Grammatical Language Intervention Study
Consent Form

Title of Research Study: Evaluation of an Explicit Approach to Teach Grammatical Forms to Children with Language Impairment (Protocol number: TBD)

Investigator Team Contact Information: Lizbeth H. Finestack, Ph.D., CCC-SLP
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?
The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, or you child may or may not be helped by volunteering for a research study.

Why is my child being invited to take part in this research study?
We are asking your child to take part in this research study because you child's is aged 5 through 8 years, has weaknesses in language learning (particularly grammatical forms), is a native speaker of mainstream English, and does not have another diagnosis, such as autism spectrum disorder, Down syndrome, seizure disorder, or hearing impairment.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The purpose of this study is to identify the most efficacious treatment approaches to use with children with language learning weaknesses. Many children with language learning weaknesses experience difficulties learning grammatical forms (such as the past tense *-ed*, like in the sentence "Yesterday we jump*ed* over the puddle"). It can take children a long time to learn these forms even with treatment. We want to see if we can help children learn these problematic forms faster using new treatment approaches. Results from this study will inform clinical practice.

How long will the research last?
We expect that your child will be in this research study for approximately 21 months, but this time will vary depending on the number of sessions completed each week. This includes 2, 1.5-hour assessment sessions, up to 64 treatment sessions that are about 30 minutes, and four post-treatment assessments sessions (immediately, 1 month, 6 months, and 1 year after the completion of the treatment sessions).

What will I need to do to participate?
You will be asked to complete several questionnaires about your child's development and skills. We will also ask you to share your child's Individualized Education Plan with us, if you have one. Your child will be to complete assessments of their language and cognitive skills. They will also complete treatment sessions in which they will listen to models of the targeted grammatical forms and be asked to produce the forms while telling short stories.
More detailed information about the study procedures can be found under *"What happens if I say yes, I want to be in this research?"*

Is there any way that being in this study could be bad for me?
The foreseeable risks of participating in this study are minimal. The tasks that your child will complete are similar to those that they may do at school. There is some risk of a data breach that affects your private information. You could feel annoyed by the questions asked in the phone interview, or your child could feel bored or frustrated during the assessment and treatment sessions.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, it is possible that your child will improve their understanding and use of grammatical forms that are targeted in the treatment sessions.

What happens if I do not want to be in this research?
There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 200 children will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

If you say that you want your child to be in the research study, we will schedule two 1.5 hr assessment sessions for your child. These sessions will be held at the University of Minnesota or at an alternative location at a time that is convenient for you. If you come to the University, we will pay for your parking or public transportation. During these sessions, a trained examiner will ask you to complete several questionnaires about your child's development and language abilities (45 min). We will also ask you to share a copy of your child's current Individualized Education Plan, if they have one. If your child is currently receiving speech-language or reading services, we will ask you to have their clinician complete a form regarding the treatment.

Your child will complete several assessments including the following:

- Hearing screening (10 min)
- Dialect assessment (20 min)
- Assessment of specific speech forms used in the intervention (3 min)
- Assessment of specific grammatical forms (15 min)
- Assessment of an array of grammatical forms (20 min)
- Assessment of general cognitive skills (30 min)
- Comprehensive language assessment (45 min)
- Conversational language sample (20 min)
- Assessment of metalinguistic awareness (15 min)

If after completing any of the assessments, it becomes apparent that your child is not eligible for the study because of scores that are too high or too low, we will end testing. We want to make certain that the treatment is appropriate for your child.

If based on testing, we confirm that your child qualifies for the study, they will be randomized to one of two treatment groups. The experimental treatment your child will receive will be chosen by chance, like flipping a coin. Neither you nor the investigator will choose what experimental treatment your child receives. Your child will have a 50/50 chance of being in either treatment group. You will not be told which experimental treatment your child is receiving; however, the investigator will know.

The two experimental treatments will be nearly identical. Both have been shown in previous studies to help improve the grammatical language of children. In this study, we will identify if one is better than the other, or if outcomes are better when multiple treatments are used.

For the treatment sessions, a trained interventionist (different than the examiner) will provide 32 sessions of the randomly assigned treatment. The treatment will focus on improving your

child's production of four specific grammatical forms (like past tense *-ed* in words like *jumped, walked, hiked)*. Each intervention session will last about 30 minutes and can occur in a quiet location that is convenient to you, such as your home, childcare center, or public library. You are also welcome to come to the University of Minnesota for treatment sessions (with parking reimbursement). Ideally, your child will complete at least two treatment sessions per week; however, we will work around your schedule.

During each treatment session, your child will complete several different activities. They will be asked to imitate a series of sentences presented by the interventionist. The interventionist will model two short stories with related toys and then ask your child to retell the stories. Finally, your child will be asked to listen to the interventionist present a series of sentences that include the target form. The only difference between the two experimental treatments is the feedback provided by the interventionist throughout the sessions.

At the end of the 4th session, an examiner will ask your child several questions about how they are liking the treatment sessions. Then, at the end of the 32nd session (approximately 4 months of treatment), your child will complete the 15-minute assessment of specific grammatical forms to monitor their progress. Based on their performance, we will re-randomize your child to another group. If your child is demonstrating good progress, they will be randomized to one of three groups with a 33.3% chance of receiving no more treatment, 33% chance of receiving more of the same experimental treatment, and a 33% chance of receiving the other experimental treatment. If your child is not making good progress they will have a 50/50 chance of receiving either one of the experimental treatments. Children who are randomized to receive more treatment will then complete an additional 32 sessions as described above.

After completing their treatment sessions, your child will complete four additional assessment sessions that will be completed by a trained examiner. The sessions will occur immediately, 1 month, 6 months, and 12 months after completing treatment and can be done at the University of Minnesota or another quiet location that is convenient for you. Each session will require no more than 1 hour.

For this project, it is necessary for us to audio and/or video record each assessment and treatment session. Agreement to be recorded is required for participation. You have the option to limit the use of the recording to only the research team or to allow the recordings to be used for other purposes, such as conference presentations.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. If you decide to leave the research study, contact the investigator so that investigator stops all attempts to complete study procedures. If you decide to leave the research study, we will keep the data we have already collected about you unless you tell us to destroy it.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your relationship with the researchers or the University of

Minnesota.

Is there any way being in this study could be bad for me?
There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

You or your child might feel annoyed or uncomfortable with one or more of the questions asked. You both are allowed to skip questions that you do not wish to answer.

Your child could feel bored or frustrated by testing and during the treatment sessions. The examiners and interventionists will provide breaks as needed and try to make the activities fun for your child. For example, they may reward your child with a sticker or small toy after completing an activity.

Will it cost me anything to participate in this research study?
There will be no cost to you for any of the study activities or procedures.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, it is possible that your child will improve their language skills as a result of the experimental treatments.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

We may share data and publish the results of this research. However, we will keep your name and other identifying information confidential. If identifiers are removed from your identifiable private information, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Additional sharing of your information for mandatory reporting:
If we learn about current or ongoing child or vulnerable adult abuse or neglect we may be required or permitted by law or policy to report this information to authorities.

Will I receive research results?
We will provide you with summary reports of your child's performance on the standardized assessments. Because this information is collected as part of a research study, it is not designed to formally evaluate, diagnose, or treat your child. After each study phase, we will provide a report regarding your child's progress in the treatment program.

What will be done with my data when this study is over?
We will use and may share data and for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Will anyone besides the study team be at my consent meeting?
You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g., name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?
This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Will I be compensated for my participation?
If you agree to take part in this research study, we will pay you $10 after completing the first two assessment sessions, $50 after completing the first set of 32 treatment sessions, $80 after completing the second set of 32 treatment sessions, and $50 after completing each of the follow-up sessions ($240 in total). Your child will receive $10 gift cards after completing the initial two assessment sessions, each set of 32 treatment sessions, and at each follow-up session ($60 in total).

Use of Identifiable Health Information
We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Optional Elements
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the investigator will attempt to limit such identification. I understand the risks associated with such identification.
_____	_____	The investigator (Dr. Lizbeth H. Finestack) may contact me in the future to see whether I am interested in participating in other research studies.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____
Printed Name of Child Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is unable to read the information
☐ The participant is visually impaired
☐ The participant is non-English speaking
☐ The participant is physically unable to sign the consent form. Please describe:
_____
☐ Other *(please specify)*:
_____