

Supporting Refugee and Immigrant Youth's Mental Health: Examining Effectiveness and  
Implementation of a School-Based Intervention

NCT05208359

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**ANN & ROBERT H. LURIE CHILDREN'S HOSPITAL OF CHICAGO  
AND  
LOYOLA UNIVERSITY CHICAGO  
INSTITUTIONAL REVIEW BOARD**

**Permission for a Child to Participate in a Research Project**

Investigators at Loyola University Chicago and Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's) invite you to consider participating in a research study entitled:

**Study Name:** *Supporting Refugee and Immigrant Youth: Assessing Feasibility, Acceptability, and Impact of a School-based Intervention*

**Sponsored by:** Loyola University Chicago, Catherine DeCarlo Santiago, Ph.D., and Lurie Children's Hospital, Tali Raviv, Ph.D., Rebecca Ford-Paz, Ph.D., Colleen Cicchetti, Ph.D., Stephanie Torres, Ph.D., and Bianca Vargas-Ocasio, M.S.W.

This consent form describes a research study for which your child might qualify being conducted by researchers at Loyola University Chicago and Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's"). Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to allow your child to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as your family before you decide to allow your child to take part in this study. The study staff will also explain the study to you and answer any questions that you may have.

**WHAT IS THE PURPOSE AND GOAL OF THIS STUDY?**

The goal of the STRONG program is to support newcomer immigrant and refugee youth. The purpose of this research study is to understand how well this program helps newcomer students adjust and to function better in school.

**IF I AGREE TO HAVE MY CHILD TAKE PART IN THIS STUDY, WHAT WOULD MY CHILD NEED TO DO?**

If you agree to allow your child to participate in this study, we would ask them to:

- Participate in the STRONG program (see information sheet).
- Your child will be assigned to one of two groups, the Early Group or the Later Group. The assignment will be random, like the flip of a coin. This means that you and your child cannot choose which group to be in and will have a 50% chance of being put in either group. The Early Group will begin meeting soon after you sign this consent and the Later Group will start the program in the spring.
- This study will involve a meeting with you now, a meeting again in about 3 months, and a final meeting in about 6 months to complete some short questionnaires. Questionnaires include questions about your child's feelings, behaviors, their ability to handle difficult situations, and a demographic form. Because we are interested in understanding how

STRONG might be helpful across various newcomer pathways, we would like to ask about your status as a refugee or immigrant on the demographic form. Your answers are voluntary. You can skip any questions that you prefer not to answer. These questionnaires take approximately 20 minutes to complete.

- This study will also involve a meeting with your child now, a meeting again in about 3 months, and a final meeting in about 6 months complete some short questionnaires. During this meeting we will ask your child to answer some questions about how they have been thinking and feeling recently, sense of connectedness to school, views of school climate, and how well they are managing stress or difficulties. These questionnaires take about 30 minutes to complete.
- We will ask your student's teacher to complete a short questionnaire about your child's functioning now, in 3 months, and again in 6 months. These questionnaires will remain confidential and any personal information that identifies your child will be kept confidential. These forms will be kept in a locked cabinet and will not be part of your child's school record.
- At the end of the school year, we would like to record information about your child's attendance, grades and any suspensions from his or her school records. We will obtain these records from your child's school or district office and use this information to help us see if the STRONG program impacts how students perform in school. This is the only purpose it will be used for. No information will be shared with anyone outside of study staff, except as required by law. If you choose not to consent to this portion of the STRONG program (recording your child's school attendance and academic records), your child may still participate in the STRONG program.
- All data will be de-identified through use of assigned identification numbers.
- You and your child will each receive a \$30 gift card for your time in completing questionnaires at each meeting.

### **ARE THERE BENEFITS (GOOD THINGS) TO TAKING PART IN THE STUDY?**

The STRONG program may help your child's adjustment process and allow them to function better in school and at home. By evaluating how well the program works, we hope to improve our understanding of how best to help newcomer school-aged children.

### **WHAT ARE THE POSSIBLE RISKS, SIDE EFFECTS, OR DISCOMFORTS (BAD THINGS) RELATED TO THE STUDY?**

Although not designed to do so, there may be times when answering the questionnaires may be upsetting to you or your child. Any of the questions can be skipped or you can stop the questionnaire at any time. Skipping questions or deciding not to finish the questionnaire will not affect your child's status in the group or as a student.

### **WHAT OTHER OPTIONS DOES MY CHILD HAVE?**

If you do not want your child to be in the STRONG program, you may contact the school counselor or a community agency to receive services.

**WHAT ARE THE COSTS RELATED TO THIS STUDY?**

There are no costs associated with participating in this study. The program is offered free of charge.

**WILL I BE TOLD ABOUT NEW INFORMATION?**

We will tell you if we learn new information that may make you change your mind about your child being in this study.

**WILL THERE BE COMPENSATION FOR MY CHILD'S PARTICIPATION?**

Your child (age 11 and up) will receive a gift card worth \$30 for their participation in each survey (\$90 in gift cards total). In addition, you will receive a gift card worth \$30 for your participation in each survey (\$90 in gift cards total).

**WHO WILL KNOW ABOUT WHAT MY CHILD DID IN THE STUDY OR HAVE ACCESS TO MY CHILD'S PRIVATE INFORMATION?**

Any information that is obtained with this study that can identify your child will remain confidential. We will not tell anyone your child's answers or your answers to the questionnaire, except:

- 1) If we determine that you or your child might be harmed or might harm others, we will give information about you or your child to people who could provide protection from that harm. (For example, if we determine that there is a medical emergency, we will give such information to emergency medical technicians.)
- 2) If you or your child tells us about the abuse of a child or of an old person, including the abuse of your child, we must report it to a study leader, who will report it to the authorities such as the Department of Child and Family Services. ("Abuse" includes physical, sexual, or emotional abuse and neglect).

Only the following are allowed to see the information that you give us:

- Loyola University study staff and Loyola University Chicago Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who participate in research studies at Loyola University).
- Lurie Children's study staff and Lurie Children's Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who participate in research studies at Lurie Children's).

Following the study, the information you provide may be used for research purposes. However, no identifying information from you or your child will be included in the research. Once the research is over, the identifying information is destroyed.

Your child's teacher will know they are participating in the program and may fill out a form about how your child is doing, but will not know any details about what happens in the program. The teacher's answers will be kept confidential from other school staff members.

Your child will not be individually identified in any written or oral reports of this study to professionals or the media.

***In addition to the above protections, this study has a certificate of confidentiality:***

*The study is covered by a Certificate of Confidentiality from the U.S. government. It adds special protections for your/your child's information. This document says that the researchers cannot be forced to identify you/your child even if this is asked for by a court order. If you/your child need/needs medical help, or if you/your child could harm yourself/themselves or others, your/your child's information may be shared. The researchers may also share your/your child's information if it is required by law. For example, researchers must follow the laws about reporting suspected child abuse and infectious diseases. The government may also see your/your child's information if there is an audit of this study. You can still ask the researchers to share your/your child's information, if needed.*

*This document does not stop you from choosing to share your/your child's information. If you want your/your child's information shared with an insurer, medical care provider, or any other person not part of this research, you must give consent to the researchers to share it.*

**WHAT ARE MY CHILD'S RIGHTS AS A PARTICIPANT?**

You and your child can choose whether to be in the STRONG program or not. Your child cannot participate unless you give permission. Even if you give permission, your child has the right to choose not to be in the program. If you and your child volunteer to be in the program, you may stop at any time without consequences of any kind. Choosing not to take part, or stopping, will not change your child's grades or other things at school in any way. You or your child may also refuse to answer any questions and still remain in the program.

By signing this consent form, you agree to have your child take part in this study. You are not giving up any of you or your child's legal rights. Your child can stop participating in this study at any time. Your choice will not affect your child's regular care.

You can take your child out of this study at any time. Neither you nor your child will be penalized for doing this. Your child's treatment by, and relations with the physician(s) and staff at Lurie Children's, now and in the future, will not be affected in any way if you do not want your child to take part in this study, or if you enter your child into the study and then withdraw your child from it.

**Additional Information:**

**Who can answer my questions about this study?**

If you have any questions about the research methods, you should contact the principal investigator, Catherine DeCarlo Santiago, Ph.D. at 773-508-2712 or [csantiago4@luc.edu](mailto:csantiago4@luc.edu) or you may contact Rebecca Ford-Paz, Ph.D. at 312-227-6039 or [rfordpaz@luriechildrens.org](mailto:rfordpaz@luriechildrens.org).

If you have any questions about your rights as a research subject, wish to discuss problems, concerns, and questions, obtain information, or offer input to someone who is not directly involved with this study, you may contact the Loyola University Office of Research Services at (773) 508-2689.

*You may also contact the Ann & Robert H. Lurie Children's Hospital of Chicago, IRB Office at (312) 503-7110 or via email at [IRB@luriechildrens.org](mailto:IRB@luriechildrens.org).*

Parents please be aware that under the Protection of Pupil Rights Act. 20 U.S.C. Section 1232(c)(1)(A), you have the right to review a copy of the questions asked of or materials that will be used with your students. If you would like to do so, you should contact Catherine DeCarlo Santiago, Ph.D. at 773-508-2712 to obtain a copy of the questions or materials.

You will be given a copy of this consent form.

Please **CHECK** each choice below indicating YES if you agree and NO if you do not agree:

☐ YES – I AGREE to allow my child to participate in the STRONG Program.

☐ NO – I DO NOT AGREE to allow my child to participate in the STRONG Program.

☐ YES – I AGREE to allow the research team to collect a short questionnaire from my child's teacher (now, in 3 months, and again in 6 months).

☐ NO – I DO NOT AGREE to allow the research team to collect a short questionnaire from my child's teacher (now, in 3 months, and again in 6 months).

☐ YES – I AGREE to allow the research team record information about my child's attendance, grades and any suspensions from his or her school records

☐ NO – I DO NOT AGREE record information about your child's attendance, grades and any suspensions from his or her school records.

☐ YES – I AGREE to participate in completing some questionnaires about my child's feelings and behaviors, my own thoughts and feelings, and my relationship with my child (now, in 3 months, and again in 6 months).

☐ NO – I DO NOT AGREE to participate in completing some questionnaires about my child's feelings and behaviors, my own thoughts and feelings, and my relationship with my child (now, in 3 months, and again in 6 months).

☐ YES – I AGREE to allow my child to participate in completing some questionnaires about his/her feelings, thoughts and behaviors (now, in 3 months, and again in 6 months).

☐ NO – I DO NOT AGREE to allow my child to participate in completing some questionnaires about his/her feelings, thoughts and behaviors (now, in 3 months, and again in 6 months).

## SIGNATURES

The study has been explained to me and I have read this consent form, have been given the opportunity to consider my decision, and have had all my questions answered. I agree to have my child take part in this research study as explained in this consent form.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent or Legally Authorized Representative (LAR)

\_\_\_\_\_  
Printed name of child

\_\_\_\_\_  
Printed name of parent/LAR

\_\_\_\_\_  
Relationship to child

I certify that I have explained the above to the parent(s) and/or surrogate(s) and believe that the signature(s) was affixed freely. I also agree to answer any questions that may arise.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

**PI SIGNATURE** *(should be obtained as soon as possible, generally within 7 days):*

I am aware that this parent has consented for their child to participate in this study. As the person responsible for the conduct of the study, I am available to answer questions and will oversee the child's participation in this study.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Principal Investigator

## INTERPRETER/WITNESS SIGNATURE:

*Complete only when obtaining consent from a non-English speaking parent/LAR: Use a translated short form along with this document. The participant should sign the short form; the interpreter/witness should sign both; and the person obtaining consent should sign this form.*

By signing this consent and the translated short form, I attest that the elements of informed consent were presented verbally to the parent(s)/LAR in their native language. They were given the opportunity to have all questions answered. Consent was obtained freely as is indicated by their signature on the short form.

\_\_\_\_\_  
Printed Name of Interpreter/Witness  
*May be the interpreter, but cannot be the same as the person obtaining consent.*

\_\_\_\_\_  
Signature of Interpreter/Witness  
*Or the unique ID# of the phone interpreter and their company name.*