Study Protocol and Statistical Analysis Plan

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Study Official Title: Randomized Trial of a Leadership and Organizational Change Strategy to Improve the Implementation and Sustainment of Digital Measurement-based Care in Youth Mental Health Services

Brief Title: Working to Implement and Sustain Digital Outcome Measures (WISDOM)

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Social and Behavioral Sciences Human Research Protocol

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PROTOCOL TITLE:

Randomized trial of a leadership and organizational change strategy to improve the implementation and sustainment of digital measurement-based care in youth mental health services

SHORT TITLE:

Working to Implement and Sustain Digital Outcome Measures (WISDOM)

BOISE STATE UNIVERSITY IRB NUMBER:

041-SB19-081

ABSTRACT:

This study will test the effects of an intervention called Leadership and Organizational Change for Implementation (LOCI), relative to implementation as usual (IAU), on clinician fidelity to, and youth service outcomes of, a well-established digital measurement-based care intervention in outpatient community mental health clinics. The study involves a randomized controlled trial of LOCI in 21 publicly-funded mental health clinics, incorporating 120 clinicians who deliver outpatient psychotherapy to youth and, over two phases, a total of 720 caregivers of youth outpatients who receive services at the clinics.

OVERALL OBJECTIVES:

This study will test the LOCI implementation strategy in two phases to determine whether it improves fidelity to a digital measurement-based care intervention called the Outcomes Questionnaire-Analyst (OQ-A) as well as service outcomes of youth (i.e., symptoms and functioning during the first 6 months of treatment as reported by caregivers). All clinics and clinicians will receive training in the OQ-A system as well as implementation support (technical assistance) from the OQ-A developer (this represents the implementation as usual condition). In addition, half the clinics will be randomly assigned to LOCI to support implementation and sustainment of the OQ-A system.

Leaders in organizations assigned to the LOCI condition will participate in the LOCI intervention for 12 months. LOCI provides consultation and training to organizational leaders in how to support the implementation of evidence-based practices such as the OQ-A system (see intervention details below). To test the effects of LOCI, we will examine outcomes of (a) fidelity to the OQ-A system (measured at the youth level), and (b) youth service outcomes (as reported by caregivers) during two phases following initial training in the OQ-A system: Phase 1 - initial implementation (months 1-12 post- OQ-A training), and Phase 2 - sustainment (months 13-24 post- OQ-A training). Clinician fidelity to the OQ-A system will be measured via (a) electronic meta-data from the OQ-A system, which indicates whether or not clinicians viewed the feedback reports, and (b) via caregiver reports. Youth service outcomes will be measured via caregiver reports of the youth's symptoms and functioning for six months following the youth's initiation of treatment.

The project addresses the following specific aims and associated hypotheses:

Aim 1: Test the effects of LOCI on the implementation of a digital measurement-based care intervention called the OQ-A (**Phase 1**).

Hypotheses: Relative to implementation as usual, (1a) clinicians in LOCI organizations will exhibit higher fidelity to OQ-A, and (1b) youths in LOCI organizations will experience superior service outcomes (i.e. improvements in symptoms and functioning), for 1-12 months following initial OQ-A training.

Aim 2: Test the effects of LOCI on the sustainment of the digital OQ-A intervention (**Phase 2**).

Hypotheses: Relative to implementation as usual, (2a) clinicians in LOCI organizations will exhibit higher fidelity to OQ-A 13-24 months following initial OQ-A training, and (2b) youths in LOCI organizations will experience superior service outcomes (i.e., improvements in symptoms/ functioning) 13-24 months following initial OQ-A training.

Aim 3: Test the mechanisms that link LOCI to OQ-A fidelity.

Hypotheses: (3a) Relative to implementation as usual, LOCI will improve leaders' transformational, transactional, and implementation leadership, organizational implementation climate, and clinicians' intentions to use the OQ-A system; (3b) Improvements in leadership, climate, and intentions will mediate LOCI's effects on OQ-A fidelity.

Primary outcomes variable(s):

The primary outcomes will be fidelity to the OQ-A system, measured via meta-data from the OQ system, and youth clinical outcomes, measured as symptoms and functioning, during the initial six months of services for each youth.

Secondary outcome variable(s):

The secondary outcomes will be LOCI's effects on first-level leadership behaviors, organizational implementation climate, and clinicians' intentions to use the OQ-A system.

STUDY BACKGROUND

Psychiatric disorders are the leading cause of mortality and disability among youth in high income countries, accounting for 21% of total disease burden, and afflicting 1 in 10 youths in the US with severe impairment.1-3 In the US, this extreme disease burden is matched by medical care expenditures, which are higher for youth psychiatric disorders than any other childhood illness ($16.8 billion in 2011),4 and by investments in clinical research, which have developed over 1,200 effective interventions, or evidence-based practices (EBPs), shown to improve youth well-being in randomized trials.5, 6 However, despite these significant investments, less than half of youths treated in community settings experience symptom improvement,7, 8 a situation largely attributed to the low rates at which community providers adopt EBPs and, even when adopted, the low fidelity with which EBPs are implemented and sustained.9-12

Policymakers and service systems have sought to address this implementation deficit through legislative mandates and widespread EBP training programs for clinicians; however, these efforts have failed to meaningfully change practice patterns or improve patient outcomes.13-17 Recent reviews indicate that many deficits in EBP implementation and sustainment can be traced to a lack of organization-level 'social infrastructure,' that is, social contexts and leadership that do not support and motivate clinicians to use EBP. Without this organizational social infrastructure, EBP training and technical efforts fail.12,

18-20 These observations are consistent with decades of research on organizational climate theory21-24 and with theories of behavior change,25-27 which we have integrated to generate our primary hypothesis: achieving effective implementation and sustainment of EBPs in community settings requires mechanisms of a strong organizational implementation climate and high clinician motivation generated through effective clinic leadership. With NIH support, we have pilot tested a highly transportable implementation strategy called the Leadership and Organizational Change for Implementation (LOCI) intervention that targets these mechanisms through (1) short-term, intensive consultation with senior leaders (i.e., executives/ administrators) and (2) training and coaching of first-level leaders (i.e., clinical supervisors). Preliminary studies indicate LOCI is feasible, acceptable, and improves implementation leadership and implementation climate.28, 29 We propose a randomized controlled trial of LOCI in 20 children's mental health clinics, incorporating 120 clinicians and a total of 720 youth outpatients during two phases of initial implementation (months 1-12) and sustainment (months 13-24), to test LOCI's effects relative to implementation as usual (IAU) on clinician fidelity and youth clinical outcomes of a well-established digital measurement-based care (MBC) intervention.30, 31

Digital MBC systems, which integrate with electronic health records to collect treatment outcome data from patients and provide clinicians with real-time feedback and recommendations based on 'big data' actuarial algorithms, are a high-impact digital health technology and EBP32 shown in 29 RCTs to generate improvements in clinical outcomes equivalent with the best psychotherapy protocols (i.e., d=.3-.5) across patient ages, diagnoses, and treatment modalities.32, 33 Despite the promise of this approach, digital MBC systems are rarely used in community settings for youth,34, 35 and when they are, fidelity and sustainment are often poor, primarily due to deficits in organizational leadership and social context.36-40 This trial tests whether the LOCI strategy can improve the implementation and sustainment of digital MBC for youth.

STUDY POPULATION

Target Population:

We will recruit and collect data from four groups of people for this project: 1) executives and upper-level leaders (i.e., CEOs, Executive Directors, program administrators) of outpatient mental health clinics that serve youth, 2) clinic first-level leaders (i.e. clinical supervisors) in these clinics, 3) clinicians serving children with emotional and behavioral disorders in the clinics, and 4) parents/ caregivers of children with emotional and behavioral disorders who receive mental health services from participating clinics.

Accrual:

Based on our a priori power analyses, we anticipate the study will require the following number of participants in each group to generate adequate power to test our hypotheses:

Clinics - N=20
Executive leaders - N=20
First-level clinic leaders - N=40
Clinicians - N=120
Parents/ caregivers of youth – Total N=720 (recruited in two phases of N=360 per phase)

These figures will serve as recruitment targets. However, we also note that we plan to open enrollment in the study to all clinicians at participating clinics and to all leaders in LOCI clinics as a way of improving the ecological validity of our results. Thus, our final sample size numbers may exceed those reported above.

Eligibility Criteria:

Inclusion criteria for all groups of participants are intentionally broad to ensure robust and valid results.

Inclusion Criteria for Clinics

(1) Provide outpatient psychotherapy services to children who have emotional and/ or behavioral disorders and their families

(2) Has at least 3 FTE clinicians on staff

(3) Not currently implementing a digital measurement-based care system clinic wide

Inclusion Criteria for Executives and Upper Leaders

(1) Identified as CEO, Executive Director, or high-level administrator at an enrolled clinic

Inclusion Criteria for first-level leaders (i.e., direct supervisors of front-line clinical providers)

(1) Identified as a clinical supervisor or clinical work-group supervisor/ leader at an enrolled clinic

Inclusion Criteria for Clinicians

(1) Employed at a participating clinic

(2) Provides services to youth clients (age 18 or under)

Inclusion Criteria for Parents/ Caregivers of Youth

(1) Biological parent or custodial parent/ guardian of a youth who:

(a) is ages 4- to 17-years-old,

(b) has been diagnosed with an emotional or behavioral disorder by clinic staff,

(c) has been deemed appropriate for treatment at the clinic by the clinic's staff and has been admitted into services at the clinic.

Subject Recruitment and Screening:

This project involves multiple levels of recruitment which will be implemented by members of the research team including the PI, Co-Is, a Postdoctoral Researcher/Project Coordinator, a full-time Research Associate, and trained graduate student research assistants. All members of the research team will complete training and certification (CITI) in Human Subjects research prior to recruiting participants and will be trained in relevant recruitment protocols by the PI, Co-I Esp, or the Postdoctoral Researcher. We note that all recruitment will occur in mental health outpatient clinics located in Idaho, Oregon, and Nevada.

Recuitment will proceed in stages beginning with the recruitment of executive directors and CEOs of behavioral health clinics that deliver outpatient mental health services to youth. Once these leaders have agreed that their clinic will participate in the study, we will recruit first-level leaders (i.e., supervisors of clinicians), and clinicians who work in participating clinics. We will obtain a Memorandum of Understanding for all clinics that particpiate. After recruiting clinic staff, parents/ caregivers of youth who are served by the clinics will be notified about the study via a cover letter and invited to participate if they wish. Parents/ Caregivers who have questions about the study will be referred to a member of the research team. The individuals who will compete these various stages of recruitment will be as follows:

(1) recruitment of clinic executives - PI (primary), Co-Is (primary), Postdoctoral Researcher/Project Coordinator,

(2) recruitment of first-level clinic leaders and clinicians – PI, Co-I Esp (primary), Postdoc Researcher/Project Coordinatory (primary), Research Associate (primary), graduate research assistant
(3) recruitment of caregivers of youth – Postdoc Researcher/Project Coordinator (primary), Research Associate (primary), graduate research assistant, PI, Co-I Esp

Details of the recruitment process for each group as follows:

(1) Clinic Executives will be recruited by the PI and Co-Is Esp, Aarons, and Ehrhart via two strategies. One strategy involves presenting an overview of the study at standing system meetings (e.g., regional behavioral health provider meetings; directors meetings sponsored by Medicaid) and other large-scale events and distributing follow up email through system contact lists and targeted emails to program/clinic leaders to arrange site visits and consultations. The second recruitment strategy involves directly contacting executives of behavioral health clinics in Idaho, Oregon, and Nevada via email, phone, and/or postal mail to request a in-person or vitual meeting with clinic leaders to present the study and assess their interest in participating. We will directly contact the CEOs/ Executive Directors of clinics and the PI, Co-Is Esp, Aarons, and Ehrhart, and/ or the Postdoctoral Researcher/Project Coordinator will hold informational meetings with clinic executives to discuss the study procedures in detail and request their clinic's participation in the project. Executive leaders who agree for their clinic to participate in the study will sign a Memorandum of Understanding outlining roles and responsibilities of all parties.

(2) After obtaining permission from clinic executives, we will work to recruit first-level leaders and clinicians who work in each clinic. Recruitment of first-level leaders will be completed by the PI, Co-Is Esp, Aarons, and Ehrhart, as well as the Postdoc Researcher and/ or Research Associate. With the executive's support, we will introduce the study to first-level leaders and clinicians (ideally during standing staff meetings) and ask them to participate. A member of the research team will make a presentation during regularly scheduled staff or team meetings at the participating clinics. Details of the project and requirements of participation will be discussed during this presentation. Following the presentation, the research team will ask for permission from the Executive and First-level leaders to receive a list of eligible clinicians so we can contact them via an automated Qualtrics email that includes a link to the survey. The clinicians will also be informed that they will receive an email from our team with a link to surveys. Once the research team receives the list of eligible clinicians from the agency executive or first-level leader, emails with links to the consent form and surveys will be sent via BSU Qualtrics. The email includes the research team’s contact information, details about the study, and procedures. Clinicians will have one month to complete the survey if interested.

There will be no consequences for clinicians who choose not to participate in the study. Clinicians will be assured that choosing to participate or not participate in the research will in no way affect their employment. All clinicians will be free to withdraw their participation at any time.

(3) Caregivers will be recruited for the study via a multistep process.

First, during the intake appointment, a clinician or clinic staff member will provide caregivers with a cover letter either in person or via electronic health record system. The cover letter will be available in English and Spanish (translated professionally).The cover letter will state that the clinic is participating in a research study and that the parent is invited to participate if they wish; however, it

will be stressed that the parent's decision regarding participation in the study will have no effect on their ability to receive treatment at the clinic. The letter will provide details regarding the assessments caregivers will be asked to complete as part of the study. It will ask parents to indicate if they are interested in being contacted by a member of the research team for more information about study and to potentially participate. Parents who wish to participate in the study will check "YES" on the form and provide their contact information (name, email, and phone number); parents who do not wish to participate will check "DECLINE" and/ or leave the form incomplete. Parents will return their intake paperwork to a clinic staff member who will remove the cover letter and will fax or email the letters to a secure fax line or email address provided by the research team. They will then place it in an envelope in a secure area behind a locked door with restricted access (e.g., where other medical files are stored). Participating clinics are used to storing sensitive medical files and other data and restricting access to these files. After the letter has been received by the research team, clinics staff will be asked to shred/discard letters. If parents have questions about the study, they will be directed to the PI or Postdoc/Project Coordinator by providing them with the research team's contact information.

Approximately 2-3 times per week, a member of the research team will contact the clinic to see if there are any forms to be faxed or mailed. All forms will be saved in a secure, electronic database housed on password protected Boise State University computers. This database will be used to track contacts with caregivers for the following steps of the recruitment process.

Caregivers who signed the form indicating they are interested in learning more and potentially participate in the study, will receive a phone to screen for eligibility and conduct an informed consent interview. Please refer to the “Procedures” section of the protocol for details on what happens after a participant is recruited and screened.

Early Withdrawal of Subjects:

At any time during participation, subjects can decide to withdraw from the study. They can do this by not completing the surveys or by requesting that the assessments be terminated.

Vulnerable Populations:

We will not be recruiting minors.

Populations vulnerable to undue influence or coercion:

Subjects are informed that participation is completely voluntary. There is no penalty for withdrawing or terminating their participation at any time during the study. There will be no consequences for clinicians who choose not to participate in the study. Clinicians will be assured that choosing to participate or not participate in the research will in no way affect their employment. In addition, caregivers will also be assured that choosing to participating or not participating in the research will no way affect services at their clinic. All subjects will be free to withdraw their participation at any time.

Design:

This study is a cluster randomized controlled trial. We will randomize 22 clinics (target n = 20) to an implementation as usual (IAU) control group or to an experimental group that includes IAU + LOCI. Clinics that are randomly assigned to the LOCI condition will begin LOCI activities one month before the initial OQ-A training. One month after initiation of LOCI, all clinicians in both LOCI and IAU clinics will participate in an initial, in-person, OQ-A training workshop delivered by the system developer. For six months following the OQ-A training, all clinics will have access to implementation support provided by

the OQ-A developer. LOCI activities will continue for a total of 12 months. Recruitment of caregivers into the study for Phase 1 will begin immediately after the OQ-A training and will conclude 12 months after the training. Measurement of clinician fidelity and service outcomes for these youth will continue for six months after completion of LOCI because caregivers recruited in month 12 need to be followed for six months after initiation of treatment. Recruitment of caregivers into the study for Phase 2 will begin in month 13 after the initial OQ-A training and will continue for 12 months with caregivers recruited in month 24 followed for an additional 6 months to ensure adequate follow-up time. Caregivers will be asked to complete measures that assess their child/youth's symptoms and functioning as well as the clinicians' use of the OQ-A system during a total of 7 telephone calls during a 6 month period (baseline, then monthly thereafter for 6 months).

Study Duration:

The study involves a randomized controlled trial of LOCI in 21 children's mental health clinics, incorporating 120 clinicians and a total of 720 youth outpatients during two phases of initial implementation (months 1-12 post- OQ-A training) and sustainment (months 13-24 post- OQ-A training). All clinics will receive training in the OQ-A system and implementation support from the OQ-A developer for 6 months (this represents implementation as usual). In addition, half the clinics will be randomly assigned to LOCI to support implementation and sustainment of the OQ-A system. Leaders in organizations assigned to the LOCI condition will participate in the LOCI intervention for 12 months. The other half of agencies will be randomly assigned to the web-based leadership condition. Caregivers of youth who receive services from clinicians in participating clinics will be surveyed for six months to assess service outcomes (measured as changes in the target youth's symptoms and functioning).

STUDY METHODS

Study Instruments:

- Primary outcomes for Aim 1 are clinician fidelity to MBC and improvement in youth symptoms and functioning. Clinician fidelity to MBC will be measured using triangulated data from (a) gold-standard observational electronic meta-data collected automatically by the OQ-A system, and (b) parent/ caregiver reports. For each youth at each session, the OQ-A records whether an outcome measure was administered, whether the clinician viewed the feedback report, when the clinician viewed the feedback in relation to the session, and whether supplemental measures regarding treatment process (e.g., therapeutic alliance, self-efficacy) were administered to aid in diagnosing problems. This data will be downloaded from the OQ-A system for each participating youth each month and, following validated procedures outlined by Bickman et al.,36, 41 used to generate an MBC Fidelity Index that characterizes clinicians' fidelity to MBC fidelity for each youth's entire course of treatment. In addition, parents will report on MBC fidelity using the MBC Fidelity Scale, a 3-item measure validated in previous research.90 The 3 items produce a continuous score that captures (a) the extent to which the clinician invited the caregiver and/ or youth to complete a standardized outcome measure at each session, (b) the extent to which the clinician discussed scores on the measure with the caregiver at each session, and (c) the extent to which the clinician used outcome measure data to make recommendations about the child's treatment or changes to the treatment plan. Parents will report on clinicians' MBC fidelity during monthly phone assessments described above and these scores will be averaged into a single score characterizing the clinician's total fidelity to MBC for the youth's entire course of treatment.
- Youth clinical outcomes will be assessed using two caregiver- and youth-reported measures. The primary outcome is the 48-item Shortform Assessment for Children (SAC) Total Problems Score. The SAC is a well-established, parent-reported, measure of youth internalizing and externalizing

symptoms used in several previous randomized trials.91-94 The SAC has demonstrated excellent score reliability and validity in psychometric evaluations as well as sensitivity to change in clinical trials of youth mental health services. The measure provides a total problem score; higher scores indicate more severe symptoms. The Columbia Impairment Scale (CIS) is a 13-item measure of the youth's psychosocial functioning and general impairment in the areas of home, school, and community settings. The CIS has excellent score reliability, validity, and sensitivity to change as well as a clinical cut-score for assessing impairment; it is incorporated into several national epidemiological studies of youth psychopathology.98-101 Caregivers will be compensated for completing the SAC, SDQ, and CIS at baseline and monthly thereafter (for a total of 6 months) via telephone calls.

- We will assess targeted mechanisms of LOCI using the following measures: The Multifactor Leadership Questionnaire (MLQ)113 is one of the most widely used measures of transformational and transactional leadership in organizations, including mental health agencies, and has excellent psychometric properties (alpha = .76 to .90).62-64 Clinicians rate the extent to which their leader engages in specific leadership behaviors on a 5-point scale (0=Not at all, 4=Frequently, if not always). Transformational leadership is assessed by four subscales: Idealized Influence (8 items, α=.87), Inspirational Motivation (4 items, α=.91), Intellectual Stimulation (4 items, α=.90), and Individual Consideration (4 items, α=.90). The Implementation Leadership Scale (ILS)70 is a very brief 12-item measure developed with NIH support by our team to assess leaders' behaviors that support EBP implementation in four areas: Proactive Leadership (α=.95), Knowledgeable Leadership (α=.96), Supportive Leadership (α=.95), and Perseverant Leadership (α=.96). The ILS yields subscale scores and a total score (α=.98) which have demonstrated excellent reliability and convergent and discriminant validity. The Implementation Climate Scale (ICS) was developed by our team with NIH support and has demonstrated excellent internal consistency, α = .91 (18 items, 3 items on each subscale) and strong validity evidence.73 The ICS assesses clinicians' shared perceptions of the policies, procedures, practices, and behaviors that are rewarded, supported, and expected to facilitate effective EBP implementation. Items are scored on a 5-point Likert type scale (0="Not at all" to 4="To a very great extent"). The six subscales are: Focus on EBP (α=.91), Educational Support for EBP (α=.84), Recognition for EBP (α=.88), Rewards for EBP (α=.81), Selection for EBP (α=.89), and Selection for Openness (α=.91). Social psychologists have developed measures of intention with strong psychometric properties that are meant to be adapted to any behavior of interest; 25, 114 we have adapted these resulting in a 3-item scale assessing clinician intentions to use MBC. In addition, we will modify the psychometrically validated Evidence-Based Treatment Intentions scale to assess clinicians' specific intentions to use MBC in their practice with clients.

Administration of Surveys and/or Process:

The sources of data for this study will include:

1) Web-based surveys (leaders, clinicians);
2) Digital meta-data from the OQ-A system regarding the extent to which clinicians used the system for each youth;
3) Web-based or telephone surveys completed by parents/caregivers regarding their youth's service outcomes and experiences at baseline and at follow-ups if they choose this mode of administration.

Web-based survey data will be collected on the secure BSU Qualtrics site and managed by the professional data manager in BSU's Office of Information Technology. Clinicians, leaders, and caregivers will complete the surveys at a time and location of their choosing.

Telephonic survey data will be collected by trained research assistants supervised by the PI and Co-I and entered directly into a secure database housed on professionally-managed and password protected BSU computers. Telephone interviews will take place at times and locations that are convenient for caregivers.

Members of the research team will conduct telephone, in-person or virtual interviews in an office with the door closed. All data maintained by the research project will be coded with a unique identifying number for which the key will be separately stored and access limited to investigators and shared only to the extent necessary to collect data or for required reporting purposes.

Digital meta-data will be collected automatically by the secure OQ-A software system and securely uploaded to password protected BSU servers or computers by the PI or other member of the research team. Digital meta-data will also be coded with a unique identifying number to protect participant privacy.

Data Management:

Survey and questionnaire data will be collected from leaders, clinicians, and caregivers of youth via either (a) secure web-based surveys, or (b) research administered telephone calls. Web-based survey data will be collected on the secure BSU Qualtrics site and managed by the professional data manager in BSU's Office of Information Technology. Telephonic data will be collected by trained research assistants supervised by the PI and Postdoc/Project Coordinator and entered directly into a secure database housed on professionally-managed secure BSU servers. All data maintained by the research project will be coded with a unique identifying number for which the key will be separately stored and access limited to investigators and shared only to the extent necessary to collect data or for required reporting purposes. Digital meta-data will be collected by the secure OQ-A software system and securely uploaded to Boise State servers by the PI or other member of the research team.

STUDY PROCEDURES

Procedures:

Please refer to the "Subject Recruitment and Screening" section of the protocol for details on how we will recruit and screen potential participants.

Details of the procedure process following enrollment for each group as follows:

(1) Following enrollment in the study and randomization at the clinic level, all participating clinicians and first-level leaders at all participating clinics will receive initial training in the OQ-A system as well as 6 months of follow-up implementation support from the OQ-A developer. This will include an initial in-person training session plus follow-up technical support and consultation. We will ask clinicians to attend these trainings and to use the OQ-A system with their clients; however, whether or not they use the system is up to them and, in fact, the extent to which they use the system (i.e., fidelity) is one of the study outcomes. Details regarding the OQ-A system, training, and implementation support is provided below.

(2) Executives, first-level leaders, and clinicians in all conditions will be asked to complete web-based surveys to assess LOCI's effects on organizational, leadership, and clinician outcomes. These surveys will occur a total of 5 times over 18 months (baseline, 4-month, 8-month, 12-month, 18-month) and are estimated to take 30 to 40 minutes each. The surveys will ask about

clinicians' perceptions of their work experiences and attitudes toward and use of the OQ-A system and other evidence-based practices. Participants will be compensated for their time (see Subject Compensation).

(3) Recruitment of caregivers into the study for Phase 1 will begin immediately after the OQ-A training and will conclude 12 months after the training. Recruitment of caregivers into the study for Phase 2 will begin in month 13 after the initial OQ-A training and will continue for 12 months with caregivers recruited in month 24 followed for an additional 6 months to ensure adequate follow-up time. Caregivers will be asked to complete measures that assess their child/youth's symptoms and functioning as well as the clinicians' use of the OQ-A system on a total of 7 surveys during a 6 month period (baseline, then monthly thereafter for 6 months). These surveys are estimated to take 10-15 minutes each and caregivers will be compensated for their time (see Subject Compensation).

All participants receive email and phone call reminders to complete their follow up survey in order to boost study engagement and assist with technical support.

Details of the OQ-A intervention:

(1) The Outcomes Questionnaire – Analyst for Youth (OQ-A) is a secure, HIPAA-compliant, cloud-based digital measurement-based care software application that provides regular (e.g., weekly) feedback to clinicians about patients' progress in treatment. The OQ system has been tested in 12 clinical trials across 4 countries (US, Netherlands, Norway, Germany) incorporating 7,882 patients and has been shown to significantly improve psychotherapy outcomes with a mean effect size relative to treatment as usual of d = .48.

(2) Each week prior to the session, caregivers (and youths, if applicable) complete brief, standardized, psychometrically validated outcome measures and treatment process measures (e.g., therapeutic alliance) on an electronic device (e.g., tablet or mobile phone). These digital measures are automatically scored by the software application using actuarial 'big data' algorithms and a feedback report is generated and delivered to the clinician within seconds. Feedback reports describe the youth's progress in treatment benchmarked against data from a large population. The software issues empirically-based alerts indicating whether the youth is on track toward positive outcomes or at risk for treatment failure or dropout. Data from the treatment process measures assesses empirically-validated predictors of treatment outcome including therapeutic alliance, motivation, self-efficacy, and social support. The OQ-A is designed to detect treatment progress regardless of treatment modality, diagnosis, or discipline of the clinician. It is important to note that none of the OQ-A measures completed by caregivers or youth will be used in the research; these measures will only be used to provide feedback to clinicians via the OQ-A system.

(3) All clinicians in LOCI and implementation as usual will receive initial training from the OQ-A developer as well as six months of implementation support covering both clinical and technical aspects of OQ-A implementation. Following the six months of implementation support, all clinics will continue to have access to the online initial training and booster training and technical support from the OQ-A customer care team, which assists with technical troubleshooting and minor clinical issues for all licensees.

Details of the LOCI intervention:

First-level leaders and executive leaders in the LOCI condition will participate in LOCI for 12 months. There are two key features of LOCI: (1) training and coaching for first-level leaders, and (2) executive-led organizational strategies to support the LOCI leaders and their efforts to build an implementation climate in their clinics. LOCI has six components which are described in the LOCI manual along with slides and handouts. The 6 key components of LOCI are:

(1) Assessment: LOCI is a data-driven process with leader development plans and goals based on 360º assessment with the leader's self-ratings, ratings from his/her subordinates (i.e., clinicians), and ratings from the leader's manager/supervisor. The data are synthesized into a detailed feedback report and then used in the development of a personal development plan.

(2) Initial Training: The LOCI training begins with a two-day leadership didactic and interactive session. This component includes introduction to the full-range leadership model, identifying transformational and transactional leadership behaviors, implementation leadership, identifying leader behaviors that can be used to build a climate for OQ-A implementation, and group activities (e.g., breakout groups, meals) to facilitate social interaction and learning consolidation among trainees. The training also addresses implementation climate and the nature of OQ-A so that leaders can articulate a rationale for how and why use of the OQ-A system can improve client outcomes.

Leadership Development Planning: During the initial training, trainers and coaches work individually with each trainee in reviewing their personalized 360º assessment data, identifying strengths and areas for development, and setting a timeline for issues to be addressed immediately and those to be addressed later in coaching. Leader trainees emerge with data-based development plans including broad goals and specific action items that will guide coaching sessions throughout the remainder of the program.

(3) Coaching: Brief weekly coaching calls are provided for each LOCI participant. Coaching calls range from 15-20 minutes in duration and keep participants on track with their goals and development plans. The coach will be directly supervised by the developers of LOCI (Co-Is Aarons, Ehrhart). The weekly coaching calls focus on tracking the trainees' progress in their development plans, updating the plans based on emergent issues or needs, problem solving, providing additional leadership support, and identifying organizational strategy needs. Plan-Do-Study-Act (PDSA) cycles are utilized to assess incremental progress toward measurable overall and time-limited goals. Group conference calls with leader trainees are held monthly to facilitate problem solving and networking among LOCI participants and trainees as they discuss their progress and solutions to barriers.

(4) Organizational Strategy Development: LOCI facilitators (led by Co-I Esp) meet concurrently with executive managers, middle managers, and LOCI trainees (within agency) during monthly meetings across the 12 month period to tailor organizational strategies to support the trainee in creating an implementation climate that supports use of the OQ-A system. This involves ongoing plan-do-study-act cycles using web-survey data to evaluate how strategies are being implemented and utilized and if adjustments are needed. As a guiding heuristic, we utilize "climate embedding mechanisms" (i.e., what leaders to do communicate that use of the OQ-A is expected, supported, and rewarded in the organization) that are tailored for OQ-A

implementation for each agency and workgroup. Examples of potential strategies include mid-level managers attending workgroup meetings in support of first-level leaders, providing recognition for providers who exemplify excellence in using the OQ-A system, providing additional training for the OQ-A or other clinical approaches identified as necessary to get clients back on track, altering OQ-A feedback processes, or executives communications to clinicians emphasizing the importance of OQ-A in service provision.

(5) Follow-up Sessions: Prior to each booster session, additional 360º assessments are completed. LOCI participants attend booster sessions at 4 and 8 months after the initial training. Leadership principles, intervention goals, and organizational strategies to support leadership are reinforced through group discussion and problem-solving. The booster sessions are considered longer term plan-do-study-act cycles in which 360º assessments are utilized to assess progress and guide modification of the leaders' development plans.

(6) Graduation: Graduation is a ritual (i.e., secondary embedding mechanism) deliberately included in LOCI to mark completion of the program. Accomplishments of the participants are celebrated, challenges are processed, and future plans are shared.

Analysis Plan:

For all aims, basic data screening procedures will be conducted to screen for errors and explore normality, linearity, form, and outliers. Prior to conducting main analyses, we will examine the psychometric properties of total scales and subscales of all measures (e.g., coefficient alpha, confirmatory factor analyses) to assess the latent constructs captured by the measures and we will explore the bivariate associations among all variables. Data will be transformed as appropriate. We will confirm randomization validity (e.g., chi-square tests, t-tests, Kruskal-Wallis). Minor differences will be statistically controlled during model-building. We will explore for selection bias from attrition. Data missing at random will be modeled using full maximum likelihood estimation.

Based on our theoretical model, we have selected generalized linear mixed models (GLMMs) as our general analytic framework. GLMMs are ideal for this study because they (1) accommodate the complex nested structure of the data (e.g., youth nested in clinicians nested in clinics), (2) permit testing of cross-level Hypotheses (e.g., effects of organization-level LOCI on clinician- and youth-level outcomes), and (3) permit the specification of different functional forms to address different types of outcomes including mean differences (e.g., in clinician fidelity) as well as differences in growth rates over time (i.e., youth clinical outcomes). Models will include random effects addressing the nesting of repeated observations within youth and youth within clinics, as appropriate. All analyses will use an intent-to-treat approach. Hypothesis 1a will be tested using a generalized linear mixed effects model with a binomial response distribution and logit link function to address the events/trials nature of the MBC fidelity index. To facilitate interpretation, we calculated average predicted probabilities for each condition, representing the adjusted average fidelity index (or completion rate) in each group. Hypothesis 1b will be tested using a linear mixed effects growth model with a condition (LOCI vs. control) by time cross-level interaction. If a statistically significant ($P<.05$) interaction is observed, simple slopes analyses will be conducted to examine the rate of change in each condition. Models will be estimated using maximum likelihood, which accounts for missing data on the outcome under the missing at random assumption. Prior to testing Hypothesis 1b, we will use model comparison tests based on the Bayesian Information Criteria to determine the best-fitting functional form for growth and optimal random effects structure.

To address potential imbalance across clusters and to account for variables included in the constrained randomization, we will include covariates in all analyses. The familywise error rate for the two primary outcomes was controlled using the Benjamini-Hochberg[4] procedure.

Controlling for Familywise Error Rate. Across our two primary outcomes (i.e., MBC fidelity index and change in SAC total problem score), the Benjamini and Hochberg (1995)[98] False Discovery Rate procedure will be used to correct for multiple tests, which is preferable to the overly conservative Bonferroni correction.

Power Analysis:
Taking into account 25% attrition of youth and clinicians, our target enrollment is 360 youth nested within 20 behavioral health clinics (180 youth in LOCI organizations and 180 youth in IAU organizations) for Phase 1. To estimate the minimum detectable effect size give our sample, we assumed: (1) 360 youth nested within 20 clinics, (2) an alpha level of .05 and a power level of .80, and (3) a level-3 ICC ranging from .05 to .10 for youth symptoms/ functioning based on our prior studies. Given these assumptions, 360 youth nested within 20 clinics is a large enough sample size to find statistically significant intervention effects of d = .44 to .53 (Cohen's d), classically described as a medium effect.

RISK/BENEFIT ASSESSMENT

Risks:
There are no known serious health or psychological risks of participating in this study. The digital OQ-A measurement-based care system used in this study represents a quality improvement intervention designed to provide clinicians with feedback about their patients' progress in treatment based on patients' self-reported outcomes. The OQ-A has strong empirical support from multiple randomized trials. Patients complete an electronic survey on a tablet prior to their session, the OQ-A software automatically analyzes this data, and provides clinicians with feedback to inform treatment decisions. The LOCI implementation strategy tested in this study represents an effort to strengthen the delivery of evidence-based practices for children in publicly-funded mental health clinics, with the direct intervention targeted at organizational leaders through training and consultation. The study design does not require any changes to treatment or services for any youth or family. All families will receive the usual clinical assessments and clinical care provided by clinics.

Potential risks to participants revolve primarily around potential loss of confidentiality. For the mental health professional participants (leaders/ clinicians) this relates to confidentiality regarding their practice behaviors (i.e., fidelity). Participants will be reassured that their decision to participate (or not) in the study will have no impact on their role as providers in the service settings. In addition, participants will be informed that their clinic will not have access to research data on clinician fidelity or client outcomes thereby eliminating the potential use of this information to evaluate clinicians' performance.

For youth and caregivers who participate, there is potential risk of loss of confidentiality related to sensitive information provided by their caregivers in response to study outcome measures assessing child symptoms and functioning. All information obtained from participants will be held confidential unless there is a report of serious harm to a child or threat of harm to self or others. This limitation will be addressed specifically in the consent form.

Subject Confidentiality:

When connected only to a numeric identifier, the majority of the research data does not contain information that could identify a participant. Therefore, we will use protocols to separate personally identifying information from the research data by generating a numeric research identifier in all data sets. All digital meta-data, web-based survey data, and telephonic survey data will be labeled using ID numbers only and stored on secure, password protected computers and servers that are professionally protected and managed by BSU's Office of Information Technology. Personally identifying information (i.e., the key that links names to ID numbers) will be stored in a single database that is located on secure servers at Boise State University and separate from the data files. Access to this key will be restricted to authorized research personnel only and will include a password that is only known to the PI and appropriate research members.

How will confidentiality of data be maintained?

In addition, we will follow use the following procedures to ensure the confidentiality of electronic data including:

(1) all computer screens will have a five-minute time limit that will produce a locked screen if left unattended and will require BSU login and password authenticaion to re-access the computer,

(2) The study database will be located on the BSU computer network and will only be available to the project team. Boise State University's Office of Information Technology stores confidential information from a multitude of research projects, and thus, maintains stringent security measures,

(3) Research data collected will be coded with a participant's unique identifier, or number. Personally identifying data (i.e., names) will not appear on any research data,

(4) All individuals with access to data will sign confidentiality agreements to never disclose any individual information regarding any aspect of the study,

(5) All persons working on this research project will have undergone extensive orientation and training on issues regarding the maintenance and protection of confidentiality (sending confidential material to a community printer, using names while conducting phone interviews, etc.) as well as standard training in research ethics and the protection of human subjects (e.g., CITI).

Subject Compensation:

1. Executives, first-level leaders, and clinicians will be paid for their time to complete the 5 web-based surveys. These individuals will receive a $30 for the first (baseline) survey, $30 for the 4-month survey, $45 for the 8-month survey, $50 for the 12-month survey, and $55 for 18-month survey for this study; a total of $210 in gift cards (5 questionnaires = $210). The gift card will be delivered either electronically or via mail following completion of each survey.
2. Caregivers of youth will be paid for their time to complete phone or web-based surveys with researchers at baseline and once per month thereafter for up to 6 months. Caregivers will receive a $15 gift card upon completion of each survey via either electronic mail or standard mail delivery.

Data and Safety Monitoring

We will convene a 3 member DSMB that will represent experience and expertise in research on evidence-based practice implementation in clinical and other service settings for youth as well as methodological expertise related to the conduct of randomized trials with vulnerable populations.

The DSMB will convene annually, with ad hoc meetings to be called for by the Chair as needed. The R01 staff will be responsible for scheduling these meetings and for keeping minutes of their proceedings. These minutes will be sent to each member of the DSMB for approval before their distribution to the PI and Co-Is.

The PI will be responsible for maintaining communication with the DSMB. Members of the DSMB are not involved directly with the trial and do not have conflicts of interest with the study PI or Co-Is.

The DSMB will perform several duties. First, they will review and approve the research protocol and plans for data and safety monitoring prior to study commencement. Second, they will evaluate the progress of the trial. This will include assessment of participant recruitment and accrual, occurrence of adverse events, and study outcomes. This assessment will be performed at meetings every 12 months during the trial and more frequently, if decided by the DSMB. The PI will be responsible for responding to all recommendations of the DSMB and submitting DSMB reports to the Boise State University IRB and NIMH.

Risk / Benefit Assessment:

Clinic executives, first-level leaders, and clinicians will benefit from the study by receiving access to training and digital health technology that they can use to more effectively measure and monitor the progress of their clients in treatment. Clinical staff will receive continuing education credits for completion of training activities which will be provided free of charge. These resources will improve clinicians' and clinics' ability to effectively serve clients and are of value to clinicians because continuing education credits can be used to satisfy licensing requirements.

Caregivers of youth who participate in this study may benefit from receiving more effective services and from the opportunity to provide feedback to clinicians about their child's progress during treatment.

Leaders and clinics that participate in LOCI will benefit from receiving free leadership training and organizational consultation to improve the implementation of evidence-based practices in their organizations which may improve the overall leadership ability of participating leaders as well as the functioning of the clinic and the overall work environment.

INFORMED CONSENT PROCESS

Informed Consent:

Please refer to the “Subject Recruitment and Screening” section of the protocol for details on how we will recruit and screen potential participants.

This project involves four different groups of participants: (A) clinic executives, first-level clinic leaders, clinicians, and (B) parent/ caregivers of youth who are served by participating clinicians. Informed consent procedures will be as follows for these groups:

A. Clinic Executives, first-level leaders, and clinicians - After obtaining permission from clinic executives for their clinic to participate in the study (as described above), we will introduce the study to first-level leaders and clinicians (ideally during standing staff meetings) and ask them to participate by sending an email via BSU Qualtrics that includes a information about the study and a link to the consent form and survey at baseline, 4 months, 8 months, 12 months, and 18 months (see recruitment and screening):

1) Each time an executive, first-level leader, or clinician completes a web-based survey for the study, the survey will include an introductory page that reminds them of their rights as participants in the study and the voluntary nature of participation. Respondents will indicate they are willing to complete the assessments by clicking "AGREE" to continue to the assessments.

There will be no consequences for clinicians who choose not to participate in the study. Clinicians will be assured that choosing to participate or not participate in the research will in no way affect their employment. All clinicians will be free to withdraw their participation at any time.

B. Caregivers of youth served by participating clinics - Caregivers will be consented in a multistep and ongoing process by a member of the research team (i.e., Postdoc, Research Associate, PI, Co-I Esp, graduate research assistant):

(1) If a caregiver indicates they agree to be contacted by a member of the research team by selecting "YES" on the cover letter and sharing their contact information, a member of the research team will contact the caregiver via phone. During this call, the research team member will first review the study parameters with the caregiver (following a script) and obtain verbal consent that the caregiver wishes to participate in the study. The research team member will document this by signing a form indicating the caregiver provided verbal consent.

(2) At each subsequent contact with caregivers (total of 7 contacts over 6 months), caregivers will be reminded of their rights as research participants and will indicate they are willing to complete the assessments. This process will be completed via either (a) an electronic cover page on web-based surveys in which caregivers must indicate they consent to participate by clicking "AGREE" to continue to the assessments, or (b) a telephone conversation with the researcher in which the caregiver verbally indicates he or she is willing to complete the assessments.

Documented consent will be secured prior to the initiation of study participation. Parents/caregivers whose preferred language is Spanish will be contacted by a member of the research team who can review the study parameters and obtain verbal consent in Spanish. In addition, the web-based survey/assessment will be available in English and Spanish.

RESOURCE NECESSARY FOR HUMAN RESEARCH PROTECTION

The team includes academic investigators with experience in research on implementation science, leadership and organizational climate, measurement-based care, and youth mental health services. Dr. Nathaniel Williams (PI), Associate Professor in the School of Social Work at Boise State University, Research and Program Evaluation Coordinator in Boise State University's Institute for the Study of Behavioral Health and Addiction, and a licensed clinical social worker. Dr. Williams is an implementation scientist with substantive expertise in issues related to organizational climate and leadership. Dr. Susan Esp (Co-I), is an Associate Professor in the School of Social Work at Boise State University. Dr. Esp expertise lies in counseling and substance use disorder intervention, behavioral health, and public health. Dr. Greg Aarons (Co-I), is a Professor in the Department of Psychiatry at the University of California, San Diego (UCSD), a faculty member in the UCSD/SDSU Joint Doctoral Program in Clinical Psychology, Director of the Child and Adolescent Services Research Center (CASRC) and Co-Director of the Center for Organizational Research on Implementation and Leadership (CORIL). Dr. Aarons extensive work focuses on identifying and improving systems, organizational, and individual factors the impact

successful implementation and sustainment of evidence-based practices and quality of health care and public sector settings. Dr. Mark Ehrhart (Co-I), is a Professor in the Industrial/Organizational Psychology Program at the University of Central Florida. Dr. Ehrhart's work focuses on leadership and strategic climate, including climate for implementation, and developing measures of implementation climate. Dr. Lauren Brookman-Frazee (Co-I), is a Professor in the Department of Psychiatry at the University of California, San Diego (UCSD). Dr. Brookman-Frazee research focuses on improving the effectiveness of community services for children with mental health and development needed. All investigators and project staff supervised by investigators will have documented up-to-date training in human subjects research ethics, protections of human subjects, and good clinical practices, as required by law and as verified by the BSU IRB.

References

1. Hedeker D, Gibbons R. Longitudinal Data Analysis Johns Wiley & Sons. Inc, Hoboken, New Jersey. 2006;
2. Raudenbush SW, Bryk AS. Hierarchical linear models: Applications and data analysis methods. vol 1. sage; 2002.
3. StataCorp L. Stata statistical software: release 17 College Station. TX StataCorp LP. 2021.
4. Benjamini Y, Hochberg Y. Controlling the false discovery rate: a practical and powerful approach to multiple testing. Journal of the Royal statistical society: series B (Methodological). 1995;57(1):289-300. doi: 10.1111/j.2517-6161.1995.tb02031.x
5. Spybrook J, Bloom H, Congdon R, et al. Optimal design plus empirical evidence: Documentation for the "Optimal Design" software. William T Grant Foundation Retrieved on November. 2011;5:2012.
6. Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed. L. Erlbaum Associates; 1988. doi: https://doi.org/10.4324/9780203771587