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A pragmatic feasibility trial of the Primary Care Intervention for PTSD: A health service delivery model to reduce health disparities for low-income and BIPOC youth

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ABSTRACT

Objective: This study is a non-randomized pragmatic trial to assess the feasibility and acceptability of the Primary Care Intervention for Posttraumatic stress disorder (PCIP) (Srivastava et al., 2021), an Integrated Behavioral Health Care treatment for PTSD in adolescents.

Method: Following routine clinic procedures, youth who were suspected of having trauma-related mental health symptoms were referred by their primary care providers to integrated care social workers for evaluation. The integrated care social workers referred the first 23 youth whom they suspected of having PTSD to the research study. Twenty youth consented to the study and 19 completed the pre-assessment (17 female; mean age = 19.32, SD = 2.11; range 14-22 years). More than 40% identified as Black and a third as Hispanic/Latinx. PCIP mechanisms and clinical outcomes were assessed pre- and post-treatment, and at one-month follow-up. Participants and therapists completed post-treatment qualitative interviews to assess feasibility and acceptability, and treatment sessions were audio recorded to assess fidelity.

Results: Findings suggest high acceptability, satisfaction, and feasibility of the PCIP delivered in "real-life" safety net pediatric primary care. Integrated care social workers had high treatment fidelity. Despite the small sample size, there was significant improvement in symptom scores of anxiety (g = 0.68, p = 0.02) and substance use (g = 0.36, p = 0.04) from pre to post, and depression symptoms (g = 0.38, p = 0.04) from pre to follow-up. Qualitative data from patients who completed exit interviews and integrated social workers indicated high satisfaction with the treatment, with some participants reporting that the integrated intervention was more acceptable and less stigmatizing than seeking mental health care outside of primary care.

Conclusions: The PCIP may improve treatment engagement and access for vulnerable youth. Promising findings of high acceptability, feasibility, and initial clinical effectiveness suggest that PCIP warrants larger-scale study as part of routine care in pediatric integrated care.

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1. Introduction

Low-income youth who are Black, Indigenous, or Persons of color (BIPOC) have increased risk of exposure to trauma and subsequent development of posttraumatic stress disorder (PTSD) (Crouch et al., 2000; Lopez et al., 2017; Price et al., 2019; Pulsifer et al., 2019). Approximately 7% of U.S. adolescents will have PTSD by the time they are 18 years old (Merikangas et al., 2010). However, it is estimated that 30%-50% of adolescents receiving health services in safety net hospitals and federally qualified health centers (FQHCs)—which provide care to a higher proportion of patients who are racial/ethnic minorities, non-English speaking, uninsured, underinsured, undocumented, or low-income (Gaskin, Hadley, & P, 199 9; Lasser et al., 2021; Nath et al., 2016)—have symptoms consistent with a diagnosis of PTSD (Ng et al., 2022; Selwyn et al., 2019). Untreated PTSD in adolescents is associated not only with poor mental health, but also with academic failure, high-risk sexual behaviors, suicide attempts, substance use disorders, relationship problems, and arrests (Cohen et al., 2010; Kartha et al., 2008; Lipschitz et al., 2000). Early identification and immediate treatment of PTSD symptoms in primary care may help reduce these poor

Although low-income and BIPOC youth are more likely to develop PTSD, they are less likely to receive treatment for it, and those who do are more likely to drop out before treatment completion (Alim et al., 2006; Chung et al., 2003, 2003de Arellano et al., 2018; Liebschutz et al., 2007; Lipschitz et al., 2000; Lopez et al., 2017; Mowbray et al., 2018). This disparity in care may stem, in part, from low-income and BIPOC youth receiving fewer mental health services overall, regardless of diagnosis, compared to higher income and non-Hispanic White youth (Bartram & Stewart, 2019; Chung et al., 2003; Cook et al., 2016; Cook et al., 2017; Fitts et al., 2019; Le Cook et al., 2013; Nobles, Valentine, Gerber, Shtasel, & Marques, 2016, Nov - Dec; Pulsifer et al., 2019). This disparity has been observed at both the individual level, such as low-income and BIPOC youth with a mental health need being less likely to be offered care (Borowsky et al., 2000; Fitts et al., 2019), and at the agency level, such as health care clinics that serve low-income patients having less access to clinic or community based mental health services for referrals (Fitts et al., 2019; Wielen et al., 2015).

Moreover, even when referred for mental health services, individuals who are racial/ethnic minorities are less likely to engage in specialty mental health treatment (Maura & Weisman de Mamani, 2017, Dec) and are less likely to receive high quality and evidence based treatment (Dougherty et al., 2014; Vidal & Connell, 2019). Logistical, structural, and attitudinal barriers and linguistic and cultural factors also contribute to disparities in treatment access and utilization, including location based convenience and availability of services, cost and time constraints, prejudice and discrimination, mistrust in health service systems, differences in perceived need, and perceived stigma and self-efficacy (Alang, 2019; Alegría et al., 2015; Chakawa, 2022; Green et al., 2020; Ortega & Alegría, 2002; Wong et al., 2018).

Integrated Behavioral Health Care (IBHC) has been found to improve uptake of mental health services for all patients, and particularly for low-income patients of color, because of the ease of access and lower stigma associated with this treatment (Ayalon et al., 2007; Curran et al., 2012; Johnson & Possemato, 2019; O'Loughlin et al., 2019). IBHC allows patients to access mental health treatment in a familiar setting and leverages existing relationships with primary care providers to increase uptake of mental health services (Joseph et al., 2017; Kaltman et al., 2014; Vera et al., 2010). IBHC has been found to improve mental health care access, quality of care, patient satisfaction, and mental health symptoms within and across diverse patient populations (Archer et al., 2012; Chwastiak et al., 2017; Katon et al., 2010; Miller et al., 2013; Uga, Kulkarni, Heeramun, & Bottum, 2017, Jul-Aug; Woltmann et al., 2012).

Even with the many benefits of IBHC, youth with PTSD are often denied IBHC mental health treatment because it is not feasible to provide first-line evidence-based interventions (EBIs) for PTSD in pediatric

primary care IBHC (Cohen et al., 2008; Curran et al., 2012) due to typical restrictions limiting the number of treatment sessions to five or fewer. For example, Trauma-Focused Cognitive Behavioral Therapy (TF-CBT), the PTSD intervention with the largest evidence base for adolescents (Cohen et al., 2006, 2008, 2010; Kowalik et al., 2011; Morina et al., 2016), requires 8 to 25 90-min or hour-long weekly sessions. Furthermore, TF-CBT includes exposure to trauma memories and requires caregiver participation, both of which were deemed infeasible in pediatric IBHC in formative research, in part due to the prioritization of treatment brevity (Srivastava et al., 2021). Although brief IBHC interventions for PTSD have been developed for adults (Harmon et al., 2014; Possemato, 2011; Possemato et al., 2016; Sijbrandij et al., 2007), to our knowledge none have been developed for children or adolescents.

Therefore, even when IBHC providers are available in pediatric primary care for youth with anxiety, depression, or other disorders, youth with PTSD are typically referred for specialized mental health services provided in psychiatry or mental health clinics (Banh, Saxe, Mangione, & Horton, 2008, Nov-Dec). Unfortunately, patient follow-through on referrals to specialty care is very low (Banh et al., 2008, Nov-Dec). This gap in available and utilized services is particularly concerning given the increased focus nationwide on the identification of PTSD symptoms in youth. Many states, including California, have begun incentivizing the screening of all child Medicaid patients for Adverse Childhood Experiences (ACEs) in pediatric primary care, which will likely lead to universal trauma screening of low-income youth. However, if a youth screens positive for ACEs and is then subsequently identified to have PTSD symptoms, there are currently no EBIs to address PTSD that are feasible to implement in the pediatric primary care setting. Given these concerns, clinical researchers in the U.S. have called for the development of stepped-care approaches that provide brief, low-intensity interventions for PTSD in child and adolescent primary care settings before considering referral to specialty care if warranted (Cohen et al., 2008; Schneider et al., 2013).

The goal of this study was to use a non-randomized pragmatic trial to collect preliminary data on the feasibility and acceptability of the Primary Care Intervention for Posttraumatic stress disorder (PCIP; (Srivastava et al., 2021) delivered in an Adolescent Medicine primary care clinic by frontline integrated care social workers as part of routine care. The PCIP was developed for use in pediatric primary care clinics, including those that serve a large number of low-income and BIPOC youth, using the existing clinic staff, making it a potentially sustainable and efficient model for pediatric IBHC (Srivastava et al., 2021). The PCIP consists of three 30- to 50-min sessions, designed to be delivered over three weeks to three months. Following guidance from the original BREATHE intervention, completion of two sessions was hypothesized to be the minimum exposure needed for clinical change (Mueser et al., 2015; Srivastava et al., 2021). The brief, low-intensity, flexible format of the PCIP is feasible within the standard practices of IBHC in terms of duration, frequency, and number of sessions. Therapists were asked to assess PTSD symptoms at the end of treatment to determine if PCIP reduced symptoms and improved functioning. Therapists were then asked to refer patients who are still in need of, and interested in, further treatment to specialty care. The short course of treatment and the potential to be a sufficient treatment for many patients, with the option for further care if needed, increases the PCIP's potential reach and impact (Beaglehole et al., 2008; Glasgow et al., 1999). Because of these factors, this program has high potential for adoption, implementation, and sustainability in pediatric IBHC settings, thereby increasing equity and access to care in youth with PTSD symptoms.

The PCIP would be deemed feasible if (a) the IBHC social workers could deliver the PCIP with high fidelity to the treatment model following relatively limited training and supervision, and (b) the IBHC social workers report that the PCIP fits within routine clinic work flow and available resources at the clinic. The PCIP would be determined to be acceptable if (a) patients and IBHC social workers report that they were satisfied with the treatment, and (b) patients and IBHC social

workers qualitatively reported that the PCIP engaged the hypothesized treatment mechanisms and resulted in positive improvements on clinical outcomes. In addition, because rates of treatment uptake (i.e. attendance at a first treatment session) for youth referred for trauma treatment range from 26% to 72% (Coulter, 2010; McKay et al., 2005; McPherson et al., 2011), the PCIP would also be considered acceptable if (c) 50% or more of eligible patients offered the program accepted it and attended the first session. Moreover, youth with a trauma-history are more likely to drop out of care (Lau & Weisz, 2003), with completion rates in effectiveness studies in "real world" settings of minimally adequate doses between 9% and 77%, with many studies having completion rates of less than 50% (Eslinger et al., 2014; McKay et al., 2005; McPherson et al., 2011; Murphy et al., 2013; Steinberg et al., 2019; Wamser-Nanney & Steinzor, 2017; Yasinski et al., 2018). Therefore, the PCIP will also be considered acceptable if (d) more than 75% of patients who begin treatment receive the minimally adequate dose of two PCIP sessions.

The PCIP was designed to overcome obstacles to the timely treatment of PTSD symptoms and associated sequelae that result in disparities between low-income and BIPOC youth compared to their higher income and non-Hispanic White counterparts. If found to be effective and implementable, the PCIP could allow youth with PTSD to receive timely care following identification by their pediatrician, which could substantially improve treatment engagement and access, particularly for low-income patients of color (Ayalon et al., 2007; Johnson & Possemato, 2019). By integrating this brief PTSD treatment into the standard of care in pediatric IBHC, we provide a "real-life" delivery model for reducing disparities amongst youth at higher risk for PTSD and long-term negative health outcomes.

2. Method

2.1. The Primary Care Intervention for Posttraumatic stress disorder (PCIP)

The Brief Relaxation, Education and Trauma Healing (BREATHE) intervention is a three-session low-intensity EBI for PTSD designed for adults in specialty care from which the PCIP was adapted (Mueser et al., 2015; Nishith et al., 2015; Srivastava et al., 2021). The BREATHE intervention was demonstrated in a randomized controlled trial (RCT) to be effective in adults at reducing PTSD symptoms to sub-clinical levels with just three sessions for 30% of patients, compared to 40% of patients receiving a 12-16 session cognitive restructuring EBI for PTSD (Mueser et al., 2015). Moreover, patients receiving BREATHE maintained reductions in PTSD, depression, and anxiety symptoms through one-year of follow and had equivalent levels of improvement in post-traumatic cognitions, depression and anxiety, and quality of life as participants in the 12-session EBI (Mueser et al., 2015). Retention rates in BREATHE during the RCT were high (95% vs. 75% in the 12-session EBI), suggesting that the BREATHE was acceptable and well-tolerated. Adaptations to the BREATHE intervention were based on qualitative data from pediatric primary care patients, parents, and medical and behavioral health providers (n = 19) (Srivastava et al., 2021). For example, the PCIP was reduced from 1-hour sessions to three, thirty-to 50-min sessions (additional sessions could be provided depending on client's needs) delivered adjacent to co-occurring medical appointments and delivered in rooms in the primary care clinic to decrease attrition. Sessions were designed to be weekly, but with flexibility for biweekly or monthly. Psychoeducation was adapted to be delivered during the first session through worksheets alone instead of worksheets supplemented with a video in the original BREATHE program, in part because the diverse adolescent participants reported not identifying with the older White patients in the videos, and felt that the lack of diversity in the videos was reducing their engagement with the treatment. In addition, in response to the qualitative data, we added active discussion and practice of positive coping skills. Like in the original BREATHE program,

psychoeducation and breathing retraining were both introduced in the first session to ensure that youth received both primary mechanisms of action. This feature of the original BREATHE was retained to be responsive to provider concerns about high rates of dropout after the first contact with IBHC in general. In addition, literature shows that youth, particularly BIPOC youth, often expect and hope to receive psychoeducation and coping skills during the first session (Gallardo & Gomez, 2015; Watsford et al., 2013).

The hypothesized mechanisms that underlie PCIP are: (1) psychoeducation to increase knowledge about, and self-recognition of, PTSD symptoms (Wong et al., 2013), which enhances motivation for treatment and reduces inaccurate trauma-related cognitions (Nishith et al., 2015); (2) breathing retraining to increase vagal tone, normalize maladaptive overactivation of the sympathetic nervous system, reduce physiological arousal when confronted with trauma reminders (Philippot et al., 2002; Porges, 2003; Streeter et al., 2012; Williamson et al., 2014) and subsequent misinterpretation of ambiguous stimuli as threats (Hamblen & Mueser, 2021); and (3) enhancing positive coping strategies to facilitate effective management of stress and comorbid symptoms of anxiety and depression (Thompson et al., 2018). Further, homework, allows the patient to review and practice skills in "real world" settings, leading to generalization, proficiency, and confidence.

2.2. Study setting

The Adolescent Center at Boston Medical Center (BMC) provides multidisciplinary care to over 2000 urban adolescent and young adult patients ranging in age from 12 to 22 years old and conducts over 6000 clinic visits each year. Patients come from diverse cultural, racial, linguistic, socioeconomic, and national origins and backgrounds. Many have unmet psychosocial and mental health needs. In addition to primary care, the Adolescent Center provides subspecialty services including substance use evaluation and treatment, follow up after sexual assault, services to transgender youth, a program for pregnant and parenting teens, and a menstrual disorders clinic. There are 19 Adolescent Center staff, comprised of four adolescent medicine-trained physicians, a nurse practitioner, five urgent care clinic staff with expertise caring for adolescents, a family planner, three nursing staff, two medical practice assistants, two social workers and one patient navigator.

At the time of the study, between August 2018 and June 2019, 1049 patients between the ages of 12-26 received IBHC services in the BMC Department of Pediatrics. Of the 1049 patients, 75% (n = 783) had public payor health insurance, 71.5% (n = 750) were female, and 51% (n = 537) were Black, 20% (n = 208) were non-Black Hispanic/Latinx, 14% (n = 149) were non-Hispanic White, 1.5% (n = 16) were Asian, one was American Indian/Native American, two were listed as other race/ ethnicity, and 13% (n = 136) had race/ethnicity recorded as declined/ not available. When we instituted universal screening of adolescents in the clinic using the Child PTSD Symptom Scale for DSM-5 Interview (CPSS-5-I; (Foa et al., 2018), we found that 30% met criteria for PTSD, 7% met criteria for subsyndromal PTSD, and an additional 19% for impairing PTSD symptoms associated with a non-Criterion A trauma which could include events such as relationship difficulties, non-violent deaths of loved ones, and parental incarceration. Altogether, 56% of adolescents receiving pediatric primary care services at BMC had trauma-related symptoms that were impairing their functioning (Ng et al., 2022).

2.3. Ethics statement

This study was approved by the Boston University Medical Center Institutional Review Board (# H-37715).

2.4. Provider training and supervision

By design, the providers of the PCIP were social workers providing

integrated care in the BMC Department of Pediatrics, who then also provided the PCIP as part of routine care. At the time of the study there were two full-time Adolescent Medicine mental health social workers, three Pediatrics mental health social workers, and one Psychiatry social worker who provided care in the Pediatrics clinic, all of whom were White cisgender women. The clinic social workers had many years of experience providing integrated mental health care including CBT techniques and strategies to address depression and anxiety symptoms. However, they had minimal training and experience treating PTSD.

Two half-day trainings on the identification of PTSD, trauma-focused care, and implementation of the intervention using didactics and role playing were offered by authors 1 and 2 to all mental health social workers in the Department of Pediatrics, regardless of whether they chose to participate in the research study. Of the six social workers, four provided the PCIP as part of the research study. Ongoing supervision of the intervention by author 1 was offered to social workers, but as a group they decided not to have supervision, and instead have consultation available on an as-needed basis. During the feasibility trial, one social worker requested in-person consultation for a client who was living in a traumatizing and toxic group foster home environment.

2.5. Recruitment and participants

As part of routine care, the Adolescent Center integrated care social workers were paged by clinic staff and providers whenever there was a behavioral or mental health concern about a patient. Following a routine mental health evaluation, the integrated care social workers used their clinical judgment to refer youth who they suspected of having PTSD to the research study. Social workers contacted research staff to notify them of patients who were interested in participating in the research.

We sought to enroll the first 20 primary care patients of the Adolescent Medicine clinic who (1) were between the ages of 12–26 years of age, (2) spoke and read English proficiently, (3) were identified by the integrated care clinic social workers as likely having PTSD, and (4) agreed to participate in the PCIP and the research components, including quantitative and qualitative assessment and access to medical chart information. Patients aged 18 years and older gave written consent to participate in the study. Patients below age 18 gave assent and their parents/guardians gave written consent or verbal consent over the phone. Parental consent for patients under 18 was only required for participating in the research, but not to receive the treatment as part of their routine medical care.

Social workers who provided the PCIP to a patient participating in the study gave verbal informed consent to provide qualitative data on their experience providing the PCIP to study participants. All patients who participated in the research received a \$20 payment on a debit card as remuneration for their time for each pre, post, and follow-up assessment. The treating social workers received \$50 as gratuities for their time spent scheduling study appointments, conducting audio recordings, participating in post-treatment interviews, and liaising with the research staff.

2.6. Implementation outcomes and data collection

Treatment Initiation and Dropout. The number of potential participants approached for participation, number who consented to the study, and the number who completed each of the three PCIP sessions were recorded. Following the original BREATHE protocol (Mueser et al., 2015; Nishith et al., 2015), treatment completion was defined as completing the first two PCIP sessions. The number of PCIP no shows or cancellations were obtained from medical charts.

Engagement in Specialty Mental Health Services During or Following the PCIP. The number of patients who were referred for further mental health treatment within one month after the PCIP and the number of patients who followed through on mental health referrals within three months after the PCIP were obtained from participant

medical records.

Feasibility, Acceptability, and Satisfaction. The social workers who administered the PCIP and the patients who received it were asked to participate in post-treatment semi-structured interviews to understand their perspectives on the feasibility, acceptability, satisfaction with the program, and their observations or experiences of changes in symptoms and functioning. Interviews with patients occurred after the post-intervention quantitative assessment. In cases where a patient had disengaged from the PCIP treatment but was willing to complete assessments, the qualitative interviews were conducted after the patient's last completed treatment session, and interviewers prompted specifically for barriers to completing the treatment sessions or reasons why the patient disengaged.

Social workers who delivered the PCIP were approached for participation in brief qualitative interviews after each of their patients had completed or dropped out of the PCIP. Social workers interviews included questions about PCIP implementation, effectiveness, and barriers and facilitators of treatment. The interviewers had limited contact with social workers in terms of the treatment training and study research procedures in order to minimize demand characteristics or biased responses to interview prompts, and included one bachelor-level research assistants, author 7.

Fidelity. The fidelity of the social workers to the PCIP was assessed using ratings of audio recorded treatment sessions. Two research assistants listened to each audio recording session and completed a brief fidelity checklist of expected treatment components and adherence to the treatment protocol. The fidelity checklist was adapted from the fidelity checklists used in the evaluation of the original BREATHE intervention (Lu et al., 2012). The PCIP fidelity checklist covered 14 domains with approximately four ratings each for a total of 52 ratings per session. Fidelity was scored as the mean of how competently the planned activities were delivered and how closely the therapists adhered to the intervention (1 = Poor, 2 = Satisfactory, 3 = Excellent, or Not applicable). There was strong agreement across the fidelity raters, overall Cohen's $\kappa = 0.836$, p < 0.001. See Supplemental File 1 for a list of the 14 fidelity domains and descriptive statistics of competency ratings.

2.7. Exploratory effectiveness outcomes and data collection

Quantitative data on PCIP treatment mechanisms and clinical outcomes were assessed at three time points: (1) Pre-Treatment (T1) conducted within the two weeks prior to the first PCIP treatment session, (2) Post-Treatment (T2) conducted within the two weeks after the last PCIP treatment session, and (3) the One-Month Follow-Up (T3), conducted approximately one month after the last PCIP session. All quantitative data were recorded via paper log by study staff or as self-report. Demographic data were collected at T1. Participants could still complete the T2 and T3 assessments even if they did not finish all three PCIP sessions. Participants were given the option to complete the questionnaires alone using pen and paper or to have the measures administered verbally by a research assistant. If participants chose to complete the measures alone, research assistants remained available to answer questions. If participants were unable to attend assessments in-person, measures were administered verbally over the phone by research assistants.

Covariates and Descriptives. During the pre-assessment, patients completed a questionnaire to collect information on gender, sex, age, race/ethnicity, education, previous and current engagement in psychotherapy, and previous and current prescribed psychotropic medication. In addition, mental health diagnoses and additional co-occurring non-PCIP sessions with BMC social workers were recorded from patient's medical charts.

PTSD Knowledge. Accurate Knowledge about PTSD was assessed using the PTSD Knowledge Test, which has been used previously to assess change in PTSD knowledge after the BREATHE intervention (Mueser et al., 2009). The PTSD Knowledge Test is a 15-item true/false

and multiple-choice test that assesses information about trauma exposure, PTSD symptoms, associated problems, and treatment outcomes. Cronbach's alpha in this sample was .60. Items 7 ("An example of re-experiencing an event is") and 15 (T/F "Is the following statement true or false? 'The only people who get PTSD are people who have been in a war"') were constant in the sample and so they were dropped. In addition, the alpha was improved to 0.64 with the removal of item 8 (T/F "People who have PTSD often have other problems like using too much alcohol or drugs." Therefore, the PTSD Knowledge Test score reported in this sample is composed of the sum score of the correct answers for the remaining 12 items.

PTSD Symptoms and Hyperarousal. Participants were given the Child PTSD Symptom Scale (CPSS; (Foa et al., 2001) which has been validated with youth between the ages of 8 and 18, and assesses the frequency of 17 PTSD symptoms in the past two weeks that are associated with the participant's most distressing event. Symptoms are rated on a scale from 0 (not at all or only at one time) to 3 (5 or more times a week/almost always). Arousal was assessed using the five hyperarousal items on the CPSS. Cronbach's alpha for arousal in this sample was .74. PTSD symptoms in the past two weeks were assessed using the sum score of the 17 symptom items on the CPSS. The Cronbach's alpha for PTSD symptoms for this sample was .89.

PTSD Related Functional Impairment. PTSD-related Functional Impairment was assessed using the seven functional impairment items from the CPSS which ask participants to indicate whether any PTSD symptoms interfered (Yes = 1, No = 0) in seven domains of life. The Cronbach's alpha was .52, so item level scores were reported.

Trauma Exposure. On the CPSS, participants were asked to answer the following questions, "Please write down your most distressing event" and "Length of time since the event." Most distressing event and time since event were recorded. The most distressing event for participants were separated into events that met, and those that did not meet, DSM-5 Criterion A requirements.

Post-trauma Cognitions. Post-traumatic cognitions were assessed by the Post-Traumatic Cognitions Inventory (PTCI; (Foa et al., 1999)), a 33-item scale. Participants indicate on a scale of 1 (Totally disagree) to 7 (totally agree) how much they agree with thoughts related to their traumatic experiences, and scores are summed with higher scores indicating more distressing post-traumatic cognitions. Cronbach's alpha for post-traumatic cognitions in this sample was .91.

Depression and Anxiety Symptoms. Depression symptoms were assessed using 20 items on the Center for the Epidemiological Studies Depression Scale for Children (CES-DC; (Faulstich et al., 1986). The CES-DC assesses the frequency of 20 self-report symptoms in the past week on a scale of 0 (not at all) to 3 (a lot). Item scores were summed with higher scores indicating higher levels of depression and anxiety. The Cronbach's alpha for this sample was .86. Depression symptoms were also assessed using the 10 items from the low mood subscale of the Revised Children's Anxiety and Depression Scale (RCADS; (Chorpita et al., 2000), which assesses current mood symptoms on a scale of 0 (never) to 3 (always). Cronbach's alpha of the RCADS low mood scale was 0.82. Anxiety symptoms were assessed using the five anxiety subscales of the RCADS, which consists of the sum of 37 items (Chorpita et al., 2000). The Cronbach's alpha of the Anxiety Scale was 0.92.

Substance Use. Substance use was assessed using the CRAFFT Screening Tool for Adolescent Substance Abuse (CRAFFT; (Knight et al., 1999). The CRAFFT is a 9-item (1 Yes; 0 No) measure in which the first 3 items assess consumption of alcohol, marijuana, and other recreational drugs in the past 12 months, and the last six items assess problematic use. The CRAFFT was developed and validated as a clinical tool for use with adolescents between 14 and 18. For this study, the CRAFFT was scored as a sum score of all 9 items. Cronbach's alpha was .86.

Functional Impairment. Participant functional impairment (e.g., school/work, social relationships) was assessed using the Columbia Impairment Scale (CIS) youth version, which is a 13-item scale assessing difficulties with functioning rated 0 (no problem) to 4 (very bad

problem; (Bird et al., 1993). The scale score was the sum and the Cronbach's alpha was .79.

Breathing Retraining Practice. Practice of the breathing exercises in between therapy sessions was coded from the therapy session audio files as a binary outcome for each session.

Development of Coping Action Plans and Coping Practice. Participant use of coping skills was measured by whether and how often participants used positive coping strategies between treatment sessions, and coded from the treatment session audio files as part of fidelity assessment. Raters indicated use of coping skills by participants as "yes" or "no" via fidelity assessments during each session and at the end of treatment, and these were summed to create a frequency score.

2.8. Data analysis

The qualitative interviews with patients and social workers were audiotaped and then transcribed verbatim by research assistants. Thematic content analysis was iterative and followed both an inductive and directed approach with key themes outlined in a priori framework guided by qualitative analytic recommendations (Hsieh & Shannon, 2005). Coders led by author 3 worked collaboratively to adapt the codebook as additional themes emerged from the data related to the central research questions of feasibility, acceptability, and satisfaction. Final themes and codebook were agreed upon and transcripts were coded by three independent coders guided by the codebook using Dedoose Version 8.0.35 (2018). Kappa was calculated for each theme to assess inter-rater reliability with strong overall agreement (k at light's kappa = .828 (Light, 1971). To assess overall satisfaction, the qualitative transcripts were coded by research assistants for statements describing participant and social worker satisfaction with the intervention. Descriptive and summary statistics on fidelity ratings were calculated and reported. Fidelity codes by category were rated from 1 to 3 by two independent raters reviewing all treatment audio files (1 = Poor, 2 = Satisfactory, 3 = Excellent, or Not Completed/Not Applicable) and were summed for a mean score.

Given that this study was a small, pragmatic non-randomized trial designed to collect preliminary data on the feasibility, tolerability, and acceptability of the PCIP intervention delivered in routine integrated pediatric primary care, primary data analysis was limited to summary statistics of demographics, hypothesized PCIP mechanisms, and clinical outcomes scores at each time point and difference scores between time points. In addition, t-tests, analyses of variance (ANOVAs), and chisquare tests were used to assess whether demographic variables were associated with clinical measures at pre-assessment. Fisher's exact tests and ANOVA were used to assess differences in demographic and clinical variables between participants who completed the PCIP, dropped out of the PCIP, or did not start the PCIP.

With a small underpowered sample size, the within-group change estimates are highly imprecise and do not allow for accurate, unbiased, inferential statistics (Leon et al., 2011; Sim, 2019; Thabane et al., 2010). Therefore, hypothesis testing on change in treatment mechanisms and clinical outcomes was exploratory. We used paired samples t-tests with Hedges' g effect sizes and McNemar's chi-square test to explore change between pre- (T1) and post-treatment (T2) and one month follow-up assessment (T3) scores. All analyses were conducted using Stata version 16 (StataCorp, 2019).

3. Results

3.1. Recruitment

Recruitment began in August 2018 and continued until 20 patients provided informed consent, in April 2019. Twenty-three adolescents were referred to study staff with potential interest in participating in the trial, of whom 20 consented, and 19 completed the pre-assessment (82.61% enrollment rate). See CONSORT diagram (Fig. 1) for study

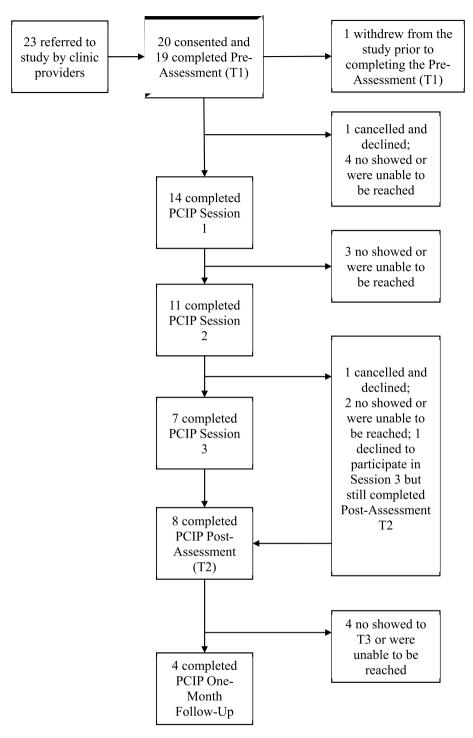


Fig. 1. Study flowchart.

flowchart.

3.2. Demographics

Of the 19 participants, 17 were women/girls and 2 were men/boys; 3 of the 19 also identified as transgender. The participants ranged in age from 14 to 22 years old (M age = 19.32, SD = 2.11). More than 40% (n = 8) identified as Black or African-American, and an additional third (31.58%) identified as Hispanic. Slightly more than half (n = 10; 52.63%) were currently attending school or college. Most of the participants (78.95%) reported that they had been in therapy before, and six (31.58%) reported that they were currently in therapy. Extracted

medical record data indicated that 13 of the 19 (68.42%) participants had a documented PTSD diagnosis in their BMC chart at the time of the study. In addition, six were diagnosed with major depression (31.58%), six with a trauma and stress-related disorder (31.58%), three with an anxiety disorder (15.79%), and one with ADHD (5.26%). Overall, all participants were diagnosed with at least one mental disorder and seven of 19 (36.84%) participants were diagnosed with two or more comorbid mental health disorders. In addition, 11 (57.89%) had been prescribed medication for a mental health concern in their lifetime, with five participants (26.32%) currently taking medication for a mental health concern. The most commonly prescribed medications were SSRIs for depression and/or anxiety (n = 6), followed by unknown medications

for depression/anxiety (n = 2), bipolar disorder (n = 1), lithium (n = 1), and Adderall (n = 1). See Table 1 for the complete demographics.

3.3. Trauma exposure

Thirteen of 19 participants (68.42%) reported distressing events that likely met DSM-5 Criterion A trauma criteria, including five (26%) who reported being sexually abused and/or sexually assaulted, three who reported being physically abused by a parent (16%), two who reported being victims of intimate partner violence (11%), two who reported that they had been kidnapped or held against their will (11%), and one who reported that their mother had overdosed (5%). Three participants reported that their most distressing event was the death of a loved one (16%), but did not include enough information to determine whether

the deaths had been violent or accidental, and three participants reported distressing events that did not rise to the level of Criterion A trauma (i.e., the end of a relationship, unemployment, and parents choosing to terminate their parental rights). Four (21%) of the participants reported that the event or events had occurred within the last month, two (11%) reported it had occurred between one and 6 months ago, six (32%) reported that it had occurred between one and five years ago, and seven (37%) reported that it had occurred more than five years ago. Participants who reported experiencing a Criterion A trauma reported slightly more knowledge about PTSD than those who did not report a Criterion A trauma (M = 9.92, SD = 0.31 vs. M = 8.67, SD = 0.49; t = -2.22, p = 0.04).

Table 1
Baseline variables by dropout

BASELINE SCORES	Total Sample		Completed 2 or more sessions of PCIP		Completed only 1 session of PCIP		Did not start PCIP		F or Fisher's exact	p
Variable (N = 19)	n/M	%/SD	n/M	%/SD	n/M	%/SD	n/M	%/SD		
Demographics (n/%)										
Female	17	89.47	9	81.82	3	100	5	100		1.00
Age (M/SD)	19.32	2.11	19.27	2.61	19.00	1.00	19.60	1.52	0.07	0.93
Race/Ethnicity										0.54
Black	8	42.11	3	27.27	2	66.67	3	60.00		
Hispanic	6	31.58	5	45.45	1	20.00	1	20.00		
Hispanic/Black	2	10.53	1	9.09	0	0.00	1	20.00		
Asian	1	5.26	1	9.09	0	0.00	0	0.00		
Black/Native American	1	5.26	1	9.09	0	0.00	0	0.00		
White	1	5.26	0	0.00	1	33.33	0	0.00		
Currently in school/college	10	52.63	6	54.55	2	66.67	2	40.00		1.00
Highest grade completed (M/SD)	11.58	1.80	11.72	2.15	10.33	1.53	12.00	0.71	0.88	0.43
Mental health history (n/%)										
Previous psychotherapy	15	78.95	10	90.91	1	33.33	4	80.00		0.13
Current psychotherapy	6	31.58	5	45.45	0	0.00	1	20.00		0.4
Previous psychotropic medication	11	57.89	6	54.55	1	33.33	4	80.00		0.5
Current psychotropic medication	5	26.32	3	27.27	0	0.00	2	40.00		0.7
Mental health diagnoses in medical record										
PTSD	13	68.43	9	81.82	1	33.33	3	60.00		0.3
Trauma and stressor related disorder	6	31.58	3	27.27	2	66.67	1	20.00		0.5
Major depressive disorder	6	31.58	3	60.00	0	0.00	3	60.00		0.3
Anxiety disorder	3	15.79	2	18.18	0	0.00	1	20.00		1.0
ADHD	1	5.26	0	0.00	0	0	1	20.00		0.4
Total # of mental health diagnoses (M/SD)	1.53	0.77	1.55	0.82	1.00	0	1.80	0.84	1.02	0.3
Traumatic events (n/%)										
Met Criterion A requirements	13	68.42	9	81.82	0	0.00	4	80.00		0.03
Time since event in years (M/SD)	4.52	4.14	3.08	3.59	2.67	2.51	8.80	3.27	5.41	0.0
Hypothesized mechanisms (M/SD)										
Post-Traumatic Cognitions	143.11	29.69	145.00	27.54	153.67	33.86	132.60	35.59	0.50	0.63
PTSD Knowledge	9.53	1.26	9.64	1.12	8.33	1.53	10.00	1.22	1.90	0.18
Hyperarousal	10.74	3.77	11.09	3.65	8.33	5.51	11.40	3.21	0.71	0.50
Other PTSD symptoms & impairment (M/										
Γotal PTSD symptoms	32.68	11.12	32.27	10.25	31.33	14.84	34.40	13.35	0.08	0.93
Re-experiencing	9.37	3.79	9.18	3.52	10.33	3.79	9.20	5.07	0.10	0.90
Avoidance	12.58	5.14	12.00	4.54	12.67	6.03	13.80	6.80	0.19	0.82
PTSD-related impairment (Yes/No), (n/%)										
Prayers	3	15.79	0	0	2	66.67	1	20.00		0.0
Chores and duties at home	9	47.37	5	45.45	2	66.67	2	40.00		1.00
Relationship with Friends	15	78.95	8	72.73	2	66.67	5	100.00		0.4
Fun and hobbies	17	89.47	11	100	3	100.00	3	60.00		0.0
Schoolwork	7	36.84	5	45.45	1	33.333	1	20.00		0.8
Relationships with Family	13	68.42	7	63.64	2	66.67	4	80.00		1.00
General Happiness with your life	19	100.00	7	100	7	100	5	100		_
Total PTSD-related impairment (M/SD)			4.27	1.42	5.00	1.00	4.20	1.30	0.40	0.67
Other clinical outcomes (M/SD)				-						
CES-DC Depression Symptoms	39.63	10.01	39.91	10.05	39.33	13.61	39.20	10.26	0.01	0.99
RCADS Low Mood Symptoms	18.37	5.51	18.64	5.52	18.00	7.55	18.00	5.61	0.03	0.97
RCADS Anxiety Symptoms	59.89	18.69	60.00	17.88	58.00	23.90	60.80	21.98	0.02	0.98
Substance Misuse	4.32	2.87	4.64	2.58	3.67	4.73	4.00	2.92	0.16	0.85
General Functional Impairment	24.84	9.29	25.18	8.93	21.33	15.31	26.20	7.73	0.25	0.7

3.4. Baseline mental health

Participants reported substantial mental health symptoms (see Table 1), with 15 of the 19 (78.95%) reporting clinically severe or extremely severe PTSD symptoms with CPSS scores of 31 or higher, and 4 (21.05%) reporting subclinical/mild symptoms with CPSS scores between 11 and 15. Four of the participants with symptoms in the severe/ extremely severe range did not have a PTSD diagnosis in their medical charts, while two in the subclinical range did have a recorded PTSD diagnosis. In addition, all 19 participants reported depression symptoms on the CES-DC that were above the clinical cut-off for depression. Results of t-tests identified some significant differences in clinical measures by demographic variables at pre-assessment. Participants who reported that they had previously had therapy reported more hyperarousal symptoms than those who had not at baseline (t = -2.32, p = 0.03). Similarly, participants who were currently receiving non-PCIP mental health treatment reported more hyperarousal symptoms than those who were not (t = -2.26, p = 0.04). Participants who reported having previously been prescribed psychotropic medication reported fewer low mood (t = 2.37, p = 0.03) and anxiety symptoms (t = 2.63, p = 0.02) on the RCADS than participants who had not previously been prescribed psychotropic medication. Finally, although there were only two males in the sample, a gender difference for substance misuse was observed, such that males reported more substance misuse symptoms than females (t =2.47, p = 0.02).

3.5. Implementation results

Treatment Initiation. Five of the 19 (26%) participants who completed informed consent and the baseline assessment, did not start session one of the PCIP (see Fig. 1 for study flowchart). Among these five participants, one (20%) engaged in other mental health services in Adolescent Medicine or Psychiatry during the study.

Treatment Dropout. Of the 14 participants who started the PCIP, seven (50%) completed all three sessions, four completed two sessions (29%), and three completed only one session (21%). Therefore 11 of 14 (79%) received the minimum therapeutic dose of at least two PCIP sessions. Among the 11 participants who completed PCIP sessions 1 and 2, the mean number of days between the sessions was 16.82 days (SD = 11.97; range = 4–42 days). Among the 7 participants who completed PCIP sessions 2 and 3, the mean number of days between the sessions was 12.57 days (SD = 4.93; range = 5-19 days). On average each participant cancelled or no showed to 2.76 (SD = 1.71) scheduled PCIP visits during the course of the study.

Results of Fisher's exact test and ANOVA assessing differences between participants who completed the PCIP (defined as completing at least two sessions; n = 11), only completed one session of the PCIP (n =3), or did not start the PCIP (n = 5) indicated that the number of years since the event predicted treatment dropout or initiation, such that fewer years had elapsed since the traumatic event for participants who completed treatment (M = 3.08 years, SD = 3.59) and those who completed one session (M = 2.67, SD = 2.51) compared to those who never started the PCIP (M = 8.80, SD = 3.27; p = 0.016). In addition, none of the three participants who only completed one session reported trauma events that met Criterion A requirements. In contrast, more than 80% of the participants who completed the PCIP or never started the PCIP reported Criterion A traumas (p = 0.038). Finally, although 66.67% of youth who completed only one session and 20% of youth who never started PCIP reported that PTSD symptoms interfered with their prayers, none of the 11 youth who completed the PCIP reported this as a problem (p = 0.027). See Table 1 for all comparisons. No other trauma exposure, baseline clinical measures, health care utilization, or demographic variables predicted treatment dropout or initiation (see Table 1).

Results of the qualitative data from the post-treatment interviews with social workers and treatment session transcripts indicated that

possible reasons for treatment dropout of the seven participants who did not complete three sessions of the PCIP were: unexpected changes in work schedules (two participants), transportation difficulties, therapist schedule conflicts, preference for a "specialist" therapist, and living in an unsafe environment.

Engagement in Specialty Mental Health Services. PCIP was designed to be a treatment that could both standalone and also be the first step of a stepped care model that includes specialty mental health services. BMC provides specialty mental health services through the department of psychiatry. However, only 2 of 19 (10.53%) participants were seen in specialty psychiatry care in the three months after they completed, dropped out of, or never started PCIP. One of the participants completed two PCIP sessions, while the other completed three. None of the participants who completed zero or one session were seen in psychiatry within three months after PCIP conclusion or dropout.

Fidelity. The average overall rating for fidelity to the intervention was 2.77 (SD=0.501) out of 3, indicating high fidelity (see Supplemental File 1). Of the 14 domains, the poorest fidelity was the clinicians' Overview of Program, with an average score of 2.62 (SD=0.633) indicating fidelity in the satisfactory to excellent range. The following domains were the highest rated, receiving near perfect fidelity and were rated as excellent over 90% of the time: Agenda Setting (M=2.93 SD=0.325, 94.5% of cases), Breathing retraining (M=2.93, SD=0.308, 94.4% of cases), and Overall Manual Adherence (M=2.96, SD=0.272, 98.1% of cases).

Satisfaction and Acceptability of the PCIP. Quotes from post-treatment qualitative interviews with patients and social workers and session transcripts indicated that 11 of the 14 patients (79%) who started the PCIP found it helpful. All of the eight patients who participated in exit interviews said they were satisfied with the treatment and would recommend it to others, such as for individuals "who have [...] anger issue or anxiety," or "if someone really needs help, and they feel lost and don't know what else to do. I would recommend it."

One patient completed all three sessions of the treatment but did not mention finding it helpful in the qualitative transcribed interview; this person had experienced an incident of intimate partner violence on the first day of the PCIP therapy, and her therapist noted that she "was definitely somebody who could have used more [sessions], like a longer kind of set of sessions." Of the two other patients who reported they did not find the PCIP helpful, one was living in a group foster home where she was experiencing ongoing stress, and needed more support than the PCIP provided. Her social worker noted "I felt stuck as far as recognizing that she really needed a lot of help and support and was really struggling and wanting to engage, but ... within those sort of parameters of the intervention, they didn't seem to be effective for her." The social worker of the second patient noted that the patient did not report much distress from the beginning of treatment and speculated she may have engaged in therapy primarily to receive the financial compensation for the assessments.

Two patients noted feeling stressed at the onset of treatment due to concerns about talking about past traumas, but reported that their fears eased with each session. When asked what they would tell someone else interested in participating in treatment one patient responded, "In the beginning, it's hard to like deal with all the emotions, but I felt like it's successful. So, I would definitely recommend it." Another noted "At first I wasn't satisfied, but now I am satisfied, cause now I know how to probably, properly use like these breathing techniques or other strategies to calm down."

Integration of Treatment Into Primary Care. Some patients noted that they felt less stigma attending therapy in primary care compared to specialized mental health services, "I think [in the primary care setting] is fine, because if you go like to specific mental health probably ... I think it's gonna make people feel like something is wrong with them. Like nothing is wrong with you. You just need help." In addition, social workers noted that the intervention was able to function well as part of a stepped care model by providing immediate short-term intervention

prior to possible referral: "I actually think this treatment was helpful in engaging her in more long-term trauma therapy which was what ... the end result was connecting her to long-term therapy, so I think this helped kind of bridge that for her, and like wait time for long-term therapy, so I think it was really effective."

Length of Treatment. All of the patients stated that the brief format was acceptable, and for some was preferable to longer therapy. One patient noted that "it's a good treatment, and it's pretty useful if you don't want a long therapy term session." Providers also observed that the length of the treatment was appealing and made treatment more accessible to patients who would otherwise not have considered a longer therapy. For example, one provider said about a patient:

"Short-term intervention was really appealing to her and I think that that got her in the door. I think the idea of ongoing, long-term, is sometimes really daunting, so to think, like, I'm gonna just—maybe get some quick tools. I don't have to come forever, it's not gonna be the rest of my life [...] and then once she was in, I think she was more, invested and interested."

However, providers also indicated that the brevity of treatment was not appropriate for all patients. Regarding one patient a provider stated, "I think she is someone who short-term intervention isn't gonna be a great fit for, that she really needs a long-term real attention to relationship building over a long period of time." Additionally, one participant had experienced an incident of intimate partner violence (IPV) on the day of the first PCIP session, and the social worker noted that she could have benefited from additional treatment to address safety and other concerns.

Limitations of PCIP. Providers noted the treatment may not be sufficient for all patients, specifically patients with attachment and interpersonal trauma symptoms and, "not as much anxiety-driven." One provider specified that,

"I think that this [treatment] is such a good intervention for the hypervigilance and for flashback, intrusive thoughts kind of symptoms. And for those folks whose trauma experiences have impacted them in those ways. I think the attachment trauma is just so hard, [this treatment] might be like a necessary piece of the puzzle, but I think it's only a small piece."

In addition, one participant was living in a traumatizing foster home situation and reported that the activities of the PCIP such as breathing retraining and coping were not helpful given her toxic home environment. The client required attention to immediate safety concerns and case management, and the client and social worker agreed to stop the PCIP and shift to attending to these needs.

3.6. PCIP components acceptability results

Psychoeducation. Social workers reported that psychoeducation was acceptable for patients, noting that, "Patients overall were very receptive to psychoeducation portions which helped 'normalize symptoms.'" One participant stated "Getting a better understanding of why things are happening. At first, I was just like crazy, but I am ... I actually do have PTSD. I do have the different symptoms. So just like getting the education on it is really beneficial. Being able to open up to other people is also beneficial." In addition, patients reported changed posttraumatic cognitions following psychoeducation. Another said "I have learned that the event was mainly not my fault That, sometimes, there's more always more ways to cope with stress, than the ones I already know." Even for patients with previous therapy experience the psychoeducation was a, "good refresher and a reminder."

Breathing Retraining. Breathing retraining practice in between therapy sessions was coded from the therapy session audio files and all participants reported at least attempting breathing retraining practice in between sessions. Patient engagement with the breathing retraining practice was high, and clinicians noted high satisfaction with most

participants. Additionally, social workers stated the breathing skills were helpful to patients and, "that these were skills that could be practiced and done in the moment and during a stressful situation [...] and help manage the anxieties." In referring to one patient the social worker noted, "the breathing was also incredibly important, because it [gave] her coping strategies to use when she was feeling really like, out of control." One patient noted that the breathing retraining practice had specifically helped her overcome a fear of using public transportation which was originally a significant barrier in her life, and that "she felt really good about that." But the breathing component was not helpful for all patients. One stated that, "I have done breathing a million times with a whole bunch of therapists ... I don't like it and it doesn't work."

Positive Coping and Homework. Development of Coping Action Plans and Coping Practice as measured by whether and how often participants used positive coping in between treatment sessions was coded from the treatment session audio files. Results indicated that only one participant did not work with the provider to develop positive coping action plan for practice outside of sessions. Examples of plans included use of white noise for breathing exercises before bed, and practice on buses and public transportation. All participants reported completing or attempting homework and coping practice between sessions. One provider stated that for one participant, "doing the homework, and integrating the tools into her life, really helped decrease her symptoms." Clinicians noted similar patters across all participants. Regarding one participant's use of positive self-talk and mindfulness exercises coping practice discussed in the second session, the participant, "expressed a significant decrease in her symptoms of anxiety, and, just in general."

3.7. Preliminary PCIP effectiveness results

Of the eight participants who completed the post-assessment (seven of whom completed three PCIP sessions, and one completed two sessions) four had PTSD symptoms that showed clinical improvement: one had PTSD symptoms that changed from extremely severe to severe, one changed from severe to moderate, one changed from severe to mild, and one changed from mild to below threshold. Three had severe PTSD symptoms at both baseline and post-assessment, and one had symptoms that worsened from severe to extremely severe.

Results of exploratory paired t-tests suggested a potential pattern of positive change (see Table 2). Despite the small sample size, there was significant improvement in symptom scores of anxiety (g=0.68, p=0.02) and substance use (g=0.36, p=0.04) symptoms from pre to post, and depression symptoms (g=0.38, p=0.04) from pre to follow-up. In addition, there were trends in symptom improvement for reexperiencing (g=0.52, p=0.09) and low mood (g=0.38, p=0.08) symptoms and for reductions in PTSD-related impairment for engaging in fun and hobbies (100% vs. 62.5%, p=0.08) from pre to post. Other mean scores improved in the hypothesized direction, but the change was non-significant.

4. Discussion

The results of this pragmatic non-randomized trial found that the PCIP was feasible for existing integrated care social workers to provide as part of routine care in a safety net pediatric primary care clinic serving primarily low-income and BIPOC adolescents. The IBHC social workers who provided PCIP had high fidelity to the intervention. This high fidelity is particularly notable given that training was limited to two half-days with optional case consultation and no regular ongoing supervision, and that the social workers were providing the PCIP in the context of their ongoing responsibilities and limitations of normal clinic flow. The social workers were very experienced and reported that they had previously used CBT techniques (Srivastava et al., 2021), which may have contributed to the high fidelity, although their experience treating trauma-related disorders was limited. The simplicity, directiveness, and brevity of the PCIP may have also contributed to the high fidelity. The

 Table 2

 Comparison of Pre-assessment to Post-assessment and One-month Follow-up scores.

Variable	Paired <i>t</i> -Test Pre to Post $(n = 8)$								Paired t-Test Pre to One-Month Follow-Up ($n = 4$)							
	T1 Mean	T1 SD	T2 Mean	T2 SD	t	p	Hedges'	T1 Mean	T1 SD	T3 Mean	T3 SD	t	p	Hedges'		
Post-Traumatic Cognitions	149.63	29.00	131.63	43.51	1.65	0.14	0.43	141.50	30.16	119.25	39.26	2.02	0.14	0.46		
PTSD Knowledge	9.875	1.13	10.38	0.92	-1.08	0.32	-0.43	9.75	0.96	9.25	1.50	0.58	0.60	0.29		
Hyperarousal	11.38	3.16	10.00	4.04	1.46	0.19	0.34	9.50	3.70	8.00	4.76	0.77	0.50	0.26		
Re-experiencing	10.13	2.64	8.13	4.09	1.97	0.09	0.52	10.00	3.27	8.00	4.76	1.15	0.33	0.36		
Avoidance	12.25	4.77	11.63	5.76	0.40	0.70	0.11	11.00	5.35	8.75	7.80	1.51	0.23	0.24		
Total PTSD symptoms	33.75	8.73	29.75	12.33	1.33	0.23	0.33	30.50	10.63	24.75	16.60	1.17	0.33	0.30		
CES-DC Depression Symptoms	40.63	11.82	33.75	14.82	1.84	0.11	0.46	35.00	14.17	26.25	19.16	3.51*	0.04	0.38		
RCADS Low Mood Symptoms	20.00	4.66	17.50	6.87	2.07	0.08	0.38	17.75	4.43	13.00	9.31	1.52	0.23	0.47		
RCADS Anxiety Symptoms	63.75	17.42	47.38	24.99	2.90*	0.02	0.68	62.75	13.30	45.00	33.60	1.47	0.24	0.51		
Substance Misuse	4.88	3.00	3.75	2.60	2.55*	0.04	0.36	5.25	1.89	3.75	1.26	1.57	0.22	0.68		
General Functional Impairment	26.13	9.79	22.63	12.32	0.87	0.42	0.28	23.75	11.95	17.00	13.29	1.42	0.25	0.39		
PTSD-related impairment	T1 n	T1%	T2 n	T2%	McNemar's chi2	p		T1 n	T1%	Т3 п	T3%	McNemar's chi2	p			
Prayers	0	0	0	0	_	_		0	0	1	25	1.00	0.32	-		
Chores and duties at home	4	50.00	5	62.50	0.33	0.56		1	25	1	25	_	-			
Relationship with Friends	5	62.50	6	75.00	1.00	0.32		1	25	3	75	2.00	0.16			
Fun and hobbies	8	100	5	62.50	3.00	0.08		1	100	2	50	2.00	0.16			
Schoolwork	4	50	4	50	0.00	1.00		1	25	1	25	_	_			
Relationships with Family	5	62.50	7	87.50	2.00	0.16		2	50	3	75	1.00	0.32			
General Happiness with your life	8	100	7	87.50	1.00	0.32		4	100	3	75.00	1.00	0.32			

ability to quickly and adequately train providers in PCIP suggests that it might be sustainable in this setting and scalable to other pediatric primary care settings, including clinics with less experienced staff, high turnover, or high workflow, which often makes training and implementation of other EBIs very difficult.

In addition, the PCIP was acceptable to patients and to providers, and researchers were successful in enrolling low-income and BIPOC adolescent patients in the PCIP and the study. Overall, of the 23 patients who were approached for participation, 14 completed session one, an overall treatment uptake rate of 61%, which is a higher rate of reported session one completion than many other studies of trauma treatments for youth (Coulter, 2010; McKay et al., 2005; McPherson et al., 2011). Moreover, of the 14 participants who started the PCIP, 79% received the minimally adequate dose of two sessions, and 50% completed all three sessions, which meets or exceeds the rate of most trauma treatments for youth (Eslinger et al., 2014; McKay et al., 2005; McPherson et al., 2011; Murphy et al., 2013; Steinberg et al., 2019; Wamser-Nanney & Steinzor, 2017; Yasinski et al., 2018), and is better than the dropout rate from IBHC mental health services in the BMC Department of Pediatrics. Of the 1049 patients scheduled for IBHC services in BMC Pediatrics at the time of this study, 910 engaged in care and attended at least one therapy visit (86.7%), but of the 910, only 231 (25.4%) completed three or more sessions. In the context of such a high overall clinic dropout rate, a retention rate in which 79% of youth who started the PCIP received the minimally adequate dose and 50% completed it, is comparatively high, and a statistically significant difference ($\chi^2 = 4.37$, p = 0.036).

Results from the qualitative data indicates that four of the seven participants (57%) who did not complete three sessions, dropped out of care due to scheduling or transportation conflicts, and only two of the seven participants were reported as dropping out due to needing a

different treatment or more intensive mental health care. Therefore, neither dissatisfaction with the PCIP nor preference for a longer treatment were reported to be primary drivers of treatment dropout. Future research on the PCIP may benefit from including strategies to reduce scheduling and transportation difficulties, within the limitations of the primary care clinics. For example, offering sessions in the evenings, providing public transportation cards, or offering the intervention through telehealth. In addition, qualitative interviews with participants who completed the treatment indicated that some had anticipatory anxiety about starting treatment, particularly discussing their traumatic experiences. It may be that some of this anxiety contributed to nonengagement (i.e., not attending session one). Explaining that PCIP does not require talking about or processing traumatic experiences when first introducing the program could further alleviate some of this concern and increase initial engagement.

Notably, all three participants who completed one session of the PCIP and then dropped out of care did not report a Criterion A trauma as their most distressing event. It may be that for this subset of youth, the PCIP which provides psychoeducation about Criterion A events, may not have met their needs in its current form. Additionally, none of the 11 youth who completed at least two sessions of the PCIP reported that PTSD symptoms interfered with their prayers, while two of the three youth who only completed one PCIP session and then dropped out reported that this was a concern (p = 0.027). It may be that the approach of the PCIP is not engaging youth who are more religious and that more attention to religion and spirituality in the first session might improve retention and engagement. Alternatively, youth who report PTSD symptoms interfering with prayer may be experiencing symptoms such as moral injury, shame, or guilt, that are not only interfering with their religious practice, but also their engagement in care. Research on

whether efficacy and dropout are moderated by trauma-exposure type and whether the intervention should be modified to better address non-Criterion A events and the relationship between trauma, PTSD, and religion or spirituality is needed.

Although the sample is small, and the X^2 test was non-significant (p = 0.54), the results indicate that 37.5% of Black youth did not initiate treatment compared to 16.7% of Hispanic youth, and that 25% of Black youth dropped out of treatment (i.e., completing only 1 session) compared to 16.7% of Hispanic youth. Several predictors of differences in treatment initiation and dropout among racial-ethnic groups have been found in the scientific literature, and most of these relate to both structural barriers (e.g. transportation) and/or disengagement due to difficulty in the therapeutic relationship and mistrust (Ghafoori et al., 2019). Further tailoring of the intervention might focus on adaptations that address these factors, including examining engagement based on whether there is therapist-patient match, identifying and proactively discussing solutions to structural barriers, or making sure that videos and materials are adequately reflective of Black youth and their experiences. Additionally, in a study on PTSD intervention in adults, although African American participants were more likely to drop out of treatment, there were no differences in their post-treatment PTSD scores compared to White participants, suggesting that racial differences in dropout may have been partly explained by greater and more rapid symptom improvement of African American people (Lester et al., 2010). Future research should investigate whether differences in clinical outcomes may partially explain differential dropout by race/ethnicity.

There are many ways in which treatments and treatment settings could be adapted to better serve minoritized youth. For example, there may be increased acceptability of therapeutic services for minoritized individuals when the mental health provider's background (i.e., race/ ethnicity, gender identity, sexual orientation, etc.) matches that of the patient, although the psychological literature on whether this increases treatment outcomes specifically is mixed and very limited (Karlsson, 2005). However, patient-provider background match may be especially important to BIPOC youth. Indeed, cultural match was one of the qualitatively suggested adaptations from adolescent participants during the formative research for the PCIP (Srivastava et al., 2021). This intentional pairing could increase acceptability of psychological services for patients and increase their retention in the treatment, which could increase the possibility of accessing more psychological treatment in the future (i.e., as a scaffolded-approach). Unfortunately, considering that mental health providers delivering this treatment would likely be embedded in primary care, and, as of data in 2015, the field of psychological professionals is majority White (81%) and cis-female (69%) (American Psychological Association, 2022), it may be infeasible for most clinics to match participants based on these characteristics. Additionally, there are important considerations for future researchers working with minoritized individuals to consider including the measurement of identity factors in research (i.e., race/ethnicity) and the criteria the field uses to diagnose psychological problems (i.e., PTSD) and its lack of reflection of the experiences of BIPOC individuals.

Qualitative results suggested that the brevity of the treatment - only three sessions - and its availability in pediatric primary care, which was perceived by some patients as less stigmatized than specialty mental health care, made it highly acceptable and accessible for patients. In addition, the PCIP was offered by existing integrated care social workers who had experience working with youth and were able to provide additional support and case management when crises arose that were beyond the purview of PCIP, such as IPV. This demonstrates the importance of offering PCIP within existing systems of care that can address multiple overlapping needs.

Despite positive feedback on the PCIP generally, some social workers believed that for a subset of patients, particularly those who experienced "attachment and interpersonal" trauma, the PCIP may not have been sufficient and that more intensive treatment was needed. Results indicated that patients with more early life trauma were less likely to start

treatment than patients with more recent traumatic experiences, and so it may be that these youth require more engagement overall, and may have benefited from the PCIP once engaged. Further research is needed on both the efficacy of the PCIP overall, and whether participants with more early childhood attachment-related traumas should be referred to a different level of care or whether adaptations to PCIP should be made to better accommodate these youth.

Although specialty mental health treatment was available to all patients participating in the PCIP, and therapists were asked to refer patients who could benefit from further treatment to psychiatry, only two of the patients who completed two or more PCIP sessions attended any appointments in psychiatry after the PCIP concluded, and none of the patients who completed zero or one PCIP session received specialty mental health services within three months of treatment dropout. This suggests that although some patients may have benefited from additional treatment, the vast majority of patients did not pursue additional or alternative treatment. Considering the high patient need and the evidence of a large gap between levels of care in this population, this is further support for the need for a brief treatment option rather than the options of no care or intensive longer-term evidence-based treatment offered in specialty mental health settings.

Results also indicated that the PCIP was satisfactory and acceptable to patients and social workers and led to clinically-meaningful PTSD symptom improvements for half of participants who completed the post-assessments and significant pre-post improvements for associated symptoms of anxiety, depression, and substance use. All patients who completed the post-assessment qualitative interviews reported that they benefited from the PCIP and would recommend it to others, and providers also reported that patients benefited from treatment. Moreover, five of the seven participants who did not complete all three sessions also reported to have benefited from the treatment. The hypothesized mechanisms of change of normalizing symptoms through psychoeducation, breathing retraining to reduce physiological arousal, and coping skills to improve daily functioning were also supported by the qualitative data.

This pragmatic feasibility study is strengthened by having been conducted under "real-life" conditions of an integrated care pediatric primary care clinic. However, this was a small, open pilot trial and so results must be tempered by those limitations. Results may not be generalizable to other clinics or populations, and we cannot compare our results to treatment as usual or to other evidence-based treatments for PTSD. The promising findings of high acceptability, feasibility, and initial clinical effectiveness provide support for further investigation in a larger-scale study of PCIP. Specifically, further research is needed to assess the efficacy, implementation, and uptake of the PCIP compared to treatment-as-usual and to other evidence-based treatments for PTSD, and whether there are subsets of youth who may have differential response to the PCIP or who would benefit from direct referral to specialty care. Additionally, treatment, assessments, and interviews were conducted solely in English and therefore results are limited to fluent English speakers. Future research should assess the acceptability and feasibility of PCIP delivered in other languages such as Spanish, which is the second most commonly spoken language of patients at BMC, and through the use of medical interpreters.

5. Conclusion

The PCIP is the first IBHC treatment for PTSD in adolescents ages 12–21. The use of only three sessions, limited training needed for high treatment fidelity, and simplicity of implementation made the PCIP feasible within a fast-paced resource limited primary care clinic and fit within the clinic's traditional IBHC model of care. The PCIP was designed to address health system barriers to delivering PTSD treatment in a pediatric primary care clinic that primarily serve low-income and BIPOC youth, thereby providing a treatment option to allow vulnerable patients to immediately start managing their PTSD symptoms in a

familiar and accessible health service setting. The findings suggest the promise of clinically significant improvement in a few sessions, and high acceptability and feasibility of PCIP implementation as a standard of care in "real-life" pediatric IBHC. The PCIP may facilitate faster connection to care upon identification by their pediatrician, which may substantially improve treatment engagement and access, particularly for low-income and BIPOC youth (Ayalon et al., 2007; Johnson & Possemato, 2019). Future research to assess PCIP's effectiveness in comparison to treatment-as-usual or referral to specialty care treatment, as well as larger-scale implementation of PCIP as a care standard is warranted.

CRediT authorship contribution statement

Lauren C. Ng: Conceptualization, Methodology, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing - review & editing, Visualization, Supervision, Project administration, Funding acquisition. Alexandria N. Miller: Formal analysis, Investigation, Resources, Data curation, Writing - review & editing. Gray Bowers: Formal analysis, Data curation, Writing - original draft, Writing - review & editing, Visualization, Project administration. Yuhan Cheng: Formal analysis, Investigation, Data curation, Writing – review & editing. Rebecca Brigham: Methodology, Investigation, Writing - review & editing, Supervision. Ming-Him Tai: Investigaton, Writing - review & editing. Ash M. Smith: Investigation, Writing - review & editing. Kim T. Mueser: Conceptualization, Writing – review & editing. Lisa R. Fortuna: Conceptualization, Writing – review & editing, Funding acquisition. Mandy Coles: Conceptualization, Methodology, Investigation, Writing - review & editing, Supervision, Funding acquisition.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

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