Michigan Mental Health Integration Partnership - Implementing PTSD Treatment in Federally Qualified Health Centers for Michigan Medicaid Enrollees
PE-PC Pilot

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PROTOCOL SUMMARY

Title:	PE-PC Pilot
Study Description:	A study to evaluate the delivery and sustainability of a brief trauma-focused treatment, Prolonged Exposure for Primary Care (PE-PC), an evidence-based intervention for PTSD, delivered via telehealth to patients in Community Health Centers (CHCs) in Michigan.
Outcomes:	Primary Outcome: PE-PC participants will experience reductions in PTSD symptoms as measured by the PTSD Checklist for DSM-5 (PCL-5) at 2 months and 4 months. Secondary Outcomes: PE-PC participants will experience reductions in depression as measured by the PHQ-9 at 2 months and 4 months. We will also examine the mechanisms of PE-PC's effect by measuring the two potential mediators of intervention effectiveness, recovery goals (Recovery Assessment Scale; RAS) and posttraumatic cognitions (Post-Traumatic Cognitions Inventory; PTCI).
Intervention Information:	Deliver PE-PC to patients via telehealth. This treatment consists of four 30-minute sessions of in-vivo and narrative exposure, with content drawn from the PE model.[1]
Study Population:	The sample will consist of 50 participants, age 18 and older, of any gender, race or ethnicity, who are currently enrolled at a CHC and screen positive for PTSD on the PCL-5 (PCL-5 ≥ 33).
Locations:	University of Michigan Family Medical Center of Michigan Hamilton Community Health Network Family Health Care
Estimated Study Start Date:	October 1, 2018
Study Duration:	2 years

1 BACKGROUND & RATIONALE

1.1 Background

Posttraumatic stress disorder (PTSD) is a disorder that develops following exposure to traumatic events such as rape, assault, natural disaster, or combat. It is associated with distress, impairment, and greater risk for adverse health outcomes, including among Michigan Medicaid enrollees.[2] The percentage of patients screening positive for PTSD in primary care settings has been estimated to range from 14%-23%.[3-6]

Despite this high prevalence, treatment for PTSD is severely limited at CHCs.[7] In addition, patients with PTSD may be reluctant to seek care in specialty mental health clinics.[8] Furthermore, community mental health providers rarely have training in efficacious PTSD treatments, and community dissemination and implementation efforts have had mixed success.[9] Thus, there is significant need for a brief PTSD treatment delivered in the primary care setting. Providing brief PTSD treatment in the primary care setting aligns with the MDHHS Section 298 Initiative to coordinate physical health services and behavioral health services.

1.2 Study Rationale

The purpose of this project is to expand access to trauma-focused treatment among Medicaid Enrollees with PTSD, thereby improving the quality of mental health services delivered to this population. This project directly addresses the Michigan Department of Health and Human Services (MDHHS) Mental Health and Wellness commission priority to provide "better access to high quality, coordinated and consistent service and care between agencies, service providers and across geographical boundaries."

The project goals are to evaluate the delivery and sustainability of a brief trauma-focused treatment, Prolonged Exposure for Primary Care (PE-PC), an evidence-based intervention for PTSD, when delivered via telehealth to patients enrolled at CHCs in Michigan. CHCs serve 680,000 Michigan residents across 260 delivery sites. Ninety-two percent of CHC patients have incomes below 200 percent of the federal poverty level. Approximately 16 percent of CHC patients are uninsured, and more than half rely on Medicaid for their insurance. Thus, providing PTSD treatment to CHC patients will improve care to Medicaid enrollees and promote Mental Health and Wellness commission priorities of developing a trauma informed system that includes implementation of evidence-based trauma-informed care.

To address the high burden of PTSD in Medicaid enrollees in Michigan CHCs, we plan to deliver PE-PC to patients in CHCs. This treatment consists of four 30-minute sessions of in-vivo and narrative exposure, with content drawn from the PE model.[1] Recently published efficacy data from a randomized controlled trial showed that PE-PC significantly reduced PTSD and depression symptoms as compared to usual primary care treatment.[10] These changes were maintained at 6-month follow-up.

2 OUTCOMES

2.1 Primary Outcome

The Primary Outcome measure is change in PTSD symptoms as measured by the PTSD Checklist for DSM-5 (PCL-5). PCL-5 will be administered at baseline, 2-months post-enrollment (around the time of treatment completion) and 4-months post- enrollment. Two 2-month and 4-month surveys will be administered regardless of whether the patient has completed the intervention.

1. PCL-5 [Time Frame: Baseline, 2-months, 4-months]
   The PCL-5[11] is a 20-item self-report measure designed to assess PTSD symptoms as defined by the DSM-5. Each item of the PCL-5 is scored on a five point scale ranging from 0 ("not at all") to 4 ("extremely"). The PCL-5 has strong internal consistency, test-retest reliability, and convergent and discriminant validity.[12,13] Scores ≥ 33 indicate a probable diagnosis of PTSD.

2.2 Secondary Outcomes

1. Depressive symptoms (measured by the Patient Health Questionnaire; PHQ-9)[14,15] [Time Frame: Baseline, 2-months, 4-months]
2. Recovery goals (measured by the Recovery Assessment Scale; RAS)[16,17] [Time Frame: Baseline, 2-months, 4-months]
3. Posttraumatic cognitions (measured by the Post-Traumatic Cognitions Inventory; PTCI)[18] [Time Frame: Baseline, 2-months, 4-months]

3 STUDY DESIGN

The goal of this pilot project is to deliver PE-PC to 50 patients via telehealth and evaluate patients' engagement with the treatment, satisfaction, and PTSD-related outcomes. This is an open trial. All participants will receive the same intervention.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

The population of interest is individuals with PTSD who receive services from CHCs in Michigan.

4.1 Inclusion Criteria

The goal of the study inclusion and exclusion criteria is to identify a broadly representative sample of CHC patients with PTSD.

Patients will be eligible for the study if they:

1) are age 18 years or older
2) receive care at a Michigan CHC
3) have a PCL-5 score ≥33
4) have had psychotropic medication stability for at least 4 weeks

4.2 Exclusion Criteria

Patients will be excluded if they are: 1) substantially cognitively impaired, 2) unable to agree to study procedures for any reason (including incompetency), 3) at high risk of suicide, or 4) currently engaged in a trauma-focused behavioral treatment (such as Prolonged Exposure or Cognitive Processing Therapy). Patients who do not speak English will be excluded for logistical reasons.

4.3 Recruitment

Participants will be recruited from the following CHCs: Family Medical Center of Michigan, Hamilton Community Health Network, and Family Health Care. All three clinics are all currently engaged in University of Michigan research studies and strongly endorse the current study.

5 STUDY INTERVENTIONS

5.1 Delivery and Duration

PE-PC will be delivered by the telepsychologist via interactive video technology, or telehealth.

5.2 Interventionist Training

Therapist training and PE-PC implementation PE-PC will be guided by Dr. Sheila Rauch and Dr. Jeffrey Cigrang, treatment developers of PE-PC. Dr. Rauch and Dr. Cigrang have established a PE-PC training protocol that includes didactic training followed by phone consultation on training cases. Trainers will augment this training with case review to establish competence.

5.3 Delivery of Treatment

Eligible participants are individuals presenting in CHCs who screen positive for PTSD, using validated screening measures currently used in multiple Michigan CHCs. Those who screen positive will be connected by a warm handoff to the research assistant (or will call us after being provided with our contact information), who will review inclusion/exclusion criteria, present the study information sheet, and schedule the first meeting with the telepsychologist.

PE-PC treatment will follow the PE-PC manual and patient workbook. Treatment content for PE-PC is drawn from the PE model and condensed so as to deliver the most efficacious components of PE. PE-PC consists of four, 30-minute appointments scheduled approximately once a week over 4-6 weeks (to accommodate scheduling and missed appointments). Before beginning the 4-session treatment, the telepsychologist will schedule an initial appointment with the patient to determine the index trauma and answer any questions about the treatment. During the first PE-PC session, the PC-MHI provider will review the "Confronting Uncomfortable Memories" activity workbook to be completed at home and brought back for use in subsequent sessions. The workbook asks the patient to write a detailed first-person narrative of the event associated with the greatest level of current distress, including recollection of personal thoughts, feelings, and physical reactions. Emotional processing questions are also included. In addition, the telepsychologist will plan for in-vivo exposure activities between sessions. The patient will be instructed to complete the memory exposure for 30 minutes each day between sessions. At the second PE-PC session, the telepsychologist will review the patient's exposures, problem-solve any implementation difficulties, and process the exercises. The patient will then read the narrative and his or her answers to the emotional processing questions out loud and they will process the exercise. Practice continues between sessions. This session format and content are repeated at the third and fourth sessions. At the end of the fourth session, the telepsychologist and patient will review treatment progress assisted by results of the PTSD Checklist for DSM-5 (PCL-5) administered during the fourth session. Participants who still need or desire treatment at the conclusion of PE-PC will receive referrals to other mental health resources.

6 STATISTICAL ANALYSIS

We used paired t-tests and multiple regression to determine symptom change over time. Multiple imputation was used to impute missing data. Ten imputed datasets were generated, and coefficients and standard errors were adjusted for the variability between imputations according to Rubin's combination rule.[19] We included auxiliary variables that were correlated with the missing variables at $r > 0.4$.[20] Imputation procedures were conducted in SAS, using the Markov Chain Monte Carlo approach.

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