

A Hybrid Type 2 Trial of Trauma-Focused Cognitive Behavioral Therapy and a Pragmatic Individual-Level Implementation Strategy

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Informed Consent for Student and Provider

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Parent/Legal Guardian Consent Script for Research Staff

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Hi, may I please speak with [PARENT/LEGAL GUARDIAN'S NAME]? My name is [NAME], and I'm calling from the University of Washington to talk to you about the Trauma-informed Intervention Project. Is this [**if the time was previously arranged** [STILL]] a good time to talk?

[If they have time, proceed. If not, ask when would be a good time to schedule a call back.]

We understand that [CHILD'S NAME]'s school support provider, [PROVIDER'S NAME], talked with you about providing Trauma-focused treatment, and that you would be willing to hear about the study we are doing with families across the state of [WASHINGTON/MINNESOTA].

We emailed you a link to some information about the Trauma-informed Intervention Project that you need to know before you decide if you and [CHILD'S NAME] want to be in our study. Did you receive that?

[If no] Oh, can we make sure that we have your correct contact information? We can email or text you the link right now if you'd like.

[If yes] Great, I'd like to go over the information together and then if you are interested in participating in the study, I'll go ahead and talk briefly with [CHILD'S NAME] and tell them about the study and if they're interested ask them the study questions. Is that ok?

[When they are ready to proceed—] If you are able to access the **Study Information for Parents**, it will make it easier to go over the information together.

[NEXT: follow the script below to review consent with the parent: go through each section, find out if the parent/legal guardian has any questions.]

PARENT/LEGAL GUARDIAN CONSENT SCRIPT

First of all, if you have any questions as we go over the information please don't hesitate to ask.

One thing you might be interested in is who we are and why we are doing this study. We are from the School Mental Health, Assessment, Research, and Training (SMART) Center at the University of Washington. Our goal is to partner with and learn from schools, families, and students about better ways of supporting students' mental health to enable their success in school and, eventually, as adults. We work with schools, families, and students across the country and we want to help create a world where all students are able to access what they need to be successful. Do you have any questions about us?

Now getting into the document...The first section is about why the research is taking place. The goal of the Trauma-informed Intervention Project is to improve trauma treatment for students in across the nation by studying how to best support the providers who work with these kids. We want to learn how to help providers do the best job they can.

The next section is about what you would be asked to do if you decide to participate:

- You will complete a phone survey today that asks questions about how [CHILD'S NAME] has been feeling and acting, which gives us information to examine whether the support your child receives from school has a positive impact.
- If [CHILD'S NAME] and you agree, we would do two more phone surveys with you and [CHILD'S NAME] — once in 3 months and again in 6 months. Each survey will take about 20 minutes and we will send a \$50 gift card for each survey that you complete. Today is longer since we are talking about the study information, about 30 – 40 minutes.

- We would also ask for your permission to audio record (voice only) sessions with [CHILD'S NAME] school support provider. We do this so we can understand what the providers are doing to support your child.
- Lastly, we may want to audio record one of your phone calls with us. We do this occasionally to make sure our staff is doing a good job writing down all of your answers. After we listen, we will delete the recording. We will always ask you in advance if it is ok to record the call. Just so you know, we are not currently recording this call. We will always ask for your permission.

Any questions so far? [Answer any questions. If none, proceed—]

Now let's look at the section about possible **risks or harms**. This part tells you that some of the questions may make you feel uncomfortable because they are about difficult things your child may have experienced. If you get tired of answering questions, you can always take a break, and if there is a particular question you don't want to answer, that is ok.

The next section is about the possible **benefits** of being part of this study. For example, the school support provider will be receiving extra training, so your child may receive better services. Also, this research provides an opportunity for you to help provide information about how to better support other students and their families in the future.

The other important thing to know about the study is that it is **completely voluntary**. That means you do not have to do this.

Both you and your child may choose to participate or not, or may stop being in the study at any time without any penalty. If you do not want to be part of the study, you can say no. The same goes for your child. If you decide you do not want to take part, it will not change the treatment your child is receiving.

Do you have any questions about the risks or benefits of being in the study? [Answer any questions. If none, proceed—]

There are just a few more important things I want to tell you about the study. The next section is about **Confidentiality**. Everything you tell us is **Confidential**. We want you to know that we do many things to protect your privacy and that everything you tell us will be kept **private**. For example:

- We put ID numbers on the survey answers you give us, not your name. Only researchers from the study see the answers to questions or know the ID numbers. No one, including your child's school support provider, sees the answers. We do not share your answers with your child, and we do not share their answers with you.
- The audio recordings are also saved without names. The audio recordings will only be used to know how the school support provider works with your family. We won't use them for anything else.
- We keep all of our study materials in safe and secure offices and protected computer databases.
- What we do with the information you give us is combine it with information from other parents and students. Names are never mentioned.

The only reason we would share private information is if you or your child tells us that they or someone they know is in danger of serious harm or abuse, or if they have been seriously harmed or abused. If that happens, we will tell someone who could keep you and your child safe, like Child Protective Services, the police, or a mental health professional. Again, our main goal is to keep your child safe.

The types of questions that we will ask you and your child include questions about feelings, moods, and behaviors, and how your child is doing in school.

You know that [NAME OF PROVIDER] who [CHILD'S NAME] is working with at school is part of the study, too. We want to know how [NAME OF PROVIDER] is doing when delivering supports, so we would like your permission to audio record the sessions they have with your child. We would only be recording their voices, not doing any video recording. We'll

use these recordings to collect data about how the sessions went, and then we will delete the recordings at the end of the study.

If you do choose to be in this study, we will let your school support provider know to start audio recording treatment sessions. As a reminder, we will email a \$50 gift card each to you and [CHILD'S NAME] to thank you both for your time, each time you complete the surveys over the phone with us. If you and [CHILD'S NAME] both agree to audio recording sessions, but you do not have time to complete all of the phone interviews, your family can still take part in the study.

We would also like to gather information from your child's provider about the scary or stressful experiences [CHILD'S NAME] told them about, and which they are working on in their meetings. We do this for two reasons: First, to protect your privacy, so that our team doesn't know the specific experiences your child has had unless you say it is OK. Second, so that we don't ever need to ask [CHILD'S NAME] to tell us directly about the scary or stressful things that have happened to them.

Do you have any questions about anything I have said or what we would ask you and your child to do? [Answer any questions. If none, proceed—]

Do you think you would like to have you and [CHILD'S NAME] take part in the Trauma-informed Intervention Project?

[*If NO*—] Thank you for taking the time to talk to me today. Would you be comfortable sharing with me what your concerns are about their participation?

[*If YES*—] That's great. Now I would like to talk to [CHILD'S NAME] about the study and see if they are interested in taking part. If they want to take part, I'll ask them our study questions. And then get back on the phone with you to ask you some questions as well.

Would it be ok if I please talk to [CHILD'S NAME] now?

[If **NO**—set up a time as soon as possible to talk with the child.]

[If **YES**—proceed with the assent process and measures with the child.]

CHILD ASSENT SCRIPT

Hi [CHILD'S NAME]. My name is [YOUR NAME] and I am from the University of Washington. How are you doing today?

I'm calling to tell you about the research study that we are doing with kids all over the state of [WASHINGTON/MINNESOTA]. We gave some information to your [MOM/DAD/OTHER LEGAL GUARDIAN'S NAME] and I just talked with them about the study. They said it would be ok to talk to you and tell you about it too, because we like to make sure everyone has a chance to learn about the study.

I'd like to start by telling you a little bit about our research group and our study. We are from the School Mental Health, Assessment, Research, and Training (SMART) Center at the University of Washington. We care a lot about working with and learning from people like you, teachers, and families about better ways of supporting students to be mentally healthy so they can go on to do the things they think matter most in life. We work with young people like you across the country and we want to be a part of making the world a place where all young people can get the support they need. Any questions about us?

Your [MOM/DAD/OTHER LEGAL GUARDIAN'S NAME] has agreed to be in the study, but now it is your turn to decide if you want to be in the study. Have you seen the form we sent called **“Study Information for Youth”?**

[*If YES—*] Great. Is it easy to get it now so you can follow along as we talk about it?

[*If NO—*] No problem. I can tell you about it. [*If the child doesn't have it, proceed anyway.*]

So, the first section describes what the study is about. The purpose of the study is to learn how to help school support providers do a good job helping students who had difficult things happen to them. We really want to help kids get the care and support they need.

Before I tell you more, do you have any questions about why we are doing the study?
[Answer any questions. If none, proceed—]

Okay, the next section is about what will happen if you decide to take part in this study.

If you want to be in the study, I will ask you some questions today to see if our study seems like a good fit for you. This should all take about 20 minutes.

After today, if you are in the study, I will call you again in 3 months to ask you our study questions, and again in 6 months. Each survey will take about 20 minutes and we will send a \$50 gift card for each survey that you complete. Today is longer since we are talking about the study information, about 30 – 40 minutes.

- Some of the questions I ask might make you feel uncomfortable. For example, I will ask you things like if you have nightmares or about difficult things that happen to some kids.
- You don't have to answer every question. You can skip any question you don't want to answer. You can stop any time you want to.
- Your school support provider is part of the study, too. We want to know how they are doing, so we want to audio record your therapy sessions. We would only be recording your voices, not video. No one you know will listen to these recordings, and we will delete them at the end of the study.
- We would also like to ask the person you are meeting with from school about the scary or stressful experiences you told them about when you first met. We do this so that we can understand the kinds of things kids are dealing with without needing each kid to tell us about their experiences directly.

Does that sound OK? [If necessary, ensure the child understands they can skip questions if they make them feel uncomfortable and they can stop at any time if they don't want to keep going. If they sound comfortable, proceed.]

Do you have any questions so far? [Answer any questions. If none, proceed—]

The next part tells you that a benefit of being in the study is that you might help us find out how to help other kids.

Next, if you end up being in the study, we will let your school support provider know to start audio recording treatment sessions and ask them for the experiences you told them about so you never have to tell us. We will mail you a gift card for \$50 to thank you for your time each time you complete a phone interview with us.

I also want to tell you how we keep your information private. It's really important for you to know that everything you tell us will be kept confidential, or in other words, **private**. We won't tell anyone what you say, not even your parent(s). We have many ways to keep your information private:

- We put numbers on the answers you give us, not your name.
 - We keep all of our study information in a locked, safe place.
 - After the study is over, we get rid of any information, like your name or your parent's name that could tell anyone you were in the study.

The only time that we would share your information is if we learn that you are being hurt or are thinking about hurting yourself in a serious way. If you told us about something like that, we would tell people who could help keep you safe.

Do you have any questions about your privacy? [If YES, answer. If NO, proceed—]

Occasionally, we may want to audio record one of our phone calls with you. We do this to make sure our staff is doing a good job. After we listen to hear how our staff is doing, we

delete the recording. We will always ask you in advance if it is ok to record the call. I am not recording this call today.

That's the information about the study. Your [*MOM/DAD/OTHER LEGAL GUARDIAN'S NAME*] gave permission for you to be in the study already, but you get a choice, too.

You can say yes or you can say no to being in the study. If you agree to audio recording sessions, but want to skip some or all of the study questions, that's OK. If you don't want to be in the study, you can still get counseling. If you decide you do want to be in the study, you can change your mind later and stop.

Do you have any questions about what we would ask you to do before you decide? [Answer any questions. If none, proceed—]

Would you like to be in the Trauma-informed Intervention Project?

[*If NO*—] Thank you for taking the time to talk to me today. If you don't mind, could you tell me why you don't want to participate?

[*If YES*—] That's great. Let's get started with the study questions...

First, there are a few things I want to tell you about the questions I'll be asking you.

- I'm required to read all of the questions and instructions word for word.
- I ask the same questions of everyone in the study so I'm not asking any question just of you.
- This is not a test... there are no right or wrong answers—just what is true for you.
- If there's a question or word that you don't understand, it is important that you tell me.

- Please be as honest as possible... Remember, all of your answers will be kept private.

Can you get out the Youth Response Card in the packet we emailed to your [MOM/DAD/OTHER LEGAL GUARDIAN'S NAME]? We'll use it for some of the questions and I'll tell you when it's time to use it.

[If child doesn't have it... ask if they have a piece of paper and a pen, then have them write down the answer choices they will need. If they don't have it, proceed anyway, but repeat the response options as necessary.]

Also, it's best to answer the questions in a quiet, private spot...are you in a good spot now?

OK, let's begin.

[Complete questionnaires – SEE NEXT PAGE]

Provider Consent

Researchers:

Aaron Lyon, Ph.D., Associate Professor, Department of Psychiatry, (206) 221-8604;

RESEARCHER STATEMENT

We are asking you to be in a research study. The purpose of this form is to help you decide whether to be in the study or not. Should you have any questions about the purpose of the research, what we are asking you to do, the possible risks and benefits, your rights as a volunteer, or anything else about the research or this form, please contact the research lead. If you are willing to be part of this study, we are asking you to consent using this web-based form.

PURPOSE OF STUDY

The goals of the study are to (1) evaluate the effectiveness of two evidence-informed interventions for youth trauma with students and to (2) evaluate the impact of two strategies for enhancing intervention adoption and use. The research is funded by The National Institute of Mental Health (NIMH).

STUDY PROCEDURES

You are one of approximately 120 School Mental Health providers being invited to take part in the study. Your participation will last 18-21 months.

If you agree to take part, we will ask you to:

- Complete web-based surveys about your perceptions of evidence-based treatments up to 12 times over two years. Each survey will take approximately 5 to 15 minutes.
- Agree to be randomized to either a Trauma Focused Cognitive Behavioral Therapy (TF-CBT) condition (and one of the two strategies for enhancing adoption and use) or a Resource Efficient Trauma Intervention (RETI) condition.
- Assess students referred to you for appropriateness for TF-CBT or RETI treatment and the study using a measure we will provide.
- Deliver TF-CBT or RETI treatment to 4-6 students enrolled in the study.

- Once the researchers enroll a student into the study, record your treatment sessions with the student (students and parents will give permission for the recording during the research enrollment process).
- Possible participation in a 30-45 minute qualitative interview if selected randomly (up to 20 providers only).

If you are randomized to TF-CBT, we will ask you to:

- Complete training and become certified in TF-CBT. This involves:
- Complete an online TF-CBT training. You will receive a \$100 gift card upon completion;
- Attend a multi-day virtual or in-person training;
- Participate in 6 months (twice a month) of remote consultation.

If you are randomized to RETI, we will ask you to:

- 4 - 6 hours of RETI training.

RISK, STRESS, OR DISCOMFORT

A standard risk is a breach of confidentiality. Some aspects of data collection will be recorded which may cause temporary discomfort to providers.

BENEFITS OF THE STUDY

There are no direct benefits to you for participating in the study. You may appreciate the opportunity to contribute to the larger body of knowledge related to improving services for students in schools. The research may lead to discoveries that enhance the understanding of how to successfully implement evidence-based practices in schools that will prevent problems or lead to better academic and emotional outcomes for students.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. We take steps to guard your privacy. Your name will not be used in the research: you will be assigned a study code. We will do our very best to be sure that only the researchers see the study data. We will keep all study information in locked files that only the researchers can access. Some aspects of data collection (e.g., qualitative interviews) will be recorded and may be professionally transcribed by a company that provides secure data uploading and has adequate data protection measures in place. The data will be protected with encryption; the transfer of

audio files will be done via secure, HIPAA approved cloud services. All audio files will only be listened to by members of our study staff or contracted TF-CBT fidelity coders.

Consistent with NIMH policies, the information that we obtain from you for this study might be used for future studies with other authorized research teams. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

The researchers will write papers and make presentations that will educate the public about what they learn from the study. No names or other identifying information will be used in any papers or presentations that may result from this study. When our research team looks at or reports study findings, all answers will be combined with the answers of the other participants and no names will be used. Government or university staff members sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your data may be examined. The reviewers will protect your privacy. If you have any questions, Dr. Lyon or the research staff will answer them at any time.

We have a Certificate of Confidentiality from the National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- Local or state authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

OTHER INFORMATION

Participation in this project is voluntary. You may choose not to participate or may withdraw from the study at any time without any penalty or loss of benefits to which they are otherwise entitled. Study results will be provided to participating organizations.

If you choose to participate, we will send you a \$400 gift card as a thank you for your participation in the active treatment phase (year 1) for completing web-based surveys and delivering treatment to students. We will later send you a \$200 gift card as a thank you for your participation in the sustainment phase (year 2) for completing web-based surveys after treatment with all students is completed. For those participants that recruit 4 or more students into the study, they will be eligible for a one-time entry raffle for a 2021 generation iPad.

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.

If you have questions about the research or if you have been harmed by the study, please contact one of the researchers listed on the top of the first page. Please indicate your willingness to take part in this study or not by checking the box below. Checking the box "YES to study participation" will result in linking you to the study survey. If you have questions about your rights as a research subject, you can call the Human Subjects Division at (206) 543-0098.

Statement of Consent:

I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed on the top of the first page. If I choose, I can print a copy of this consent form [at this location](#).

I agree to participate in the study

I decline to participate in the study