

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**

**Child Assent to Participate in a Research Project**

**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.

1. My name is *[RESEARCH STAFF NAME]*. We want to tell you about a research study at Loyola University Chicago and Lurie Children's Hospital. Research studies help us find better ways to take care of and treat children. Taking part in a research study is voluntary. It is your choice to take part in this research study.
2. We are asking you to take part in this skill-building program for students like you called the STRONG program.

**What will happen in this study?**

- If you agree to be in this study, we will ask you to come to a group that meets one time each week for 10 weeks. The groups are held during your class time. During the group you will learn coping skills and talk about your journey to the United States. This group will have 4-8 students from your school and will be led by a school counselor.
- In the group, you will learn some new ways to feel better, and will be able to practice them with the counselor and with other children in the group. You will also meet alone with the school counselor to talk about your journey.
- You 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 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 form and the Later Group will start the program in the Spring.

- If you are 11 years or older, we will ask you to complete some short questionnaires. Questions will include how you have been thinking and feeling recently, how you feel about school, and how well you are managing stress or difficulties. These questions help us to understand how the program is working for you. This questionnaire will take about 30 minutes and will be given to you 3 times: the first time will be now, then again in about 3 months, and a final meeting in about 6 months.
- We will also ask your parent and school teacher to answer questions three times, at the same times as you fill out the questionnaire. This means your teacher will know you were in the group, but no one else at school will see your teacher's answers.
- Answering the questions may make you feel upset. You can skip any question or stop answering questions at any time. Skipping questions or stopping the questionnaire won't change your grades or anything else at school.
- If you are in the STRONG program, we will ask you to talk about your journey to the United States which may be stressful, and you may feel upset. Talking about this journey should make you feel better over time though.
- Remember, you don't have to take part in any part of the program, and you can stop being in the program at any time, and it won't change anything about your standing at your school or your grades.
- The STRONG program may help you feel better so that you are able to do better in school and at home.
- Both you and your parent will each be receiving a \$30 gift card for your time in completing the questionnaires we talked about in each meeting.

3. If you are in the program, the counselor leading the group may take some notes about how you are doing in the group. The notes are kept private. We will use what you tell us on the questionnaires only for the program. We will not tell anyone that you are in the program or tell anything about you to anyone outside of the program. However, there are exceptions to this.

- If we need to protect you from harm. We will give information about you to others if we need to protect you and keep you safe (for example, a medical emergency or if you are going to harm yourself).
- If you tell us about someone hurting a child or an older person, or that someone is hurting you, we must report it to a study leader, who may

- report it to the authorities, like the Department of Child and Family Services. ("Abuse" includes physical, sexual, or emotional abuse, and neglect.)
- Also, we will ask the other children in the group to not talk about what is said in the meetings, but we cannot guarantee that they will keep everything private.

***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.*

We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes" you can still decide not to do this.

If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop.

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call Catherine DeCarlo Santiago, Ph.D. at 773-508-2712 or [csantiago4@luc.edu](mailto:csantiago4@luc.edu), or you can call Rebecca Ford-Paz, Ph.D. at 312-227-6039 or [rfordpaz@luriechildrens.org](mailto:rfordpaz@luriechildrens.org) or ask us at any time.

**DO YOU WANT TO PARTICIPATE IN THIS STUDY?***(Research staff will check appropriate box depending on child's response)*

YES

NO

**SIGNATURE OF STUDY PARTICIPANT**

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Signature of Participant

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Date**SIGNATURE OF PERSON OBTAINING ASSENT**

In my judgment the participant is voluntarily and knowingly agreeing to participate in this research study.

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Signature of Person Obtaining Assent

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Date

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Printed Name of Person Obtaining Assent

Student General Assent  
Version Date: 10/19/2021

Loyola University Chicago: Lakeside Campuses  
Institutional Review Board for  
The Protection of Human Subjects

Date of Approval: 09/08/2022

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