Official Study Title: Increasing Accuracy and Efficiency of Fidelity Measurement in CBT

Brief Title: Project FACTS (Fidelity Accuracy: Comparing Three Strategies)

NCT02820623

May 11, 2020

Executive Summary

1. Description of theory, methodology, intent of study

Our objective is to compare the accuracy, costs, and cost-effectiveness of three fidelity measurement methods to assess fidelity to cognitive-behavioral therapy for youth. We will randomize up to 170 therapists, implementing cognitive-behavioral therapy to 3 conditions: self-report, chart stimulated recall, and behavioral rehearsal (N = about 56 for each group). To calculate our outcomes of interest, each condition will be compared to the gold-standard fidelity measurement method, direct observation.

OBJECTIVES

Objective 1: To identify the most accurate fidelity measurement method.
Objective 2: To estimate the economic costs and cost-effectiveness of the fidelity measurement methods.
Objective 3: To compare stakeholders' motivation to use each method, as well as identify their perceived barriers and facilitators to use of each method.

This study will have a significant positive impact in two ways. First, it will validate fidelity measurement methods that can then be used by implementation scientists for research. Second, it will produce tools that can be used by community mental health clinics to monitor therapist fidelity, an indicator of therapy quality.

BACKGROUND

The significance of this study is its potential to reduce the research-to-practice gap by identifying accurate and cost-effective fidelity measurement methods that both researchers and stakeholders in community mental health clinics can use to monitor fidelity of evidence-based practices. This will allow for the public health impact of evidence-based psychosocial interventions to reach its potential. Specifically, we use the exemplar treatment, cognitive-behavioral therapy (CBT), an established evidence-based practice for a wide range of child and adult psychiatric disorders, to test the three fidelity measurement methods. The proposed research is based on a framework which identifies fidelity as a key implementation outcome.

Therapist fidelity is frequently measured due to its mediating role between implementation of evidence-based practices and client outcomes. Fidelity can also be conceptualized as an indicator of quality of care, which is a priority for many national organizations such as the Institute of Medicine. Fidelity includes adherence (how closely the components of a protocol are followed) and competence (how skillfully the components are implemented and therapist responsiveness to the child). The gold-standard fidelity measurement technique is direct observation, which is infeasible in community agencies due to lack of recording devices, time, and trained coders. Community mental health clinics sorely need methods of measuring fidelity that are accurate and cost-effective. Accurate methods refer to those with strong reliability and validity, whereas cost-effective methods refer to those that can be used with the limited resources in routine practice settings while providing benefit.

Therapists' self-report of their own fidelity is easy to administer, brief, and low-cost. However, the correspondence between self-report and independent observers is low (e.g., kappa of .22 in one

study). Leading scholars have suggested that self-report is frequently inaccurate because self-report measures typically include many terms that are unfamiliar to therapists; and because therapists are not trained in rating their own behavior (i.e., how to rate high vs. low behavior). One way to address these concerns is to ensure that the operational definitions of each item are clear and to train therapists in how to rate their own behavior. Additionally, two innovative methods from the medical literature, chart-stimulated recall and behavioral rehearsal, hold promise for fidelity measurement. Chart-stimulated recall entails a brief interview with a clinician about the care provided to a client, while allowing the clinician to review the client's file to assist recall. Behavioral rehearsal refers to a simulated interaction between a clinician and another individual around treatment delivery. Our goal is to test the accuracy, costs, and cost-effectiveness of each of these three methods in comparison to direct observation.

STUDY SAMPLE AND DATA SOURCE

The City of Philadelphia Department of Behavioral Health and Intellectual disAbility Services (DBHIDS) has sponsored multiple initiatives to train therapists at community mental health clinics in the City of Philadelphia to administer CBT for a range of youth psychiatric disorders (e.g., Beck initiative, trauma initiative). As part of these initiatives, more than 300 therapists from 30 agencies have been trained in CBT over the past seven years, and 40-60 new therapists in two to five new agencies are added annually. Therapists participate in training as part of their agency employment; they will not be required to participate in this study to receive training.

Organizations. To identify organizations who have participated in these initiatives, we worked with DBHIDS leadership. We then reached out to each agency to ascertain their interest in potentially participating in this study (see attached Letters of Support from 12 agencies). Every agency that we reached out to agreed to participate. The study sample will include therapists employed by these 12 agencies who implement CBT.

Therapists. We will recruit up to 170 therapists who provide mental health treatment services in at least 12 community mental health agencies in the City of Philadelphia who (1) have been trained in CBT through the Beck Initiative and/or the trauma initiative, (2) respond to a brief screening survey that they use CBT; and/or (3) are nominated by a supervisor as a therapist who uses CBT. We anticipate that therapists will be 80% female and will be 55% Caucasian, 25% African American, 10% Latino, 5% Asian and 5% of other races/ethnicities.

Supervisors. We will recruit 12 individuals in leadership positions (supervisors and administrators) in community mental health agencies in the City of Philadelphia.

Children, Youth, and their legal guardian(s). We will recruit approximately 3 youth clients per therapist for a total of 405 youth clients (if younger than 18 years old, we will also obtain written or verbal consent from the client's legal guardian)*. We base our projections for youth clients on administrative data from Medicaid claims. Youth clients range in age from 7-24 with a variety of presenting disorders. Based on these data, we anticipate that youth will be 55% male, and primarily African American or Hispanic/Latino. Any randomly selected child aged 7-24 who is presenting for treatment for any psychosocial difficulties may participate if appropriate assent and/or consent is ascertained. Exclusion criteria include if the child does not have a legal guardian who is able to consent (e.g., DHS is the guardian).

*Note, our intention is to enroll three youth clients per therapist. However, we will ask therapists immediately following the session if this was a "crisis" session or therapy as usual. We are looking for at least three samples of behavior that are not crisis sessions so we can code their behavior; therefore, we may need to enroll more than three clients per therapist if there are sessions that are deemed to not meet criteria for inclusion. Sessions need to include at least ten minutes where the client is in the room (i.e., guardian only sessions will not be counted towards the three sessions needed for this study).

The study will begin human subject activities in Fall 2016 (following full approval from the City of Philadelphia IRB) and continue enrolling human subjects until mid-2020.

PROCEDURES

Aim 1: We will recruit therapists in the City of Philadelphia who (1) have been trained in CBT through a city sponsored CBT initiative, (2) respond to a brief screening survey that they use CBT; and/or (3) are nominated by a supervisor as a therapist who uses CBT. More than 300 therapists from 30 agencies have been trained over the past 7 years, and 40-60 new therapists in 2-5 new agencies are added annually. Therapists participate in training as part of their agency employment; they will not be required to participate in this study to receive training. Therapists, agency leadership, and DBH have expressed considerable enthusiasm for the proposed study. We have included letters of support from agency administrators as well as the DBHIDS Commissioner, Dr. Arthur Evans.

Therapists will be consented during a study meeting at each agency where we will provide lunch and information about the study. At that meeting, the manager of research projects, with the assistance of the biostatistician, Dr. Marcus, will randomize therapists into one of the three measurement arms. To maintain balance, we will ensure that we have equal numbers of therapists in each study arm in each site.

Therapists report approximately 30 client encounters per week. We base our projections for youth clients on administrative data from Medicaid claims. On average, youth attend 5.7 sessions (SD = 8.6). Our recruitment goal is 3 unique encounters (i.e., separate clients who each had a CBT session) per therapist for a total of 405 youth client encounters. We will use sequential sampling to identify client encounters to include in the trial. We will sample as a function of individual client session number to ensure that we enroll clients receiving services across the treatment span because CBT techniques used in sessions early on in treatment are different than those used later in treatment. For example, treatment of anxious youth would typically begin with psychoeducation and rapport building in initial sessions before progressing to exposure strategies later in treatment. Once therapists are enrolled in the study, our research staff will work with the therapists directly each week to provide the information they need to check in with eligible families for participation (e.g., recruitment notice, script to obtain verbal assent/consent for the research team to approach the family). Because of our desire to randomly sample treatment sessions from different treatment stages (2-9 (early treatment) and 10+ (late treatment), we will first randomly select the days the research staff will be present at the agency and then randomly select the blocks of time within each day (per each therapist's schedule) during which the research staff will enroll clients for each therapist. For instance, if we randomly select Monday, Tuesday and Wednesday as the days the

research staff will be at the agency that week and a therapist participant planned to be at the agency from 11 AM to 7 PM each of those days, then we would randomly select either the first block (11 AM to 3 PM) or the second block (3 PM to 7 PM) of time in which to approach clients of that therapist. Before each block of time begins, the research staff will check in with the therapist to determine how many of the clients scheduled for that block of time are eligible (i.e. youth clients 7-24 years with whom the therapist uses CBT strategies). We will also ask the therapist to indicate if the client is in early or late treatment stages. We will ask therapists to introduce the study to eligible clients within each randomly selected block of time until three clients have been enrolled. We will provide $25 compensation to complete this process until 3 separate clients who each had a CBT session are enrolled (we will not include if the therapist identifies the session as a crisis of the week session). Based on conversations with our community advisory board, we have been advised that we will need to be flexible at each agency with regard to how we ascertain this information.

We will not have research staff directly approach families to avoid confidentiality concerns. Therapists will approach the family and obtain verbal consent and assent for the research team to contact the family. Any randomly selected child aged 7-24 who is presenting for treatment for any psychosocial difficulties may participate. Exclusion criteria include if the child does not have a legal guardian who can consent to their participation (e.g., DHS-involved youth). Children and their families will be recruited and retained with the help of study team members who will be embedded within agencies where enrolled therapists are seeing eligible clients. When study team members learn of a consent to contact from the therapist, they obtain verbal or written consent and assent from the guardian and client to record the encounter. If the therapist and client both request that a research team member sit with the recorders during the session, then a research team member will sit in the room and hold the recorder. Youth will be paid $10 for allowing their therapy session to be audio-taped. Study participation for youth only entails recording their one session.

Due to COVID-19, we have also decided to implement remote recruitment of therapists and clients. Research staff will recruit therapists by emailing them directly and introducing the study. If therapists are interested in participating in the study, research staff will consent therapists over the phone. Once consented, research staff will work with therapists to identify eligible clients using sequential sampling, which will ensure that we enroll clients receiving services across the treatment span. Therapists will introduce the study to eligible clients (and if necessary, guardians) via a virtual platform to obtain verbal consent (and if necessary, assent). If the client (and if necessary, guardian) are interested, research staff will enroll and consent clients through a virtual platform. Research staff will place the audio recorder next to the computer in a private room, press “record” on the audio recorder, close the door and leave the room. Therapists will notify the research staff through text message once the session is over. Youth will be paid with an electronic $10 Amazon gift card for allowing their therapy session to be audio-taped.

All three conditions (described below) will be compared with direct observation (i.e., audio-recordings of each session). Therapists will be randomized to one of the three experimental measurement conditions. Therapists in the self-report condition will be asked to complete the self-report measure within 48 hours of the encounter, to ensure appropriate recall and also because that is typically when therapists are expected to complete their notes (personal communication, Gretchen Murchison, Community Behavioral Health). Therapists in the other two conditions will

complete chart-stimulated recall or behavioral rehearsal within one week of the encounter. We selected one week because therapists report receiving one hour of weekly supervision, suggesting that this time period is best in planning for future potential trials integrating these methods into community supervision. Therapists will be paid upon completion of their fidelity method (i.e., self-report, chart stimulated recall, behavioral rehearsal). Once a therapist enrolls three separate clients who each had a CBT session and has completed the fidelity measurement for each client, they have completed participation in this aim of the study (we estimate it will take a month to enroll three clients who each had a CBT session and complete fidelity measurements). More than three clients may be enrolled if a session was recorded and we find out that CBT was not used (e.g., the therapist thought CBT would be used in the session but it ended up being a crisis management session).

If assigned to the self-report condition, therapists will be asked to complete a brief self-report measure on their own time within 48 hours after each recorded session (once for each client; three times total; anticipated time = 30-60 minutes). Therapists can complete this measure via REDCap, a HIPAA compliant platform, or using paper-and-pencil, whichever is their preference. Therapists will be compensated $50 for the completion of the self-report measure for their three clients. Additionally, to learn how to use this self-report measure, the research staff will ask therapists to engage in up to 30 minutes of training, for which they will be compensated an additional $25.
If assigned to the chart-stimulated recall condition, therapists will be asked to meet with research staff for one hour. During that hour, therapists will bring the chart of each client that was recorded for a brief interview (approximately 20 minutes per client session). In this interview, therapists will be asked questions about different techniques they may have used in session with their client. Therapists will be allowed to use the chart for the client to spur their memory of the session but the research staff will not be allowed to view the chart. The research staff will ask to complete this interview with therapists within one week after the session was recorded with the client. Therapists will be compensated $50 for the completion of chart-stimulated recall for three clients.

If assigned to the behavioral rehearsal condition, therapists will be asked to meet with the research staff for one hour. During that hour, they will participate in a role-play demonstrating the strategies they used in session with the three clients that were recorded. Research staff will ask to complete this meeting within one week after the session was recorded with the client. Therapists will be compensated $50 for the completion of behavioral rehearsal for three clients. If behavioral rehearsal takes longer than one hour, then the therapist will be compensated $25 for each additional half hour it takes to complete the condition.
Aim 2: The research team will work closely with clinic leadership to collect cost data. The process begins by presenting the brief Drug Abuse Treatment Cost Analysis Program (DATCAP) materials to clinic leadership most familiar with the operations and financing of the program. After these personnel have reviewed the materials, conference calls are conducted between them and the researchers to formulate strategies for preliminary data collection and to answer questions. The researchers will provide clinic leadership with guidance regarding the type and source of resource use and cost information to gather. The researchers then conduct a site visit at each agency, which includes face-to-face meetings with clinic leadership and instrument completion. Cost analysis items include information about how much time is spent on each fidelity measurement method, the time it takes to develop the materials for the method, and the resources that are used for each condition (e.g., office room, computers). Please note, we have not included a consent form for Aim 2 of the study (i.e., assessing the cost-effectiveness of each fidelity measurement method) as this will be

accomplished by using the DATCAP to collect administrative level data on each organization; absolutely no individual level or identifying information will be collected as part of this economic evaluation.

Aim 3: Up to 170 therapists and 12 individuals in leadership positions (i.e., supervisors and administrators) will be recruited to participate in a brief quantitative survey during data collection in Aim 1 that will address Aim 3 objectives. For the qualitative data collection, we will use purposive sampling to recruit 48 individuals. The sample will include 36 therapists (12 therapists from each of the three conditions) and 12 individuals in leadership positions (supervisors and administrators). We selected 12 for each group of interest given research that suggests this is the ideal number for thematic saturation.

Motivation will be quantitatively measured using a 7-point scale. This item will be compared for each of the three methods. We will ask therapists about their current and future motivation to use their assigned fidelity method. Because of concerns that willingness to adopt could be influenced by social interaction between therapists in various conditions, we will measure knowledge of the other conditions in the willingness to adopt measure as a potential covariate to be included in the mixed-effects multivariate regression models for Aim 3.

Qualitative data will be collected using validated, standard open-ended questions that have been developed to elicit the beliefs underlying one's motivation. For example, we will ask advantages and disadvantages the stakeholders attribute to using the particular method they were assigned to, as well as direct observation. We will also ask who they believe will approve and disapprove of them using a particular method. These and other questions will be asked to identify perceived barriers and facilitators influencing use of that method. We will also ask therapists and leadership to elaborate upon the quantitative scores provided on the willingness measure, and to generate information on their beliefs about the integration of these techniques in supervision in the future. All of the questions will be compiled in a questionnaire that will undergo cognitive response testing, which is a strategy that identifies ambiguous or awkward wording. Once the participant completes the qualitative interview (est. time, 1 hour), they have completed participation for this study.

All research activities for Aims 1 and 3, including data collection and engagement with human subjects, will be conducted by members of the University of Pennsylvania research team. All Aim 2 research activities will be conducted by members of the University of Pennsylvania research team as well as by co-investigators from Temple University.

ANALYSIS PLAN

All analyses are by intent-to-treat and will occur at the University of Pennsylvania Center for Mental Health Policy and Services Research under the direction of study biostatistician, Steven Marcus, PhD. Differences across the three arms of the study will be analyzed using SAS PROC MIXED. We will conduct three mixed-effects multivariate regression models. The dependent variable is difference in score between direct observation and the specific fidelity method under consideration. We will measure the dependent variables in three ways: raw score adherence, raw score competence, and total fidelity t-score (composite of adherence and competence raw score). We will conduct two sets of analyses. In the first set, the model will include two fixed effects (fidelity measurement method and site) and a random effect for therapist to account for the nesting

of patients within therapists. Our primary interest is in the beta coefficient for the fidelity measurement method, which tells us whether there is any difference in accuracy between the intervention arms. Our first hypothesis is that both chart-stimulated recall and behavioral rehearsal (i.e., total fidelity t-score) will be more accurate than self-report. Our second hypothesis is that chart-stimulated recall will capture adherence best. Our third hypothesis is that behavioral rehearsal will capture competence best. To test these hypotheses, we will use the model described above to conduct custom contrasts in the regression models to examine whether the mean of the dependent variable differs for each pair-wise comparison of our intervention arms. We will then repeat that analysis after transforming the dependent variable into t-scores to allow computation of standardized differences for each pairwise comparison, so that we can rank accuracy. The second model will include an additional fixed-effect term for time and an interaction (time X fidelity measurement method), allowing us to examine if there are changes in outcome over time by measurement method. This is important in case there are differential practice effects across condition over time.

2. Description of Philadelphia Department of Public Health, Department of Behavioral Health or Risk Management involvement

This project is investigator-initiated. However, it is a result of many conversations with community stakeholders, including DBHDIS leadership. DBHIDS is not formally involved with this project and will not receive any identified data; however, we will share study findings to ensure that policy is shaped by the research, as consistent with best practices (e.g., present at Research Grand Rounds).

DURATION OF STUDY

Therapists will be randomized to one of the three experimental measurement conditions (self-report, chart-stimulated recall, and behavioral rehearsal). Therapists in the self-report condition will be asked to complete the self-report measure within 48 hours of the encounter, to ensure appropriate recall and also because that is typically when therapists are expected to complete their notes (personal communication, Gretchen Murchison, Community Behavioral Health). Therapists in the other two conditions will complete chart-stimulated recall or behavioral rehearsal within one week of the encounter. We selected one week because therapists report receiving one hour of weekly supervision, suggesting that this time period is best in planning for future potential trials integrating these methods into community supervision. We anticipate that we will complete data collection for three therapists and their clients (three each; nine total clients) encounters each month. Therefore, each therapist participant will likely be enrolled in the study for a month; client participants will be enrolled for the one day that their therapy session is taped. Based on these projections, this study will take 45 months to complete. The study will likely begin human subjects activities in Fall 2016 and run until mid-2020. See a timeline of the proposed study below:

Table 3.

Activity	Year 1 (2016)				Year 2				Year 3				Year 4				Year 5			
	Quarter				Quarter				Quarter				Quarter				Quarter			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Preparation (i.e., hire staff, IRB approval, recruit agencies)	•	•																		
Aim 1: Accuracy			•	•	•	•	•	•	•	•	•									
Aim 2: Cost-Effectiveness					•	•	•	•	•	•	•	•	•							

Aim 3: Motivation and Barriers/Facilitators											•	•	•	•	•				
Data analysis											•	•	•	•	•	•	•		
Manuscript preparation																	•	•	•

3. Aspects of research

The findings from the research will be reported to the City of Philadelphia DBHIDS through Research Grand Rounds and agencies that provide child mental health services so that the stakeholders will have the opportunity to review and discuss this information. Further, we will prepare findings for publication.

4. Risks to subjects

SUBJECT RISKS
There are no known physical or legal risks to participating in the study. Clinicians will be asked to answer questions about their practice and will also be observed in session. Leadership will be asked to report on cost information, as well as their perceptions of the fidelity measurement techniques. Self-report, brief observation, and semi-structured interviews could lead participants to feel temporarily uncomfortable. Dr. Beidas, a licensed clinical psychologist, will be available to speak with any participants who feel unduly distressed, and appropriate referrals will be made. Participants will not be required to participate and lack of participation will not impact their employment. Our experience in similar previous research is that therapists who are not interested in participating in the research will leave after hearing about the study. This does not impact their employment because we ask managers/leadership to leave the room after introducing us during the launch meeting. Supervisors will know who is participating but they will not explicitly know who declined to participate since they will not be present at the launch meeting.

In the event that child abuse/neglect or suicidality/homicidality is identified during consent/assent or while listening to a session (either in person or during the coding of a session which typically occurs one month after the session), Dr. Beidas or a clinically trained member of the research team will follow up with the client's therapist to ensure that a safety plan is in place and to work with the therapist to ensure that any information about child abuse/neglect or intent to harm self or others has been reported to the authorities, as required by law.

In the event that serious concerns about client safety or therapist misconduct is developed during consent/assent or while listening to a session (either in person or during the coding of a session, i.e., the therapist promises not to disclose information that must be reported to authorities as required by law), Dr. Beidas or a clinically trained member of the research team will follow up with the therapist within two business days of becoming aware of the event to discuss the situation and develop a plan to ensure client safety and compliance with the law. If the study team is unable to reach the therapist after multiple attempts, they might also follow up with the therapist's supervisor determine whether the event is reportable and to ensure that the report is filed if deemed appropriate.

SUBJECT CONFIDENTIALITY
As part of informed consent and assent, participants (i.e., therapists, legal guardians, and youth) will be informed that all information they provide will be kept confidential (unless it is determined

that it must be reported as required by law), within the personnel of the Center for Mental Health Policy and Services Research (CMHPSR). No information gathered as part of this research will be shared with agency executive directors, supervisors, or DBHIDS (unless it is determined that certain information must be reported as required by law). Participants will be asked to sign a consent form that thoroughly describes the procedures to be followed in the study and the type of assessments involved. The Philadelphia Department of Public Health Institutional Review Board will have approved the protocol and consent prior to the initiation of the study. The following institutions will sign institutional authorization agreements so that the Philadelphia Department of Public Health Institutional Review Board can serve as the IRB of record: University of Pennsylvania, Temple University, University of Washington IRB, and the Medical University of South Carolina. The University of Pennsylvania has already agreed to cede to the Philadelphia Department of Public Health Institutional Review Board. We will submit these signed authorization agreements as a modification. Participants will be provided with copies of the signed consent forms while original copies of the signed consent forms will be kept in locked files at the CMHPSR which no one will have access to other than Dr. Beidas and the research team. All data will be coded with a subject identification number. The names that correlate to those numbers will be kept separate, such that any identifying information will be stored in one file, while experimental data will be kept in a separate file. Only Dr. Beidas and the research team will have access to these files. All project staff will complete training on confidentiality through the Collaborative IRB Training Initiative (CITI) course.

All data, including the master list linking identifiers to the ID number and recordings will be destroyed in 2024. NIH policy requires that data be retained for a period of three years from the date of the final Federal Financial Report. The award period is from 2016-2021. That means that we must retain all study data until 2024, eight years following the start of the study. Assuming that data collection begins as planned in 2016, that means that the data of a youth who consented in 2016 will be kept until 2024 (eight years later).

Privacy and confidentiality is of the utmost importance given that a breach in privacy and/or confidentiality could result in serious consequences for participating clinicians (e.g., employment implications). Thus, breach of privacy and/or confidentiality is the biggest risk of participating in this study.

To ensure privacy, self-report measures will be completed either by hand in the privacy of the therapist's office or using the HIPAA compliant web-based survey platform, REDCap, hosted by the University of Pennsylvania. Therapists will have the option of completing measures using paper-and-pencil or via web given our previous experiences that therapists prefer different options. Paper-and-pencil measures, only identified with ID numbers, will be sealed in a manila envelope and handed to the embedded research staff person in the agency who will immediately transport the data to Penn. Semi-structured interviews will be conducted in a private location of the therapist's preference. In our previous studies, this has typically been a closed room in the agency where the therapist works. The therapist meets with the interviewer one-on-one in this room and the content of the interview is recorded. To ensure recordings are kept confidential, the procedures described below will be followed. Once a session is audio-recorded, the research staff on site will take the recording device and plug it into a laptop that is connected to an encrypted external hard drive that is password-protected and helps make sure that only our team can access the information.

The audio file will be transferred directly to the encrypted external hard drive and erased from the recording device. The research staff will transport the encrypted external hard drive back to the University of Pennsylvania, where the audio file will be uploaded to REDCap, a password-protected HIPAA-compliant server. The audio file will be maintained in REDCap and on an encrypted external hard drive (inside a locked filing cabinet in a locked office) for three years after the study has ended. The audio file is later transcribed and de-identified by individuals who are trained in human subjects protection. Our research team will provide written feedback to each therapist on his/her recorded session behavior. This feedback will include a de-identified summary of the session, the areas of strength and potential growth, and the scores earned by the therapist as coded using the Therapy Process Observational Coding System for Child Psychotherapy. The research team will not share this individualized feedback with anyone else besides the therapist; the therapist is welcome to use the feedback in whatever manner they choose.

If a therapist is randomized to chart-stimulated recall, a member of the study team will sit with the therapist while the therapist reviews the client's mental health chart. The study team will not access any information from the client's mental health chart. However, there is a small chance that the study team may see parts of the client's mental health records during chart-stimulated recall. The study team does not intend to look at any parts of the client's mental health records and will take steps to minimize seeing the record (e.g. choose not to sit facing the chart, ask the therapist not to show the chart to the study team).

To ensure confidentiality, we will use the following methods: (a) all self-report data, rating scales, observations, and interviews will be kept in a locked filing cabinet; (b) subject identity will be masked using numeric codes and password-protected master list which only Dr. Beidas and the manager of research projects will have access to; (c) data will be entered directly into password-protected files which only Dr. Beidas and the manager of research projects will know, and (d) files kept on the computer will only be identified with subject numbers and will not contain identifying information.

DATA DISCLOSURE

The proposed research will include data from up to 170 therapists and 12 administrators who work in community-based settings that have participated in the City of Philadelphia DBHIDS training initiatives. Data from approximately 405 youth receiving treatment from these therapists will also be included. The final dataset will include quantitative data (accuracy, cost-effectiveness, willingness) and qualitative data (motivation, barriers, facilitators) for each clinician and supervisor who participated. The final dataset will be stripped of identifiers prior to sharing. Release of data for data sharing will occur after publication of the main findings from the dataset. We will make the data and associated documentation available to users under our own auspices by mailing an encrypted hard-drive to users. A data-sharing agreement must be signed that accounts for (1) commitment to using the data only for research, (2) IRB approval at the host institution, (3) a plan for securing the data using appropriate technology, and (4) an agreed upon plan to destroy or return the data upon completion.

5. Numbers of participants

We will recruit up to 170 therapists who provide mental health treatment services in community mental health agencies in the City of Philadelphia who (1) have been trained in CBT through a city-sponsored initiative (2) respond to a brief screening survey that they use CBT; and/or (3) are nominated by a supervisor as a therapist who uses CBT. We will recruit approximately 3 youth clients receiving CBT in their session per therapist for a total of 405 youth clients (if younger than 18 years old, we will also obtain consent from the client's legal guardian).

*Note, our intention is to enroll 3 youth clients per therapist. However, we will ask therapists immediately following the session if this was a "crisis" session or therapy as usual. We are looking for at least three samples of behavior that are not crisis sessions so we can code their behavior; therefore, we may need to enroll more than three clients per therapist if there are sessions that are deemed to not meet criteria for inclusion. There is often no way for a therapist to know when a crisis session will occur until the session has already started, by which point the family will have already consented and assented to being in the study. If it is deemed that a session does not meet criteria for inclusion, we will still pay the family for participation.

6. Contact information for Principal Investigator

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7. Notation if requesting exemption from or alteration of written consent documentation and/or waiver of HIPAA authorization

We will obtain consent from therapists and supervisors to participate in the study, and research staff will obtain consent from young adults aged 18-24, as well as assent from youth ages 7-17 and consent from their parents/legal guardians.

We have requested waiver of documentation of parental consent when a youth client 7-17 years presents to their treatment session without a parent/legal guardian. While piloting our procedures at our first agency, we have identified a major barrier to enrollment of these clients. Many youth clients present to the community mental health agencies for their treatment session without a parent/legal guardian, particularly adolescents who can come to session on their own using public transportation. We have discussed potential solutions to this barrier with therapist stakeholders and have learned that a parent/legal guardian can often be reached by phone during the client's session even if they do not accompany youth to session. As such, we have requested waiver of documentation of parental consent when a youth client 7-17 years presents to their treatment session without a parent/legal guardian. Our justification is as follows:

- The research involves no more than minimal risk to the subjects, as we are asking youth clients to agree to the audio recording of their session. The primary risk related to study participation is the breach of confidentiality of the audio recording. We minimize this risk by immediately transferring

the audio recording to an encrypted hard drive.

- The waiver or alteration will not adversely affect the rights and welfare of the subjects, since we will still obtain assent in person from the youth client and consent from the parent/guardian over the phone in the presence of the youth client. The only difference from our currently approved consenting process is that the parent/legal guardian will not be physically present in the room during parental consent and a signed consent form will not be obtained from the parent/legal guardian.
- The research could not practicably be carried out without the waiver or alteration, because many youth clients 7-17 years present to their treatment session without a parent/legal guardian. If we do not obtain this waiver of documentation of consent, then we would have to significantly increase the amount of time needed to enroll three clients per therapist, which could be perceived as too burdensome on an agency and could influence agencies and therapists not to participate in this study. Additionally, this research could not practicably be carried out without waiver of documentation of parental consent for youth who want to participate but whose parent/legal guardian cannot feasibly attend the session. We want to be able to provide these youth with a fair opportunity to participate if they express interest in participating in this study.

Our process to obtain verbal consent from parents/legal guardians is as follows: when a youth client 7-17 years present to their treatment session without a parent/legal guardian, then the therapist will call the parent/legal guardian and if s/he agrees to hear more about the study, the research team will speak to the parent/legal guardian on the phone in the presence of the therapist and client. If the parent/legal guardian verbally consents to allow their child to participate in the study and the client assents to participate in the study, the research team will obtained signed assent from the youth client and write a note documenting the consenting process of the parent/legal guardian. This note will be maintained with the client's assent form in a locked filing cabinet in a locked office room.

We have requested alteration of documentation of youth, caregiver, and young adult assent/consent when participants cannot sign consent/assent forms in-person (as in the case of the COVID-19 outbreak). Specifically, when a client and/or caregiver is interested in participating in the study, we will obtain verbal assent and/or consent from the client and/or caregiver. Research staff typically meet with clients and caregivers around their scheduled therapy sessions at community mental health agencies to minimize burden to families. However, when it is not possible to meet with clients and caregivers in-person, we will enroll them through a virtual platform. Not allowing eligible clients and caregivers to participate in the study virtually during times when in-person enrollments are not possible presents a recruitment barrier for the study. As such, we are requesting alteration of documentation of caregiver consent, youth (7-17) assent, and young adult (18-24) consent when a virtual enrollment is to be conducted. When this occurs, the therapist will contact the client and/or caregiver ahead of time to see if they are interested in participating in the study. If the client and/or caregiver is interested, research staff will obtain verbal assent/consent via a virtual platform. As with in-person consents, assent will be obtained from youth ages 7-17, consent will be obtained from young adults age 18-24, and consent will be obtained from caregivers of clients age 7-17. If verbal assent/consent is not obtained from all necessary parties, study participation will not take place.