

Adaptation of a PTSD intervention for use in primary care in a low-income country: The Brief Relaxation, Education and Trauma HEaling intervention for Ethiopia (BREATHE Ethiopia)

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ABSTRACT

Posttraumatic Stress Disorder (PTSD) symptoms amongst people with serious mental illness (SMI) are prevalent in Ethiopia and throughout the world, yet treatment is scarce, particularly in low-resource settings with few mental health providers. This study describes the process of adapting a PTSD treatment, originally designed to be delivered by mental health providers in specialty mental health clinics in the US, to be appropriate, acceptable and sustainable when delivered by non-specialist providers in routine care in rural Ethiopian primary care clinics. Methods included a literature review, qualitative interviews (N = 48), an adaptation workshop (N = 12), and theater, cognitive, and usability testing (N = 14) with people with SMI, caregivers of people with SMI, health care providers, and community leaders. Participants found the intervention to be appropriate and acceptable, while also noting multiple patient, family, provider, clinic and community-level barriers that might impact successful delivery and receipt of the intervention. The intervention was adapted to address as many barriers as possible, while maintaining adherence to the original intervention's theoretical and conceptual model. While many of these barriers could be addressed with adaptations, others such as high rates of poverty and limited population-level mental health awareness, require policy and community-based solutions and systemic change. Future research is needed to assess whether the intervention is feasible and effective in this setting.

1. Introduction

Serious mental illness (SMI) including psychotic, bipolar, and

persistent major depressive disorder, is one of the most common forms of mental illness seen in primary care clinics in low- and middle-income countries (LMICs) (Ventevogel et al., 2011; Kane et al., 2014). In

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high-income countries, 25–50 % of people with SMI are thought to have posttraumatic stress disorder (PTSD) (Grubaugh et al., 2011; Bajor et al., 2013); more than seven times the proportion in the general population (Kessler et al., 2005). In Ethiopia, where this study was conducted, a prior history of mental illness has been associated with increased risk of PTSD symptoms (Melkam et al., 2023). The high rate of PTSD and SMI comorbidity has been attributed in part to higher rates of trauma and social adversity experienced by individuals with SMI (Mauritz et al., 2013; Sin et al., 2017; Mueser et al., 2004), trauma exposure increasing the risk of future SMI symptoms through a diathesis-stress or stress-vulnerability model (Mueser et al., 2002), and conversely, pre-existing psychiatric symptoms increasing risk of developing PTSD after exposure to trauma (North et al., 1997). Moreover, SMI symptoms and associated challenges, such as substance misuse and cognitive impairment, have been positively associated with risk of future trauma exposure (Mueser et al., 2004; Grubaugh et al., 2011).

For individuals with SMI, comorbid PTSD has been associated with more severe positive psychosis symptoms, depression and anxiety symptoms, more suicidal ideation, and greater interpersonal deficits and lower quality of life (Mueser et al., 2004a; Mueser et al., 2004b; Lysaker and Larocco, 2008; Duke et al., 2010; Mueser et al., 2010; Ng et al., 2016; Seow et al., 2016). Researchers have posited that comorbid PTSD exacerbates co-occurring SMI symptoms, further undermining psychosocial functioning (Mueser et al., 2004; Seow et al., 2016). Perhaps as a result, people with SMI who have experienced traumatic events are less likely to adhere to medication and are prescribed higher doses of anti-psychotics and mood stabilizers compared to those without a trauma history (Conus et al., 2010; Schneeberger et al., 2014). There is limited research on treatments for PTSD in people with SMI (Sin et al., 2017; Mabey and van Servellen, 2014), but some evidence-based interventions (EBIs), such as eye movement desensitization and reprocessing (EMDR), exposure based CBT, and CBT for PTSD have been shown to improve PTSD, depression, anxiety and other psychiatric symptoms in individuals with comorbid schizophrenia spectrum-disorders or bipolar disorder (Mabey and van Servellen, 2014; Frueh et al., 2009; Trappler and Newville, 2007; Mueser et al., 2008; van den Berg et al., 2015). However, these interventions were developed in high-income countries (HICs) and have not been evaluated in the diverse cultural and social contexts found in LMICs. Although some interventions for PTSD have been adapted for use in LMICs, trials have excluded people with SMI (Bolton et al., 2014; Murray et al., 2013, 2014; Neuner et al., 2008). Likewise, only a handful of psychosocial intervention studies for people with SMI have been conducted in LMICs, none of which assessed PTSD (van Ginneken et al., 2013; De Silva et al., 2013; Chatterjee et al., 2014; Sokhela and Uys, 1998). Consequently, very limited data on interventions for comorbid PTSD and SMI are available from LMICs (Ntlantsana et al., 2024).

The need for adaptation aligns with systematic reviews and meta-analyses which have found that culturally-adapted interventions are not only effective (Rathod et al., 2018; Ellis et al., 2022; Griner and Smith, 2006), but are generally more effective than un-adapted interventions (Healey et al., 2017; Arora et al., 2021). Indeed, some studies have found a positive association between the number and quality of the adaptations made and intervention effectiveness (Arora et al., 2021; Harper Shehadeh et al., 2016). Additionally, culturally adapted interventions are most effective when the adaptations are made for specific groups or communities (Griner and Smith, 2006). Adaptations are also common — systematic reviews of psychological interventions in LMICs have found that only 14 % were developed elsewhere and were implemented without adaptation (Ng, 2023; Ventura-Conerly et al., 2023), although the extensiveness of adaptations ranges widely from minor surface level adaptations to very substantial modifications (Ennis et al., 2020). Nonetheless, a criticism of treatment adaptation is that it may dilute treatment fidelity in service of facilitating implementation and dissemination (McHugh et al., 2009). However research on modular and principle-based interventions has found

that interventions that maintain fidelity to theoretical and conceptual principles of empirically supported treatments can be personalized or adapted to specific settings and clients while maintaining their effectiveness (McHugh et al., 2009).

Although research indicates that adaptations can be made to improve the fit of an intervention to specific culture and context, most articles on the topic provide insufficient information about adaptation process. Specifically, it is uncommon for descriptions of the process to provide enough detail about the rationale for, process of, and specific adaptations made to determine whether and how the theoretical and conceptual principles underlying the intervention were preserved (Healey et al., 2017; Arora et al., 2021; Harper Shehadeh et al., 2016; Ennis et al., 2020). This paper seeks to fill part of that gap by providing a detailed description of the multiple steps taken and iterative adaptations made to increase the appropriateness, acceptability, and sustainability of the BREATHE Ethiopia study while maintaining its core elements.

In Ethiopia, more than 1 % of the population (Alem et al., 2009) lives with SMI and 10 % have at least one relative with SMI (Girma et al., 2013a). People with SMI in Ethiopia experience high rates of stigma, neglect, road traffic accidents, and human rights abuses such as chaining and restraint, and physical or sexual violence (Girma et al., 2013a; Tiruneh et al., 2014; Assefa et al., 2012; Girma et al., 2013b; Girma et al., 2014a; Girma et al., 2014b; Mulatu, 1999; Shibre et al., 2001; Shibre et al., 2003; Teferra et al., 2011; Fekadu et al., 2016; Alem, 2000; Tsigebrhan et al., 2014; Ametaj et al., 2021; Ng et al., 2019). In addition, they report commonly experiencing other highly stressful events including labor abuse, family neglect, exposure to the elements, and financial difficulties (Ametaj et al., 2021; Nordanger, 2007). Overall, 25 % of people with SMI in Ethiopia die from unnatural causes (Fekadu et al., 2015). In the general population, nearly half of rural Ethiopians experienced major threatening events in the previous six months (Fekadu et al., 2014). Factors such as poverty, limited healthcare access, road traffic injuries, intimate partner violence, sexual assault and exploitation, child labor and marriage, migration and trafficking, and displacement and armed conflict disproportionately affect people in Ethiopia and may contribute to elevated PTSD rates (Ametaj et al., 2021; Abeya et al., 2011; Devries et al., 2011; Feseha et al., 2012; Garoma et al., 2012; Gelaye et al., 2009; Tadege, 2008; Nicodimos et al., 2009; Semahegn et al., 2013; Fekadu et al., 2006; Gage, 2013; Anbesse et al., 2009; de Jong et al., 2003; Ouyang, 2008; Shannon et al., 2015; Araya et al., 2007; Malaju et al., 2022; Denu et al., 2021). The need for culturally and contextually appropriate evidence-based PTSD interventions in Ethiopia was already apparent (Melkam et al., 2023), but unfortunately has likely grown since civil war and ensuing and ongoing ethnic conflicts broke out in the country in 2020. Societal concern about the mental health effects of traumatic exposure is evident (Birhan et al., 2023; Tinsae et al., 2024; Gebreyesus et al., 2024; Madoro et al., 2020; Melese et al., 2024; Salelew et al., 2024). Although limited by a lack of validated measures, levels of PTSD symptoms in the clinical range have been endorsed by 39 % of the overall population (Melkam et al., 2023) and 48 % of people living in war-affected areas of Ethiopia (Tinsae et al., 2024). Several recent studies of community-based samples in Ethiopia have documented the prevalence of clinically significant PTSD symptoms in war affected communities as being between 19 % and 56 % (Birhan et al., 2023; Anbesaw et al., 2022; Teshome et al., 2023; Kas-saye et al., 2023). Moreover, 58 % (Madoro et al., 2020)-68 % (Makango et al., 2023) of people who have been internally displaced by the conflict report levels of PTSD symptoms in the clinical range.

Strong social capital, community responses, and (for the sub-group of people for whom symptoms persist or are severe) mental health interventions may help mitigate the mental health impacts of trauma. However, there is currently little provision of mental health services in Ethiopia for individuals with conditions that require treatment (Inter-Agency Standing Committee (IASC), 2007; Yigzaw et al., 2023). This is partly due to a shortage of mental health professionals throughout the country (–2025 National Mental Health Strategic, 2020;

World Health Organization, 2020). Moreover, although 80 % of the population live in rural areas, almost all of the mental health providers work in Addis Ababa (WHO and Ministry of Health, 2006), making regular care inaccessible for most.

Given the shortage of mental health specialists, the Ethiopian government has prioritized the integration of mental health services into primary care to increase access (Federal Democratic Republic of Ethiopia, 2012). As part of this initiative, psychotropic medications for SMI are being introduced in primary care clinics (Fekadu et al., 2016; Fekadu et al., 2014; Lund et al., 2012). In several clinics, primary care staff have been trained to identify psychosis, including schizophrenia and bipolar disorder, prescribe psychiatric medication, provide basic psychosocial care, support and monitoring, and refer for more intensive services to the district hospital and to the specialty psychiatric hospital in Addis Ababa. Health extension workers (community health workers) are also trained to identify people with psychosis in the community and link them to the primary care services (Fekadu et al., 2016). These models of care have been found to be cost-effective, safe, and efficacious (Hanlon et al., 2019, 2022). Health care providers involved in these programs report increased willingness to offer broader treatment options, including psychological therapies, to people with SMI (Hook et al., 2021).

In addition to medication management, a few evidence-based psychological therapies that are appropriate for use in Ethiopian primary care have been developed and tested, including for depression symptoms and intimate partner violence in pregnant women (Keynejad et al., 2023; Bitew et al., 2021; Keynejad et al., 2024) and for managing bipolar disorder (Demissie et al., 2021), but their focus is narrow, and barriers to their implementation and sustainability must be addressed (Hook et al., 2021; Hanlon et al., 2014). In Ethiopia, primary care clinics are staffed by health officers and nurses with minimal mental health training, limited time for patient care, and high staff turnover (Fekadu et al., 2016; Hanlon et al., 2014; Abera et al., 2014; Mendenhall et al., 2014; Birhanu et al., 2010), contributing to job strain and logistical difficulties in providing psychological therapies (Hook et al., 2021). Additionally, poor provider-patient communication and a lack of training in therapeutic counseling skills are barriers to the implementation of psychological therapies in Ethiopian primary care (Hook et al., 2021).

Rural populations also face barriers to primary care including low literacy rates, long distances to clinics, and poverty, all of which discourage help seeking (Lund et al., 2012; Hook et al., 2021; Hanlon et al., 2014; Birhanu et al., 2010; Girma et al., 2024). Despite these challenges, service users, caregivers and providers in Ethiopia support provision of mental health services in primary care due to ease of access, lower costs, and reduced caregiver burden (Hook et al., 2021; Mayston et al., 2015). Over 90 % of primary health care workers in Ethiopia recognize mental illness as a significant issue and want mental health services, including psychological therapies, integrated into their health facilities (Hook et al., 2021; Abera et al., 2014; Mayston et al., 2015).

There is a need for an intervention for PTSD symptoms for people with comorbid SMI that can be delivered in Ethiopian primary care settings by existing clinic staff as part of routine care. Successful implementation of a PTSD treatment at the primary care level is of particular concern because first-line EBIs for PTSD, such as Cognitive Processing Therapy (CPT) (Resick and Schnicke, 1993) and Prolonged Exposure (PE) (Foa et al., 2007) require intensive specialized training and 10 to 12 weekly 60–90 min sessions. Even where evidence-based PTSD interventions are used regularly, they are usually not implemented with fidelity, with clinicians typically only using half of the core components of the EBIs (Wilk et al., 2013). Frequently identified barriers to implementing these interventions include limited time within existing clinic systems and heavy workloads (Chard et al., 2012; Borah et al., 2013).

Recently, brief interventions for PTSD that are appropriate for primary care in the United States (US) have been developed (Hoeft et al., 2019), but these interventions have primarily been implemented by

integrated care case managers or behavioral health providers, with primary care providers (if involved) overseeing medication management. The vast majority of these studies have been conducted in US Veterans Affairs (VA) or military primary care clinics, with mostly male US veterans (Hoeft et al., 2019; Gehringer et al., 2020). While these approaches are promising, they rely on specialized providers with mental health expertise and may not generalize to LMIC primary care settings which are typically staffed with only general medical health officers and nurses without mental health training. Given these concerns, the WHO has developed guidelines for PTSD care in LMIC primary care settings which suggest that primary care providers offer interventions that take only hours to learn and to implement, and include providing psychoeducation about PTSD, strengthening social support and positive coping and stress management including breathing exercises (World Health Organization and United Nations High Commissioner for Refugees, 2015; World Health Organization and United Nations High Commissioner for Refugees, 2013). The WHO guidelines further state that “advanced intervention” such as trauma-focused CBT or EMDR, should not be provided at the primary care level, but that referral to trained and supervised therapists for these treatments, if available, may be warranted (World Health Organization and United Nations High Commissioner for Refugees, 2015; World Health Organization and United Nations High Commissioner for Refugees, 2013). By focusing on an intervention based on these guidelines, we aim to improve feasibility, appropriateness, and adoption and implementation in the Ethiopian health care system (Zoellner et al., 2014).

Therefore, the goal of this study was to adapt an evidence-based PTSD intervention for people with comorbid SMI that could be feasibly delivered within routine care by primary care providers in Sodo and South Sodo Districts in Ethiopia. To achieve this goal, we had two specific aims: The first was to identify clinically- and culturally-relevant characteristics of people with SMI that could be incorporated into the manual to enhance acceptability and patient satisfaction; the second was to identify patient-, provider-, and facility-level barriers to implementation that could be addressed in the intervention manual to increase implementation and intervention success.

2. Methods

Setting. The study took place in primary care medical facilities in Sodo and South Sodo districts, Ethiopia in the East Gurage Zone (Fekadu et al., 2016). These districts are 90 % rural and agrarian, with over 150,000 residents spread across widely dispersed villages that are difficult to access. Between them, the districts have one primary hospital with two non-specialist physicians and a psychiatric nurse, as well as eight primary care clinics predominantly staffed by nurses and health officers. Each health center has between eight and 24 staff members, and there is high staff turnover. Each clinic serves approximately 20,000 people. Medication management for SMI is available in the clinics, and health extension workers (i.e., community health workers) provide limited community outreach to individuals with SMI.

Procedures. To adapt the intervention for individuals with comorbid SMI and PTSD that could be delivered in Ethiopian primary care settings, we followed the “Assess” and “Select” steps of the widely used Center for Disease Control’s Map of Adaptation Process: A Systematic Approach for Adapting Evidence-Based Behavioral Interventions (MAP) (McKleroy et al., 2006). This is a “bottom up” stage approach that systematically documents and tests the fit of the intervention to the community and treatment setting and identifies whether and which cultural adaptations are necessary (Ennis et al., 2020). The “Assess” step involves gathering information about six topics including the target population, evaluating the fit of potential EBIs and organizational capacity, and seeking input from stakeholders, while the “Select” step focuses on choosing and adapting the EBI with stakeholder input, and provides detailed suggestions for how to do so (e.g., build capacity on subject and implementation skills, consult with community, consult with staff)

(McKleroy et al., 2006). We aimed to preserve the core elements of the intervention as defined by the developers, documenting all adaptation activities and justifications (Perez et al., 2019; Check and Tuzzio, 2021). Details of these specific steps are described below and in Fig. 1 the flow chart of activities.

Procedures Step 1. Intervention Identification and Selection. First, in 2017 we conducted a literature review in PsycInfo and PubMed to identify interventions suitable for adaptation. To ensure the intervention for PTSD in people with SMI could be effectively implemented in Ethiopian primary care settings, we focused on finding an intervention that: (1) has demonstrated effectiveness in the SMI population; (2) is straightforward and standardized, given the limited experience of primary care staff in delivering mental health services (Mayston et al., 2015); (3) is brief, to accommodate the time constraints of primary care settings, and (4) can be delivered flexibly to large numbers of people in low-resource settings to increase reach and impact (Glasgow et al., 1999; Beaglehole et al., 2008), thereby increasing equity and access to care.

Procedures Step 2: Qualitative interviews with key stakeholders (N = 48). Semi-structured qualitative interviews were conducted with people with SMI, caregivers, providers, community leaders, and members of the Ethiopian PRogramme for Improving Mental health care (PRIME) community advisory board (CAB) (Fekadu et al., 2016). PRIME was a multi-country research program investigating the implementation of district level mental health care in primary care. In this program, primary care providers use the WHO Mental health gap intervention guide (mhGAP-IG) to assess, diagnose, treat, and provide basic psychosocial support to people with SMI (Nishith et al., 2015; Fekadu et al., 2014; Lund et al., 2012).

The interview guides were developed using existing literature and results of preliminary studies (Ng et al., 2019). The guides included open-ended questions to facilitate inductive analyses and more specific probes to identify and understand: (1) clinically- and culturally-relevant characteristics of people with SMI that could be incorporated into the intervention to improve acceptability and satisfaction and (2) patient-

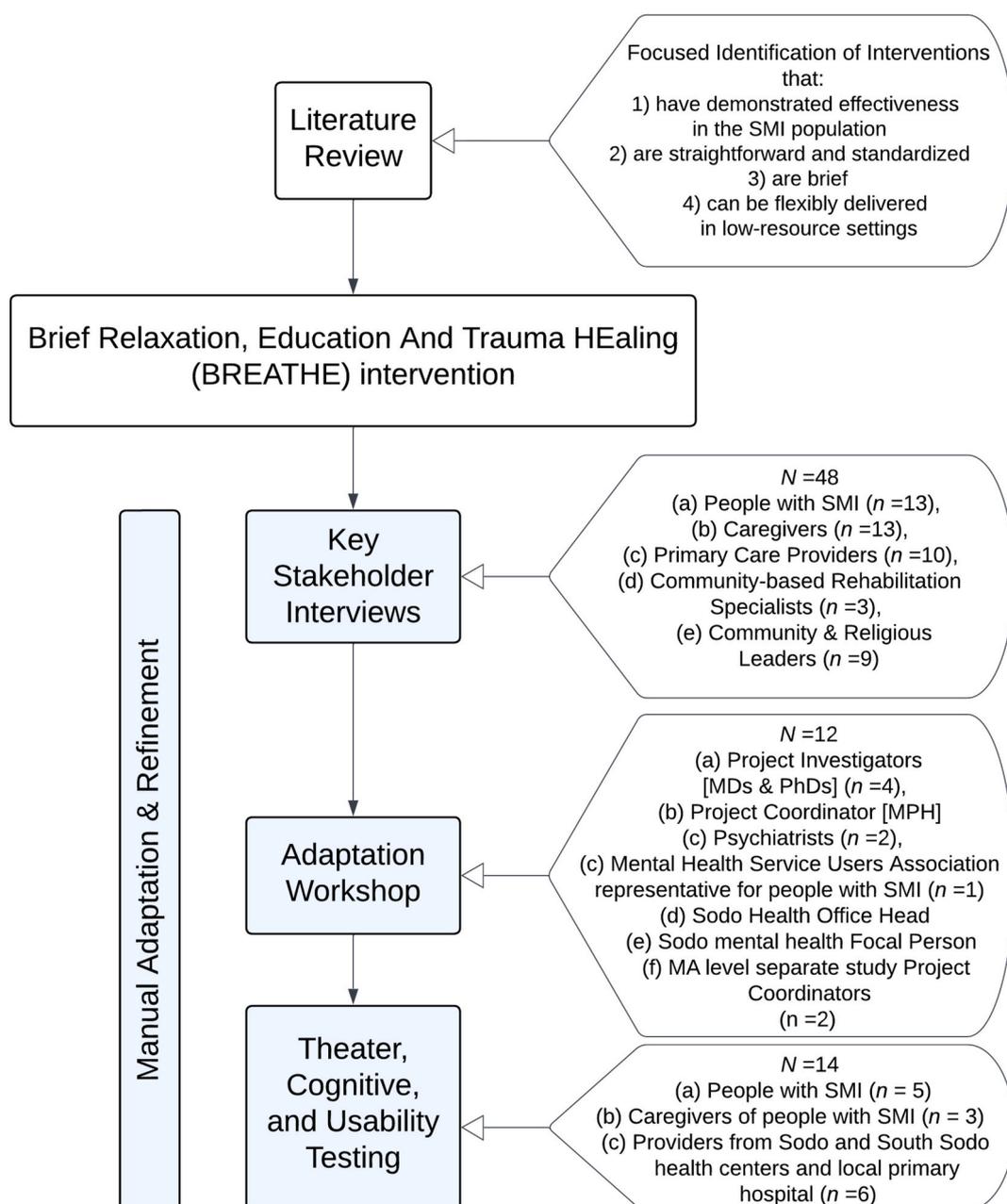


Fig. 1. Flowchart of intervention Identification and adaptation.

provider-, and facility-level barriers and facilitators of implementation. Interview questions were refined iteratively, with common themes from early interviews leading to the inclusion of relevant topics in subsequent interviews.

Interviews were conducted in Amharic at the primary care centers by a master's level Amharic/English bilingual interviewer. The interviewer had previous experience conducting qualitative interviews with people with SMI through PRIME and had received additional training on study protocols and discussing sensitive topics relevant to trauma and PTSD. Interviews were audio recorded, transcribed and translated verbatim into English by translators from the Department of Psychiatry at Addis Ababa University. Interviews were conducted from November 2017 until saturation was reached in May 2018. The study was approved by the Institutional Review Boards (IRB) of Addis Ababa University College of Health Sciences and the Boston University Medical School. Other data from these interviews has been published previously (Ametaj et al., 2021; Hook et al., 2021).

Recruitment and eligibility. Purposeful sampling was used to recruit people with SMI, caregivers, healthcare providers, and community and religious leaders from the catchment area of the eight primary care clinics in Sodo and South Sodo. Eligible participants included individuals enrolled in the PRIME study who had been diagnosed with SMI by trained primary care providers and psychiatric nurses ($n = 300$) and their caregivers. PRIME participants who had not recently participated in other ongoing studies were identified and recruited by PRIME staff for this qualitative study. People with SMI were excluded if they reported active suicidal or homicidal ideation or a suicide attempt within the past 30 days. Caregivers were identified by people with SMI as close family members or friends who provided them with support.

In addition, district and community-based healthcare providers who provided care for, or supervised the care of, people with mental health concerns were approached for participation. Finally, community and religious leaders who were members of the PRIME CAB or were identified by the CAB as being a community or religious leader, traditional or faith healer, or a head of a health bureau were approached for participation. All participants were required to be at least 18 years old, capable of providing informed consent, able to communicate in Amharic, and able to complete a 30- to 60-min interview. Participants received 100 ETB for their time and were reimbursed for travel costs.

Data Analysis. The analysis was iterative and followed a descriptive qualitative thematic content analysis approach (Hsieh and Shannon, 2005; Bernard, 2011). Concepts were used to create a codebook, which included labels, definitions, and illustrative quotes from the data. NVivo 12.0 software (NVivo qualitative data analysis software, 2018) was used for coding. To address the central research questions, five trained coders utilized both a "conventional" inductive approach and a "directed" *a priori* approach to the content analysis. Initially, coders collaboratively analyzed a subset of English interview transcripts until Kappa scores of 0.85 were reached across all coded themes. Afterward, coders worked independently, continuing discussions to refine theories, and make connections between research questions, coding categories, and raw data. The codebook and final themes were agreed upon in consultation with the full research team.

Procedures Step 3: Adaptation workshop with key stakeholders (N = 12). In May 2019, results from the qualitative interviews were presented at a manual adaptation workshop in Addis Ababa. Invitations were extended to researchers working with people with SMI in the study districts, Ethiopian mental health professionals, service user associations, and district health care administrators and government officials.

During the workshop, project investigators presented the study rationale, qualitative interview findings, and an introduction to the intervention. Feedback was gathered on the qualitative interview results and the potential adaptations, focusing on clarifying intervention content and procedures. The Principal Investigator (LN) and the project coordinator (EGS) took detailed notes on the discussion, perspectives, and final consensus on the adaptations. After adaptation, we developed

a manual that describes the purpose, principles, and methodology of the adapted intervention. Following World Health Organization (WHO) protocols (World Health Organization, 2015), members of the Addis Ababa Department of Psychiatry forward- and back-translated the intervention manual, materials, and instruments.

Procedures Step 4: Theater, cognitive and usability testing of the adapted manual and materials with people with SMI and providers (N = 14). In January 2022, the adapted manual and materials were pre-tested (McKleroy et al., 2006) using theater (Wingood and DiClemente, 2008), cognitive (Willis et al., 1994; Jobe and Mingay, 1989) and usability testing (Barrera et al., 2013a) with a convenience sample of people with SMI, caregivers of people with SMI, and healthcare providers from the Sodo and South Sodo health centers and local primary hospital. This process aimed to refine the translation, accuracy, appropriateness, utility, and attractiveness of the manual and materials. Separate workshops were held for people with SMI and for providers.

During theater testing, two project coordinators and a PhD student in the AAU Department of Psychiatry, who had previously developed and tested a psychosocial intervention for people with bipolar disorder in Sodo district (Demissie et al., 2021) role played the intervention for the audience of workshop participants. Selections of the adapted intervention were acted out, including the introduction to the intervention, breathing retraining, psychoeducation about trauma and PTSD, coping skills, and addressing problems associated with PTSD (e.g., substance use, interpersonal difficulties). After each segment, facilitators conducted focus groups to gather feedback on the content, delivery, and acceptability of the treatment. Sample questions included, "How could we make this information clearer?" "What concerns do you have?" and "Do you think that you could complete the breathing retraining tracker independently, why or why not?" Researchers took detailed notes of areas for improvement and suggested adaptations.

Following theater testing, the same sample participated in cognitive and usability testing. The goal was to ensure that all participants (i.e., researchers, providers and people with SMI) understood the tools and that instructions were clear and response options appropriate. Cognitive testing (Alaimo et al., 1999) involved verbal probing, where participants were asked specific questions about the manual, such as "What does that mean to you?" to assess understanding. Usability testing involved participants using the materials and thinking aloud as they interacted with them (Barrera et al., 2013a). Researchers took detailed notes, and feedback was reviewed to refine the materials and make them more useable and appropriate.

3. Results

3.1. Results step 1. Intervention Identification and Selection

The 2017 literature search resulted in 193 abstracts in PsycInfo and 233 in PubMed, with nine abstracts describing PTSD interventions that had been developed for, or were described as potentially appropriate for, primary care (Engel et al., 2015; Kaltman et al., 2016; Brunet et al., 2013; Engel et al., 2008; Nishith et al., 2015; Craske et al., 2011; Possemato et al., 2016; Cigrang et al., 2015; Harmon et al., 2014). Four pre-established criteria (see Fig. 1) were that the intervention (1) have demonstrated effectiveness in the SMI population, (2) be straightforward and standardized, (3) be brief, and (4) be able to be flexibly delivered in low-resource settings. Only one intervention met criteria #1: the Brief Relaxation, Education And Trauma HEaling (BREATHE) intervention (Nishith et al., 2015). All nine interventions met criteria #2, and eight of the nine consisted of eight or fewer sessions and therefore met criteria #3. However, all nine interventions were developed for and tested in high-resource clinics in the United States and therefore none were face valid for meeting criteria #4. Given these results the BREATHE intervention was selected for adaptation.

BREATHE is a brief, low-intensity evidence-based intervention to treat PTSD in people with SMI (Mueser et al., 2015; Nishith et al., 2015;

Mueser et al., 2024). It consists of three sessions that include psychoeducation on trauma and PTSD to normalize symptoms and reduce inaccurate trauma-related misinformation or misunderstandings, alongside breathing retraining to reduce anxiety and physiological arousal (Mueser et al., 2024). BREATHE adapts widely used techniques for PTSD to accommodate the heightened stress sensitivity, cognitive limitations, and psychotic symptoms sometimes observed in people with SMI (Mueser et al., 2015). Specifically, to address heightened stress sensitivity, the BREATHE program intentionally does not employ exposure techniques. To account for cognitive limitations that some people with SMI experience, the BREATHE program provides simplified psychoeducation and allows for flexibility in the therapist delivery of these components. Finally, the BREATHE program provides guidance on how to integrate the treatment into the individual's ongoing case management and medication management services (Mueser et al., 2004).

BREATHE has been evaluated in open trials (Nishith et al., 2015) and randomized controlled trials that compared BREATHE to 12 to 16-session cognitive behavioral therapy (CBT) for PTSD with people with comorbid PTSD and SMI (Kredlow et al., 2017). In all trials participants have demonstrated significant clinical improvement in PTSD and depression symptoms which were maintained through three-month follow-up, and BREATHE was just as successful as CBT for PTSD at improving PTSD, depression, and anxiety symptoms and quality of life and functioning post-treatment through 12-month follow-up (Kredlow et al., 2017). BREATHE has also been implemented successfully to scale in community mental health programs serving people with SMI in the US both in-person (Mueser et al., 2024) and through telehealth (Lu et al., 2024). Given its brevity and low-intensity approach, BREATHE can be effectively delivered to large numbers of people within the primary care setting while minimizing disruptions to provider workflows (Mueser et al., 2024).

3.2. Results step 2. qualitative interviews with key stakeholders

Forty-eight participants (42 % women) took part, including 13 people with SMI (i.e., psychotic and bipolar disorders), 13 caregivers, 13 healthcare providers (10 primary care providers, 3 community-based rehabilitation specialists), and nine community and religious leaders. See Supplemental Table 1 and previously published papers (Ametaj et al., 2021; Hook et al., 2021) for more details on sample characteristics.

The first goal of the intervention was to identify clinically- and culturally-relevant characteristics of people with SMI that could be addressed to improve intervention acceptability. Findings showed that individuals with SMI in Ethiopia experienced a range of traumatic events, many consistent with the International Classification of Diseases (ICD) (World Health Organization, 2019) and the Diagnostic and Statistical Manual (DSM) (American Psychiatric Association, 2013) definitions of a traumatic event (e.g., sudden death of loved ones, intimate partner violence, sexual and physical assault). In addition, some events not covered by the ICD/DSM, including restraining, chaining and seclusion, property loss, fires, and animal attacks, were also common. As a result, adapting ICD/DSM-based trauma screeners was necessary to capture these experiences. Further details are available in Ametaj et al., 2021. Results also indicated that post-trauma reactions experienced by individuals with SMI generally aligned with DSM/ICD symptoms of PTSD, although some local expressions of distress were observed, such as somatic symptoms (e.g., burning sensations), and reluctance to share experiences or emotions with others (Ametaj et al., 2021). The section of the manual that provides psychoeducation about post-trauma symptoms was adapted to reflect these local experiences.

Participants described common coping strategies used by people with SMI who have experienced traumatic events, including seeking advice from health professionals or friends, attending religious services, and consulting with community leaders (see Table 1 for complete list of

Table 1

Coping strategies identified in the qualitative interviews that were helpful and were commonly used to manage trauma risk and PTSD symptoms.

Strategies	Description	Example quote
Following advice	Following advice from leaders, health professionals, or community members	R: They will come to their pastor, especially project workers, they talk [about] their problem. If you approach someone out of love they will share, and then we will know everything. We wouldn't do it for everyone, the society also gives advice. I: The society gives advice? R: Yes – Leader #1
Religion	Going to religious places, attending religious services, or engaging in religious practices	R: Like I said, most people in the community go to church. This is what we see in front of us [witness]. There are situations where they are not open. Other than that, when we don't have a way to understand what they feel inside and even if we can't say this is what they feel and don't have tangible things. Not less than 50 percent come to church – Leader #3 I: When you became very stressed because of the past memories and when you became sick, what did you use to solve the stress and to become calm? R: I did nothing. I will sleep ... eh. I will sleep to calm myself ...eh ... I will sit with other people and will sleep again. – Person with SMI #6
Sleeping	Sleeping to get some relief from their stressful conditions	I: What did you do when you felt stressed? R: When I feel stressed I go here and there I: Did you want to talk with people around you? Does that help you? R: Yes, I go and try to talk to people and I tell them my feelings then I get a bit of relief. I: Ok so having a talk with someone makes you relieved. R: Yes. – Person with SMI #1 R: As I told you now, I will walk when I become sick. I do like that. I. Is that? R. Yes, I will walk and I will be good – Person with SMI #6 R: Thus, I have seen different types of sexual assaults in my day-to-day life, related to work and that can even be supported by tangible evidences. We are trying to deal with such types of cases which came to our office every time. I: What are the things you put as a solution for such cases while you were discussing on these issue? R: Well, some of the events might be solved by managerial procedures. But, some of them, when we don't believe that the issue could be solved by managerial procedures, or it is beyond the level of the managements, they will be
Socializing	Socializing with friends or neighbors or spending time with others	
Walking	Taking a walk	
Seeking Justice or Mediation	Seeking justice for the experienced traumatic event, using someone as a mediator	

(continued on next page)

Table 1 (continued)

Strategies	Description	Example quote
		referred to the justice bureau and they will be solved accordingly. There are cases that pass through the justice bureau and there are also people in prison due to the procedure. – Leader #8

Note. I = Interviewer; R = Respondent.

coping strategies). Although not a core component of the theory of change of the original BREATHE intervention, these coping strategies were incorporated into the intervention to enhance its cultural relevance and acceptability. Additionally, other common positive activities that the research team deemed feasible and acceptable were added (e.g., exercise, music, prayers, cooking, and spending time in nature).

The second goal was to identify barriers and facilitators to intervention implementation. Participants highlighted common challenges related to implementing psychotherapy generally (Hook et al., 2021), trauma-focused therapy, and therapy with people with SMI. However, no unique barriers specific to the BREATHE intervention were identified.

3.3. Patient-level barriers and facilitators

Participants highlighted several barriers to treatment engagement, particularly a lack of awareness about mental health and trauma. Many people with SMI may not understand the purpose of the service or realize its relevance to their situation. To address this, participants suggested community education on trauma and PTSD. Some also noted that there can be a general mistrust of the medical approach to SMI treatment, which could be alleviated through psychoeducation to increase acceptance of the service. See Table 2 for patient and caregiver-level barriers and facilitators.

Symptoms of SMI, such as cognitive impairments and aggressive or disruptive behaviors, were identified as barriers to engaging with the intervention. These symptoms might reduce the person’s ability to understand the content and participate effectively. Moreover, non-adherence to prescribed medications often exacerbated these challenges, and in some cases, medication side effects themselves were seen as obstacles to participation. Stress related to stigma and discrimination of mental illness was also a significant barrier, as it affected the level of support people with SMI received from their communities and increased fears of discrimination when seeking care.

Access to the health center was another potential barrier, with transportation difficulties being a common issue. Some suggested providing the intervention at home, though others believed that having it available at health centers would increase usage. Financial support, especially for transportation, was seen as crucial to improving access and making the intervention more feasible.

Caregiver stress and frustration were also highlighted as potential barriers to treatment engagement, but could also be a reason to include families in the treatment. In addition to potentially benefiting themselves, participants noted that caregivers might facilitate treatment engagement by providing more insight into people with SMI’s experiences and behaviors and assisting the patient with practicing the skills taught in between sessions. However, some people with SMI expressed concerns about confidentiality if family members were included in the treatment process.

Despite these barriers, several facilitators of the intervention were identified. Participants felt that the intervention aligned well with the existing basic psychosocial support already provided at clinics (e.g., advice from providers), which increased their interest in receiving treatment from the same staff. Participants with SMI also appreciated the opportunity for non-medication-based treatment options.

Table 2

Patient- and caregiver-level barriers and facilitators of mental health treatment.

Barriers	Description	Example quote
Lack of awareness and education about mental health problems and trauma	Lack of community awareness about mental health problems and treatment options. People with SMI may not understand the purpose of the service or may not be aware that it may be relevant for them and so may not seek out, or engage in, care.	I: So what should be done to avoid patients being chained or isolated from the society? R: We can minimize being chained or things like this as much as possible by raising awareness there is no other choice, when you think about it the awareness in some areas is still very poor, I don’t know what the reason is, There is still a lot to do on the area, there are still some who got chained and it is not really about the awareness but they haven’t internalizes it. Doing what we are doing now it is difficult to expect change from this, in order to see change, a lot has to be done on the [level of] society and families, things change from time to time and so families forget what they are taught so by giving awareness we can make a difference – Health care provider #1
Lack of trust in the treatment given	People with SMI, families of people with SMI and communities’ beliefs about, and confidence in, the medical treatment given for mental illness may hinder engagement in care.	I: How confident are the patients or the attendants with the service provided here R: You mean with I: The medical service. There is no doubt 60 % of them don’t trust it, but there are a few that trust it if they have tried it previously in different religious institutions they will develop confidence on you because they don’t have any other option. Those who are in 60 % will hear information about someone else’s child having to be cured by going to a religious institution, so it is difficult for them to trust us. – Health care provider #7
Medication non-adherence	Discontinuation of medication and not taking medication regularly	R: There are some who refrained from taking the medication and moved to other areas. There is this kid that I was following up. He moved to another area and because of this he was not taking his medications. I: So he refrained from taking the medication? R: He refrained taking the medication he had a good improvement he started to rationalize things and was back to work, but because he refrained from taking the medication he was back to

(continued on next page)

Table 2 (continued)

Side effects of medication	Side effects of medications might hinder people with SMI from being engaged in the treatment	<p>where he was – Health care provider #1</p> <p>I: Did you discontinue?</p> <p>R: In this year, no I did not discontinue. Last time in October it got very bad, it [caused gastrointestinal problems] so I discontinued my medication and then it even got so bad I couldn't sleep. Four or five days ago I came to get treated and [redacted] told me I shouldn't have discontinued without consulting a health care worker. He said what happened, what is your reason? I told him I couldn't take it anymore, that's why I stopped the medication by myself. – Person with SMI #2</p>
Mental illness stigma/discrimination	People with SMI's' hope for improvement and treatment seeking is affected by others' negative perceptions and behaviors towards them	<p>R: The status of the community is that, especially now, since we are raising the issue of mental health, a lot remains because if one family has one child with mental illness, it will hide this fact for a long time because often times it is either related with sin or something that came from what one has done, many do not directly think it is a mental health problem, an actual health problem. They might not even think that it is something that could be treated and cured. Maybe now, with some of the work that has been done, there might be thoughts that it is a condition that could be treated and cured, but still the community, especially if you go to those remote kebeles now, in some house, they hide their kids, you might find older children chained up, so, especially these kinds of mental health problems. Now these few cognitive cases and problems, if there are such problems, it is sometimes associated with sin. Discussing with people and in some cases going to treatment is not common since actually people go to holy water places or try traditional treatments but never think it might have medical treatment, so, since they might also fear the social stigma associated with it, he might not want to be open about it, if you don't happen to pop in the house and see the situation and know it at family level, it is</p>

Table 2 (continued)

Disruptive or challenging behaviors due to SMI symptoms	Challenging behaviors related to SMI symptoms can undermine service engagement	<p>only then. This is where the problem is within the community. This is what I think.' – Leader #6</p> <p>R: About her? In relation to her?...yesshe just goes round the neighborhood and she might want to hit other people's children. She goes to other people's neighborhood and disturbs them. She also wants to hit us using a stick.</p> <p>I: Did she ever hit you that led to you getting stressed?</p> <p>R: She hits us yes ... ah she hits us.</p>
Caregiver stress and lack of hope	Caregivers report high stress and burden due to caring for people with SMI and this may limit access to care for people with SMI	<p>I: Of all the things that you encountered, which is the one that hurts or that causes you stress and that concerns you the most?</p> <p>R: When she goes and disturbs other people's home and then when she hits kids. That hurts. I tell her to stay at home but she refuses.- Caregiver #1</p> <p>I: In this month, were there feelings of suicidal thoughts or attempts that you had?</p> <p>R: I do think about it, later on, it is because of that. That is, it is because of my mother, when she is like this, she just cries, I don't even think she is ok.</p> <p>I: But you in this month, it is not before this month, this month, have you had such thoughts?</p> <p>R: Yes, I hated everything, I got far from school and thought of running away but when I thought about it, sitting down, now, if I were to disappear, it would be worse, more problems for them, so I have sat down and tolerated it all.</p> <p>I: Have you ever attempted suicide?</p> <p>R: Yes, not to kill myself but to just disappear from home</p> <p>I: To disappear from home on your own?</p> <p>R: Yes. – Caregiver #14</p>
Both a barrier and facilitator	Description	Example quotes
Home visiting	Visiting the person with SMI in their home may have a positive or negative impact	<p>I: "How comfortable is it to do the treatment ... in the health center? Does it have a burden ... ?</p> <p>R: "Yes, there will be shortage of staff and time for the follow up, helping them and treating them, as I told you before. [But] unless they came here it is difficult for the health professionals to go to their homes to treat [them] and</p>

(continued on next page)

Table 2 (continued)

Location of the service	Whether the location of the service is close or far to someone's home, or is or is not convenient, can affect service engagement	ask their history.” – Health care provider #11 R: They also tell her to come and take a counseling service but, as you know, since we come from far rural areas we don't usually come here – Caregiver #3 I: What are the simplest techniques to make the treatment easier for you? If this wasn't here, what do you think, what's the easiest way to get the treatment? How about its distance? is it far? R: It is not far. It is nearby. – Caregiver #8 I: yes, is it better to counsel him alone or together with family members? R: to gather with his family – Caregiver #2 I: When you go for the counseling service and to take the drug, do you go together with another person? R. No. I: Are you alone? R: Yes. I: Ok. R: I will go for the counseling service alone and will take the drug. I: Are you alone during the counseling service? R: Yes I: Which one do you prefer? Is it going with another family member or alone? Which one is better for you to speak freely? Is it alone or with other family member? R: I like to go for the counseling service alone. What did others do? – Person with SMI #5
Family involvement	Involving family members of the person with SMI in the intervention	I: yes, is it better to counsel him alone or together with family members? R: to gather with his family – Caregiver #2 I: When you go for the counseling service and to take the drug, do you go together with another person? R. No. I: Are you alone? R: Yes. I: Ok. R: I will go for the counseling service alone and will take the drug. I: Are you alone during the counseling service? R: Yes I: Which one do you prefer? Is it going with another family member or alone? Which one is better for you to speak freely? Is it alone or with other family member? R: I like to go for the counseling service alone. What did others do? – Person with SMI #5
Facilitator	Description	Example quote
Financial support	Providing financial support for transportation and free or low-cost clinical services can increase treatment access	R. As I told you, they have to consider the fee ... As you know people live accordingly, the rare people who can pay high or low, everyone lives according to his capacity not according to other people's life standard. It is like that. So you can see, people are very happy when they are receiving service for a low price, considering their life. I am also very happy. I feel very bad when people die for not receiving proper service because of the price. – Person with SMI #4
Educating the community and family	Increasing community and family awareness about mental health and the mental health service	I: What is it that is expected from the health centers? R: I mean, creating awareness, that is, actually

Table 2 (continued)

Frequency of therapy sessions	The schedule of the intervention session was acceptable	provision can increase treatment access.	about everything, about the origin of the condition, what and how things should be done, the precautions that you tell them with regards to mental illness that is, telling them thoroughly, putting those patients isolated from the community, that alone could never be a solution for them and in fact, creating a social group for their treatment process, this kind of things that should be done, creating awareness is it. The health center is closely related with health extension workers and during home-to-home visits and awareness creation, mental health could be worked on as one aspect of overall health of a society. – Health care provider #6 I: If you were told you need to come to the health center for the sake of your health every week, would you be willing to come? R: Yes, I am willing – Person with SMI #3 I: if it is for the sake of your health and if you have to come to the health center ... what if it is weekly or monthly? R: If you ... consider the length of the treatment, it is fine. I: You mean if it is for short time? R: If it is going to be for short minutes it is ok. – Caregiver #4 I: If the health center starts such a service, what's expected from us to do, what do you suggest would be good? R: well people may not know such service exists so it is good to advertise it, people may be afraid to share their problems and it's good to advertise. - Caregiver #5 I: Ok, what do you think is the advantage of having such types of discussion with the health professionals? What is the advantage and disadvantage of having the counseling service with the health professionals? R: It doesn't have any disadvantage. I told you what I have in mind and you will advise me on things so that I will get calm. For example, I just told you what I feel and you advised me with good advice Obviously, you
Advertising the PTSD service	Advertising the PTSD intervention would increase demand for the service.		
Positive views of existing counseling services	People with SMI expressed positive views of existing counseling services, including as an additional treatment option along with medication		

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Table 2 (continued)

Positive views about discussing past traumatic events and PTSD	People with SMI and caregivers of people with SMI express positive views about discussing past traumatic events and PTSD	<p>don't advise me with a bad thing, right? Since you are talking to me patiently, I have also told you about my personal issues. I will be going back home feeling relaxed because I talked to you about my personal issues.</p> <p>I: Therefore, your mind will be stress-free when you talk?</p> <p>R: Yes, that's right – Caregiver #7</p> <p>I: The counseling service for these people who are facing difficulty, the counseling service, if you had to get the counseling every now and then by coming here, are you willing to come here, um, every time, if they gave you counseling service?</p> <p>R: Yes, I would very much be happy.</p> <p>I: Would you tell them your secrets or do you trust the health workers?</p> <p>R: I am very happy and I do want them, why, you will give a break to your mind, um, you will also learn from it. – Person with SMI #3</p> <p>I: What did you feel?</p> <p>R: I feel relief and feel like something is out from my stomach</p> <p>I: How was [the breathing retraining exercise]?</p> <p>R: It is good.</p> <p>I: Did you like it?</p> <p>R: Very much – Caregiver #11</p>
Positive reactions to breathing retraining	People with SMI and caregivers of people with SMI expressed positive attitudes about, or experiences with, breathing retraining exercises	

Additionally, both patients and their families felt that discussing trauma might be therapeutic, with all participants reporting that they enjoyed practicing the breathing retraining during the qualitative interviews and thought that it would be helpful. Further exploration of specific considerations for and barriers to care in this setting have been reported in [Hook et al., 2021](#).

3.4. Provider and facility-level barriers and facilitators

See [Table 3](#) for a full list of provider- and facility-level barriers and facilitators. Several aspects of the intervention aligned well with the existing healthcare structure. People with SMI were already receiving treatment from various primary care providers, including health officers, nurses, and psychiatric nurses, and participants noted that any of these providers could deliver the intervention. Providers reported that counseling people with SMI was a valued part of their role and that their training through the WHO mhGAP ([World Health Organization and United Nations High Commissioner for Refugees, 2015](#)) had equipped them to offer advice and guidance, particularly in a directive manner. They also expressed enthusiasm for learning and implementing new psychosocial interventions.

Despite receiving some education on diagnosing and treating mental disorders, providers noted a lack of training and knowledge specific to PTSD and trauma exposure. Some were concerned that discussing traumatic events might distress people with SMI, while others believed that processing these experiences could be therapeutic and instill hope.

Table 3

Provider and facility-level barriers and facilitators of mental health treatment.

Provider-Level Barrier	Description	Example quote
Lack of provider knowledge and training about PTSD and trauma	Lack of knowledge among health professionals about PTSD and trauma	<p>R: Yes, there is such kinds of thing. Sometimes we could learn about [PTSD and trauma] but we don't have awareness of it. I am learning, but if you ask me about different things ... I might not know it. It is very difficult to say I do [not] have knowledge because I am learned.... They don't have the awareness and don't know what to do and how to treat when an injured patient comes in He might need him to talk, discuss with him or just to touch him He might need encouraging words or expects him to talk to him [about] something which makes him relieve his pain. If a patient is female and comes here after quarreling, she might need encouraging words. This thing will get an improvement. – Health care provider #3</p> <p>I: Did you have any incidence like them being emotional or angry when you ask them questions?</p> <p>R: Yes there is. When I ask them about their past life, they say it doesn't concern me and it's their secret or they may get emotional. In this case you need to change the subject otherwise the talking will be disrupted. The thing is you need to divert the idea and work on that thing If you ask the patient about their past life directly as I told you before they will get emotional. So the thing you should do is ask the families to know about the truth If the patient is able to talk, he will be relieved. If the patient can tell his own feelings he will give a psychological treatment to himself. – Health care provider #12</p>
Provider concern about discussing trauma with people with SMI	Providers may think that discussing traumatic events may increase stress or SMI symptoms	
Facilitator	Description	Example quote
Multiple types of primary health care providers can provide the intervention	People with SMI are treated by a variety of health care providers in the primary care clinics and the intervention could be provided by any of these professionals.	<p>I: Who is giving you these services?</p> <p>R: The health workers in the health center. The others who are coming from the district are coming to our village to counsel us – Person with</p> <p style="text-align: right;"><i>(continued on next page)</i></p>

Table 3 (continued)

Counseling is already part of providers' responsibilities, and that they believe it is helpful	Providers describe counseling as an aspect of their current responsibilities	<p>SMI #8 I: Ok, who gave you the treatment service when you came here? R: I don't know. I: Don't you know them? Are they doctors, nurses or what? R: Yes, they are like that. Some are doctors and some other are nurses. – Person with SMI #5 I: What does it mean, how do you understand it ... ? P: I mean, some patient, I think it is the way to treat a patient side by side with a drug, that is what I think about psychological therapies and in fact it is like without the side effects. It is a tool by which we treat people for me psychological therapies, so when giving psychological therapies, we need to include many things, like we shouldn't focus on one thing only and focus on that, it is not like that. If we are dealing with a patient, we are dealing with social life, spiritual life, personal life, and just basically everyday life of the individual should be included and to be able to know the problems that are there from him. It is a tool that enables this and then again it is a tool by which we are able to solve and tell the solution for the problem that is there. – Health care providers #6</p>
Providers report positive experiences with previous MHGAP training	Providers have used mhGAP training to provide counseling services to patients with mental health concerns	<p>I: Because you are a psychiatry nurse do you think having an additional training on MHGAP is useful? R: I am very happy to be trained with MHGAP because it is very confusing when you come directly from school and start working on the area. When I first started this job, I was really confused for more than two months. There was lots of issues on diagnosing patients, I can say that MHGAP has made me complete. There is no doubt that the training completed me. It helps me to do my job well. The MHGAP's questions were very precise and easy to understand, so yes it was very useful. – Health care provider #7</p>

Table 3 (continued)

Positive responses to learning and providing new psychosocial interventions	Providers report positive responses to learning and providing new psychosocial interventions	<p>I: What are the favorable conditions in the health center at present? R: As a health center, there is readiness on the side of health professionals. By readiness I mean, the health professionals are ready to learn new things and to make it practical. Especially those health workers who have day to day relations with their patients are ready to learn new things. As I said earlier, we are providing integrated services. They are ready to accept new things and to make it practical. Otherwise, they don't need additional thing to treat mentally ill persons. – Health care provider #4</p>
Positive provider perspectives on talking about traumatic events	Providers report that discussing past traumatic histories of people with SMI will improve their outcomes	<p>I: When individuals are facing difficulties in their lives like, sudden death, it can be in the family, it can be serious illness, just as I told you it can be losing possessions, it can be a case of robbery; they encounter these in their life, right? So in order to stand these challenges, what advice do you have for them which can be helpful? R: If they can get a counseling service with another group of people; if they visit a health center and express their feelings, I think it can be better. I: If they get a counseling service, which type of counseling service do you think would be better for them to receive? Specifically what type of counseling; what type of care? R: It is all the same, the accident related to property. You explain it, the counseling service, in different ways. You advise them, depending on the situation, all the things that are lost can be substituted and you tell them that by working hard, it can all be recovered. You inform them to have hope and make them have faith and not to lose hope. – Health care provider #5</p>
Both a barrier and a facilitator	Description	Example quote
Provider communication and approach	Providers communication and approach to the	R: When we come here to meet with your people

(continued on next page)

Table 3 (continued)

people with SMI and their caregivers can be both a facilitator and a barrier	<p>they say ‘Why are you here?’</p> <p>I: They say that?</p> <p>R: Yes</p> <p>I: So if these things could be avoided?</p> <p>R: It would be nice.</p> <p>I: So the health center should treat our patients with us?</p> <p>R: If they are willing.</p> <p>I: Why do you think they won’t be?</p> <p>R: Because they look to their own interest.</p> <p>I: What do you mean?</p> <p>R: They are not happy with outsiders.</p> <p>I: Outsider meaning patients or those who treat patients?</p> <p>R: Ones when we came to meet your people they said ‘What do you want?’ as if we’re new patients and they even said her chart was lost. Finally some lady found it and told us to get some kind of medicine. We bought that and went.</p> <p>I: So the ones here are not willing to give you service?</p> <p>R: No, they’re not. – Caregiver #5</p>
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Facility-Level Barrier	Description	Example quote
Long clinic waiting times	Long patient waits until they get to see the health professionals affect their engagement in the service	<p>I: What if anything would make it difficult or easy for you or another health care provider to participate in this intervention? What would work? Why?</p> <p>R: The one thing is the patient load. For example, we screen from patients in the [outpatient department] after you screen them and diagnose them as mentally ill patients. It is not that suitable to give counseling in detail because there are patients waiting. Due to the caseload patients who are waiting outside they might think you are joking. The other thing here is a lack of adequate numbers of professional. There are only two health officers and during a day one will call to the emergency [outpatient department] and the other may call to abortion service and during that time the waiting time for the patients increases, so these patients will be neglected. Or sometimes they may be appointed</p>

Table 3 (continued)

Lack of scheduled appointments in current clinic workflows	The lack of scheduled appointments to see health professionals reduces service engagement	<p>for another time or day, but if the professionals are available it cannot be balanced with the patient load. For example, for the hospital ... there are 60–70 patients per day. In this situation it is difficult to dig deeply into patient history and to give counseling. – Health care provider #9</p> <p>R: well, getting service quicker and medicine and if they could tell me a specific time to come get help so I wouldn’t waste time and such – Caregiver #5</p>
Not having the availability to always follow-up with the same health professional	Inconsistent providers for mental health treatment	<p>I: Here, you are providing the service alone but in other health facilities professionals work in shifts so if a patient communicated with one today he might not meet that professional when he comes the second time. How would this affect patients and what do you recommend on these?</p> <p>R: That is a big problem, patients here always ask for me. They don’t know me by name but they will ask for the short guy ... and they are not willing to share their secret with anyone but me. When I am not around because I ask patient’s whole history and when they come for the second time and if I am not around they need to tell all of what was discussed previously and this has to be considered ahead of time or else they will be irritated. – Health care provider #7</p>
Psychotropic medication shortages may reduce engagement in services, including psychotherapy	Lack of availability of necessary psychiatric medication contributes to participants’ engagement with the service	<p>I: Is there anything we can do to expand or to improve that you would like to say?</p> <p>R: Expanding the service is expected. This is the beginning. All I what to say is the availability of the basic medications.</p> <p>I: The availability of the medication?</p> <p>R: Yes work on the shortage and disappearance of the medication, the rest is good – Leader #2</p>

Participants with SMI emphasized that a provider’s communication style significantly influenced their engagement. A receptive, kind, and empathetic approach encouraged participation, while an unwelcoming demeanor discouraged it.

Limited provider training in mental health psychoeducation and core psychotherapy skills was also identified as a barrier. This gap could

contribute to broader challenges such as patient and family distrust of mental health treatment, medication non-adherence, and difficulties managing disruptive behaviors. In addition to provider communication, people with SMI cited long clinic wait times—exacerbated by a lack of scheduled appointments—and inconsistent follow-ups with different providers as factors that diminished their willingness to participate. Addressing these concerns, they noted, would increase their engagement and commitment to treatment.

3.5. Results step 3: adaptation workshop with key stakeholders

A total of 12 participants attended (six women; 50 %). Participants included four project investigators (three psychiatrists from Addis Ababa University (AAU) and one psychologist from Boston University), the project coordinator who has a master’s degree in public health from AAU, two additional psychiatrists from AAU, a representative of the Mental Health Service Users Association, the Sodo local government health office head, the Sodo local government mental health focal person, and two additional master’s level project coordinators involved in separate mental health intervention studies in Sodo and South Sodo.

The adaptation workshop focused on four key areas: (1) translating essential terms, (2) improving the design of the manual and handouts to enhance cultural relevance and usability, (3) addressing implementation barriers identified in qualitative interviews, and (4) identifying and resolving additional challenges to intervention effectiveness. See Table 4 for complete list of the barriers and facilitators that were identified and the adaptations that were made during the adaptation workshop.

Translation Adjustments. The workshop finalized Amharic translations for key terms, for example selecting “አስቸጋሪ የህይወት አጋጣሚዎችን ተከትሎ የሚመጣ ጭንቀት” for “posttraumatic stress disorder” (translated back as “anxiety/stress following difficult life events”) and “ጭንቀትን ለማስወገድ የሚደረግ የአተነፋፈስ ስልጠና” for “breathing retraining” (“breathing training to relieve stress/anxiety”). Some English terms, such as “hyperarousal,” did not translate clearly into Amharic. In these cases, the English terms were revised (in this case to “startled easily/overly or excessively alert”) resulting in more accurate Amharic equivalent translations (“በትንሽ ነገር መበርገግ/ከመጠን በላይ ነፃ መሆን/ድንገተ መሆን.”)

Manual and Material Design Updates. To improve usability, stakeholders revised the 3-point rating scale used to track homework progress. Instead of the original sad, neutral, and happy faces or red, yellow, and green colors, they chose green for “very good,” yellow for “no change,” and gray for “worse,” as these colors were meaningful indicators in Ethiopia. Additionally, the manual and handouts were redesigned to feature illustrations created by a local artist, ensuring they accurately represented the people, activities, and clothing typical of Sodo and South Sodo districts. To enhance usability, stakeholders recommended simplifying or removing complex in-clinic and homework handouts for busy primary care providers while ensuring materials remained engaging and accessible. The use of clear illustrations alongside text descriptions and homework logs that could be used with or without text increased acceptability, particularly for those with low or no literacy.

Addressing Implementation Barriers. All adaptations suggested in the qualitative interviews were incorporated into the manual, materials, and training. In addition, the adaptation workshop identified several new barriers, including the limited availability of therapy supervisors in Sodo and South Sodo, lengthy session durations that strained provider time and space, and the need for a robust risk management plan for suicidal ideation and ongoing domestic violence or family conflict. Adaptations to address these concerns included: (a) providing supervision both in-person and remotely by clinical psychologists based in Addis Ababa, (b) reducing session length from 60 to 20 min while increasing the total number of sessions from three to five, allowing for the same content to be covered in shorter increments, and (c) developing a structured risk management plan for addressing suicidal ideation, domestic violence,

Table 4
Identified barriers and facilitators to intervention implementation with corresponding suggested adaptations.

Individual and Family-Level Barriers and Suggested Adaptations	
Barrier	Suggested adaptation to the intervention to address the barrier
Patients may be living with untreated SMI symptoms	Ensure that all participants identified for screening are connected to care, regardless of whether they are eligible for, or enroll in, the PTSD trial. Add in the importance of SMI medication adherence to psychoeducation in the intervention
SMI symptoms may contribute to potentially disruptive or dangerous behavior	Use the newly added coping skills module to enhance patient coping skills and provide more psychoeducation about medication adherence
High poverty and the need for financial support, particularly for transportation costs to attend sessions	For the purposes of the study, provide 100 ETB for transportation for every session. For sustainability, see if there are ways to link patients to existing services to help with poverty, housing, food security, and transportation needs.
Lack of consensus on including family members in the treatment	Ask the patient if they want their caregiver to participate in their treatment and how they would like them to participate (e.g., present throughout the session or only to assist with homework). Develop a specific plan about when confidentiality is broken, how is it broken and how is this communicated to the patient
Caregivers experiencing high stress, frustration, and lack of hope	Assess caregivers for burnout and mental health treatment and offer modules on caregiver wellness and coping.
Provider and Facility-Level Barriers and Suggested Adaptations	
Lack of consensus on treatment in the home or in the clinic	Locate the service in the clinic because the goal is to have a completely integrated health system rather than a separate independent service for mental health
Lack of consensus on having sessions once a week or once a month	Plan for once a week but allow maximum flexibility of up to once a month to accommodate patient and clinic needs
Providers lack trainings and knowledge about PTSD and trauma exposure.	Provide training for providers on PTSD and trauma, in addition to training on the intervention.
Provider concern that discussing exposure to traumatic events would be distressing to people with SMI	Provide additional psychoeducation in the manuals and during trainings on trauma treatment, techniques to address patient distress, and how to talk to patients about increased distress as they engage in care
Unwelcoming or negative provider communication style	Include a module in the manual and training on empathic, reflective and active listening, basic therapy skills, and rapport building.
Long clinic wait times due in part to lack of scheduled appointments	Try to have appointments scheduled with individual providers but allow for timing of visits to be flexible and when fewer patients are expected to be in the clinic – for example during market day.
Follow-up appointments are often not with the same providers	Plan on patients having the same provider, but design each session to be independent in case someone cannot see the same person regularly
Limited psychological therapy providers in Sodo and South Sodo to provide supervision	Have psychologists located in Addis Ababa provide supervision in person and over the phone
50-min treatment sessions will back up the primary care clinic services	Decrease the length of time for each session to 20 min, but increase the number of sessions from 3 to 5 to accommodate the shorter sessions
The intervention will have to be conducted in the exam rooms since there are no dedicated counseling rooms. This is by design so the mental health services are fully integrated,	If there is an available exam room the preference is for the intervention to use the private exam room space for patient comfort and confidentiality.

(continued on next page)

Table 4 (continued)

Individual and Family-Level Barriers and Suggested Adaptations	
Barrier	Suggested adaptation to the intervention to address the barrier
however, this means that seeing patients ties up an exam room	
A robust risk of harm plan in required for suicidal ideation and worsening SMI symptoms	Developed a detailed plan for identifying and responding to risk of harm prior to, during, and after treatment that includes primary care providers, psychiatric nurses, referrals to hospitals in Addis, and caregiver involvement as needed.
Community and Systemic-Level Barriers and Suggested Adaptations	
People with SMI, families, and community members may lack awareness and education about mental health problems and potentially traumatic events	Include additional psychoeducation in the intervention. To increase awareness of the intervention, provide information to health extension workers (HEWs) on trauma and SMI and have them assist in identifying and referring people with SMI who may have experienced trauma to the health center for assessment.
Substances in Ethiopia are different than those in US where the intervention was developed	Adapt the types of substances and reactions that are described in the manual to those that are commonly used in Ethiopia
Ongoing trauma such as domestic violence and family conflict	Assess for ongoing trauma during the intervention and implement the risk of harm module as needed. Connect patient to existing resources and NGOs in the area.
Mental illness stigma and discrimination from community members, legal and law enforcement problems, and employment exploitation of people with SMI	Provide community awareness raising that consists of health education meetings and information about discrimination and traumatic events run by health professionals and health extension workers in the health centers and during social gatherings or market days.
SMI medication shortages	Collaborate with PRIME to address mental health medication shortages at affected clinics

and family conflict.

Unresolved Barriers Beyond Study Scope. Three additional barriers were identified, but the strategies to address them were beyond the scope of what could be accomplished in this intervention. These barriers were: (a) mental illness stigma and discrimination from community members, (b) caregiver stress, frustration, and lack of hope in supporting individuals with SMI, and (c) SMI medication shortages at clinics. Proposed strategies to mitigate these challenges included community awareness events to reduce stigma, caregiver support programs to enhance resilience, and collaboration with PRIME to investigate and address medication shortages in affected clinics.

3.6. Results step 4: theater, usability, and cognitive testing

Fourteen people (7 women, 50 %) participated in the theater, usability, and cognitive testing including five people with SMI, three caregivers of people with SMI, and six providers from the Sodo and South Sodo health centers and local primary hospital. Providers included health officers, clinical nurses, and psychiatric nurses. Feedback on the intervention content, manual, and materials focused on several key areas: (a) acceptability of the intervention, (b) patient-level facilitators of implementation and effectiveness, (c) patient-level barriers, (d) provider- and clinic-level barriers, (e) content adaptations, (f) manual and materials adaptations, and (g) provider training considerations.

Acceptability. Both people with SMI and providers expressed high acceptance and enthusiasm for the intervention. Participants with SMI noted that the descriptions of traumatic events in the theater testing closely reflected their own experiences and that the treatment offered

hope for symptom improvement, serving as a valuable complement to their current care. Both groups found the breathing retraining, positive activities, and coping strategies relevant and beneficial. Participants with SMI noted that initial sessions may be emotionally challenging but believed they would become easier over the course of treatment.

Patient-level facilitators. Participants with SMI stated they would attend sessions and practice skills if they saw the intervention as important to their health. Providers emphasized that a culture of respect for health professionals would encourage attendance, especially if intervention sessions were coordinated with medication visits. Participants found the session length appropriate, treatment accessible and affordable, and coping strategies easy and convenient, provided they were well explained. While some participants had limited literacy, they noted that caregivers, who often had some education, could help with homework and worksheets.

Patient-level barriers. Participants and providers highlighted high levels of mental health stigma and stressed the need for psychoeducation for patients, caregivers, and providers to normalize symptoms and increase understanding of the use of a psychological intervention alongside medication. Some participants might struggle with understanding and completing homework exercises, requiring extra support from caregivers, and additional clarity was needed on when, where, and how often to practice breathing retraining. In addition, although participants found the intervention understandable, providers expressed concerns that some people with SMI might have difficulty grasping certain concepts due to their SMI symptoms. Lastly, concerns about transportation costs were reiterated.

Provider and clinic barriers. Some participants with SMI preferred having a single therapist throughout treatment to avoid repeat disclosure of difficult experiences. However, providers noted that this might not always be feasible and emphasized the importance of setting expectations while trying to accommodate this preference when possible. Providers also stressed the need to clearly discuss confidentiality and its limits, particularly in the first session. Clinic constraints, including patient flow and limited space, remained a concern, and providers worried that even 20-min sessions might be difficult to accommodate. As a solution, they suggested allowing more than five sessions if needed to ensure full content delivery.

Intervention content adaptations. Four key content adaptations were recommended: (1) More scientific background—Providers wanted additional information on the intervention's rationale, mechanisms, and efficacy (e.g., the science behind breathing retraining), (2) Clearer session overview—Providers and participants requested a detailed outline of what each session would cover, (3) Caregiver involvement—It was requested that providers ask patients if they want their caregivers involved after explaining each of the intervention components to the person with SMI, and if caregivers were involved, providers should actively engage them in the intervention (e.g., asking questions, assisting with homework), and (4) Guidance on substance misuse—Since substance use often co-occurs with PTSD and SMI, providers wanted more training on how to support patients with alcohol or drug-related concerns.

Manual and material adaptations. Providers requested a quick-reference handout or booklet summarizing intervention steps to support treatment delivery. Participants and providers also suggested colorful, illustrated handouts or booklets depicting key concepts such as the breathing retraining steps, symptoms, and coping strategies. These visuals were especially important for those with limited literacy.

Provider training considerations. Providers emphasized the need for considerable training to ensure fidelity in delivering the intervention, reflecting their limited prior experience with psychological interventions. Key training areas included: (1) Understanding PTSD—Symptoms, how trauma contributes to related issues (e.g., substance use), and effective treatment approaches, (2) Breathing retraining—How to teach it, explain its purpose, and address common barriers to practice, (3) Enhancing patient engagement—How to motivate

patients to participate in psychological therapies, given that treatment has primarily focused on medication, and (4) Effective communication—Participants stressed that providers needed training in warm, empathetic, and open communication. While they appreciated the provider's delivery during theater testing, they noted that clinic providers often used a more paternalistic or didactic approach rather than therapeutic listening. The adapted Amharic and English versions of the manual are available as Supplemental Files 2 and 3.

4. Discussion

This study adapted a PTSD intervention for individuals with comorbid SMI to be delivered by primary care providers in Ethiopian clinics as part of routine care. Using stakeholder interviews, an adaptation workshop, and theater, cognitive, and usability testing, we followed best practices for adapting evidence-based interventions (EBIs) (Gearing et al., 2013; Barrera et al., 2013b), including assessing the community, consulting experts and stakeholders, adapting the original EBI, and testing the adapted materials (Arora et al., 2021; Escoffery et al., 2018).

The adaptations align with strategies for implementing EBIs in resource-limited settings, emphasizing feasibility and retention while preserving core components (Moore et al., 2013). Notably, most adaptations in natural settings are made reactively, rather than proactively, which often results in poorer alignment with the original intervention goals or mechanisms (Moore et al., 2013). In contrast, by gathering data on barriers and facilitators to implementation during the intervention development phase, we were able to select adaptations that address barriers while still retaining the “active ingredients” of the intervention, including psychoeducation to increase knowledge about PTSD and reduce PTSD-related stigma and inaccurate trauma-related cognitions, and breathing retraining to reduce physiological over-arousal and increase use of stress management strategies (Mueser et al., 2015; Nishith et al., 2015).

Results indicated that the goals, content, and mechanisms of the intervention were relevant to the needs of the community, and that the intervention filled an important gap in care. However, a number of potential barriers were identified that had to be addressed in order to create an acceptable and useable intervention. Cultural adaptations included incorporating local coping strategies, refining mental health terminology, using culturally appropriate examples and illustrations, and simplifying materials for individuals with lower literacy levels. The adaptations aligned with all four of the mechanisms through which cultural adaptations have been hypothesized to improve outcomes: addressing systemic barriers to care, increasing community engagement to identify and ameliorate barriers, integrating cultural values and beliefs into the intervention, and improving the service experience (Healey et al., 2017).

Structural adaptations focused on increasing feasibility and sustainability in primary care (Escoffery et al., 2018b), and included shortening sessions to 20 min, expanding from three to five sessions, maintaining provider continuity when possible, and offering remote supervision from psychologists in Addis Ababa. Use of digital mental health interventions is a promising approach to address some of the challenges with lack of human resources and space in health clinics and financial and geographic challenges that make travel to a clinic difficult. However the utility of digital mental health interventions in LMICs broadly (Wani et al., 2024), and Ethiopia specifically (Manyazewal et al., 2021), is often limited by access to reliable internet and electricity, mobile phone affordability, cellular network disruptions, and insufficient digital literacy. Indeed, digital health interventions in Ethiopia have been found to be the least acceptable for residents who are low-income, live in rural areas, have limited formal education, and who share a phone with other family members (Abdissa et al., 2025), characteristics that are common to many, if not most, of the individuals with SMI in Ethiopia and many other LMICs. Therefore, we decided to

provide the intervention in-person in the clinic, delivered by providers who already see the patients in-person for medication management, despite the potential feasibility challenges for patients and providers.

Notably, the original BREATHE intervention was designed to be delivered by experienced mental health providers with existing skills in psychological therapies. In contrast, the primary care providers in our study had very little knowledge or experience in psychotherapy, trauma, or PTSD and had never been trained to deliver psychological therapies. Lack of training or supervision, in the context of high staff turnover, is a common challenge in research on task shifting mental health interventions to medical providers and community health workers in LMICs (Sørensen et al., 2017; Barnett et al., 2023). To address these needs, training was expanded to cover trauma science, PTSD symptoms, and psychotherapy techniques. Additional instruction addressed other issues like substance use and referral pathways such as to other primary care providers trained in mhGAP, psychiatric nurses in local hospitals, or psychiatrists in the capital Addis Ababa. Finally, participants emphasized the need for further training in fundamental psychotherapy skills. Previous research implementing task-shared interventions into Ethiopian primary care clinics has also found that additional training in the critical competencies of therapeutic communication, rapport building, and empathic and active listening was essential (Kohrt et al., 2025), as these skills are not generally emphasized in primary care practice in Ethiopia (Keynejad et al., 2023; Bitew et al., 2021; Keynejad et al., 2024).

There were differing opinions about the involvement of caregivers in the intervention. Specific recommendations in the literature on involving caregivers suggest including them in the development and provision of services, while having clear guidelines about sharing information that balance consent of the person with SMI, confidentiality, and the needs of caregivers (Rowe, 2012). Participants noted that caregivers provide a great deal of support to many people with SMI, a finding echoed in the research literature (Rowe, 2012), and increased caregiver involvement in treatment may be especially important in this setting where limited access to formal social services results in caregivers playing a central role in the support of people with SMI. Indeed, there was recognition by our participants that the caregivers themselves were experiencing a great deal of stress, frustration, and lack of hope, which might in turn result in stress for the individual with SMI and impede their access to care. Systematic reviews of the experiences of caregivers have found high rates of reported burden, stress, and financial hardship (Rowe, 2012). We considered adapting the intervention to address some of these needs, but thus far interventions for caregivers with SMI are primarily focused on psychoeducation (which is already provided in BREATHE) and support groups (Yesufu-Udechuku et al., 2015), and interventions to address the stressors of the caregivers are likely needed at the individual, family, community, and systemic levels, which were beyond the scope of a brief psychological therapy for PTSD.

Additionally, in Ethiopia typically treatment decision making for people with SMI is made by health workers and caregivers, without much input from the person with SMI, potentially leading to their perspective being overridden if caregivers were included in the intervention sessions (Girma et al., 2022; Abayneh et al., 2017). Moreover, in some cases caregivers themselves may be implicated in a patient's traumatic experiences, and therefore the individual with SMI may be hesitant to include them in the intervention. Indeed, previous studies have found that caregiver stress might inadvertently lead to people with SMI experiencing traumatic events, such as chaining and assault, and caregiver stress may exacerbate existing SMI and post-trauma symptoms (Ng et al., 2023). On the other hand, inclusion of caregivers in the intervention may provide opportunities for caregivers to receive psychoeducation about PTSD and SMI, which might reduce some of their distress and improve their relationships with the individual with SMI. To address the sometimes conflicting concerns of participants in our study, we allowed the inclusion of caregivers in the BREATHE Ethiopia intervention to be suggested by providers, but flexible, and at the discretion

of the person with SMI. Future research on incorporating BREATHE Ethiopia in a family intervention would be useful.

Additional barriers that we identified that require more systemic interventions were high levels of mental health stigma in the community and lack of community knowledge of mental health. These barriers to mental health intervention implementation have been widely documented across settings, including in Ethiopia (Girma et al., 2022), and have been found to prevent individuals from knowing that they had a mental health need, seeking out care, and receiving care long term (Gearing et al., 2013; Heim et al., 2020). While interventions to address mental health stigma have been developed, most have only assessed attitudinal, rather than behavioral, change, and rigorous studies of their effectiveness are limited (Heim et al., 2020). In addition, participants reported that many community members believed that mental health problems could only be addressed with traditional or faith healing or with medication, and that knowledge of psychological therapies was extremely limited and may not be perceived as being efficacious. This finding is in line with other studies in Ethiopia which have identified common perceived causes of mental illness including spiritual concerns, violations of psycho-cultural norms, economic difficulties and physical medical conditions (Girma et al., 2022). To address these barriers, participants noted that psychoeducation for the entire community about traumatic events, mental health, and the efficacy and utility of psychological therapies in the form of community awareness raising events was needed. Using health extension workers to raise community awareness about mental health has been recommended as a potentially acceptable stigma reduction approach in Ethiopia (Girma et al., 2022; Baheretibeb et al., 2022). Therefore we adapted the intervention to include training health extension workers (HEWs) to provide initial brief psychoeducation about trauma to individuals with SMI in the community when they were introducing the intervention to patients.

A final potential barrier to treatment that we identified was high community poverty which results in difficulty paying for treatment and transportation costs to attend sessions. This financial barrier is common across settings, but is particularly challenging and prevalent in LMICs which by definition have lower per capita income, but are less likely to have robust public or private insurance systems and more likely to require out of pocket payment for mental health treatment (Gearing et al., 2013; Dixon et al., 2006). Indeed, experts have reported that insufficient financing of mental health services is the top barrier to improving mental health services in LMICs (Saraceno et al., 2007). In Ethiopia specifically, primary care clinics are the most easily accessible setting for care; however previous studies have found that geographical distance to the clinics and cost of treatment remained the main barriers for individuals with SMI accessing mental health treatment (Hailemariam et al., 2019). While these barriers require a more systemic solution, for the purposes of this study we opted to provide patients with some transportation costs and to include resources to link future patients with existing community or government resources to assist with transportation costs. Providing supplemental resources, services, and support has been found to be an effective adaptation to improve health outcomes (Healey et al., 2017).

It is possible that even with the current adaptations, the intervention remains infeasible for providers to deliver in usual care or for patients and caregivers to access due to time constraints, financial and transportation concerns, stigma, or lack of community awareness about the service. Moreover, BREATHE Ethiopia is designed to be adjunctive to other interventions including medication management, and so scale up is dependent upon the availability and affordability of these other services. These questions should be addressed in future research based on experience trying to implement the adapted BREATHE program. The next steps of the BREATHE Ethiopia adaptation process are training staff, implementing the intervention and evaluating it in trials (Escoffery et al., 2018; Ng et al., 2021). Future research is also required to determine whether the adaptations sufficiently adhered to the original BREATHE intervention's core components (Nishith et al., 2015b). In

addition, future research is needed on the sustainability of BREATHE Ethiopia and other psychological interventions in the context of low-resourced settings with high staff turnover and whether the intervention remains sustainable after research funding and support has ended. If the results of the trials are promising, then the intervention could be implemented in additional primary care clinics in the country.

5. Conclusion

This study describes the process of adapting a PTSD treatment originally designed to be delivered by mental health providers in specialty mental health clinics in the US to be appropriate, acceptable and sustainable when delivered by non-specialist providers as part of routine care in rural Ethiopian primary care clinics. Integrating the perspectives of multiple stakeholders and utilizing qualitative interviews, expert workshops, and cognitive, usability and theater testing we identified multiple patient, family, provider, clinic and community-level barriers that might impact successful delivery and receipt of the intervention. The intervention was adapted to address as many barriers as possible, while maintaining adherence to the original interventions theoretical and conceptual model and "active ingredients." Future research is needed to assess whether the intervention is feasible and effective in this setting. Finally, while many of these barriers could be addressed with adaptations, others such as high rates of poverty and limited population-level psychoeducation, require policy and community-based solutions and systemic change.

CRedit authorship contribution statement

Lauren C. Ng: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Gray K. Bowers:** Writing – review & editing, Visualization, Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Dagmawit Tesfaye:** Writing – review & editing, Project administration, Investigation, Formal analysis, Data curation. **Eyerusalem Getachew Serba:** Writing – review & editing, Validation, Project administration, Investigation, Formal analysis, Data curation. **Abebaw Fekadu:** Writing – review & editing, Supervision, Resources, Methodology, Funding acquisition, Conceptualization. **Kimberly Hook:** Writing – review & editing, Validation, Formal analysis. **Amantia Ametaj:** Writing – review & editing, Formal analysis, Data curation. **David C. Henderson:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Kim T. Mueser:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Charlotte Hanlon:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization.

Ethics approval and consent to participate

This study was approved by the Institutional Review Boards of Addis Ababa University College of Health Sciences, Boston University Medical School/Boston Medical Center, and the University of California Los Angeles (UCLA).

Availability of data and materials

The dataset used and analyzed during this study is available from the corresponding author upon reasonable request.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used ChatGPT to improve readability. After using this tool, the authors reviewed and

edited the content as needed and take full responsibility for the content of the publication.

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Declaration of competing interest

The authors declare that they have no competing interests.

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For the purpose of open access, the authors have applied a Creative Commons Attribution (CC BY) license to any Author Accepted Author Manuscript version arising from this submission.

Appendix A. Supplementary data

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