Parent-Level Predictors of Early Language Interaction Quality and Intervention Outcomes (KOALA Study 2)

3/5/2024

NCT03525951

University of Wisconsin - Madison
Research Participant Information and Consent Form

Study Title: Parent-Level Predictors of Early Language Interaction Quality and Intervention Outcomes (KOALA Study 2)

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Dr. Alper's e-mail: rebecca.alper@waisman.wisc.edu

Study Description

We invite you to take part because you are the caregiver of a child between 16 to 20 months (about 1.5 years) or 2.5 to 4 years.
This study wants to see what promotes positive, caregiver-child interactions. We also want to learn how to use these interactions to help with language difficulties.
We will ask you to do language and learning tasks and might ask you to interact in new ways.
About 150 caregiver-child pairs will take part in this study.

- The comparison group will include up to 75 children between 16 to 20 months (about 1.5 years) with typical language skills and their caregivers.
- The training group will include up to 75 children between 2.5 to 4 years with language difficulties or delays and their caregivers.
- Some children in the training group may have autism spectrum disorder (ASD).

This research will be done remotely (by phone or Secure Zoom).

What will I be asked to do?

If you decide to take part in this study, we will ask you to complete two data collection sessions about 5 to 8 weeks apart.
Sessions are often divided into more than 1 part.
The training group will receive coaching sessions between the two data collection sessions (6 to 7 sessions total). Following the coaching session(s), the training group will have the option to complete a survey about their overall experience.
While unlikely, if a researcher believes that the study tasks are causing you or your child undue distress, the researcher may stop your participation with the PI's approval.
You may choose to stop participating at any point. The research team will keep any data collected before you decided to stop unless you tell us differently in writing.

- You may ask the research team to delete your data at any point.
- We may have already presented or published some of the findings depending on when you ask us to delete your data.

The total participation time for the comparison group will be around 6 to 8 hours across all sessions (about 3 to 4 sessions total).
The total participation time for the training group will be around 10 to 12 hours across all sessions (about 6 to 7 sessions total).

IRB Approval Date: 3/5/2024
University of Wisconsin – Madison

Recording Information

Video and audio recordings will be made of your participation. By taking part in this study, you agree to allow you and your child to be video and audio recorded. Unless you say differently, only approved research team members will have access to your recordings.

The data collected in this study will be stored for at least 7 years unless you say differently in writing.

Are there any risks to me?

This study has minimal risks.

You or your child might experience boredom, discomfort with being observed/recorded, schedule disruption, or loss of confidentiality or privacy.

We will schedule and adapt the sessions to try to meet your and your child's needs.

We do our study sessions and phone calls from a private room.

You and your child will be assigned a participant ID number to help protect your confidentiality.

We will store your identifiable data in locked cabinets or in HIPAA-compliant locations, only accessible to the research team.

Are there any benefits to me?

We cannot promise any benefits to you or others from your study participation.

The training is part of research, not clinical speech-language therapy. But possible benefits include better interactions with your child.

This research may also help others by building parent training and early intervention programs.

What if this research has other findings about me unrelated to the research questions?

Caregivers: We will not clinically interpret the results for you. Some study surveys relate to topics of stress, anxiety, or depression. We do not evaluate these clinically, but we have a list of family resources available that includes mental health providers. We will post this on our public website. If you disclose that you might harm yourself or someone else, we will share this and your contact information with the relevant agencies (e.g., police, healthcare professionals).

Children: The study activities are done for research; not for diagnosis. Our team includes students and research assistants. So, research team members doing study tasks with you may be someone who is not a licensed, certified speech-language pathologist. We will not provide your child with a formal clinical diagnosis. But, you will be notified if:

1) Your child does not already have an ASD diagnosis but meets the criteria for more evaluation based on a score on an ASD screening tool.
2) Your child receives language scores that would include them in the training group or exclude them from the comparison group.
3) You or your child cannot take part based on your concerns about your or your child's hearing.

You may ask for referral resources and a copy of your child's standardized language tasks scores in writing.

Will I get paid for my participation?

We will pay you $5 for completing screening and up to an additional $225 or $180 for completing study sessions depending on group placement. This study will take 6 to 7 study sessions for the training group and 3 to 4 study sessions for the comparison group.

You will receive an initial $5 payment after completing screening, $65 after completing the baseline tasks, and one final payment after completing the study. This final payment will only include compensation for finished sessions.

Study Activity Completed	**Compensation**	
	Training Group	Comparison Group
Screening	$5	$5
Baseline tasks	$65	$65
Coaching session #1	$15	n/a
Coaching session #2	$15	n/a
Coaching session #3	$15	n/a
Follow-up tasks	$115	$115
Total	$230	$185

UW-Madison requires that there be a separate payment process for non-US residents. Please be sure to notify the study coordinator if you are a non-US resident.

Federal tax law requires you to report this payment as income to the Internal Revenue Service if you are compensated more than $599.99 (in total) this year for participating in research. If payments for this study put your research compensation over $599.99 for the year, you are required to report it to the Internal Revenue Service.

How will my confidentiality be protected?

This study is confidential. Your name and any other identifying information will **not** be published.

To the extent allowed by law, we only let people who require access see your personal information.

We do our study sessions and phone calls from a private room.

Researchers will access any information identifying you or your child in private spaces.

The study team has safety plans to protect your information, but there is always a risk of losing confidentiality.

The Institutional Review Board (IRB), the University of Wisconsin-Madison, and other representatives of these organizations may go through and copy your information.

The National Institute on Deafness and Other Communication Disorders (NIDCD) funds our research. The NIDCD is part of the National Institutes of Health and may also review copies of your information.

We are mandatory reporters of child, elder, and at-risk adult abuse and/or neglect. We are legally required to report these instances to the relevant university and law enforcement agencies.

If you disclose that you might harm yourself or others, we will let the applicable resources know and send them your contact information, including your name, phone number, and/or email.

A description of this clinical trial will be available on http://clinicaltrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time using the study ID: NCT03525951.

You may also agree to share your data through Databrary (more information in another document). Whether and how you share your data will not affect your ability to take part in this study.

The research team will store your data for at least 7 years unless you tell us differently in writing.

The research team will store information identifying you or your child in locked cabinets or HIPAA-compliant locations, like SMPH REDCap, an online HIPAA-compliant portal.

We will not use the information identifying you or your child for reasons not related to research unless you consent for us to do so (for example, consent for educational use).

Whom should I contact if I have questions?

You may ask any questions about the research at any time.

If you have questions, concerns, or complaints, or think taking part in the research has hurt you, contact the research team or the PI.

- The research team can be reached at L3Lab@waisman.wisc.edu.
- The PI, Dr. Rebecca M. Alper, can be reached at 608-890-2259 or rebecca.alper@waisman.wisc.edu.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and help with resolving problems.

If you decide not to participate or to be taken out of the study, you may do so without penalty.

Language, Literacy, and Learning Lab

Your signature shows you have read this consent form, had a chance to ask questions about your participation in this research, and voluntarily agree to take part. You will receive a copy of this form for your records.

Signature Block for Parents

By signing/writing/typing/saying your and your child's name, you are documenting your permission for you and the named child to take part in this research.

As part of this study, you agree to allow you and your child to be video and audio recorded. You may choose to have this video and audio used only for research or to be shared with more people. You have the right to stop participating in this study at any time.

Choose One:

I DO allow for me and my child to be videotaped and audio recorded for this study only for research. These video and audio recordings will only be used for data purposes and will NOT be seen by anyone outside of the research team.

I DO allow for me and my child to be videotaped and audio recorded for this study for both research and other purposes. These video and audio recordings may be used for data purposes, trainings/presentations in research and professional settings, and/or in digital and print media related to the research (for example, on the lab website).

Part of your participation includes being contacted about this study. You may choose whether you would like to be contacted in the future as new research studies come up.

I DO allow for the research team to contact me in the future about opportunities for other research. This involves storing my name, my child's name, my child's date of birth, and my contact information (phone and e-mail) in a secure space.

Printed name of child	
Signature of parent or guardian	Date
Printed name of parent or guardian	Parent Guardian (See note below)

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Printed name of the person obtaining the consent form

Note on permission by guardians: A person may give permission for a child only if that person can give a written document showing that they are legally authorized to consent to the child's general medical care. Attach the document to the signed consent form.

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Signature of Person Obtaining Consent Date