CLINICAL STUDY PROTOCOL

Observational Study of Individual or Group Template

Feedback and Outcomes for Clinically Useful Student Services (FOCUSS)

Protocol Number

2000030199

Protocol Version

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Version #2

Synopsis

Purpose

Feedback and Outcomes for Clinically Useful Student Services (FOCUSS) is a pilot implementation-effectiveness study to increase the use of measurement-based care (MBC) among school-based mental health clinicians who provide psychosocial treatment interventions to K-12 students with various mental health needs. The purpose of the study is to examine the implementation outcomes (i.e., feasibility, appropriateness, acceptability, and fidelity) of MBC in school-based mental health treatment services. We also plan to observe the effectiveness of MBC on student engagement and treatment outcomes as a secondary goal. This pilot implementation-effectiveness trial is designed to inform a future, large-scale trial with more participants.

Potential Impact

Millions of children and adolescents are diagnosed with a mental health disorder each year. Of these, only half receive any mental health treatment. More mental health treatment services are delivered in schools than any other child-serving sector. Schools offer an unparalleled opportunity to improve children's access to mental health treatment, but the *quality* of care provided in the school setting is highly variable and generally not evidence-based. School-based mental health clinicians lead the provision of mental health services for children; they must provide effective treatment.

A vital opportunity to improve school mental health (SMH) quality is the successful implementation of measurement-based care (MBC). MBC is the routine collection and use of student- or parent-reported symptom and functioning data to monitor progress collaboratively with the family and inform treatment decisions. MBC can be applied to a wide variety of mental health disorders and treatment plans. MBC is associated with greater and faster reduction of symptoms, improvements in functioning, patient engagement, and shared decision-making, but clinicians do not use it regularly and little is known about its implementation and effectiveness in SMH.

Planned analyses

Data analysis will assess the implementation outcomes (i.e., acceptability, appropriateness, feasibility and fidelity) of MBC resulting from implementation strategies used to increase MBC among SMH clinicians. I hypothesize that clinicians' MBC implementation outcome ratings will increase following the implementation strategies provided as compared to their ratings during the baseline period. Secondary analyses will explore the effect of MBC on engagement and mental health outcomes to support a future R01 application. Linear mixed effects modeling will be used to account for correlation over time and clustering within clinician.

Primary Objective

The primary objective of this study is to determine whether a multi-method implementation support package will help school-based mental health clinicians use MBC strategies, as measured by MBC implementation outcomes (e.g., feasibility, acceptability, appropriateness, and use or fidelity) with K-12 students. The multi-method implementation strategy package was designed based on prior research, and includes initial training, ongoing monthly consultation, tailoring implementation supports to needs identified by clinicians prior to implementation, and working with school district leadership to promote implementation (e.g., by reducing burdensome documentation requirements). I hypothesize that clinicians' ratings of MBC implementation outcomes will increase

following the implementation strategies provided as compared to their ratings during the baseline period without strategies.

Secondary Objective

The secondary objective of this study is to determine whether MBC implementation in schools is associated with engagement in treatment and student outcomes (i.e., reduction in symptoms and improvements in functioning) over the course of SMH treatment.

Study Design

A clustered, multiple-baseline design will be used to examine the impact of implementation support on clinicians' fidelity, use and ratings of MBC appropriateness, acceptability and fidelity. Approximately 50 SMH clinicians will participate from up to three school districts as a part of their regular professional development activities. In these school districts, measurement based care implementation is a district-wide quality improvement initiative. All clinicians will receive the same implementation supports; there is no random assignment to condition. Following an initial control period of at least 1 month, school districts will start receiving implementation supports. Baseline MBC use, attitudes, acceptability, feasibility and appropriateness (per clinician self-report) will be collected, as well as needs assessment data from clinician surveys to inform necessary adjustments to the implementation supports. Baseline engagement and student outcomes will be collected after initial clinician training session. MBC implementation outcomes (i.e., MBC use, attitudes, acceptability, appropriateness, and feasibility), engagement and student outcomes will be collected at 3-month and 6-month follow-up during intervention supports, plus a 9-month follow-up interval. This allows clinicians in the school districts to be compared to each other and to their own baseline. The primary comparison is pre-post ratings of implementation outcomes for all N=50 clinicians. The secondary comparisons are pre-post ratings of engagement and student outcomes, and between-agency differences.

Clinicians will receive a 3-hour professional development on MBC in Fall 2022 that is required by the three participating school districts. Monthly, post-training group consultation calls will be conducted for 6-months, and online, self-report surveys will be collected at baseline, 3-month, 6-month and 9-month intervals. Clinicians will be asked to implement measurement-based care, using the Better Outcomes Now (BON) online feedback system, with at least 5 students each. Data in BON are deidentified and this activity is part of routine care provided by clinicians, so does not require special consent. These data will also be used to inform group consultation supporting clinicians' practices.

Approximately 150 parents of students working with the participating clinicians will be recruited and enrolled using active consent. Parents will be asked to consent to 1) permission to review student records for goals and progress; and 2) 25-minute study phone calls at baseline, 3-months, 6-months and 9-months to provide parent-reported information on engagement and child outcomes throughout treatment. These data will be used to assess family engagement and child outcomes associated with measurement-based care delivered by the clinicians.

This study will be conducted in established, commonly accepted educational settings where mental health services are routinely provided. The interactions between children, families, their SMH clinicians on school campuses are part of their regular service delivery. The MBC training clinicians provide will be integrated into services as usual. The MBC measures and practices are considered best practices, and evidence-based practices, for children's mental health services. However, clinicians in usual care settings including schools under-implement MBC. They do not pose any risk when integrated into usual care. There are no group assignments. Clinician and parent reported study

measures are retrospective throughout the school year that SMH services are being provided.

Study Date Range and Duration

This study is expected to last approximately two calendar years, with each cohort of clinicians and parents recruited within the 2021-2022 or 2022-23 school year as the participating sites are school districts. Parents will be recruited in fall of 2021, and then again in the fall of 2022, based on clinicians who are signed up to receive the district-required MBC training each fall. Data collection will occur at baseline, 3 months, 6 months and 9 months.

Number of Study Sites (2)

[REDACTED] Public Schools, [ADDRESS REDACTED]

[REDACTED] Public Schools, [ADDRESS REDACTED]

*Other school district sites may be identified depending on their interest in participation.

Primary Outcome Variables

The primary objective of this study is to examine implementation outcomes. **Implementation outcomes** are selected from a published taxonomy of outcomes include acceptability, appropriateness, feasibility and fidelity. **Acceptability, appropriateness, and feasibility** will be measured by clinician self-report on the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM) via web-based, clinician-report survey. These 4-item measures were developed based on input from 36 implementation scientists and 27 mental health professionals; structural validity, test-retest reliability, and sensitivity to change have been established. **MBC use (fidelity)** will be evaluated by chart review in BON for evidence of two progress monitoring measures, the Session Rating Scale 3.0 (SRS) and Outcomes Rating Scale 3.0 (ORS). The MBC training provided as part of this study will include how to use MBC and document it in BON. The ORS will be completed before each session to assess prior-week functioning, and the SRS will be completed at the end of the session to assess student/parent perceptions of alliance with the clinician.

Secondary and Exploratory Outcome Variables

The secondary objective of this study is to examine effectiveness outcomes. **Effectiveness outcomes** of MBC will be measured using actual scores on the SRS and ORS, as documented in the student's service record. The SRS and ORS are part of the Partners for Change Outcome Management System (PCOMS), a system used to enhance patient involvement in mental health services and improve therapeutic alliance and treatment progress. **Student engagement** will be measured by the SRS. **Parent engagement** will be measured by the Therapeutic Alliance Scales for Caregivers and Parents. **Symptoms and functioning** will be measured using the ORS. Emotional and behavioral symptoms will also be measured by the Pediatric Symptom Checklist, 35-item version (PSC-35) which has well-established reliability and validity to assess and monitor progress of internalizing and externalizing symptoms for children ages 4-18. The Therapeutic Alliance Scales for Caregivers and Parents and the PSC-35 will be collected directly from parents/guardians over the phone at baseline and follow-up intervals.

Study Population

This study plans to enroll up to 150 parents/legal guardians of children or adolescents receiving SMH treatment from one of the 50 participating clinicians. We anticipate SMH

clinicians to be primarily licensed, Masters-level (~95%), in fields of social work (~70%) and counseling (~30%), female (~80%), Caucasian (~70%), median age of 30 years old and 1 to 20 years practicing in SMH. Parents will be enrolled if their child or adolescent is enrolled in mental health services in a participating district and served by a participating SMH clinician. We anticipate parents to be primarily female (~70%) and their children to be representative of students served by SMH clinicians in the districts serving as study sites.

Number of Participants

We plan to work with 50 clinicians and enroll up to 150 parents of children or adolescents with mental illness. The rationale for this sample size is based on having a large enough sample of clinicians trained that a range of implementation outcomes can be observed and described as pilot data for a larger-scale, fully-powered study. The rationale for the 150 students is based on our prior research in quality improvement and implementation research in schools, where it is more feasible to introduce a new practice to clinicians by telling them they can select a subset of their caseload for MBC implementation. Clinicians will introduce the opportunity to participate in the study to the parents of the students they implement MBC with.

Study Schedule

Clinician participation will require approximately 9 hours of study participation during the 2021-22 or 2022-23 school year. This includes 6 hours of training and ongoing consultation (e.g., 6, 60-minute post-training group consultation calls) plus 2 hours and 30 minutes of online surveys (five surveys in total; one baseline survey before the study begins, one post-training survey, and then follow-ups at 3 months, 6 months and 9 months).

Parent/guardian participation will require approximately 1 hour, 40 minutes of study participation during the 2021-22 or 2022-23 school year. This includes phone consent and four phone interviews of approximately 20-25 minutes each at baseline, 3 months, 6 months and 9 months.

Protocol Revision History

Version Date	Summary of Substantial Changes
8/1/22	1. The prior protocol involved active consent for clinicians as study participants to receive post-training consultation and study measures following a required, district-wide, 3-hour training on measurement-based care (MBC). The revised protocol waives documentation of consent for clinicians. Instead, clinicians will receive an informational email from their district leader about this project as a district-wide quality improvement initiative to implement measurement-based care (MBC). The revised protocol includes the 3-hour training, post-training consultation and study measures for all clinicians in the district. A waiver of documentation of consent is appropriate due to the low-risk nature of the study and no assignment to different study conditions; all clinicians receive training and support for MBC implementation. This change is at the request of our district partners (see two support letters) to include more clinicians in the project because they are implementing MBC as part of routine care in the schools. This change has also been documented with NIMH. There will be no impact on data safety or monitoring plan, methods/procedures of the study, or budget. Parents of children served will still be consented to study participation, involving phone surveys of child outcomes and permission to access basic service data (see below), which is optional. 2. Previously we stated that progress notes in medical records would be accessed from the school site and reviewed. We learned that session by session documentation of school-based services does not exist in this way. Therefore, the current modification reflects updated language about requesting parental consent to request basic treatment information about their student such as diagnosis, goals, and any documentation of progress using the online system (Better Outcomes Now or BON) we are training them on. All student data are entered in a deidentified manner to BON as a part of routine services provided, and our team has administrator access to BON to provide ongoing consultation for clinicians about how to use the system clinically. For parents who consent to study participation, we will ask clinicians and/or their supervisors to securely transfer basic student services information (e.g., diagnosis, goals, services start date) and their BON identifier so we can review their progress data and link it to parent-reported outcomes. There is no change to patient safety and in fact we anticipate parents may view this as less invasive than access to progress notes in medical records because we are now asking for access to more basic and less sensitive PHI and treatment-related data. 3. We added the Oldenburg Burnout Inventory (Demerouti & Mostert, 2010) to the clinician survey to assess for impact of training on staff wellbeing, and staff wellbeing as a potential moderator of implementation outcomes.

Statement of Compliance

This document is a protocol for a human research study. The purpose of this protocol is to ensure that this study is to be conducted according to the Common Rule at 45CFR46 (human subjects) and other applicable government regulations and Institutional research policies and procedures.

Abbreviations

Abbreviation	Explanation
SMH	**School-based mental health**
MBC	**Measurement-based care**

Glossary of Terms

Glossary	Explanation
School-based mental health treatment	**Individual, group, and or family psychotherapy provided on school grounds to reduce symptoms related to an identified mental health concern.**
Measurement-based care	**Routine collection and use of student- and/or parent/guardian-reported progress measures to inform shared decision making and treatment planning with the student and parent/guardian.**

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1 Background/Literature Review

1.1 Background

Underutilization of mental health treatment among children and adolescents is a public health crisis that has improved little over the last several decades. [SUPPORTING LITERATURE REDACTED]

Despite improvements in *access* to care, school mental health treatment *quality* is inconsistent. [SUPPORTING LITERATURE REDACTED]. One evidence-based approach to improve the quality SMH services is increasing clinicians' use of symptom rating scales at the beginning and throughout treatment to drive clinical decision making and chart progress. This practice is referred to as measurement-based care (MBC), or the routine collection and use of student data throughout treatment, including initial screening and assessment, problem definition and analysis, finalizing treatment objectives and intervention tactics, and monitoring treatment progress. [SUPPORTING LITERATURE REDACTED]

MBC is an effective, evidence-based practice to improve treatment quality. [SUPPORTING LITERATURE REDACTED]

Although there is strong support for MBC in primary care and community settings, including some studies with children, MBC effectiveness in SMH has not been rigorously tested. Moreover, the mechanisms of MBC effects on patient outcomes are not well known. We propose to pilot test a set of implementation strategies (that were identified in a previous aim of this same grant award) to increase school mental health (SMH) clinician use of measurement-based care (MBC), and further explore the effectiveness of MBC on student/family engagement and child outcomes.

1.2 Prior Experience

Preliminary research was conducted to inform this study. Specifically, Dr. Connors and her team conducted a prior study aim within this grant award to first identify the implementation strategies being tested in this current study phase. In the prior study aim, 52 SMH Stakeholder Expert Panelists (i.e., SMH clinicians, supervisors, and researchers who actively partner with schools) were purposively sampled using the National SMH Census, a nationally-representative survey of SMH school and district teams' services and data usage. Using a modified Delphi technique, panelists reviewed the definition of MBC as well as clinical vignettes demonstrating how MBC would be used by a clinician providing mental health treatment to students. Then, panelists responded to two rounds of online surveys to 1) rate an existing list of 33 implementation strategies for feasibility and importance, 2) identify synonyms, definition changes, and recommendations about how the strategy should be used, and 3) suggested additional strategies not on the existing list. Mixed methods analysis and GoZone plots revealed six top-rated implementation strategies for MBC in schools, which include the following:

1. Assess for readiness and identify barriers and facilitators
2. Identify and prepare champions
3. Develop a usable implementation plan
4. Offer a clinician-informed menu of free, brief measures
5. Develop and provide access to training materials
6. Make implementation easier by removing burdensome documents

These top-rated strategies will be the foundation of the implementation strategy package being tested in the current FOCUSS study. As a result of strategy #1 above, baseline clinician surveys will include a needs assessment to inform additional implementation strategies and/or tailoring of strategies that should be applied.

We also found that mean importance and feasibility ratings were high overall, with importance higher than feasibility on average. Ratings were not significantly different between researchers and practitioners with three exceptions. First, clinicians reported it is more important and more feasible to make implementation easier by removing burdensome paperwork (feasibility t(44)=-2.96, p=0.01; importance (t(29)=-2.72, p=0.01). Second, researchers reported it's more important to monitor the implementation effort (t(41)=2.51, p=0.02).Third, clinicians reported train-the-trainer is more feasible (t(45)=-2.06, p=0.05).

In addition to this prior research, Dr. Connors has also led several implementation studies with school district personnel to implement various elements of MBC in the past.

2 Rationale/Significance

2.1 Rationale and Study Significance

The fact that the evidence-base of SMH services is highly inconsistent, this has deleterious effects on the welfare of all students. The routine use of psychosocial symptom and functioning assessment data (MBC) to inform SMH treatment is an effective, evidence-based practice that can improve service quality at low cost. In practice, clinicians over-rely on clinical judgment and have little time to learn and use more effective practices. It is imperative that we change clinician practice to include MBC. The proposed research includes cutting-edge implementation science methods to identify and test the most promising strategies to increase MBC practice in the school context. This study seeks to generate initial knowledge about contextually-specific implementation strategies to increase school-based clinicians' use of MBC with their patients.

2.2 Purpose of Study/Potential Impact

The goals of this study are to collect preliminary data on implementation outcomes associated with MBC implementation strategies identified in our prior research, as well as on effectiveness of MBC to improve student engagement and treatment outcomes. The logic for this line of research is that the right implementation strategies will produce desired implementation outcomes, most importantly clinician fidelity (i.e., use of MBC in their practice). The effect of implementation strategies on MBC use is likely mediated by how acceptable, appropriate, and feasible MBC is rated by clinicians (key implementation outcomes that will be measured). MBC use is hypothesized to improve student progress and outcomes such as reduced symptoms and improved functioning, possibly through the mechanism of engagement.

If successful, this pilot study will provide a foundation for future investigation to determine exactly how MBC can be implemented in "real world" SMH services, which could have a dramatic public health impact on the quality of mental health services received by children and adolescents in school. This study also has the potential to generate generalizable knowledge about the impact of MBC on student engagement and treatment outcomes, to further bolster the growing evidence-base of MBC effectiveness with children and adolescents.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

Risks related to chart review for Parent participants. The risk from chart reviews for parent participants is minimal and relatively uncommon. There is a slight risk of breach of confidentiality. All data collection forms will be coded with an ID number that is unique. Only the study team will have access to the link between the ID and participant's name. All data security procedures commensurate with the clinical and/or school site's maintenance of

secure health records will be followed in detail. For paper charts that might involve secure procedures for signing out and returning charts, as well as reviewing charts on premises in a secure location at the clinic. For electronic medical records that may involve a data request to the participating agency and secure data transfer. Electronic data files with identifiable information will be maintained separately from other data files and will only be used for administrative purposes (e.g., preparing aggregate reports to share with the study team). Data containing names and personal information will never be included in published materials. All personnel will receive certification in human subjects' protection from the Yale HRPP prior to beginning work on this project.

Risks related to Clinicians participating in training and implementation supports and providing feedback via electronic surveys. The risk from participating in MBC training and implementation supports and providing feedback via electronic surveys for clinicians is minimal and relatively uncommon. The information page will ensure clinicians are aware that their responses to implementation feedback surveys will only be shared in aggregate and will not affect their employment or performance review in any way. Moreover, clinical administrators will not be included in the data collection process whereby clinicians provide self-reported implementation experiences and outcomes. At the start of the study, the PI and at least one local study team member will meet with each administrator to identify possible sources of bias and generate solutions. District leadership will know which participants are involved in the project because they will attend district-organized professional development trainings and consultation. However, all clinician-reported survey data regarding their implementation experiences will be coded with an ID number that is unique. Only the study team will have access to the link between the ID and participant's name. Electronic data files with identifiable information will be maintained separately from other data files and will only be used for administrative purposes (e.g., preparing aggregate reports to share with the study team). Data containing names and personal information will never be included in published materials. All personnel will receive certification in human subjects' protection from the Yale HRPP prior to beginning work on this project.

2.3.2 Potential Benefits

Clinicians and the students/patients they serve will be offered a potentially effective intervention for collaboratively monitoring their progress in mental health treatment over time. Clinician participants who use the measurement-based care processes that they will be trained and supported to use will have the opportunity to learn an evidence-based practice they can use with any of their patients as they wish. Clinicians will also receive one year user access to Better Outcomes Now (www.betteroutcomesnow.com) which is an online system to collect, score, view and discuss student progress on the Outcome Rating Scale and Session Rating Scale. They will receive training and consultation on how to use this evidence-based, practical system with students and families, whether you are meeting with them virtually or in person.

Children and parents who engage in the measurement-based care processes that clinicians will be trained and supported to use may experience greater therapist/patient alliance and improvement in symptoms and functioning at the end of treatment. We feel the potential benefits to be gained outweighs the risks of the study.

3 Study Purpose and Objectives

3.1 Hypothesis

Hypothesis 1: Clinicians' ratings of MBC implementation outcomes will increase following implementation strategies provided as compared to ratings during the baseline period. (Primary Objective)

Hypothesis 2: MBC fidelity (per MBC feedback system review) and use (per clinician self-report) will increase following implementation strategies provided as compared to ratings during the baseline period, with documentation of measure collection more prevalent than documentation of discussing progress or changing the treatment plan in accordance with measures. (Primary Objective)

Hypothesis 3: MBC fidelity and use will be positively associated with engagement and mental health symptom and functioning progress over time. (Secondary Objective)

Although underpowered to establish outcomes as a result of strategies applied with certainty, this pilot will provide mentored research experience and preliminary data for planning a future large-scale hybrid trial.

3.2 Primary Objective

The primary objective of this study is to determine whether a multi-method implementation support package will help school-based mental health clinicians use MBC strategies, as measured by MBC implementation outcomes (e.g., feasibility, acceptability, appropriateness, and use or fidelity) with K-12 students. The multi-method implementation strategy package was designed based on prior research, and includes initial training, ongoing monthly consultation, tailoring implementation supports to needs identified by clinicians prior to implementation, and working with school district leadership to promote implementation (e.g., by reducing burdensome documentation requirements). I hypothesize that clinicians' ratings of MBC implementation outcomes will increase following the implementation strategies provided as compared to their ratings during the baseline period without strategies and fidelity (i.e., use of) MBC with students served in SMH treatment.

3.3 Secondary Objective

The secondary objective of this study is to determine whether MBC implementation in schools is associated with engagement in treatment and student outcomes (i.e., reduction in symptoms and improvements in functioning) over the course of SMH treatment.

4 Study Design

4.1.1 General Design Description

A clustered, multiple-baseline design will be used to examine the impact of the implementation support condition on clinicians' fidelity, use and ratings of MBC appropriateness, acceptability and fidelity. Approximately 50 SMH clinicians will be recruited to participate from two school districts. All clinicians will receive the same implementation supports; there is no random assignment to condition. Following an initial control period of at least 1 month, school districts will start receiving implementation supports. During the initial control period, baseline MBC use, attitudes, acceptability, feasibility and appropriateness (per clinician self-report) will be collected, as well as needs assessment data from clinician surveys to inform necessary adjustments to the implementation supports. Baseline engagement and student outcomes will be collected after initial clinician training session. MBC implementation outcomes (i.e., MBC use, attitudes, acceptability, appropriateness, and feasibility), engagement and student outcomes will be collected at 3-month and 6-month follow-up during intervention supports, plus a 9-month follow-up interval. This allows clinicians in the two school districts to be compared to each other and to their own baseline. The primary comparison is pre-post ratings of implementation outcomes for all N=50 clinicians. The secondary comparisons are pre-post ratings of engagement and student outcomes, and between-agency differences.

Study Date Range and Duration

This study is expected to last approximately one calendar year from recruitment to follow-up, aligned with the 2021-2022 and 2022-23 academic years as the participating sites are school districts. Clinicians will start training and consultation in the fall of 2021 or 2022 and parents/guardians will be recruited in the fall of 2021 or 2022. Data collection will occur at baseline, 3 months, 6 months and 9 months.

4.1.2 Number of Study Sites (2)

1. [REDACTED] Public Schools, [ADDRESS REDACTED]
2. [REDACTED] Public Schools, [ADDRESS REDACTED]

*Other school district sites may be identified depending on their interest in participation

4.2 Outcome Variables

4.2.1 Primary Outcome Variables

The primary objective of this study is to examine implementation outcomes. Implementation outcomes are selected from a published taxonomy of outcomes include acceptability, appropriateness, feasibility and fidelity. **Acceptability, appropriateness, and feasibility** will be measured by clinician self-report on the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM) via web-based, clinician-report survey. These 4-item measures were developed based on input from 36 implementation scientists and 27 mental health professionals; structural validity, test-retest reliability, and sensitivity to change have been established. **MBC use (fidelity)** will be evaluated by chart review for evidence of two progress monitoring measures, the Session Rating Scale 3.0 (SRS) and Outcomes Rating Scale 3.0 (ORS). The ORS should be completed before each session to assess prior-week functioning, and the SRS will be completed at the end of the session to assess student/parent perceptions of alliance with the clinician. These will be stored in the Better Outcomes Now (BON) secure online system.

4.2.2 Secondary and Exploratory Outcome Variables

The secondary objective of this study is to examine effectiveness outcomes. **Effectiveness outcomes** of MBC will be measured using actual scores on the SRS and ORS, as documented in the student's service record. The SRS and ORS are part of the Partners for Change Outcome Management System (PCOMS), a system used to enhance patient involvement in mental health services and improve therapeutic alliance and treatment progress. **Student engagement** will be measured by the SRS. **Parent engagement** will be measured by the Therapeutic Alliance Scales for Caregivers and Parents. **Symptoms and functioning** will be measured using the ORS. Emotional and behavioral symptoms will also be measured by the Pediatric Symptom Checklist, 35-item version (PSC-35) which has well-established reliability and validity to assess and monitor progress of internalizing and externalizing symptoms for children ages 4-18. The Therapeutic Alliance Scales for Caregivers and Parents and the PSC-35 will be collected directly from parents/guardians over the phone at baseline and follow-up intervals.

4.3 Study Population

This study plans to enroll 50 SMH clinicians and 150 parents/guardians of children or adolescents receiving SMH treatment from one of the 50 participating clinicians. We anticipate SMH clinicians to be primarily licensed, Masters-level (~95%), in fields of social work (~70%) and counseling (~30%), female (~80%), Caucasian (~70%), median age of 30 years old and 1 to 20 years practicing in SMH. Parents will be enrolled if their child or adolescent is enrolled in mental health services in a participating district and served by a participating SMH clinician. We anticipate parents to be primarily female (~70%) and their children to be representative of students served by SMH clinicians in the districts serving as study sites.

4.3.1 Number of Participants

We plan to work with 50 SMH clinicians and up to 150 parents of children or adolescents with mental illness receiving MBC in SMH services. All SMH clinicians at each district will be invited to participate, and we anticipate approximately 10-40 clinicians from each district depending on their size. All 150 parents of children and adolescents with mental illness receiving MBC in SMH services will be invited to participate. The rationale for this sample size is based on having a large enough sample of clinicians trained that a range of implementation outcomes can be observed and described as pilot data for a larger-scale, fully-powered study. The rationale for the 150 students is based on our prior research in quality improvement and implementation research in schools, where it is more feasible to introduce a new practice to clinicians by telling them they can select a subset of their caseload for MBC implementation. We will outreach to students the clinician reports they are using MBC with. Selection of a subset of cases will involve a random selection of recently consented cases.

4.3.2 Eligibility Criteria/Vulnerable Populations

Parent/Guardian Participants

To be eligible for inclusion in the study, a parent or legal guardian must meet all of the following criteria:

- Female, male or other gender ≥18 years of age at the time of recruitment.
- Parent or legal guardian of a child age 5 to 18 at the time of recruitment who is enrolled in school-based mental health treatment services with one of the clinician participants included in the study (see inclusion criteria for clinician participants above).
- Enrolled in school-based mental health services within 3 months prior to the recruitment date.
- English speaking.
- Ability to provide informed consent.

Parents/guardians who do not meet all inclusion criteria are excluded. There are no other exclusion criteria.

5 Study Methods/Procedures

5.1 Study Procedures

Study procedures involve collecting implementation data from clinicians (approximately N=50) as part of a district-wide measurement-based care training in initiative and recruiting parent/guardian (up to N=150) participants to provide feedback on the implementation outcomes of a pilot training and post-training consultation on measurement-based care. Study information will be provided to clinicians via email and secure, electronic survey and study consent will be provided to parents/guardians by a study team member conducting phone consent. Study procedures are built around a 3-hour professional development and monthly, post-training consultation calls that are required by participating school districts. Clinicians will also be asked to use MBC measures (e.g., Outcome Rating Scale and Session Rating Scale) with 5 students on their caseload, and completing study evaluation surveys (for which clinicians will be compensated with $25 Amazon gift cards for each survey completed at baseline, post-training, 3-, 6-, and 9-month follow-up).
Parents/guardians of youth served by participating clinicians will be asked to consent to phone check ins (at baseline, 3-, 6-, and 9-month intervals) to report child symptoms and parent engagement. Parent/guardian participants will also be asked to consent to records

review in order for the study team to assess fidelity to MBC training and consultation. Additional study procedure details are described in the following sections.

Study Procedures vs Standard of Care

Youth (ages 5-18) who receive school-based mental health services from participating clinicians will receive measurement-based care (MBC) as part of their usual care services. MBC is aligned with best practices in psychosocial treatment delivery but is under-implemented in usual care due to numerous barriers. MBC practices, which include routine progress monitoring and feedback to inform data-driven, client-centered treatment plan adjustments, only stands to improve the quality and standard of usual care delivered to children and their families in school settings.

5.1.1 Data Collection

Data Sources. Data sourced for this study will include computerized and hard copy research records. Any hard copy research records will be scanned and saved electronically on a Yale secure server before shredding the paper copy. Data sources will include:

(1) Quantitative data from clinician self-report surveys about **MBC acceptability**, **appropriateness**, and **feasibility** as well as **MBC use** every three months during implementation supports. Some qualitative feedback will also be solicited on the survey for clinicians to expand on any details the standardized measures of these implementation outcomes could not capture. *(Primary outcome variables)*
(2) Quantitative data on **MBC use (clinician fidelity)** coded by chart review protocol, in which fidelity includes presence of SRS and ORS measures in the online BON/PCOMS system to approximate fidelity per clinician. *(Primary outcome variables)*
(3) Quantitative data on proximal and distal **student engagement and functioning outcomes** collected by the clinician as part of the project, retrieved from medical records and/or the PCOMS system directly (SRS, ORS). *(Secondary outcome variables)*
(4) Quantitative data on **parent engagement** and distal **student symptoms** collected by the study team as part of the project from parents over the phone (Therapeutic Alliance Scales, PSC-35). *(Secondary outcome variables)*
(5) Tracking data on parent **recruitment**, **clinician attendance**/engagement in implementation supports. *(Implementation mechanisms)*

Data sources 1-4 above refer to primary and secondary outcomes of explicit focus in the analyses and are listed in the table below.

Table 1. List of Measures and Data Collection Methods

Outcome	Measure	Method	Reporter	Interval
MBC Acceptability (content, complexity, relative advantage)	Acceptability of Intervention Measure (AIM)	Online survey	Clinician	Pre-training 3M follow up 6M follow up 9M follow up
MBC Appropriateness (for setting, provider, students served)	Intervention Appropriateness Measure (IAM)			
Feasibility (for SMH practice)	Feasibility of Intervention Measure (FIM)			
MBC Use	Current Assessment Practice Evaluation - Revised (CAPER)			

MBC Attitudes	Attitudes toward Standardized Assessment – Monitoring and Feedback (ASA-MF)			
Implementation Determinants	MBC Feedback Form – Assess Barriers and Facilitators			Pre-training
ORS/SRS Acceptability	Usage Rating Profile – Assessment (URP-A)			3M follow up 6M follow up 9M follow up
Fidelity (MBC Use)	Retrospective coding of PCOMS measures (SRS, ORS)	Chart review and/or BON system	Study Team	Monthly
Student Engagement	Session Rating Scale (SRS)			
Student Functioning	Outcome Rating Scale (ORS)			
Student Symptoms	Pediatric Symptom Checklist (PSC-35)	Phone	Parent	Baseline* 3M follow up 6M follow up 9M follow up
Parent Engagement	Therapeutic Alliance Scales for Caregivers and Parents			
**after clinician consent, near initial clinician training*				

Secure Data Recording and Maintenance:

Online survey data will be maintained in the PI's Yale Qualtrics account, accessible only by members of the study team listed on the IRB protocol. Online survey data will be downloaded and maintained on secure Yale storage servers and networks (i.e., Yale Box, network drive). Clinicians will provide their identifying information (name, email address) when they consent as well as a secure 4-digit anonymous code. They will be asked to submit this same 4-digit code with each follow-up survey. This will ensure the study team can track individual clinician responses over time, but each survey is completed confidentially. A password-protected Excel file including clinician identifying information and 4-digit codes will be maintained on secure Yale storage servers and networks, accessible only to study team members.

Chart review data may be in various formats depending on the format of documentation and storage systems at each district (study site). We only need basic information such as child diagnosis, date entered services, treatment goals, and number of sessions attended. We will also ask for their anonymous BON code so we can link those data (see below). Consistent with best practices in chart review methodology, we will work with each district to identify a "data extractor" at their site who can obtain the relevant data for students of consented parents within the requisite time frame and prepare them for the study team. Our team will provide a list of names of children based on parental consent obtained, as well as the data we are requesting. Once we receive the chart data, we will deidentify it with a unique study identifier and keep the list of linked study IDs to names in a separate password-protected file. We expect that the requested chart review material can be transferred in electronic format to our site at Yale, we will use Yale's secure file transfer system, save the material on our secure Yale storage server or network, and then complete the enter the services data for each child. These files will be saved on our secure Yale storage server and network and entered into a database.

BON/PCOMS system data (including the Outcome Rating Scale and Session Rating Scale) will be maintained in the Better Outcomes Now (www.betteroutcomesnow.com) secure online system. Clinicians enter these data directly into PCOMS using their own anonymous code for students. There are no identifiable information in PCOMS. Our study team will be the PCOMS trainers and also have administrative privileges in PCOMS to support MBC

implementation. In order to protect the confidentiality of parents consenting to the study, the study team will not share the names of consented families with clinicians in order to access their PCOMS data. Instead, we will use aggregate, deidentified PCOMS data at the clinician level to estimate MBC fidelity. This is a HIPAA-compliant site developed specifically for secure progress monitoring data entry and viewing my clinicians and their clients.

Parent-reported data collected via study phone calls will be recorded in "real time" by study team members on the Parent Survey Form either in hard copy form or electronically. All hard copy record forms will be scanned in and saved electronically on a Yale secure server before hard copy records are shredded. Parent-reported data will be entered into SPSS and saved on a Yale secure server.

The highest standards of participant confidentiality will be kept, and no participants will have identifiable information available. Computerized records of data are kept in a password-only accessible computer in a locked room. Appropriate firewalls and protections of computerized data are maintained to ensure that entry by those other than research personnel is not possible. Only study team members (the PI, her mentor, and her research assistant) will have access to individually identifiable private information about human subjects, which will only be used for tracking and follow-up purposes until data collection and compensation procedures are finalized.

5.1.2 Adverse Events Definition and Reporting

This protocol presents minimal risks to the subjects and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such events occur, Reportable Events (which are events that are serious or life-threatening and unanticipated, or anticipated but occurring with a greater frequency than expected) and/or Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities will be reported immediately (if possible), followed by a written report within 5 calendar days of the Principal Investigator becoming aware of the event to the IRB (using the appropriate forms from the website) and any appropriate funding and regulatory agencies. Dr. Connors will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project. Dr. Connors will be responsible for monitoring the data and assuring protocol compliance and safety reviews. She will conduct these reviews during her weekly supervision with research staff. Study staff will be trained to inform the PI of any adverse event or unanticipated problem in a timely fashion. Dr. Connors will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment based on the severity of the event.

5.2 Study Schedule

Clinician involvement will require approximately 9 hours of project activities during the 2021-22 or 2022-23 school year. All activities are part of their routine services and district-approved professional development schedule. Clinician involvement includes 6 hours of training and ongoing consultation plus 2 hours and 30 minutes of online surveys.

Project activities listed on Clinician Information Sheet will include:

- **A 3-hour interactive training** on measurement-based care in schools. This training will include how to collect, score, and use student- and parent-reported progress measures with students and families to improve engagement, personalize services and inform intervention planning and adjustments throughout the school year.
- **Six, 60-minute, monthly post-training consultation calls** for six months following the training. These calls will be with other participating clinicians and the PI to facilitate peer learning and support for implementing measurement-based care in

schools. Strategies and adaptations to match the school setting and student and family strengths and needs will be discussed.

- **Four, 30-minute online feedback surveys** from clinicians to understand measurement-based care acceptability, appropriateness, and feasibility in schools, plus clinician use of measures and related experiences with implementation. These will occur before the first training and 3 months, 6 months, and 9 months after the training throughout the school year. You will receive a $25 Amazon gift card for each survey you complete.
- **Collecting student progress data.** You will be asked to collect brief measures of student progress periodically throughout treatment, review it with the student and family and document this in an online system that we will grant you access to called Better Outcomes Now (BON). Collecting and discussing these measures will take 5-10 minutes of session time, 2-4 times per month and will be part of the regular services you already provide. We ask that you do this with at least five (5) of your students.
- **Parent recruitment.** We will ask you to refer at least five (5) parents to the research study component of this project. We will ask you to present the opportunity to participate in the study to the parents of students you work with. Parent participation is optional and will involve completing four brief phone check ins with one of our study team members during the school year. Parents will receive a $25 Amazon gift card for each phone check in they complete. If the parent agrees to participate, the study team will also review their BON account for documentation of measures being collected and discussed. We will do this by asking you to provide our study team with their anonymous BON code so we know who the student is in BON. (As administrators, we can access all BON data, but it is deidentified). Records review in BON will occur confidentially by the study team and only if parent permission is provided.

Parent/guardian participation will require approximately 1 hour, 40 minutes of study participation during the 2021-22 or 2022-23 school year. This includes phone consent and four phone interviews of approximately 20-25 minutes each at baseline, 3 months, 6 months and 9 months.

5.3 Informed Consent

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study intervention. Study information will be provided via online survey for clinicians and study consent will be provided over the phone for parents. The following consent materials are submitted with this protocol:

- Clinician Information Form
- Parent Consent from

5.2.1 Screening (if applicable)

Not applicable.

5.2.2 Recruitment, Enrollment and Retention (if applicable)

5.3.3 Clinician Participants

Clinicians (N=50) who provide psychosocial interventions to K-12 students in our identified districts will be informed of the project using the following steps:

1. Clinicians receive an email from their supervisor (e.g., a “site leader” which could be a district or community mental health agency administrator, depending on whether

they are school- or community-employed) that the FOCUSS study team will contact them directly about participation. See “Clinician Notice of FOCUSS Study Email from Site Leader” . This will include “FOCUSS Flyer – Clinician”.
2. Site leaders will send the study team a list of names and email addresses of eligible clinicians.
3. Study team members will email clinicians directly with the “FOCUSS Flyer – Clinician” form attached. The email message will remind clinicians about the project and include a link to the first online survey. See “Qualtrics Invitation Email from Study Team – Clinicians”
4. Clinicians can view the Clinician Information Sheet and FOCUSS Flyer-Clinician on the first page of the online Qualtrics survey and provide contact information for the study team for any questions or clarifications they may have.
5. Two (2) reminders will be sent to clinicians who do not open the survey link. All clinicians will receive emails about the 3 month, 6 month, and 9 month surveys regardless of baseline survey completion. All follow-up surveys will include a link to the Clinician Information Sheet and FOCUSS Flyer-Clinician on the first page, as a reminder, and for any clinicians completing a follow-up survey as their first survey.

Parent/Guardian Participants

Consent will be collected over the phone for parents. Parent/guardians (N=150) who have a child receiving school-based mental health treatment from one of the participating clinicians will be recruited and consented using the following steps:

1. The clinician and/or designated site clinical staff will ask the parent/guardian of each recruited student if they are willing to be contacted by the study team. They will do this using the “Clinician Parent/Guardian Recruitment Script”.
2. If so, the parent’s contact information will be shared with relevant study team member using the “Research Interest Sheet – FOCUSS”, who will contact the parent via phone and/or email and then introduce the study, read the consent form, and request informed consent over the phone.
3. The study team member will indicate the parent’s consent (yes or no), and if yes, document the parent’s name, relationship to child, date, and their name and signature.

Study Visits (if applicable)

We will conduct study phone calls with parents at baseline, 3 months, 6 months, and 9 months. Each phone call will last approximately 20-25 minutes. Parents will be asked to provide ratings over the phone about their engagement in their child’s mental health services and their child’s mental health symptoms.

5.3 Statistical Method

5.3.1 Statistical Design

Quantitative Analyses

Quality control checks of the data and examination of variable distributions will be performed prior to formal analysis. There are *three* types of outcomes: (1) clinician report of acceptability, appropriateness, and feasibility (implementation outcomes), (2) clinician use of MBC (also an implementation outcome, fidelity), and (3) student engagement, progress and outcomes (effectiveness of MBC). For (1) and (2), the primary analysis will be a multilevel growth model with time (Level 1) nested within clinician (Level 2) for each of the implementation outcomes as they are clinician self-reported on clinician surveys. We will examine linear change of time as a continuous measure as well as time by time transitions across the longitudinal intervals of data collection. Attitudes toward MBC and other

independent variables (e.g., clinician professional and demographic characteristics, consultation call attendance, school district) will be entered into the models to examine correlations. In particular, we hypothesize parallel growth between attitudes and use of MBC over time.

For (3) we will conduct a 3-Level multilevel growth model with time (Level 1) nested within student/parent reported outcome (Level 1) nested within clinician (Level 3). Models will be estimated for each parent-reported outcome (e.g., parent-reported engagement, parent-reported symptoms on the PSC-35). Independent variables that will be entered as covariates in these models include MBC implementation outcomes, with the specific hypothesis that MBC use will be predictive of positive engagement and symptom reduction.

Also, for (3), the ORS and SRS are assessed at each session, hence, a mixed effects regression model will be used that accounts for intra-student correlation across student sessions and clustering of students within clinician. The unit of analysis will be session, however in primary analyses, to avoid an overly complicated model, session will not be modeled as a fixed effect in the regression model for the mean. Fixed effects will include time (baseline and post MP assessment for MP1, 2, or 3) and treatment condition (i.e. whether the clinician's agency is under the intervention or control condition).

Results of all the above analyses will be expressed in terms of 95% confidence intervals for effects and contrasts which together with estimates of intra-clinician correlation and variance will inform the power analysis for a larger trial.

Mixed Methods Analyses

For (2) we will also analyze chart review data. We will develop and test our MBC fidelity rubric on a subset of consented students at midpoint in the school year to assess intercoder reliability, test our coding form on the text of progress notes, and refine both our coding form and process for accessing records in an efficient, reliable manner. These analyses will yield mixed methods data on clinician use of MBC to be triangulated with clinician self-reported use of MBC on surveys to evaluate relative advantages and disadvantages of these methods to assess use of MBC. Qualitative data generated from chart reviews will be analyzed using Rapid Qualitative Analysis whereby two coders plus the PI will create summaries of chart review findings per student using a standard summary form, which is then entered into a matrix for the entire sample to be reviewed, coded iteratively, and synthesized for main themes and sub codes. These findings will directly inform the future R01 application methods regarding the collection and use of chart review and/or clinician surveys to assess MBC use/fidelity following implementation supports.

5.3.2 Sample Size Considerations

We plan to enroll 50 SMH clinicians and up to 150 parents of children or adolescents with mental illness. The rationale for this sample size is based on having a large enough sample of clinicians trained that a range of implementation outcomes can be observed and described as pilot data for a larger-scale, fully-powered study. The rationale for the 150 students is based on our prior research in quality improvement and implementation research in schools, where it is more feasible to introduce a new practice to clinicians by telling them they can select a subset of their caseload for MBC implementation. We will outreach to students the clinician reports they are using MBC with. Selection of a subset of cases will involve a random selection of recently consented cases.

5.3.3 Planned Analyses

Please see details in 5.4.1

5.3.4 Analysis of Subject Characteristics (if applicable)

Quality control checks of the data and examination of variable distributions will be performed prior to formal analysis. Descriptive statistics and intercorrelations will be examined for all datasets. Demographic characteristics of clinician participants and parent/guardian participants will be examined and reported in all scholarly reports and products. If any demographic characteristics are significantly related to implementation or effectiveness outcomes, they will be entered as control variables in the linear mixed analyses.

5.3.5 Interim Analysis (if applicable)

Not applicable.

5.3.6 Handling of Missing Data

Missing data will be analyzed to examine any patterns of missingness not at random, including case-wise (i.e., overall percentage, patterns, various longitudinal intervals of missingness) and variable-wise (i.e., overall percentage, patterns) missing values analysis. Linear mixed modeling is robust to missing data and does not require listwise deletion of cases with missing data. Therefore, if missing data are missing at random (MAR) all data will be used. Otherwise, analyses with and without missing data will be compared to examine whether results differ when including cases and variables with data missing not at random.

6 Trial Administration

6.1 Ethical Considerations: Informed Consent/Assent and HIPAA Authorization

Consent forms will be Institutional Review Board (IRB)-approved and the participant/legally authorized representative (LAR) will be asked to read and review the document.

For clinicians, the online survey will contain the Clinician Information Sheet to explain the project and answer contact information is available for study team members if any questions that may arise. A copy of the Clinician Information Sheet will also be emailed to the participants/LAR for their records

For parent participants, consent forms will be Institutional Review Board (IRB)-approved and the participant/LAR will be asked to read and review the document. The study team member will explain the research study to the parent or guardian and answer any questions that may arise. This conversation will take place in a private room or over a private zoom call due to COVID-19 restrictions. Participants/LAR will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants/LAR will have the opportunity to discuss the study with their family or think about it prior to agreeing to participate. The parent or guardian will indicate their consent via verbal authorization with the research study team member prior to any procedures being done specifically for the study. Participants/LAR will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants/LAR for their records

Additional consent details are as follows:

- No deception will be used.
- Clinicians will be compensated up to $100 via Amazon Gift Cards for their participation. Parent participants will be compensated up to $100 via Amazon Gift Cards for their participation upon completion of follow up phone calls with the study team.
- All research records will be kept in password-protected, Yale-approved network locations in a locked room with participants' evaluation study materials identified by code only. A separate file will hold the password. Appropriate firewalls and protections of computerized data are maintained to ensure that entry by those other

than research personnel is not possible. Only study team members (the PI, her mentor, and her research assistant) will have access to individually identifiable private information about human subjects, which will only be used for tracking and follow-up purposes until data collection and compensation procedures are finalized.
- Participants will not be personally identified in any publications or reports of the study. Any data used will be re-copied to research files with the participant identified by code only. The highest standards of participant confidentiality will be kept, and no participants will have identifiable information available.
- Parents enrolled will be asked to agree report symptom data on the Pediatric Symptom Checklist, 35 items (PSC-35) as well as to access their students' progress, goals, and related services data from documentation maintained by their clinician.As such, at least one family member or guardian will consent to secondary data collection and record review from their students' treatment record.
- Child consent will not be obtained.

6.2 Institutional Review Board (IRB) Review

The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol or study team will require an approved IRB amendment before implementation. The IRB will determine whether informed consent and HIPAA authorization are required. All reportable events and unanticipated problems will be reported to the IRB by the PI within 5 working days after she becomes aware of the event or problem. This study is prospective research, conducted in established and commonly accepted educational settings where children receive mental health treatment services. This study focuses on implementation of a best practice in clinical service delivery to improve the quality of usual care. A study closure report will be submitted to the IRB after all research activities have been completed.

6.3 Subject Confidentiality

Participant confidentiality and privacy is strictly held in trust by the participating investigators and their staff. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the sponsor.

All research activities will be conducted in as private a setting as possible.

The study monitor, representatives of the Institutional Review Board (IRB), or regulatory agencies may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. All data will be stored on Yale secure file storage platforms and servers, with password protection and accessible only to the study team. Our team will not retain any paper copy study records; any paper copies will be scanned in, saved electronically, then shredded. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or, if applicable, sponsor requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at Yale University, Department of Psychiatry, Division of Prevention and Community Research. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study

management systems used will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at Yale University.

6.4 Deviations/Unanticipated Problems

A protocol deviation is any noncompliance with the study protocol. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site investigator to identify and report deviations 5 working days of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the study sponsor, and the reviewing Institutional Review Board (IRB) per their policies.

Unanticipated problems involving risks to participants or others include, in general, any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research (“possibly related” means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and to the study sponsor. The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and study sponsor, if applicable within [insert timeline in accordance with of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB and study sponsor within [insert timeline in accordance with policy] of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within & [insert timeline in accordance with policy] of the IRB's receipt of the report of the problem from the investigator.

6.5 Data Quality Assurance

The study team will be appropriately trained in handling and reviewing participant data for data quality assurance. The PI will use scaffolded supervision and oversight (i.e., modeled

with debrief, then co-completed, then observed with feedback followed by check ins at weekly study team meetings) to ensure quality control and data assurance as it pertains to participant recruitment, tracking and compensation as well as data collection, storage, management, and analyses.

6.6 Study Records

Recruitment Flyers and Communications:

1. Clinician Notice of FOCUSS Study Email from Site Leader
2. Qualtrics Invitation Email from Study Team – Clinicians
3. FOCUSS Clinician Information Sheet
4. FOCUSS Flyer – Clinician
5. FOCUSS Flyer - Parents
6. Clinician Parent/Guardian Recruitment Script
7. Research Interest Sheet - FOCUSS

Consent Forms:

8. FOCUSS - Parent Consent

Data Collection Surveys and Forms:

9. FOCUSS - Clinician Welcome Survey
10. FOCUSS - Clinician Follow-Up Survey
11. FOCUSS - Parent Phone Survey

6.7 Access to Source

Source data will be maintained per Medical Records policy in a password protected, secure, Health Insurance Portability and Accountability Act (HIPAA) compliant, web-based electronic database with a built-in audit trail.

Only Institutional Review Board (IRB) approved research team members who have current HIPAA and Collaborative Institutional Training Initiative (CITI) Good Clinical Practice (GCP) and human subject's protection training will be authorized to access records.

6.8 Data or Specimen Storage/Security

See Section 5.5.1 "Secure Data Recording and Maintenance" .

6.9 Retention of Records

Study records (both deidentified data and password-protected file with links to identifiers) will be retained for a minimum of three (3) years after the completion of the study. All records will be electronic. The PI (Dr. Connors) will need to be contacted to move or destroy the records. The master list linking the unique study identification number to the research data will be destroyed after all analyses are completed.

6.10 Study Monitoring

The data safety and monitoring plan is consistent with what is required for clinical trials funded by NIMH, as follows:

The PI (Connors) is ultimately responsible for study monitoring to ensure the safety of participants and the validity and integrity of the data. With assistance from the primary mentor (Tebes), the PI will ensure that all individuals involved in the research are familiar with the data and safety monitoring plan and have adequate systems in place for adverse events reporting, data integrity, confidentiality, and protection of participants' safety.

Data and Safety Monitoring will be overseen by a Data and Safety Monitoring Board (DSMB) established for this study. The Board will be comprised of three investigators at Yale with relevant research expertise in mental health services research and/or implementation

science who are two full professors and one associate professor of psychiatry (psychology). One member's expertise is in implementation science and community-engaged research with children and families and is a former member of Yale School of Medicine's IRB (the Yale Human Subjects Committee, or HSC). Another member's expertise is in school-based research focused on the implementation and evaluation of social emotional learning programs with children, families, and school personnel. The third member's expertise is in applied, community-partnered research to promote mental health and wellness and prevent substance use with a focus on issues pertaining to equity, social justice and systemic oppression for marginalized and underrepresented groups. All are knowledgeable about the responsible conduct of research with children, families, and community-based organizations.

The DSMB will meet annually in person to review study procedures, including: 1) the study protocol; 2) the consent form; 3) occurrences of side effects/adverse events; and 4) the study data management system. As needed, the three investigators comprising the DSMB will meet without ex-officio members for closed discussions about serious adverse events (SAE). As needed, the DSMB will review de-identified data, but may review identified data when discussing SAEs. The DSMB will also be notified of the occurrence of any adverse events (AE) and SAEs, and may choose to meet on an ad hoc basis when notified of either of these events. DSMB members will also be notified when AEs and SAEs are reported to the Yale IRB.

6.11 Study Modification

Any study modifications will be submitted to the IRB for review and approval with a revised protocol. Changes will not be implemented in the study until modifications are approved.

6.12 Study Completion

The study will be completed on or before June 30, 2023. Data collection will be completed by June 30, 2023, with data cleaning, analysis and reporting to follow. We will notify the IRB when the study is completed and submit a closure report or other required paperwork at that time to close the study.

6.13 Funding Source

Salary support and other research funding for this study is provided by the National Institute of Mental Health (K08 MH116119).

6.14 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the school district (for SMH clinicians) and SMH clinicians (for parents), is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the appropriate conflict of interest review committee has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a Quality Assurance Committee from YCCI or the Psychiatry Department with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All investigators will follow the applicable conflict of interest policies.

6.15 Publication Plan

Scholarly publications and presentations resulting from this study will only report participant data in aggregate. Primary and secondary outcomes will be analyzed by subgroups of clinicians and parents, which may further be disaggregated by district, child age, and other independent variables. No analyses will report subgroups small enough such that any individual participant would be potentially identifiable (e.g., school counselor in an elementary school in a named district may be too identifying in a small district). If illustrative cases appear in publications, presentations or other reports, care will be taken to ensure details provided are in no way a disclosure of identifiable information. The PI holds primary responsibility for publishing the study results. Per the funder's guidelines, all published results will be made available in open access format.