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Leveraging Telehealth to Evaluate Infants with Prodromal ASD Characteristics Using the Telehealth Evaluation of Development for Infants

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Lay Abstract

Many families seeking early evaluations for autism spectrum disorder (ASD) face long waitlists, must often travel to centers with appropriate expertise, and are frequently told by providers to "wait and see." This results in significant stress for families and delayed supports to infants and their caregivers who could benefit. This study evaluated whether telehealth could be used to identify and evaluate infants with early ASD characteristics in the first year of life. In this study, we evaluated 41 infants via telehealth using a standard set of probes and scored behavior related to social communication, play, imitation, and other developmental domains. We found the majority of infants demonstrated elevated likelihood of ASD on both parent-reported questionnaires and examiner-rated behavior. Caregiver ratings of the overall utility of the protocol used in this study were high. Overall, this study demonstrates the feasibility for telehealth-based approaches to evaluate infants' with elevated likelihood of ASD in the first year of life, which could help to improve families' access to care and to expand our capacity to conduct studies evaluating possible intervention supports.

Despite the advances in early identification of autism spectrum disorder (ASD), routine screening and evaluation for infants with early ASD markers have not been widely implemented in existing service systems (Green et al., 2013; Koegel, et al., 2014; Rogers et al., 2014). One major barrier is the lack of efficacious universal behavioral screeners for infants younger than 12 months. Development of such tools is challenging given the protracted onset of behavioral characteristics over the first several years of life and the difficulty distinguishing ASD-relevant markers from developmental delays, other neurodevelopmental disorders, and some normative behaviors (e.g. repetitive motor actions) early in development (Hatch et al., 2020; Pierce et al., 2011). A second major barrier is that when parents recognize and raise concerns, there are typically long delays before children receive specialized evaluations and subsequent services (Zuckerman, Lindly, & Sinche,

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2015). These service gaps are even more pronounced for children from racial and ethnic minorities and families living in rural or low resource communities (Antezana, Scarpa, Valdespino, Albright, & Richey, 2017; Mandell et al., 2009; Stahmer et al., 2019). In the United States, autism-specific services usually require a documented diagnosis, leaving families of infants with early prodromal ASD characteristics with very few resources available to them for either evaluation or services. While there have been some promising initial findings from parent-mediated intervention studies, there remains a pressing need to conduct the prospective longitudinal studies and treatment trials needed to understand the developmental trajectories and outcomes of infants with early ASD characteristics and to develop and test efficacious interventions to support their development. We suggest that utilization of telehealth approaches can help to address these barriers by increasing families' access to early evaluations when concerns arise, helping to prioritize clinic waitlists, and expanding the scope of early identification and treatment research beyond infant sibling designs by supporting the participation of more infants with prodromal characteristics and families from rural communities or for whom travel to a University site is a significant barrier. In the present research, we evaluated the feasibility of recruiting and evaluating infants with significant likelihood for ASD from a distance using a promising semi-structured protocol, the Telehealth Evaluation of Development for Infants (TEDI).

Early Behavioral Indicators of ASD

Decades of studies carefully following multiple cohorts of infant siblings of children with ASD, who have increased recurrence rates relative to the general population, have yielded critical insights into the timing of the onset patterns, stability of early symptoms, recurrence rates, and the range of developmental trajectories and outcomes within this population (Ozonoff & Iosif, 2019; Ozonoff et al., 2011; Zwaigenbaum et al., 2015). Significant differences at the group level begin to emerge around 12 months, with infants ultimately diagnosed with ASD showing differences in social attention, social communication, and object use compared to their non-diagnosed peers. Approximately half of infants siblings ultimately diagnosed with ASD by 36 months are identified by 18 months, with the other half not meeting behavioral criteria until 24 or 36 months (Ozonoff et al., 2015). Additional long-term follow-up of these cohorts have revealed a further sub-set of infants who do not meet diagnostic criteria until later in middle childhood (Ozonoff et al., 2018). The rigor with which these samples have been monitored since early infancy suggest behavioral markers are not 'missed' in infancy, but rather that this heterogeneous and protracted onset period is a defining characteristic of this population. Another challenge to early identification of prodromal ASD is that many early behavioral features are nonspecific and shared with other clinical groups. For example, infant siblings of children with ASD or ADHD themselves later diagnosed with either show overlapping trajectories in inattention and hyperactivity between 12 and 36 months (Miller et al., 2020). Repetitive motor movement are common in other conditions such as Fragile X and are also observed across typical development in early infancy (Baranek et al., 2005; Iverson & Thelen, 1999). These features may be one reason many existing universal screening measures for ASD tend to perform poorly as *predictive tools* in young infants and toddlers (Guthrie et al., 2019; Parikh, Iosif, & Ozonoff, 2020; Robins, 2020).

Despite the heterogeneity in ASD emergence, there is evidence to suggest that early-appearing ASD characteristics are clinically meaningful. Infants diagnosed by 14 months show a rapid developmental deceleration between 6 and 14 months compared to infants who are diagnosed after 14 months (Landa, Stuart, Gross, & Faherty, 2013). In a prospective study of infant siblings, Zwaigenbaum and colleagues (2020) found that nearly 70% of infants' diagnosed by 24 months had 12-month scores on the Autism Observation Scale for Infants (AOSI) above the cut-off, versus only 39.2% of infants whose initial diagnosis was made at 36 months. Sacrey and colleagues (Sacrey et al., 2016, 2020) found that parent concerns as early as 6 months of age differentiate infant siblings with later ASD outcomes from non-diagnosed peers and infants without a family history of ASD; parent concerns on a structured questionnaire completed at 9 months predicted outcome classification with 70% accuracy. This is consistent with the literature using retrospective parent reports which have reported that while the mean age of parent first concern is around 18 months, many parents report signs emerging in the first year (Chawarska et al., 2007; De Giacomo & Fombonne, 1998; Herlihy, Knoch, Vibert, & Fein, 2013).

Screening for Symptomatic Infants

Several groups have now begun applying the insights gained from infant sibling studies to screen infants in community settings. Most of these screening studies have used standardized caregiver-completed questionnaires at 12-month pediatric visits, but others have used birth-record mailings or clinically-referred samples (Baranek et al., 2015; Barbaro & Dissanayake, 2010; Pierce et al., 2011; Turner-Brown, Baranek, Reznick, Watson, & Crais, 2013; Whitehouse et al., 2019; Wieckowski et al., 2021). Across these multiple studies, one consistent finding is that the number of infants picked up by the screenings and ultimately diagnosed with ASD is fairly low. For example, Turner-Brown and colleagues (2013) initially screened 1,305 infants and ultimately identified 9 with ASD (from a subsample of 699 toddlers who completed follow-up screeners at age 3). More recent work suggests that repeated screenings may help to improve identification rates as more infants have behavioral features unfold over time. Wieckowski and colleagues (2021) initially screened 5,784 infants and ultimately diagnosed 368 toddlers with ASD (6.4%). While caregiver-completed screeners are typically brief and relatively low-burden in terms of staffing and parent time, randomized controlled treatment trials relying on these ascertainment methods are ultimately restricted by geographic range or provider network size. Further, there is evidence that many families identified via universal screening may not have been seeking or receptive to initiating intervention (Freuler et al., 2014). Many families decline evaluation and or treatment after a positive screen even after enrolling in treatment studies (Pierce et al., 2011; Rogers et al., 2014). Geographic distance from the intervention site is a barrier to participation for many families (Bradshaw et al., 2020; Hyde et al., 2020). Even highly motivated families actively seeking specialized evaluations for their young infants typically face long waitlists and often must travel to sites with appropriate expertise (Kanne & Bishop, 2020).

Expanding Early Assessment Via Telehealth

The ongoing COVID-19 pandemic has highlighted the potential for telehealth to meet many of these challenges. The pandemic has facilitated a rapid shift to telehealth-based tools, including diagnostic assessments for ASD (for a review see Berger *et al.*, 2021). These tools have primarily focused on translation of existing diagnostic tools (e.g. the ADOS-2; Lord *et al.*, 2012) or novel diagnostic assessment for toddlers 12 – 36 months. Encouragingly, in recent years there has been a steady increase in the use of telehealth within existing public early intervention service systems, supporting the feasibility of telehealth implementation in these settings (Cole, Pickard, & Stredler-Brown, 2019; Cole et al., 2016). Previous work suggests that in general, telehealth delivery of parent coaching and early intervention services is satisfactory to families (Rooks-Ellis, Howorth, Boulette, Kunze, & Sulinski, 2020; Vismara et al., 2018). While there has been a rapid deployment of telehealth within early intervention service systems, to date there are few, if any, reliable and valid measures for conducting ASD-specific screening or evaluations for *infants* – those 12 months and younger - via telehealth. Developing telehealth tools to meet these needs is imperative to realizing the full promise of telehealth for reaching into rural and underserved communities (Zwaigenbaum & Warren, 2020).

The Present Research

We have previously developed a systematic protocol for conducting behavioral assessments for infants via telehealth, the Telehealth Evaluation of Development for Infants (TEDI; Talbott et al., 2020). The TEDI utilizes a parent-coaching model to engage parents and infants in a specific set of semi-structured parent-child interactions. These semi-structured interactions provide the context for scoring specific examiner-rated measures and for further offline behavioral coding. A list of the specific activities and associated measures used in the current study is summarized in Table 1. Additional activities that can be added for evaluations with older infants and toddlers but not used in the sessions here include snack, pretend play, and puzzles and construction toys. A copy of the TEDI protocol is available from the first author. Preliminary feasibility and acceptability of this approach is promising (Talbott et al., 2020). Here, we build on these initial findings in a larger cohort of infants with early social communication concerns, in order to address the following research questions

1. Can infants with significant ASD characteristics in the first year of life be identified outside the infant sibling context?
2. What is the inter-rater and test-retest reliability of behavioral measures evaluated via telehealth?
3. Are infants' profiles consistent with the existing infant sibling literature?
4. Are there associations between examiner-scored observational data and parent-report measures?
5. Are telehealth procedures feasible and acceptable to families?

Method

Overview

This study utilizes data collected via telehealth from multiple cohorts of infants with early ASD symptoms. Study procedures for all cohorts were conducted under the approval of the Institutional Review Board at the University of California, Davis. Informed consent was obtained from all parents prior to data collection; parents received compensation for their time. Primary data collection components included online caregiver surveys and synchronous telehealth sessions with a study examiner, using the TEDI protocol to collect a series of specific parent-child interaction activities. Telehealth sessions were conducted by PhD-level examiners. Examiners were not blind to family history or parent concerns, as these were discussed during the course of the assessment and contributed to examiners' overall clinical best estimate rating of likelihood of ASD (described further below). While prior work has found no effects on examiner's knowledge of family history of ASD on AOSI scores (Estes et al., 2015), our approach differs from prior infant sibling studies with AOSI examiners naïve to family history.

Participants

Forty-one infants aged 6–12 months whose parents had social communication or ASD concerns were recruited nationally across three cohorts. Cohort 1 ($n = 11$) was recruited via word-of-mouth and self-referral as part of an initial pilot study. Data from these infants have been presented previously (Talbott et al., 2020). This cohort participated in an initial intake and retest assessment. A subset of infants in Cohort 1 received a brief telehealth-based parent-coaching intervention as part of a single-subject case design following the initial and retest assessments. Analysis of the single-subjects design treatment study are underway (Dufek, Talbott, & Rogers, 2020). Two additional cohorts were recruited nationally for the present study. Recruitment involved postings on family-facing websites (e.g. UC Davis MIND Institute social media pages, child development organization recruitment pages) and sending the study webpage to early intervention agencies and other providers (e.g. state part C coordinators). Many families also self-referred through the study webpage or by contacting the Institute and/or laboratory). The first of these (Cohort 2; $n = 10$) participated in a single assessment visit. The final cohort (Cohort 3; $n = 20$) participated in an initial intake and retest assessment and are currently being followed longitudinally. Recruitment for this cohort is ongoing. Eligibility criteria for all cohorts included: 1) Infant age between 6 and 12 months at screening; 2) score in the concerns range on any domain of the Infant-Toddler Checklist (Wetherby, Brosnan-Maddox, Peace, & Newton, 2008); 3) English as primary caregiver language; 4) access to a computer or mobile device in the home capable of running the telehealth session; 5) No significant medical (e.g. seizures, head injuries), motor, hearing, or auditory impairments that render the assessment developmentally inappropriate; 6) no known genetic syndromes associated with ASD (e.g. Fragile X); 7) gestational age over 34 weeks. The last two criteria (i.e. possible or known genetic conditions and prematurity) were eliminated for Cohorts 2 and 3 in order to increase the generalizability of the results. Demographic characteristics of the full sample are presented in Table 2.

Procedure

Upon enrollment, we sent families links to online surveys and a small kit of toys needed for the assessment. These included blocks, a soft book, rattles, a small blanket, bubbles, and other similar items. A set of laminated cards contained in the kit provided information about each activity that would be conducted during the live telehealth session and some suggested scripts and prompts parents could use. These cards were not intended to support parents in conducting the telehealth session activities independently, but to provide a sense of the scope of the activities and interactions that would take place in the session. Prior pilot work indicated parents' strong preference for these supportive materials, paired with live coaching during the session (Talbott et al., 2020). Sessions were conducted by Ph.D.-level examiners (developmental and clinical psychologists) with significant experience evaluating infants and toddlers with ASD or at high likelihood of ASD. Examiners followed the manualized TEDI protocol for coaching parents through each activity and scored specific measures live during the session (detailed below in measures section). The protocol is designed for sessions to last between 45 and 90 minutes, depending on the child's age, abilities, and family needs. At the conclusion of all sessions, parents were asked to report whether the session was representative of their infants' usual behavior. If a session was reported as not representative, the session would have been repeated. Caregivers were sent a satisfaction questionnaire following the initial visit or retest visit if a retest was completed.

Community Involvement: Community partners were not involved in this study. We plan to develop a community advisory board to further refine this protocol for further testing in community-based settings.

Measures

CSBS-DP Infant-Toddler Checklist (ITC; Wetherby and Prizant 2002). This 25-item checklist assesses 6- to 24-month-old infants' language, communication, play skills, and parents' concerns. Parents completed the ITC during initial screening to determine study eligibility.

Ages and Stages Questionnaires, 3rd Ed. (ASQ-3; Squires and Bricker, 2006). This caregiver-completed questionnaire measures development in five areas (gross motor, fine motor, communication, problem solving, personal-social) and a screening classification is provided for each domain: Typically Developing, Monitor, or Refer for Further Assessment. Parents completed the ASQ-3 online prior to the assessment.

Ages and Stages Questionnaire: Social Emotional, 2nd Ed. (ASQ:SE-2; Squires, Bricker and Twombly, 2015). This caregiver-completed questionnaire measures development across 7 social-emotional domains. An overall social-emotional screening classification is provided: Typically Developing, Monitor, or Refer for Further Assessment. Parents completed the ASQ: SE-2 online prior to the assessment.

Autism Parent Screen for Infants (APSI; Sacrey *et al.*, 2016). The APSI is a 26-item forced-choice parent-report questionnaire with content probing early pre-diagnostic behavioral symptoms including eye contact, social development, gestures, and emotion regulation. At 12 months, a cut-off score of 10 is associated with a relative risk ratio of 3.61

(Sacrey et al., 2018). The APSI was completed online prior to the assessment for Cohorts 2 and 3.

Autism Observation Scale for Infants (AOSI; Bryson *et al.*, 2008). The AOSI consists of semi-structured play and systematic presses that assess target behaviors including visual tracking and attention disengagement, coordination of eye gaze and action, imitation, affective responses, early social-communicative behaviors, behavioral reactivity, and sensory-motor development. At 12 months, a cut-off score of "7" results in a relative risk ratio of 1.58 (Sacrey et al., 2018). The AOSI was scored by examiners during the telehealth session.

P-ESDM Infant-Toddler Curriculum Checklist (IT-CC; Rogers *et al.*, 2020). This tool consists of 136 criterion-based items organized in nine developmental domains: receptive understanding of gestures and words, expressive use of gestures and words, joint attention, social interaction, imitation, cognition, and play skills. Items span the developmental range from 8 to 30 months and are scored from TEDI activity probes. A previous study assessing toddlers with ASD live reported high month-to-month test-retest reliability ($r = .90$), and very high concurrent validity with a standardized developmental measure, the Mullen Scales of Early Learning (Mullen, 1995; $r = .90$, $p < .001$). Here, raw total scores across all domains were summed to create a final IT-CC Total Score.

Telehealth Usability Questionnaire (Parmanto, Lewis, Jr., Graham, & Bertolet, 2016). The TUQ is a 21-item questionnaire designed to assess usability of telehealth applications across 5 domains: usefulness, ease of use, effectiveness, reliability, and satisfaction. Items are rated on a 1–7 likert scale. It was completed by parents online following the telehealth assessment for Cohorts 2 and 3.

Examiner Clinical Best Estimate Ratings (CBE). After each assessment session, examiners complete a summary judgement of likelihood of ASD using all available data, including family history and parent concerns. Cohort 1 was done via consensus and represented any level of concern beyond "no concern." Ratings for Cohorts 2 and 3 were made independently consisted of three likelihood categories: Low, Moderate, or High. Ratings included a confidence rating of that classification (1–5 scale). To evaluate consistency in examiner CBE ratings, a CBE by Confidence (Overall CBE) variable was created, with high scores indicating high risk and high certainty.

Results

Infants were on average 10.5 months (range 6.83 to 15.0 months, chronological age) at first evaluation, with second sessions for Cohorts 1 and 3 repeated an average of 1.5 weeks apart (range: 5 – 41 days). No session was repeated due to lack of representativeness. Our primary analyses are based on data from the first visit across all three cohorts, unless otherwise specified.

Can infants with significant ASD characteristics in the first year of life be identified outside the infant sibling context?

In terms of developmental level, the majority of infants' scores fell into the "Refer for Assessment" range on at least one domain of the ASQ-3 (29/41 infants, 70.7% of the sample) and the ASQ-SE2 (29/31 infants, 93.5% of the sample). Proportions of infants falling into the "Monitor" and "Further Assessment" Ranges for each of the ASQ subdomains are described in Table 3.

Descriptively, AOSI Total Scores (time 1a; $n = 40$) were elevated ($M = 12.35$, $SD = 4.98$) compared to the suggested cut-off risk score of 7 (Table 3). A chi-square test indicated a significant majority of infants' scores were higher than the suggested cut-off point score of 7, χ^2 (1, $N = 40$) = 22.500, $p < .001$.

APSI Total Scores were also elevated ($M = 21.00$, $SD = 9.26$, $N = 30$). Because the APSI uses different suggested cut-off's for 6, 9, and 12 months, an APSI cut-off classification (under or over the cut off) was determined for each infant based on their nearest age band, and a Chi-square analyses was used to determine whether a significant proportion of infants scored above the cut-off. χ^2 (1, $N = 30$) = 8.533, $p = .003$. Mean scores and sample proportions are presented in Table 3.

Overall CBE ratings indicated significant likelihood for ASD for the majority of infants in Cohorts 2 and 3 (see Table 3). Of 30 infants, 20 (68%) were rated High Likelihood, 9 (30%) Moderate Likelihood, and 1 as Low Likelihood. The mean examiner confidence rating was 3.57 (SD = .90), indicating neutral to slight confidence in the CBE rating given.

What is the Interrater and Test-Retest Reliability of Behavioral Measures Obtained Via Telehealth?

Inter-rater reliability was ascertained by having a second examiner independently score the AOSI and IT-CC measures and make CBE ratings from session recordings. As we have previously reported inter-rater reliability for AOSI scores in Cohort 1 (Talbott et al., 2020), we conducted a separate set of inter-rater reliability analyses for the present study using Cohort 2 ($n = 10$). Intra-class correlation coefficients (two-way, random model, absolutely consistency) indicated high inter-rater agreement for AOSI Total Scores (ICC = .94), AOSI Number of Markers (ICC = .89), and IT-CC Total scores (ICC = .88) and poor inter-rater agreement for Overall CBE (ICC = .32). Intra-class correlation coefficients for individual IT-CC domains ranged from poor to excellent: Early Gestures 0.80, Speech 0.86, Communicative Gestures 0.83, Verbal Comm. 0.86, Jt. Attention 0.92, Dyadic Engagement 0.17, Imitation 0.48, Cognition 0.64 and Play 0.68.

Test-retest reliability was evaluated across visits 1a and 1b for AOSI (Cohorts 1 and 3, $n = 30$), IT-CC, and CBE (Cohort 3 only, $n = 20$). In terms of AOSI scores, Total Score was significantly correlated across visits (AOSI Total $r = .459$, $p = .01$ AOSI Markers $r = .245$, $p = .19$). AOSI risk classification (above or below cut-off) was highly consistent, with 26/30 infants meeting the same classification criteria across the two visits. IT-CC Total Score was strongly correlated across sessions, $r = .75$ $p < .001$. Overall CBE ratings were not significantly correlated across sessions, $r = .27$, $p = .24$ (11/20 infants received the

same rating across both visits). However, all but two infants were rated as moderate or high likelihood of ASD at least one visit, so these ratings may not represent clinically meaningful differences.

Are infants' profiles consistent with the existing infant sibling literature?

To further situate these scores within the existing infant sibling literature, we compared the frequency of scores of 2 or 3 (indicating significant presence of that behavior) within our sample to the frequency reported within previously published infant sibling cohorts, at the item-level, for both the AOSI and APSI. The AOSI comparison sample consisted of 54 infant siblings with known ASD diagnostic outcomes assessed at 6, 9, 12, 15, and 18 months as part of a prospective, longitudinal study (Zwaigenbaum et al., 2020). We used item-level scores reported at 9 months as it was closest to the mean age of our sample. The mean AOSI Total Score reported by Zwaigenbaum et al. (2020) at 9 months was 6.6 (SD = 3.6). The APSI comparison sample consisted of 9-month old infant siblings with known ASD diagnostic outcomes at 36 months ($n = 34$; reported by Sacrey *et al.*, 2020). For both measures, we utilized chi-square analyses to test whether the proportion of infants scoring 2 or more on a given item in the current sample differed from the proportion expected based on the previously reported data. Item-level data for the AOSI and the APSI are presented in Tables 4 and 5, respectively. Overall, there were several items in both measures with significantly higher rates of elevated scores within our sample. However, very few items received scores of 2 or higher for a majority of infants. Items that more than half the sample received a score of 2 or higher included social babbling and eye contact AOSI and failure to point, or use gestures on the APSI.

Are There Associations Between Examiner-Scored Observational Data and Parent-Report Measures?

We examined associations between examiner-rated AOSI Total Score and parent-rated APSI Total Scores using Pearson's zero-order correlations, which indicated a significant and strong positive association between these measures ($r = .464$, $p = .010$, $n = 30$).

Are Telehealth Procedures Feasible and Acceptable to Families?

We have previously reported positive findings for feasibility benchmarks and parent acceptability in Cohort 1 (Talbott et al., 2020). We utilized an expanded satisfaction questionnaire Cohorts 2 and 3 ($n = 30$) to evaluate five specific dimensions of acceptability: Usefulness, Ease of Use, Effectiveness, Reliability, and Satisfaction. A one-sample Wilcoxon signed rank test comparing mean ratings to a neutral rating indicates significant overall parent satisfaction with the TEDI (TUQ Total Mean Score: $Z = 465$, $p < .001$) as well as on each of the subdomains (all p's $\leq .001$, remaining significant after correction for multiple comparisons). Mean scores are presented in Table 6. Anecdotally, parents' responses to open-ended requests for feedback were overwhelmingly positive and highlighted the convenience of having materials sent, their child feeling comfortable in a familiar environment, and feeling supported and engaged with the examiners.

Discussion

In this study, we demonstrated the initial feasibility of conducting an informative developmental assessment via telehealth and identifying infants with significant symptoms of ASD in the first year of life. This approach was acceptable to families, and demonstrated reasonable inter-rater and test-retest reliability, supporting its potential use as a tool for developmental monitoring and early identification in community settings. The behavioral profiles we observed in this preliminary sample mirror those previously reported in the infant sibling literature amongst infants ultimately diagnosed with ASD, suggesting the behavioral indicators of ASD identified via prospective infant sibling studies may be generalizable to infants recruited more broadly. Following the current cohorts of infants into toddlerhood and determining diagnostic outcomes will help to clarify which, if any, early behavioral characteristics are particularly strong indicators of subsequent ASD outcomes. Notably, a significantly higher proportion of infants in our sample demonstrated elevated scores (i.e. scores of 2 or higher) on both examiner and parent behavior ratings compared to previous infant sibling cohorts with known ASD outcomes. This suggests the infants in our sample represent infants with the earliest-appearing behavioral differences, versus infants whose ASD traits unfold in the second or third years of life. However, given the preliminary nature of the current sample, these results will need to be replicated in a larger cohort. Another important finding was the lack of consensus around a core set of behavioral characteristics. Very few individual behavioral domains were elevated in more than 50% of the sample. Again, this is consistent with the existing infant sibling literature which has not been able to identify robust universal early behavioral markers in the first year of life. Instead, these findings add to the literature suggesting early concerns reflect a broad array of behavioral differences which may be shared amongst infants with ASD, developmental delays, or other neurodevelopmental conditions.

Although somewhat lower that the initial AOSI 2-week test-retest reliability of .61 for 12-month-olds reported by Bryson and colleagues (2008), the modest correlations for the behavioral measures across testing sessions and between caregiver and examiner ratings observed in the current study is consistent with some recent findings. Hudry and colleagues (2020) examined inter-rater and test-retest reliability in AOSI total scores and number of markers across a 6-month interval in a sample of community-ascertained infants participating in a treatment trial. They reported a correlation of .44 for AOSI total scores across the two timepoints. Likewise, Sacrey and colleagues (2018b) reported poor agreement between parent and clinician item-level ratings at 12 and 18 months. Given the increased variability telehealth administration introduces in terms of setting, interactive partner, and audiovisual quality, the test-retest reliability observed in the current study across multiple measures is a positive finding and supports the use of telehealth-based assessments in future investigations. Anecdotally, when asked about the representativeness of the session, many parents noted subtle differences in their child's behavior across the two sessions, despite endorsing the overall session as representative of their child's behavior. These observations were often new skills ("he's never imitated me before today!" and temperamental differences related to sleep or hunger states). On occasion, objects or situations elicited low-frequency but highly relevant behaviors (e.g. visual examination of

laundry basket, caregiver report of excessive interest in cylinder-shaped toys) that likely contributed to examiners' summary ratings. These differences may have contributed to the low agreement in clinical best estimate ratings across sessions. Together, the modest stability in scores and variability in specific items underscore the need for multiple assessments and routine developmental surveillance, as has been previously articulated (Hudry et al., 2020; Wieckowski et al., 2021).

There are several limitations to the current study that should be acknowledged. First, this was a convenience sample, consisting of parents who were recruited directly into the study via online recruitment, by word-of-mouth, or self-referral. Participants were predominantly Caucasian and of high socio-economic status, limiting the conclusions we can draw regarding generalizability and feasibility more broadly. Further, examiners were highly trained with expertise in early ASD identification and future work is needed to evaluate whether these procedures could be carried out in a community setting. There are clear disparities in access to autism research and clinical services for families of color and those living in rural and under-resourced communities (Mandell et al., 2009; Smith, Gehricke, Iadarola, Wolfe, & Kuhlthau, 2020; Stahmer et al., 2019). Telehealth-based services can help to increase access for many families, but may also add new barriers including costs associated with needed equipment and data usage, the shortage of high-speed internet in many rural communities, and increased burden on parents to conduct components of the evaluation. We hope to address this in future work by utilizing community-based participatory research models, partnering with stakeholders to conduct further adaptations to ensure the TEDI protocol will address families' needs and fit within existing services systems. Another limitation to the current study is the absence of longitudinal or outcome data, which limits our ability to examine differences in behavioral profiles amongst infants who are later diagnosed. Our next steps include following the current sample over time to better understand their developmental trajectories and clinical outcomes. We anticipate that infants in this sample will have a range of developmental and diagnostic outcomes that are likely to include, but not be limited to ASD. As we and others have suggested previously, development of intervention approaches that appropriately meet the needs of infants with early ASD-relevant traits do not necessarily need to be ASD-specific or delayed until a diagnostic determination can be made (Constantino, Charman, & Jones, 2021; Talbott & Miller, 2020). Demonstration that specific intervention approaches support developmental progress across infants with shared behavioral profiles during a non-specific pre-diagnostic period would significantly improve families' access to supportive services.

Much of the existing literature on early behavioral screening for ASD has focused on universal screening using caregiver-completed checklists, typically administered in primary care settings. Several studies using community-based ascertainment based on such universal screeners have reported follow-through from a positive screening (i.e. screening indicating elevated likelihood of ASD) to evaluation or intervention to be quite low (Monteiro, Dempsey, Berry, Voigt, & Goin-Kochel, 2019; Pierce et al., 2011; Turner-Brown, Baranek, Reznick, Watson, & Crais, 2012; Wieckowski et al., 2021). This may reflect discrepancies between screening classification and provider or parent concerns, low rate of provider referral, barriers for families to attend evaluations, and/or family preference. Here we consider an alternative approach, focusing on infants' whose parents have expressed

concerns about their development in order to better understand the behavioral profiles and clinical significance of these potential prodromal characteristics. Given the negative impact of unmet service needs and a protracted "diagnostic odyssey" on caregiver stress, we contend that in addition to better understanding the early development of infants with early ASD characteristics, this approach addresses a critical need in terms of infant mental health and overall family functioning (Zwaigenbaum et al., 2015). We hope to address this aspect in future analyses examining caregiver-reports of early concerns and mental health correlates, families' involvement in existing early intervention services, and the potential for telehealth-based early evaluations to support families during this period of diagnostic uncertainty. It is our hope that telehealth-based approaches like the one we have presented here will provide new opportunities to expand studies of early development into community-based settings, to support future high-quality randomized controlled trials of supportive interventions, and ultimately, to increase families' access to early specialized evaluations and services.

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Table 1.

TEDI Activities and Scored Measures

Activity Title	Description	Measures Scored
1. Floor Play	3-minute unstructured parent-child interaction	ECI[a] IT-CC AIMS[b]
2. Where did it go?	Visual tracking and disengagement	AOSI IT-CC
3. Free play #1	3-minute parent-child interaction; at tabletop with provided toys	AOSI ECI IT-CC
4. Peek-a-boo	Tickles are prompted if child does not respond to peek-a-boo	AOSI IT-CC
5. Imitation	Modeled oral-motor and object actions, varying by age	AOSI IT-CC
6. Free play #2	3-minute parent-child interaction; at tabletop with provided toys	AOSI ECI IT-CC
7. Singing a song	Familiar song or non-object social routine, selected by caregiver (e.g. itsy-bitsy spider, head shoulder knees and toes)	IT-CC
8. Bubbles/Wind-up	3 minute semi-structured interaction; caregiver asked to pause for requests	IT-CC
9. Novel object	1 minute object exploration probe	IT-CC
10. Book	Caregiver selected book	IT-CC
11. I Can Move	Gross motor probes	AIMS[b]
12. Floor Play #2	3 minute unstructured parent child interaction	ECI IT-CC AIMS[b]

Note: The IT-CC is scored throughout all activities, with additional probes as needed to complete, following the administration guidelines

[a]ECI= Early Communication Indicator

[b]AIMS= Alberta Infant Motor Scale; data coding and analysis for both measures is ongoing and not presented in the current analysis.

Table 2.

Participant Demographics

Demographics	**Combined Sample (N = 41)**
Infant Age at Initial Session (*M, SD*)	10.50, 2.10
Infant Sex (*n, % male)*	20, 48.8%
Infant Race/Ethnicity (*n*, %)	
White	33, 80.5%
Hispanic or Latino	3, 7.3%
Asian	4, 9.8%
More than one Race	4, 9.8%
Infants with 1st degree family history of ASD (*n*, %)	10, 24.4%
Known genetic finding (*n*, %) [a]	4, 12.9%
Parent Education (*n*, %) [b]	
High School/GED/Vocational	2, 4.9%
Some College	2, 4.9%
College Degree	14, 34.1%
Graduate Degree	20, 48.8%
Not reported	3, 7.3%

[a] diagnoses included DDX3X, microdeletion 16p12.2, MTHFR A1298C, and psedo hypoaldosteronism type 1.

[b] Parent education data is available for 38 families.

Table 3.

Infants' Scores and Referral Classifications on Primary Measures

Domain	Proportion of sample
ASQ-3 Referral Recommendation, by Domain (*n,* %)	
Communication	
Further Assessment	23, 56.1%
Monitor	12, 29.3%
Typically Developing	6, 14.6%
Gross Motor	
Further Assessment	10, 24.4%
Monitor	10, 24.4%
Typically Developing	21, 51.2%
Fine Motor	
Further Assessment	13, 31.7%
Monitor	7, 17.1%
Typically Developing	21, 51.2%
Problem Solving	
Further Assessment	15, 36.6%
Monitor	10, 24.4%
Typically Developing	16, 39.0%
Personal-Social	
Further Assessment	17, 41.5%
Monitor	13, 31.7%
Typically Developing	11, 26.8%
ASQ-SE 2 Further Assessment Recommended (*n,* %)[a]	29, 96.5%
AOSI[b]	
AOSI Total Score, time 1a (*m,* sd)	12.35 (4.98)
AOSI Number Markers (*m,* sd)	7.43 (2.61)
Infants' above AOSI cut-off (%)	35 85.36%
APSI[c]	
APSI Total score, time 1a (*m,* sd)	21.00 (9.26)
Infants above APSI cut-off (%)	76.67%
CBE[c] of High Concerns (*n,* %)	20, 66.67%

[a] ASQ-SE2 data is available for cohorts 1 and 3 (*n* = 31)

[b] AOSI data is missing from one infant due to technical errors in the session.

[c] APSI and CBE data is available from Cohorts 2 and 3 (*n* = 30)

Table 4.

Proportion of infants scoring two or higher on individual AOSI items, current and comparison sample.

	AOSI item	% 2 + (Zwaigenbaum sample)	% 2 + (current sample)	χ^2 (df= 1, *n* = 40)	*P*
1	Visual tracking	2	12.50	22.500	<0.001*
2	Disengagement of attention	11	20.00	3.309	0.07
3	Orients to name	13	42.50	30.778	<0.001*
4	Differential response to facial emotion	–	–		–
5	Anticipatory responses	2	12.50	22.550	<0.001*
6	Imitation of actions	20	27.50	1.406	0.24
7	Social babbling	42	55.00	2.775	0.10
8	Eye contact	33	87.50	53.736	<0.001*
9	Reciprocal social smile	7	45.00	88.725	<0.001*
10	Coordination of eye gaze and action	0	–		–
11	Reactivity	4	7.50	1.276	0.26
14	Social interest and shared affect	0	–		–
15	Transitions	2	12.50	22.500	<0.001*
16	Motor control and behavior	2	7.50	6.173	0.01
17	Atypical motor behaviors	31	47.50	5.091	0.02
18	Atypical sensory behaviors	11	30.00	14.750	<0.001*
19	Engagement of attention[a]	0	–		–
20	Insistence of having or playing with particular objects or specific activities[a]	0	–		–
21	Sharing interest[a]	16	41.03	18.173	<0.001*

AOSI: Autism Observation Scale for Infants; df: degree of freedom.

*Starred items indicate those remaining significant after correction for multiple comparisons using the Benjamini and Hochberg (1995) procedure.

[a]Item-level data available for 39 infants.

Table 5.

Proportion of infants scoring two or higher on individual APSI items, current and comparison sample.

	APSI item	% 2 + (Sacrey sample)	% 2 + (current sample)	χ^2 (df= 1, *n* = 30)	*P*
1	Difficulty visually tracking a moving object	6.5	0.0	–	–
2	Visual fixation, or stare, at certain objects	19.4	36.7	5.72	0.017
3	**Fail to respond to name**	**32.3**	46.7	**2.832**	**0.092**
4	React to changes in facial expression	19.4	30.0	2.156	0.014
5	Anticipate the pleasure of social games	0	–	–	–
6	**Imitation of sounds or actions of others**	**30.0**	40.0	**1.429**	**0.23**
7	**Vocalize back-and-forth with you**	**12.9**	40.0	**19.609**	**<0.001** *
8	**Difficulty in establishing eye contact**	**12.9**	40.0	**19.609**	**<0.001** *
9	Smile in response to your smiles	0	–	–	–
10	Coordinate actions with eye gaze	9.7	3.3	1.388	0.24
11	**Tend to be over-reactive or under-reactive**	**19.4**	26.7	**1.013**	**0.31**
12	Cuddle into your body when holding them	6.5	23.3	13.987	<0.001*
13	Difficult to soothe	3.2	6.7	1.164	0.28
14	Show sustained interest and pleasure in interacting	9.7	23.3	6.366	0.012
15	Have difficulty with change	3.2	6.7	1.164	0.28
16	Difficulty using hands/holding objects	6.5	23.3	13.987	<0.001*
17	Unusual repetitive motor behaviors	16.1	40.0	12.686	<0.001*
18	Use another person's hand as a tool	0	–	–	–
19	Have unusual sensory behaviors	6.5	3.3	0.495	0.48
20	Difficulty focusing attention on objects	6.5	13.3	2.305	0.13
21	Insist on holding/playing with certain toys	0	–	–	–
22	Resist others joining in play/have fixed play routines	0	–	–	–
23	Share interests in object/event with others	16.1	43.3	16.472	<0.001*
24	Point to objects/event at a distance	80.0	86.7	0.833	0.36
25	Use gestures	71.0	66.7	0.274	0.60
26	Loss of skill over past 2–3 months	3.2	16.7	17.564	<0.001*

APSI: Autism Parent Screen for Infants.

Bolded items represent the items that distinguished HR-ASD from HR-N in the Sacrey et al. (2020) sample.

*Starred items indicate those remaining significant after correction for multiple comparisons using the Benjamini and Hochberg (1995) procedure

Table 6.

Mean Scores on Parent-Reported Telehealth Usability Questionnaire (TUQ)

TUQ Domain	Mean (SD)
Usefulness	5.96 (.70)
Ease of Use	6.40 (.69)
Effectiveness	6.22 (.66)
Reliability	4.95 (.89)
Satisfaction	6.37 (.57)
TUQ Total Mean Score	6.06 (.56)