

Patient Centered Enhancements in School Behavioral Health: A Randomized Trial

NCT number: NCT03901274

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RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: Patient-Centered Enhancements in School Behavioral Health: A Randomized Trial

Study No.: HP-00085471

Principal Investigator: Dr. Sharon Hoover, Ph.D., (410)-706-4851
Dr. Mark Weist, Ph.D., (803)-777-0449

Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

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- We are asking you and your child to be a part of a research study. It is important that you know why we are doing this study and what you will be asked to do. Please take your time and read the information below. Please ask your child's mental health clinician if you have any questions at any time.

CONCISE SUMMARY:

The purpose of this research study is to investigate mental health services in schools, and particularly how students, families, clinicians, and communities can work together to

PURPOSE OF STUDY

- The purpose of our study is to:
 1. Help students know more about what mental health is and is not
 2. Help students get mental health services when they need them
 3. Help students, families, mental health clinicians, and communities work together to make students feel better and do better in school
- You are being asked to be part of the study because we believe that we have a lot to learn from you about how to talk to students about mental health, how to encourage students to use them, and how to make other students feel and do better in school
- Approximately 600 students will participate in this study in Maryland and approximately 1,400 participants will participate overall

PROCEDURES

- As part of this study, your child's mental health clinician has had one of two types of special training. Both trainings focus on therapy practices that research has found to be most effective, ways to work collaboratively with families, and ensure the quality of mental health services. These trainings are designed to make therapy sessions better for you and your child with no anticipated negative impact on normal care
- Your child's mental health clinician was chosen randomly to participate in this special training
- We are asking you and your child to take sets of surveys throughout the study
 - At your first therapy session
 - Every three months
 - At your last therapy session
 - A set of surveys is 6-7 surveys taken at one time

- We may also ask you and your child to take the set of surveys again when your child is in high school
- Your child will take each set of surveys on an I-Pad or tablet
- You will take your first set of surveys on an I-Pad or tablet
- You will be given the option to decide how you want to complete your follow-up surveys
 - Emailed to you
 - Pen and paper
 - Phone call
 - A link texted to you
- Each set of surveys will take about 60 minutes to complete
- We will ask your child questions about these topics:
 - Their relationships (e.g., with friends, parents, and other adults)
 - “I go out to places with my friends.”
 - “I have a good relationship with my father.”
 - How they do in school
 - “I get good marks in reading/writing/English.”
 - “I get good marks in Math/Arithmetic.”
 - Things they help with at home
 - “I keep my room and belongings tidy.”
 - “I help with cleaning up after meals.”
 - How much they like their therapy sessions
 - “Did you get the kind of services you wanted?”
 - “How satisfied are you with the amount of help you received?”
 - What they know about mental health
 - “Mental health and mental illness both involve the brain and how it functions.”
 - “Feelings are controlled mostly by the heart.”
- We will ask your child questions about these topics:
 - Your participation in your child’s therapy
 - “How much did you ask your child’s mental health clinician questions?”
 - “How much did you agree with the plan for what you and your child will do at home before the next appointment?”
 - Whether or not you like your child’s therapy
 - “To what extent has our program met your needs?”
 - “I like spending time with my child’s mental health clinician.”
 - If the therapy sessions are helping you and your child
 - “Help us understand how you have been feeling by rating how well you have been doing in the following areas of your life: personal well-being, general sense of well-being.”
 - What you know about mental health
 - “Mental health can be improved by leading a physically healthy life.”
 - “If a person feels sad for a few days in a row, they likely have depression.”

- Finally, your child's school records for attendance (including lateness), discipline referrals (i.e., suspension, expulsion), and grades will be shared with the research team.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

- If you participate we will ask you will be responsible for taking sets of surveys throughout the study
 - At your first therapy session
 - Every three months
 - At your last therapy session
 - A set of surveys is 6-7 surveys taken at one time
 - We may also ask you and your child to take the set of surveys again when your child is in high school

POTENTIAL RISKS/DISCOMFORTS:

- The risk that something bad will happen in this study is very low
- Some of the questions might make you feel uncomfortable
 - Skip any questions you do not feel comfortable answering
 - Let your child's mental health clinician know if you were uncomfortable while doing the survey
 - Loss of confidentiality will be minimized by storing data in a locked office and locked cabinet. Also, electronic data will be de-identified so it cannot be linked with individual participants

POTENTIAL BENEFITS

- As part of this study, your child's mental health clinician has had special training that will make the therapy sessions better for you and your child
- What we learn has the potential to improve student services in your school district
 - With your help, we think we can make school better for other students
 - We hope that this will make you feel good!
- You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study.
- You need to decide if your child's participation in this research study is in your child's best interest

ALTERNATIVES TO PARTICIPATION

- To choose not to take care in this study, tell your child's clinician
- If you and your child choose not to take part, your therapy sessions will continue as usual

COSTS TO PARTICIPANTS

- It will not cost you anything to be part of this study

PAYMENT TO PARTICIPANTS

- If you and your child choose to participate:
 - We are going to give you \$20 for each set of surveys you complete!

- We are going to give your child a small prize valued at \$5 for each set of surveys they complete!

CONFIDENTIALITY AND ACCESS TO RECORDS

- You and your child's answers to the questions will be kept confidential
- We will use number codes instead of names on all of your answers
- Your answers will be kept on a password protected computer
- Only the people doing the research will see your answers
- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.
- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Dr. Sharon Hoover at (410)-706-4851
- You are allowed to start the study and stop later on
- You can tell your mental health clinician that you do not want to be in the study or want to stop at any time
- Nothing bad will happen if you do not want to be in the study
- Your child will be allowed to meet with the mental health clinician even if you do not want to be in this study

CAN I BE REMOVED FROM THE RESEARCH?

- The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff or complete important surveys. The sponsor can also end the research study early. Your mental health clinician will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB).

Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Checking the box below indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this consent form.

Please check the boxes below to demonstrate if you agree for you and your child to participate in this study:

- I agree to participate in this study.
- I do not wish to participate.
- I give permission for my child to participate in this study.
- I do not give permission for my child to participate in this study.

RESEARCH ASSENT FORM

Protocol Title: Patient-Centered Enhancements in School Behavioral Health: A Randomized Trial

Study No.: HP-00085471

Principal Investigator: Dr. Sharon Hoover, Ph.D., (410)-706-4851
Dr. Mark Weist, Ph.D., (803)-777-0449

Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

We want to tell you about a research study we are doing. A research study is a way to learn information about something.



We would like to learn more about how to improve how people understand mental health in schools. Mental health is all about how we think, feel, and behave.



You are being asked to join the study because we believe you can help us understand mental health in schools.

If you agree to join this study, you will be asked to:

- Take sets of surveys during your therapy sessions
 - At your first therapy session
 - Every three months
 - At your last therapy session
 - A set of surveys is 6-7 surveys taken at one time
- We may also ask you to take the set of surveys again when you are in high school
- You will take each set of surveys on an I-Pad or tablet
- Each set of surveys will take about 60 minutes to complete

- We will ask you questions about these topics:
 - Yourself
 - “I am stubborn.”
 - “How are you doing?”
 - Your relationships (e.g., with friends, parents, and other adults)
 - “I go out to places with my friends.”
 - “I have a good relationship with my father.”
 - How you do in school
 - “I get good marks in reading/writing/English.”
 - “I get good marks in Math/Arithmetic.”
 - Things that you help with at home
 - “I keep my room and belongings tidy.”
 - “I help with cleaning up after meals.”
 - How much you like your therapy sessions
 - “Did you get the kind of services you wanted?”
 - “How satisfied are you with the amount of help you received?”
 - What you know about mental health
 - “Mental health and mental illness both involve the brain and how it functions.”
 - “Feelings are controlled mostly by the heart.”



- The risk that something bad will happen in this study is very low
- If some of the questions make you feel uncomfortable:
 - That is okay
 - Skip the question
 - Tell your mental health clinician





We do not know if you will be helped by being in this study. We may learn something that will help other children feel and learn better some day.



You do not have to join this study. It is up to you. You can say okay now, and you can change your mind later. All you have to do is tell us. No one will be mad at you if you change your mind.

Anything we learn about you from this study will be kept as secret as possible.



If you have any questions, go ahead and ask your mental health clinician.





Thank you for reading this information and helping with this study!



If you want to be in this study, please check the box below. You will get a copy of this form to keep for yourself.

I agree to participate in this study.

I do not wish to participate.

Consent Agreement

Title of Study: Partnering for Student Wellness

Principal Investigator: Mark Weist, School Behavioral Health Team, University of South Carolina

Phone: 803-777-0449

Email: weist@mailbox.sc.edu

Background

You and your child are being invited to participate in a research study. Before making the decision to participate in this study, it is important that you understand the purpose of the study and your role. Please carefully read the following information. Please ask your counselor if anything is not clear to you or if you would like more information.

Purpose

[REDACTED] Schools and [REDACTED] Schools are partnering with the University of South Carolina (USC) and the University of Maryland Baltimore (UMB) Center for School Behavioral Health on a research project to investigate how the understanding of mental health services in schools can be improved. This 5-year research project will examine how improving the understanding of mental health decreases stigma in a way that will facilitate access to mental health services and support higher academic gains.

At some schools, we are trying new ways for school staff to work together with counselors, parents, and community leaders. Your child's school staff, counselor, parent leaders, and community leaders will assist with development of these strategies to improve family-community-school collaboration and students' perception of mental health topics.

Study Procedure

Your expected time commitment for this study is 30-45 minutes for each of three survey sessions. The surveys will occur at intake (when you enroll in the study), 90 days later (3-month follow-up), and another 90 days later (6-month follow-up).

Periodically throughout the school year, you and your child will be asked to complete various questionnaires, or surveys. Using a tablet or link emailed to you, you and your child will answer questions relating to engagement and satisfaction with mental health services, the impact of services on various outcomes, and follow-up effects from mental health services. You and your child will also be asked to answer questions about counseling sessions and mental health knowledge. Your child will complete surveys at school with their counselor; however, you will receive a survey link via email for the 3-month and 6-month follow up surveys.

Finally, your child's school records for attendance, referrals for behavior problems, and grades will be shared with the study team. Just like survey responses, your child's name will not be shared. This information will help us to understand whether students experience any changes in those areas while they are part of the study.

Risks

Participation is considered low risk outside of those expected in a typical counseling experience. Any risks may include discomfort when answering the questions. If you or your child feel uncomfortable about sharing your experiences, you may skip any question you do not want to answer. Please inform your clinician of any discomfort experienced when completing the survey.

Voluntary Participation

Participation in this study is your choice, and there is no penalty for not participating. You do not have to complete any survey and you may stop at any time. If you stop completing a survey, there will be no cost or loss of services, or negative outcomes.

Payments

If you choose to participate in this project, you will receive a \$20 electronic gift card for each set of surveys you complete (intake, 3-month, and 6-month follow-up). Your child will receive a token of appreciation for each set of surveys they complete.

Benefits

There will be no direct benefit to you by participating in this survey. However, we hope that what we learn will improve programs in your district and that you may have positive feelings about contributing to the important work of the study; improving schools, programs, and services for other or future students.

Alternative Procedures

If you do not want to participate in this study, please inform your clinician and your child will continue with typical counseling sessions.

Confidentiality

All of the information provided in this survey will remain completely anonymous and confidential. All information will be coded with a number so that names will not be present in any of your records. All of your information will be stored on password-protected computers. Only study personnel will have access to your information unless we learn of clear and imminent danger to you or someone else, reasonable suspicion that a child or elder is currently being abused, or by court order.

Person to Contact

For more information or to obtain answers to any questions, please contact:

Dr. Mark Weist, Professor at the University of South Carolina
(803) 777-0449 or weist@mailbox.sc.edu

Brooke Chehoski, Research Coordinator
(803) 777-7098 or chehoski@sc.edu

Please also visit our website for more information: <https://schoolbehavioralhealth.org/>

Institutional Review Board

If you have questions about you or your child's rights in participating in research, contact Lisa Johnson, IRB Manager, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 414, Columbia, SC 29208; or (803) 576-7276; or lisaj@mailbox.sc.edu.

Consent

By completing the checkboxes below, I confirm that I have read and understand the above information and have been given the opportunity to ask questions or request more information. I understand that my participation is voluntary and that I have the opportunity to withdraw at any time without penalty.

Please choose one to indicate whether you choose to participate.

- I agree to participate in this study.
- I do not wish to participate in this study.

Please choose one to indicate whether your child may participate.

- I give permission for my student to participate in the study.
- I do not give permission for my student to participate in the study.

Partnering for Student Wellness Project

Affirmation Form for Students

Project Title: Partnering for Student Wellness: Students, Families, Schools, and Communities Working Together to Promote Student Wellness

Principal Investigator:

Dr. Mark Weist

(803) 777-0449

Monday-Thursday 10:00 am – 4:00 pm

Introduction and Purpose

We want to tell you about a research study we are doing. A research study is a way to learn information about something.



The purpose of the study is to improve supportive services for students in schools, including mental health services. Mental health is how we think, feel, and behave.



Description of Study

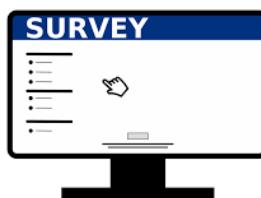
- Length
 - Four years
- Research partners and participating districts
 - University of Maryland, Baltimore
 - [REDACTED] Schools
 - University of South Carolina
 - [REDACTED] School District
- We want to:
 - Help students know more about mental health
 - Help students get mental health services when they need them
 - Help students, families, mental health counselors, and communities work together to make students feel better and do better in school

Partnering for Student Wellness Project



Study Procedures

- We are asking you to take sets of surveys during your therapy sessions
 - At your first session
 - About three months after your first session
 - About six months after your first session
- We may also ask you to take the set of surveys again when you are in high school
- You will take each set of surveys on an I-Pad or tablet
- Each set of surveys will take about 30-40 minutes to complete
- We will ask you questions about these topics:
 - Yourself
 - Your relationships (e.g., with friends, parents, and other adults)
 - How you do in school
 - Things that you help with at home
 - How much you like your therapy sessions**
 - “Did you get the kind of services you wanted?”
 - “How satisfied are you with the amount of help you received?”
 - What you know about mental health
 - “Mental health and mental illness both involve the brain and how it functions.”
 - “Feelings are controlled mostly by the heart.”



Risks

- The risk that something bad will happen in this study is very low
- Some of the questions might make you feel uncomfortable
 - That is okay
 - Skip the question
 - Tell your mental health clinician



Voluntary Participation

- You get to choose if you want to be in this study
- You are allowed to start the study and stop later on
- You can tell your mental health clinician that you do not want to be in the study or want to stop at any time
- Nothing bad will happen if you do not want to be in the study
- You will be allowed to meet with your mental health clinician even if you do not want to be in this study



Payments

- We are going to give you a small prize every time you take a set of surveys!



Benefits

- As part of this study, your mental health clinician has special training that will make your therapy sessions better for you
- What we learn will improve student services in your district
 - With your help, we think we can make school better for you and your friends
 - We hope that this will make you feel good!



Alternative Procedures

- Tell your mental health clinician if you do not want to be a part of the study
- You will continue with your therapy sessions as usual



Confidentiality

- Your answers to the questions will be kept secret
- We will use number codes instead of your name on all of your answers
- Your answers will be kept on a password protected computer
- Only the people doing the research will see your answers



Person to Contact

- If you have any questions, contact Dr. Mark Weist, Victoria Rizzardi, or visit our website
- Dr. Mark Weist, professor at USC
 - (803) 777-0449
 - weist@mailbox.sc.edu
- Brooke Chehoski, research coordinator
 - (803) 777-7098
 - chehoski@sc.edu

If you have any questions, go ahead and ask your mental health clinician.

Partnering for Student Wellness Project



Thank you for reading this information and helping with this study!



Now that you have read this form and have asked all of your questions, choose an option below.

- I agree to be in this research study
- I do not agree to be in this research study