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Study Title:

Development of a Training Intervention to Improve Mental Health Treatment Effectiveness and Engagement for Youth with Documented Mental Health Disparities

Clinical Trials Number

NCT05626231

Principal Investigator

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Research Summary:

Specific Aims/Study Objective:

Pilot the training intervention in a non-specialty mental health care setting. An open trial with mental health providers (N = 44) treating gender-minority youth (youth patients) patients across multiple U.S. clinics will be conducted to examine the feasibility and acceptability of conducting a future RCT. During the intervention, data on the utilization of online materials (e.g., time spent in each module), survey data, answers to short-answer questions, and intervention acceptability data will be collected. In line with NIMH's emphasis on the efficient deployment of effective and solution-oriented interventions, follow-up assessments will collect data on the primary outcome (i.e., providers' use of evidence-based practices (EBP) and implementation data (e.g., barriers to adoption). Data on hypothesized mechanisms (knowledge, attitudes, self-efficacy) will be collected immediately before and after the training intervention, as well as 3, 6 and 12 months later. Additionally, providers will complete a brief monthly assessment . To explore potential training intervention-related changes in patient engagement and symptomatology (distal outcomes), chart data (e.g., treatment attendance) and weekly and quarterly survey data (e.g., treatment satisfaction, internalizing problems) from youth patients and their parents will be collected and analyzed. Additionally, up to patients and parents will be invited to complete 2 surveys , at 16 time points beginning 2 weeks before the training begins. Provider-level implementation data (e.g.,acceptability, appropriateness, feasibility) will be used to refine the intervention for larger-scale testing. To reduce participant burden, those who have not responded to any survey or reminder emails/texts in three weeks will have the opportunity to opt out of receiving further surveys or reminders. Participants who completed surveys and consented to future studies will be invited to participate in a 1-hour follow-up assessment, with 45 minutes dedicated to a semi-structured qualitative interview and 15 minutes dedicated to surveys.

Materials, Methods, and Analysis:

The open trial will be conducted in a multi-site mental mental health care agency specializing in EBP for youth and families. At the anticipated time of the open trial, the clinic expects to employ 52 providers.

Training intervention procedures. The partner agency uses a HIPAA-compliant video conferencing service for telehealth, remote training, and supervision. Thus, they have the capacity to engage all of their multi-site clinicians simultaneously in online training. All providers will be compensated for follow-up assessments, but not for training completion, in order to maximize external validity.

Measurement and Assessment. *Provider assessments:* Though participation in the training will be required of all partner agency providers, assessments will be voluntary. During the intervention, data on the utilization of online materials (e.g., time spent in each module), survey data, answers to short-answer questions, and intervention acceptability data will be collected. Pre-, post-, monthly assessments following training

completion, and 3-month, 6-month, and 12-month follow-up assessments will be conducted for those who consent to study participation, and will focus on both implementation and service outcomes (measures described below). All quantitative and written qualitative data will be collected electronically Qualtrics. Additionally, a small number of non-partner agency providers may complete the training and may also complete the assessments. *Patient outcomes:* To explore potential intervention-related changes in patient engagement and mental health (i.e., preliminary effectiveness), chart and survey data will be analyzed. The partner agency has multiple ongoing research partnerships, and thus the agency-wide informed consent for treatment requires all patients to agree to have their deidentified data used for research purposes. For the proposed study, the partner agency will share their (1) comprehensive chart data and (2) intake assessment and treatment-specific survey data administered in routine practice for all patients ages 12-25. Patients currently complete surveys at home on an electronic device. The partner agency has also agreed to administer additional patient measures. as soon as IRB approval has been secured. The research team will also administer a separate survey to participating patients and patients' parents about their provider's use of evidence-based practices and their mental health.

Materials or tools used to collect the data:

Provider assessments: Though participation in the training will be required of all partner agency providers, assessments will be voluntary. Non-partner agency providers who take the training may also voluntarily take assessments. Pre-, post-, monthly assessments following training completion, and 3-month, 6-month, and 12-month follow-up assessments will be conducted for those who consent to study participation, and will focus on both implementation and service outcomes. All quantitative and written qualitative data will be collected electronically through Qualtrics. Baseline measures will assess demographics (e.g., age, race), background and previous training data and knowledge .

Additionally, data on the utilization of online materials (e.g., time spent in each module), answers to short-answer questions, and intervention acceptability data will be collected.

Patient outcomes: To explore potential intervention-related changes in patient engagement and mental health (i.e., preliminary effectiveness), chart and survey data will be analyzed. The partner agency has multiple ongoing research partnerships, and thus the agency-wide informed consent for treatment requires all patients to agree to have their deidentified data used for research purposes. For the proposed study, the partner agency will share their (1) comprehensive chart data (e.g., demographics, diagnoses, treatment) and (2) intake assessment and treatment-specific survey data administered in routine practice for all patients ages 12-25. The PI initiated the DUA process between the partner agency and BC on 6/9/2021 and finalized the DUA on 9/13/2022. Patients currently complete surveys at home on an electronic device. The partner agency has also agreed to administer and share additional patient measures.

During follow up assessments, participants will be interviewed using a semi-structured interview protocol. Minor adaptations will be made to be each participant's protocol based on their previous survey responses.

Patient measure details: Deidentified chart and survey data from the partner agency will be analyzed to examine the effects of the training intervention on patient outcomes. Primary outcomes are (1) treatment engagement and (2) mental and behavioral health. Treatment engagement will be measured using both behavioral (i.e., retention) data and attitudinal data. Behavioral engagement data will be derived from the partner agency chart data, including the number of sessions attended, session participants (e.g.,youth patients only, parent-youth patient), number of sessions canceled and no-showed, and reason for termination. Attitudinal engagement data will be measured via two self-report surveys administered separately to youth patients and parents throughout the duration of the open trial at 16 time points. Mental and behavioral health will be assessed through quarterly and weekly measures, each separately administered to youth patients and parents. Finally, in line with best practices in patient exit interviews (Beehler et al., 2009; Hrisos et al., 2009), we will develop a brief survey (e.g., 19 items) asking youth patients and (separately) their parents to indicate whether or not their provider used key evidence-based practices during their most recent session. During the pilot trial, youth patients and parents will complete this brief measure along with the other surveys administered weekly by the partner agency.

Statistical analysis

Hypotheses: The primary purpose of the open trial pilot is to test the methods and procedures to be used in a larger trial. More specifically, the acceptability and feasibility of the training intervention, as well as the feasibility of a larger trial, will be explored. In order to determine the effect sizes necessary to power a full trial, several intervention hypotheses will be examined. Regarding the provider outcomes, I hypothesize that: (H1) trained providers will use more evidence-based practices after training and at follow-up assessments compared to before training, and (H2) this change will be mediated by the three mechanisms (knowledge, attitudes, self-efficacy). Regarding patient outcomes, I hypothesize that (H3) compared to pre-intervention time points, levels of treatment engagement will be higher after the intervention and (H4) the trajectory of mental health symptom reduction will improve (i.e., become steeper). In addition, (H5) patient changes will be specific to youth patient participants, such that youth patient participants at the partner agency do not evidence intervention-related changes.

Analyses: Feasibility and acceptability of conducting a future RCT will be assessed by reporting summary statistics on relevant variables. All acceptability statistics will be benchmarked against similar trials of provider-trainings previously conducted by the research team (Lelutiu-Weinberger & Pachankis, 2017; Lelutiu-Weinberger et al., 2016). The preliminary effectiveness (H1, H3, H4) of the intervention will be assessed by examining trajectories of change in provider- and patient-outcomes through hierarchical linear modeling (HLM), which is recommended by the IOM for obtaining valid and reliable results from small clinical trials (Institute of Medicine, 2001). HLM is robust to ignorably missing data and thus allows for the inclusion of participants who do not complete all assessments (e.g., due to attrition; McCartney et al., 2006; Singer & Willett, 2003). To examine mechanisms (H2), the Bayesian method (Koopman et al., 2015) will be used, as it has been recommended and validated for this purpose in small samples (N = 20-80). To examine the specificity of intervention effects (H5), data from all the partner agency patients will be analyzed in multi-group analyses examining potential outcome differences across non-youth patient participants and youth patient participants. Successful implementation will be assessed using mixed methods data from providers. Consistent with several qualitative provider-focused implementation studies (Distel et al., 2019; Hamm et al., 2015; Stein et al., 2010; Stirman et al., 2013), qualitative content analysis (Schreier, 2012) will be used to analyze written and interview data from providers. Recommended practices for mixed methods implementation science research will also be utilized (Palinkas et al., 2011). For example, triangulation will assess the convergence of themes from interview data and responses on the survey of evidence-based practice utilization. ChatGPT 4.0 will be used to assist in analyzing data from providers, youth, and parents. All data will be completely de-identified before entering the ChatGPT 4.0 system. These analyses will shed light on providers' long-term experiences implementing evidence-based practices (e.g., barriers and facilitators to adoption) and have direct implications for protocol refinement.