Virtual Implicit Bias Reduction and Neutralization Training (VIBRANT)

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Study Protocol and Study Analysis

STUDY TITLE

Addressing Bias among School Mental Health Professionals to Improve Equitable Implementation of Evidence-Based Practice – Virtual Implicit Bias Reduction and Neutralization Training (VIBRANT)

EXECUTIVE SUMMARY

Statement of Purpose

This study aims to develop and test effective strategies for increasing equitable delivery of evidence-based mental health services to improve care quality for students in middle and high schools, especially those with marginalized identities.

Research Questions (or Research Problem of Practice)

Despite decades of problem recognition, Black and Latinx youth continue to receive lower quantity and quality of mental healthcare compared to their Non-Hispanic White (NHW) peers. While school-based mental healthcare has been shown to be effective in decreasing access disparities, racial/ethnic minoritized youth continue to receive fewer needed mental health services even in schools. Healthcare professional's bias has been identified as a significant contributor to these kinds of health disparities. Thus, we (the UW SMART Center research team led by Dr. Freda Liu) developed the Virtual Implicit Bias Reduction and Neutralization Training (VIBRANT) for school-based mental health professionals. This study aims to (1) evaluate the effectiveness of the VIBRANT training on equitable implementation of one easy to learn evidence-based practice—measurement-based care (MBC, aka Progress Monitoring), (2) examine the training's impact on school-based mental health professional's implicit bias and therapeutic alliance with their clients, and Black and Latino/a/x youth's experience receiving mental health services and their mental health symptoms.

Methods (including sample, data collection, and analysis plan)

The VIBRANT study aims to recruit a total of 80 school-based mental health professionals and 160 youth who identify as African/American and/or Hispanic/Latino/a/x and their caregivers. Primary study data will be collected from all study participants as brief online survey measures at multiple time points. Generalized mixed effects models will be used to test our primary aims.

Time Required of Study Participants

Throughout the 4-month study period, school mental health professionals are anticipated to spend about 10 hours on study-related activities. Youth and caregiver participants are anticipated to spend a total of about 30 minutes on study related tasks during the 3 months they are in the study.

Dissemination Plan

The results of this study will be reported to our funder (NIMH), scholars, and the public via progress reports, peer-reviewed publications and conference presentations when the study is complete

(anticipated in 2025). Partner school districts, agencies and participants can receive updates and preliminary results before official study results are published.

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STATEMENT OF PURPOSE

Pediatric mental health inequities persist despite decades of problem recognition. Black and Latinx youth continue to receive lower quantity and quality of needed mental healthcare compared to non-Hispanic White youth. Even in settings where access disparities are reduced, such as in schools (the most common setting in which youth access mental healthcare), treatment disparities persist. Healthcare providers' implicit bias has been identified as a major contributor to these disparities via negative impacts on the patient-provider relationship and inequitable delivery of high-quality evidence-based practices (EBP). The implementation of any EBP runs the risk of worsening existing health disparities due to differential access, delivery, or effectiveness of the intervention. Implicit bias of mental health professional (MHP) delivering EBPs can be a critical and unaddressed barrier of implementation for any EBP.

Although some implicit bias interventions for healthcare providers are emerging, studies have rarely included mental health professionals. In a previous NIH funded study, our research team iteratively developed a brief (~45 minutes), interactive online Virtual Implicit Bias Reduction and Neutralization Training (VIBRANT) for school mental health professionals. In a small open trial, school mental health professionals found VIBRANT to be highly usable, appropriate, acceptable, and feasible to implement in their clinical practice. After completing the VIBRANT training, MHP demonstrated notable improvements in implicit bias knowledge, and a downward trend in implicit bias (as measured by the Implicit Association Test) over 14 weeks. Moreover, MHP with the greatest reductions in implicit bias also reported the strongest rapport with their patients. Based on these promising findings, the current (NIH funded) study aims to conduct a randomized pilot trial of VIBRANT—an implementation strategy for promoting equitable adoption, penetration, fidelity, and sustainment of EBPs—with **80 school mental health professionals.**

One highly learnable, efficient, and scalable EBP that is particularly well-suited for the education sector is Measurement-Base Care (MBC)—the systematic collection of patient-reported progress data to inform collaborative decision-making. MBC is also known as Progress Monitoring in the education service sectors. The proposed study aims to evaluate VIBRANT's feasibility to promote equitable adoption, penetration, fidelity, and sustainment of MBC, with a validated, brief, interactive online training for MBC. We will also examine VIBRANT's impact on proximal mechanisms of change including MHP's implicit bias as well as distal youth mental health outcomes (i.e., symptoms and functioning) with **160 Black and Latinx youths**.

RESEARCH QUESTIONS AND HYPOTHESES

This study aims to address *2 main questions:*

1) Does the implicit bias training (VIBRANT) help mental health professionals implement measurement-based care (MBC) in more equitable ways (e.g., using MBC with similar frequency and fidelity with minoritized youth as non-Hispanic white youth?
2) Does VIBRANT training reduce MHP's implicit bias; such that minoritized youth (specifically those who identify as Black and/or Latinx) have better experiences and outcomes while receiving mental health services with VIBRANT-trained MHP compared to MHP who only received MBC training?

This study is a randomized controlled hybrid type-3 effectiveness-implementation pilot trial which is designed to determine whether our research procedures are feasible for a future larger-scale trial.

It is hypothesized that the VIBRANT implicit bias training would (1) support the equitable implementation of any evidence-based practice (e.g. MBC, TF-CBT, FAST) in school-based settings, (2) reduce mental health professionals' implicit bias, and improve minoritized youths experiences and outcomes in receiving mental health services.

METHODS

Sample

This study involves three distinct participant types:

1) **School mental health professionals (SMHPs)** who provide on-going individualized services (sees students for multiple sessions to work on specific problems, issues, or skills,) to students in middle or high school. Because we are interested in seeing how training affects how MHPs may interact with students of diverse backgrounds, we are looking to recruit MHP with diverse caseloads consisting of approximately 15% or more students who identify as Black or Latinx. This study aims to recruit a total of 80 SMHPs.
2) **African American/Black and/or Hispanic/Latino/a/x youth** who are receiving mental health services at school with a participating MHP. All youth participants should be in grades 6-12 and are actively receiving on-going individualized mental health services with the participating SMHP. This study is looking to recruit about 2-students per participating SMHP for a total of 160 students.
3) **Caregivers/Legal guardians of participating students.** This study aims to recruit up to one caregiver for each participating student for up to 160 caregivers. Youth may consent to participate in this study without a caregiver if they are of the legal consenting age for mental health services in their state of residence.

Recruitment and Screening of Participants:

Participants will be recruited through healthcare agencies staffing school-based health center or mental health programs or school districts (employing their own school mental health professionals). We aim to recruit 40 school mental health professionals (SMHPs) per year and will ask each of them to recruit 2 youths from their caseload who identify as Black and/or Latinx for a total of 80 students per year. Across 2 years, that is a total of 80 SMHPs, 160 Black/Latinx youth, and up to 160 caregivers reporting on their participating youths.

School mental health professionals recruitment & screening: SMHP participants will be recruited from participating healthcare agencies that staff school-based health clinics, or school districts that employ SMHPs directly to provide school-based mental health. Agency and school administrators will be approached to discuss their agency and school's participation. We will complete additional school and agency IRB processes as needed. Administrative leadership of participating agencies and school districts may provide us with the email addresses of school mental health professionals for recruitment or pass on our study information, including our screening and consent forms, to their SMHPs. Potential participants may receive an email from the study research coordinator at the beginning of the school year with an invitation to participate, a study information form, and a link to the electronic screening questionnaire. SMHPs who screen in as eligible will be presented with the electronic study informed consent information.

Since we are working with organizations across the nation, there is variation across each state in terms of statutes governing the minimum age of consent for mental health services. Due to this, youth will assent or consent using the same form. We will determine whether students need parent/caregiver consent by asking SMHPs to report student's age and whether the student is consenting to their own mental health services in our Student Referral Form if. We have ensured that these consent/assent forms' reading level is developmentally appropriate across all ages of 12-19.

When the SMHPs are sharing information about our study to families, we have provided templated language that SMHPs can use when talking to families. In this templated language we mention that families have the option to consent via a live Zoom call. For student and or caregiver participants who choose to complete consent via a live Zoom call, consent will be sought at the end of the consent conversation when all the information has been reviewed and potential participants' questions answered. Potential participants may choose to join that live Zoom meeting from any location that would provide enough privacy of their choosing. Research team members will ensure all Zoom meetings are taken from a private location.

Youth and Caregiver recruitment & screening: Each participating SMHP will help identify 2 or more youths who will join the study. The youths must identify as Black/African American and/or Hispanic/Latinx who are English or Spanish speaking and receiving mental health services from that SMHP. Once SMHPs identify youths eligible for the study and determine that the youth is interested in more information and open to being contacted by our project team for participation in the study, they will pass on contact information for the youth and their legal guardian (with the youth's permission) to our UW research team via our Student Referral Form. We provide SMHPs templated language they can use when discussing the study with families. A research team member will then reach out to the youth and caregiver (through their preferred method of contact as indicated on the student referral form, e.g., email, phone call, text, etc.) to complete screening, verifying eligibility, and obtain assent/consent. SMHPs may also share a study flyer with interested youth and/or caregivers but will not engage in any consent procedures or additional research communication and defer all additional questions to the study team. The youth screening process consists simply of the research staff confirming with the youth that they intend to continue working with the participating SMHP to receive on-going services (e.g., more than 2 visits).

Caregivers of participating youths may be invited to join the study as participants to report on the behavioral and emotional well-being of the youth. The determination of whether a student needs to obtain parental consent before assenting to participate in the study will be dependent on the laws

regarding age of consent to mental health services in the state they reside in. Study team members conducting consent procedures via phone will briefly screen caregiver for eligibility at the beginning of the consent conversation by simply confirming that the potential participant is a primary caregiver/legal guardian for the participating youth with adequate knowledge to answer questions about the youth's behavioral and emotional well-being. When the study team is contacting the caregiver via email/text, we screen the caregiver by sending an initial email/text first confirming the caregiver is indeed the legal guardian/primary caregiver that can answer questions about the youth's behavioral and emotional well-being before sending a link to the electronic consent form.

Data Collection:

Primary Data

School-based mental health professionals (SMHP) surveys will include items on SMHP's demographics, previous training experiences and current practice in measurement-based care (MBC), knowledge quizzes for MBC and implicit bias management, the implicit association test (IAT), acknowledgement of implicit bias questionnaire, rating of usability, acceptability, appropriateness, and feasibility for the online trainings they receive, rating of satisfaction with consultation, and therapeutic alliance with students participating in the study. In addition to online surveys, SMHPs will complete weekly caseload service logs. SMHPs will create their log at baseline by entering unidentifiable info for every patient referred and currently on their caseload (using pseudonyms) along with demographic information (gender, age, grade, race, ethnicity). During subsequent assessment timepoints, SMHPs will log every student patient seen during the prior week and indicate which if any of the 3 core MBC practices (i.e., measure administration, SMHP reviewing results, discussing results with patient to support collaborative treatment planning) were completed for each identified case. Experimental group SMHPs (e.g., those who received the VIBRANT training) will also note on their service log whether they used specific bias reduction strategies.

Youth surveys will include items about their current symptomatology, previous experiences of discrimination, ratings of their working alliance (quality of relationship) with the participating SMHP, and experience of cultural differences in counseling. Caregiver surveys will include questions about their child's mental health symptoms.
More information on the instruments and assessments included in these online surveys is provided below. REDCap and Qualtrics programs are used for secure online data collection.

Timeline of research activities:

School-Based Mental Health Professionals

Once a school-based MHP is enrolled in our study we will ask them to participate in the study activities described in the table below. The estimated amount of time each activity may take is also included in the table below.

Participating MHP Study Activities	Approximate Time Required
1. Self-paced interactive online training modules via Canvas (learning management system)	1 – 2 hours
2. Post-training consultation calls. These consult calls are hosted online via Zoom and will consist of 3-5	Each session is 60 minutes (2-3 sessions throughout the study)

school MHPs per call. Prior to beginning the consultation call, we ask MHPs for their permission to record the consultation call via Zoom. MHPs will be interacting with other MHPs on the group consult call.	
3. Refer ~ 2 or more students to participate in the study who identify as African American/Black and/or Latino/a/x via our Student Referral Form	~ 5 minutes to complete study referral form for each student referred
4. Complete weekly caseload service logs to reflect on strategies learned in training over the course of the 3-month study	~ 5 minutes a week
5. Complete weekly online discussion board posts (via Canvas application) to interact with other MHPs on the strategies they are using with their clients	~ 5-10 minutes a week
6. Record sessions with participating student and upload recording	~ 5 minutes to upload each recorded session to a secure link
7. Complete 5 online surveys over the course of the study	~ 25 minutes per survey

In summary, each participating SMHP will spend about 10 hours on study-related tasks over the 4 months study period.

Additionally, we provide clinicians with a participant guide to help them in contacting families (youth and/or caregivers), how to submit a student referral, and how to upload audio recordings to ensure understanding of study related processes and ensure alignment with following local and federal level regulations/laws.

Participating MHPs will receive study incentives for their completion of various tasks. Please refer to the table below for more information on MHP incentives.

Study Related Task	Incentive Amount
Baseline Survey Completion	$70.00
Training Completion	CE Credits
Post Training Survey Completion	$80.00
Identification of Youth Participants	$25.00 x 2
1-Month Follow Up Survey	$50.00
2-Month Follow Up Survey	$50.00
Audio Recording Uploads	$50.00
Caseload Service Logs	$50.00
3-Month Follow Up Survey	$50.00

Youth and Caregivers

For youth and caregivers participating in the study, they will complete online surveys as listed in the table below along with the required time for each survey.

Youth and Caregiver Study Activities	Time Required

Complete both a pre and post survey to share their experiences of • Mental health symptoms • Receipt of school-based mental health services • Quality of relationship with participating MHP	15-20 minutes per survey (immediately after consent, 3 months after consent)

In summary, youth and caregivers will spend about 30 minutes on study related tasks throughout the 3-months they remain in the study.

Each student and caregiver will receive incentives for completing study survey (see table below).

Study Related Task	Incentive Amount
Baseline Survey Completion	$25.00
3-Month Follow-Up Survey Completion	$25.00

Consent / Assent Forms

Consent process for SMHPs:

SMHPs who express interest in the study and choose to participate will complete an electronic consent form. A copy of this form has been attached to this proposal.

Recruitment and consent materials will clearly state the voluntary nature of the study and make clear that there will be no negative consequences for choosing not to participate. The study will not provide feedback to agencies or school districts (SMHP employers or supervisors) on who ultimately participates in the study as SMHPs' participation in research is confidential.

Consent/Assent Process for Youth & Caregivers:

Before the research team contacts families for consent, SMHPs will ask the families for their permission to share their contact information with our research team via our "Student Referral Survey". While youths will be initially approached by their participating SMHPs to inform them of the study, recruitment and consent activities will be the responsibility of trained research staff at the University of Washington. SMHPs will be instructed to clearly explain the completely voluntary nature of the study and assure youths that their participation in the study will not affect the care they receive with the SMHP or their standing at school in any way. This will further be affirmed by trained research staff during the consent process. When the SMHPs are sharing information about our study to families, we have provided templated language that SMHPs can use when talking to families.

Once the research team receives the student/caregiver's contact information, the research team member will contact student/caregiver to explain the study and answer any questions. A research team member will also send the student and/or caregiver a link via email or text message (based on their preference) for the student/caregiver to access the consent form, which they may review independently or live with a research team member in a telephone or Zoom call. When completing asynchronously,

potential participants can read through the electronic document and sign the form electronically. When completed live, consent will be sought at the end of the consent conversation when all the information has been reviewed and potential participants' questions answered. Potential participants may choose to join that live Zoom meeting from any location that would provide enough privacy of their choosing. The student/caregiver will be asked to electronically sign their survey to confirm their choice in participating in the study. A copy of this survey has been attached to this proposal.

Since we are working with organizations across the nation, there is variation across each state regarding policies around what is minimum age of consent that a youth can consent to accessing their own mental health services. Due to this, the research team is trained to pay attention to the age of referred students in conjunction with their state of residence and apply appropriate consent/assent procedures. For states that require caregiver's consent for youth's mental health services, youth's assent will be sought once their parents/legal guardian/caregiver consents for them to participate in the study. Upon gaining parental/legal guardian/caregiver consent, the study team will send an electronic assent form to the youth via a secure REDCap survey link. Consent and assent conversations are handled the same way as described in the above paragraph.
To help with this, in our Student Referral Form we ask if the student is consenting to their own mental health services, and we ask what the student's age is as well (regardless of if they can consent to their own mental health services or not). We use the same form for youth assent and consent and have ensured that these consent forms' reading level is developmentally appropriate across all ages of 11-19.

The UW IRB has granted our study a waiver of parental consent for youth who are of legal age to consent for their own mental health care in their state of residence. Therefore, youth who are 14 or older can decide for themselves whether they would like to participate in this study without parental permission. However, for students who are 13 or younger, a legal guardian/caregiver must consent for that student to participate in the study.

Waived elements of informed consent (for SMHPs and families)

Although this study is designed to evaluate the efficacy of an online implicit bias training as an equity focused implementation strategy for measurement-based care, we are concerned about sampling bias if we advertised the study as one of an implicit bias training. Awareness of the study being about implicit bias may also prime participants in ways that affects their performance on the implicit association test (one of the outcome measures). Thus, the study will be advertised as an evaluation of strategies to promote equitable implementation of an evidence-based practice—measurement-based care (MBC). Potential SMHP participants will be told that they will be randomized to conditions to receive different online trainings. Control group SMHPs will receive the online training and subsequent consultation related to MBC only. Experimental condition SMHPs will receive both the online training for MBC (BOLT) and the one for managing implicit bias management strategies (VIBRANT) and receive consultation relevant to both topics. SMHP participants will become aware or at least suspect the implicit bias aspect of the research study as soon as they complete the baseline survey which includes a quick knowledge check on implicit bias. Focusing what we share when recruiting SMHPs on equitable implementation without describing the implicit bias aspect of that is only in place to reduce recruitment bias. Since the purpose of the study is about VIBRANT as an equity focused implementation strategy, we don't consider not describing the implicit bias aspect of the training in full detail at the time of recruitment to be deception.

For SMHP participants that originally were randomized to the control condition to receive only MBC training, after they've completed their 12 weeks of participation in the study, they will be informed that they were randomized to receive MBC and that they have the option to receive the VIBRANT training if they're interested in receiving it.

Instruments

SMHP surveys will include items on SMHP's demographics, previous training experiences and current practice in measurement-based care (MBC), knowledge quizzes for MBC and implicit bias management, the implicit association test (IAT), acknowledgement of bias questionnaire, rating of usability, acceptability, appropriateness, and feasibility for the online trainings they receive, rating of satisfaction with consultation, and therapeutic alliance with students participating in the study.

Youth surveys will include items about their current symptomatology, previous experiences of discrimination, and ratings of their working alliance (quality of relationship) with the participating SMHP and experience of microaggression in counseling.

These surveys and measures together will be used to assess SMHP's knowledge improvement and retention pre- and post-training. In addition, these surveys and measures will assess the training's impact on SMHP's practice and implicit bias. Youth measures will help ensure we capture the student voice and help us understand whether the training the SMHP receive impacts minoritized youth's experiences receiving services and their mental health outcomes.

All participant surveys will be delivered to participants from the UW study team via an emailed link. Participants can then complete their survey online at their convenience.

Secondary Data: N/A

Anticipated benefits to participants

A direct benefit of participating in this research study cannot be guaranteed; however, participants may receive some satisfaction or indirect benefit from contributing to this research and generalizable knowledge designed to improve the quality of school-based mental health services. SMHP participants may gain professional skills as a result of measurement-based care (BOLT) and implicit bias (VIBRANT) trainings and post-training consultation. SMHP will be offered continuing education credits for completion of their online trainings and participating in consultation. Youth participants may also experience enhanced mental health services as well as improvement in their mental health symptoms and overall functioning as a result of SMHP having received the aforementioned training and consultation. Risks involved are minimal, and no greater than risks that they would experience during the course of routine activities, and viewed as reasonable given the anticipated benefits.

Anticipated Risks to participants

There are three potential risks associated with participation in the study. The first is that a SMHP, student, or caregiver participant may experience discomfort while answering study questions. SMHPs may be concerned about the confidentiality of data collected, and whether their responses or decision to participate will impact their jobs or job evaluations, or that data collected on them or their student patient will reflect poorly on their competence. Some SMHPs may also feel discomfort confronted with their own implicit biases and/or encounter difficulties when implementing MBC. SMHP participants will

be told at the outset of the study that they will not be evaluated on their performance or responses in any way. Participants will also be informed of the measures taken to protect the confidentiality of their data. For youth, many of the questions they are asked will be about their mental health symptoms and daily functioning, which may feel personal. Answering these questions may cause discomfort or feelings of embarrassment for some youth. Parents may also feel uncomfortable about some questions related to their child's behaviors and function as well as about their household (e.g., income). Nevertheless, all questions asked of parents and youth are routine in the conduct of mental health evaluations and interventions and significant distress is actually highly unlikely. Any discomfort experienced is likely to be temporary and to dissipate quickly over time. Moreover, all youth and caregivers are invited to complete measures via the secure online data collection platform (unless they prefer to respond via phone interview), to increase privacy, and are welcome to skip any questions they don't want to answer. All youth and caregivers who choose to complete data collection via phone interview will be afforded with the opportunity for trained research staff to support their comprehension of questions, minimize the likelihood of adverse experiences, and respond skillfully if a participant does experience an adverse reaction. Our developmentally appropriate procedures and instruments in the proposed project are based on established protocols that have been used by our investigative team in previous NIMH-funded research and have not been found to produce significant distress in either youth or caregivers. Participants in similar studies rarely report research-related distress, and the majority report benefit from participation and have no regrets.

The second possible risk is that SMHPs and/or youths may be uneasy being recorded during therapy sessions and/or be concerned about privacy. SMHPs may also experience the recordings as potentially evaluative and uncomfortable. Although such initial unease is typical, our experience indicates that it is short-lived for both youth and SMHPs. Any discomfort experienced related to recording is likely to be temporary and to dissipate quickly, as rapport and trust are built between youths and SMHPs and SMHPs and the researchers. Most individuals quickly forget that the recording is on and habituate to the situation.

The third potential risk is breach of confidentiality due to failures in data security. We will follow the UW GUIDANCE on Data Security Protections for the level appropriate for our study.

Procedures for maintaining confidentiality of subject data

All study data will be de-identified, downloaded from our secure online survey tool and stored in a secure, HIPAA and FERPA compliant server at the University of Washington. When data is disseminated and shared to the community, all responses will be described in aggregate, and no identifiers will be used.

Therapy session recordings conducted between SMHPs and students will be stored on a secure server until qualitative data coding and analysis is complete. This will not exceed three years from the end of the study data collection period.

Per the audio recorder protocol, once the clinician uploads the audio file to our HIPAA & FERPA compliant database server REDCap via our audio upload survey, we ask clinicians to delete the audio files from the recording device immediately.

The transcription of the recordings will be conducted by Lyssn, a HIPAA compliant application designed to support the analysis of mental behavioral health therapy sessions. The transcriptions will be exported, reviewed by our internal team to de-identify and uploaded to our password-protected shared

network server data folder that will only be accessed by our internal team. Once the de-identified transcript has been uploaded to the UW secure server, the transcript and any data associated with the recording will be deleted from the Lyssn application. Only de-identified transcripts will be kept.

All participant survey and IAT data will de-identified and labeled with a study ID number. Any identifying information linking participants' identifiers to a study ID number will be stored in a permission file location accessible only to research team members, separated from study data, on a secure UW server.

Referral Form and Consent/Assent data or any identifying information linking participants' identifiers to a study ID number will be stored on a secure UW server and kept separate from analytical data files. Analytical data files will be kept free from participant identifiers.

All study data collected that could identify research participants in the study will be destroyed after the end of the applicable records retention period required by state and/or federal law of 6 years.

None of the survey questions used in our study include any questions that could lead to information that would require mandated reporting. Participating SMHPs may learn of situations in the usual course of therapy with participating youths that may lead to mandated reporting, but that would be a typical part of the SMHPs' job irrespective of their participation in the study. Thus, that mandated reporting duty remains with the SMHP (who would have explained that during their typical consent to care process with the youth) and not with our research study.

UW Human Subjects Division – IRB guidance for HIPAA

PHI

- **Protected health information (PHI)** is defined as *"individually identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral."*
- **As governed by federal HIPAA regulations and UW institutional polices:** Researchers that obtain and use PHI must obtain a) authorization from the subject; or b) a waiver of authorization granted by an IRB, unless the PHI is 1) de-identified; 2) a limited data set or 3) from decedents.
- **PHI held in the form of clinical knowledge.** Healthcare providers may assist in study recruiting by informing (in writing, by email, or verbally) a researcher about potential subjects, or informing potential subjects about a study, based on their knowledge of their patients rather than by examining medical records. This is not considered to be an access and use of PHI.

Individually identifiable information:

Information, including demographic data, that:

- Identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual, **AND**
- Relates to:
  The individual's past, present, or future physical or mental health or condition
  The provision of health care to the individual **OR**
  The past, present, or future payment for health care to the individual

De-identified PHI:

PHI is no longer considered individually identifiable if there is no basis to believe it can be used to identify the individual. There are two ways to de-identify PHI:

- Removal of 18 HIPAA-specified identifiers (Use and Disclosure of Protected Health Information (PHI) – COMP.103), provided that there is no knowledge that the resulting information could be used alone or in combination with other information to identify individuals **OR**
- A person with appropriate knowledge and experience applying generally accepted statistical and scientific methods for rendering information not individually identifiable: **(1)** applies such principles/methods; **(2)** determines the risk is very small that the information could be used alone or in combination with other available information to identify an individual, **and (3)** documents the methods/results that justify the determination.
- **Limited data set.** PHI from which 16 specific individual identifiers have been removed (COMP.103).

ACTIVITIES PREPARATORY TO RESEARCH

- Federal HIPAA law allows researchers to access PHI without obtaining authorization or a HIPAA waiver if the PHI will be used solely to prepare a research protocol or plan the research activity. For example, a researcher may review PHI to design a research study or to assess whether a sufficient number or type of records exist to conduct the research.
- Screening records to identify possible subjects is **not** considered an activity preparatory to research.
- Review COMP.103 for additional requirements.

Statement describing when subject data will be destroyed

All study data collected that could identify research participants in the study will be destroyed after the end of the applicable records retention period required by state and/or federal law of 6 years.

FUNDING DOCUMENTATION

This study is funded by the National Institute of Mental Health (1R34MH128386-01A1). More information about our funding is available at the following link: RePORT ⟩ RePORTER (nih.gov)

DISSEMINATION

Results of this study will be reported to our funder (NIMH), scholars, and the public via progress reports, peer-reviewed publications, and conference presentations when the study is complete. Partner school districts and agencies, as well as participants, may choose to receive updates and preliminary results via an electronic study newsletter, sent via email, before official study results are published .

The research team supports the commitment of NIMH to publish and disseminate materials and data generated using NIMH funding. We agree to abide by the NIMH Data Archive (NDA) Data Sharing Terms and Conditions. Lead PI Dr. Liu will be responsible for communicating with NDA support staff to establish an appropriate data submission schedule. Toward this end, we will store all study data with indirect identifiers (i.e., subject codes) so that it cannot be linked back to individuals. Therapy session video recordings and any other identifying information of participants will not be stored with sharable data upon completion of the study.

VIBRANT DATA SAFETY AND MONITORING PLAN

Data Quality Assurance and Confidentiality: Data quality assurance will be monitored on an ongoing basis by the research team. Dr. Liu will supervise routine protocol compliance checks conducted by internal research team, maintaining approved standards for data transport, and ensuring that they are strictly adhered to. All study data will be stored in password-protected computer files and identified with study IDs. Any paper files will be stored in de-identified in locked filing cabinets, separate from any information linking specific participants to project identification numbers. Analytic data files will contain no identifying information. Other confidentiality issues are discussed in the Protections Against Risks section of the *Protection of Human Subjects*.

Roles and Responsibilities: Data not directly entered by research participants will be entered by research staff at the University of Washington (UW) School Mental Health Assessment Research and Training (SMART) Center. All data cleaning, creation of scale scores, analyses, and documentation will be conducted by the research staff under the supervision of Dr. Liu (PI). The PIs will be responsible for long term management of the data, including the maintenance of confidentiality of the data and making the data available to others for at least 10 years.

Adverse Events: Project staff will be trained to identify potential adverse events and instructed to report them immediately to Drs. Liu and Lyon. Should any study participant express concerns about the study or their participation or appear distressed during any study activities, the witnessing research team member/ participating clinician will bring the matter to the attention of the PIs to determine the appropriate course of action. Drs. Liu and Lyon (co-PIs) in consultation with the Data Safety and Monitoring Board (DSMB, see below), will distinguish serious adverse events (SAE) from non-serious adverse events (AE). Both Drs. Liu and Lyon are licensed clinical psychologists with experience establishing adverse event and safety protocols in research projects. Serious adverse events will be documented and discussed with the DSMB and institutional review board (IRB) as soon as possible and reported to the IRB and NIH project officer within 48 hours. An annual report will be submitted to the NIH and IRB summarizing all adverse events (SAE and AE). Other protections against adverse events for participants are described in *Protection of Human Subjects.*

Data Safety Monitoring Board (DSMB): Given that this research includes a clinical trial involving youths receiving mental health care, a DSMB will be established to monitor the safety of participants across all care providers. The DSMB will be established and operate in accordance with the NIMH Policy Governing Independent Safety Monitors and Independent DSMBs (https://www.nimh.nih.gov/funding/clinical-research/policy-governing-independent-safety-monitors-and-independent-data-and-safety-monitoring-boards.shtml). The DSMB will monitor the execution of the research protocol and study procedures and will ensure that reporting of adverse events follows the requirements of the UW and NIH. The DSMB will

review the protocol and procedures at study start, including how adverse events will be defined in the trial and the reporting procedures. The DSMB will conduct semi-annual reviews thereafter to determine whether patient safety is being adequately safeguarded and study goals are being met. The DSMB will consist of three mental health specialists (MSW/MS/MA, PhD, PsyD or MD) with expertise in the delivery of school-based mental health services and one biostatistician. The DSMB will be kept apprised of adverse and notable events on an ongoing basis and will serve as the final arbiter of whether individual participants should be removed from the protocol.

VIBRANT ANALYTIC PLAN

General Analytic Approach

Basic data screening and descriptive analyses will be conducted for all variables. We will plot relationships to screen for errors and examine distributional norms and trends. We will examine missing data to determine the reasons for the missing data and take appropriate measures depending on the form and function of the missing data. It is generally preferable to use statistical based solutions as a last resort, therefore data screening will occur immediately post data collection so that we may contact participants to complete data that were missing.

Main Aim	**Sub Aim**	**Analysis methods**
Aim 1: Evaluate VIBRANT's feasibility to promote equitable adoption, penetration, fidelity, and sustainment of MBC, with a validated, brief, interactive online training for MBC	Evaluate VIBRANT's feasibility to promote equitable adoption	Multilevel model: - Independent variable: Condition (MBC vs VIBRANT) - Dependent variable: Adoption - Nesting: Time within clinicians
	Evaluate VIBRANT's feasibility to promote equitable penetration	Regression: - Independent variable: Condition (MBC vs VIBRANT) - Dependent variable: Division of number of youth on clinicians' self-reported caseload who they have used MBC practices by the total number of youth in caseload
	Evaluate VIBRANT's feasibility to promote equitable fidelity	Multilevel model: - Independent variable: Condition (MBC vs VIBRANT) - Dependent variable: Self reported fidelity - Nesting: Student within clinician Chi square test: - Difference in self-reported fidelity count by condition (MBC vs VIBRANT)
Aim 2: Examine VIBRANT's impact on proximal mechanisms of change including clinicians' implicit bias as well as distal youth	Examine VIBRANT's impact on proximal mechanisms of change including clinicians' implicit bias	Multilevel model: - Independent variable: Condition (MBC vs VIBRANT) - Dependent variable: Average IAT Scores - Nesting: Time within clinicians

mental health outcomes (i.e., symptoms and functioning) with Black and Latinx youth	Examine VIBRANT's impact on proximal in distal youth mental health outcomes (i.e., symptoms and functioning) with Black and Latinx youth	Regression: - Independent variable: Condition (MBC vs VIBRANT) - Dependent variable: Post Total Youth WAI score - Controlling: Baseline Total Youth WAI Score Regression: - Independent variable: Condition (MBC vs VIBRANT) - Dependent variable: Post Total Youth SDQ score - Controlling: Baseline Total Youth SDQ Score Regression: - Independent variable: Condition (MBC vs VIBRANT) - Dependent variable: Post Total Clinician SDQ score - Controlling: Baseline Total Clinician SDQ Score