Video Article

A Familiarization Protocol Facilitates the Participation of Children with ASD in Electrophysiological Research

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URL: https://www.jove.com/video/55941
DOI: doi:10.3791/55941

Keywords: Neuroscience, Issue 125, Autism, developmental disorders, research, EEG data collection, visual schedule, social narrative.

Date Published: 7/31/2017

Citation: Turcios, J., Cook, B., Irwin, J., Rispoli, T., Landi, N. A Familiarization Protocol Facilitates the Participation of Children with ASD in Electrophysiological Research. *J. Vis. Exp.* (125), e55941, doi:10.3791/55941 (2017).

Abstract

This paper includes a detailed description of a familiarization protocol, which is used as an integral component of a larger research protocol to collect electroencephalography (EEG) data and Event-Related Potentials (ERPs). At present, the systems available for the collection of high-quality EEG/ERP data make significant demands on children with developmental disabilities, such as those with an Autism Spectrum Disorder (ASD). Children with ASD may have difficulty adapting to novel situations, tolerating uncomfortable sensory stimuli, and sitting quietly. This familiarization protocol uses Evidence-Based Practices (EBPs) to increase research participants' knowledge and understanding of the specific activities and steps of the research protocol. The tools in this familiarization protocol are a social narrative, a visual schedule, the Premack principle, role-playing, and modeling. The goal of this familiarization protocol is to increase understanding and agency and to potentially reduce anxiety for child participants, resulting in a greater likelihood of the successful completion of the research protocol for the collection of EEG/ERP data.

Video Link

The video component of this article can be found at https://www.jove.com/video/55941/

Introduction

Autism spectrum disorders (ASDs) are neurodevelopmental disorders characterized by a constellation of social communicative difficulties and restricted, repetitive patterns of behavior[1,2]. As the number of identified individuals who meet the criteria for ASD increases, so does the desire to better understand the neurological underpinnings associated with ASD. Experts have suggested that future research should include the development of processes for the early detection of atypical brain function, which may then lead to interventions to support the brain systems hypothesized to impact social behavior[14]. In particular, this research uses temporally sensitive neuroimaging approaches- namely, electroencephalography (EEG) and Event-Related Potentials (ERPs)- to assess Audio-Visual (AV) speech perception in children with typical development and those at-risk for ASD and other developmental disabilities. The use of electrophysiology techniques, both EEG and ERP, will provide a better understanding of the neural bases for both typical and atypical AV speech perception across development. This research approach includes the analysis of both continuous EEG data and ERPs. Because ERPs are time-locked, multi-trial-averaged portions of the EEG, this paper will discuss procedures for the collection of EEG data.

To ensure that this work is as representative of the population as possible, individuals with ASD who present with varying degrees of social, cognitive, and language ability are included as participants. At present, the systems available for the collection of high-quality EEG data make significant demands on children with developmental disabilities. Examples of behaviors that individuals with ASD may have difficulty with include adapting to novel situations, tolerating uncomfortable sensory stimuli (*i.e.* wearing an EEG cap), and sitting quietly. These difficulties may be linked to the individual's sensory processing challenges, his/her disconnect in social perspective-taking, potential cognitive difficulties, and insistence on sameness. Collectively, these characteristics may impact a child's ability to comply with the required tasks that comprise the research activity[1]. Therefore, it is important to develop research protocols that support the children's strengths and accommodate their limitations to facilitate the participation of children with ASD. The goal is to assist children with ASD in completing research activities, without duress and in a manner that leads to useable neurobiological data.

The current work is part of a larger study on eye gaze and neural response to audiovisual speech in children with language and social disabilities, including children with ASD[11,12]. The primary experimental protocol involves multiple behavioral assessment sessions, as well as

one simulated and one real EEG data collection session. Details of the EEG and ERP processing and analysis will not be discussed here; see Harwood *et al.*[9] for the ERP data processing protocols.

The focus of this paper is a familiarization protocol designed to address the challenges of getting children (particularly those with developmental disabilities such as ASD) to engage in neurobiological research. As in many research studies of this type, participants must complete a variety of standardized assessment tasks in addition to participating in EEG data collection. Due to the challenges that individuals with ASD face when coping with novel environments, tolerating uncomfortable sensory stimuli, and sitting still for extended periods of time, strategies must be developed to increase participant understanding of the research activities. Increased understanding and agency will increase the participant's ability to successfully complete all research activities. Importantly, this protocol provides multiple opportunities for each participant to make an active decision regarding his/her participation, with a clear ability to opt out and, by monitoring the emotional state throughout the experiment, continuing consent is ensured[4].

The National Professional Development Center on Autism and the National Autism Center are two organizations that have developed clear criteria for the establishment of evidence-based practices for individuals with ASD[16,22]. The protocol for the current research project used these criteria to identify, select, develop, and implement specific interventions that are applicable to addressing the challenges individuals may face in successfully participating in the research activities. The specific interventions from these sources include social narratives, visual supports in the form of a visual schedule, role-playing, and modeling[22]. In addition, the protocol includes an application of the Premack principle[18]. The Premack principle involves following a low-preference activity with a high-preference activity[13,18], providing a short, clear connection between the expected behaviors of the individual to the reward. For example, if a child answers questions for 10 min, he/she is then able to play with a preferred toy for 10 min.

Prior research suggests that social narratives are an effective intervention for children with ASD who exhibit disruptive behaviors[19]. Social narratives provide background and information about the context of a situation as a means of providing increased understanding related to social expectations. Most social narratives include expected activities, possible perspectives of others involved, and ways to interact with other people during structured activities (see **Figure 1** for an example of the social narrative used here). Social narratives have been shown to reduce anxiety and support an individual with expectations in the new situation[15].

A visual schedule can be effective in helping children with ASD to cope in novel social situations[20]. Visual supports in the frame of a schedule provide individuals with ASD a static reference to aid in predicting upcoming activities (see **Figure 2** for an example of the visual schedule used here). In addition, the removal of activities as they occur supports an understanding of the passage of time and provides a concrete visual representation of the session. Without this visual representation, individuals with ASD may become anxious if they are unable to conceptualize how much time has passed and how much time is left in an activity or session. A visual support that allows the participant to express his or her emotions may also be useful in allowing the participant to more easily cope with different emotions (see **Figure 3** for an example of an emotion-rating scale).

Role-playing and modeling provide an opportunity to view and practice new situations for individuals with ASD. The process of rehearsal provides clarity about the expected behaviors and further reduces anxiety for these novel scenarios[8,22]. Role-playing, including modeling, provides the individual with a clear opportunity to practice and make a decision regarding his/her choice of participating or opting out of a particular activity (see **Figures 5** & **6** for examples of role play and modeling with a toy bear and the child wearing the cap).

Some individuals with ASD and/or other developmental disabilities may not have developed the maturity or cognitive capability to clearly understand research tasks. Indeed, there is an ethical dilemma surrounding the participation of vulnerable groups due to their difficulties with comprehension in complex social situations and the impact this has on informed consent[17]. However, processes have been developed to better ensure informed consent without undue pressure[4,17]. For example, visual symbols and bullet points with simple explanations are provided here, and participants are asked if they agree to participate in the study as an ongoing process[3]. To facilitate the understanding of individuals with developmental disabilities, a protocol must be developed that both aligns with study goals yet adheres to ethical guidelines, including the subject choosing to participate without persuasion or undo pressure[6].

Protocol

All procedures have been approved by the appropriate research ethics committee at Southern Connecticut State University and Yale University, with consent from participants.

1. Create a Social Narrative

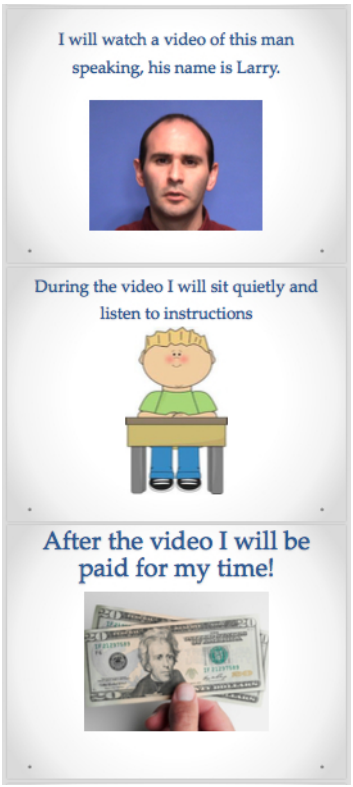

Figure 1. Social Narrative. A sample social narrative, read to the participant prior to the first appointment and by the researcher prior to initiating the experiment and obtaining consent.

Note: Sections 1, 2, and 3 present the tools that were developed for the familiarization protocol.

1. Create a social narrative that includes images and a short description of each step of the research protocol created by the researchers, starting with consent and ending with compensation (if applicable) and a short explanation.
   NOTE: When possible, the image used should have high iconicity (iconicity refers to the degree to which a symbol represents its referent)[3] to facilitate the understanding of the participant. Follow the steps for developing the social narrative (adapted from Myles, Trautman, and Schelvan)[15].
   1. In the social narrative, describe in sequential order the research activities from the participant's perspective. Write the story in first-person or second-person language and use either present or future tense.
      1. In the description, include: a) where the activity will occur; b) what the participant will do; c) what the researchers will do; d) why the participant will complete each activity; and e) the possible thoughts or feelings of the researchers or the parents, if applicable (*i.e.* "we're happy that you came;" "calm when you wait for directions;" or "Mom is happy that you can help.")
   2. Select pictures that are iconic to use within the social narrative to increase the understanding of the participant (*i.e.,* the building, the room, the EEG cap, and the researchers).
   3. Place the social narrative into a presentation software (*e.g.,* PowerPoint), including the iconic pictures. Use the presentation mode to show the narrative to the child as a story on a computer, or present it as a printed version.

2. Send the social narrative to the parent/caregiver by mail or email before the participant comes to the research appointment.
   1. Ask the parent or guardian to read the social narrative to the participant at least 3 times before the first visit of the research study.

2. Create a Visual Schedule

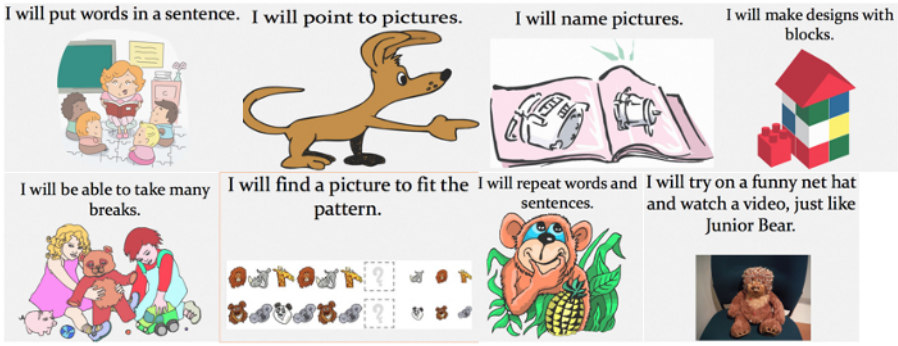

Figure 2. Visual Schedule. A sample visual schedule, presented to the participant after obtaining consent and before initiating the first step of the experiment, as well as before and after the completion of each activity.

1. Create a visual schedule that outlines each activity of the research protocol. Ensure that the visual schedule includes different cards, with pictures that represent each activity and a one- to three-word description printed under each picture (adapted from Hodgdon)[10].
    1. Within the visual schedule, include a card with a picture that represents a break, along with the written description, "Take a break."
    2. Within the visual schedule, include a card with a picture that refers to being finished or all done; this card may include the word "stop" or "finish" printed in red font.
    NOTE: The activities outlined in the visual schedule should be the same as those described in the social narrative. The written language and pictorial representations provided through these two tools should be consistent.

3. Create Emotion-rating Scales

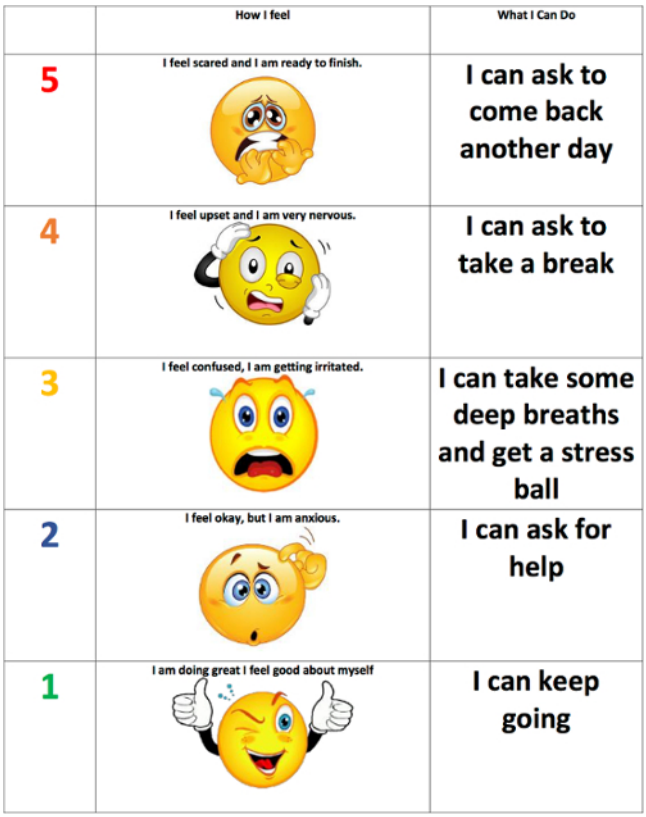

Figure 3. Self-rating Emotion Scale. A sample self-rating emotion scale, which is used by the participant to rate his/her state of emotion. The researcher uses a separate scale to rate the participant's emotion. Please click here to view a larger version of this figure.

Listening to Faces
Circle the Location: SCSU or Haskins
Participant Number: _____

Pre-Research Activities
Participant Appears:

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
Interested					
Distressed					
Excited					
Upset					
Scared					
Enthusiastic					
Proud					
Irritable					
Alert					
Nervous					
Attentive					
Jittery					
Active					
Afraid					

Participant Self Rating on the 5-Point Scale _____

Post-Social Narrative
Participant appears:

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
Interested					
Distressed					
Excited					
Upset					
Scared					
Enthusiastic					
Proud					
Irritable					
Alert					
Nervous					
Attentive					
Jittery					
Active					
Afraid					

Participant Self Rating on the 5-Point Scale _____

Figure 4. Researcher's Rating Scale. A scale used to make sure that the participant's rating is consistent with outward observed behavior. This scale is to be completed by a researcher that is in the room with the child participant. Please click here to view a larger version of this figure.

1. Create a scale that depicts a range of 5 emotions, with pictorial representations and/or written words. Select emotions that are relevant to supporting the participant with engaging in the activities in the given research protocol (*i.e.* emotions related to anxiety, pleasure, disgust, *etc.*).
   NOTE: The emotion vocabulary and selected icons should match the developmental levels of the participant (adapted from Dunn-Buron and Curtis)[7].
   1. Include an action that the participant may complete to maintain positive emotion in one column and label it "What I can do" (see **Figure 3**).
   2. Include a smiley or picture of a face in a separate column and label it "How I feel."
      NOTE: All five emotions listed under the "How I feel" column should correspond with the "What I can do" column (*i.e.*, on the "How I feel" column, "I am confused and getting irritated" would correspond with "Ask to take a break" under "What I can do.")

2. Create a Likert-type scale for rating emotions to be used by the researcher (see **Figure 4**) (adapted from the Positive and Negative Affect Schedule (PANAS)[21].
   NOTE: Below are the steps to follow when implementing the familiarization tools over two visits to complete the research protocol.

4. Visit 1: Social, Cognitive, and Language Assessments

1. Greet the participants and bring them to an area with various toys (see **Figure 5**) in a designated "play area." Ensure that the participant is comfortable within the setting.

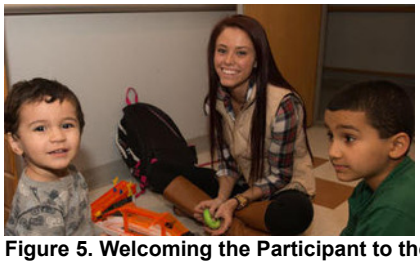

Figure 5. Welcoming the Participant to the Visit. Researcher playing with participants, familiarizing them to the environment and getting them accustomed to the context.

2. Show the participant the 5-point emotion-rating scale (see **Figure 3**) and ask them to point to the picture that best represents how they feel.
3. Ask the participant how they feel and support the participant in saying "I feel _____," while pointing to the corresponding emotion on the scale (see **Figure 3**).
    1. If the participant selects a 1 or 2, move to step 4.4. If the participant selects a 3 or 4, ask the participant to follow the suggested action under the "What I can do" section (see **Figure 3**).
    2. Give the participant 5 min to follow the suggested action.
    3. After 5 min, ask the participant rate how they feel, again. If they select 1-3, continue the session. If they select 4 or 5, end the research appointment and ask the participant to decide to come back on a different day or not to come back at all.
    NOTE: See step 3 for creating the emotion-rating scale. The researcher is to rate the participant's emotions on a separate scale at the same time (**Figure 4**) to ensure that the participant is appropriately rating their emotion state.

4. Sit next to the participant and read and review the social narrative with them (see **Figure 1**). Say "we will look over all the games that we will be playing today; ask me questions if there is a game that you are not sure of."
5. Following the review of the social narrative, assess the participant's emotional state and readiness to continue with the research by asking, "How do you feel?" while showing them the self-rating emotion scale (**Figure 3**).
    1. At the same time, ask the research assistant to use a separate scale to rate the participant (see **Figure 4**) to ensure that some of the anxiety (if any) has been reduced.

6. Hand a consent form to the parent and read the assent form with the child participant (if they cannot read it independently).
7. Ask the participant if they would like to continue and complete the activities described in the social narrative.
8. Ask the participant to sign the consent form.
NOTE: The participant should only be asked to sign if they agree to participate. If the participant says no, offer to read the social narrative again to ensure that the participant understands the requests being made.
9. Introduce the participant to the visual schedule, stating, "These (pointing to visual schedule pictures) are all of the games that we will be playing today. At the end of each game, you can take down the card for that game."
    1. Point to the "Take a Break" card and say, "You can also use this card if you need to take a break;" point to the "STOP" card and say "or this card if you do not want to play any more games for today."

10. Arrange the schedule so that all social, cognitive, and language assessments are completed prior to the final activity.
    1. Periodically, at the discretion of the researcher and based upon the attending behavior of the participant, implement a modified use of the Premack principle by stating, "Remember, first (activity name), then you may take a break."
    NOTE: This modified version of the Premack principle involved giving the child the preferred activity after the third attempt, even if the child did not complete the less preferred activity. Therefore, the participant is compensated for their time even when they do not complete the experiment.

11. Once the participant has completed half of the assessments, evaluate the participant's emotions using both emotion-rating scales (as described in step 4.5); ensure that the participant maintains a level 1 or 2 emotion rating prior to continuing activities.
    1. If the participant is at a higher level on the self-rating emotion scale, follow the action on the scale under the "What I can do" section.

Figure 6. Bear used as Sample for Wearing the Cap. Demonstration of the bear wearing the cap, allowing the participant to explore wearing the cap and holding the bear while it wears the cap, done before the participant is asked to wear the cap.

12. EEG data acquisition simulation.
    1. Introduce the participant to a stuffed bear (or doll, or any other toy of choice), and model the use of the EEG cap (see **Figure 6**) on it. Read to the participant, the section in the social narrative that describes use of the cap to the participant.
    2. Show the participant how the cap is placed on the bear's head. Allow the participant to touch the cap and interact with it by placing it on the bear's head (if needed).

3. Apply a modified version of the Premack principle by saying, "First, try the cap. Then, you will be given a gift card." If the participant says no, suggest the "First, then" statement one more time. If the participant says yes, continue to step 4.12.4.
    1. If the participant continues to say no, compensate the participant for their time (if applicable). If the participant agrees to wear the cap, continue to step 4.12.4.

4. With a tape measure, measure the participant's head circumference to determine the cap size. After this initial measurement, measure from a location on the back of the skull (inion) to a location between the eyebrows above the nose (nasion), and from the right to left ear (using the tragus).
   NOTE: This is done to identify the scalp vertex reference point for the placement of the Cz electrode. These steps are designed to be as similar to the actual acquisition protocol, which uses this procedure to maximize similarity of electrode placement across the scalp across participants.
    1. Mark the vertex reference point with a washable magic marker.
    2. Soak the appropriate-size cap in water with a potassium chloride solution and baby shampoo.

5. Place a towel around the participant's neck to prevent water from dripping on their clothing. Tell the participant to close their eyes while the cap is being placed on their head.
6. Adjust the cap on the participants' head so that it is comfortable for the participant (see **Figure 7**). Once the cap is placed on the head and adjusted, let the participant known that they can open their eyes.
7. Have the participant practice wearing the cap and sit in front of a screen to watch a movie for at least 10 min (see **Figure 8**). If this step is completed successfully, invite the participant to come back for a second appointment.
   NOTE: Participants had to wear the cap for approximately one hour during the actual research appointment. However, breaks were built into the experiment every 3 minutes.

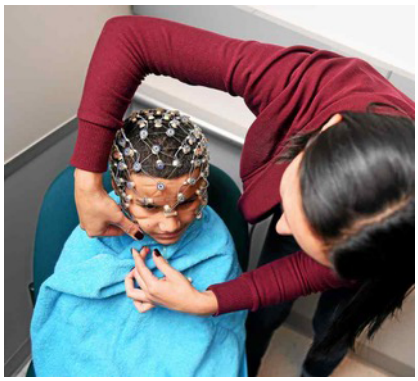

Figure 7. Placing the EEG Cap on the Participant. The researcher capping the participant to practice wearing the cap; this is the role-play portion of the protocol, when the participant wears the towel.

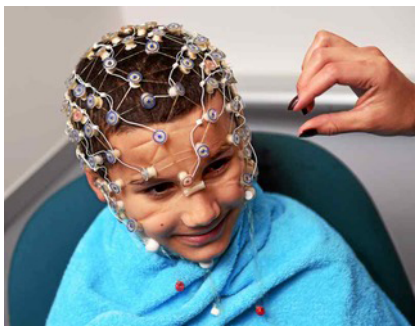

Figure 8. Adjustment of the EEG Cap. The participant is wearing the cap while the researcher adjusts it to make sure that the participant is comfortable.

13. Following the final activity, assess the participant's emotions one last time (**Figures 3** & **4**) to ensure that level-1 or -2 emotion has been maintained throughout the protocol and that wearing the cap did not increase anxiety and/or decrease the participant's level of comfort.
    NOTE: If any anxiety is present, the researcher should assist the child in following the suggested actions in the self-rating emotion scale (**Figure 3**).

5. Visit 2: EEG Data Collection

Note: As an integral part of the familiarization protocol, throughout the span of the experiment, a research assistant should code the participant's state (*i.e.* whether they alert or appears anxious; see **Figure 4**), and participants should provide a self-rating of their emotional state by pointing to a visual representation on an emotion scale (**Figure 3**).

1. Present the participant with a social narrative that describes the steps of the second appointment. Ask the participant if they are willing to wear the cap and mention, "like you did last time;" (see step 1.1.1 for creating the social narrative).

NOTE: If the participant says yes, proceed to step 5.2. If the participant says no, repeat step 5.1 with the parent in the room. If the participant continues to say no, end the experiment.

2. Present the participant with a visual schedule that includes all the EEG data collection procedures (*i.e.,* measuring the head, wearing a towel, and placing the cap on the head).
   NOTE: See step 2.1 for creating a visual schedule; a picture depicting a break is included. Periodically offer the participant the opportunity to take a break to maintain comfort and compliance.
   1. Measure the participant's head circumference and then identify and mark the vertex reference point for the Cz electrode, following the steps outlined in step 4.12, above.
      1. Mark the vertex reference point with a washable magic marker.
      2. Soak the cap in water with a potassium chloride solution and baby shampoo.
   2. Place a towel around the participant's neck to avoid water from dripping on their clothing. Tell the participant to close their eyes while the cap is being placed on their head.
   3. Position the appropriate-size cap on the participant and ask them to sit in a comfortable position.
   4. Once the ERP waves can be seen on a computer screen, ask the participant to blink and move their hands and feet. Then, have the child look at the distortion that is created in the ERP waves when they move.
3. Start the stimulus presentation and ask that the participant sit very still, "like a statue;" point to a visual sign that shows a child sitting still, along with the text, "sit still, like a statue." Use the Premack principle as needed.
   NOTE: See step 4.9 for the use of the Premack principle.
4. After completing the EEG portion of the experiment, provide the participant with the promised compensation and thank them for their participation.

Representative Results

As part of a series of studies on eye gaze and audiovisual speech perception, an initial cohort of 25 participants with ASD and average IQs (n = 25, 19 boys, 6 girls, mean age = 10.25 years) was recruited using a similar EEG protocol (**Figure 9**). 72% of the children in this previous cohort completed the EEG protocol. In the current cohort, thus far 15 participants with ASD were recruited (n = 15, 11 boys, 4 girls, mean age = 9.4 years), 12 of whom participated in the familiarization protocol. Of the 12 that completed the familiarization protocol, 100% completed the full EEG acquisition protocol (**Figure 9**).

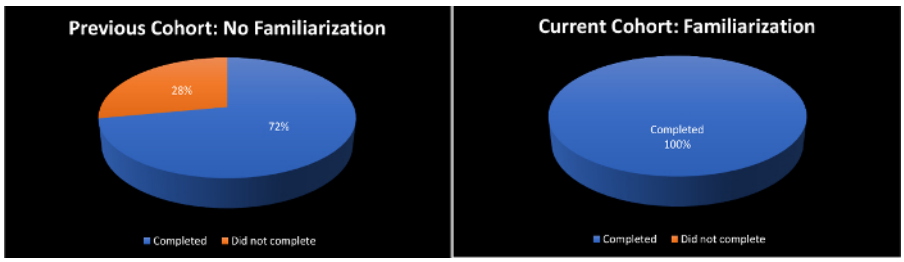

Figure 9. Completion of EEG. Representation of the number of participants that completed the experiment, with and without the use of the familiarization protocol. Please click here to view a larger version of this figure.

Discussion

The familiarization protocol outlined above applies EBPs to increase the likelihood that child participants with ASD will be able to complete multiple testing sessions and EEG data collection. Prior to the implementation of the steps in this familiarization process, participants were unable to complete all components of the EEG research acquisition protocol. Preliminary data from this study show that all participants who engage in the familiarization protocol were able to complete the full EEG data collection.

The critical steps that were implemented include the provision of a social narrative and visual schedule, the use of the Premack principle (reinforcement) and modeling/role playing, and the desensitization to the EEG cap. Social narrative and the visual schedule make the protocol expectations and steps clear to the child, from the beginning of study enrollment to the completion of the study. Reinforcement helps the child persist through the tasks and provides a sense of mastery. Role playing and desensitization allow the child to try out unfamiliar equipment and novel sensory experiences. Finally, through the use of emotion-rating measures, the researcher ensures ongoing consent while engaging child participants in assessments and challenging experimental tasks.

Given the tools used for this protocol, a number of modifications can be made to accommodate for the varied backgrounds of the participants, relating to chronological age, mental age, and level of communicative competence. To account for a wide range of emotions that may be experienced during the research protocol, investigators may utilize the researcher rating scale to adapt the self-rating scale used by the participant. The language of the social narrative and the language of the visual schedule should align with the desired research schedule and match the cognitive and/or chronological level of the participants. Changes to these tools can include adding higher-level vocabulary for older participants or images with higher iconicity for younger participants. The activities outlined in either the visual schedule or social narrative can be changed, if necessary. For example, if participants are required to sit still for long periods of time, practicing sitting still, in the form of a game, may be beneficial. The protocol can also be modified to include a toy reward at some point in the experiment, as young children may find this more rewarding than money. Lastly, parents can be asked to bring a preferred toy of the child, to be used as a reward and to apply the Premack principle. However, when using a preferred toy, researchers must be cautious that the toy does not become a distraction during the experiment.

A potential limitation of the familiarization protocol is that it is constrained by the understanding of the language embedded in the procedure, which may limit its use for individuals with very poor receptive language skills. The quality of implementation of the described tools (*i.e.* social narratives) can impact the accuracy or fidelity of the familiarization protocol. Finally, this paradigm uses a soft-sponge electrode cap, which is designed to be child-friendly; as such, the results of 100% participation after familiarization may not generalize fully to protocols that use gel-based EEG data collection systems, which require scalp abrasion, or other data collection methods that entail greater physical or emotional discomfort.

While children with ASD are highlighted here as the population of study in this project, these principles can be used with young children in general, including those with other developmental disabilities, as well as those with typical development. Furthermore, although this procedure was designed for combined behavioral and EEG data collection, it could be easily adapted for use in other experimental protocols that have multiple visits and methodologies and that require participants to adapt to different contexts. For example, social narratives, visual schedules, and emotion-rating scales could be included, along with mock scanning sessions, in combined behavioral and MRI protocols. Furthermore, these elements, in addition to the cap familiarization procedure, could be augmented to allow for familiarization with Near-Infrared Spectroscopy (NIRS) probe placement.

Disclosures

The authors have no disclosures to report.

Acknowledgements

The work was supported by NIH grants R15DC013864 and R21DC011342 (J. Irwin, PI). The parents and individuals that appear in the pictures gave permission for all pictures shown here to be used for publication purposes.

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