Addressing Disparities in Language and Social-emotional Skill Acquisition through Literacy Promotion in Primary Care: Literacy Promotion for Latinos Study

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Addressing Disparities in Language and Social-emotional Skill Acquisition through Literacy Promotion in Primary Care: Literacy Promotion for Latinos Study
Principal Investigator: Manuel Jimenez, MD, MS

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you and your child want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to compare the effect of different approaches to primary care literacy promotion on child development. If you take part in the research, you will be asked to complete surveys at 3 different time points over approximately 18 months and your child will be asked to complete language assessments at these time points. Some participants will receive text messages regarding reading with their child and some participants will also be referred to a non-profit organization that will provide additional community resources if needs are identified. Your time in the study will consist of 3 study visits over approximately 18 months. Each visit will take approximately 60 minutes to complete surveys and assessments.

Possible harms or burdens of taking part in the study include a minor risk of loss of confidentially. This risk is reduced by procedures used by the study team including use of secure, research servers. There is also a small risk of psychological discomfort because of the subject matter of parenting. Participation is completely voluntary and participation can be discontinued at any time. Possible benefits of taking part may be reading more often with your child, which can help with their development of language and social-emotional skills.

Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you and your child if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to provide verbal consent. You are not giving up any of your legal rights by agreeing to take part in this research.

Who is conducting this study?
Dr. Manuel Jimenez is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Jimenez may be reached at (732) 235-7875. He is located at Child Heath Institute of NJ 89 French St. New Brunswick, NJ 08901

Sponsor of the Study: National Institutes of Health/ Eunice Kennedy Shriver National Institute of Child Health and Human Development

Why is this study being done?
The purpose of this study is to compare the effects of different approaches to encouraging Latino families to read together on child language and social-emotional development.

Who may take part in this study and who may not?
- Inclusion criteria for this study are:

- Primary caregiver of a child age 6 months to 12 months
- Identifies as Latino
- Primary language English or Spanish
- Cell phone ownership
- Age 18 years or older
- Willing to receive text messages
- Willing to accept being randomly placed into one of three study groups. We do not decide which group you will be in; rather, we conduct a process by computer that is similar to flipping a coin to determine which group you will be in. The groups are:
  (1) Participants who receive a children's book and advice from their pediatrician about reading with their child
  (2) Participants who receive a children's book and advice from their pediatrician and will receive 3 text messages per week and one text request for simple feedback a month
  (3) Participants who receive a children's book and advice from their pediatrician and will receive 3 text messages per week and one text request for simple feedback a month; and will receive referral to a non-profit organization that will assess if they can provide any support services

Individuals unable to provide informed consent will be excluded. Children with multiple congenital anomalies or genetic disorders and previously identified developmental delays will be excluded.

Why have I been asked to take part in this study?
You are being asked to take part in this study because you meet the criteria outlined above.

How long will the study take and how many subjects will take part?
We hope to enroll up to 630 parents and their child. We will ask you to take part in 3 visits which will take around 60 minutes each. Your participation will last around 18 months.

What will I be asked to do if I take part in this study?
Due to COVID-19, we will be conducting the study over the phone and by using video-conferencing software until guidelines allow for in-person visits.

As part of your consent, you agree to be placed randomly in one of these three groups ("random" means that we do not decide which group you will be placed in; rather, we conduct a process by computer that is similar to flipping a coin):

- All parents will receive a children's book and advice about reading with children from their pediatrician as part of usual care. Some parents will receive only this intervention.
- Some parents will also receive 3 text messages per week, plus an additional follow-up text requesting simple feedback each month.
- Other parents will receive these text messages and will be offered referral to Central Jersey Family Health Consortium. This is a non-profit organization that will ask to assess if they can provide you with additional community resources. We will share some basic demographic information with this organization, including your name, phone number, and preferred language. This organization will contact you at enrollment and 9 months later to assess any needs you might have. This organization will ask for your permission to share information with our team about the community resources they suggested. You can decline having this information shared.

Upon enrollment we will ask you to:

- Answer brief survey questions over the phone or video conference. We will provide you with a link to a free video-conferencing app. We will also will provide you with a list of community resources that may be of interest to you.
- We will ask you to video-conference with us 9 months into the intervention and again 18 months into the intervention (toward the end). We will provide you with a link to a free video-conferencing app. At these visits, we will ask you to complete additional surveys. A study staff member will

assess your child's early language skills at these virtual visits. Staff will allow children to refuse to not participate in a particular task.

If and when COVID-19 restrictions on meeting in person are lifted, we will ask to conduct these visits in person at your pediatrician's office around the time of child's well visits.

What are the risks of harm or discomforts I might experience if I take part in this study?
There are minimal risks to participating in the study. The only risk is if your information is somehow accidentally shared with people who are not members of the research team, but there are precautions in place to make sure this does not happen. Data will be kept in a password protected research database and/or in a locked file cabinet at Rutgers Robert Wood Johnson Medical School. Only the principal investigator and the study team will have access to this file. Given that we will be discussing topics like parenting some questions may make you feel uncomfortable. Your participation is completely voluntary and you do not have to answer any questions that you do not want to answer.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be reading more often with your child, which can help their development. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is to not take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study? During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
No, however our research assistants will explain the intent, use, and meaning of survey instruments upon enrollment and will answer any inquiries you may have.

Will there be any cost to me to take part in this study?
No costs for participants are anticipated. However, for those receiving text messages, standard message rates apply with receiving and or sending text messages if you do not have an unlimited text message plan.

Will I be paid to take part in this study?
You will receive $ 150 in giftcard form (e-card or plastic) for taking part in this study according to the following schedule:

- $ 50 at your first visit
- $ 50 at your second visit (9-month visit)
- $ 50 at your third visit (18-month visit)

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Data will be kept separate from identifiers using a unique study ID. The information will be kept on a secure research drive and will be destroyed upon completion of data analysis. Information we gather from the surveys may be used in scientific publications, but if the findings from the study are published, you will not be identified by name.

A description of this clinical trial will be available on 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 website at any time.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). The Certificate does not stop reporting that federal, state or local laws require, such as reporting suspected child or elder abuse, some communicable diseases and threats of harm to yourself or others.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

What will happen to my information collected for this research after the study is over?
After information that could identify you has been removed, de-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you. As required by the National Institutes for Health data sharing policy we may share de-identified information with other investigators who submit a written request to Dr. Jimenez.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study? It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled. You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Manuel Jimenez Child Heath Institute of NJ 89 French St. New Brunswick, NJ 08901.

Once the link between your personal information and data has been destroyed, it will not be possible to withdraw data because there is no link.

Permission to Contact You with Additional Requests to Participate in Research
Please tell us if we may contact you in the future to tell you about other ways you may participate in this research or other research we are conducting by initialing next to your choice.

The investigators may contact me in the future to ask me to take part in more research. Yes ____ No _____

Who can I contact if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor: Dr. Manuel Jimenez, Department of Pediatrics, (732) 235-7875. If you have questions about your rights as a research subject, you can call the IRB Director at (732)235-9806 or the Rutgers Human Subjects Protection Program at (973) 972-1149.

By beginning to participate, you acknowledge that you have received this information, agree to participate in this research, and give parental permission for your child to participate in this research, with the knowledge that you are free to withdraw your participation at any time without penalty.