University of California, Los Angeles

PARENT CONSENT TO PARTICIPATE IN RESEARCH

Promoting Early Intervention Timing and Attention to Language (PETAL)

Connie Kasari, Ph.D. from the Graduate School of Education at the University of California, Los Angeles (UCLA) is conducting a research study. This research is sponsored by the National Institute of Health.

You were selected as a possible participant in this study because your child is 6-8 months of age and has an older sibling with autism.

Why is this study being conducted?

The proposed study (PETAL: Promoting Early intervention Timing and Attention to Language) aims to determine the timing of a parent mediated intervention among infants with Increased Likelihood for Autism (ILA) (at risk for autism by virtue of having an older sibling with autism) on communication and language outcomes at 24 months.

What will happen if I take part in this research study?

If you volunteer to participate in this study, the researcher will ask you to participate in the following:

Entry assessments which will include:
Filling out questionnaires about your demographics and your child's treatments and services they receive if any.
Assessments on expressive language, gestures, and child engagement will also be administered.
Your child will also be asked to wear a vest for an assessment called LENA for an entire day. This vest records the child's language environment. You will have the option to turn it off when you need privacy.
EEG that will monitor child's dysregulations.

The testing session will take *approximately 2 hours.*

Intervention which includes:
Phase 1 begins at age 6-8 months; after baseline demographic, language, behavior and brain assessments, all children are offered the MONITOR intervention. Phase 2 begins at age 9 months; after language, behavior and brain assessments, all children are randomly assigned to transition to MONITOR plus COACH (with probability 1/3) versus continue with MONITOR (with probability 2/3). Phase 3 begins at age 12 months; following language, behavior, and brain assessments, children who have not yet transitioned to MONITOR plus COACH are randomly assigned (with equal probability) to transition to MONITOR plus COACH versus continue with MONITOR. Phase 4 begins at age 15 months; following language and behavior assessments, all remaining children will transition to MONITOR plus COACH.

The MONITOR condition will provide parents with information to track the early development of their infants, along with specific developmentally targeted activities. The well validated Ages and Stages-3+ screening tool along with activity cards will provide information to parents at each age.

All parents will receive these materials at 3-month intervals, along with a developmentally chosen toy and book for their infant. The MONITOR intervention continues for all infants and parents throughout the study period even after receiving COACH intervention.
The COACH condition consists of a blended intervention of two evidence tested interventions, JASPER and Babble Bootcamp Infant-parent dyads will be randomized to receive COACH (JASPER Babble) at 9, 12 or 15 months. JASPER Babble addresses early parent-child social communication by helping to close the 'feedback loop'. When parents talk and play with their infant, the infant increases their developmental behaviors which serve to provide more opportunities for parents to respond. For infant-parent dyads randomized to COACH, we will set up once weekly remote (zoom) 1-hour coaching sessions in between assessment visits each 3 months. Similar to the ASQ-3+ monitoring intervention, parents will have access to the intervention team on as needed basis throughout the study if they request more input, and we will track this contact. Once randomized to COACH, parents will continue to receive the remotely delivered intervention throughout the study period.

Additional assessments at 9 months, 12 months, 15 months, 18 months, and 24 months:
The testing sessions will take approximately 1-1.5 hours and include the following assessments:
Assessments on expressive language, gestures, and child engagement will be administered at all time points.
Your child will also be asked to wear a vest for an assessment called LENA for an entire day during these time points. This vest records the child's language environment. You will have the option to turn it off when you need privacy.
EEG that will monitor child's dysregulations (only at 9 months and 12 months).
ADOS-2 will be administered at the 24-month time point only. This is a diagnostic evaluation, but for research purposes only.

How long will I be in the research study?

Participation will include a total of about 16-18 months. Participants will be asked to do the intervention online (weekly meeting with the research team via Zoom). But for assessments, the research team can go to the participants' homes or come into the research lab at UCLA if preferred.

Are there any potential risks or discomforts that I can expect from this study?

There are no anticipated risks from this study, although it is possible that your child may react negatively to some of the assessment measures or intervention sessions. For example, at the most extreme, your child may be fearful of an age-appropriate toy and may cry or physically pull back from the toy. If this should occur, that particular toy presentation, assessment or intervention will be stopped.

Some children feel uncomfortable wearing the EEG net. If your child finds the cap uncomfortable and the examiners cannot make them more comfortable, the cap will be removed and the testing session will be stopped. This is an entirely non-invasive procedure. There is no risk of physical pain or harm.

Are there any potential benefits if I participate?

You may benefit from the intervention by receiving detailed information about your child's language and communication skills both before the intervention begins and after the intervention is completed.

The results of the research may also contribute to society by enhancing our knowledge of intervening on social communication. Further, benefits that you and your child may derive from the intervention may lead to greater benefits for all children that have siblings with autism.

You and your child may not benefit directly from allowing you or your child's information to be shared with National Database for Autism Research (NDAR). However, the information provided to NDAR might help researchers around the world treat future children and adults with autism spectrum disorders so that they have better outcomes. NDAR will report to Congress and on its website about the different studies that researchers are conducting using NDAR data; however, NDAR will not be able to contact you or your child individually about specific studies.

What other choices do I have if I choose not to participate?
If you choose not to participate in this study, you will not be penalized in any way or excluded from future research studies.

Will I be paid for participating?
You will receive $40 gift cards after completing assessments at six time points (entry, and child's 9, 12, 15, 18, and 24 months of age). A total of $240 in gift cards for the entire study.

Will information about me and my child be kept confidential?

The information about you is protected by a federal Certificate of Confidentiality. This means that we can't be forced to release information about you for any legal proceeding, even if a court of law asks.

The Certificate allows us to use information about you for purposes of this research or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect your information we share with them.

There are limits to this protection. The Certificate does not protect your information when:
-You or your family voluntarily release information about yourselves.
-You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).
-A federal agency audits or evaluates research that it funds.
-Researchers are required to report possible intent to harm yourself or others, child abuse and elder abuse.

Also, confidentiality will be maintained by removing all names from any records that are kept by the research staff, and all data files will be maintained in locked cabinets. Videotapes will not be destroyed; instead they will be stored confidentially.

As part of the study, your child will be videotaped during the intervention sessions. You and your child will be taped interacting together, and your child will also be taped interacting with the interventionist. Additionally, assessments that were previously mentioned will be videotaped for scoring purposes at a later date. You may review these videotapes at any time.

These videotapes will be used for teaching and/or research purposes only and your child's identity will not be disclosed. You have the right to refuse to have the tapes used for educational purposes. You have the right to review, edit, or erase the research tapes of your child's participation in the research study in whole or in part.

De-identified data from this study will be submitted to the NDAR. NDAR is a computer system run by the National Institutes of Health that allows researchers studying autism to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about autism more quickly than before.

During and after the study, the researchers will send information about you or your child's health and behavior and in some cases, you or your child's genetic information, to NDAR. However, before they send it to NDAR, they will remove information such as name, address, and phone number, and replace that information with a code number. Other researchers nationwide can then file an application with the National Institutes of Health to obtain access to your study data for research purposes. Experts at the National Institutes of Health who know how to protect health and science information will look at every request carefully to minimize risks to you and your child's privacy.

Also, you should understand that the investigator will take all needed steps to report any sexual or physical abuse of a child to authorities. If any member of the program staff has or is given such information he/she is required to report it to the authorities. The obligation to report includes alleged or reasonably suspected abuse as well as known abuse.

It is possible that other investigators conducting other research might request that data collected for this study be shared for further research. For example, investigators associated with the government agency supporting this study might make this request. Even if you agree that your data may be shared with other investigators, your name or other personal identifying information would not be revealed. Though your privacy is very important to us and we will use many safety measures to protect your privacy, it is possible that there may be unforeseen privacy risks. For example, although we will not put any personal identifying information about you in a shared database, someone in the future might find some way to link your medical information or other information collected for this study back to you even in the absence of your name or other personal identifying information. Alternatively, there could be violations to the security of the separate computer systems used to store the codes linking your information to you.

While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you.

For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative).

What are my rights if I take part in this study?

You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.

Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.

You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

The research team:
If you have any questions or concerns about the research, please feel free to contact Connie Kasari, Ph.D., Graduate School of Education, University of California, Los Angeles, 1029 Moore Hall, Los Angeles, California 90095, (310) 825-8342.

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, please call the OHRPP at (310) 825-7122 or write to:
UCLA Office of the Human Research Protection Program
10889 Wilshire Blvd, Suite 830 Los Angeles, CA 90095-1406.

You will be given a copy of this information to keep for your records.

SIGNATURE OF STUDY PARTICIPANT

_____
Name of Participant

_____
Name of Parent or Legal Guardian

_____ _____
Signature of Parent or Legal Guardian Date

You have the right to refuse to have photos and videotapes used for educational and research purposes.

_____ I agree to have photos and videotapes of my child and myself used for educational and research purposes.
_____ I do not want photos and videotapes of my child and myself used for educational and research purposes.

Participation in Ongoing or Future Research Studies
Could we contact you to ask you to participate in follow-up or associated research projects by email, mail or by phone? (Circle your response)

By mail?	YES	NO
Mailing Address:		
By phone?	YES	NO
Phone number:		
By email?	YES	NO
Email address:		

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date