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

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3/5/2025

Study Protocol and Statistical Analysis Plan

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SECTION ONE: INTRODUCTION

1. **Project Overview**

The University of Washington School Mental Health Assessment, Research, and Training (SMART) Center, under the leadership of Principal Investigators Aaron Lyon Ph.D. (UW) and Clayton Cook, PhD (University of Minnesota), received funding from the National Institutes of Health to conduct a 5-year research study. The study, "A Hybrid Type 2 Trial of Trauma-Focused Cognitive Behavioral Therapy and a Pragmatic Individual-Level Implementation Strategy" is referred to simply as BASIS and took place in multiple states across the nation. The BASIS study is a randomized controlled clinical trial designed to simultaneously test the effectiveness of TF-CBT in schools on student outcomes (e.g., trauma symptoms) and the impact of BASIS on implementation outcomes (e.g., adoption of TF-CBT). This study has been reviewed and approved by the University of Washington Human Subjects Review Board.
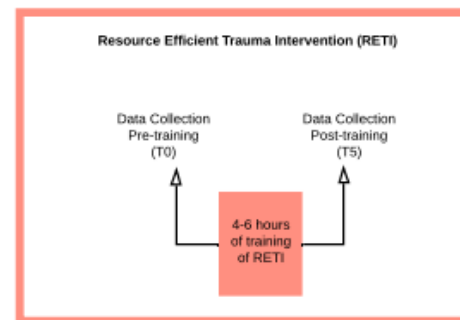
2. **STUDY PURPOSE**

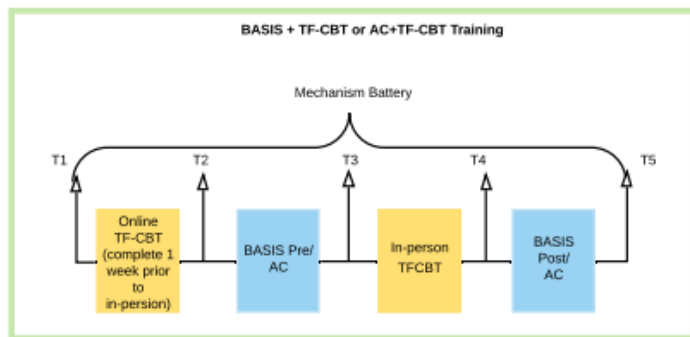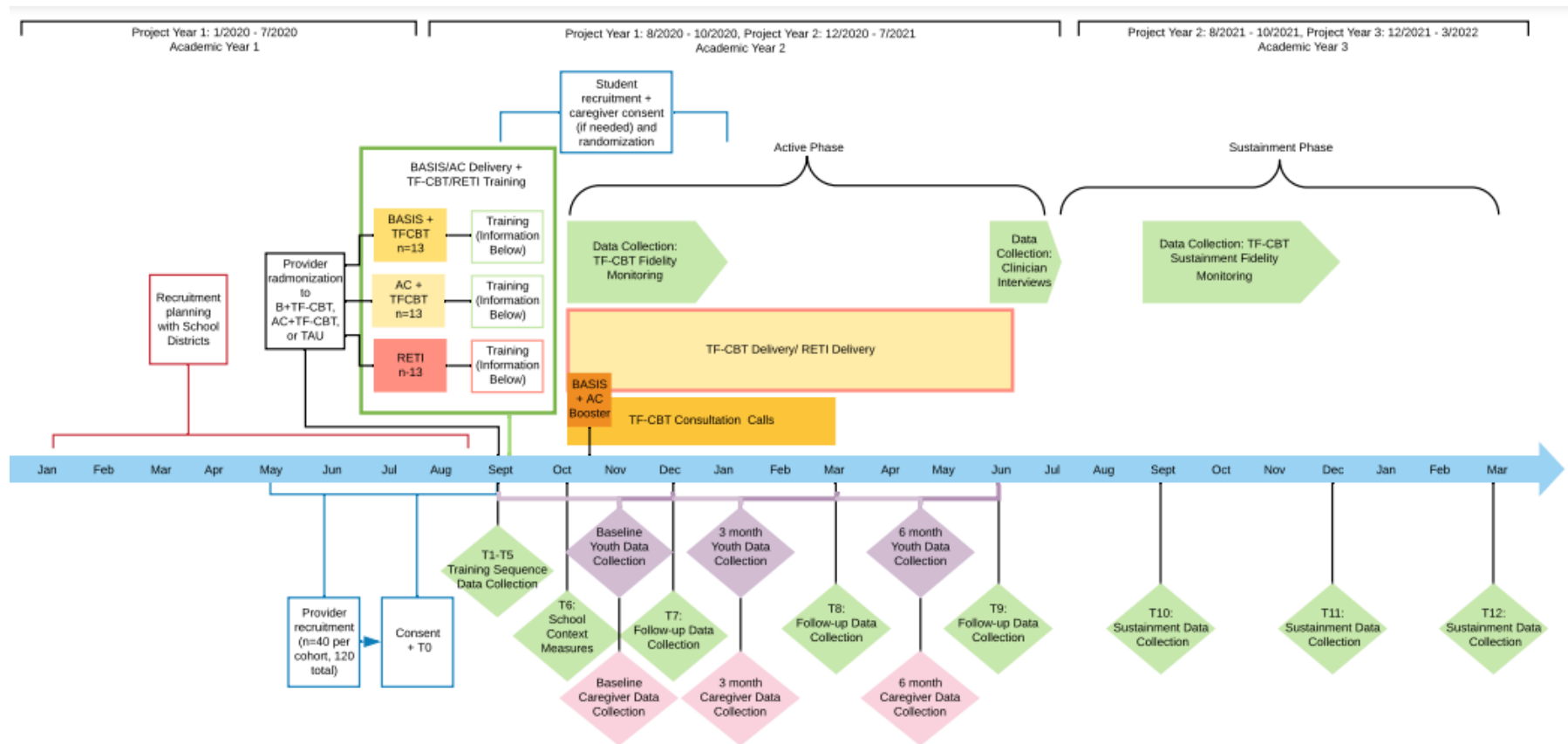Despite serving as the most common setting where youth receive mental health services, schools are confronted with two gaps that prevent youth from accessing evidence-based care: (1) an access gap characterized by the limited availability of high-quality trauma treatments; and (2) an implementation gap consisting of insufficient adoption, fidelity, and sustainment of EBTs. To address both gaps, this project proposes a hybrid

type 2 effectiveness-implementation trial simultaneously examining TF-CBT effectiveness in the education sector and the impact of the BASIS implementation strategy for promoting TF-CBT use. TF-CBT has robust support demonstrated by a variety of efficacy studies, and BASIS has support as a feasible and appropriate implementation strategy. Consistent with NIMH's experimental therapeutics approach to intervention evaluation, this project examined the mechanisms through which TF-CBT influenced clinical outcomes, as well as the mechanisms through which BASIS influences implementation outcomes.

3. **STUDY DESIGN**

We conducted a hybrid type 2 effectiveness-implementation randomized trial. There was single provider from each participating school, for first cohort, then more than one provider after the first year (n=158) were randomized to BASIS plus TF-CBT (BASIS+TF-CBT), Attention Control plus TF-CBT (AC+TF-CBT), or Resource Efficient Treatment Intervention (RETI). **Aim 1** evaluated the main effects of TF-CBT on proximal mechanisms and clinical child outcomes, as well as test intervention mechanisms as mediators, moderators, and evaluate the cost-effectiveness of the intervention. **Aim 2** evaluated the main effects of BASIS on its mechanism of change and provider implementation outcomes, as well as test implementation mechanisms as mediators, moderators, and evaluated the cost-effectiveness of BASIS strategy. In addition, sequential mixed-methods data collection will explore how mechanisms are linked to implementation outcomes for "hypothesis defying residuals" (i.e., providers whose attitudes, subjective norms, and self-efficacy surrounding Evidence-Based Treatment (EBT) implementation are inconsistent with their documented implementation behaviors).

Project Timeline Overview (see Section 2.7 of Clinical Trials Information for fully detailed timeline) Activities	Months 0-6 (Dec 2019- May 2020)	Months 6-12 (Jun 2020- Nov 2020)	Months 12-18 (Dec 2020- May 2021)	Months 18-24 (Jun 2021- Nov 2021)	Months 24-30 (Dec 2021- May 2022)	Months 30-36 (Jun 2022- Nov 2022)	Months 36-42 (Dec 2022- May 2023)	Months 42-48 (Jun 2023- Nov 2023)	Months 48-54 (Dec 2023- May 2024)	Months 54-60 (Jun 2024- Nov 2024)
Clinician recruitment (n=120)		X		X		X				
Student recruitment (n=480)		X	X	X	X	X	X			
BASIS or Attention Control delivery		X		X		X				
TF-CBT or TAU delivery		X	X	X	X	X	X	X		
Clinician data collection		X	X	X	X	X	X	X	X	
Student data collection		X	X	X	X	X	X	X		
Aim 1 & 2 analyses								X	X	
Aim 1 & 2 manuscripts & dissemination								X	X	X

Project Year 1: 1/2020 - 7/2020
Academic Year 1

Project Year 1: 8/2020 - 10/2020, Project Year 2: 12/2020 - 7/2021
Academic Year 2

Project Year 2: 8/2021 - 10/2021, Project Year 3: 12/2021 - 3/2022
Academic Year 3

Student recruitment + caregiver consent (if needed) and randomization

Active Phase

Sustainment Phase

BASIS/AC Delivery + TF-CBT/RETI Training

Recruitment planning with School Districts

Provider radmonization to B+TF-CBT, AC+TF-CBT, or TAU

BASIS + TFCBT n=13 — Training (Information Below)

AC + TFCBT n=13 — Training (Information Below)

RETI n-13 — Training (Information Below)

Data Collection: TF-CBT Fidelity Monitoring

Data Collection: Clinician Interviews

Data Collection: TF-CBT Sustainment Fidelity Monitoring

TF-CBT Delivery/ RETI Delivery

BASIS + AC Booster

TF-CBT Consultation Calls

Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sept | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sept | Oct | Nov | Dec | Jan | Feb | Mar

Provider recruitment (n=40 per cohort, 120 total)

Consent + T0

T1-T5 Training Sequence Data Collection

T6: School Context Measures

Baseline Youth Data Collection

T7: Follow-up Data Collection

3 month Youth Data Collection

T8: Follow-up Data Collection

6 month Youth Data Collection

T9: Follow-up Data Collection

T10: Sustainment Data Collection

T11: Sustainment Data Collection

T12: Sustainment Data Collection

Baseline Caregiver Data Collection

3 month Caregiver Data Collection

6 month Caregiver Data Collection

BASIS + TF-CBT or AC+TF-CBT Training

Mechanism Battery

T1 | T2 | T3 | T4 | T5

Online TF-CBT (complete 1 week prior to in-persion)

BASIS Pre/AC

In-person TFCBT

BASIS Post/AC

Resource Efficient Trauma Intervention (RETI)

Data Collection Pre-training (T0)

Data Collection Post-training (T5)

4-6 hours of training of RETI

SECTION TWO: INTERVENTION

1. **CONDITIONS OVERVIEW**

Providers were randomized to one of two TF-CBT conditions or a RETI (Resource Efficient Trauma Intervention) condition. Those randomized to TF-CBT will receive either BASIS + TF-CBT or Attention control (AC) + TF-CBT. Both BASIS and AC bookend the TF-CBT 3-day training and will be followed by an online booster session. TF-CBT gold-standard training and 6 months of follow-up consultation were delivered by Dr. David Hong, Dr. Michael Gomez, and Jennifer Wilgocki.

Three Research Groups

BASIS plus TF-CBT (B + TF-CBT)

Providers in this research condition received the BASIS intervention prior to and post TF-CBT training.

Attention Control plus TF-CBT (AC + TF-CBT)

Providers in this research condition received attention control prior to and post TF-CBT training.

Resource-Efficient Trauma Intervention (RETI)

Providers in this research group received a half-day training and handout in RETI practices.

Clinical Interventions

RETI

Resource-Efficient Trauma Intervention (RETI) can be described as scaffold treatment-as-usual. It is a less prescriptive and resource-intensive intervention. It includes four core components – initial assessment, psychoeducation, social connection, and planning – which involve identifying which students have trauma exposure, connecting them to a practitioner who provides psychoeducation and social support, and the development of a support plan. This second approach provides school service providers with greater flexibility and autonomy but has been tested less extensively.

TF-CBT

TF-CBT was selected based on its established evidence and the stated need of participating districts to address student trauma and increasing concerns about student safety. TF-CBT is a 12-16 session intervention for students aged 3 to 18 years with trauma-exposure and related mental health sequelae. TF-CBT includes individual sessions for the youth, individual sessions for parents, and conjoint sessions that include involvement. The first third of TF-CBT focuses on psychoeducation and developing coping skills to reduce trauma-

related distress (e.g., cognitive coping). The middle third focuses on cognitive processing of trauma-related cognitions and beliefs and on exposure- both imaginal exposure to traumatic events as well as situational exposure to trauma-related reminders likely to be overgeneralized (e.g., fear of the dark). The final third continues these components and focuses on the future, including enhancing future safety and preventing relapse. All school mental health providers will be required to complete TF-CBT online training (providers will be compensated) a week prior to participating in a standard 2-day training delivered by certified TF-CBT trainer, Dr. David Hong, who will be blind to condition. He will also provide biweekly group consultation to providers within the BASIS or AC condition to avoid contamination.

TF-CBT is a short-term treatment typically provided in 12 to 14 weekly sessions. Most sessions last approximately 45-50 minutes. Each individual session is designed to build the therapeutic relationship while providing education, skills, and a safe environment in which to address and process traumatic memories.

TF-CBT is an evidence-based treatment that helps children from elementary to high school to address the negative effects of trauma and promote greater emotion and behavior regulation, including processing their traumatic memories, overcoming problematic thoughts and behaviors, and developing effective coping and interpersonal skills. It also includes a treatment component for parents or other caregivers. Parents can learn skills related to stress management, positive parenting, behavior management, and effective communication.

When possible, joint parent-child sessions are held to help parents and children practice and use the skills they learned and to assist the children in sharing their trauma narratives. Components of the TF-CBT can be summarized by the word "PRACTICE":

- **P** - Psychoeducation and parenting skills— Discussing and teaching about emotional and behavioral reactions to trauma and other emotion-provoking situations as well as skills training for parents in positive parenting, child behavior management strategies and effective communication

- **R** - Relaxation techniques—Teaching relaxation methods, such as focused breathing, progressive muscle relaxation, and visual imagery, which may benefit the parent as well

- **A** - Affective expression and regulation—Helping the child and parent manage their emotional reactions to reminders of the abuse, improve their ability to identify and express emotions, and participate in self-soothing activities

- **C** - Cognitive coping and processing—Helping the child and parent understand the connection between thoughts, feelings, and behaviors and exploring and correcting inaccurate and/or unhelpful attributions related to everyday events

- **T** - Trauma narration and processing—Conducting gradual exposure exercises, including verbal, written, and/or other creative recounting of abusive events, and processing inaccurate and/or unhelpful thoughts about the abuse

- **I** - In vivo exposure—Gradual exposure to trauma reminders in the child's environment (e.g., darkness, the setting where the trauma occurred), so the child learns to control his or her own emotional reactions

- **C** - Conjoint parent/child sessions—Family work to enhance communication and create opportunities for therapeutic discussion regarding the abuse and for the child to share his/her trauma narration

- **E** - Enhancing personal safety and future growth— Education and training on personal safety skills, interpersonal relationships, and healthy sexuality and encouragement in the use of new skills in managing future stressors and trauma reminders.

Example web resources with overview of the research supporting TF-CBT:

- http://www.episcenter.psu.edu/newvpp/tfcbt/research

- https://www.cebc4cw.org/program/trauma-focused-cognitive-behavioral-therapy/

Pre-Implementation Strategy: BASIS

Beliefs and Attitudes for Successful Implementation in Schools (BASIS) is a brief, group-based pre- implementation strategy that is designed to augment standard evidence-based treatment (EBT) training and consultation for school-based clinicians and is designed to be generalizable across different mental health EBTs and service delivery contexts. It targets individual-level clinician factors associated with behavior change – clinician attitudes, subjective norms, self-efficacy, maintenance self-efficacy, intentions to implement an intervention– using strategies targeting motivation and decision-making.

BASIS is group-based and interactive, with a pre-training session (~3 hours) delivered prior to TF-CBT training, a post-training session (~45 mins) delivered immediately after training, and an online booster 30-days post-training. With training from Dr. Cook, BASIS will be delivered by Rachel Barrett, LICSW Social Worker with experience consulting with schools and implementing EBTS.

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Box 1. BASIS Components
Motivational Components (TPB Mechanisms)
1.  Strategic Education (Attitudes)
    a.  Connecting EBP to student success
    b.  Problems with implementing non-EBPs
    c.  Addressing common myths about EBPs
    d.  Evaluating evidence for practices
    e.  Promoting understanding of fidelity for EBP
2.  Social Influence (Subjective Norms)
    a.  Providing normative information
    b.  Testimonials from experts
    c.  Testimonials from similar others
    d.  Evoking public commitments
3.  Motivational Interviewing (Self-Efficacy)
    a.  Professional values clarification activity
    b.  Pros & cons activity to elicit change talk
    c.  Anticipating implementation barriers
    d.  Values-directed goal setting
    e.  "Ruler questions" (e.g., how confident are you?)
Volitional Components (HAPA Mechanism)
4.  Action Planning and Problem-Solving Planning
    (Maintenance Self-Efficacy)
    a.  Action planning to initiate implementation
    b.  Problem-solving planning to overcome barriers
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BASIS Motivational Component 1: Strategic education about EBT and intervention fidelity to improve attitudes. To influence providers' attitudes toward EBT, BASIS incorporates strategic education that focuses on increasing belief about the benefits of EBT for them and the youth they serve.

BASIS Motivational Component 2: Social influence techniques to alter perception of subject norms. Evidence-based social influence strategies consist of two broad categories: 1) social proofing messages that use data or testimonial to describe the behavior or attitudes of others, and 2) strategies to induce cognitive dissonance.

BASIS Motivational Component 3: Motivational Interviewing (MI) to enhance self-efficacy.

BASIS Volitional Components: Action planning and problem-solving planning to promote maintenance self-efficacy. Problem-solving generates solutions in response to both situational and internal (e.g., cognitive) barriers to facilitate follow through with the action plan. In combination, action planning and problem-solving planning increase the likelihood that implementation intentions translate into behavior change.

BASIS Structure:

- The BASIS pre-training session targets attitudes, subjective norms, and self-efficacy. The pre-training session is intended to help participants a) link EBT delivery to improve outcomes for students who are otherwise unable to access care, b) recognize common cognitive shortcuts that leave individuals to adopting non-EBT, c) debunk common myths about EBTs, d) identify characteristics of EBT, standards for quality of scientific evidence, and resources for determining the scientific evidence of available program, and e) deepen understanding of the critical role of fidelity.

- The BASIS post-training session includes volitional strategies to maintain implementation intentions and facilitate actual enactment of behavior change. Specifically, providers will be supported to develop action plans and problem-solving plans. Providers will be provided with an action planning template to detail precisely what TF-CBT complements, how, with whom, where/when, and the environmental cues and resources needed to initiate delivery of TF-CBT with fidelity.

- The BASIS online booster was delivered 30-days post-training, a time point indicated by our prior research when providers' implementation intentions and behaviors may weaken. The aim of the BASIS booster is to provide individualized content to providers to either increase intention to implement or maintain self-efficacy to implement the EBT, depending on whether providers have initiated TF-CBT implementation.

1. **AC + TF-CBT**

Providers randomly assigned to AC + TF-CBT will receive a 3-hour pre-training, 45-min post-training session, and an online booster 30-days post training to mirror the duration of BASIS and provide control providers with comparable amounts of attention. The in-person or virtual components of AC will be delivered by the same facilitator as BASIS (Rachel Barett) to control for facilitator effects. Content will be didactic, as in typical training for school mental health providers. The AC pre-training will provide content on the definition of Evidence-Based Treatment (EBT), how EBTs are established, why providers should use EBTs, clinical outcomes associated with different EBTs, and defining different dimensions of fidelity. The post-training session will involve having control providers reflect on TF-CBT, its core components, and discuss the outcomes associated with TF-CBT. The AC booster will prompt providers to reflect on and describe TF-CBT and identify and define each of its core components. The AC condition thus controls for dose, information provided, and interventionist effect.

1.2 Pre-Training Activities for internal teams:

2-4 Months Before Training (Ordinal Tasks must be completed in order; assumes dates have been set)

- Collect school demographics information

- Send Provider Baseline, give 1-2 weeks for completion

- Complete and ship goodie bags to district administrators

- Randomize Providers based on baseline and demographics information

1 Months Before Training

- Send Self-Paced Training link for those who are in TF-CBT

- Send out Zoom link and training calendar invites to /trainers

- Send reminder email for SPT link and reiterating dates for trainings

2 Weeks Before Training

- Check SPT completion rates, send reminders as needed

- Check-in with trainers

- Send out Zoom link and training calendar invites to participants/trainers

1 Week Before Training

- Reminder sent, links for training included

- T1 sent for completion

- Send YouTube training videos for research activities

- Friday before training – check for SPT completion and send reminders as needed

Training Day

- Send out Self-Paced Training gift cards for TF-CBT participants

- Check all T1 completion, send reminders to those who did not complete

- During training first 5 minutes: call on those who have not completed T1 to take time to complete T1

- Following training: send out T2 surveys to be completed by following morning for TF-CBT

- Following training: send out T5 surveys, payment, and relevant information for RETI participants

RANDOMIZATION

Providers and student random assignments occurred at the school level, with one provider per school recruited for the first year, and multiple people per school building was recruited for year two and three. We use this strategy to minimize analytic difficulties associated with reliably partitioning school and provider variance with small numbers of providers per school. Providers and TF-CBT trainers/consultants would be blinded to their BASIS condition assignment. To ensure comparability of conditions at baseline, minimize potential confounding, and maximize accuracy of effect estimates, we used a blocked randomization design. Schools were first blocked by state (WA, MN, IN, KY, WI VT, PA, AZ, and MD) and district. We collected baseline provider data on implementation intentions and TPB and HAPA mechanisms (e.g., attitudes, norms, self-efficacy), identify matched pairs using these variables, and randomly assign providers within pairs to condition. Students were placed into TF-CBT or RETI based on the condition into which their school's existing SMH provider was randomized.

SECTION THREE: RECRUITMENT AND CONSENTING

SCHOOL DISTRICT

Participating schools (n=133) are located across multiple states. Schools are situated in diverse settings, including rural (n=1), suburban (n=2), and urban (n=2) regions and have total enrollments of 9,658 - 37,971 students. Student populations are diverse overall, with a mean of 44% of students identifying as racial/ethnic minorities (range 30% to 60%)

PROVIDER

Provider participants include 191 school mental health providers who were consented and randomized, but only 146 completed the BASIS+TF-CBT, AC+TF-CBT, RETI training to continue in the study. Provider recruitment across all three waves will occur with the assistance of district administrators. Principals will provide us with the email addresses of school mental health providers for recruitment.

1. **Provider SCREENING CRITERIA**

In order of preference:

1. Dedicated mental health providers that have regular individual psychotherapy sessions

    a.   The school employed favorable over CBO (Community Based Organization), but CBO is a close second

2.   People who devote some, but not all of their time to direct service delivery with students (e.g., pulling kids out and doing interventions), like...

    a.   School Social Worker;

    b.   School Counselors IF they are doing direct care with students

3.   Least Preferred: Behavioral Support Specialist who are dealing more the externalizing end of the spectrum

Clinician Inclusion Criteria:

1.   Must provide school-based services in a participating district

2.   Have no previously received formal training in TF-CBT

3.   Are not actively receiving support to implement another intervention

4.   Willingness to dedicate a year to participate in the project

5.   Are open to become randomly assigned to one of the three conditions

Clinician Exclusion Criteria

- Are not administering direct care to students

- Previously received formal training in TF-CBT

- High school guidance counselors unless their role involves some direct service delivery of mental health services

Provider Screening Guidelines + Screener Survey:

Please indicate the types of training in Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) you have received. (Please check all that apply.)

- Completed the 2-day intensive live, in-person or virtual TF-CBT training. NOT ELIGIBLE

- Completed the 3-day intensive live, in-person or virtual CBT Plus training (with one day on TF-CBT). NOT ELIGIBLE

- Completed one day or less of live, in-person or virtual training. ELIGIBLE

- Completed a fully dedicated, graduate level course on TF-CBT. NOT ELIGIBLE

- Completed (or partially completed) the self-paced, online training course, TF-CBT Web. ELIGIBLE

- Completed (or partially completed) the self-paced, online TF-CBT for childhood grief training course, CTG Web. ELIGIBLE

- Completed training in another evidence-based treatment(s) for children and adolescents impacted by trauma: ELIGIBLE

   o EMDR

   o CBITS

   o Prolonged Exposure

   o Cognitive Processing Therapy

   o Other, Please specify: _____

   o Read the 2015 *Child Sexual Abuse: A Primer for Treating Children, Adolescents, and Their Nonoffending Parents* by Esther Deblinger, Anthony P. Mannarino, and Judith A. Cohen. ELIGIBLE

   o Read the 2016 *Trauma-Focused CBT for Children and Adolescents: Treatment Applications* by Judith A. Cohen, Anthony P. Mannarino, and Esther Deblinger. ELIGIBLE

   o Read the first (2006) or second (2017) edition of *Treating Trauma and Traumatic Grief in Children and Adolescents* by Judith A. Cohen, Anthony P. Mannarino, and Esther Deblinger. ELIGIBLE

   o Other, Please specify: _____ CONTINUE TO CONSENT, BUT STUDY STAFF NEEDS TO VERIFY BEFORE RANDOMIZATION

STUDENT/CAREGIVER

Youth participants (n=101), recruited by school mental health providers via their standard referral pathways (e.g., teacher - or self-referral; screening).

Inclusion

- Must meet TF-CBT eligibility criteria, including:

- Be within the TF-CBT developmental range (grades 3-12)

- Have traumatic event exposure

- Significant post-traumatic stress symptoms as indicated by a CPSS-V score ≥ 21

Exclusion

- Students with intellectual impairments or those who are not trauma exposed will be excluded

- Students (and caregivers at this time) must be English speaking

SCREENING CRITERIA

Providers will screen new cases for symptoms of trauma using a Trauma Screen (TS) and the Children PTSD Symptom Scale DSM-V (CPSS-5.) Once students are identified, providers will ask caregivers whether they are open to being contacted by the research team.

Trauma-Informed Intervention Project Student Recruitment Path
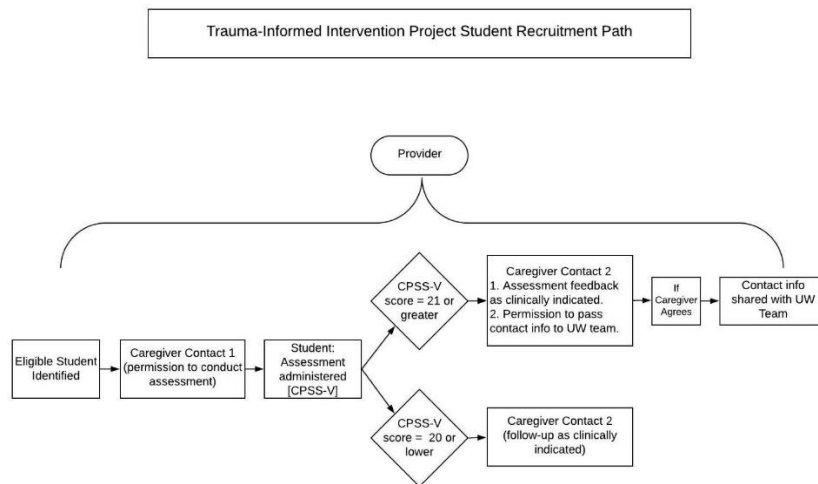
CONSENT/ASSENT AND ADMINISTRATION PROCESS

For caregivers who agree, contact information will be related to the team, who will follow up by phone to describe the research project, estimated time to participate, participant compensation, and obtain oral consent (a consent form will subsequently be mailed to

participants). For caregivers who consent, research staff will explain the study to students, answer questions, and obtain assent for participation. The procedures we used are based on prior collaboration with students on how best to communicate and approach obtaining assent.
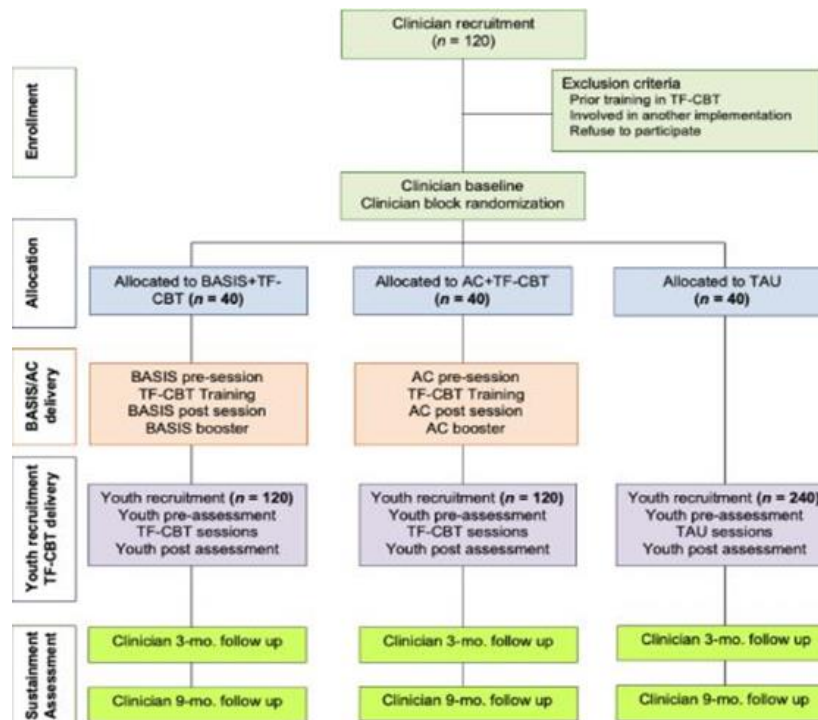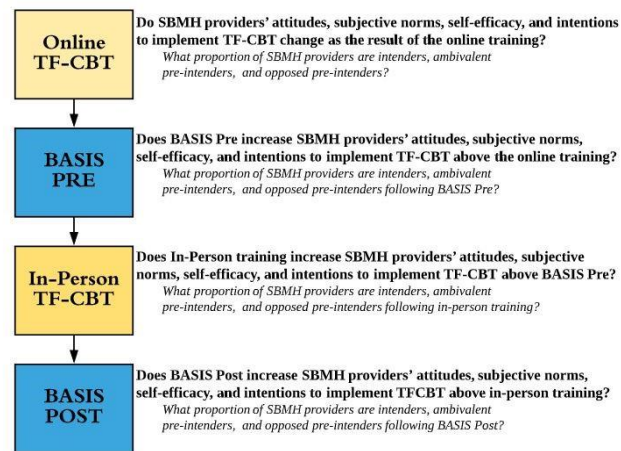

SECTION FOUR: MEASURES AND DATA COLLECTION

1. **PROVIDER MEASURES**

provider data collection will span the training sequence, and active implementation and sustainment phases (18 months in total- see Timeline). Data will include provider quantitative surveys and qualitative data interviews, fidelity assessments of recorded TF-CBT

sessions (via objective coding), and ratings of TF-CBT cases presentation completed by TF-CBT consultants. Data collection will be incentivized in both the implementation and sustainment phase.

Quantitative surveys. Provider surveys will be administered via a secure web-based system, RedCap, at 12 time points. Providers will self-report (list of measures below) their demographic characteristics, BASIS mechanisms (attitudes, subjective norms, self-efficacy, maintenance self-efficacy), implementation intentions, organizational moderators (implementation climate, leadership) and TF-CBT sessions delivered.

Research Questions for Data Collection During Clinicians Training

Online TF-CBT	**Do SBMH providers' attitudes, subjective norms, self-efficacy, and intentions to implement TF-CBT change as the result of the online training?** *What proportion of SBMH providers are intenders, ambivalent pre-intenders, and opposed pre-intenders?*
BASIS PRE	**Does BASIS Pre increase SBMH providers' attitudes, subjective norms, self-efficacy, and intentions to implement TF-CBT above the online training?** *What proportion of SBMH providers are intenders, ambivalent pre-intenders, and opposed pre-intenders following BASIS Pre?*
In-Person TF-CBT	**Does In-Person training increase SBMH providers' attitudes, subjective norms, self-efficacy, and intentions to implement TF-CBT above BASIS Pre?** *What proportion of SBMH providers are intenders, ambivalent pre-intenders, and opposed pre-intenders following in-person training?*
BASIS POST	**Does BASIS Post increase SBMH providers' attitudes, subjective norms, self-efficacy, and intentions to implement TFCBT above in-person training?** *What proportion of SBMH providers are intenders, ambivalent pre-intenders, and opposed pre-intenders following BASIS Post?*

Surveys will be self-administered by providers through RedCap during:

T1-T5 (Training sequence data collection) Measures

   BASIS Mechanism:

1.   Attitudes: EBPAS (Evidence-Based Attitudes Scales)

2.   Intentions: Modified Intention to Use Scale

3.   Self- efficacy: Modified Teacher Self-efficacy Scale (Practitioner Self-efficacy Scale)

4. Subject norms: Modified Subjective Norms Measure (descriptive and injunctive)

T5 only: MEAT/IOTTA

T6 (3-4 weeks after training, school context data collection) Measures

BASIS Mechanism:

1. Attitudes: EBPAS (Evidence-Based Attitudes Scales)

2. Intentions: Modified Intention to Use Scale

3. Self- efficacy: Modified Teacher Self-efficacy Scale (Practitioner Self-efficacy Scale)

4. Subject norms: Modified Subjective Norms Measure

Outcome Measure:

1. S-ICS (School Implementation Climate Scale)

2. S-ILS (School Implementation Leadership Scale)

3. Adoption and penetration

4. Intervention and Usability Scale

5. Time Allocation Questionnaire

T7-T9 (implementation phase: 3, 6, 9 months data collection) Measures

BASIS Mechanism:

1. Attitudes: EBPAS (Evidence-Based Attitudes Scales)

2. Intentions: Modified Intention to Use Scale

3. Self- efficacy: Modified Teacher Self-efficacy Scale (Practitioner Self-efficacy Scale)

4. Subject norms: Modified Subjective Norms Measure

Outcome measures:

1. Compatibility and Identity Questionnaire

2. Time Allocation Questionnaire

3. Adoption and Penetration Survey

Outcome measures T8 and T9

4. Intervention usability scale

T10-T12 (sustainment phase: 12, 15, 18 months data collection) Measures

BASIS Mechanism:

1. Attitudes: EBPAS (Evidence-Based Attitudes Scales)

2. Intentions: Modified Intention to Use Scale

3. Self- efficacy: Modified Teacher Self-efficacy Scale (Practitioner Self-efficacy Scale)

4. Subject norms: Modified Subjective Norms Measure

Outcome Measures:

1. Compatibility and Identity Questionnaire

2. Time allocation questionnaire

3. Adoption and penetration survey

Outcome Measure (only collected during T10):

1. S-ICS (School Implementation Climate Scale)

2. S-ILS (School Implementation Leadership Scale)

3. Intervention usability scale

Tracking across these time points is critical to determining whether and when the effects of BASIS on its target mechanisms may fade, as well as the longitudinal relationship among these mechanisms, moderators, implementation outcomes, and clinical outcomes.

Timepoint	BASIS Mechanism: 1. Attitudes	MEAT/ IOTTA	Outcome Measures:	Outcome Measures:	Outcome Measures:	Outcome Measures: Time	Outcome Measures: Compatibility

	2. Intentions 3. Self-efficacy 4. Subjective norms		1. S-ICS 2. S-ILS	Adoption and Penetration	Intervention and Usability Scale	Allocation Questionnaire	and Identity Questionnaire
T1	X						
T2	X						
T3	X						
T4	X						
T5	X	X					
T6	X		X	X	X	X	
T7	X			X		X	X
T8	X			X	X	X	X
T9	X			X		X	X
T10	X		X	X	X	X	X
T11	X			X		X	X
T12	X			X		X	X

2. **STUDENT & CAREGIVER MEASURES**

Student & Caregiver data collection will focus on mental health and functional outcomes targeted by TF-CBT. The RAs, PCs, or RC will contact families via phone to complete a REDCap survey. Student & caregiver measures will examine three different TF-CBT mechanisms and outcomes, collected at all data collection time points (T6, T7, T8); with demographics being collected at T6. At the end of the school year, academic records will be requested for all students who received TF-CBT during that year. Students' attendance, discipline, and achievement (standardized test scores, grades) will be extracted from these academic records.

Timeline for Collection

T6: Baseline (After to 1st appt with clinician, and before 2nd appt with clinician) ($20)		T7: 3 month ($20)		T8: 6 month ($20)	
Student	Caregiver	Student	Caregiver	Student	Caregiver
Consent/Assent					
Demographics					
Strengths & Difficulties Questionnaire (SDQ)		SDQ		SDQ	SDQ
Moods and Feelings Questionnaire (MFQ)		MFQ		MFQ	MFQ
Child PTSD Symptoms Scale for DSM-V (CPSS-5)		CPSS-5		CPSS-5	CPSS-5
Emotional Regulation Questionnaire (ERQ-CA)	Parent Emotional Reaction Questionnaire (PERQ)	ERQ-CA	PERQ	ERQ-CA	PERQ
Child Post-Traumatic Cognitions Inventory (CPTCI)		CPTCI		CPTCI	
Post Traumatic Avoidance Behavior Questionnaire (PABQ)		PABQ		PABQ	

TF-CBT Mechanism:

1. Belief change: Long Version CPTCI (Child Posttraumatic Cognitions Inventory)

2. Behavior avoidance: PABQ (Posttraumatic Avoidance Behavior Questionnaire) (Van Minnen & Hagenaars, 2010)

3. Emotion regulation: ERQ-CA (Emotional Regulation Questionnaire- Child & Adolescents)

Outcome measure:

1. CAPS (Children's Attributions and Perceptions Scales)

2. CPSS-V Self Report (Child PTSD Symptom Scale DSM-V)

3.

4.

5.

SECTION FIVE: QUALITATIVE DATA COLLECTION AND ANALYSIS: RECORDING AND CODING

1. **SESSIONS RECORDING**

BASIS Fidelity: A BASIS fidelity tool was developed during BASIS R21 (the pilot study to the BASIS R01, current study). The BASIS training sessions were recorded via zoom, since all the training was synchronously online.

TF-CBT Fidelity: At the end of the training sequence, mental health providers were given research training to ensure they are equipped with tools to record their sessions. The provider was also sending an audio recorder in their training goodie packages, which they used to audio record their sessions. The providers then submitted all their recordings to a redcap recording depository.

Research staff: MJ, RG, RR, ES, IM, and YS (ES, IM, and YS are no longer part of the study) were trained in TF-CBT Therapy Processing Observational Coding System (TPOCS) to group and independently code chosen session recordings (at minimum three recordings were chosen per child per provider). The group recordings occurred to ensure that all coders had interrater reliability of alpha 0.8. If coders had disagreement, it was resolved through consensus dialogue.

More information on TPOCS coding can be found here: TPOCS Training and Coding.docx

2. **PROVIDER INTERVIEW**

Individual semi-structured zoom interviews (approximately 30-45 minutes) were conducted at a convenient time for identified providers. The interview was recorded via zoom. Recordings were transcribed prior to coding by the staff with the use of zoom audio transcriptions. The mixed methods design was sequential in structure (quantitative data collected prior to qualitative data); the functions are sampling (using quantitative data to identify our qualitative sample- participants randomly choose based on if they started or didn't start TF-CBT) and expansion (using qualitative data to provide depth and breadth of understanding of the factor that contribute to provider outcomes that deviate from our theory of change; and the process is connecting (the qualitative dataset will build on the quantitative dataset). Qualitative data will explore the limits of- and potentially refine the BASIS theory of change. We developed a systematic, comprehensive semi-structured interview guide that draws from EPIS framework to examine multilevel (i.e., interventions, individual, inner setting, outer setting) determinants that explain what processes facilitated or hindered EBT implementation and sustainment. We generated questions that explore the most salient implementation or sustainment determinants and mechanisms, and how TPB variables may interact with other relevant characteristics of the implementation setting. Questions will be carefully constructed to elicit clear information without assigning valence to implementation/sustainment.

3. **CODING**

TF-CBT Fidelity:

Research staff: MJ, RG, RR, ES, IM, and YS (ES, IM, and YS are no longer part of the study) were trained in TF-CBT Therapy Processing Observational Coding System (TPOCS) to group and independently code chosen session recordings (at minimum three recordings were chosen per child per provider). The group recordings occurred to ensure that all coders had an interrater reliability of alpha 0.8. If coders had disagreement, it was resolved through consensus dialogue. More information on TPOCS coding can be found here: TPOCS Training and Coding.docx

BASIS Fidelity:

AP, YS, and MH were the coder and they coded recorded BASIS training to assess how well the BASIS trainer adhered to the BASIS training script and the engagement of the providers.

Qualitative interview:

The initial coding team used the year 1 qualitative interview transcripts to create the codebook 20240808_BASIS clinician interview codebook.docx

The codebook was continuously updated by the BASIS coding team as new themes emerged during the following years (2 years) of qualitative interviews.

The all the qualitative interviews transcripts were consensus coded by MJ and KB at the end once the codebook was finalized. There were 18 qualitative interviews, 4 from Year 1 (only one provider implemented TF-CBT), 8 from Year 2 (four providers implemented TF-CBT), and 6 from Year 3 (five providers implemented TF-CBT).

SECTION SIX: DATA ANALYSIS PLAN

The main analyses are *Aim 1b* **and** *Aim 2b*

Main aim	Sub aim	Analysis method
Aim 1: Experimentally evaluate the effectiveness of TF-CBT versus Treatment-as-Usual (TAU).	Aim 1a: Evaluate main effects on proximal intervention mechanisms of change (trauma-related cognitions, shame attributions, overgeneralization).	*Multilevel Model* • Independent: RETI vs TF-CBT • Dependent: Child measure outcomes (CPTCI, ERQ, PABQ (child and CG), SDQ (child and CG)) • Nesting: student under provider, time ** There will be four different models- 1) base model with only intercept, 2) model with only IV, DV, and time, 3) model with IV, DV, time, and TF-CBT vs RETI interaction with time, and 4) lastly, IV, DV, and study group interaction (BASIS, AC, RETI) with time.
	Aim 1b: Evaluate main effects on child mental health outcomes (symptoms of PTSD, depression, anxiety) and test intervention mechanisms via a mediational model.	*Multilevel Model* • Independent: RETI vs TF-CBT • Dependent: Child measured outcomes (CPSS-V (child and CG, SMFQ (child and CG))

		• Nesting: student under provider, time
		• Mediator: BASIS Mechanism (provider-level data)
		** There will be four different models- 1) base model with only intercept, 2) model with only IV, DV, and time, 3) model with IV, DV, time, and TF-CBT vs RETI interaction with time, and 4) lastly, IV, DV, and study group interaction (BASIS, AC, RETI) with time.
	Aim 1c: Evaluate the cost and cost-effectiveness of TF-CBT for improving clinical outcomes	

Main aim	Sub aim	Analysis method
Aim 2: Experimentally evaluate the impact of BASIS versus Attention Control (AC).	Aim 2a: Evaluate main effects on proximal implementation mechanisms of change (attitudes, subjective norms, self-efficacy, intentions to implement, and maintenance self-efficacy).	*Multilevel model* • Independent (IV): AC vs BASIS • Dependent (DV): attitudes, subjective norms, self-efficacy, intentions • Nesting: Piecewise time (training, active, sustainment) • Interaction: Time X Study group ○ T1 to T5 X BASIS ○ T6 to T9 X BASIS ○ T10 to T12 X BASIS ** There will be four different models- 1) model with only intercept, 2) model with only IV, DV, and time, 3) model with IV, DV, and study group interaction (BASIS, AC) with time, 4) 3) lastly, model with IV, DV, and study group interaction (BASIS, AC, and RETI) with time.

	Aim 2b: Evaluate main effects on objective implementation outcomes (adoption, fidelity, sustainment) and test implementation mechanisms via a mediational model.	*Cross tabulation* • Difference in TF-CBT adoption among BASIS and AC groups. • *Include missing as 0* • *Sensitivity analysis will exclude missing* *Survival analysis* • The difference in adoption for TF-CBT is adopted among BASIS and AC groups. *Fidelity* • Difference in TPOCS scores among BASIS and AC groups (there was no significant finding due to lack of data) • *One row per provider (did the provider in any tape use TF-CBT content, because there isn't enough provider data to run a multilevel mixed method analysis)*
	Aim 2c: Conduct sequential mixed-methods data collection to explain residuals (i.e., clinicians whose implementation behavior is unaccounted for by the mediation model).	*Qualitative analysis* • Consensus coding of qualitative interviews • Pulling out main themes
	Aim 2d: Evaluate the cost and cost-effectiveness of BASIS for improving clinical outcomes.	