu et al., 2021) on non-social behavioral indicators of ASD in infant siblings, which suggested that non-social signs appear much ahead of the full manifestation of social impairments. Moreover, these non-social behavioral markers could be specific for ASD, rather than a general marker of global developmental delay (DD) (Canu et al., 2021; Wiggins et al., 2021). Furthermore, behaviors outside of the social-communication domain, such as atypical sensory hyper-and hypo-reactivity, dysregulation, sensory-motor repetitions, motor challenges and atypical visual attention may be important to study for their developmental precedence (Baranek et al., 2018; Robertson & Baron-Cohen, 2017; Sacrey et al., 2014; Thye et al., 2018). Yet, the majority of early screening tools, disproportionately rely on the use of items that tap constructs within the socialcommunication domain to capture potential behavioral risk markers for ASD (see Figure 1 for the comparisons). Some of the key social-communication markers of ASD such as bringing objects to show, and pretend play behaviors have been reported to emerge and become stable later in infancy, after 15 months (Inada et al., 2010). Since the normative distributions of the presence of these behaviors dictate the extent to which they are useful as "red flags" at different ages, it may not be appropriate to apply these later-emerging social-communication behavioral risk markers to infants below 12 months of age. Overall, given the relative importance of atypical sensory reactivity and regulation patterns and motor challenges as prodromal signs of ASD prior to 1 year of age, we argue that more studies are needed to characterize and validate these autism risk constructs for use in early screening tools, particularly those intended for the general population.

The First Year Inventory, version 2.0 (FYIv2.0; Baranek et al., 2003) was developed and validated as a level-1 ASD parent-report screener for a community



**FIGURE 1** Domains and constructs of behaviors measured by level-1 early autism parent-report screeners which have been applied to infants aged below 16 months. *Note*: FYIv2.0 = First Year Inventory (Baranek et al., 2003), version 2.0; M-CHAT-R = Modified Checklist for Autism in Toddlers (Robins et al., 2009); ESAT = Early Screening of Autistic Traits (Swinkels et al., 2006); ITC = Infant Toddler Checklist (Wetherby & Prizant, 2002) sample at 12 months of age ( $\pm 2$  weeks). The FYIv2.0 contained 61 scored items, 55 of which loaded onto the original factor structure. One of the most important features of the original scale was the inclusion of a representative number of items comprising four constructs in the domain of sensory-regulatory functions, in addition to four constructs in the domain of social communication (Reznick et al., 2007). Its utility as a behavioral measure of autism risk was supported by comparing retrospective reports of parents of children with typical development versus children diagnosed with DD or ASD (Watson et al., 2007), and was further validated prospectively with a community sample (N = 699) with clinical outcomes measured at 3 years of age (Turner-Brown et al., 2013), rendering sensitivity of 44% and specificity of 99%.

As an endeavor to improve the utility of the FYIv2.0, we further tested and refined the item pool to cover a broader age range of 6-16 months (spanning conventional ages for well-child checkpoints at 6, 9, 12 and 15 months), and to bridge a gap to the age covered by a commonly used autism screener, the Modified Checklist for Autism in Toddlers, Revised with Follow-up (M-CHAT-R/F; Robins et al., 2009). This necessitated several iterations of data collection with community cohorts of infants 6-16 months using interim versions of the FYI that assessed the frequency distributions of original, revised, and new items, ensuring that items were sensitive to high levels of risk (low frequency responses) across the new age range. In addition to developing and testing items that were sensitive to this wider age range, additional revisions included: expanding the scale from a 4-point (never to often) to a 5-point (never to always) scale to allow for more discriminating responses, particularly at high levels of risk (e.g., often vs. always); converting multiple choice items to Likert-scaled items for ease of administration; refining wording/examples of some items for clarity; modifying or dropping some items that were less predictive of risk on earlier versions; and adding items on additional constructs including feeding, sleeping and motor development that were relevant to developmental risk features at the ages of interest. In sum, since the original FYIv2.0, 26 items were dropped, 35 were retained/revised, and 34 new items were added. Thus, the FYIv3.1 comprises 69 items, which were further examined for construct validity in this study.

There were two primary goals for the current study. First, we aimed to examine the factor structure of the new FYIv3.1 using a large community sample of infants from the ages of 6–16 months corrected chronological age (CCA). While we expected that the overarching twodomain conceptualization (i.e., social communication and sensory-regulatory functions) would hold for the new version, the construct-level structure might shift given the several changes mentioned above. In addition, because new items about sleep, feeding, and motor development were added, we expected new factors to emerge. Given the larger targeted age range for this new version and the possibility that some of the new factors may be sensitive to change as children get older, we included child's age (adjusted for prematurity) as a correlate of the factors to examine their associations. Secondly, we aimed to test between-group mean differences in the factor scores in a subsample of children with outcomes collected at the age of 3 years, including children with a reported clinical diagnosis of ASD and/or confirmed high autism symptoms, those with other disorders/concerns, and those with no known conditions/concerns. Based on findings from original version of the FYI, we expected the factor structure to provide good discriminative validity of these three outcome groups.

# METHOD

## Participants and procedures

We prospectively targeted a community sample, birth cohort born between January 1 and December 31, 2013, in the state of North Carolina (94 of 100 counties). Participants were caregivers of infants ages 6-16 months who were recruited through the state birth registry (vital records). There were no exclusions on the basis of race or sex. Since the FYIv3.1 had not yet been translated into Spanish, families with Hispanic/Latino ethnicity were not recruited. Recruitment packets were mailed to 40,000 families in 2014, stratifying across chronological ages. These packets included a cover letter explaining the risks/ benefits, consent procedures, as well as instructions for participation in the survey. Families had the option to fill out the survey online (Qualtrics) or return a hard copy via postage-paid business reply mail. Two complementary forms were created (forms A and B), each consisting of 48 questions with 27 core questions in common, to reduce response time burden. Each family randomly received either Form A or B in the recruitment packet and was asked to select the answer that most closely described how often their child did each behavior on a 5-point Likert scale (never to always). Items were mixed in terms of whether the higher response categories reflected more or less risk. The overall response rate was 17% (N = 6636). A total of 56% responded via online surveys; 60% of the respondents were mothers, 3% were fathers, and 2% were multiple respondents (e.g., both mother and father), while 35% of caregivers did not complete this question. After removing duplicates (N = 23)and incomplete responses (i.e., <75% of items completed; N = 142), there were 6471 surveys retained. Given the recommendation of the Centers for Disease Control and Prevention (CDC) that postnatal age should be corrected for gestational age up to at least 24 months for charting infant development (Kuczmarski, 2000), children's chronological ages were adjusted for prematurity status (i.e., those born  $\leq$ 36 weeks of gestation). The final sample included 6454 infants with CCAs ranging from 6 to 16 months.

When children reached 3 years of age (i.e., between 3 years 0 months and 3 years 11 months), the parents were re-contacted by the study investigators to complete an online survey regarding their child's developmental status and reports of diagnoses including ASD. The two measures used are described further below: the Developmental Concerns Questionnaire (DCQ) and the Social Responsiveness Scale (SRS-2). A total of 34.6% of the parents of three-year-olds (N = 2236) returned complete responses between November 19, 2016, and March 26, 2017. The demographic characteristics of the final FYI sample for factor analysis (N = 6454) and the subsample with age 3 outcome data (N = 2236) are shown in Table 1. All procedures were prospectively reviewed and approved by the IRB at the University of North Carolina at Chapel Hill.

## Measures

First Years Inventory, version 3.1 (Baranek et al., 2013)

The FYIv3.1 is a 69-item parent-report measure revised from a previous version, the FYIv2.0 that was validated in a large community sample (Reznick et al., 2007; Turner-Brown et al., 2013). The FYIv3.1 was designed to identify behavioral signs in infants ages 6–16 months who may be at risk for a later diagnosis of ASD or a related neurodevelopmental disorder. It measures the frequency of behaviors on a 5-point Likert scale, across social-communication, sensory-regulatory functions, and motor development domains. Some items are reversed scored and higher scores are less probable in the general population and indicative of more ASD risk (e.g., higher symptoms associated with autism).

Developmental Concerns Questionnaire, version 1.5 (Reznick et al., 2005)

The DCQ is a parent-report measure used in prior research (Turner-Brown et al., 2013) that inquires about whether a parent or professional has been concerned about the child's development in any way (e.g., "Have you/others had concerns about your child's development? If yes, describe your/their concerns."), and whether the child has received any clinical diagnoses (e.g., "If your child has been evaluated for any developmental concerns by a professional and has received a diagnosis, please tell us what type of professional, what diagnosis and when, and what treatment or intervention was recommended."). Responses were coded to determine whether the child has had a diagnosed developmental condition from clinicians (e.g., psychiatrists, pediatricians, or psychologists), including ASD, and/or any developmental concerns across various domains of development.

**TABLE 1** Demographics of the final FYIv3.1 samples for factor analysis (N = 6454) and age 3 outcome data (N = 2236)

	FYI sample ( $N = 64$	54)	- Subsample with age-3 outcome data ( <i>N</i> = 2236)	
	A Form	B Form		
Characteristics	(N = <b>3213</b> )	(N = <b>3241</b> )		
Age in months when taking the	12.1 (2.2)	12.0 (2.2)	12.0 (2.1)	
FYI [mean (SD); range]	6.3-16.9	6.4-17.0	7.1–16.9	
Sex (male)	1669	1603	1113	
	(52.0%)	(49.5%)	(49.8%)	
Race				
White	2505	2480	1885	
	(78.0%)	(76.5%)	(84.3%)	
Black	339 (10.5%)	399 (12.3%)	137 (6.1%)	
Asian	75 (2.3%)	78 (2.4%)	35 (1.6%)	
American Indian/Hawaiian	25 (0.8%) 21 (0.7%)		13 (0.6%)	
Multi-racial/other	269 (8.4%) 263 (8.1%)		167 (7.4%)	
Parent education (6% missing)				
Both parents have a college degree (or beyond)	1300	1251	1219	
	(40.5%)	(38.6%)	(54.5%)	
One of the parents has a college degree (or beyond)	645 (20.0%)	629 (19.4%)	486 (21.7%)	
None of the parents has a college degree	1007	1106	396	
(or beyond)	(31.3%)	(34.1%)	(17.7%)	

## Social Responsiveness Scale, 2nd edition (Constantino & Gruber, 2012)

The SRS-2 is a parent-report scale consisting of 65 items that measure deficits in social behavior associated with ASD, as outlined by the Diagnostic and Statistical Manual of Mental Disorders (4th ed.; DSM-IV-TR; American Psychiatric Association, 2000). It demonstrates good discriminative validity (sensitivity = 0.83-0.91, specificity = 0.53-0.88) among clinical and non-clinical samples of young children with diverse demographics (Moody et al., 2017). The SRS-2 was scored to determine presence and level of autism symptoms; while it is not a diagnosis, a T-score  $\geq 60$  indicates a high probability of ASD.

# Classification of outcome groups at age 3

Based on the DCQ and SRS-2 data collected at age 3, children were classified into one of the following outcome groups for analysis purposes in this study: (a) **ASD** outcome group (N = 72): based on either parental report of a clinical ASD diagnosis on the DCQ, *andlor* confirmed elevated autism symptoms on the SRS-2 with a T-score  $\geq 60$ ; (b) **OD outcome group** (N = 260): based on parental report of other developmental diagnoses, conditions, or concerns on the DCQ and an SRS-2 T-score below 60; (c) **ND outcome group** (N = 1904): based on parental report of no known diagnoses, conditions, or concerns on the DCQ, and an SRS-2 T-score below 60; (c) ND outcome group (N = 1904): based on parental report of no known diagnoses, conditions, or concerns on the DCQ, and an SRS-2 T-score below 60.

### Data analysis

Given the substantial changes to the new version of the FYI, including a large number of new items and revisions to existing items, we first ran exploratory factor analysis (EFA) with an oblique rotation (geomin). We elected not to use a split-sample approach for the evaluation of construct validity given that the FYIv3.1 is constructed to be particularly precise at very high levels of ASD risk; random splitting of the sample could have placed most or even all of these children into either the exploratory or confirmatory subsamples, thus limiting information in that range for at least one of the subsamples. All the factor analyses were performed with full information maximum likelihood (FIML) estimation, which allows parameters to be estimated despite the split-form missingness (Lei & Shiverdecker, 2020; Muthén et al., 2015). We used two classes of methods to evaluate EFA results: (1) review of the scree plot, including subjective scree analysis (Gorsuch, 1983) and parallel analysis (Horn, 1965; Humphreys & Montanelli Jr, 1975), as well as (2) structural equation modeling (SEM) measures of model fit. Subjective scree analysis is a visual inspection of the plot to determine where there are notable changes in the eigenvalues, indicators of the explanatory power of the model. Parallel analysis compares the observed scree plot with one generated from random data of the same size and rank of the observed data. These statistical measures provide valuable insight into the number of factors to retain and the construction of those factors, but the final determination of the structure is guided by theoretical and practical understanding of the measurement variables and the potential underlying constructs (Preacher & MacCallum, 2003). Additionally, several fit indices, including the comparative fit index (CFI > 0.90), the root mean square error of approximation (RMSEA < 0.06), and the standardized root mean square residual (SRMR < 0.08) were used to evaluate the model fit of EFA (Hu & Bentler, 1999). We did not use chi-square for the evaluation of model fit given that it is overly sensitive to models with a large number of items and to a large sample size (Bollen, 1989), which was the nature of our data. Overall, these evaluation methods indicated several plausible initial solutions, which were then given theoretical review to facilitate the selection of the final model.

Next, we re-estimated the final model with confirmatory factor analysis (CFA). Re-estimating the model as a CFA after the EFA enabled us to restrict each item to a single factor. This constraint provides a more parsimonious structure to the scale. We also included child's CCA as a covariate (i.e., correlated with factors) to account for potential maturational effects. The use of robust maximum likelihood estimation in CFA does not provide chisquare and related measures of fit (e.g., RMSEA and CFI) for models of the complexity proposed here, given the large number of items, factors, and the amount of missingness associated with the use of two different forms (A or B) across families. Thus, we used SRMR to evaluate the absolute fit of the model. Factor loadings, interfactor correlations and the associations between age and the factors were then examined.

Finally, for the subset of children with age 3 outcomes, individual factor scores were exported from the factor model. Mean differences across the constructs of infant behavior were statistically compared between the three outcome groups (ASD, OD, and ND) that were classified at age 3 using the criteria defined earlier. We also examined the ASD outcome group to compare mean differences for the ASD subset with a reported clinical diagnosis versus the subset with confirmed high autism symptoms on the SRS-2 but no current reported diagnosis.

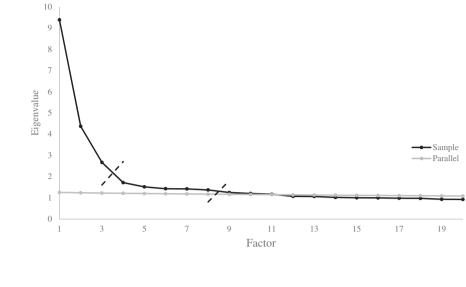
# RESULTS

Figure 2 presents the scree plot for the factor analysis. EFA results suggested at least three factors, indicated by the first large decrease in eigenvalues, and as many as eleven indicated by the parallel analysis. Inspection of the scree plot shows a second decrease in eigenvalues between eight and nine factors. The SEM indices indicated acceptable to good fits for all models with three or more factors (RMSEA all <0.03, CFI all >0.86, SRMR all <0.04). CFI was >0.90 for all models with more than five factors, and >0.95 for models with eight or more factors. The scree plot indicates the three, eight, and eleven-factor models as plausible. The three-factor solution was rejected given its relatively poor fit and as too simple to adequately capture the complexity of the behaviors under examination. The eleven-factor model required a large number of items with loadings on two or more factors. While the scree plot does suggest the eightfactor solution, MLR does not provide model fit statistics for models of this complexity. The research team reviewed the seven and eight factor solutions, and determined that a seven-factor solution was theoretically better supported than the eight-factor solution. Two of the eight factors seemed to reflect contexts (sleep and feeding) rather than theoretically useful latent domains. Further, in the seven-factor model, a SREG factor emerged that was absent in the eight-factor model. While this factor has moderate to high correlations with the other sensory-regulatory functions factors, it provided sufficiently unique information to be retained. Two of the seven factors reflected the social communication domain: CIP, and SAE. Four factors measured aspects of the sensory-regulatory functions domain: HYPER, HYPO, SREG, and SIRS. A seventh factor, MCM, was also retained.

The CFA with the seven-factor structure demonstrated a good model fit (SRMR = 0.05). Standardized factor loadings were good, with 94% greater than 0.40 and 68% greater than 0.30 (Table 2). There was a great deal of variability in the inter-factor correlations (Table 3). The correlation between the two social communication domain factors, CIP and SAE, was 0.63. The correlations of factors representing the sensoryregulatory functions domain ranged from 0.40 to 0.75. The MCM factor was strongly correlated with both of the social communication domain factors, 0.73 with CIP and 0.66 with SAE. Correlations between MCM and the four sensory-regulatory functions domain factors were smaller, ranging between 0.10 and 0.43. We also tested the associations between CCA and these seven factors. The sensory-regulatory functions domain factors had relatively low correlations with age; the strongest was between age and SIRS at -0.19, followed by hyperresponsiveness (HYPER) at 0.14. On the social communication domain, CIP was strongly correlated with age at -0.65, while SAE was only weakly associated with age, -0.10.

Next, scores for each of the seven empirically derived factors of infant behavior were tested for group differences at age 3 years. Table 4 presents group means in the first three columns and mean differences in the last three. All factors were scored such that higher scores indicated higher features or difficulties. Overall, the children in the ASD outcome group had significantly higher scores than both the children in the OD and ND outcome groups, as predicted. The difference between ASD and OD on the CIP factor was non-significant. Further, the children in the OD outcome group had higher scores than those in the ND outcome group on all factors, although the differences were smaller than between the ASD and either of the other two outcome groups. In summary, for CIP we found ASD = OD > ND, while for SAE, HYPO, HYPER, SIRS, SREG, and MCM we found ASD > OD > ND (see Figure 3 for a radar plot depicting the shape of the three groups and their profile differences across the seven factor means).

Finally, we explored whether there were differences in mean factor scores within the ASD outcome group based on whether children had received a clinical ASD diagnosis by age three (based on parent report) (n = 17), versus children who met cut-offs (T-score  $\ge 60$ ) on the SRS-2 for high autism symptoms but did not have a current clinical diagnosis as reported by parents (n = 55). [We note that



## TABLE 2 Standardized factor loadings of the FYIv3.1 items

Item	Loading	Reverse score
Communication, imitation and play (CIP) [18 items]		
Look at point	0.55	Y
Imitate parent actions	0.62	Y
Get attention to show interesting	0.67	Y
Point to communicate	0.74	Y
Typical play with toys <sup>a</sup>	0.59	Y
Use gestures	0.59	Y
Simple pretend actions <sup>a</sup>	0.76	Y
Try new play actions with other toys <sup>a</sup>	0.66	Y
Point and vocalize <sup>a</sup>	0.71	Y
Get attention to play games	0.60	Y
Play pretend with objects <sup>a</sup>	0.65	Y
Look at person named	0.68	Y
Get attention by making sounds & looking	0.37	Y
Copy sounds or noises	0.49	Y
Repeat after imitation <sup>a</sup>	0.45	Y
Get help for wants <sup>a</sup>	0.52	Y
Social clap <sup>a</sup>	0.64	Y
Join turn-taking games	0.59	Y
Social attention & affective engagement (SAE) [14 items]		
Respond to name	0.46	Y
Smile and look	0.41	Y
Interested in other babies	0.33	Y
Direct eye contact <sup>a</sup>	0.47	Y
Follow reach toward object <sup>a</sup>	0.58	Y
Enjoy mirror reflection <sup>a</sup>	0.36	Y
Show concern to someone else crying <sup>a</sup>	0.31	Y
Odd facial expressions	0.31	
Look at talking <sup>a</sup>	0.56	Y
Laugh without physical games	0.46	Y
Face for comfort	0.34	Y
Response to sadness <sup>a</sup>	0.38	Y
Orient to voice <sup>a</sup>	0.42	Y
Stop on command <sup>a</sup>	0.40	Y
Sensory hypo-responsiveness (HYPO) [eight items]		
Additional cues to respond to name <sup>a</sup>	0.48	
Trouble hearing	0.42	
Loose or floppy body	0.40	
Orient to sound <sup>a</sup>	0.28	Y
Look up from playing	0.27	Y
Difficult to look at book pages <sup>a</sup>	0.34	
Difficulty sucking <sup>a</sup>	0.33	
Unaware of pain	0.25	
Sensory hyper-responsiveness (HYPER) [seven items]		
Sensitive to textures	0.38	
Overly sensitive to pain <sup>a</sup>	0.48	
Sensitive to touch	0.46	

#### TABLE 2 (Continued)

Item	Loading	Reverse scored
Sensitive to loud sounds	0.34	
Fearful in new situations <sup>a</sup>	0.31	
Try new foods <sup>a</sup>	0.26	Y
Sensitive to tastes <sup>a</sup>	0.42	
Self-regulation in daily routines (SREG) [eight items]		
Easily soothed	0.44	Y
Sensitive to changes to routine <sup>a</sup>	0.39	
Wake up two or more times	0.40	
Fussy during routines <sup>a</sup>	0.44	
Choke or gag <sup>a</sup>	0.33	
Often needs to be calmed	0.56	
Easily woken to sounds <sup>a</sup>	0.51	
Difficulty falling asleep <sup>a</sup>	0.51	
Sensory interests, repetitions, & seeking behaviors (SIRS) [seven it	ems]	
Stuck on toy part	0.37	
Look at toys in unusual ways	0.52	
Repeatedly manipulating objects	0.66	
Repeatedly flapping hands or arms <sup>a</sup>	0.57	
Interested in flickering lights <sup>a</sup>	0.50	
Constantly play with same toy <sup>a</sup>	0.44	
Object mouthing	0.45	
Motor coordination & milestones (MCM) [seven items]		
Put sounds together	0.51	Y
Use consonants	0.56	Y
Walk	0.32	Y
Pincer grasp on small objects	0.57	Y
Body stuck in position	0.33	
Switch object from hand to hand <sup>a</sup>	0.48	Y
Blowing raspberries <sup>a</sup>	0.36	Y

<sup>a</sup>New items (relative to FYIv2.0).

	CIP	SAE	НҮРО	HYPER	SREG	SIRS	MCM
CIP	_						
SAE	0.63	—					
НҮРО	0.26	0.61	_				
HYPER	-0.01	0.25	0.74				
SREG	0.13	0.28	0.57	0.75			
SIRS	0.08	0.00	0.53	0.56	0.40		
MCM	0.73	0.66	0.43	0.22	0.22	0.10	_
Age	-0.65	-0.10	0.00	0.14	-0.01	-0.19	-0.39

TABLE 3 Inter-factor correlations of FYIv3.1 factors and age

*Note*: All correlations >0.08 are statistically significant (p < 0.001).

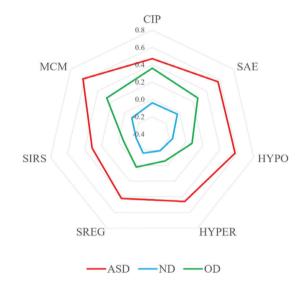
Abbreviations: CIP, communication, imitation and play; HYPER, sensory hyperresponsiveness; HYPO, sensory hyporesponsiveness; MCM, motor coordination and milestones; SAE, social attention and affective engagement; SIRS, sensory interests, repetitions, and seeking behaviors; SREG, self-regulation in daily routines.

TABLE 4 Mean differences in factor scores by outcome group at age 3 years

	$\begin{array}{l} \text{ASD} (N = 72) \\ \text{Mean} (\text{SD}) \end{array}$	ND (N = 1904) Mean (SD)	OD (N = 260) Mean (SD)	<i>F</i> (2,2233) <sup>a</sup>	ASD versus ND Mean (SE)	ASD versus OD Mean (SE)	OD versus ND Mean (SE)
CIP	0.47 (1.12)	-0.04 (0.92)	0.36 (0.93)	3.06	0.51 (0.11)***	0.11 (0.12)	0.40 (0.06)***
SAE	0.57 (1.33)	-0.03 (0.83)	0.27 (0.87)	28.92	0.60 (0.10)***	0.30 (0.11)**	0.29 (0.06)***
НҮРО	0.58 (1.14)	-0.16 (0.72)	0.07 (0.84)	42.00	0.74 (0.09)***	0.51 (0.10)***	0.23 (0.05)***
HYPER	0.46 (0.97)	-0.19 (0.70)	-0.06 (0.83)	3.25	0.65 (0.09)***	0.52 (0.10)***	0.13 (0.05)**
SREG	0.42 (1.01)	-0.16 (0.72)	0.02 (0.85)	26.43	0.58 (0.09)***	0.41 (0.10)***	0.18 (0.05)***
SIRS	0.31 (0.78)	-0.21 (0.74)	-0.06 (0.79)	19.75	0.51 (0.09)***	0.37 (0.10)***	0.15 (0.05)**
MCM	0.62 (1.22)	-0.10 (0.77)	0.27 (0.88)	49.91	0.73 (0.10)***	0.35 (0.11)**	0.38 (0.05)***

*Note*:  $ASD = parent report of an ASD diagnosis and/or SRS \ge 60$ ), OD = other diagnoses/concerns and SRS < 60, ND = no reported diagnoses/concerns and SRS < 60. Abbreviations: ASD, autism spectrum disorder; CIP, communication, imitation and play; HYPER, sensory hyperresponsiveness; HYPO, sensory hyporesponsiveness; MCM, motor coordination and milestones; SAE, social attention and affective engagement; SIRS, sensory interests, repetitions, and seeking behaviors; SREG, self-regulation in daily routines.

<sup>a</sup>All *F* tests significant at <0.001; For pairwise comparisons: \* < 0.05, \*\* < 0.01, \*\*\* < 0.001 (*p* values are not adjusted for multiple comparisons; for a family-wise alpha of 0.05 on the mean comparisons, the Bonferroni corrected critical value is 0.002).



**FIGURE 3** Radar plot of profiles of factor means by outcome group

12 of the 17 children with a clinical diagnosis of ASD by age 3 also had SRS-2 T-scores at  $\geq 60$ .] Results of this analysis showed negligible trend differences (p < 0.10) on two factors (SREG and HYPER) (see Table 5).

# DISCUSSION

This prospective study (a) examined and tested the underlying structure of the latest revision to the First Years Inventory, FYIv3.1, in a large community sample of infants ranging from 6 to 16 months of age, and (b) confirmed the ability of the measure to discriminate between three outcome groups (i.e., ASD, OD, and ND) at 3 years of age. Initial EFA suggested that a number of solutions for the structure were plausible, with a minimum of three factors and as many as eleven. After reviewing these empirical structures and their clinical relevance, the research team determined that the sevenfactor solution was ideal. This solution was verified in CFA.

The identification of the seven-factor structure reflected the multidimensional nature of behavioral manifestations of early risk markers in infants ages 6-16 months of age, representing the potential phenotypic heterogeneity that may complicate early detection. Despite the previous evidence of heterogeneous expression of behavioral risk markers of ASD across social communication and restrictive and repetitive behaviors (RRBs) (Wiggins et al., 2012; Georgiades et al., 2013) in toddlers and young children, and the utility of non-social behavioral markers particularly during infancy (Canu et al., 2021; Zwaigenbaum et al., 2005), few early screening measures were developed to reflect the cross-domain contributions, including sensory-regulatory functions or motor development, to risk for later ASD or neurodevelopmental conditions. The FYIv3.1, however, endeavored to incorporate representative numbers of both social and non-social items that could potentially facilitate earlier detection of such features. While the majority of new factors could be conceptualized within the same two broader developmental domains (social communication and sensory-regulatory functions) from the original version of the tool (i.e., FYIv2.0), the structure determined in this study produced a set of more specific constructs within those two domains for this expanded age range, and provided an additional, developmentally focused, factor related to MCM.

The two factors reflecting the social communication domain were (1) CIP, and (2) SAE. The CIP factor included items measuring joint attention and social play skills, such as pretending and imitation, which are typically acquired during infancy and early childhood and their impairments are considered as core features of ASD (Toth et al., 2006). Notably, this factor was highly associated with child's age over the period of 6–16 months, indicating that most children master these skills later

	Group 1A	Group 1B	
	Reported ASD diagnosis ( $N = 17$ )	High ASD symptoms ( $N = 55$ )	
	Mean (SD)	Mean (SD)	Difference
CIP	0.72 (1.18)	0.40 (1.11)	0.32, p = 0.334
SAE	0.77 (1.70)	0.51 (1.20)	0.26, p = 0.562
HYPER	0.11 (1.18)	0.57 (0.88)	-0.46, p = 0.084
НҮРО	0.45 (1.61)	0.63 (0.96)	-0.17, p = 0.587
SREG	0.03 (1.14)	0.54 (0.94)	-0.51, p = 0.068
SIRS	0.07 (0.71)	0.39 (0.80)	-0.32, p = 0.147
MCM	0.78 (1.49)	0.58 (1.14)	0.20, p = 0.566

Abbreviations: CIP, communication, imitation and play; HYPER, sensory hyperresponsiveness; HYPO, sensory hyporesponsiveness; MCM, motor coordination and milestones; SAE, social attention and affective engagement; SIRS, sensory interests, repetitions, and seeking behaviors; SREG, self-regulation in daily routines.

during infancy. A previous study using M-CHAT demonstrated the cross-sectional developmental chronology of non-verbal communication skills from 8 to 18 months and stressed the importance of determining the threshold for atypical development of social behaviors across infancy (Inada et al., 2010). Our findings supported this view and further showed that the SAE factor, which reflected social-emotional responses to others, was much less affected by such age-related effects. While other studies have shown that preverbal social behaviors (e.g., imperative/declarative pointing, pretend play) appear to become stable after 12 months (pass rate > 80% across the population; Inada et al., 2010), social-emotional development begins early in life with parental bonding to the child (Caulfield, 1996). Infant siblings with ASD were reported to smile less than their typically-developing counterparts and showed delayed or atypical gaze patterns to social scenes as early as at 6 months of age (Cassel et al., 2007; Chawarska et al., 2013). Thus, it is important to take child's age into consideration to optimize the validity of early screening tools that tap social-communication markers during infancy.

We also identified four factors related to the sensoryregulatory functions domain including the three sensory response patterns (1) HYPER, (2) HYPO, and (3) sensory interests, repetitions and seeking behaviors (SIRS), which are commonly described in the literature on ASD and related neurodevelopmental disorders, as well as an additional factor (4) SREG tapping infants' regulatory behaviors during important daily functions including sleeping and eating. The three sensory response patterns are currently included in the RRB domain of the DSM-5 ASD diagnostic criteria. Such sensory features have been considered potential precursors to social-communication impairments (Robertson & Baron-Cohen, 2017; Ronconi et al., 2016). Therefore, it would be important to track these sensory features over time, along with their associations and/or cascading consequences for socialcommunication and other later-emerging cognitive deficits in ASD beyond the toddler and preschool years. The

importance of confirming the self-regulation factor within this community sample study was underscored by previous evidence from infant sibling studies, whereby those siblings who went on to get a later diagnosis of ASD tended to show more challenging temperamental features (e.g., atypical sleep-wake patterns, poor soothability) across daily routines within the first year (Mallise et al., 2020; Pijl et al., 2019). A recent study demonstrated the specific associations between negative reactions to sensory stimuli at 18 months and ASD, but not ADHD, symptoms at 3 years of age (Konke et al., 2022), indicating the specificity of early sensory-related features in differentiating later ASD and other conditions.

Another innovation of the current version of the FYIv3.1 is the inclusion of items tapping MCM. It is unsurprising that the MCM factor was found to have a moderate relationship with child's age given the strong developmental nature of these items. In addition, previous studies have shown a predictive association between delayed motor milestones, including both gross (e.g., walking) and fine motor skills (e.g., oral- and manual-motor skills) with worse language outcomes (Bedford et al., 2016; Gernsbacher et al., 2008; Leonard et al., 2015; Reindal et al., 2020), a later diagnosis of ASD among infant siblings (Landa & Garrett-Mayer, 2006; LeBarton & Landa, 2019), as well as more ASD symptoms in a general population (Kovaniemi et al., 2018). Moreover, studies of infant siblings have shown delayed vocal-motor development by 18 months as indexed by the onset of babbling and rhythmic arm movement (Iverson & Wozniak, 2007). Thus, our findings confirm the potential utility of MCM behaviors for identifying early risk signs in a community sample of infants ages 6-16 months, although more research is needed to test predictive associations to other domains of behavior later in life.

Finally, the utility of the new FYIv3.1 factor structure, derived on a large community sample at 6–16 months of age, was further underscored by the significant group differences found in later preschool-age outcomes. Specifically, all factors demonstrated significant group differences across the three outcome groups at age 3 years, with stronger differences discriminating the ASD group from the other two outcome groups. Interestingly, the CIP factor showed differences between children in the ASD outcome group and those without diagnoses/ concerns (ND), but failed to significantly discriminate the ASD group from those with other developmental disorders/concerns (OD), perhaps suggesting that such items may be better indicators of general DD at very young ages, but become more specifically associated with ASD outcomes over time. In contrast, the factors of socialaffective engagement, MCM, and all four factors reflecting the sensory-regulatory function domain (i.e., HYPO, HYPER, SREG, and SIRS) showed significant discrimination between all three outcome groups, indicating higher specificity for ASD/high autism symptoms beyond just identifying DD.

These findings complement the previous evidence that sensory- and motor-related parental concerns, rather than social communication, before 12 months better predicted a later ASD diagnosis among infant siblings (Sacrey et al., 2015), and further demonstrated their potential utility of differentiating ASD from other developmental outcomes in a community sample. In summary, our findings support the multidimensionality and preliminary validity of early ASD risk constructs, as well as the potential use of the FYIv3.1 for early detection in a broader age range of 6–16 months in future clinical studies.

Interestingly, our exploration within the ASD outcome group for the two subsets of children (i.e., those with a parent-reported clinical diagnosis of ASD vs. those with high autism symptoms on the SRS-2 but without a concurrent clinical diagnosis) showed marginal differences on only two factors. This trend suggested that HYPER and self-regulation (SREG) issues may be more apparent during infancy for the subset with high symptoms who did not have a reported clinical diagnosis of ASD by age 3. Also, although factor scores for CIP for the subset of children diagnosed with ASD visually appeared somewhat higher in risk than the subset with high SRS-2 scores but not currently diagnosed, this did not approach significance due to the large variability on this factor. More research is needed to determine how early developmental differences across domains may relate to differences in diagnostic processes or referral patterns in the community - for example, infants/toddlers with more obvious social-communication impairments based on milestone checks may be referred earlier for ASD evaluation than those with high sensory-regulatory issues that are not typically part of milestone tracking. Prospective follow-up at later ages using gold-standard clinical observational tools for differential diagnosis would be beneficial to address these important questions.

## Limitations and future directions

This study included a large community sample of over 6000 infants, providing a good estimation of the FYI

factors in the general population of children ages 6-16 months. However, the exclusion of Spanish-speaking families resulted in a restriction in generalizability; future work is in progress developing and testing translations for Spanish (DuBay et al., 2021) and Mandarin Chinese languages in order to test for differences in structure across linguistically and culturally diverse populations to allow for greatly expanded use. The response rate, approximately 17%, raises concerns about the representativeness of the sample, particularly with regard to racial and ethnic diversity. Response rates to survey research, particularly those targeting general populations, generally have shown decline (Stedman et al., 2019), and thus future research will need to consider alternative recruitment strategies to increase rates and ensure more diverse and representative samples. Additionally, the split-form design for data collection in the current study resulted in missingness that may have introduced some biases to the parameter estimates. A replication of the proposed factor structure on an independent sample with complete data is needed to support its robustness in future studies. Between-group mean differences for three outcome groups (ASD, OD, and ND) provide good preliminary validity for the scale.

Given the relatively low rate of ASD in the population (1.85% from the CDC; Knopf, 2020), the use of a community sample birth cohort yields low numbers of infants who are likely to be classified as having or at-risk for ASD later in life, or to show variability in the range where the scale is most sensitive to ASD risk. Future research could include a larger sample of high-risk (clinical) groups to provide better parameter estimates in this sensitive range. Because the FYIv3.1 is designed to measure a continuum of behavioral risk markers in the general population, the scoring has traditionally weighted items based on the frequency probabilities of uncommon responses; future studies are in progress to determine the most sensitive and specific scoring algorithm and cut-points across the sevenfactor structure for best diagnostic prediction. The presence of these seven factors provides great flexibility in assessing a range of potential behaviors that are conceptually linked to ASD risk, across a profile of strengths and weaknesses in infants ages 6-16 months, and the ways in which these behaviors co-occur. As such, the FYIv3.1 may present a unique tool for phenotypic subtyping in the general population in future studies.

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## ETHICS STATEMENT

The study procedures were approved by the Institutional Review Board of the University of North Carolina at Chapel Hill (IRB #13-2648). Child participation was contingent on parental informed consent, and all indirect and direct interactions were with parents rather than children. Children were only identified by an ID number in our databases.

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