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CONSENT TO PARTICIPATE IN A RESEARCH STUDY
Caregiver Version

Short Title: Recasting and Reading Study

Full Title: Recasting and book reading under ideal (dose-controlled) and typical (dose-variable) conditions: The role of fidelity and adherence in production and comprehension outcomes for children with DLD

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KEY INFORMATION

Important aspects of the study you should know about first:

- **Purpose:** The purpose of the study is to compare different treatments (recasting/book reading) and providers (parent/lab staff) for Developmental Language Disorder (child language impairment).
- **Procedures**: If you choose to participate, we will ask you to complete questionnaires about you and the child you care for. We will test the child's hearing, pattern-matching, and a variety of language skills. If they qualify to continue, we will randomly assign the child to one of two possible language treatments, delivered by you or by our staff. During treatment, we will ask you to have the child wear an audio-recorder 2 days/week. After 10 weeks, we will test the child's progress and interview you.
- **Duration:** It will take 2-6 visits (60-90 minutes each time) to figure out if the child you care for qualifies for this study. Treatment will last for 10 weeks (16 hours) and then we will test the child and interview you (2 visits of 60-90 minutes each). We will do our best to accommodate your scheduling needs.
- **Risks**: The main risk is getting bored or tired. You may also experience some anxiety about you or the child's performance or worry about your ability to provide treatment. We will try to explain everything clearly and make sure you are comfortable with each task.
- **Benefits**: The treatments being used have shown benefits for other children like the child you care for. The child's language skills may improve after treatment, but we cannot guarantee it. This research may also help us develop treatments to help other children in the future.
- **Alternatives:** The alternative to this study is traditional speech-language therapy in a clinical or school setting. You may participate in the study even if the child you care for receives therapy elsewhere.
- **Costs and Compensation:** If you decide to participate, you may have costs related to travel/parking. You will not be compensated for your participation. The child you care for will receive $15 for initial screening, $35 for pre-testing, $100 for post-testing, and $70 for a final interview with you. The child will also be paid $10 per home audio recording that you return, up to $160. A family who completes the full study and turns in 16 home audio recordings would receive $380.
- **Participation:** Taking part in this research study is your decision. You can decide to participate and then change your mind at any point.

Please carefully read the entire document. You can ask any questions you may have before deciding if you want to participate.

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study.

Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

Any regular adult caregiver of the child (grandparent, aunt, etc.) may participate in the delivery of therapy and the interviews, provided that the parent/guardian is agreeable and has given permission. You are signing this form because you are NOT the child's parent or legal guardian. The term "the child" refers to the child who is participating in the study.

PURPOSE OF THE STUDY

The purpose of this study is to compare different treatment strategies for Developmental Language Disorder (child language impairment). In particular, we want to know more about how to teach children new types of sentences. This study will help us learn which treatment methods are most effective when delivered either in the lab or at home by you.

WHO IS BEING ASKED TO PARTICIPATE?

There will be approximately 160 children and up to 320 caregivers in this study. You are being asked to participate because the child you care for is 4-9 years old and has difficulty learning and using language. We will screen many more children (approximately 7000), but not all children screened will qualify.

Children do **not** qualify for this study if they:

- have typical language skills for their age
- are learning more than one language
- have a vision impairment (not corrected with glasses or contacts)
- have a hearing impairment
- have a cognitive impairment
- have autism spectrum disorder (ASD)
- have a complex medical history, including: brain injury, chromosomal disorder (ex: Down syndrome), motor disability (ex: cerebral palsy), or psychiatric disorder (other than ADHD)

PROCEDURES: WHAT WILL YOU BE ASKED TO DO?

Overview

First, the child's parent or legal guardian must complete consent documentation (online) for the child to participate in the study. Then we will complete 2-6 screening and pre-test visits (60-90 minutes each) remotely via Zoom. If the child qualifies to continue after screening, you and the child will then participate in 8-10 weeks of language therapy (16 hours total). During this time, we will ask you to take audio recordings at home every week (16 recordings total). After treatment, we will meet for 2 post-testing visits (60-90 minutes each) to measure the child's progress. We will also interview you about your experience at this time. We may recontact you up to 8 weeks later to confirm that we understood your interview responses correctly.

Most people will complete the study in 16 weeks. We will work at the child's pace to get the most accurate measure of their skills. We will take breaks or schedule follow-up appointments as needed to ensure the child is comfortable and engaged. Throughout the study, we will ask you to complete surveys online or in person. If desired, we can

administer tests to the child while you complete these surveys in order to minimize the total number of visits needed.

"Visits" may take place via telehealth (meeting virtually using a secure video calling service). Due to meeting virtually, we will conduct a "tech check" meeting prior to the first assessment of the child to ensure that everything goes smoothly.

We will record audio and/or video at all visits.

Screening (1-3 visits of 60-90 minutes each)

At your first visit, we will explain the study procedures to you and answer any questions you have. After you consent to participate in the study, we will ask you to fill out some surveys about you and the child.

We will test the child's hearing, pattern-matching, and a variety of language skills. Most of our tasks involve showing the child pictures in a book or on a computer screen and asking questions about them. Screening will determine if the child meets the research definition of Developmental Language Disorder (DLD).

Pre-testing (1-3 visits of 60-90 minutes each)

If the child has DLD (according to our definition) we will complete further testing to determine whether the child can benefit from our treatments. We will test the child's ability to use and understand two sentence structures (*passives* and *relative clauses*). If the child already knows these structures, they will not qualify for the study.

In one task, we will ask the child to sit in front of a computer screen and look at pictures while listening to audio recordings. Your child's eye movements will be tracked via the webcam on your camera. Recording your child's eye movements is completely harmless.

Training and Treatment (8-10 weeks)

We will randomly assign (like rolling dice or flipping a coin) the child to one of 4 possible treatment + provider combinations: book reading at home, recasting at home, book reading in the lab, or recasting in the lab. Recasting is like rephrasing what the child has just said using a specific sentence structure.

- Book Reading at Home: 3 training visits (via telehealth) + You will read books to the child at least 4 times a week (32 readings total).
- Recasting at Home: 3 training visits (via telehealth) + You will play and recast with the child for 30 min. 4x/week or 60 min. 2x/week (16 hours total).
- Book Reading in the Lab: 1 training visit + 2 visits/week where lab staff will read 2 books to them (32 readings total). Visits will be via telehealth.
- Recasting in the Lab: 1 training visit + 2 visits/week where lab staff will play and recast with them (16 hours total). Visits will be via telehealth.

At the training visit(s), we will give you a special audio recorder (LENA) that is made for children and teach you how to use it. If you are assigned to provide therapy at home, we will also teach you the proper treatment techniques. We will then ask you to demonstrate what you have learned for us.

We will arrange with you how to exchange the LENA recorder for a new one every 2 weeks. We will ask you to plan LENA recordings ahead of time so we can send you text message reminders. If you are assigned to provide therapy at home, we will also ask you to let us know when you provide treatment and how easy it is.

Throughout this time, we will ask you to complete regular surveys to keep track of how the treatment is going.

Post-testing and Caregiver Interview (1-2 visits of 60-90 minutes each)

After treatment, we will test the child on the 2 sentence structures again to measure their progress. We will ask you to complete another survey, and we will interview you to ask about your experiences participating in the study. We may contact you again up to 8 weeks after your interview to ensure that we understood your responses correctly.

FUTURE CONTACTS

In order to ensure that we understood your responses correctly, may we contact you again up to eight weeks after your interview? We may contact you up to three times post-interview.

Please write your initials next to your preferred choice.

_____ YES, you may contact me to clarify interview responses

_____ NO, you may not contact me to clarify interview responses

WHAT ARE POSSIBLE RISKS AND DISCOMFORTS?

The main risk is that the child may get bored or tired. We will take breaks and use child-friendly activities (like videos, music, online games) to reduce boredom and fatigue.

There is a risk that you may feel anxiety about your own or the child's performance on our tasks. We will try to explain everything clearly and make sure you are comfortable with each task. Please ask us any questions you have, and we will be sure to address them.

As with any clinical trial, there is a risk that you could be assigned to a less effective treatment condition. After you finish participating in the study, we will share the training materials for the other treatment conditions with you so you can use them at home. We will also help you access any public services you may be entitled to (e.g., via your public school) if you are not already receiving those services at the time of the study.

WHAT ARE POTENTIAL BENEFITS FROM THE STUDY?

Through participating in this study, the child will hear repeated examples of complex sentences. This may improve the child's ability to understand and use these types of sentences, but we cannot guarantee it. All of the treatment methods used in this study are evidence-based, meaning that past research suggests the treatment will work. The purpose of this study is to find out if these treatment methods really do work and if some are better than others. We also want to know if a treatment is better when delivered at home or in the lab and if caregivers prefer one approach to treatment over another.

The information we learn from this study could also help us design new speech/language treatments in the future. This could help us develop better treatments to promote language learning in children with DLD.

NEW FINDINGS THAT COULD AFFECT YOUR PARTICIPATION

During the course of this study, we may learn new important information. This may include information that could cause you to change your mind about participating in the study. If any new important information becomes available while you are a participant, we will let you know.

CONFIDENTIALITY: WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

We will handle your data as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.

To help protect you and the child's confidentiality, we will use an alphanumeric code to track you and the child's participation instead of using your real names. Paper records will be stored in a locked filing cabinet at the University of Delaware (UD) or the University of Maryland (UMD). Electronic records (including audio/video recordings) will be stored on password-protected servers and online databases hosted by UD or UMD.

We will share audio data with third parties for processing and analysis. LENA recordings will be processed by LENA Online. We will not give LENA Online any information about you or the child besides the child's birthdate. LENA Online does not store audio files after processing. They return reports to us about the amount and type of talk in the home. Study recordings may be transcribed by Otter.ai, an automated processing program. We will not give Otter.ai any information about you or the child. Otter.ai does not store audio files after processing.

We will store post-processed audio files on university servers for later analysis. We plan to transcribe the LENA recording audio from the time of day when you report providing treatment (for home treatment conditions) and other comparison times (for all conditions). We will also transcribe the language samples taken at pre- and post-test.

Records relating to this study will be kept for at least three years after the grant funding the study ends. These records may be viewed by the Institutional Review Boards at UD or UMD. An Institutional Review Board is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. We will share both summary and participant-level results (e.g., child age, gender, and race; gain on production probes, treatment fidelity, standardized test scores) on this website after the conclusion of the study, but your identity will be disguised so that others cannot recognize you (e.g., we will change or redact birthdates and zip codes to mask your identity). You can search this website at any time.

We must also let you know that if during your participation in this study our research team was to observe or suspect, in good faith, child abuse or neglect, we are required by state law to file a report with the appropriate officials.

USE OF DATA COLLECTED FROM YOU IN FUTURE RESEARCH:

After your personally identifiable information is removed, the data collected in this study may be used for future research without additional informed consent from you or your legally authorized representative. For instance, we may share the pattern of test results obtained (after removing the child's name and birthdate), to help us better understand which tests tend to show similar scores.

We may distribute de-identified data from this study to other researchers for future research studies, so long as the studies are approved by the review board at the researcher's institution.

We may also share audio files with other researchers who obtain permission to carry out additional research from the review board at their own institution and from the review boards at UD and UMD. You may opt out of this sharing if you would like.

_____ I would prefer that the **audio files** collected not be shared outside of the UD/UMD research program as described here.

COSTS AND COMPENSATION

You will be paid $15 for initial screening, $35 for pre-testing, $100 for post-testing, and $70 for a final caregiver interview. You will also be paid $10 per home audio recording (LENA recording), up to $160. A family who completes the full study and turns in 16 home audio recordings would receive $380.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

You do not have to participate in this study. It is your decision. If you choose to participate, you have the right to stop at any time. If you decide to stop taking part in the study, there will be no penalty or loss of benefits to which you are otherwise entitled. Your decision to stop participation, or not to participate, will not influence current or future relationships with UD and UMD.

INSTITUTIONAL REVIEW BOARD

This research study has been reviewed and approved by the University of Delaware Institutional Review Board (UD IRB), which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. If you have any questions or concerns about your rights as a research participant, you may contact the UD IRB at hsrb-research@udel.edu or (302) 831-2137.

CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues related to this research study you may contact the Principal Investigator, Dr. Amanda Owen Van Horne at (302) 831-3982 or ajovh@udel.edu.

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read and understood the information in this form, and I agree to participate in the study with the child I care for. I am 18 years of age or older and I am one of the primary caregivers for the child named below. I have been given the opportunity to ask any questions and my questions have been answered to my satisfaction. I understand that I will be given a copy of this form for my records.

_____
Child (Printed Name)

_____	_____	_____
Caregiver (Printed Name)	Caregiver (Signature)	Date
_____	_____	_____
Person Obtaining Consent (Printed Name)	Person Obtaining Consent (Signature)	Date

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OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES

Do we have your permission to contact you regarding participation in future studies? If you agree to being contacted in the future, we will keep your contact information.

Your choice about being contacted for future studies will have no impact on your participation in this study.

Please write your initials next to your preferred choice.

_____ YES, you may contact me about future studies

_____ NO, you may not contact me about future studies

OPTIONAL CONSENT FOR USE OF DATA TO TRAIN PRE-SERVICE STUDENTS & OTHER PROFFESSIONALS

Do we have your permission to use audio and/or video data collected from the child for training purposes? For example, we may share recordings of the child to teach students, educators, speech language pathologists, and other researchers how to follow testing procedures.

Your choice about future use of your data to train others will have no impact on your participation in this study.

Please write your initials next to your preferred choice.

_____ YES, I will allow the use of audio and video data collected from me and the child for training purposes.

_____ NO, I will not allow the use of audio and video data collected from me and the child for training purposes.

OPTIONAL CONSENT FOR ADDITIONAL USES OF IDENTIFIABLE VIDEO RECORDINGS/PHOTOGRAPHS

I voluntarily give my permission to the researchers in this study to use videos and photographs of me and/or the child I care for collected as part of this research study for publications, presentations, and/or educational purposes. I understand that no identifying information beyond that contained in the video/photographs will be provided to educational/scientific audiences; however, my facial features and/or those of the child may be seen.

Your choice about future use of video/photographs will have no impact on your participation in this study.

Please write your initials next to your preferred choice.

_____ YES, I will allow the use of video/photographs of me and/or the child for all purposes.

_____ ASK ME FIRST. I might allow the use of video/photographs of me and/or the child for certain purposes if the research team contacts me for written permission each time.

_____ NO, I will not allow the use of video/photographs of me or the child for any purpose.