Duke University Health System

Consent to Participate in a Research Study
El Faro: Addressing Mental Health Inequities among Latinx Children with ADHD in Durham (Aim 3)

TITLE: El Faro: Addressing Mental Health Inequities among Latinx Children with ADHD in Durham (Aim 3)
SPONSOR: Duke Children's Health and Discovery Initiative
PRINCIPLE INVESTIGATOR: John Mitchell, PhD
CO-INVESTIGATOR: Luke Smith, MD
STUDY RELATED PHONE NUMBERS:
Daytime Telephone Number: 919-681-0012 (Mitchell)/ 984-244-2205 (Smith)
24-hour Contact Number: 919-206-0741

CONCISE SUMMARY

The purpose of this study is to improve and test El Faro, a program designed to treat ADHD amongst children of Latino families. As part of the study, you will be asked to complete the 7-week El Faro program, and attend two study visits (one before and one after the program). The program introduces skills to manage your child's ADHD related behaviors and includes standard exercises for practicing skills at home. It will be conducted remotely over Zoom. Each session will last approximately 90 minutes and will occur once a week. During the two study visits, you will be asked to complete questionnaires and assessments related to your and your child's demographic information, medical history, and psychiatric health.

If you agree for you/your child to take part in this study, there may be direct medical benefit to you/your child, however, we cannot guarantee that. We hope that in the future the information learned from this study will benefit other people with ADHD. The risks associated with participating in this study include loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You and your child are being asked to take part in this research study because your child is between 6 to 12 years old and has been diagnosed with ADHD. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if your child is taking part in another research study.

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Dr. John Mitchell and Dr. Luke Smith will conduct the study and it is funded by Duke Children's Health and Discovery Initiative. The sponsor of this study will pay Duke University to perform this research, and these funds may reimburse part of Dr. John Mitchell's and Dr. Luke Smith's salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide for you and your child to participate, Dr. John Mitchell and Dr. Luke Smith will be your doctors for the study and will be in contact with your child's regular health care provider throughout the time that your child is in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to improve and test El Faro, a program designed to treat ADHD amongst children of Latino families.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 30 families (children and their caregivers) will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If you agree for you and your child to be in this study, you will be asked to sign and date this consent form. As part of the study, you will be asked to complete the 7-week El Faro program, and attend two study visits (one before and one after the program).

Visit 1 – Pre-treatment visit: The first study visit will last about two hours and will take place at El Futuro, or remotely over Zoom. During this visit, we will collect information about you and your child's demographic information, medical history, and psychiatric health via questionnaires. You will also be asked to complete some psychiatric assessments. We will use the information collected at this visit to confirm your/your child's eligibility.

We will also ask your child's primary teacher to complete a questionnaire regarding your child's ADHD related behaviors. Therefore, we will ask you to provide the study team with contact information for your child's primary teacher. The study team will mail the questionnaire for the teacher to the school. The correspondence will indicate that the child is undergoing a research study involving attention and we are requesting teacher input. We will not disclose any psychiatric status information. A self-addressed, return envelope will be included for the teachers to return the scale to the study team.

El Faro Program: El Faro is a 7-session behavioral parent training program for Hispanic parents of children with ADHD. The program introduces skills to manage your child's ADHD related behaviors and includes standard exercises for practicing skills at home. The program that will be conducted remotely over Zoom. Each session will last approximately 90 minutes and will occur once a week. The sessions will be recorded and reviewed by a parental advisory board in order to make improvements to the program.

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Visit 2 – Post-treatment visit:
After completing El Faro, you will be asked to complete a post-treatment visit lasting about two hours. During these visits, you will be asked to complete questionnaires and assessments related to you and your child's demographic information, medical history, psychiatric health, and experience participating in El Faro.

Refusing to participate in this study will involve no penalty or loss of benefits to which the subject is otherwise entitled. If you do not sign this consent form, you may continue to receive care at El Futuro or Duke, but not as a part of this study.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study for approximately 9 weeks (whenever you complete the post-treatment visit). You and your child can choose to stop participating at any time without penalty or loss of any benefits to which your child is entitled. However, if you and your child decide to stop participating in the study, we encourage you to talk to your child's doctor first.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You/your child may refuse to answer any of the questions and you may take a break at any time during the study. You/your child may stop your participation in this study at any time. There may be risks or discomforts that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree for you/your child to take part in this study, there may be direct medical benefit to you/your child, as you may learn skills to manage your child's ADHD related behaviors, however, we cannot guarantee that. We hope that in the future the information learned from this study will benefit other people with ADHD.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
If you do not take part in the study, your child may still receive medical care for ADHD at El Futuro or Duke, but not as a part of this study.

WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you and your child is kept confidential, but we cannot guarantee total confidentiality. Your and your child's personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share

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only the minimum necessary information in order to conduct the research. Your and your child's personal information may also be given out if required by law.

As part of the study, results of your and your child's study-related procedures may be reported to the Duke Children's Health and Discovery Initiative and its affiliates. In addition, your and your child's records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of Duke Children's Health and Discovery Initiative, the Duke University Health System Institutional Review Board, and others as appropriate.

You should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your/your child's research record for six years after the study is completed or until your child reaches the age of 21, whichever is longer. At that time either the research information not already in your/your child's medical record will be destroyed or information identifying your child will be removed from such study results at DUHS.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your/your child's name or other personal information will not be revealed.

Some people or groups who receive your or your child's health information might not have to follow the same privacy rules. Once your or your child's information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share your or your child's private information with anyone not involved in the study, the federal law designed to protect your or your child's health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There are no costs to you/your child for participating in the study.

WHAT ABOUT COMPENSATION?
You may be reimbursed up to $200 for your expenses related to your participation (parking, gas, child care and time). You will receive $100 for completing the pre-treatment visit and $100 for completing the post-treatment visit.

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WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you or your child are injured as a result of his/her participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your/your child's Duke physicians to provide monetary compensation or free medical care to you or your child in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. John Mitchell at 919-681-0012 or Dr. Luke Smith at 984-244-2205 during regular business hours and at 919-206-0741 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose for yourself and your child not to be in the study, or, if you agree to allow yourself and your child to be in the study, you may withdraw yourself and your child from the study at any time. If you withdraw yourself and your child from the study, no new data about you and your child will be collected for study purposes other than data needed to keep track of you and your child's withdrawal.

Your decision for yourself and your child not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you and your child are entitled, and will not affect you and your child's access to health care at Duke or at El Futuro. If you do decide to withdraw yourself and your child, we ask that you contact Dr. John Mitchell or Dr. Luke Smith in writing and let them know that you and your child are withdrawing from the study. Their mailing addresses are 2400 Pratt St. Rm. 7035, Durham, NC 27705 and 2020 Chapel Hill Road, Suite 23, Durham, NC 27707, respectively.

We will tell you and your child about new information that may affect your child's health, welfare, or willingness to stay in this study.

The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include if your child needs a treatment not allowed in this study, if you and your child do not follow the study procedures as instructed, or if the study is canceled by the sponsor or IRB. If this occurs, you will be notified and your child's study doctor will discuss other options with you and your child.

Your/your child's data may be stored and shared for future research without additional informed consent if identifiable private information, such as your/your child's name and medical record number, are removed. If your/your child's identifying information is removed from their data, we will no longer be able to identify and destroy them. The use of your/your child's data may result in commercial profit. You and your child will not be compensated for the use of the data other than what is described in this consent form.

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

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. John Mitchell at 919-681-0012 or Dr. Luke Smith at 984-244-2205 during regular business hours and at 919-206-0741 after hours and on weekends and holidays.

For questions about your/your child's rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to my child and me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for my child to be in this study, with the understanding that I may withdraw my child at any time. We have discussed the study with my child, who agrees to be in the study. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Child (if 12 years or older)	Date	Time
_____	_____	_____
Signature of Parent/Guardian	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time