NORTHERN ARIZONA UNIVERSITY

Office of Research Compliance

Consent to Participate in Research

Study Title: Caregiver Spanish Intervention Training for Children with Developmental Language Disorder

Principal Investigator: Lindsey Hiebert, PhD, CCC-SLP

Sponsor: Southwest Health Equity Research Collaborative U5 Grant U54MD012388 Pilot Project Program

This is a consent form for participation in a research study. Your participation, and the participation of your child, in this research study is voluntary. This form contains important information about this study and what to expect if you decide to participate with your child. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

We invite you and your child to participate in a research study on the teaching of robust vocabulary. We hope to learn 1.) if we can teach parents how to teach robust vocabulary to their children, 2.) if children can learn robust vocabulary in Spanish from their parents, and 3.) if our intervention training can be part of their daily life, and if not, what can we change to make it easier to integrate into daily life? We have selected you as a potential participant in this study because you have a 4 to 6-year-old child with a language disorder or at risk for a language disorder.

Summary of the research

The purpose of this study is to determine whether Spanish-speaking caregivers can learn to teach science vocabulary to their children with the use and educational app and a short training video with target words. The children will take language, speech, and hearing tests, as well as science and vocabulary pretests with a speech-language pathologist. You will be asked to answer some questions about your language use in the house and other places. If you and your child qualify for the study, the researcher will randomly place you in a group to 1) use the app, or 2) use books. Since you are chosen at random, there is no way of knowing which group you and your child will be in before you start. Participants will take part in an 11-week study (3 weeks of testing at the beginning, middle, and end of study, and 8 weeks of intervention). The testing will be conducted in a place that is comfortable for your child (home, school, university clinic). The intervention can be done at home (researchers will not be present for this part of the study, but we will be available to support you or answer questions). We want you to play (group 1) or read (group 2) with your child two times a week (~30 minutes) and send the audio recording of your interaction to our researchers.

Caregivers in the treatment group will also be asked to attend a focus group scheduled after completion of the intervention. Success with the intervention will be measured by your use of the conversation strategies and use of target vocabulary words during treatment. We will test whether children learn the target vocabulary words. Focus group discussion will let researchers know what changes could be made to make the training and intervention more successful from the participant perspective. During the study, caregivers in Group 1 will be asked to download science lessons (in Spanish) each week and watch a vocabulary intervention training video. The app includes cartoons for children, additional parent training videos, and suggested activities and questions to imbed vocabulary teaching. Activities should take about 30 minutes, twice a week. A new group of downloadable videos will be available each week. Caregivers in Group 2 will have Spanish storybooks (provided by researchers) to read twice a week. Caregivers in both groups will be asked to audio record science activities or book sharing and submit recordings to researchers via REDCap or SharePoint link. Participation in the study will have minimal risk. You can see the participation program below.

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	End
Children	Language and vocab exam	Intervention	Intervention	intervention	Intervention	Science and vocab exams	Intervention	Intervention	Intervention	Intervention	Science and vocab exams	
Parents	Questionnarie and traning	Send recordings	Send recordings	Send recordings	Send recordings	Talk to researchers	Send recordings	Send recordings	Send recordings	Send recordings	Talk to researchers	Focus group

A description of this clinical investigation will be available at http://www.ClinicalTrials.gov, as required by US law. This website will not include information that identifies you. At, most the website will include a summary of the results. You can consult this website at any time.

Why is this study being done?

Developmental Language Disorder (DLD) affects 7% of the population, however, it is less known and researched than other speech-language disorders that impact far fewer people, such as stuttering. DLD affects monolingual and bilingual children equally, but there is an inequity in available resources for evidence-based interventions for bilingual children. The Spanish-speaking children in Arizona make up 20% of the population, but they are mostly being assessed and treated for DLD by speech-language pathologists that do not speak Spanish (>95%). This leaves approximately 904,400 Spanish-speaking children in Arizona that are not being treated for DLD in their language. With Spanish-speaking bilingual children benefiting most from being treated for DLD in *both* Spanish and English, there is a substantial inequity in access to appropriate intervention for bilingual children with DLD in the state. We will try to provide help for these children in our state with a Spanish vocabulary intervention at home with their caregiver. This intervention may also increase the child's vocabulary to help them be more successful in school.

What will happen if I take part in this study?

Caregivers who participate in this study will be expected to have their child participate in the testing on weeks 1, 6, and 11. You may decide the location for testing. You will also be expected to audio record therapy with your child twice a week during weeks 2-5 and 7-10. Interactions will be based on science activities suggested for you or Spanish storybooks provided by researchers. Caregivers randomized into Group 1 will be trained to administer the vocabulary intervention to their children in Spanish with vocabulary words provided by researchers. Caregivers in Group 1 will also receive feedback on their use of target vocabulary and communication strategies. Finally, caregivers in Group 1 will be invited to take part in a focus group after completion of the intervention and testing. Caregivers in Group 2 will receive training on the use of audio recorders and will receive four books with science themes in Spanish to read with their child.

Children will participate in a language evaluation in Spanish and English at the start of the study along with a hearing screening. They will also be tested for science and vocabulary knowledge before, in the middle, and at the end of their intervention. Science and vocabulary testing will be conducted in Spanish only times one and two and in both Spanish and English at the end of the study.

Demographic information will be collected for research purposes. Each caregiver-child will be assigned an alphanumeric code to protect their confidentiality. During focus groups, first names or assigned pseudonyms will be used during discussion. Information obtained from testing, audio recordings, or interviews will be deidentified and stored in a secure REDCap account owned by Dr. Hiebert.

How long will I be in the study?

The duration of time spent in the study will be no less than one week (1-2 visits) and no more than 12 weeks (1 additional week for participation in a focus group). Participants should plan to spend 1-2 hours per week doing intervention or testing.

How many people will take part in this study?

This study aims to recruit 64 caregiver-child pairs in order to have the power necessary to make the planned analyses. We will recruit up to 140 pairs of participants to at least have 70 pairs that qualify for the study to have 64 complete all the study activities.

Can I stop being in the study?

Participation in this study is voluntary and you may withdraw at any time. If you or your child decide not to participate for any reason, there will be no penalty. If you or your child decide to stop participation, it will not involve any penalty or loss of benefits to which you and your child

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This stamp must be on all consenting documents

are otherwise entitled. Refusal to participate will not affect your relationship with the school your child attends, or with Northern Arizona University. If participants withdraw from the study, they will keep any equipment or materials already sent to them. A Tango gift card will be provided for the activities they participated in. No additional information on treatment procedures will be shared with participants after they discontinue. They will still receive a speech-language-hearing report on their child and any published information on the study. If participants in Group 1 withdraw during the intervention, they may still be invited to participate in a focus group to let researchers know the reason/s for their withdrawal. If you decide that you do not want to be contacted by researchers, we will accept that decision.

What risks or benefits can I expect from being in the study?

All the procedures used in this project are noninvasive and pose no unusual threat to the participants' health, safety, welfare, or human rights. If you have any questions/ concerns contact Dr. Hiebert, Lindsey.Hiebert@nau.edu or 928-523-2109. Children may become bored during the testing or activities. Testing will be no longer than 90 minutes and will take place in a place of your choice, at home, at a familiar place in the community (e.g., library, school), or at the university clinic in a room designated for children. Some caregivers will take part in focus groups within the community. There is some risk to loss of confidentiality. To minimize the risk, we will use first names only in the focus group and explain the expectation of confidentiality outside of the focus group. Caregivers will need to take time out of their day twice a week for about 30 minutes to work on intervention with their child (science activities or book reading), which may take away from their other duties. Downloading the training app will take up memory space on smart phones. Wi-Fi will not be required but would eliminate the need to download large data files from the app. Parents will be asked to take audio recordings of science activities or book reading. The recordings will be sent electronically to the researchers via secure REDCap or SharePoint link to ensure data safety. A quick training on use of audio recorders and recording submission will take place in week 1 or 2 of the study. Parents will receive a report on their child's language skills.

Will I be paid for participating in the study or experience any costs?

This study may require travel to clinic/offices at Northern Arizona University, or public community centers, such as schools or libraries. The testing procedures may take place in these areas or in your home. All focus groups will take place in public community centers. All intervention will take place in a location chosen by caretakers (e.g., home). All necessary materials such as recorders, books, etc., will be provided to families at no cost to them.

A Tango gift card will be provided to participants in an amount that reflects the activities in which they participated. Each child assessment (initial, middle, and final) is worth $20, each recording uploaded is worth $5, and participation in a focus group is worth $25. Participants will receive a gift card anywhere from $20 to $170 depending on the number of activities

completed. Participants may choose to receive compensation at the end of the study, or as completion points such as after each assessment or science unit (4-week period). You may choose to get one gift card for the full amount at the end of the study, or at specified points during the study (after each testing session).

Will my study-related information be kept confidential?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

All electronic data collected will be stored in a secure REDCap account belonging to Dr. Hiebert. All devices that the research assistants will work on will be password-protected. They will not have access to the electronic data on their personal devices. Hard copy data will be stored in the office of Dr. Hiebert in a locked file cabinet. Caregivers will upload audio files directly to the secured REDCap account or SharePoint folder link to eliminate the risk of confidentiality. All participants will be assigned an alphanumeric code to ensure their confidentiality in the research project.

Only trained research assistants certified to participate in this study will have access to electronic or paper documents with participant information. The information that you provide in the study will be handled confidentially. The Northern Arizona University Institutional Review Board; other federal, state, or international regulatory agencies; or the sponsor of the study, if any, may review the research records for monitoring purposes.

Once transcriptions have been completed, all recordings will be destroyed.

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Will my study-related information be used for future research?
Coded transcriptions may be used for future research or shared with another researcher for future research studies without additional consent. Dr. Hiebert will keep your and your child's de-identified information for future studies or may share it with other researchers without asking you for additional consent.

Who can answer my questions about the study?
For questions, concerns, or complaints about the study you may contact Dr. Lindsey Hiebert at 928-523-2109 or at lindsey.hiebert@nau.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Research Protection Program at 928-523-9551 or online at http://nau.edu/Research/Compliance/Human-Research/Welcome/.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Lindsey Hiebert at 928-523-2109 or at lindsey.hiebert@nau.edu.

AGREEMENT TO PARTICIPATE

I have read (or someone has read to me) this form, and I am aware that I and my child are being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I affirm that I am at least 18 years of age and voluntarily agree to participate in this study and give permission for my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject	Signature of subject	Date

AGREEMENT TO BE AUDIORECORDED

Subject Signature:_____ Date:_____

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Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	Signature of person obtaining consent	Date