

EMT en Español for Spanish-speaking Toddlers With Language Delays
NCT04066049
6/26/2020

**Institutional Review Board
Informed Consent Document for Research**

Principal Investigator: Tatiana N. Peredo **Revision Date:** 6/18/2020

Study Title: *EMT en Español: Early communication intervention to support school readiness skills for Spanish-speaking toddlers with language delays*

Institution/Hospital: Vanderbilt University

This informed consent document applies to adult parents/legal guardians of young children.

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

The purpose of this study is to determine if a language therapy approach is effective for children who speak Spanish. Participation in the study will last 18 months, with two to three testing visits occurring every 6 months. Some families will also receive 36 therapy sessions during the first 5 months, other families will be offered 10 sessions of the therapy after completing the last tests. Sessions last about an hour and some are done in person in your home and some are done virtually via zoom. You can continue to participate or begin participation in any other educational or therapy program and still take part in this study.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because your family speaks Spanish and your child is between 30 and 36 months old and not talking as much as other children their age. Participation in this study takes around 18 months. Families are asked to participate in completing forms and testing for the child. Some families receive 36 sessions of therapy right away (two times per week for about 5 months) and some families receive 10 sessions after 18 months. Some sessions are completed in person and some are virtual over zoom. You will receive information about your child's development and money for participating in assessments. Your child might benefit from the therapy. We will test your child at the beginning of the study, after 6 months, after 12 months, and after 18 months. **Children who do not have the required**

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thinking and talking skills will not be able to be in the study. We will test your child today to determine if you and your child can take part in the study.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:

To see if your child is right for this study, we will test your child's talking and thinking skills. We will also do a screening test for Autism. If we have concerns after this test, we will offer you a more comprehensive evaluation at no cost to you. We will ask your child to play with toys and do some games as part of these tests. All tests should take about 1 to 2 hours and should be done today. The therapist (study staff) will meet with you to tell you if your child is right for the study at the end of this visit.

If your child is right for the study, you will be randomly assigned to either receive the therapy (2 times per week for around 5 months, 36 sessions and 4 workshops) or participate in tests only for the first 18 months and then we will offer you up to 10 sessions of therapy. We will come to your home or a preferred location close to you for the testing sessions and some of the therapy sessions and all of the workshop sessions will be virtual over zoom. . All of the study activities are summarized below and noted if they are virtual or in person.

What we are asking from you	When				
	1	2	3	4	5
Child testing for thinking skills (in person)	X				
Child testing for language skills in Spanish and English (in person)	X				
Screening test/s for Autism (in person)	X				
Complete a form with information about your child and family (you complete the form and return it to the assessor during an in person visit)		X			
Interview with the therapist (study staff) about your child and family, your beliefs as a parent, things your child likes/ dislikes, activities you do together (virtual)		X			
Interview about the language/s your child hears and uses throughout the day (in person)		X	X	X	X
Questionnaire about how you have been feeling over the last few weeks (you complete the form and return it to the assessor during an in person visit)		X			
Questionnaire about your child's behavior and thinking skills (you complete		X	X	X	X

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the form and return it to the assessor during an in person visit)					
Questionnaire about how you think your child learns (you complete the form and return it to the assessor during an in person visit)		X	X	X	X
Questionnaire about your child's therapies and educational programs (you complete the form and return it to the assessor during an in person visit)		X	X	X	X
Play with your child for 15 minutes with our toys for us to see how you communicate together (in person)		X	X	X	X
Look at books with your child for 5 minutes with our books for us to see how you communicate together (in person)		X	X	X	X
Child will play with therapist (study staff) for 20 minutes with our toys in Spanish (in person)		X	X	X	X
Child will play with therapist (study staff) for 20 minutes with our toys in English (in person)		X	X	X	X
Child will participate in test for vocabulary words your child understands (in person)		X	X	X	X
Child will participate in test for vocabulary words your child says (in person)		X	X	X	X
Child will participate in an activity where we ask them to wait to eat a treat (in Spanish; in person)		X	X	X	X
Child will participate in an activity where we ask them to wait to eat a treat (in English; in person)		X	X	X	X
Child will participate in an activity where we ask them to do the opposite of what we say (in Spanish; in person)					X
Child will participate in an activity where we ask them to do the opposite of what we say (in English; in person)					X
Child will retell a story to a therapist (study staff) in Spanish; in person				X	X
Child will retell a story to a therapist (study staff) in English; in person				X	X
Test of your child's language skills in English and Spanish (after child is 4 years old; in person)					X
1= things we will do today to see if your child can be in the study 2= we will schedule two 1-1.5 hour sessions in the next two weeks if your child has the right skills to be in the study 3= we will schedule two 1-1.5 hour sessions in about 6 months from today for this testing 4= we will schedule two 1-1.5 hour sessions in about 12 months from today for this testing 5= we will schedule two 1-1.5 hour sessions in about 18 months from today for this testing					

Additional things we will ask you to do if you are in the therapy group:

Therapy sessions: If your family is randomized to the therapy group, you and your child will participate in 18 therapy sessions and your child will participate in 18 therapy sessions and you will participate in 4 workshops (total 40 sessions per family) over 4- 5 months. All 18 of the individual therapy sessions with your child are done in person at your home or preferred location. We will do some of the sessions in which we are

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teaching you the strategies in person at your home and some virtually over zoom. The 4 workshops will be virtual. Typically the first 5 sessions will be in person and the remaining 13 will be virtual, but we will work with you to figure out the best combination for your family. Each session will last about 1 hour and we will typically have 2 sessions per week. If you have to miss a therapy session, we will reschedule the session. If you miss four sessions in a row without a reason and cannot make up any of these sessions, we might tell you that you and your child cannot be in the study anymore. Please let us know before any scheduled in person visits if you, your child, or anyone who lives in your home is sick. We will work with you to reschedule in person visits once everyone is healthy.

Our parent therapy sessions include teaching the parent the therapy techniques. Each session will start with talking about the therapy strategies we will use that day and planning the day's activities. During sessions, we will practice the therapy techniques in things you do with your child (for example, play with toys, looking at books, washing hands, meal times, getting your child dressed, brushing teeth, brushing hair, coloring). After talking about the techniques with you, your teacher will play with your child with toys for about 5-15 minutes during in person sessions. You will then play with your child for 5-30 minutes. You will practice in home activities that are normal for you and your child while the teacher helps you by telling you how to use the therapy techniques. You and the teacher will talk about how things went that day at the end of the session. The virtual sessions follow a similar structure, but the therapist does not engage directly with your child.

Our child therapy sessions include the teacher interacting with your child with toys and books. These sessions will last about 45 minutes.

Tell us about the training and strategies we taught you: We will ask you to fill out papers to tell us about your experience with our therapy and what you thought about all of the strategies that we taught you to use with your child.

Additional things we will ask you to do if you are not in the therapy group:

10 therapy sessions after you and your child complete all study activities: We will offer you 10 sessions at the end of the study. You can choose if you want these to be us teaching you the strategies, one of our therapists (study staff) with your child only, or a mix of both types of therapy sessions. Some or all of these sessions can be done virtually over zoom.

1. Expected costs: There are no costs to you for being part of this study.

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- 2. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:** This study requires an 18 month time commitment from you and your child. The time for all of the study activities may be an inconvenience to you. Your child may not like some of the tests or therapy activities. If this happens, that test or activity will be stopped. We will do what we can to keep the personal information in your child's study records private and confidential, but absolute confidentiality cannot be guaranteed. Your information or your child's information may be shared with institutional and/or governmental authorities if you or your child is in danger or if we are required to do so by law.

- 3. Good effects that might result from this study:**
 - a) The benefits to science and humankind that might result from this study.** This study may result in an effective language therapy approach that could be offered in the community to children similar to your child.
 - b) The benefits you might get from being in this study.** Your child may enjoy taking part in tests and activities. If your child receives the therapy, they may talk and understand more language.

- 4. Study results:** Results of the study will only be looked at by the researchers at the end of the entire study and after all families have completed all testing and after the researchers have been able to look at the results (Year 2026). We will not share results of the study with participants. However, if you wish to be informed of the final results you may contact Tatiana Peredo after June 2024 and ask for this information (contact information below).

- 5. Alternative treatments available:** You can continue with any language therapies your child currently receives or seek out additional therapies and still participate in this study. You can also choose not to participate in the study.

- 6. Compensation for participation:** If your child has the necessary skills to be in the study you will receive \$50 for each of the 4 assessment periods that you participate in (\$50 after testing is completed in the next two weeks, \$50 around 6 months from today, \$50 around 12 months from today, \$50 around 18 months from today). If you complete all of the study activities, you will receive an extra \$75 at the end of the study (around 18 months from today).

- 7. Circumstances under which the Principal Investigator may withdraw you from study participation:** If your child is unable to complete the initial testing because he/she is too upset, we might talk to you and decide this study is not a fit for your child. If you miss 3

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appointments and do not contact us ahead of time to reschedule, you will be removed from the study. If you cancel more than 4 appointments that you are not able to reschedule within the study timeframes, you may be removed from the study. However, we are happy to work with you and reschedule any visits you might miss due to illness. If we remove you from the study, we will tell you the reason you are no longer able to be in the study.

8. What happens if you choose to withdraw from study participation? You may withdraw from the study at any time. You will only receive money for assessments that you complete.

9. A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time."

10. Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact **Tatiana Peredo** at **615-322-8160**.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality: All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed.

All sessions of you and/or your child will be video recorded. Videos are deleted from videocameras within 72 hours of your session. All video recordings of sessions with you and/or your child will be kept as confidential as legally possible. Study information will be labeled with numbers and not with the names of you or your child.

All of your personal information and all video files will be kept in locked places or password locked places. Only members of the study team will see the tapes and information about you and your child.

If these video recordings are shown to other researchers and educators at workshops, seminars, or conferences, it will be done only with your knowledge and your permission. Videos and information from tests and questionnaires without yours or your child's name or identifying information will be saved indefinitely on a password protected secure hard drive. The study team will be able to look at information from the study and utilize videos (with your permission) for education and marketing. .

14. Privacy: Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board, Federal Government Office for Human

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Research Protections, if you or someone else is in danger or if we are required to do so by law.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate. If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. **You will get a copy of this form after it is signed if you decide to take part in this study.**

Date

Signature of parent

Consent obtained by:

Date

Signature

Printed Name and Title

PERMISSION FOR USE OF VIDEOTAPES AND PHOTOS

I give permission for videos/images of my child and/or me in this project to be used for training/education and marketing purposes. I understand that neither my name nor my child's name will be given.

____yes ____no

Signature

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PERMISSION FOR FUTURE CONTACT

I give permission for Vanderbilt Kidtalk to contact me about future studies they are conducting. When I am contacted about study possibilities, I can decide at that time about participating in the study or not. I understand that agreeing to be contacted in no way obligates me to be in any study in the future. I understand that they will maintain my name, phone numbers, email address, and home address to contact me, unless I request that my name and information be deleted from the contact list. To be removed from the contact list, I can call (615)322-8160 or email ann.kaiser@vanderbilt.edu and tell them I no longer wish to be contacted about future studies. I will be given a copy of this form for my records.

____yes ____no

Parent or guardian signature

Phone Numbers

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