Official Title: Personalized Assessment of Client Experiences (PACE)
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1) Protocol Title

Improving Measurement-Based Care in Youth Mental Health: A Comparison of Unidimensional and Multidimensional Approaches

2) IRB Review History*

N/A

3) Objectives*

This pilot study will use a mechanism-driven approach to compare two models of MBC in youth-serving community mental health settings: Multidimensional MBC, which includes measures of multiple domains that are patient-centered, treatment-driven, and symptom-focused, and Unidimensional MBC, which includes symptom measures only. Multidimensional MBC provides feedback on a broader array of process and progress outcomes that may be more relevant to clients and provide more actionable feedback to clinicians, and thus should have a stronger impact on target mechanisms and client outcomes. However, unidimensional MBC is lower burden for patients and providers, so might have more implementation success. The study will employ a Type 1 Effectiveness Implementation Hybrid design to assess the comparative effectiveness of these two approaches while gathering data to inform future implementation. Analyses will account for whether or not a client is on-track or not-on-track for improved outcomes, a likely moderator of MBC's effect on outcomes.

Aim 1: Conduct preliminary development activities to ensure fit between the two MBC approaches, the measurement of mechanisms, and the clinical context.

Aim 1a: Conduct stakeholder individual and group interviews to gather feedback on the two MBC approaches, implementation support strategies, and proposed measures of MBC mechanisms.

Aim 1b: Develop algorithms to determine on-track (OT) or not-on-track (NOT) status and program the MBC platform to administer study measures and randomize participants.

Aim 1c: Conduct a pre-pilot of study procedures.

Aim 2: Conduct a pilot randomized control trial (N = 900 youth clients, with an n = 400 research subsample) comparing multidimensional to unidimensional MBC.

Aim 2a: Test the predictive validity of the OT/NOT algorithms with outcome status at treatment end.

Aim 2b: Conduct an enrollment and attrition analysis to investigate potential factors associated with condition, client, or clinician that could influence a future RCT.

Aim 2c: Compare the effects of multidimensional and unidimensional MBC on proposed MBC mechanisms and youth outcomes.

Aim 2d: Examine whether the effects of MBC condition on outcomes are mediated by MBC mechanisms and/or moderated by OT/NOT status, diagnosis, and/or treatment type.

Aim 3: Conduct a mixed-methods analysis of implementation factors related to multidimensional or unidimensional MBC.

Aim 3a: Examine whether fidelity to MBC differs by condition.

Aim 3b: Examine whether implementation outcomes and challenges differ by MBC condition.

4) Background*

Approximately 14 to 20% of youth experience a mental disorder annually[1], with an estimated cost of $247 billion dollars per year in the United States alone[2]. Youth mental health concerns are often chronic and related to functional impairments including decreased educational attainment, juvenile justice involvement, and substance abuse[1,3-7]. Data consistently point to a "quality chasm" between routine mental health services and evidence-based practices (EBPs)[3,8]. Although numerous evidence-based treatments (EBTs) have been developed to address these concerns, results of effectiveness trials examining their performance in "as usual" clinical settings have yielded mixed results, and only small benefits over usual care on average[9].

An approach to improving healthcare that holds great potential is Measurement Based Care (MBC). MBC is grounded in the frequent and systematic use of assessment to regularly track the processes and outcomes of care[10] with feedback provided to clinicians[11,12]. MBC has support as an EBP, with several meta-analyses[13-18] and systematic reviews[19,20] indicating an positive effect on patient outcomes, particularly in adult samples. As systematic quality measurement has been identified as a key component of organizational improvement by the Institute of Medicine[8], MBC also supports data-informed decision-making for quality improvement[21], paving the way for data-driven implementation of evidence-based practices. For ease of use and real-time data availability, MBC systems typically utilize technology for online measure administration and generation of feedback reports.

MBC addresses many of the limitations that have restricted the reach of many other youth mental health practices. First, many EBPs are designed to address single diagnoses or clusters similar disorders, whereas comorbidity rates are high in youth psychopathology.[15] This single-problem focus may decrease real-world effectiveness, and make EBPs less appealing to clinicians, who are concerned that they are not relevant to their clients[25,26]. A second, related problem is that clinicians face a significant training burden to become competent in the many single-problem EBPs that would be necessary to cover their caseloads.[28] Third, surveys of clinicians indicate they perceive many EBPs as too rigid for personalized treatment[25,29], whereas their attitudes toward MBC and other EBPs that cut across multiple diagnostic groups are positive[22,23]. MBC is a transdiagnostic intervention that supports personalized treatment across an agency's full caseload, increasing its utility and appeal. MBC can be leveraged to inform clinician utilization of a range of interventions, including being embedded as "clinical dashboards" to guide use of other EBPs[24].

A significant barrier to advancing the use of MBC is a lack of research that tests the mechanisms underlying effective MBC. MBC is founded upon the premise that high-quality and continuous feedback will improve clinician competency, enhancing client outcomes[53]. In typical care, clinicians receive limited standardized information client outcomes[51,52], often make inaccurate appraisals of their own competence[54], and hence fail to make adjustments to their practice when needed. MBC alerts clinicians to clients who are not responding to treatment, prompting them to change therapeutic strategies[55-57]. Clinicians may also share feedback results with clients, which could increase client engagement[58,59] and enhance therapeutic alliance[60,61]. One study has shown a link between problems identified in feedback reports and content addressed in session[25], suggesting that MBC feedback can influence clinician behavior.

However, the underlying mechanisms of action of MBC remain largely theoretical. Research is needed that explicitly investigates MBC mechanisms in order to enhance MBC effectiveness and improve implementation support.

Little is known about the essential components of MBC. Models of MBC vary in a number of ways, including the frequency and content of assessment, the format and target of feedback, etc. Efforts to draw conclusions about these components have been hampered by differences between studies, and there is a need for studies to directly compare different forms of MBC[20]. One key issue that has cascading effects across the entire MBC process is what assessment data to gather. Current approaches can be grouped into *unidimensional* approaches that track symptoms[26-36] and multidimensional approaches that also track therapy processes such as therapeutic alliance[37,38]. Because multidimensional MBC focuses on both treatment progress and processes, it leads to feedback that is more actionable than unidimensional approaches, which only provide feedback on symptoms. Actionable feedback is key to MBC success[19,39-41]; multidimensional MBC may therefore be more effective. It also recognizes patient and caregiver preference for measures that assess positive aspects of treatment progress[42-46]. However, multidimensional MBC may have higher burden for clients and clinicians than unidimensional MBC, which could have implications for fidelity and sustainability.

Systematic reviews and meta-analyses of MBC have not discriminated between these approaches[13-20,47]. However, individual randomized controlled trials (RCTs) have supported both approaches. Multidimensional MBC has been shown to be more effective than controls, with small-to-medium effects in adults[48-60] and small effects in youth[37,38]. Unidimensional approaches have small effects in adult samples[26,27,30-36], but the only youth study found no effect of feedback. Further, MBC effectiveness may be moderated by whether a client is on-track (OT) or not-on-track (NOT) for improved outcomes, with MBC found to be most beneficial for clients flagged as NOT[51,59,60]. The only direct comparisons for multidimensional and unidimensional MBC have occurred within the NOT group. Three studies have examined the effects of adding a single administration of a multidimensional MBC battery after a unidimensional system flags an adult client as NOT[51,59,60], finding improved outcomes for the group that received the multidimensional feedback ($d = .31$[51]).

MBC implementation is complex[21,61-65], involving changes at the client (measure completion), clinician (feedback viewing and utilization), and organizational (e.g., training, implementing new technology) levels. This complexity likely contributes to MBC being implemented with high quality in fewer than 20% of clinical settings[61]. Extant literature on MBC implementation has primarily focused on client- and clinician-reported barriers[22,63,66,67], with implementation supports often focused on these barries[22,68-70]. While these are important, organizational-level factors, such as information flow matched to structural and workflow processes[71], have been largely neglected. A recent review[72-74], guided by the Consolidated Framework for Implementation Research (CFIR)[75,76], suggests that implementation is influenced by five factors[72]: intervention characteristics, the extra-organizational setting, the inner-organizational setting, individual stakeholder characteristics, and process factors (e.g., planning, evaluating). Given that implementation burden may be lower in unidimensional MBC, yet usefulness and acceptability may be higher for multidimensional MBC, a comprehensive implementation approach is necessary. PI Douglas found that comprehensive MBC implementation support guided by the CFIR was associated with successful implementation and improved outcomes at one agency versus an implementation failure at a second agency[37]. A key priority is therefore implementation research focused on factors that influence MBC adoption

and sustainability over time[77].

In sum, compared to treatment as usual, MBC has small-to-medium effect sizes, with larger effects for clients who are NOT, and preliminary data from adult samples suggest that multidimensional approaches may be more effective than unidimensional MBC, particularly within the NOT group (e.g., d = .31[51]). Although the effects of MBC are somewhat modest, its transdiagnostic reach is broad and it can also facilitate the implementation of other EBPs with larger effect sizes[24]. However, despite its potential, research on underlying MBC mechanisms, essential components, and effective implementation is minimal. This R34 addresses these gaps by developing procedures, mechanism measures, and implementation strategies to support a future R01 to study the effects of unidimensional MBC and multidimensional MBC on youth outcomes.

5) Inclusion and Exclusion Criteria*

The study will involve three groups of participants: 1) Clinicians; 2) Agency Leaders; and 3) Youth. Clinician Inclusion Criteria: (1) Clinician will be at least a part-time employee providing psychosocial treatment at the study agencies. (2) Clinician may conduct sessions in English or Spanish, but must be able to speak, read and understand English well enough to participate in English-language interviews, trainings, and consultation calls. Agency Leader Inclusion Criteria: (1) Agency leaders will be individuals in leadership positions (e.g., CEO, clinical director) at the study agencies. (2) Must be able to speak, read and understand English well enough to participate in English-language interviews. Youth Inclusion Criteria: (1) Male or female youth between the ages of 11-17 years receiving mental health services in the outpatient, intensive outpatient, and/or intensive home-based services at the participating clinics; the research subsample will be restricted to ages 11-16 to avoid having to re-consent individuals who turn 18 during the study. (2) If the family consents to complete additional research measures, one parent and/or primary caregiver must be available and willing to participate in all study assessments. (3) Adolescent and at least one parent/guardian are able to complete all study procedures in English or Spanish. For the Aim 1 pre-pilot, the adolescent and guardian must be able to complete all study procedures in English; this decision was made so that study materials could be finalized prior to translating them into Spanish.

6) Number of Subjects*

Up to 15 agency leaders, up to 200 clinicians, and up to 2000 youth will take part in the study.

7) Study-Wide Recruitment Methods*

Recruitment and Referral Sources. Participants will be drawn from up to four clinic locations in Tennessee of Health Connect America, Inc. (HCA).

Youth and their caregivers (N = up to 20 dyads) will be included in the small pilot that is part of Aim 1. Clinicians taking part in this pilot study will be asked to try out the measurement-base care (MBC) system with clients on their existing caseloads. The research team will provide

clinicians with information about how to select appropriate cases and a recruitment flyer (Pre-Pilot Recruitment Flyer) and will encourage them to discuss client selection with their supervisors if needed. In the first treatment session where the youth and caregivers complete the MBC measures through the Mirah platform, an invitation to complete additional research measures will be provided, along with consent/assent statements. Families will have the option to: 1) enroll in the study at that time, 2) ask to be contacted for further information before deciding, or 3) decline participation. Families who agree to participate will randomly assigned to either multidimensional or unidimensional treatment through the Mirah system and de-identified data will be provided to the research team. Families will receive up to $20 in gift cards for completing additional study measures.

Youth and their caregivers will be included in Aims 2 and 3 in three ways. First, the four study clinics will be using the measurement-based care system with all clients receiving in outpatient and intensive outpatient mental health services (up to 2000 youth falling in the target age range) and have agreed to incorporate the study randomization scheme as a quality improvement effort. PI Douglas has successfully used this approach in two previous randomized controlled trials of MBC[46,47]. Second, in the session where the youth and caregivers complete the MBC measures through the Mirah platform, they will be recruited via the Mirah Platform to complete additional measures using the same procedures described for the Study 1 pilot trial. Recruitment will take the form of presenting a recruitment screen, followed by the consent form if they indicate they are interested in learning more about the study at the end of their measures; families will also be notified that this will be happening via a flyer that the clinic will be using to tell them about the Mirah system. These flyers are tailored for each office, but we have uploaded one as an example (Mirah PACE flyer- Nashville). We have also uploaded a copy of the recruitment screen (Recruitment Information for Research Subsample). The clinics may use Mirah at the clinic intake session, before the decision has been made which services the youth will receive. If a family consents to be in the research sample and then the youth does not go on to be assigned to one on the services using Mirah, they will be contacted and informed that they will no longer be eligible to take part in the study. Up to 400 youth and their caregivers will be enrolled in these additional research activities. Finally, for the final phase of the mixed-method study of implementation factors, a subset of up to12 families who agreed to take part in the research study, stratified by their level of adherence to the MBC system, will be recruited with the assistance of their clinicians, who will provide them with a flyer describing the study (uploaded as PACE Family Triad Interview Recruitment Flyer) and asked if they would be interested in being contacted by research staff to hear about an opportunity to participate in qualitative interviews to better understand their experiences using the system. Families will be paid up to $60 in gift cards ($30 per informant) for participating in those interviews.

The PIs will directly recruit Agency Leaders (N = 5-15) to participate in qualitative interviews to throughout the study. Leaders will include one agency leader (e.g., the clinical director) at each clinic, and one administrator from the Health Connect central leadership. They will be paid $20 per hour for participating in these interviews.

Each of the clinics will have an on-site "MBC champion" who will support recruitment efforts, coordinate data collection activities with the research team, and generally serve as a local leader for the MBC efforts. MBC champions and agency leaders will contact clinicians to recruit them

for the study. The research team will provide recruitment flyers to facilitate recruitment and will hold informational conference calls to help with recruitment as needed. During Aim 1 activities, up to 10 clinicians will take part in individual or group interviews to inform development activities. In addition, 5 clinicians will take part in the small pilot trial to refine procedures before Study 2, including cognitive interviews to refine study measures. In order to incentivize participation, clinicians will receive $20 per hour for participating in study focus groups, $30 per hour for taking part in individual interviews, and $36 per pilot case for completing ongoing measures.

For Aim 2, agency leaders will recruit up to 200 clinicians over the duration of the study to participate in the trial. All agency clinicians will utilize the MBC system and take part in MBC implementation activities as part of the program-wide implementation, but clinicians will be informed that their participation in any additional research activities is voluntary and will not affect their relationship with the clinics. In order to incentivize participation, clinicians will receive $30 per hour for participating in qualitative individual interviews and $36 per case for completing ongoing measures for any of their clients whose caregivers consent to complete the extra research measures. A group interview with clinicians (N= up to 10) will be held at the beginning of the pilot in year 2. Agency staff members will also complete a follow-up survey at the end of Year 3.

8) **Study Timelines***

The proposed study is a three-year pilot effectiveness trial, comprised of two Aims. Aim 1 activities will include a variety of development activities to prepare for the Aim 2 Effectiveness Implementation Hybrid Study. The project timeline is detailed below. Agency Leaders and Clinicians will participate for up to three years and youth participants will participate for up to 18 months.

Project Timeline	Year 1				Year 2				Year 3			
Quarters by Year	1	2	3	4	1	2	3	4	1	2	3	4
Study Start												
Finalize preliminary study materials and scheduling for phase 1 activities												
Study 1: Aim 1 Development Activities												
1. Site visit for orientation (including with on-site study champions), leadership and clinician interviews												
2. Develop algorithms												
3. MBC technology additions and preparation of pre-pilot study materials												
4. Site visit for pre-pilot training and pre-pilot launch												
5. Three-month pre-pilot study of procedures												
6. Cognitive interviews on mechanism measures												

7. Finalize preparation of revised study materials												
8. Site visit for initial training and study launch including clinician interviews												
Study 2: Effectiveness Implementation Hybrid Trial												
1. Site visit for initial training and study launch including clinician interviews												
2. Ongoing coaching and implementation support; onboarding new clinicians												
3. Recruitment of new clients to participate in study procedures												
4. Research measure collection (baseline, 6, & 12 weeks)												
5. Ongoing collection of MBC mechanism measures												
6. Session-by-session administration of MBC measures and clinician use of feedback												
7. Ongoing collection of MBC implementation measures and metadata												
8. Ongoing enrollment and attrition analysis by study arm												
9. Semi-structured interviews with up to 12 triads (clinician, caregiver, patient); leadership interviews; clinician follow-up survey												
Analysis and Reporting												
1. Randomized-experiment quantitative analyses												
2. Qualitative analyses												
3. Integration of all analyses and report preparation												
4. Write and submit R01 application for full SMART												
Complete and Submit Yearly Progress Reports, Implement Dissemination Plan												

9) Study Endpoints*

The primary study endpoints are the youth- and caregiver-reported Symptoms and Functioning Severity Scale and the youth- and caregiver-reported Ohio Problems and Functioning Scale (Research Subsample Only)

10) Procedures Involved*

Below, we present a general overview of the study methods as outlined in the grant proposal. Please note that this R34 development grant is designed to generate procedures iteratively over the course of the study, so materials and procedures will be updated and submitted as they are developed through the procedures outlined below.

METHODS FOR AIM 1: PRELIMINARY DEVELOPMENT ACTIVITIES

The goal of Aim 1 is to conduct development activities to ensure fit between agency workflow and the MBC system, implementation support tools, and research procedures. In **Development Phase 1 (Aim 1a)**, qualitative data collection will refine research measures and protocols, and assess potential implementation barriers and facilitators. Three qualitative components will be conducted with semi-structured protocols. First, either at the initial site visit or via phone or video conferencing shortly thereafter, individual or group interviews will be held with agency leaders (1-3 per clinic, for up to 15 interview participants) to help develop procedures for the pre-pilot study and discuss organizational-level factors that may influence MBC implementation. Second, individual or group interviews will also be held at the initial site visit or via phone or video conferencing shortly thereafter with up to 10 eligible clinicians combined from all five clinics. The interviews will gather information about clinical decision-making, typical clinic workflow, and any existing strategies for tracking treatment progress. Participants in individual and group interviews will respond to open-ended questions and be asked to react to sample MBC materials, study measures, and study procedures, and will be paid $20 per hour for their time. Interviews will last 30 to 90 minutes, depending on participant availability and preferences. The interviews will be recorded and transcribed for coding, with results used to modify the project materials. The interview questions have been submitted under study documents.

In **Development Phase 2 (Aim 1b)**, we will develop algorithms to identify NOT and OT trajectories for the SFSS to generate alerts that will be embedded into the MBC feedback reports, support moderator analyses of intervention condition by OT/NOT effects, and set the stage for the randomization scheme for the R01 SMART. Analyses will utilize existing limited identifier datasets from 2 previous RCTs[46,47], including data from 597 youth treated by 165 clinicians using multidimensional MBC at 30 sites. During this phase, Mirah staff will also embed study measures into the system, update feedback reports with the alerts, and build a system to automate study randomization.

In **Development Phase 3 (Aim 1c),** five clinicians will pilot the MBC system with up to 4 clients each; clinicians will select clients from their own caseloads based on the clinician's decision that it would be appropriate to begin using MBC with the client. Before beginning to treat their clients in the pre-pilot, clinicians will complete a packet of some or all of the baseline

measures planned for the full RCT (See upload of Baseline Clinician Measures); these measures will be collected either via REDCAP or Mirah. Procedures for this pre-pilot will be identical to for Aim 2 (see below) to identify challenges related to recruitment, randomization, and/or data collection. The only change to the Aim 2 procedures is that these pre-pilot cases will only be followed for 6 weeks, complete two rounds of research measures rather than three, and be paid up to $20 for participation (a $10 gift card for each round of assessment measures completed). The use of MBC is also part of consenting to the study, so the MBC measures from the pre-pilot have been uploaded as a study document (MBC Measures Pre-pilot). 15- to 30-minute cognitive interviews will be held with the five clinicians to refine measures and feedback reports, conducted by telephone or video conference immediately following clinical coaching calls. In cognitive interviewing, the participant's thinking 'out loud' when reviewing materials is recorded to assess how the clinician is viewing and interpreting them. Clinicians will review study mechanism measures to determine how they interpret the items and response options, ensure wording is clear, and ensure adequacy and accuracy of the items; they also to review a feedback report aloud. Each clinician will take part in up to 5 cognitive interviews during the pre-pilot. The interviews will be recorded and transcribed for coding. Following the pre-pilot and these interviews, final revisions will be made to study procedures and feedback reports as needed.

METHODS FOR AIM 2. PILOT EFFECTIVENESS IMPLEMENTATION HYBRID TRIAL

Design. This study will utilize a Type 1 Effectiveness Implementation Hybrid design, in which an effectiveness trial (Aim 2) is conducted while simultaneously gathering data to inform future implementation (Aim 3). The effectiveness trial will be a two-group RCT, with clients randomized to unidimensional or multidimensional MBC. The HCA clinics have agreed to randomize all of their youth clients to one of these two conditions, as they view this as a quality improvement initiative. Consent will be obtained from a subset of 400 clients and caregivers (i.e. the Research Subsample) to complete additional research measures. The implementation study will be a mixed-methods analysis.

Procedures for effectiveness trial. After Aim 1 is complete, program-wide implementation of MBC will begin. The initial training will consist of a series of workshop style trainings conducted during regular agency staff meetings and ongoing consultation will be provided to agency staff thereafter. The training approach is a data-driven one, where questionnaires are used throughout the training and consultation to tailor implementation to that specific context. These questionnaires will be considered part of the implementation activities and will be administered to all staff members participating in the trainings. Clinicians who consent to be in the research study will be giving permission for these implementation data to be linked to the research data they provide for their clients; responses from other HCA staff will be de-identified and used to characterize the implementation under Aim 3. Prior to extracting these data for research purposes, we will submit a variable list to the IRB for approval. When the initial training is complete, the trial will begin program-wide at the participating HCA clinics. As the clinics add clients ages 11-17 to the Mirah system, the system will automatically randomize them to either unidimensional or multidimensional MBC on a 1:1 ratio. All clients and their caregivers will complete MBC measures as part of routine services, and the researchers will receive limited identifier datasets containing MBC data and Mirah metadata for all participants, an identifiable

dataset for individuals who consent to take part in the research subsample. We have uploaded a variable list of the variables we will be requesting from Mirah. After the first time a youth and their caregiver complete the MBC measures, the Mirah system will proceed to screens with recruitment and consent information for participation in the Research Subsample. Youth and caregivers will be asked to assent/consent to complete additional research measures. Each time they complete Mirah measures for routine sessions, youth and caregivers will be administered one additional mechanism item; this item will be included in up to 12 sessions after they enroll in the study. In addition, they will complete a longer set of research measures will including the Ohio Scales and additional mechanism measures; these will be administered at study enrollment, 6 weeks later, and 12 weeks after study enrollment. These longer sets of research measures will be administered via the REDCap system, with links e-mailed directly to the family by research staff. Additional Research Subsample Measures have been uploaded under Study Documents. Families who consent to be a part of this Research Subsample will be paid up to $30 for completing these measures (the project will e-mail them a $10 gift card per major assessment completed either directly through e-mail or by using Qualtrics and Tango Card). Clinicians treating clients in the Research Subsample will also be asked to complete additional measures for those clients and will be paid $36 for completing those measures. The Mirah system does not have a way to only recruit clients whose clinicians have consented to be in the research study or to tailor the measure schedule for those clients. Therefore, if a client agrees to be in the study and their clinician has not, the study will contact the clinician, let them know that they will be receiving links to research measures, and see whether they would like to consent to be in the study at that point. If they do not, then they will be instructed to disregard the requests for them to complete measures. These measures are also included in the Research Subsample Measures upload under Study Documents.

METHODS FOR AIM 3. MIXED-METHODS ANALYSIS OF IMPLEMENTATION FACTORS

Design. The Aim 3 qualitative data collection will focus on implementation barriers, facilitators, and outcomes. As in Aim 1, semi-structured individual and group interviews will be used to derive rich descriptive understanding of internal thought processes and feelings associated with MBC (e.g., acceptability or decision-making) and perceived links to behavior (e.g., fidelity of measure completion or feedback viewing). Three major differences are: a change in focus to factors associated with implementation and utilization; the inclusion of client and caregiver perspectives; and the addition of purposeful sampling based on quantitative fidelity data. Qualitative data will then be analyzed together with quantitative fidelity and implementation indicators.

Procedures for mixed-methods data collection. Aim 3 qualitative components will include: (1) clinician individual and group interviews before the RCT, (2) agency leader individual and group interviews before and after of the RCT, (3) up to 12 triad interviews, selected from Research Subsample youth, caregivers, and clinicians, and (4) field notes, responses to implementation questionnaires, and audio recordings of training activities such as consultation calls. For the clinician and agency leader interviews, a priori themes to guide questioning have been developed through a review of the MBC literature and related fields and are organized by five factors from the CFIR model[78,79]: intervention characteristics (e.g., MBC measures), extra-organizational (e.g., payer MBC reimbursement), inner-organizational setting (e.g., leadership support for MBC

use), individual stakeholder characteristics (e.g., perceived value of MBC), and process factors (e.g., ongoing support needs). The post-RCT agency leader interview script has been uploaded as FINAL Leader Semi-Structured Interview Protocol).

For the triad interviews, participating clinics will provide a list of clinicians and their MBC implementation data. We will recruit up to 12 clinicians with a range of fidelity of feedback viewing over the previous month, identified using Mirah metadata. Clinicians will be recruited with the assistance of agency leaders, using a recruitment flyer that can be distributed by e-mail or handed out in meetings (PACE Clinician Triad Interview Recruitment Flyer). Interested clinicians will be contacted by the research team to schedule an interview to be conducted via zoom. At that appointment, clinicians will be verbally consented (PACE Clinician Triad Interview Script) and then complete an individual qualitative interview with the study staff (PACE Clinician Triad Interview Verbal Consent Script). Interviews will be recorded.

We will ask these clinicians to help recruit one family from their case load to participate in the study. Clinicians will be provided a flyer explaining the study (PACE Family Triad Interview Recruitment Flyer) and obtain permission for interested families to be contacted by the research team by phone, text, or e-mail using the clinic's standard release form. The flyer will include information stating that the family's decision to take part in the study will not affect their treatment and clinicians will be asked to provide similar reassurance when telling families about the study. The research team will then reach out to interested families to further explain the study and schedule the interviews to be conducted via zoom. Caregivers will be scheduled first, followed by youth. At each interview the informant will first be asked to verbally consent/assent to the study (PACE Caregiver Triad Interview Verbal Consent Script; PACE Youth Triad Interview Verbal Assent Script), followed by a semi-structured interview conducted by study staff (PACE Client and Caregiver Qualitative Interview). These interviews will be recorded. As the triad interviews are conducted, we will assess for saturation of differing levels of MBC implementation and recruitment will cease when the qualitative data are thematically saturated. All participants (clinicians, youth clients, and caregivers) will receive $30 for participating in the one-hour qualitative interview. While the sample size is not sufficient for generalizability (or in qualitative parlance, *transferability*), the clinician interviews will further inform our understanding of the MBC mechanisms of action related to the CFIT theory. The separate interviews with youth and caregivers will allow for a better understanding of the MBC mechanisms of action related to the therapeutic assessment theory.

The study PIs and/or project research assistants will observe and take notes during project implementation activities for later qualitative coding and we will retain answers to the questionnaires used during training and consultation. We will also ask participants to consent to recording consultation calls and other training activities. It is possible that individuals who have not consented will take part in those activities. As such, all recordings will be transcribed, any identifying information removed, and then deleted to avoid retaining recordings of individuals who did not consent to the study.

Aim 3 quantitative data includes Mirah metadata on fidelity (measure completion and feedback viewing rates) and measure completion time; and data on implementation monitoring (training attendance, evaluations, case review) and implementation barriers, facilitators, and outcomes

(answers to implementation questionnaires, youth and caregiver perceptions of MBC acceptability) Aim 3 quantitative data will also include a clinician follow-up survey, which includes measures related clinician attitudes, use of MBC, organization-level factors, and implementation efforts (Pace staff post survey FINAL); measures will be collected via REDCAP. As clinicians joined the study, we asked clinicians to consent to allow their identified responses to the implementation questionnaires to be linked to our research data; responses from clinicians who do not consent to take part in the research will be de-identified and used to characterize the implementation activities only. An additional consent form will be administered together with the follow-up survey via REDCAP to cover that research activity (PACE Provider Follow-Up Consent).

11) Data and Specimen Banking*

N/A, no specimens will be collected as a part of this research study

12) Data Management*

STUDY ANALYSES

Qualitative Analyses. To code the data from the individual and group interviews (**Aim 1a**), we will use a categorizing strategy of coding and thematic analysis[108,122], in which the data will be systematically coded into discrete categories based on a two-pronged approach that relies on: (a) an *a priori* analytic framework; and (b) emergent categories or themes using "grounded theory"[123]. Then, analysis will move to comparing similarities and differences between participants and clinics. Thus, the emerging theories will be grounded in real-world patterns[124] within and between sites. Analyses will include thick descriptions of the patterns and themes that emerge as well as the associations between the background characteristics of participants, the sites with which they are affiliated, and their responses to our questions and probes. Computer-assisted data analysis software (e.g., NVivo) will be used for coding[122] patterns among individuals and sites.

Quantitative Analyses. Aims 1b and 2 will involve using multilevel modeling (MLM) approaches[125], to account for nesting of repeated measures within clients and clinicians. In all Aim 2 models, we will treat site as a fixed effect, due to the limited number of clinics (n=3).For **Aim 1b**, on-track (OT) and not-on-track (NOT) algorithms will developed using an extant dataset[46,47] (N = 597). Analyses will progress in two stages, following established procedures previously applied to the Outcomes Questionnaire system[118-120], the most widely-tested MBC system[19]. The first stage of the analysis involves generating expected change trajectories for SFSS scores over time. MLM will be used to estimate these individual change trajectories with weekly scores nested within participants, who are in turn nested within therapists. Models will be tested using the Hierarchical Linear Modeling (HLM) software package[126] and restricted maximum likelihood (RML) estimation. Prior to hypothesis testing, we will examine SFSS distributions and apply transformations (e.g., square root, logarithmic) for the weeks in treatment variable as necessary[118].

The second stage of the analysis involves: (1) developing a system to identify cases at risk of showing treatment deterioration (NOT), and (2) testing its predictive accuracy. Identification of NOT cases is based on the expected change trajectories (intercepts, slopes, and random effects) estimated in Stage 1. Following Cannon et al[118], we will split the data into two random samples, a reference sample and a validation sample. As a first step, the base rate of treatment

deterioration—a significant worsening of symptoms over the course of treatment—will be identified in the reference sample. Consistent with previous studies[118-120], identification of the base rate will be based on a combination of the reliable change index[127] (RCI) and clinical cutoff scores. Established SFSS values for the RCI and the clinical cutoff score[128] will be used to identify cases with clinical deterioration, operationalized as an SFSS increase over treatment exceeding the RCI and a case ending treatment in the clinically significant range of functioning. The deterioration base rate from the reference sample will serve as a basis for deriving prediction intervals around the expected mean change trajectory in the validation sample. Cases identified as exceeding the prediction interval at any point during treatment will comprise the NOT group. Cases within the interval form the OT group.

The validation sample will then be used to check the validity of the warning system in predicting true treatment deterioration. Analyses will examine whether classifying a client as NOT accurately predicts whether they end treatment classified as deteriorated. Sensitivity and specificity will be calculated and the algorithms will be adjusted as needed until adequate levels are reached, using Cannon et al.'s[118] specificity values of .55 and specificity values of .75 as guides. We will then test the predictive validity of the finalized OT/NOT algorithm (**Aim 2a**) using the full RCT sample (N = 900). To prepare for the SMART R01, we will also conduct simulations, varying estimates entering the expected change trajectories to investigate transition points in the OT/NOT intervals to assess optimal timing of when to conduct the second randomization.

Aim 2b will investigate potential factors associated with condition, client, or clinician that could influence a future SMART. GLMM (MLM with a logistic linking function) will be used to investigate factors associated with treatment and attrition from the study. In addition, differences between the full RCT sample (N = 900) and the Research Subsample (N = 400) will be examined utilizing data from electronic health records (EHR) to determine whether enrollment in the Research Subsample, and completing all 12 weeks, is associated with any demographic or clinical factors. We will also examine enrollment and attrition rates for clients within clinicians to determine whether any clinician factors might be associated with client-level participation in the study, along with comparing enrollment rates across clinics. As above, these analyses will inform design of the R01 SMART, including power analyses that take into account rates of NOT/OT and projected attrition.

MLM will also be used to compare the effects of study condition on SFSS change trajectories, Ohio Scores, and MBC mechanisms (**Aim 2c**). We will examine differences in MBC outcomes by feedback condition, nesting within treating clinician and controlling for clinic. If sample sizes in the research subsample prove too small for this analytic approach, analyses of variance will be used to test a time by treatment interaction. As a first step in comparing conditions on MBC mechanisms, we will aggregate the scores across sessions (within therapist) by averaging them or summing count variables (e.g., matches between a client being identified as NOT and the therapist recognizing deterioration) to create composite variables for each mechanism domain in Figure 2.

Finally, we will extend the MLMs tested to accommodate potential mediators and moderation by NOT status, diagnosis, and treatment type (**Aim 2d**). Mediation will be tested using the products of coefficients method [129], using bootstrapping to adjust for nonnormal, asymmetric confidence intervals[130]. Algorithms for testing mediation using these methods are available in the package RMediation[131] available in the software platform R. Moderation by NOT status will be tested by entering NOT status, along with the feedback condition by NOT

status interaction and other model covariates. Similar models will examine moderation by diagnosis and treatment type.

Mixed-methods analyses. **Aim 3** will be analyzed using mixed methods to examine implementation factors related to MBC. We will rely on the complementarity of qualitative and quantitative data to ensure interrelation of the data through an iterative analysis process[132,133]. We see a significant purpose of this mixed method approach as *exploratory*, and will use the results of qualitative methods to inform and modify both future quantitative methods (e.g., surveys) and design implementation enhancement efforts[134]. We will use a combination of stakeholder individual interviews, group interviews, surveys, and observations of training activities to examine cognitive and behavioral factors such as MBC acceptability, perceived sustainability, etc., among clients, clinicians, and agency supervisors and administrators. With the exception of the triangulation of quantitative data, these qualitative data will be coded using a priori and grounded theory themes using Nvivo software as described in C10.1 above. Quantitative data will explore group differences in client-level implementation factors (e.g., time burden to complete measures) with youth and caregiver ratings of acceptability of MBC measure completion time and meta data on actual measure completion time from Mirah analytics. Agency leader and clinician survey data on clinician-level MBC attitudes and organization-level implementation factors will be aggregated by agency at project start and end, which allows for triangulation of data at baseline and project end with concurrent agency leader and clinician. Triad interviews with matched clients, caregivers, and clinicians will be explored qualitatively to inform our understanding of the MBC mechanisms of action related to the CFIT theory (e.g., recognition of actionable feedback, cognitive dissonance, and clinical actions). The separate interviews with youth and caregivers will allow for a better understanding of the MBC mechanisms of action related to the therapeutic assessment theory (e.g., treatment engagement, therapeutic alliance).

Sample size and power calculations. Given the preliminary nature of this pilot study, power calculations focused on power for the analyses of the group differences in outcomes (Hypothesis 2c.1). Power calculations were conducted using Optimal Design 3.1. We assumed 8% of the outcome variance at the clinician level[135] for an n of 22 clinicians (over the duration of the study) and 900 adolescents, $\beta = .80$, and $p = .05$. Using these estimates, Aim 2c, examining the impact of feedback condition on treatment response (assessed by the SFSS) will be optimally powered to detect a small effect of $d = .25$. The only previous estimate of differences between multidimensional and unidimensional MBC focused on the NOT subgroup only, finding an effect of ($d = .31$); the overall effect size for this study is expected to be smaller because the analyses will focus on the NOT and OT groups combined. Using a more conservative small effect size of $d = .20$ yields power of approximately .75. With respect to power assessing differences by feedback condition in the Research Subsample (n = at least 22 clinicians and 400 adolescents) will be optimally powered for a small-moderate effect of $d = .30$. Assuming an effect size of $d = .25$ yields power of .62.

DATA SECURITY, STORAGE, AND QUALITY CONTROL

Quantitative data will be collected electronically via either the University of Miami REDCAP system or directly through Mirah. Mirah is a HIPAA compliant system for collecting and scoring clinical measures. It uses Secure Sockets Layer (SSL) encryption to protect all data during transfers and stores is on a secure server. Data access will be restricted to study personnel, with permissions set to only those necessary to perform

tasks. Whenever possible, staff will download data directly from REDCAP or Mirah, but any file transfers between sites will be done via an approved secure platform such as secure send. Downloaded files will be stored on the psychology department's server, box.com, one drive, and/or google drive. The project coordinator will be regularly reviewing data for threats to data quality, such as missing data. Built-in validation protocols in REDCAP and Mirah will prevent entry of invalid responses.

Qualitative interview recordings, transcripts, and codes will also be stored securely on psychology department's server, box.com, one drive, and/or google drive.

13) Provisions to Monitor the Data to Ensure the Safety of Subjects*

This study only presents minimal risks to participants.

14) Withdrawal of Subjects*

Participants and their parents/guardians may be withdrawn from the study without their consent if they are withdrawn from clinical care in the participating clinics. Should the client be terminated or transferred in accordance with the local clinic policy, he/she will be withdrawn from the study. In addition, participants may be withdrawn for the following reasons:

- The participant is no longer able to attend clinic visits or complete research assessments.
- There may be other reasons that are unforeseen at this time.

Those participants who voluntarily withdraw from treatment may be asked to complete the 6 and 12 week assessments for data collection purposes, if appropriate.

Clinicians may be excluded from the study for any of the following reasons:

- They leave the clinic and are no longer seeing clients at the agency.
- They are unable to attend and/or participate in training and consultation meetings.
- They are determined inappropriate for the research study (i.e. failure to adhere to treatment, failure to adhere to study procedures).

15) Risks to Subjects*

This study is considered to involve minimal risk for all participants. For the clinician and agency leader participants, participants, the main risk is that they will be asked information about their work in a group interview setting where their colleagues might hear their answers. In addition, the clinicians taking part in the pre-pilot and RCT may experience slight discomfort participating in MBC consultation calls or from seeing client progress reports. However, clinicians could experience this same discomfort in the routine supervision they receive. For youth and caregiver participants, there could be some risk of discomfort from disclosing information through the Mirah platform, although this discomfort is not anticipated to exceed that involved in typical

clinical procedures. In addition, they may experience minor discomfort giving feedback about their experiences using the MBC system.

For agency leader and clinician participants, the PIs will emphasize with participants and agency administrators that participation is voluntary and that clinics cannot penalize individuals who decline participation. All information obtained through individual and group interviews and surveys will be kept private, with only summaries of information relevant to implementation provided to clinics if it is possible to do so without violating participant confidentiality. To decrease risks to individuals participating in group interviews, we will: 1) ensure that none of the participants are in a supervisory role over other participants, and 2) begin the session by discussing the importance of confidentiality and the limits to confidentiality based on the group setting, and asking all participants to not discuss anything from the interview outside of the group.

As detailed above, the primary strategy for protection against risk for youth is that the study will not collect any identifying information, which protects the privacy of clients and ensures the confidentiality of their data. Because the study activities present minimal risk and are similar to activities they are already choosing to engage in by enrolling in treatment, we do not anticipate a risk of adverse events.

16) Potential Benefits to Subjects*

Youth participants will potentially experience alleviation of distress associated with a mental health condition. In both study conditions, youth have access to MBC, an evidence-based practice that is not currently used in these agencies.

Therapist participants will have access to training and consultation in a MBC.

17) Vulnerable Populations*

This research involves youth 17 and under. A number of safeguards have been put in place and careful consideration has gone in to the decision to conduct this research with this particular population. The PIs have extensive experience conducting research and clinical work with this population. All study staff involved will be trained in conducting research with vulnerable populations, including minors. All study therapists will have experience treating mental health concerns in youth. The risks to the study are minimal, so the benefits outweigh the risks to participants.

18) Multi-Site Research*

Dr. Susan Douglas at Vanderbilt University and Dr. Jensen-Doss at the University of Miami as co-PIs for this grant and will be responsible for the management of the entire project including developing and implementing project policies and procedures. Both Drs. Douglas and Jensen-Doss will share equal responsibility for implementation of the scientific agenda. Additionally, the PIs will both be responsible for ensuring that the project adheres to US Laws and NIH policies, including guidelines for the protection of human subjects. Dr. Douglas will take primary

responsibility for the qualitative arm, implementation support and measurement, and quarterly site visits to clinics. Dr. Jensen-Doss will take primarily responsibility for the quantitative arm. She will also oversee database management and data analyses, in collaboration with the statistical consultant. The PIs will share responsibility for overseeing the training and supervision of project staff. Dr. Jensen-Doss will serve as contact PI and will assume fiscal and administrative management, responsibility for communication with NIMH, and submission of annual reports. As the primary award site, the University of Miami (UM) will have primary administrative responsibility for the project, with funds to Vanderbilt awarded via a subcontract. The UM Institutional Review Board (IRB) will serve as the coordinating IRB- we will initiate the process to establish UM as the coordinating IRB after the grant is funded.

Communication Schedule: The two PIs will have at least weekly phone or skype meetings to review progress towards study aims, address any problems that arise, and manage the project. The PIs will also hold joint phone or skype meetings weekly with the project coordinator to ensure fidelity to project procedures, with Dr. Jensen-Doss holding additional in-person meetings with the project coordinator as-needed. Funds are also budgeted for in-person meetings, including an initial start-up meeting at UM, six site visits across the life of the project, meetings at one conference per year, and a closing meeting at Vanderbilt in Year 3.

19) Community-Based Participatory Research*

N/A

20) Sharing of Results with Subjects*

The Mirah platform will be used to conduct the MBC, and clinicians will collect and view these data as part of their routine care. The research-specific instruments will not be shared with clinicians, and it will also not be possible for the study to share the results directly with participants, as the researchers will only receive limited identifier datasets from Mirah.

21) Setting

The study will take place in up to four locations of a community mental health agency serving a diverse client population in Tennessee. The four clinics are part of Health Connect America (HCA), which provides behavioral health treatment in 45 offices in five states. The corporate headquarters is located 20 minutes from Nashville, TN (location of PI Douglas). HCA has not previously routinely used MBC. They have agreed to conduct the study program-wide in five TN clinics with youth receiving intensive outpatient (two programs, referred to as intensive outpatient and intensive home-based services by the agency) and outpatient mental health services, with a client flow estimated at up to 2000 youth over an 18-month period. All recruitment and study activities will take place at HCA

22) Resources Available

Project staff will include:

PIs (Jensen-Doss, Douglas at Vanderbilt): Both PIs have extensive experience conducting research with children, with clinical populations, and in clinical settings.

Research Assistant: This individual will hold a bachelor's degree. This individual will be supervised closely by the PIs and the postdoctoral fellow.

Co-I (Craig Henderson, Sam Houston State University): The Co-I is an experienced biostatistician with expertise in the quantitative methods to be utilized.

Study resources include:

Univeristy of Miami: PI Jensen-Doss

The University of Miami provides Dr. Jensen-Doss with a dedicated faculty office, laboratory space, offices for postdoctoral associates and additional graduate student office space, all on the same floor in a relatively new psychology building completed in 2003. This space is large enough to house all UM site staff working on this grant. All of this space is wired for internet, wifi and phone access. The UM Department of Psychology has an in-house team of three consultants for hardware and software needs and an additional IT support technician. Over a dozen servers provide separate functions including printing, e-mail, and software applications. Network directories are encrypted, backed up nightly and scanned in order to be virus-free. UM will provide access to tools (e.g., copying machine, fax, computers, phones, etc.) needed for project implementation.

Vanderbilt University: PI Douglas

Dr. Douglas has resources available to her to fully support her activities as a principal investigator on the project, including a dedicated faculty office and an office for a master's student research assistant, all on the second floor of the building occupied by the Department of Leadership, Policy, and Organizations (LPO) on the Peabody College campus. The space is wired for internet, wifi and phone access. Vanderbilt will provide access to tools (e.g., copying machine, fax, computers, microphones and audio recorders, phones, etc.) needed for project implementation. Vanderbilt University's Information Technology (VUIT) provides computing resources, services and support to all Vanderbilt faculty, staff, and students. VUIT maintains and supports all network operations. This includes access to the Internet, collaboration, storage, telecommunication and video networks. Technical support specialists help to facilitate access to statistical and research tools, and provide consultation on the appropriate uses of software and storage of data. Research relationship managers connect researchers with cutting-edge resources, such as the Advanced Computing Center for Research and Education (ACCRE), a 5,000 core research cluster. The Office of Research has shared research resources and facilities that offer cutting edge scientific services, enabling access to high-end equipment, advanced techniques and specialized expertise for all Vanderbilt investigators.

Sam Houston State University: Co-I Henderson

Dr. Henderson has resources available to him to fully support his activities as the statistician on the project, including desktop computers which are on a protected and firewalled network, and require secure login credentials. Software appropriate for word processing, data storage, retrieval and statistical analysis (SAS, SPSS, Mplus, Stata, HLM) are readily available to him along with several high-quality printers. Dr. Henderson has ample room to house the proposed research without acquiring additional space, including two research offices with computer equipment, file cabinets, book shelves, and meeting tables.

Mirah

Mirah is a software and services company founded in 2015 to make measurement-based care better and more available to mental health clinicians and patients. Mirah's staff includes both technology and clinical experts to provide cutting-edge mental health products and clinical support. Mirah's clinical team consists of licensed medical and mental health professionals representing the fields of psychiatry, psychology, and social work. Mirah has a software and product team with years of experience delivering world-class health IT products to market. Mirah's flagship product, the Mirah platform, enables fast, robust, and regular measurement and tracking of patient symptoms in a mental health setting. The Mirah Platform is currently successfully used across community care, research hospital, government, and private practice settings.

Mirah's engineering team has the resources and capabilities to rapidly prototype, develop, and launch new features and content to support the changing needs of customers and the market. These resources will support this proposal by providing any necessary adaptations to the Mirah Platform necessary to achieve the study goals, specifically including the addition of research measures and the development of a randomization scheme that will automate random assignment to groups for new clients involved in research studies. Mirah's clinical staff includes leaders and advisors from a broad spectrum of mental health institutions, including, among others, McLean Hospital, Harvard Medical School, and Vanderbilt University. The clinical team brings vast experience in implementing and practicing measurement-based care in a variety of settings, and can use that experience to support this effort.

Health Connect America

Health Connect America, Inc. (HCA) is a fully licensed and certified private, not-for-profit corporation with national headquarters in Franklin, Tennessee and 45 locations in five states (Tennessee, Mississippi, Virginia, Alabama, and Georgia). HCA provides a full continuum of services for individuals and families at risk. With roots going back to 2005, HCA provides community-based, office-based, and home-based therapy, case management, medication management and counseling for children, adolescents, adults, and families with the steadfast goal of promoting personal positive growth, healthy coping skills, preserving/repairing relationships and natural support systems and adding additional needed community support systems. HCA staff are trained in various evidenced based models of treatment, such as Cognitive Behavioral Therapy, Rational Emotive Therapy, Trauma-Focused Cognitive Behavioral Therapy and specific training to use models that address issues of domestic violence, substance abuse and sexual behavior problems. HCA serves as a subcontractor for both private and public agencies, and accepts self-pay, Medicaid, and third party payers, and is accredited by the Council on Accreditation (COA).

Three programs (Intensive Outpatient Services, Intensive Home-based Services and Outpatient Services) serving youth aged 11 to 17 years and their families in five clinics in Tennessee will take part in this study. As detailed in the Recruitment and Retention Plan documents, HCA has ample access to clients and clinicians to support the proposed research. As detailed in their letter of support, HCA is enthusiastic about participating in the proposed project. At their national headquarters and each of the clinic locations, HCA has sufficient conference room and office space to support the proposed training and data collection activities. Agency leadership has agreed to support staff time for participation in training and ongoing

implementation support activities. They have wireless internet access throughout the agency to support use of the tablet-based MBC data collection, and their electronic health record (EHR) system, CareLogic, will be partially integrated with the Mirah system to facilitate feasibility of use.

23) Prior Approvals

N/A

24) Recruitment Methods

Please see above in Section 7 (Study-Wide Recruitment Methods).

25) Local Number of Subjects

Up to 15 agency leaders, up to 200 clinicians, and up to 2000 youth will take part in the study.

26) Confidentiality

X Data obtained or created for this research will be stored on an encrypted electronic device or system owned by the University of Miami or on a cloud storage system that has been approved by the University of Miami for storage or research data.

X The Investigator (or research staff) will record (e.g. write down, abstract) data collected in a manner that does not include any indirect or direct identifiers and the recorded data will not be linked to the individual's' identity.

☐ The investigator (or research staff) will record (e.g. write down, abstract) the data collected in a manner that does not include any direct identifiers of the subject. The investigator will assign a code to each subject and link the code to the subject's identity. The research team will maintain the link to the subject's identity on a document separate from the research data. Both documents will be stored in separate files on a University of Miami encrypted device or on a University of Miami approved cloud storage system. The research team will destroy the identifiers at the earliest opportunity.

X The research team will maintain the research data for at least three years.

☐ *Bio*-Specimens obtained for this research will be stored without any direct or indirect identifiers.

☐ *Bio*-Specimens obtained for this research will be stored in a de-identified coded manner.

X When required to transport data or bio-specimens for this research, the research team will transport the data and bio-specimens in a de-identified (or anonymous) manner with a link to the individual subject's identity maintain separately from the data and/or bio-specimen.

27) Provisions to Protect the Privacy Interests of Subjects

All information obtained through individual and group interviews and surveys will be kept private, with only summaries of information relevant to implementation provided to clinics if it is possible to do so without violating participant confidentiality. To decrease risks to individuals participating in the group interviews, we will: 1) ensure that none of the participants are in a supervisory role over other participants, and 2) begin the session by discussing the importance of confidentiality and the limits to confidentiality based on the group setting, and asking all participants to not discuss anything from the interview outside of the group.

As detailed above, the primary strategy for protection against risk for youth is that the study will not collect any identifying information, which protects the privacy of clients and ensures the confidentiality of their data.

28) Compensation for Research-Related Injury

N/A/ The study is minimal risk.

29) Economic Burden to Subjects

There is no economic burden to subjects, as the study procedures are part of the care they are already receiving or part of their regular workday.

30) Consent Process

There are four groups of participants with different consent procedures.

Clinicians and Agency Leaders interviewed in person will provide written or online consent using a REDCap consent form, obtained by the study PIs. Consent may be explained in a group setting, but individuals will be allowed to talk with the study PIs privately if they have any questions or concerns about the consent form. For the agency leader and clinician group interviews, if individuals are interviewed via phone or video conference, they will be sent the consent form ahead of time, and provided the opportunity to ask questions before or at the interview. For the triad interview participants, we will obtain verbal consent at the start of the interview. We are requesting a waiver of written consent for these individuals, given the low risk nature of this data collection and logistic difficulties of obtaining written consent remotely.

Clinicians for the pre-pilot will be contacted by the study PIs, who will do consent with them individually by phone or video chat. For the full trial, consent forms will be sent out by e-mail to all clinicians prior to the first training in Mirah and they will be asked to contact the study if they have any questions. If new clinicians join the agency during the study, they will be contacted by e-mail and consented at that point. A new consent will also be administered electronically together with the follow-up clinician survey. We are also requesting a waiver of signed consent for the clinicians taking part in the Aim 1 pre-pilot and the full trial because they may need to be consented remotely due to COVID-19 and because many activities involve electronic surveys. We will obtain consent via REDCAP.

Clients and Caregivers from the General Patient Population. We are requesting a waiver of consent for the individuals receiving MBC as part of the agency-wide implementation of MBC. Because the agency is using MBC agency-wide as part of their routine services, is interested in randomization to two different forms of MBC as a program evaluation question, and is only providing limited identifier datasets to the researchers, the study presents minimal risk to these participants. Obtaining consent would increase the study risk because the study would receive identifying information from participants.

Clients and Caregivers in the Research Subsample. At least 420 clients and caregivers will complete additional research measures via the Mirah system during the Aim 1c pre-pilot and the Aim 2 trial. Consent procedures will differ slightly for the two phases of the study. For the pre-pilot, caregivers will view a consent form and youth an assent form the first time they complete these measures in the Mirah system. If they have questions before participating, they will have the option to provide a phone number and ask for all call from study staff before deciding. For the aim 2 Research Subsample, which involves a much larger sample of youth being recruited when they start treatment, youth and caregivers will view recruitment information when they complete their clinic intake questionnaires via Mirah. If they click that they are interested in the study, they will proceed to a screen with the consent/assent document. After reading the document, they will indicate yes, no, or "I have questions." If they have questions, they will next proceed to a Frequently Asked Questions (Research Subsample Frequently Asked Questions Page, uploaded in consent materials) page to see if their question is there. If not, they will be provided with the project phone number to call to ask questions. If they indicate at the intake that they have questions and do not consent, the study recruitment and consent/assent information will be presented one more time prior to their completion of the Mirah measures for their first session. If they do not agree to be in the study at that point, they will no longer be eligible to be part of the research subsample. Because youth and caregivers receive different links to complete their Mirah questionnaires, they will be asked to assent and consent separately, and it is possible that youth may consent prior to their caregivers consenting. However, neither youth nor caregivers will complete and research measures unless both have consented/assented. We are requesting a waiver of signed consent for both the pre-pilot and research subsample subsample participants. For the pre-pilot obtaining written consent would increase the study risk by providing identifying information to the study team. For the research subsample, the research

team will obtain identifying information from participants in order to give them gift cards, but the study is online, so it is not feasible to get signed consent and the study is minimal risk.

Clients and Caregivers Taking Part in the Qualitative Study Activities. Clients and caregivers taking part in the triad interviews will provide verbal consent and assent. Consent and assent will be obtained privately by study staff at the time of the interviews. We are requesting a waiver of written consent because interviews are taking place remotely.

31) Process to Document Consent in Writing

As detailed under #30, we are requesting a waiver of written consent for some participants and a waiver of consent for others.

32) Authorization for Use and Disclosure of Protected Health Information (HIPAA)

Type of Request:

☐ Waiver of Authorization for access to medical record for subject identification/recruitment.

X Waiver of Authorization for access to medical record to obtain data for the research.

Confirm that you will destroy or de-identify the information you collect at the earliest opportunity.

X I confirm

Confirm that the information you collect will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible. ***X I confirm***

33) Drugs or Devices

N/A

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