Sustainment of Mental Health Supports in Under-Resourced Urban Schools

NCT04869657

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Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: Sustainment of Mental Health Supports in Urban Schools

Version Date: February 5, 2024

Principal Investigator: Ricardo Eiraldi Telephone: 215-590-7759

Your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff.

Study Overview

Your child is being asked to take part in this research study because they are in 4th through 8th grade in the participating school district and have demonstrated some behavioral or emotional difficulties.

The purpose of this study is to figure out the best way to help school staff and students promote positive behavior at school.

If you and your child agree to take part, their participation will last for 8 to 12 weeks. Your child will need to attend regular group sessions that offer support for students who struggle with their emotions or behavior. These meetings will be offered at school by a counselor. They will provide valuable information about how to help your child with your emotions and behavior. As a participant in the research your child will:

- Attend meetings either on a weekly basis
- Complete questionnaires about their academics and social skills
- Have questionnaires completed by their primary caregiver, their group leader, and one of their teachers.

The main risks of this study are temporary embarrassment/discomfort that comes from discussing sensitive things.

Your child may benefit by learning ways to better handle their emotions.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you and/or your child can leave the study at any time.

Please see below for additional details about the study.

How many people will take part?

About 560 students across up to 16 schools in the participating school district will take part in this study over the course of 5 years.

What is involved in the study?

If you and your child agree to take part, your child will be enrolled in a program which best meets their needs. The programs all offer support for students who struggle with their emotions or behavior, and will be offered at school by a counselor. They will provide valuable information about how to help your child with their emotions and behavior.

What are the study procedures?

The study involves the following tests and procedures:

Intervention Sessions: Participation in the intervention consists of either 8 or 12 group sessions. All group sessions are weekly and will be scheduled during your child's lunch hour or at a time when it does not interfere with their main subjects. If the session occurs over lunch, your child will be permitted to eat during the session. Each group session that your child participates in will be audio-recorded. We will not review your child in the recording. The reason the sessions are recorded is so that the research team can review them to be sure that they are being done the way they should be. The recordings will be stored in a locked file cabinet at Children's Hospital of Philadelphia, until they can be electronically stored on a secured web space, which are only accessed by study team members and are protected with a username and password. They will not be shown to your child's teachers or used in the grading system. The recordings are intended to be for research purposes only, **but may be used in the future for educational activities, like training future staff members or presenting to professional audiences**.

Questionnaires: Before and after the program, we will collect information about your child's academic and social skills. Also, we will ask your child's primary caretaker, one of their teachers, and their group leader to complete questionnaires to inform us about how they're doing in school, their behavior, and social skills. If we are not able to meet in person to do this, we will complete the questionnaires via phone call, or video chat. Any technology used to obtain the responses will be secure to ensure privacy. Any interactions with study staff during questionnaires will not be recorded.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risks associated with the intervention sessions:

There are no known physical or legal risks to participating in the interventions.

- As is the case with all therapeutic programs, one risk of participating in this study is that the program might not be helpful for every participant. If your child is still having difficulty with behavior or emotions after they have finished the program, or if you are interested in other programs, we will work with you to identify appropriate referrals in the community or through the Department of Child and Adolescent Psychiatry and Behavioral Sciences (DCAPBS) of Children's Hospital of Philadelphia.
- Another potential risk of participation is that participants may become upset during the coping skills training. We will try to protect against the risk of these feelings, which could happen when your child talks about sensitive things. If your child is uncomfortable, we will be sure to support them and remind them that they do not have to participate if they do not want to.

Risks associated with questionnaires:

There are no physical risks but your child might experience momentary embarrassment or discomfort. Your child does not have to answer any questions that make your child too uncomfortable. If members of the study team or your child's counselor or teacher notice a change in your child's mood or emotions, they will tell the research team members and may remove your child from the study, so that they may assist you in getting the right treatment for your child. They will work with you and your child to be sure you child is connected to the right kind of help.

Are there any benefits to taking part in this study?

Your child may benefit from this study by receiving continuous monitoring and help with their disruptive behavior and/or anxiety problems. However, we cannot guarantee or promise that your child will receive any direct benefit by participating in this study. The knowledge gained from this research may help researchers determine the type of support that therapists need in schools in order to deliver the best services for children with disruptive behavior and/or anxiety problems.

Do you need to give your consent in order to participate?

If you and your child decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record. Your child will also sign a form stating that they also want to participate.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You and your child do not have to take part if you choose not to.

If you and/or your child decide not to take part or change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You and/or your child can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?

The study doctor may take your child off of the study if:

- Their condition worsens.
- The study is stopped.
- They cannot meet all the requirements of the study, i.e. are missing too many treatment sessions
- New information suggests taking part in the study may not be in your child's best interests.

What choices do you have other than this study?

There are options for you other than this study including:

- Receiving behavior therapy care in your community or school outside this study.
- You may discuss other options available to you with your counselor or teacher.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about your child will be collected. This will include private information from questionnaires and audio-recorded intervention sessions. This will include information such as age, grade level, gender, race/ethnicity, and socioeconomic status. We will also collect information about your child's academic performance and behavioral and social functioning. We will do our best to keep your child's personal information private and confidential. However, we cannot guarantee absolute confidentiality and your child's personal information may be disclosed if required by law. The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your child's identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP, Devereux and UPenn;

- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- Groups monitoring the safety of this study;
- The National Institute of Mental Health who is sponsoring this research;

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

The identifiable information from this study will be destroyed 6 years after the study is completed.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you and/or your child will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data could be shared for:

- other scientific research;

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institutes of Mental Health may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your child's health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Ricardo Eiraldi
Children's Hospital of Philadelphia
Roberts Center for Pediatric Research
2716 South Street, Room 8293
Philadelphia, PA 19146

In the letter, state that you changed your mind and do not want any more of your child's health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information:

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

Financial Information

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

Will you be paid for taking part in this study?

- Your child's primary caregiver will be paid $10 for their time and effort in completing the questionnaires two times during study participation.
- Children/participants will not be paid for participating, but they will be given a small gift or snack so that we can thank them for their time in completing the surveys before and after the group sessions. They will also receive small gifts (e.g., pencils, notebooks, small toys) for participating and reaching certain goals in group sessions.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

Who is funding this research study?

The National Institute of Mental Health is providing funding for this study.

What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. Ricardo Eiraldi at 215-590-7759. You may also talk to your child's teacher or counselor if you have questions or concerns.The Institutional Review Board (IRB) at Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and

welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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

Sharing Data with the National Institutes of Health (NIH)

Why will my data be shared with the National Institutes of Health (NIH)?

The National Institute of Mental Health is funding this study. As part of the National Institutes of Health (NIH), the NIMH's goal is to maximize the benefits that come from the research.

The NIH repository stores information anddata from many studies. The NIH then shares that information with researchers. We will send the information about your child and the other participants to a repository at the NIH. The information will be de-identified (no names or other direct information about your child will be included). The NIH will not be able to re-identify you or any other individual.

The NIH intends to share the collected information with other researchers for future research. The researchers who receive data must promise to keep the data confidential and to use it only for the purpose approved by NIH. They must also promise to not try to re-identify anyone.

Risks Associated with Sharing Data with the NIH

There are risks associated with sharing your data with the NIH but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you. If that happened, it's possible that you and/or your child could experience stress, anxiety or embarrassment.

Benefits Associated with Sharing Data with the NIH

Sharing your information for future research will not directly benefit your child. It is hoped that it will lead to a greater understanding of the interaction between mental health interventions and your child's mental health. This knowledge could help others in the future.

Controlled or Unrestricted Access

The data about you will either be made available by the NIH through controlled access or unrestricted. Controlled access means the data are made available for other research only after investigators have obtained approval from NIH to use the requested data for a particular project. Data for unrestricted access are publicly available to anyone.

What will be done with my data when this study is over?

Your child's data will not be used for any future research after this study is complete.

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Documentation of Verbal Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

Name of Subject

The research study and consent form was explained to:

Person Providing Consent	Relation to subject: ☐ Parent ☐ Legal Guardian ☐ DHS Officer

The person who provided consent confirmed that all of their questions had been answered and they agreed to their/their child's participation in this research study.

They confirmed that they were legally authorized to consent to their child's participation.

They agreed to let CHOP use and share their child's health information.

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date