Cognoa, Inc.
Protocol # PRO-003
“Cognoa ASD digital therapeutic engagement and usability study”

Protocol Number:	PRO-003
Protocol Title:	Cognoa ASD digital therapeutic engagement and usability study
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Version, Date:	Version 3.0 May 3, 2020

Statement of Compliance

The study will be conducted in accordance with the design and specific provisions of this IRB approved protocol, in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

NOTE: The confidential information in the following document is provided to you as an Investigator, potential Investigator, or consultant for review by you, your staff, and applicable Institutional Review Board. By accepting this document, you agree that the information contained herein will not be disclosed to others without written authorization from Cognoa, Inc. except to the extent necessary to obtain informed consent from those persons to whom the device will be administered.

Protocol Signature Page – Principal Investigator

PROTOCOL #: PRO-003

Study Title: Cognoa ASD Digital Therapeutic Engagement and Usability Study

Protocol Version Version 3.0 May 3, 2020

I have received and read the protocol dated May 3, 2020 and agree to adhere to the requirements. I am aware that my adherence to the above protocol is mandatory and that any changes in the protocol or informed consent form must first be approved by Cognoa, Inc. and the Institutional Review Board, except those changes necessary to eliminate apparent immediate hazards to subjects. I will provide copies of this protocol and all pertinent information to the study personnel under my supervision. I will discuss this material with them and ensure they are fully informed regarding their role in the study. I will ensure that the study is conducted in compliance with the protocol, Good Clinical Practice (GCP), and all applicable regulatory requirements, and with the reviewing Institutional Review Board (IRB) requirements. I agree to commence this study only after documented IRB approval is obtained.

Principal Investigator: _____ _____

Signature Date

_____

Printed Name

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Protocol Summary

Title	Cognoa ASD digital therapeutic engagement and usability study
Objective	To assess the usability and efficacy of the device.
Study Design	Single-arm prospective interventional study
Enrollment	Up to 30 participants
Outcome Measures	Change in scores on the Vineland-3 domain level caregiver report social skills and relationships Measures of Usability
Subject Population	Caregivers and female and male participants between the ages $\geq$ 3 years and < 9 years of age on date of enrollment from a general population diagnosed with ASD
Planned Schedule	Enrollment, baseline assessment, 4 weeks of intervention 4-6 times a week, weekly surveys of usability, final assessment.

Overview of Autism Spectrum Disorder

Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder that affects socialization, communication and behavior. According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), a guide created by the American Psychiatric Association and used by health-care professionals (HCPs) to diagnose mental disorders, ASD primarily consists of persistent deficits in social communication and social interaction as well as the presence of restricted, repetitive patterns of behaviors, interests, and/or activities that can persist throughout life.

ASD is said to be a “developmental disorder” because symptoms generally appear in the first two years of life and is known as a “spectrum” because there is a wide variation in the type and severity of symptoms people experience. Symptoms can include lack of joint attention, poor eye contact, difficulty reading social cues and facial expressions, failure to develop peer relationships, lack of social or emotional reciprocity, delayed speech development, difficulty sustaining conversations, lack of make-believe play, repetitive motor mannerisms, rigid adherence to routines, restricted interests and hyper- and/or hypo sensitivity to sensory input.

ASD can have a significant impact on a child’s day-to-day functioning including but not limited to impairments in communicating and getting needs met as well as difficulties with activities of daily living such as eating, dressing, playing, and sleeping. Most studies related to comorbidities in ASD have shown increased rates of anxiety and attentional disorders, when left untreated, reflecting cognitive, language, and social problems (Leyfer, Folstein, Bacalman, et al., 2006).

Caregivers are also greatly impacted with higher rates of stress, depression, anxiety, and other mental health disorders than in parents of children with other developmental delays and disabilities (Dumas, Wolf, et al., 1991; Hayes & Watson, 2013).

Standard of Care – Treatment of Autism Spectrum Disorder & Barriers

Reciprocal social behavior, a foundational capacity to engage in contingent social interactions important for learning and relationships, is typically disrupted in autism spectrum disorder (ASD). If unaddressed, the social deficits experienced by individuals with ASD can lead to lifelong struggles and a disabling condition. The National Institute of Mental Health (NIMH Report to Congress) and Interagency Autism Coordinating Committee (IACC Portfolio Analysis Report) identified the development of interventions to address social impairment in individuals with autism as a high priority. Individuals with ASD typically have few friends and experience loneliness due to difficulties recognizing subtle social cues and emotional states in others (Bauminger et al., 1999). ASD individuals who have social communication difficulties have significant challenges with the ability to form and maintain relationships. Without appropriate effective

intervention, therefore, ASD can result in loneliness, isolation, and an increased risk of depression and suicide (Hedley and Uljarevic, 2018). As such, developing friendships is recognized as one of the top goals of children, adolescents, and adults with ASD (Orsmond et al., 2004).

There is no cure for Autism. Interventions consist in treating symptoms, to reduce their severity and improve behavioral, social, emotional, and cognitive functioning. They include intensive behavioral interventions, rehabilitative services such as speech therapy, occupational therapy, physical therapy, social skills training, and counseling. Traditional pharmacotherapy may also be used to treat symptoms in ASD patients (e.g irritability, aggression) but does not affect the core symptoms of ASD (Choueiri & Zimmerman, 2017).

Among all children with an ASD diagnosis, 64% had received behavioral therapy in the past 12 months while 27% used medication to ease the symptoms (Zuckerman et al, 2017). No current medical intervention demonstrates clear benefit for social or communication symptoms in ASDs other than behavioral therapy approaches (however, 2 recent studies have concluded that standard behavioral therapy assessed in RCTs do not show effect). Furthermore, there are no currently FDA approved pharmacotherapies indicated for use to treat the core symptoms of ASD directly. Psychotropics are sometimes prescribed for irritability, such as risperidone and aripiprazole, especially in children who received an ASD diagnosis at older ages (Ji & Findling, 2016; Zuckerman, Lindly, & Chavez, 2017). Monitoring guidelines for these medications, due to possible side effects, include monitoring weight, height, and body mass index, extrapyramidal symptom screening, blood pressure, abdominal girth and liver enzymes, fasting plasma glucose, and fasting lipids. Adherence to monitoring for all measures in one study was only 20% (Javaheri et al., 2019). Intranasal oxytocin has shown some potential for improving some aspects of social functioning such as emotion recognition and eye gaze (Preti et al., 2014). Although FDA granted Roche Breakthrough Therapy designation in 2018 for its Balovaptan product (selective small molecule antagonist of the vasopressin V1A receptor), it remains in Phase III.

The current standard of care for treating socialization difficulties in children with ASD is behavioral therapy, and most prominently a therapy called Applied Behavioral Analysis (ABA) (Lovaas, 2003). ABA relies on teaching social skills in clinical sessions, via tools such as flashcards involving memorization of facial emotions (**Figure 1**) (Landa et al., 2011 and Lerman et al., 2004). Severity of autism is also associated with higher rates of behavioral interventions, whereas only one in four children with mild ASD received any intervention.

ABA therapy is delivered both in the home as well as via clinic-based services, depending on a myriad of factors such as child age, availability of therapists, cost, transportation and logistics concerns, and treatment model of the provider. Parent and family participation and engagement outside of treatment hours, however, is consistently recognized as positively contributing to successful outcomes in children.

Greater parental involvement during treatments that fit into natural everyday routines not only increase the effectiveness of interventions but also improves parents' sense of self-efficacy and reduces their levels of stress (Hastings and Symes 2002; Moes 1995; Koegel et al. 1996a).

Figure 1. Flashcard examples used in ABA therapy today.

Experts recommend 20 hours per week of Applied Behavioral Analysis with a behavioral therapist for at least two years (Mazurek et al., 2014). Although ABA therapy can be effective in increasing IQ, improving eye contact, face-to-face gaze, and emotion recognition, children who receive ABA often struggle to generalize learned behaviors to natural interactions and are dependent on prompts (Lovaas et al., 1987). That is to say, they may perform better at emotional recognition and corresponding tasks in the same environment with a therapist, but may not perform as well outside of the controlled environment.

1 Study Device Description

The study device is an investigational digital therapy that uses Augmented Reality-based social behavioral therapy, as an adjunct to standard outpatient applied behavioral analysis therapy, to improve adaptive behavior, specifically social skills in children with Autism Spectrum Disorder.

The Device is a smart device (smartphone)-based therapy aid for children with ASD to encourage facial engagement, emotion recognition, and provide real-time feedback (via cues) to the child during social interactions at home. The intervention is provided to the child via a mobile application that is centered around a Facial Expression Recognition Activity (FERA), powered by machine-learning, and an Emotions Guessing Game (EGG); these two steps provide the main therapeutic mechanisms of action. The application is engaging and provides a regimented therapy administration to improve outcomes associated with socialization domains in Autism Spectrum Disorder.

The Device is a SaMD-based system comprising:

- A caregiver and child-facing smartphone mobile application ("app") that provides the therapeutic content, including the FERA and EGG, instructions and other functions, using the smartphone camera for interactive activities in the therapy (primarily for the FERA)

- An underlying machine-learning engine for the FERA that drives the emotional recognition cue element of the therapy (explained further below).

- Several supporting software and backend services and infrastructure, including privacy and security encryption and infrastructure in compliance with HIPAA and other best practices for data security.

The Facial Expression Recognition Activity (FERA): the caregiver moderates the session, wherein the child aims the smartphone at the caregiver or other familiar adult within their natural and familiar environments (namely their own home or that of their extended family and friends), and either "finds" or tries to elicit 1 of several emotions that is prompted by audio in-app. Often, in the home setting, the emotion will be generated by the caregiver; the instructions to the caregiver will be to replicate the requested emotion or, during use of the Device in areas with multiple people, the

caregiver will be instructed to help the child find individuals expressing the prompted emotion; if none exist, the caregiver may choose to replicate the emotion (similar to EGG, described below) or prompt another individual in close proximity to replicate the emotion without alerting the child. The child points the phone camera towards the individual who they believe is expressing the prompted emotion; the mobile app has an Augmented Reality (AR) component that alerts the child when a face is detected. The screen then provides the child real-time audio and visual feedback correctly labeling the emotional expression displayed on the face.
The Emotional Guessing Game Activity (EGG): after the FERA activity is completed, the caregiver and child enters the EGG component of the application. The EGG stores previous images that the child has evaluated -- for example, the expressive faces successfully discovered during the FERA activities -- mixed with stock face images (from pre-reviewed sources). The goal of this activity is to reinforce and remind the child of their correct choices to improve retention. The child can then try to correctly match or label the emotional expressions displayed in the images. The goal from this EGG is to provide a bridge between FERA sessions that reinforces the learnings from the AR-based FERA in a different, 2D environment. It also provides additional social interaction opportunities between caregiver and child to review and discuss the emotions together.

2 Study Objectives

Cognoa will measure usability, engagement with the device, and changes in parent-reported socialization during a 4-week period of intervention at home with the Cognoa ASD therapeutic device.

2.1 Study Purpose

The purpose of this study is to evaluate the safety, effectiveness and usability of the device smartphone application, and Quick Start Guide) with intended users.

3 Study Outcome Measures

- Usability assessment of Cognoa ASD Therapeutic Device
- Change in scores on the Vineland-3 domain level caregiver report social skills and relationships from baseline to 4 week measurement

4 Study Duration

Duration of subject participation is approximately 4 weeks.

Total study duration is approximately 12 weeks.

5 Study Population

5.1 Study participant Recruitment and Selection

Up to 30 caregivers and children diagnosed with ASD ages $\geq$ 3 to < 9 years of age will be recruited from across the U.S.

Only subjects who meet all eligibility criteria will be enrolled into the study. Eligibility will be determined during a scheduled phone call by Cognoa recruiters.

5.2 Inclusion Criteria:

- Functional English language capability in the home environment.
- Parent, Guardian, or legal authorized representative (LAR) must be able to read, understand and sign the Informed Consent Form (ICF)
- Female or Male, $\geq$ 3 to < 9 years of age and parent/caregiver
- Diagnosis of Autism Spectrum Disorder
- Parent, Guardian, or legal authorized representative (LAR) must have smartphone capabilities for downloading Testflight software to access the Cognoa for Child development app; and the Cognoa Digital Therapeutic app (iOS 12.0 and up and Apple iPhone 8 and higher)

5.3 Exclusion Criteria:

- Participants with any other medical, behavioral, or developmental condition that in the opinion of the investigator may confound study data/assessments.
- Participants with planned extensive travel (more than 1 week) during the course of the 4-week intervention time period.
- Participants with deafness or blindness.
- Participants with known physical impairments affecting their ability to use their hands.
- Participants with active diagnosis of epilepsy and uncontrolled seizures.
- Participants whose age on the date of enrollment is outside the target age range.

6 Study Assessment

Parents who consent will be given access to the study device through its caregiver and child-facing smartphone app that provides therapeutic content. In order to access the study device app, parents will be provided access to two other apps. The first is Testflight. TestFlight is an online service for over-the-air installation and testing of mobile applications, currently owned by Apple Inc. that allows users to test iOS apps before they are released to the App Store. Parents will also be provided access to the Cognoa for Child Development app in order to create an account as a means to gain access to the study device app. The parents will only be able to engage with the study device app once they have created an account in the Cognoa for Child for Development app.
Parents will be instructed to use the study device with their child at home (not in public places) 4-6 times a week for 4 weeks. Parent report of the child's socialization will be measured at baseline (prior to starting to use the study device) and at the conclusion of the 4-week intervention period. Vineland-3 domain level caregiver report social skills and relationships will be administered over the phone by a trained research assistant or in an app. Usability metrics will also be collected by survey weekly (e.g. ease of use for child, frustration level, fatigue). Device usage, engagement, and progress metrics from the study device app will be collected throughout the study. Parent report of child's socialization will be collected using the Vineland-3 pre and post use of the study device. In addition, parents will fill out a Usability survey weekly throughout the study. These are the only 2 measures/surveys that parents fill out once enrolled in the study.

6.1 Training

The investigator and site research staff will be trained on the protocol and on all study procedures.

Monitoring of the site will occur to evaluate the progress of the study, verify the accuracy and completeness of data, assure that all protocol requirements, applicable FDA regulations and investigator obligations are being fulfilled and resolve any inconsistencies in the study records.

6.2 Usability Metrics

- Average duration of sessions using the device
- Total number of sessions completed
- Ratings of fatigue
- Ratings of frustration
- Ratings of irritability
- Ratings of comprehension of Instructions for caregivers
- Ratings of comprehension of Instructions for children
- Ratings of user app burdensome
- Ratings for the loading screen
- Ratings for the text to understand
- Ratings of video showing how to play first time

- Ratings of user free play

7 Data Collection and Storage

Data collection will be completed using electronic and/or paper report forms provided by Cognoa and data will be recorded into Cognoa dedicated study data repository. Data fields will include:

- Date of ICF
- Participant demographics
- Device usage metrics
- VABS-3 caregiver report social skills and relationships domain answers and scores
- Usability metrics

The study data will be maintained in a secure location throughout the duration of the study. The pictures of the caregivers taken by the study participants will be stored in the device app, as well as on an Amazon S3 cloud server with secured access and SSL encryption.

Upon study completion or termination, records will be kept at a secure location until at least 2 years after the last approval of a marketing application and until there are no pending or contemplated marketing applications or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product.

8 Adverse Events

8.1 Definitions

An **adverse event (AE)** is defined as untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, device users or other persons, whether or not it is related to the investigational medical device. Expected adverse Device Events (ADEs) may be previously identified in nature, incidence, severity or outcome in the study protocol, informed consent document, device operator manual, other risk analysis documentation or regulatory application.

A **serious adverse event (SAE)** is any adverse event, whether related to the use of the investigational device or not, that:

- led to a death;
- led to a serious deterioration in the health of the subject that:
- resulted in a life-threatening illness or injury;
- resulted in a permanent impairment of a body structure or body function;

- required in-patient hospitalization or prolongation of existing hospitalization;
- resulted in medical or surgical intervention to prevent permanent impairment to a body structure or a body function;
- led to fetal distress, fetal death or a congenital abnormality or birth defect.

An **anticipated serious adverse device effect (ASADE)** is any SAE on health or safety or any life-threatening problem or death caused by, or associated with the device, if that effect, problem, or death was previously identified in nature, severity, or degree of incidence in the investigational plan, informed consent, operator manual, other risk analysis documentation or regulatory application; or any other serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

An **unanticipated serious adverse device effect (USADE)** is any SAE on health or safety or any life-threatening problem or death caused by, or associated with the device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, informed consent, operator manual, other risk analysis documentation, or regulatory application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

In subjects, the ADEs/SADEs include the effects related to the investigational medical device (clinical study device), or the procedures involved. For device users or other persons (other clinical staff in the treatment room) ADE/SADE is restricted to the effects related to investigational medical devices. ADEs/SADEs may include the effects (1) resulting from insufficient or inadequate instructions for use, deployment, installation, or operation, or any malfunction of the investigational medical device; or (2) resulting from user error or from intentional misuse of the investigational medical device.

8.2 Recording AEs/ADEs and SAEs/SADEs

All reported AEs/SAEs or ADEs/SADEs will be: (1) evaluated and must be recorded in the participant's study case report forms (CRFs); (2) monitored and tracked from the time of the first treatment.
At each contact with the participant, the investigator must seek information on AEs/ADEs/SADEs by specific questioning and, as appropriate, by examination. AEs/ADEs/SADEs may be observed by the investigator and/or clinical research staff, elicited from the participant and/or family member or volunteered by the participant. All observed and volunteered adverse signs and symptoms, anticipated or unanticipated, regardless of severity or frequency, will be recorded in the case histories (medical chart and CRFs). Included in the descriptions should be the nature of the sign or symptom, the date of

onset, date of resolution (duration), the severity, anticipated or unanticipated, the relationship to study treatment or other therapy, the action taken (if any), and the outcome.

All SAEs/SADEs, anticipated or unanticipated, must be reported to Cognoa immediately but not later than 5 working days. The SADE must be recorded in: (1) the CRF and (2) a written report must be submitted to Cognoa within five (5) working days after the. Investigator first learns of the event and is to include a full description of the event and sequelae, in the format detailed by the Cognoa Serious Adverse Event Form.

8.3 Follow-up of participants after AEs

All reported AEs/ADEs/SAEs/SADEs should be followed until resolution or until the participant's participation in the study ends. Resolutions of AEs/ADEs/SAEs/SADEs are to be documented on the appropriate CRFs. All ADEs that result in permanent discontinuation from this clinical trial, whether serious or not, should also be reported on the participant Non-Completion of Study Form.

9 Potential Risks/Benefits

9.1 Potential Risks

Risks related to the study are expected to be minimal.

Physical risks for participating in the study are expected to be minimal. Children may experience some fatigue holding the device during intervention sessions. Children may also experience some irritation and frustration while using the device.

Caregivers/parents may feel some emotional discomfort from being asked or answering questions about their child's behavior.

Another potential risk is the possible release of sensitive medical, behavioral, or educational information. To mitigate the risk of releasing sensitive personal information, we adhere to confidentiality protocols to protect the privacy of personal information. When data is published, it is always anonymous and in a manner so that specific families or subjects cannot be identified.

9.2 Potential Benefits

The subjects may or may not benefit from being enrolled in the study.

10 Study Management and Administrative Considerations

10.1 Informed Consent

The investigator or the investor's designee will inform all subjects regarding the purpose of the study and expected duration, as well as any potential risks and benefits that may result from participation. The subjects shall be informed by the investigator or investor's designee that they are free to refuse participation in this clinical study. If they elect to participate, it will be made clear that they may withdraw from the study at any time without prejudicing further care.

The caregivers of the child will be given access to the informed consent form via email. The objective of the informed consent form is to ensure that they understand the purpose of the study, the risks and benefits of participating and the voluntary nature of their participation.

10.2 Participant Confidentiality

This study preserves the confidentiality of all subjects. The following safeguards will be in place to protect the privacy of the individuals who are the subjects of the health information to be used in the research and the confidentiality of that information:

The subjects will be informed by the investigator or the investigator's designee that their records will be kept as confidential as possible but may be subject to review by: (1) Cognoa, or its representative; (2) reviewing IRB; and/or (3) by appropriate regulatory bodies (e.g. the US Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies).

Only personal information required for the study will be collected. This will include information related to the eligibility for participation (see inclusion/exclusion criteria). Personal information will be collected and used to ensure subject eligibility for study participation, to conduct the study and to assess the results of the study as required and permitted by law. Subjects have the right to see and copy any of the information gathered about them and request changes if the information is not correct, until it is no longer kept by the investigator. Permission to use or disclose personal information, except for data that have been collected and relied on may be cancelled by the subject by written notice. If the subject withdraws from the study, the information collected to that time may still be used to preserve the scientific integrity of the study. There is no expiration date to this authorization.

Subjects' identities will be kept confidential. Subjects will be assigned a unique study code that will not reveal the subjects' identity, and this code will be used on all study records.

10.3 Financial Considerations

Subject Compensation:

The subject's caregiver will be compensated up to $200 for their participation.

$100 for completion of the baseline assessment and $100 at the conclusion of the study following the final assessment and completion of the 4 weeks of device use 4-6 times a week.

10.4 Study Discontinuation

Cognoa, Inc. (the sponsor) has the right to terminate this study at any time. Reasons for terminating the study may include, but are not limited to, the following: subject enrollment is unsatisfactory; number of protocol deviations is unacceptable; data is inaccurate or incomplete; questionable site compliance with Good Clinical Practice; or incidences of adverse events in this or other studies indicating a potential health hazard to subjects.

References

American Psychiatric Association. (2013). DSM-V (Diagnostic and Statistical Manual of Mental Disorders, 5th edition). In American Journal of Psychiatry.

Bauminger, N., & Kasari, C. (1999). Brief report: theory of mind in high-functioning children with autism. Journal of Autism and Developmental Disorders, 29(1), 81–86. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/10097997

Choueiri, R. N., & Zimmerman, A. W. (2017, February 1). New Assessments and Treatments in ASD. Current Treatment Options in Neurology, Vol. 19, p. 6. https://doi.org/10.1007/s11940-017-0443-8

Dumas, J. E., Wolf, L. C., Fisman, S. N., & Culligan, A. (1991). Parenting Stress, Child Behavior Problems, and Dysphoria in Parents of Children with Autism, Down Syndrome, Behavior Disorders, and Normal Development. Exceptionality. https://doi.org/10.1080/09362839109524770

Hastings R, Symes M. Early intensive behavioural intervention for children with autism: Parental therapeutic

self-efficacy. Research in Developmental Disabilities. 2002; 23:332–341. [PubMed: 12401484]

Hayes, S. A., & Watson, S. L. (2013). The impact of parenting stress: A meta-analysis of studies comparing the experience of parenting stress in parents of children with and without autism spectrum disorder. Journal of Autism and Developmental Disorders. https://doi.org/10.1007/s10803-012-1604-y

Hedley, D., & Uljarević, M. (2018). Systematic Review of Suicide in Autism Spectrum Disorder: Current Trends and Implications. Current Developmental Disorders Reports, 5(1), 65–76. https://doi.org/10.1007/s40474-018-0133-6

Javaheri, K. R., & McLennan, J. D. (2019). Adherence to Antipsychotic Adverse Effect Monitoring Among a Referred Sample of Children with Intellectual Disabilities. Journal of Child and Adolescent Psychopharmacology. https://doi.org/10.1089/cap.2018.0167

Ji, N. Y., Findling, R. L., Young, N., & Findling, R. L. (2015). An update on pharmacotherapy for autism spectrum disorder in children and adolescents. Current Opinion in Psychiatry. https://doi.org/10.1097/YCO.0000000000000132

Koegel RL, Bimbela A, Schreibman L. Collateral effects of parent training on family interactions. Journal of Autism and Developmental Disorders. 1996a; 26:347–359. [PubMed: 8792265]

Landa, R. J., Holman, K. C., O'Neill, A. H., & Stuart, E. A. (2011). Intervention targeting development of socially synchronous engagement in toddlers with autism spectrum disorder: A randomized controlled trial. Journal of Child Psychology and Psychiatry and Allied Disciplines. https://doi.org/10.1111/j.1469-7610.2010.02288.x

Lerman, D. C., Vorndran, C., Addison, L., & Kuhn, S. A. C. (2004). A RAPID ASSESSMENT OF SKILLS IN YOUNG CHILDREN WITH AUTISM. Journal of Applied Behavior Analysis, 37(1), 11–26. https://doi.org/doi:10.1901/jaba.2004.37-11

Leyfer, O. T., Folstein, S. E., Bacalman, S., Davis, N. O., Dinh, E., Morgan, J., … Lainhart, J.
E. (2006). Comorbid Psychiatric Disorders in Children with Autism: Interview Development and Rates of Disorders. Journal of Autism and Developmental Disorders, 36(7), 849–861. https://doi.org/10.1007/s10803-006-0123-0

Lovaas, O. I. (1987). Behavioral treatment and normal educational and intellectual functioning in young autistic children. Journal of Consulting and Clinical Psychology.

Lovaas, O. I. (2003). Teaching individuals with developmental delays: Basic intervention techniques. In Teaching individuals with developmental delays: Basic intervention techniques.

Mazurek, M. O., Handen, B. L., Wodka, E. L., Nowinski, L., Butter, E., & Engelhardt, C. R. (2014). Age at first autism spectrum disorder diagnosis: The role of birth cohort, demographic factors, and clinical features. Journal of Developmental and Behavioral Pediatrics. https://doi.org/10.1097/DBP.0000000000000097

Moes, D. Parent education and parenting stress. In: Koegel, RL.; Koegel, LK., editors. Teaching children with autism: Strategies for initiating positive interactions and improving learning opportunities. Baltimore, MD: Paul H. Brookes; 1995. p. 79-93.

Orsmond, G. I., Krauss, M. W., & Seltzer, M. M. (2004). Peer relationships and social and recreational activities among adolescents and adults with autism. Journal of Autism and Developmental Disorders.

Preti, A., Melis, M., Siddi, S., Vellante, M., Doneddu, G., & Fadda, R. (2014). Oxytocin and autism: a systematic review of randomized controlled trials. Journal of Child and Adolescent Psychopharmacology, 24(2), 54–68. https://doi.org/10.1089/cap.2013.0040

Zuckerman, K. E., Friedman, N. D. B., Chavez, A. E., Shui, A. M., & Kuhlthau, K. A. (2017). Parent-Reported Severity and Health/Educational Services Use Among US Children with Autism: Results from a National Survey. Journal of Developmental and Behavioral Pediatrics : JDBP, 38(4), 260–268. https://doi.org/10.1097/DBP.0000000000000437