Evaluation of a Remote Training Strategy for School Personnel

NCT05034198

September 9, 2022

Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: **Evaluation of a Remote Training Strategy for School Personnel**

Version Date: September 9, 2022

Consent Name: Student Intervention

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

You, or 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. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Study Overview

You have been invited to take part in this research study because you are in 4th through 8th grade in a school that is serving rural communities and have demonstrated some behavioral or emotional difficulties.

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

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

- Attend meetings either on a weekly or daily basis
- Complete questionnaires about your academic and social skills
- Have questionnaires completed by your primary caregiver and one of your teachers

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

You may benefit by learning ways to better handle your 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 can leave the study at any time.

Please see below for additional details about the study.

What is the purpose of this research study?

The purpose of this research study is to help your school support students who may experience some behavioral or emotional difficulties.

What is involved in the study?

If you agree to take part, you will be enrolled in an intervention which best meets your needs. The interventions offer support for students who struggle with their emotions or behavior and will be offered to you at school by a school counselor or other school staff member. The interventions will provide valuable information about how to help you with your emotions or behavior.

How long will you be in this study?

If you agree to take part, your participation will last between 8 and 12 weeks. Each week, the group session will meet for 40 minutes (or one class period during the school day). If you are not in a group, you will meet with a teacher at the beginning of the school day and then again at the end of the school day until you show improvement.

How many people will take part?

About 312 students across 24 schools located in rural areas will take part in this study over the course of 3 years. Additionally, each school will have three behavioral health staff, and one school administrator participate for one year.

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, or 2 daily brief (5 minutes) individual meetings for a few months. All group sessions are weekly and will be scheduled during your lunch hour or at a time when it does not interfere with your main subjects. If the session occurs over lunch, you will be permitted to eat during the session. Each group session that you participates in will be audio-recorded. We will not evaluate you 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 (and/or uploaded) on a secured web space, which is only accessed by study team members and is protected

with special access permissions (username/password). They will not be shown to your 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 at professional meetings**.

Questionnaires: Before and after the program, we will collect information about your academic and social skills. Also, we will ask your primary caretaker and one of your teachers to complete questionnaires to inform us about your behavior and social skills. We will complete the questionnaires via phone call, video chat, or they will be provided via email. 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 it might not be helpful for every participant. If you are still having difficulty with behavior or emotions after you have finished the program, or if you are interested in other programs, we will work with you to identify appropriate referrals in your community.
- 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 you talk about sensitive things. If you are uncomfortable, we will be sure to support you and remind you that you do not have to participate if you do not want to.

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

Are there any benefits to taking part in this study?

You may benefit from this study by receiving continuous monitoring and help with your disruptive behavior and/or anxiety problems. Information from this study may directly benefit participants by guiding the appropriate training design and planning for each participant. However, we cannot guarantee or promise that you 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 counselors and mentors need in schools in order to deliver the best services for children with disruptive behavior and/or anxiety disorders

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

If you decide to participate in this study, you must provide verbal consent and a member from the study team will document your consent. A copy of the consent form will be emailed to you to keep as a record.

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 do not have to take part if you choose not to.

If you 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 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 you off of the study if:

- Your condition worsens.
- The study is stopped.
- You 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 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 you 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 academic

performance and behavioral and social functioning. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality, and your 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 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 and Devereux;
- 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 Agency for Healthcare Research and Quality who is sponsoring this research;
- If you agree, your data will be shared through databases that may be publicly available to anyone. The data will not include identifiers like your name, medical record number or date of birth. To use your data, researchers must promise not to try to re-identify you. You can tell us at the end of this form whether you will allow us to share your data in this way;

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 verbally agreeing to participate, 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.

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 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 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, they will be withdrawn from the study.

Financial Information

Will you be paid for taking part in this study?

- Your primary caregiver will receive $20 for their time and effort in completing the questionnaires two times during study participation.

- You will receive small gifts or snacks so that we can thank you for your time in completing the surveys before and after groups sessions. You will also receive small gifts (e.g., pencils, notebooks, small toys) for participating and reaching certain goals in group sessions.

Who is funding this research study?

The Agency for Healthcare Research and Quality is providing funding for this study.

What if you have questions about the study?

If you have questions about this study, call the study doctor, Dr. Ricardo Eiraldi at 215-590-7759. You may also talk to your teacher or counselor if you have questions or concerns.

The Institutional Review Board (IRB) at The 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.

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

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