

**DEVELOPING A PILOT STUDY OF EVIDENCE-BASED PTSD TREATMENT IN
PORT-AU-PRINCE, HAITI**

by

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ABSTRACT

Post-Traumatic Stress Disorder (PTSD) is a significant public health problem in Haiti, with prevalence as high as 36.8% in Port-au-Prince. Untreated PTSD is known to result in high rates of depression, anxiety, substance use, suicide, premature mortality, medical complications, homelessness, unemployment, sexual-risk-taking behaviors, domestic violence, and second-generation mental and physical health problems. The clinical science of PTSD has advanced quickly, producing gold-standard therapies with strong evidentiary support and effectiveness rates of approximately 85%. While prevalence of PTSD in Port-au-Prince is five times that seen in the United States, there are no published studies testing these therapies' effectiveness and no treatment programs offering these gold-standard approaches in Haiti.

Bringing effective PTSD therapy to Haiti requires a careful analysis of the historical, political, cultural, and religious context. Haiti's experience of public health interventions has been shaped by a complex history of colonialism, foreign intervention, missionary medicine, conflict between belief systems, second-class or non-existent services for the poor majority, and persistent power imbalances between provider institutions and the patients they serve. Such troubling dynamics have been particularly acute in mental health. For a mental health intervention to be effective and accepted in this context, practitioners must be aware of these undercurrents, define services as a concrete benefit to participants, not compromise international

gold-standards of care, position services as compliments to existing healing strategies, establish local oversight, transparently share findings, and partner with local organizations to scale up.

The proposed pilot program aims to fill these gaps in the literature and services by testing whether individual Prolonged Exposure (PE) Therapy, an intensive 12-week talk therapy protocol, is effective at reducing symptom severity among adults with PTSD in the Cité Soleil neighborhood of Port-au-Prince. This thesis develops the pilot program implementation plan, evaluation plan, and supporting literature reviews. If the pilot is able to show effectiveness on this small scale, the proposed project will make a significant contribution to public health by advancing the literature of evidence-based PTSD treatment in Haiti, and laying the foundation for expanding effective PTSD care to the hundreds of thousands of Haitians suffering from this debilitating, but highly treatable condition.

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1. INTRODUCTION:

Post-Traumatic Stress Disorder (PTSD) is a significant public health problem in Haiti, with prevalence as high as 36.8% in the general adult population of Port-au-Prince (Cénat & Derivois, 2014). Untreated PTSD is known to result in high rates of depression, anxiety, substance use (Brady, Killeen, Brewerton, & Lucerini, 2000), suicide (Kessler, Chiu, Demler, & Walters, 2005), premature mortality (Boscarino, 2006), medical complications (Beckham et al., 1998), homelessness, unemployment (Tanielian & Jaycox, 2008), sexual-risk-taking behaviors (Holmes, Foa, & Sammel, 2005), domestic violence (Jordan et al., 1992), and second generation mental and physical health problems in children of parents with untreated PTSD (Davidson, Smith, & Kudler, 1989). While the prevalence of PTSD in Port-au-Prince is nearly five times the rate seen in the United States (Kessler et al., 2005), there have been no published studies testing whether the latest gold-standard therapies from the West are effective in this context, and no treatment programs currently offering these evidence-based approaches to recovery.

Bringing effective PTSD therapy to Haiti, however, requires a careful analysis of the historical, political, cultural, and religious context. Haiti's experience of public health interventions has been shaped by a complex history of colonialism, foreign intervention, missionary medicine, conflict between belief systems, second-class or non-existent services for the poor majority, and persistent power imbalances between provider institutions and the patients they serve (Brodwin, 1996; Farmer, 2001; Polyné, 2013; Schuller, 2012; Schwartz, 2008). Such troubling dynamics have been particularly acute in mental health (Nicolas, Jean-Jacques, & Wheatley, 2012; World Health Organization, 2010). For a mental health intervention to be effective and accepted in this context, practitioners must be aware of these undercurrents, define service as a concrete benefit to participants, not compromise international gold-standards of care,

position services as compliments to existing healing strategies, establish local oversight, transparently share findings, and partner with local organizations to scale up.

The proposed pilot program aims to fill this gap in the literature, and in service delivery, by testing whether individual Prolonged Exposure (PE), an intensive 12-week talk therapy protocol grounded in Cognitive Behavioral Therapy (CBT), is effective at reducing PTSD symptom severity among adults with PTSD in the Cité Soleil neighborhood of Port-au-Prince, Haiti. This thesis develops the pilot program implementation plan, evaluation plan, and supporting literature reviews to guide implementation. If the pilot is able to show effectiveness on a small scale, the proposed project will both advance the literature on adapting evidence-based PTSD to the Haitian context and lay the foundation for expanding effective PTSD care to the estimated 375,000-534,000 people in Port-au-Prince alone currently suffering from this debilitating but highly treatable condition (Cénat & Derivois, 2014; Cerdá et al., 2013).

2. LITERATURE REVIEW

2.1 A PRESSING PUBLIC HEALTH NEED

PTSD is a significant and untreated public health problem in Haiti, affecting up to a third of the adult population. Public awareness and treatment programs for PTSD have grown rapidly in North America and Europe (DiMauro, Carter, Folk, & Kashdan, 2014), particularly for military veterans (Quartana et al., 2014; Tanielian & Jaycox, 2008). However, recognition of PTSD as a public health problem and the delivery of effective treatments are still in their infancy in low-income countries, like Haiti (World Health Organization, 2010). Identifying PTSD as a serious public health problem in Haiti and developing an intervention approach first necessitates a literature review of the following: the definition of PTSD, its causes and the consequences of

non-treatment; what is known about its prevalence in Haiti and location-specific risk-factors; the current state of evidence-based treatment strategies, including screening tools and diagnostic instruments; what is known about the effectiveness of evidence-based PTSD therapy, specifically PE, in diverse international settings; the context for public health and mental health interventions in Haiti, specifically examining the complex historical, political, cultural, and religious context relevant to this type of public health issue and possible intervention strategies; and finally an introduction to Mennonite Central Committee, an organization uniquely positioned to lead the type of pilot intervention and evaluation supported by the literature review.

2.1.1 PTSD: Definition, Causes, & Consequences of Non-Treatment

The technical names and clinical definitions for PTSD have changed significantly over time. One of the first clinically defined syndromes for a pathological response to psychological trauma was called “disordered palpitations of the heart” or “soldiers heart,” and developed during the American Civil War in the 1860’s. While simplistic by modern standards, this case definition acknowledged physical manifestations including a racing heart, psychological distress, and behavioral indicators including alcohol abuse (DiMauro et al., 2014). Later wars brought additional labels, including “Traumatic Neurosis” in the Franco-Prussian War, “Shell Shock” in World War I, and “War Neurosis” following World War II. However, it was only in 1980, with the release of the DSM-III and the coining of “Post-Traumatic Stress Disorder,” that the definition advanced to a more recognizable form that acknowledged the long-term nature of the disorder without treatment, the fact that it could manifest in otherwise healthy individuals (including civilians), and that it was a clinical disease with causes beyond the patient’s control (Jones & Wessely, 2007). Since then, the definition has continued to evolve to better define

symptoms, clarify relationships with related disorders, reduce pathologizing of normal reactions to trauma, reduce stigma, and improve the accuracy of diagnostic instruments (DiMauro et al., 2014).

The most recent detailed diagnostic criteria for this disorder can be found in the latest edition of the American Psychiatric Associations' Diagnostic and Statistical Manual (DSM-5). Within this framework, PTSD is diagnosed with eight criteria: type of stressor (exposure to or threat of death, serious injury, or sexual violence); intrusive symptoms (recurrent involuntary memories, traumatic nightmares, and dissociative reactions); avoidance symptoms; negative changes in cognition and mood; changes in arousal and reactivity (namely aggression, high startle reflex, self-destructive behavior, and hypervigilance); duration of symptoms (more than a month); level of distress and functional impairment; and exclusion of other causes (American Psychiatric Association, 2013). The National Institute of Mental Health explains PTSD concisely as “a changed or damaged” version of the body’s natural fight-flight-or-freeze response to danger, which “develops after a terrifying ordeal that involved physical harm or the threat of physical harm...it can result from a variety of traumatic incidents, such as mugging, rape, torture, being kidnapped or held captive, child abuse, car accidents, train wrecks, plane crashes, bombings, or natural disasters...PTSD can cause many symptoms, including...re-experiencing...avoidance...[and] hyperarousal” and results in serious and varied health consequences that disrupt a person’s life (National Institute for Mental Health, 2015). In other words, the body’s generally healthy and helpful fight-flight-or-freeze response is overwhelmed and unable to cope with the level of trauma(s) faced, thereby locking-in and distorting this natural defense mechanism into a chronic and debilitating health condition.

PTSD results when a person's natural resilience to stress and trauma is overwhelmed and unable to resolve naturally, generating a serious mental health condition that is unlikely to resolve without specific targeted intervention. The tertiary and secondary causes of PTSD include: war, crime, poverty, political instability, natural disaster, and interpersonal violence including sexual violence (Fontana & Schwartz, 1997; Tanielian & Jaycox, 2008). These distal determinants increase the likelihood of people experiencing traumatic life events. However, not everyone experiencing a traumatic life event will develop PTSD. In fact, lifetime PTSD prevalence among combat veterans is about 30% (Kulka et al., 1990). This compares to an average PTSD prevalence rate in the general population of developed countries of only 6.8% (Kessler et al., 2005), despite an estimated 90% of this population experiencing a qualifying trauma at some point in their lives (McDonald & Calhoun, 2010). Rates of PTSD among women are significantly higher in developed countries, at 9.7%, due primarily to higher rates of interpersonal and sexual violence (Kessler et al., 2005). The high percentage of people experiencing psychological trauma who do not develop PTSD, is due to the powerful role resilience factors such as strong social supports, intact family systems, access to mental health services, education, stable economic situations, strong religious communities and beliefs, healthy use of coping skills, and safe environments can play (Agaibi & Wilson, 2005). Conversely, identified risk factors for developing PTSD following traumatic exposure include: gender (female), age of first trauma exposure (younger), low socio-economic status, low education, low intelligence, minority status, other mental health diagnoses, adverse childhood events, previous traumatic exposures, family psychiatric history, severity of trauma, lack of social support, and other life stressors (Brewin, Andrews, & Valentine, 2000).

The public health consequences of untreated PTSD include: depression, anxiety, substance use (Brady et al., 2000), suicide (Kessler et al., 2005), premature mortality (Boscarino, 2006), medical complications (Beckham et al., 1998), homelessness, unemployment (Tanielian & Jaycox, 2008), sexual-risk-taking behaviors (Holmes et al., 2005), domestic violence (Jordan et al., 1992), and second generation mental and physical health problems in children of parents with untreated PTSD (Davidson et al., 1989). While calculation of the true cost of a disease at the population level is challenging, especially between different country contexts, it has been estimated that untreated PTSD in one individual brings a cost roughly equivalent to 6.2 times per capita gross domestic product. This cost is largely derived from lost productivity, premature mortality, and increased lifetime medical costs (Tanielian & Jaycox, 2008). In a country, like Haiti, without national insurance or a functioning welfare system, these high chronic costs of the untreated disease are borne almost entirely by the individual, family, and local community (Wagenaar, Kohrt, Hagaman, McLean, & Kaiser, 2014).

There has been vigorous debate in the literature about the application of PTSD as a diagnosis across cultural groups. A portion of this debate is simply part of a larger discussion of the extent to which mental health diagnosis and treatment are culturally constrained, or globally applicable. This literature began in the early 20th century, when mental health professionals found their diagnostic categories and psychotherapeutic techniques out of step in foreign cultures. The two extreme positions of this debate quickly established themselves: complete cultural relativism in mental health versus complete biological determinism and universalism (Paniagua & Yamada, 2013). As psychopharmacology has advanced and proven its effectiveness across cultural groups, this debate has shifted for many areas of mental health, with culture more commonly seen as a component of how people understand, describe, and approach underlying

mental health conditions, rather than a dominant determinant of diagnosis and treatment (Yamada & Marsella, 2013). A notable hold out to this trend is PTSD, where a strong minority of academics still believes that PTSD is merely a phenomenon of Western culture, making both diagnosis and treatment in new cultural settings suspect (Wilson & Tang, 2007).

Resistance to PTSD as a diagnostic category across cultures, derives from two major critiques: 1) different cultures have distinct frameworks for understanding traumatic psychological experience, with varying levels of resilience and different types of coping strategies (Hoshmand, 2007); and 2) different cultures have different traditionally accepted treatments for psychological trauma, some with significant anecdotal success (Moodley & West, 2005). Much of this argument, however, comes in response to poorly conceived and ultimately damaging initiatives that equated traumatic exposure with an assumption of deterministic pathology. Following wars in Rwanda and Bosnia and the tsunami in South East Asia, humanitarian groups and governments made claims of mass PTSD as part of their justification for invasive and costly interventions, without any supporting data of clinical prevalence or severity, or research on the cultural applicability of treatments in those settings (Wilson, 2007). Unfortunately for the legitimacy of international PTSD treatment, these interventions were not generally targeted at individuals meeting the latest diagnostic criteria and the interventions did not utilize the latest evidence-based treatments. Unsurprisingly then, these interventions failed to show significant effectiveness and were not well received by the target communities (Shah, 2007).

More recent work has largely overcome these methodological and ethical limitations by using culturally sensitive approaches, validated in clients' native languages, using the latest diagnostic definitions, and evidence-based treatments. For example, a recent review of evidence-

based PTSD diagnosis and treatment in diverse refugee populations found similar effectiveness rates and client acceptance to those seen previously in Western populations (Nickerson, Bryant, Silove, & Steel, 2011). Many other studies using these approaches have found similar results across diverse ethnic groups, with clinical effects consistent with prior studies conducted with Western populations (Droždek, Kamperman, Tol, Knipscheer, & Kleber, 2014; Edwards, 2005; Forbes et al., 2010; Paunovic & Öst, 2001). This data suggests that clinical PTSD does exist across cultures and can be successfully treated in comparable ways in a wide variety of contexts.

2.1.2 Risk & Prevalence In Haiti

Haitians are at elevated risk for developing PTSD due to the country's high levels of extreme poverty, economic dislocation, weak education systems, political violence, political instability, and frequent exposure to severe natural disasters (Brewin et al., 2000; Fontana & Schwartz, 1997; World Health Organization, 2010). Haiti is a low-income country by any definition, with an average annual income per capita of \$810, compared to \$9,536 for the region, or \$1,615 for Sub-Saharan Africa (World Bank, 2014b). Even this low average income is highly concentrated, with Haiti ranking as the most unequal county in the most unequal region in the world. An estimated 24% of Haitians live in extreme poverty, unable to meet even basic nutritional needs, and 45% are both chronically poor, and unable to access basic services like health, education, and sanitation (World Bank, 2014a). Haiti's population of 10.3 million people is highly concentrated in urban areas with poor infrastructure, resulting in 76% of urban households in Haiti classified as slums, the highest rate in the world (Smith, 2012). Similarly, economic underdevelopment has resulted in only 17% of the population having access to improved sanitation, leading to high rates of communicable disease. Low levels of economic

development are perpetuated and reinforced by a weak state and fragmented service delivery system. For example, with 92% of schools run by non-state actors who charge significant fees, school attendance is largely determined by income bracket, resulting in only 23% of children in the poorest quintile of households attending secondary school (Pan American Health Organization, 2012). Lack of equitable access to education has contributed to a basic youth literacy rate in Haiti of only 72%, compared to 97% for the region (UNICEF, 2015).

Interpersonal and political violence further heighten vulnerability and increases the risks of traumatic exposure and the development of PTSD. Political and social violence have been features of Haitian history since colonization and slavery, through revolution and civil wars, to occupation by foreign powers, dictatorships, and more recently, political discord and organized crime (Dubois, 2012; Girard, 2010). At a more personal level, studies have found up to 70% of Haitian women report experiencing personal violence during their lifetime, and 36% report sexual violence (A. J. Gage, 2005). More recent studies have found rates of intimate partner violence among adolescent girls in Port-au-Prince as high as 43%, and rates of physical or sexual violence among all adolescents as high as 75% (A. Gage, 2014). These problems extend beyond the capital city. A recent study in northern Haiti found similar trends, with severe psychological, social, and economic problems caused by the high prevalence of violence in these communities (Bolton, Surkan, Gray, & Desmousseaux, 2012).

The risk was further heightened for residents of Port-au-Prince and surrounding communities by the 2010 earthquake, which left an estimated 220,000 dead and 1.9 million displaced (Shultz, Marcelin, Madanes, Espinel, & Neria, 2011). This tragic event was the worst natural disaster to hit a Caribbean country in recorded history. Striking in the densest population center in the poorest country in the region, the earthquake caused unparalleled damage both

economically and in human suffering (Farmer, 2012). An estimated 91% of people living in Port-au-Prince had a close friend or relative killed or severely injured in the earthquake (Cerdá et al., 2013). In one day, the surviving population of Port-au-Prince and the surrounding area almost universally experienced severe trauma, economic dislocation, and social disintegration (Farmer, 2012).

This constellation of risk factors makes it highly probable that the population of Haiti, and Port-au-Prince in particular, have high rates of PTSD, even if not officially diagnosed by the medical system. Unfortunately, nation-wide representative health data is extremely limited and unreliable (Kaiser, Kohrt, Keys, Khoury, & Brewster, 2013; McShane, 2011; World Health Organization, 2011). However, two recent studies have used rigorous designs, random sampling, evidence-based instruments, multi-instrument validation, and the latest diagnostic criteria to assess the prevalence of PTSD in Port-au-Prince. These studies find PTSD rates among adults in the city ranging from 24.6% (Cerdá et al., 2013) to 36.8% (Cénat & Derivois, 2014). Recall that even among combat veterans, rates of PTSD rarely top 30% (Kulka et al., 1990) and the general population in developed countries have rates of around 7% (Kessler et al., 2005). This likely prevalence range of 25-37% yields an estimated effected population in Port-au-Prince alone of 375,000-534,000 adults suffering from untreated (or unsuccessfully treated) PTSD.

2.2 EVIDENCE-BASED PTSD TREATMENT

PTSD is unlikely to resolve without intervention (Zohar et al., 2011), but has been shown to be highly responsive to evidence-based treatments (Bass & Golding, 2012). The two interventions with the most evidentiary support are Prolonged Exposure Therapy (PE) and Cognitive Processing Therapy (CPT) (E. B. Foa, Gillihan, & Bryant, 2013; Forbes et al., 2010).

Complete and permanent remittance rates for both modalities is around 40%, with a further 45% of patients receiving statistically and clinically significant reductions in symptoms (Eftekhari et al., 2013; Tanielian & Jaycox, 2008). These two therapies, both built on the theoretical foundation of Cognitive Behavioral Therapy (Schnurr, 2008), have been studied extensively in Western and non-Western populations and found consistently positive results (Eftekhari et al., 2013; Forbes et al., 2010; Nickerson et al., 2011). While both therapies are based on the Cognitive Behavioral Therapy model of problem-focused reprogramming of ingrained mental and behavioral patterns, they differ in approach. CPT is more focused on conscious cognition and developing new ways of challenging distorted beliefs and questioning emotional reactions to stimuli perceived as threatening. In addition to using cognitive reframing tools, PE also directly addresses the fight-flight-or-freeze response through facilitated and safe exposure to the perceived threats. Of these two evidence-based modalities, PE has the longest track record of success, and is generally considered the gold standard of PTSD treatment by the Institute of Medicine, American Psychological Association, Veterans Affairs Office of Mental Health Services, and the US Substance Abuse and Mental Health Service Administration (Institute of Medicine, 2007; Management of Post-Traumatic Stress Working Group, 2010; Powers, Halpern, Ferenschak, Gillihan, & Foa, 2010; Schnurr, 2008; Substance Abuse and Mental Health Services Administration, 2014).

2.2.1 Prolonged Exposure Therapy

The theoretical foundation of PE comes from a branch of Cognitive Behavioral Therapy known as Emotional Processing Theory (EPT). This theory, developed in 1986 by Foa and Kozak, sees pathological fear and anxiety as outgrowths of the normal danger avoidance

response mechanism. In normal operation, this mechanism helps people (and animals) avoid danger by coding certain stimuli as inherently dangerous. This coding is generally established through painful or traumatic experience, and functions below the state of conscious awareness. Exposure to these stimuli in the future triggers a flood of emotional response in the brain, what is called acute anxiety, signaling that this situation is to be avoided at all costs. The theory postulates that pathological fears (such as PTSD or phobias) are created when the brain locks in particular stimuli as highly dangerous, when in fact they are not (E. B. Foa & Kozak, 1986). When the brain's fear response becomes so acute and unconnected to real danger, it can create a reinforcing loop of perceived dangers and felt anxieties that become nearly impossible for the individual to break without targeted treatment. This pathological fear response underlies PTSD, and leads to the disorder's characteristic multifaceted symptoms, poor health outcomes, and long-term persistence when not treated (E. B. Foa, 2011).

From this starting point, EPT assumes that long-term treatment is made possible by recoding the brain's fear response system around the particular stimuli triggering the pathological response. The basic approach is to expose the individual to the triggering stimuli in a safe setting and with sufficient support, so that they can experience the stimuli past the point of anxiety, and begin to reprogram the fear response. By experiencing the stimuli safely, the brain can begin to reinterpret its meaning, a type of learning which has the potential to permanently modify both the physical and psychological responses (E. B. Foa, 2011; Substance Abuse and Mental Health Services Administration, 2014). This understanding of pathological fear and the ability to reprogram the brain lies at the heart of many successful exposure therapies used for a variety of anxiety related disorders, including phobias and PTSD (Rauch & Foa, 2006).

The protocol for PE is built around cognitive reframing and two main methods of exposure to the triggering stimuli: “*imaginal*” and “*in vivo*.” *Imaginal* exposure consists of the therapist facilitating the patient’s complete narrative recollection of the traumatic memory. This narrative is recorded during the sessions, and is replayed by the patient as homework between sessions. *In vivo* exposure consists of the patient actively participating in avoided trigger activities in measured doses. For example, a patient who avoids crowded situations like grocery stores may be assigned to spend 20-40 minutes in a grocery store, five to seven times per week. During each exposure (either *in vivo* or *imaginal*), the patient is experiencing the trigger in a controlled environment that allows their brain to begin relearning the stimuli as nonthreatening. The protocol consists of 8-15 outpatient appointments with a trained therapist, each lasting 60-90 minutes. The initial session consists of a confirmation of the PTSD diagnosis by the treating clinician and determination of the index trauma (the most disruptive traumatic event and its associated triggers). This establishment of an index trauma is essential for PE to proceed, as the therapy focuses on this one index trauma and its triggers as the key to unlocking the brain’s hyperactive fear response. Sessions one through three consist of patient education, discussion of common reactions to PTSD and treatment, helping the patient understand their condition within the framework of PTSD, teaching breathing and relaxation techniques, explaining the PE protocol and the theory behind exposure therapy, and developing a list of trigger stimuli and avoided behaviors that can be used in *in vivo* exposures. Sessions four through treatment completion consist of measuring PTSD symptom severity (with the PCL-5 instrument) and depression severity (with the PHQ9 screening instrument), review of the past week’s *in vivo* homework, review of the patient’s response to the recorded *imaginal* trauma narrative, review of relaxation techniques, a 45-60 minute *imaginal* exposure, processing cognitive distortions, and

deciding on *in vivo* homework for the following week. As treatment progresses, *imaginal* exposures increasingly focus on “hot spots” in the trauma narrative, areas with the strongest continued emotional response, rather than a complete narration of the entire trauma memory (E. Foa, Hembree, & Rothbaum, 2007).

2.2.2 Screening Tools & Diagnostic Instruments

Success in treatment is predicated on accurate screening, diagnosis, and inclusion criteria. These elements are clearly established within the latest defined protocol for PE (E. Foa et al., 2007). The best general purpose PTSD screening tool for the primary care setting is the PC-PTSD (Management of Post-Traumatic Stress Working Group, 2010). This simple four-question tool (right) takes less than one minute to administer, and has relatively high reliability, given its simplicity and low implementation cost: a positive predictive value of 65% and a negative predictive value of 92%. The tool is designed for use in primary care appointments as either a general screening tool for all patients, or a targeted screening for patients exhibiting psychological distress (Prins et al., 2003).

| |
|---|
| <p>In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past month, you:</p> <ol style="list-style-type: none">1. Have had nightmares about it or thought about it when you did not want to? YES / NO2. Tried hard not to think about it or went out of your way to avoid situations that reminded you of it? YES / NO3. Were constantly on guard, watchful, or easily startled? YES / NO4. Felt numb or detached from others, activities, or your surroundings? YES / NO |
|---|

Figure 1: PC-PTSD Screening Tool (Prins et al., 2003)

Once a patient screens positive for PTSD using the PC-PTSD tool, they should be referred to a mental health specialist for assessment and diagnosis. An accurate assessment of PTSD is best made using the latest diagnostic criteria from DSM-5, and the gold-standard evidence-based Clinically Administered PTSD Scale (CAPS) assessment tool (Blake et al., 1990). CAPS-5 is the latest version of this well tested instrument, adapted to match the latest DSM-5 criteria (Mooren & Stöfösel, 2014). CAPS is a semi-structured, clinician-administered interview which, although time-consuming to administer, has proven the most valid diagnostic instrument for PTSD available (Management of Post-Traumatic Stress Working Group, 2010; Weathers, Keane, & Davidson, 2001).

2.2.3 Applying Prolonged Exposure Therapy in Diverse Settings

While there have been no published studies specifically testing PE in Haiti, the Caribbean, with Caribbean diaspora populations, or with culturally and genetically similar populations in West Africa, there is a growing body of evidence that PE is consistently effective across diverse populations, both internationally and with refugee populations in Western countries. A recent critical review of studies testing PTSD therapies in refugee populations found CBT-based approaches, including PE, to be consistently effective at reducing symptom severity regardless of the participants place of origin or cultural framework (Nickerson et al., 2011). PE and its adaptations have been studied extensively with Western and non-Western populations in diverse settings and found consistently positive results (Eftekhari et al., 2013; E. B. Foa et al., 2013; Forbes et al., 2010). These studies include many well-designed randomized control trials that show strong efficacy of the intervention with diverse populations from low-income countries, including multiple African regions, South America, Southeast Asia, and Eastern

Europe, both in the places of origin of participants and in refugee resettlement settings in low and middle income countries (Bichescu, Neuner, Schauer, & Elbert, 2007; Droždek et al., 2014; E. B. Foa et al., 2013; Hinton et al., 2004; Neuner et al., 2010; Neuner, Schauer, Klaschik, Karunakara, & Elbert, 2004; Nickerson et al., 2011; Powers et al., 2010).

When compared to other talk-therapy treatments for PTSD, such as Cognitive Processing Therapy, PE relies less on analytical discussion with shared cultural constructs, and more on facilitating the patient's own narrative and meaning making. Rather than directly challenging 'stuck points' and 'unhelpful' beliefs, which may have deep cultural roots, PE allows the patient's own trauma narrative and self-identified avoidance activities to guide treatment. Reframing within PE relies on the patient themselves identifying contradictions between their beliefs about the trauma and their own trauma narrative (E. Foa et al., 2007). While the discussed evidence lends strong support to the hypothesis that PE will be effective in other low-income international contexts, such as Haiti, prior to initiating a targeted intervention, a deeper understanding of Haiti's specific historical, political, religious, and cultural context is necessary.

2.3 THE CONTEXT OF PUBLIC HEALTH IN HAITI

Among its neighbors, Haiti is an outlier for its poverty (World Bank, 2014a), weak public health system (Farmer, 2012), fragmented healthcare delivery (Dowell, Tappero, & Frieden, 2011; Edmonds, 2012), and poor health outcomes (Pan American Health Organization, 2012). Under-five mortality in Haiti stands at 73 per 1,000 live births, compared to 39 per 1,000 for the next highest country in the region, Bolivia, and 18 per 1,000 for the region as a whole (World Health Organization, 2013). The proportion of the population with access to improved drinking water sources is 62% in Haiti, compared to 81% in its next closest peer, Dominican Republic, and a regional average of 94% (World Health Organization, 2012b). Life expectancy at birth is

62 years in Haiti, 14 years lower than the regional average of 76 (World Health Organization, 2012a). Tuberculosis prevalence in Haiti is 296 per 100,000, compared to the regional average of 40. Annual malaria incidence is 1,299 per 100,000, compared to the regional average of 139 (World Health Organization, 2013). The same pattern can be seen across a wide spectrum of health indicators, including maternal mortality, infant mortality, deaths from communicable diseases, low vaccination rates, zoonoses such as rabies, and deaths due to malnutrition and diarrhea (Pan American Health Organization, 2012). While many of Haiti's public health statistics are starting to head in the right direction, progress has been slow, uneven, and halting when compared to its peers in the region (Farmer, 2012).

Following broader global trends, improvements in mental health care in Haiti have lagged far behind even this slow progress in physical medicine (World Health Organization, 2011). Mental health care is inaccessible for most Haitians (Wagenaar et al., 2014), and what services exist are poorly suited to treating PTSD and similar conditions (Bailey, Bailey, & Akpudo, 2010; Nicolas et al., 2012). Haiti's mental health infrastructure is extremely limited, even when compared to other low-income countries globally. According to World Health Organization statistics, Haiti has only one practicing psychiatrist for every 500,000 people, and only one psychologist, social worker, or mental health nurse for every 330,000 people (World Health Organization, 2011). Other locally collected data indicate rates roughly double these, with as many as 20 psychiatrists, 30 mental health nurses, 50 social workers, and 100 psychologists operating in the country (Nicolas et al., 2012). However, with the vast majority of mental health staff concentrating on inpatient serious mental illness, namely schizophrenia and psychosis, there are almost no staff or resources available for chronic lower intensity conditions like PTSD (World Health Organization, 2010). While Haiti's public health shortcomings are relatively well

known, a deeper and more useful understanding of Haiti's public health and mental health systems requires framing the current state within its broader historical, political, cultural, and religious context.

2.3.1 Historical & Political Context

Haiti's weak state, political instability, economic underdevelopment, and fragmentation of service delivery have resulted in what has been described as "the hemisphere's weakest public health system" (Dowell et al., 2011, p. 300). International donors, reluctant to provide money to the Haitian government, have increasingly channeled funds to Non-Governmental Organizations (NGOs), leading to a proliferation of these organizations and the pejorative label, "The Republic of NGOs" (Farmer, 2013, p. 170). By most estimates, Haiti's social service system is now more privatized than any other country in the region, with approximately 80% of all services, from health to education, provided by NGOs (Edmonds, 2012). In 2008, for example, net foreign aid to Haiti was \$92 per person, but only \$2.77 of this was channeled through the Haitian government (Ramachandran & Walz, 2012). The funding that followed the 2010 earthquake was even more skewed away from public programs, with 99.1% going to NGOs and international organizations (Katz, 2013). This flood of funding outside of public control has fueled a rapid and largely unaccountable growth in the NGO sector (Farmer, 2012). There is such limited accountability for NGOs that it is difficult to even determine how many are operating in the country. Estimates range from 20,000 to 343, the low estimate being the number of organizations that have actually gone through the legal registration process with the government of Haiti (Ramachandran & Walz, 2012). The vast majority of health services in the country are provided through loosely regulated private actors. Even by the most generous calculations, the Haitian

government only controls about 36% of health infrastructure, concentrated in a few urban tertiary hospitals and universities (Ivers, 2011).

If Haiti's privatized, largely uncoordinated, and loosely regulated health sector was delivering good health outcomes at reasonable cost, one could argue for the merits of this model. However, most researchers, practitioners, and users of Haitian healthcare have concluded that the system is not working for the people of Haiti (Dowell et al., 2011; Farmer, 2012; Schwartz, 2008). NGO funding is volatile, and by its very nature, poorly suited to long-term democratically accountable public health programming (Barnett, 2011). Without enforced minimum standards of care and reliable resources, health care facilities in Haiti are resistant to implementing leading edge therapies and often provide shockingly poor levels of care to patients. For example, over 30% of all healthcare facilities in Haiti lack access to clean water for patient use (Pan American Health Organization, 2012). Stories abound of unsanitary conditions, doctors abandoning clinics, patient abuse, corruption, critical shortages of supplies and medications, poorly trained staff, and exorbitant fees (Brodwin, 1996; Farmer, 2001; Kidder, 2009; Schwartz, 2008). Without a clear understanding of how Haiti's current public health context differs from its peers in the region, and critically how it differs from the contexts in which public health interventions were designed and tested, it is impossible to begin the process of adapting tools, techniques, and programs to Haiti.

Successfully adapting interventions to the Haitian context also requires a deeper analysis of Haiti's history, and its relationship to the West and Western medicine. The modern history of the area that would become Haiti began with exploitation for the benefit of foreigners. This is a dynamic that some would argue continues into the 21st century and provides the dominant frame for Haiti's relationship with the outside world (Goddard, 2011). When Europeans landed on the

island of Hispaniola, they encountered a complex civilization, complete with developed agricultural practices, religious systems, political organization, healing practices, and diverse language and ethnic groups. There is wide disagreement on Hispaniola's population prior to Columbus's landing, from as high as four million people, to as low as 400,000 (Monzote, 2011). European colonialism, first Spanish and then French, could only succeed in this context by "pushing aside, removing, enslaving, or killing" the existing populations (Higman, 2011, p. 53). This was done with brutal efficiency during the first decades of occupation, decimating the indigenous populations through disease, forced labor, violence, and displacement.

After exhausting indigenous labor supplies, and experimenting with indentured European labor, colonial leaders fixed on imported African slaves to feed the growing demand for plantation labor on the island. The colony's demand for slave labor grew quickly as cotton, indigo, coffee, and, most importantly, sugar production took off. At the peak of its colonial prosperity in 1790, French Saint-Domingue was importing 48,000 slaves per year (Girard, 2010). The horrors and indignities of plantation slavery are well documented, and form a persistent element of Haitian identity into modern times (Miguel, 2005). For many slaves bound for Haiti, their first interaction with Western medicine and public health was the crude smallpox vaccines often given at African slaving ports, or during transatlantic transport. Provided in the context of the slave trade, this was the first of many public health initiatives in Haiti where the direct 'beneficiaries' tended to view the intervention as an exploitative and invasive effort designed for the benefit of others (Klein & Vinson, 2007). A second early experience of a public health intervention was the promulgation of the "*Code Noir*," a 1685 slave code issued by the French monarchy. It was designed to demonstrate France's benevolent "Catholic character," reduce the risk of slave rebellions by limiting the worst excesses of slavery, and bring order to the growing

colonial slave system. The *Code Noir* attempted this through a variety of decrees, many horrific, but some of which had positive public health implications, including maximum working hours, guaranteed days off work, minimum clothing standards, minimum food rations, and prohibitions against rape (2006). However, since the *Code Noir* was widely cited but largely ignored by those in authority, its main contribution to Haiti's history of public health was to establish the enduring precedent of policies and political pronouncements written for public consumption, but ignored or subverted in practice (Fick, 1990).

The majority of slaves worked on rural plantations, where risks to health were severe, and opportunities to access the scientific medicine of the day were almost nonexistent. Most large plantations had clinics to care for injured or ill slaves. However, these clinics were only lightly staffed by traveling French physicians, most of whom had little formal training. The bulk of the clinic work was done by the slaves themselves, drawing from diverse African healing traditions, indigenous local herbal medicine, 17th century French humoral and folk medicine, Catholic ritual healing, and second-rate scientific medicine when available. This eclectic mix of traditions would come to form the foundation of traditional Haitian healing practice, including the development of Vodoun healing (Brodwin, 1996). The open-minded and pragmatic use of all available healing resources was born out of necessity during plantation slavery, but also mirrors wider African patterns of openness to medical pluralism (Flint, 2008; Langwick, 2011).

The slave revolution, which led to Haitian independence in 1804, raised high hopes for a new social order, and better living standards for the people of Haiti. The costs of revolution had been immense: upwards of 100,000 people died in the last year of fighting alone; the economy had been destroyed; and the new nation was isolated and punished by the international community (Gibson, 2014). While some elements of Haitian life and culture would change

dramatically, including the development of small-holder peasant agriculture, the country was profoundly shaped by its colonial heritage and the internationally imposed costs of revolution against the slavery-dependent social order of the day. As historian Laurent Dubois (2012) concisely states, “Colonial Saint-Domingue had been constructed around a hierarchical social order, an autocratic and militarized political system, and an export-oriented economy. From the moment of its founding to the present day, Haiti would find itself burdened by all three” (p. 16).

Believing that Haiti’s independence (and their personal power) rested on military capacity, Haiti’s leaders invested scarce state resources in security and diplomacy, including a massive 150 million franc (equal to \$21 billion today) indemnity to France in exchange for diplomatic recognition (Dubois, 2011). With little state or international support for health services, Haiti’s peasant farmers relied almost entirely on local resources and traditional healing practices. The major exception to this rule was two medical schools founded in the first decades of independent Haiti, one in Le Cap and one in Port-au-Prince. The Port-au-Prince school remained in operation until it was shut down during the US occupation (1915-1934) and replaced with a US controlled institution staffed by US doctors (Brodwin, 1996).

However, even with functioning medical schools and a fledgling ministry of health, Western medicine was concentrated in the cities and largely targeted to the elite. The most significant advances in healthcare delivery for rural Haitians came with foreign missionary medicine in the early 1900s and NGO medicine later in the century. Missionary medicine had always been a presence in the country. Haiti’s first hospital, opened in 1694 in Cap Francois (later Cap Haitian), belonged to the Catholic Sisters of Charity. However, it was the US occupation of Haiti from 1915-1934 that started the flood of foreign agencies that has continued to today. Without significant state oversight or coordination, clinics, pharmacies, and some full-

fledged hospitals began to spring up across Haiti, usually in conjunction with mission compounds. While these medical services varied dramatically in quality, missionary medicine generally represented the most advanced Western medicine available to rural Haitians (Brodwin, 1996). The motivations behind these mission health services ran the gamut from altruistic to self-serving, from utilitarian tools to grow church membership, to covert political programs (Brodwin, 1996; Schwartz, 2008; Silvia, 2014). By mid-century, non-religious NGOs began major operations as well, including the notable examples of Hôpital Albert Schweitzer in 1956, and Partners in Health in 1987. The addition of hundreds of health-related NGOs over the last half-century has added layers and expanded the reach of this fragmented delivery system, but has not fundamentally changed its structure. The relationship of most Haitians to healthcare delivery is still one mediated across the power differential of charity and foreign priorities, rather than a language of healthcare rights and democratic oversight (Farmer, 2012).

Haiti's unique public health and political history provide a context that must be considered when developing and implementing new public health programs in the country. Particularly when a new mental health program, such as PTSD treatment, is being designed, several critical lessons emerge from a review of this literature: 1) practitioners, administrators, and funders alike need to be cognizant of this long history, frequently characterized by exploitation, misunderstanding, and second-rate medicine, and take steps to avoid the perception of repeating these patterns; 2) the poor majority of Haitian people have historically been used as means, rather than ends in themselves, and efforts should be taken to direct programs and messaging toward the individual benefit of participants themselves; 3) Haiti's poverty and unique culture have often been used as excuses to be satisfied with second-rate medicine, what Paul Farmer describes as "shit for the poor" (Farmer, 2001, p. 21), new programs should avoid

this trap by insisting on gold-standard evidence-based therapies; and 4) programs should be designed to grow local capacity, insist on local oversight, and if successful, be turned over to local partners for scaling up when possible.

2.3.2 Cultural & Religious Context

Given the close link for many Haitians between Western medicine and Christian missions, it is important to understand the deeper sociological and religious context of medicine and healing in Haiti. Within Haiti, there are four broad overlapping and interconnected systems of healing that impact popular understanding and treatment of mental health conditions like PTSD: 1) Serving the *lwa* (spirits) in popular Haitian religion, or Vodoun; 2) *fèy*, or traditional herbal remedies; 3) Christian healing (both Catholic & Protestant), including exorcism; and 4) Western secular medicine. Each of these systems of thought and practice includes great diversity. While each system could be considered independently, the dominant Haitian approach to healing is pragmatic and syncretic pluralism, not ridged adherence to any one system of practice or belief. Individuals seeking healing will often combine elements from multiple traditions, in a pragmatic form of medical syncretism, even when doing so means accepting seemingly contradictory perspectives on both cause and treatment. Similarly, practitioners within each healing tradition are often willing to pursue hybrid therapeutic interventions in order to find relief for their patients with the resources available (Brodwin, 1996).

The traditional religious system of Vodoun (also spelled Voodoo or Vodun) is probably the most written about, stereotyped, and least understood feature of Haitian culture. The Western mischaracterization of the religion is best captured in Alfred Métraux's opening words to his groundbreaking 1959 ethnographic study of the topic: "Certain exotic words are charged with

evocative power. [For the West] Voodoo is one. It usually conjures up visions of mysterious deaths, secret rites—or dark saturnalia celebrated by ‘blood-maddened, sex-maddened, god-maddened’ negroes” (Métraux, 1959, p. 15). In everyday life, however, Vodoun functions much like any other religious system: providing meaning, community ritual, healing, connection, and purpose. Healing rituals in particular, form the backbone of the religion, and the bulk of its ceremonies are dedicated to this purpose (Brodwin, 1996; Davis, 1997; Métraux, 1959). Vodoun is a unique syncretistic faith; developed in Haiti from the wide variety of West African belief systems brought over with slaves, 17th century French folk religion picked up during colonialism, and Catholic elements repurposed from the official state religion. The primary reason most Haitians consult a Vodoun practitioner is to determine whether their illness is a *maladi bondye* (“illness of god”) or a *maladi satan* (“illness of satan”). These categories of illness differentiate between the natural “illnesses of god”, with worldly explanations and medical treatments, and supernatural “illnesses of satan,” which require spiritual intervention. If the illness is a natural *maladi bondye*, the practitioner will refer the patient to specialists in this field: herbalists or Western medical practitioners. Only if the illness is determined to be of supernatural causes, sent upon the client by an aggrieved person or spirit, would the Vodoun practitioner use spiritual resources to combat this illness (Brodwin, 1996). As anthropologists Csordas & Lewton (1998) concisely summarize this scope of practice: “Vodoun addresses problems of social origin as well as...conditions that biomedicine fails to cure” (p. 453).

Of critical importance for public health, the boundary between these categories is not rigid, and has shifted over time as once mysterious illnesses become understandable and treatable within the frame of natural *maladi bondye*. For example, when AIDS arrived in Haiti in the early 1980s, it was a novel condition, with devastating physical symptoms, and Western medicine had

no effective treatment. To many Haitians, this put the condition squarely in the realm of *maladi satan*. However, as Western medicine's diagnosis and treatment improved (especially with the provision of life saving antiretrovirals by organizations like Partners in Health), the disease increasingly became seen as a natural illness, with natural causes, best treated by Western medicine (Farmer, 2006). Similarly, in the area of mental health, scholars have traditionally deemed Vodoun beliefs about the supernatural causes and cures of mental illness to be a barrier to appropriate medical care. In fact, three-quarters of rural Haitians say they would seek religious-based healing for mental health conditions rather than going to a Western medical practitioner (Wagenaar et al., 2014). However, a more detailed analysis of actual practice in mental health cases found that patients were evaluating perceived effectiveness of care, and that in general, "[Vodoun] practitioners expressed a desire to collaborate with biomedical practitioners and often referred patients to hospitals" when they believed that Western medicine would help (Khoury, Kaiser, Keys, Brewster, & Kohrt, 2012). While there is evidence of Vodoun healing serving as a substitute for Western medicine, the underlying factors in people's health decisions are more complicated than the often assumed "backward beliefs," and have proven to be open to change when effective interventions are made accessible geographically, financially, and culturally (Brodwin, 1996; Muula, Polycarpe, Job, Siziya, & Rudatsikira, 2009).

The second pillar of folk healing practice in Haiti is *fèy*, or herbal medicine. This practice is probably Haiti's most commonly used healing system, and is often the first place people go when seeking healing (Farmer, 2001). *Fèy*, broadly understood, represents a spectrum of healing practices from cheap home remedies doled out by relatives, to potent and sometimes expensive concoctions including pharmaceuticals put together by specialist practitioners in the field. While *fèy* practitioners make reference to the angels or spirits that guide them in their work, the theory

of disease and treatment they are operating under is fundamentally rooted in the natural world and biochemical processes. Practitioners gain expertise in *fèy* through apprenticeships, study, and experiential practice. Because *fèy* is seen primarily as non-religious in orientation, it has had less conflict with other religiously-oriented healing frameworks, including missionary-based Western medicine (Brodwin, 1996). The broad accommodation of *fèy* by Western medicine in Haiti, is particularly interesting given that in many ways it is more directly in competition than is Vodoun, which sees itself as operating in a different realm of reality. Beyond religious biases of Western medical practitioners, perhaps a reason for greater acceptance is that without religious language, Western medical practitioners and *fèy* practitioners can more easily communicate about cause and cure, and sometimes reach agreement. An interesting study conducted in France found that 18 of 20 commonly used traditional Haitian healing practices for pain management mirrored processes used in Western medicine, while only two representing what the study considered supernatural or superstitious practice (Sanou et al., 2012). Findings like these, combined with the widely shared pragmatism of Haitian healers, suggest opportunities for collaboration between public health and traditional practitioners.

Christianity, while usually not acknowledged as an alternative healing philosophy, plays a major role in Haitian thought and practice, particularly in the area of mental health. Officially sanctioned Christianity (both Catholic and Protestant) has generally positioned itself in opposition to Haitian spirituality, specifically Vodoun, and in alignment with Western medicine (Brodwin, 1996). The clearest examples of this are mission hospitals, where Christianity and Western medicine are presented as a packaged alternative to Vodoun and traditional medicine (Schwartz, 2008). However, common Christian practices in Haiti, such as exorcisms and healing prayer rituals, complicate this simple narrative. Christian missionary institutions in Haiti, in their

many forms, have often been the major drivers behind a belief system associating sickness with guilt or evil, which has increased stigma and complicated treatment (Brodwin, 1996). This has been particularly troubling in mental health conditions, which have often been viewed as spirit possession by Christian practitioners and therefore associated, to varying degrees, with moral guilt (Wagenaar et al., 2014). *Fèy* and Western medicine generally agree that the causes and cures of illness lie in the natural world. Vodoun does ascribe illness to spirits, some of which are ‘sent’ by other people, but it does not tend to presume that bad things happen to bad people or that the spirits causing illness have a moral character (either good or evil). Christian practitioners’ tendencies to label spirits as evil has meant that in cases of supposed spiritually-caused-illness, patients have sometimes been characterized as sharing in the moral blame. Also, practitioners addressing spiritual forces outside the Christian framework, such as in Vodoun, are often deemed to be tainted by the same evil associated with those spirits (Brodwin, 1996). This implicit moral framework of illness, healing, and spirituality, combined with the power and prestige of Christian institutions, means that many Haitians have felt embarrassed of traditional healing practices such as Vodoun, and reticent to openly acknowledge using or believing in non-Christian spiritual healing (Brodwin, 1996; Farmer, 2001; Linde, 2001; Métraux, 1959).

As seen in the perceived alignment between Western medicine and Christianity, or the moving boundary between *maladi bondye* and *maladi satan*, explanations of illness and decisions of treatment are always embedded in structures of power and access to resources. While measures of total health resources (such as doctors per person, or per capita health spending) put Haiti near the bottom of regional rankings, these global measures do not account for the country’s massive inequalities. What medical resources are available, tend to be concentrated in cities and inaccessible by geography and price to many Haitians. The level of

Western medical care actually accessible to the average Haitian is literally and figuratively miles away from the modern private-pay clinics of Port-au-Prince. With high concentrations of medical services in urban areas, an estimated 40% of the population has no access to Western medical care even if they could afford it (Pan American Health Organization, 2012).

Additionally, if Haitians do reach a healthcare facility, they are likely to find it too understaffed and under-resourced to provide adequate care. Following internationally standardized protocols, Health Action International, the World Health Organization, and the Haitian Ministry of Health and Population conducted a representative randomized assessment of health facilities across the country. One area they analyzed was stocking of basic medications. The median facility was found to have only 17.6% of these basic medications on hand. This is less than half the average rate for low-income countries globally, and represents the lowest rate of any country in the world. Of note, private-pay clinics averaged 54.3% in Haiti, and even higher when looking at urban clinics (Health Action International, 2011). The chasm between medicine's promise and actually delivery of quality services to the people who need it, is even higher in the areas of mental health (World Health Organization, 2010).

Haiti's complex social and religious dynamics combined with the all-too-often failed promises of accessible and effective Western medicine creates a uniquely challenging context in which to initiate a new mental health treatment program. Several key lessons from this literature review should be considered in the design of such an intervention: 1) Prior to initiation, new programs and staff should take time to understand the religious and cultural context of participants, and how that may effect program design, implementation, and evaluation; 2) utilize evaluation techniques, such as in-depth one-on-one qualitative interviews, which can better explore the impact of Haiti's rich context on disease manifestation and treatment, and help to

guide program improvements in future iterations; 3) be mindful of historical, cultural, and religious baggage, especially if using a religious organization in implementation; 4) from a public health perspective, see the cultural preference for pragmatic syncretism as an opportunity to gain broad acceptance through proven results, rather than seeing certain cultural or religious views as impediments to success; and 5) develop framing strategies and language that acknowledge and use participants' dominant meaning making models, without excluding or marginalizing specific religious and cultural perspectives.

2.4. MENNONITE CENTRAL COMMITTEE

The proposed PTSD treatment pilot program is developed for implementation by the international non-profit agency Mennonite Central Committee (MCC). With 95 years of experience in international relief, development, and health operations and 57 years working in Haiti, MCC is a well-respected and established multi-service agency in the field. Through its history in diverse international contexts, MCC has developed a uniquely well suited approach to service that is based on a people-centered approach of long-term relationship building, a consistent focus on peace, justice, and human dignity, and a commitment to remaining a small, responsive, innovative, and grassroots-driven organization (Shetler, 2008). As the premier international relief, development, and peace agency of the global Anabaptist churches, MCC understands its mission from a distinctly Christian Anabaptist perspective, but its work is self-consciously not evangelistic or discriminatory based on religion (Mennonite Central Committee, 2012). MCC's deep-rooted partnerships in Haiti, its non-evangelistic and non-discriminatory approach, its successful experience in launching innovative programs in Haiti that are turned over to local partners to sustain and scale, its depth of experience in health and public health

programs in Haiti, the unique qualifications of its staff, and its strategic focus on trauma recovery in Haiti, make it an ideal agency to lead the proposed pilot initiative.

MCC was created in 1920 by North American Mennonites to aid coreligionists suffering from war and hunger in Eastern Europe. Until the late 1940s, the majority of MCC's international work focused on the aid and resettlement of fellow Anabaptists, an effort that would galvanize a deep foundation of support and trust with MCC's constituency and set a tone of partnership and mutual accountability with the people MCC aided (Toews, 1996). Building on this sense of partnership and accountability between donors, agency staff, and beneficiaries, was a religious conviction that this connection was sacred and not to be compromised or ignored for selfish or shortsighted ends (Lehman, 1945). In following this model, MCC has traditionally invested significant time and resources into building and maintaining relationships before, during, and after the direct implementation of projects. This investment has been valuable to MCC for ideological reasons as well as for the instrumental purpose of creating opportunities and trust for innovative and groundbreaking work. Additionally, MCC has invested significant trust and independence in its staff, giving them the flexibility and opportunity to shape programming on the ground (Martin & Martin, 2007). This flexibility in staffing and funding, high-levels of trust with local partners, and strong ethical commitment to the dignity and wellbeing of beneficiaries at the organizational level provides a unique context for innovating in the field of public health in the complex context of Haiti.

MCC began work in Haiti in 1958, through a combination of health and agricultural development programs. MCC's first major programs included medical and administrative staffing for the newly founded Hôpital Albert Schweitzer starting in 1958, and establishing a hospital and public health program in the northern village of Grande-Rivière-du-Nord in 1959.

Through these and other health related programs, MCC developed in-country experience and expertise in directly providing health services, developing and implementing health education and preventive health programs, including vaccination, water, and sanitation, integrating health and development programs, including agriculture, reforestation, education, and community organizing, and working with and through diverse local and international partnerships. The hospital and public health program at Grande-Rivière-du-Nord was conducted from the beginning in coordination with the Haitian Ministry of Health. Once the clinic was established, renovated, staffed, and operational, a transition plan was successfully implemented to turn over control to the Ministry of Health, who continues to run the clinic today. This initiative was the first of many in a proven pattern of launching innovative programs which were then spun off to local partners and government agencies (Hess, 2008). Today, MCC's Haiti program consists of a diverse portfolio of development and public health programs including reforestation, environmental sustainability, nutrition, agriculture, safe housing, education, peace and justice advocacy, human rights, water, sanitation, trauma recovery, conflict resolution, and community organizing. MCC staffing consists of both national Haitian staff, primarily working in the large agroforestry branch in Desarmes, and an international staff, primarily seconded to partner organizations and projects (Mennonite Central Committee, 2014).

The incoming Country Directors for MCC Haiti (arriving November 2015) are proposed as the primary implementation team for the pilot PTSD treatment program. The author, Paul Shetler Fast, has Masters degrees in International Development and Public Health, and experience in managing complex health programs and conducting both quantitative and qualitative research in domestic and international settings. His role would be a 10% time commitment to the project, focused on project design, IRB approvals, funding oversight,

evaluation, and reporting. Co-Director Rebecca Shetler Fast is a Licensed Clinical Social Worker (LCSW) with a Master of Social Work degree and specialized experience and certification in the provision of both PE and Cognitive Processing Therapy for PTSD. As an experienced PTSD specialist, her 50% time commitment would be as the lead clinician on the project responsible for screening, diagnosis and treatment during the study, clinical direction for the project, coordination with local oversight committees, coordination with local partner organizations, training of referring healthcare providers in PTSD screening, and collection of primary evaluation data. Given the verbal proficiency required for successful PE, clinical assessments and treatment would not be initiated until Ms. Shetler Fast was professionally fluent in Haitian Creole. Salary support for the contributions of both Country Directors would come directly from MCC. All other project funding will be raised independently by the Country Directors, and administered through MCC's Haiti office.

3. PILOT PROGRAM IMPLEMENTATION PLAN

The proposed pilot program will involve the provision of the full course of evidence-based, individual PE to 50 adults diagnosed with PTSD from the Cité Soleil neighborhood of Port-au-Prince. The clinic location will be hosted at one of two well-respected partner agencies in Cité Soleil, CHOSCAL (*Centre Hospitalier Sainte-Catherine Laboure*, St. Catherine Laboure Hospital) or SAKALA (*Sant Kominote Altenatif Ak Lape*, Community Center for Peaceful Alternatives). Individuals with suspected PTSD will be referred to the pilot program by community health workers in primary care settings using the evidence-based PC-PTSD screening tool. The initial stage of the project (prior to accepting referrals), will involve training these community health workers from various health organizations in Cité Soleil, on the basics

of PTSD, the potential efficacy of evidence-based treatments, the purpose of the pilot program, how to screen patients for possible PTSD using a translated version of the PC-PTSD, and the referral process to the pilot program. Participating community health workers will be asked to incorporate PTSD screening into routine primary care visits for all adults seen in their practice until the project has recruited at least 50 willing participants, who receive a confirmatory diagnosis of PTSD by the project's clinical staff member. The intervention will begin when the full cohort of 50 patients have agreed to participate. With only five referring primary care providers in the community, each seeing an average of 15 patients per clinic day, a community adult PTSD prevalence rate of 25% (Cerdá et al., 2013), acceptance of referral from positively screened patients at 50%, a confirmatory PTSD diagnosis of 65% among those referred (Prins et al., 2003), and a 50% opt-in rate for the study, it is anticipated to take approximately 16 clinic days (roughly three weeks) to recruit the study population.

Once referrals are received, the pilot project's LCSW will conduct a thorough assessment using the gold-standard semi-structured interview instrument CAPS-5 and DSM-5 diagnostic criteria. Persons not meeting the diagnostic criteria for PTSD will be referred back to their primary care provider with the results of the assessment for appropriate follow up. All persons receiving a confirmatory positive PTSD diagnosis will be offered inclusion in the program. If willing to participate and consenting to the study protocol (including random assignment), each person will be randomly assigned to either the waitlist control group or the immediate treatment group. Both groups will have the PCL-5 PTSD symptom severity index administered during intake. This score will serve as the baseline measure of PTSD symptom severity for both groups.

The immediate treatment group will begin a full course of PE, with 12 weekly 90-minute one-on-one therapy sessions with a trained clinician (for a full discussion of PE theory and

protocol, see section 2.2.1). At the conclusion of treatment, a second PCL-5 score will be collected for the treatment group, to serve as a measure of immediate-post-treatment PTSD symptom severity. A final PCL-5 score will be collected from the treatment group three months after the conclusion of treatment, during a follow-up visit as a measure of the treatment's ability to effect long-term symptom relief. The waitlist control group will not receive any PTSD treatment during their time on the waitlist. Since no evidence-based PTSD therapies are currently offered in Port-au-Prince, this represents the current community standard of care (World Health Organization, 2010). In addition to the baseline PCL-5 score collected at intake to the program, a second measurement will be collected from the waitlist control group at three months and six months (the same time periods used in the treatment group). At the conclusion of the six month waitlist period, all waitlist controls will be brought into active treatment and receive the same course of therapy offered to those in the immediate treatment group. These PCL-5 scores for both treatment and control groups will serve as the primary quantitative measure of treatment success. At the three-month follow up visit for the immediate treatment group, after the final PCL-5 scores are collected, a qualitative one-on-one interview will be conducted with a select group of patients. This interview will aim to do the following: gather in-depth information on individual-level risk, resilience, and cultural factors that may influence PTSD development; understand differential treatment success; and inform future iterations of treatment to better adapt to Haiti's cultural context. As part of treatment, participants will receive an inexpensive digital audio recorder/player and headphones. Per PE protocol, these will be used to record *imaginal* sessions for the patient to listen to as homework. Participants will also be reimbursed for time and travel costs. A marginal fee will be provided to the host agency for use of the clinic space. There will be no cost to the patients for assessment or treatment.

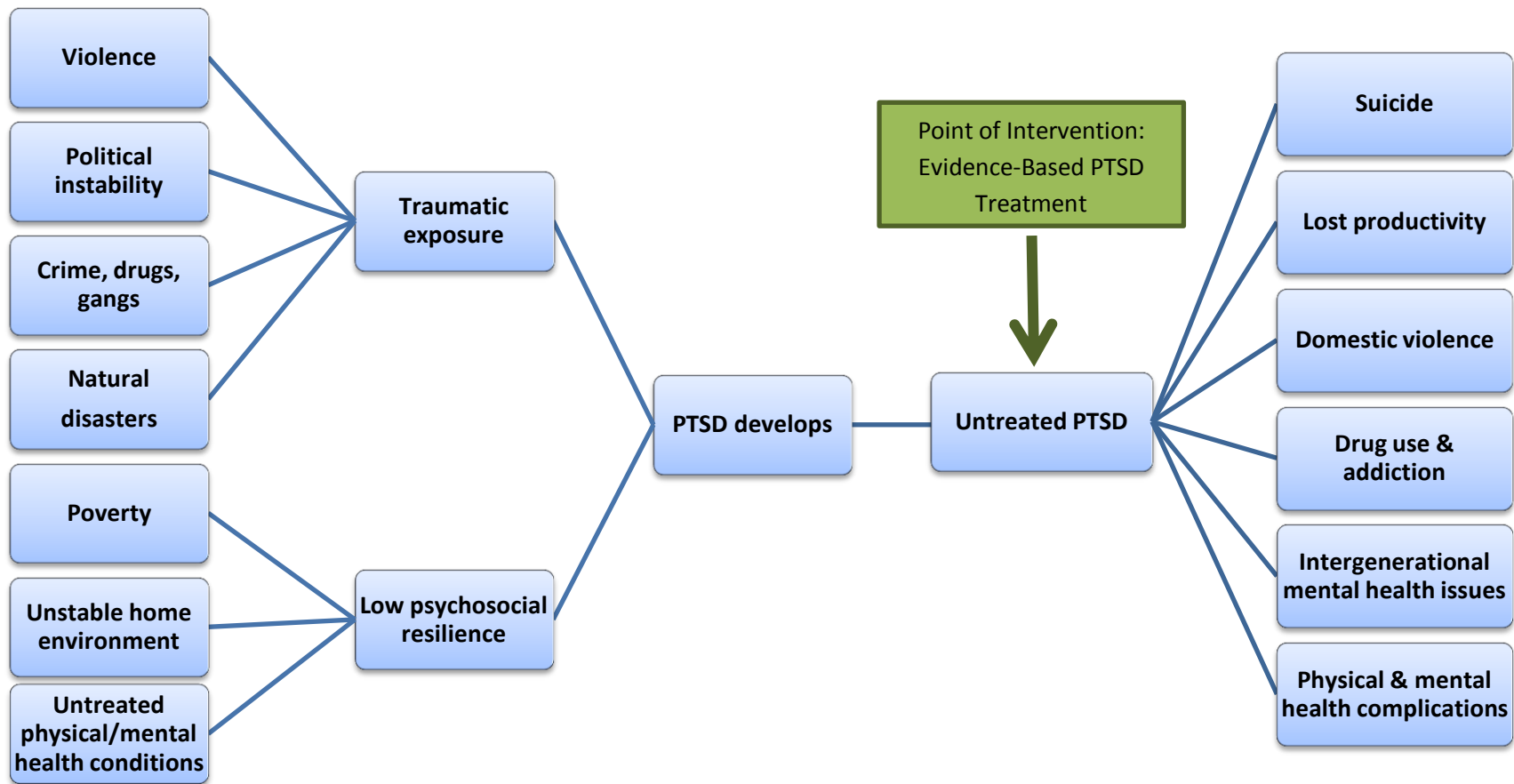


Figure 2: Theoretical Model of PTSD

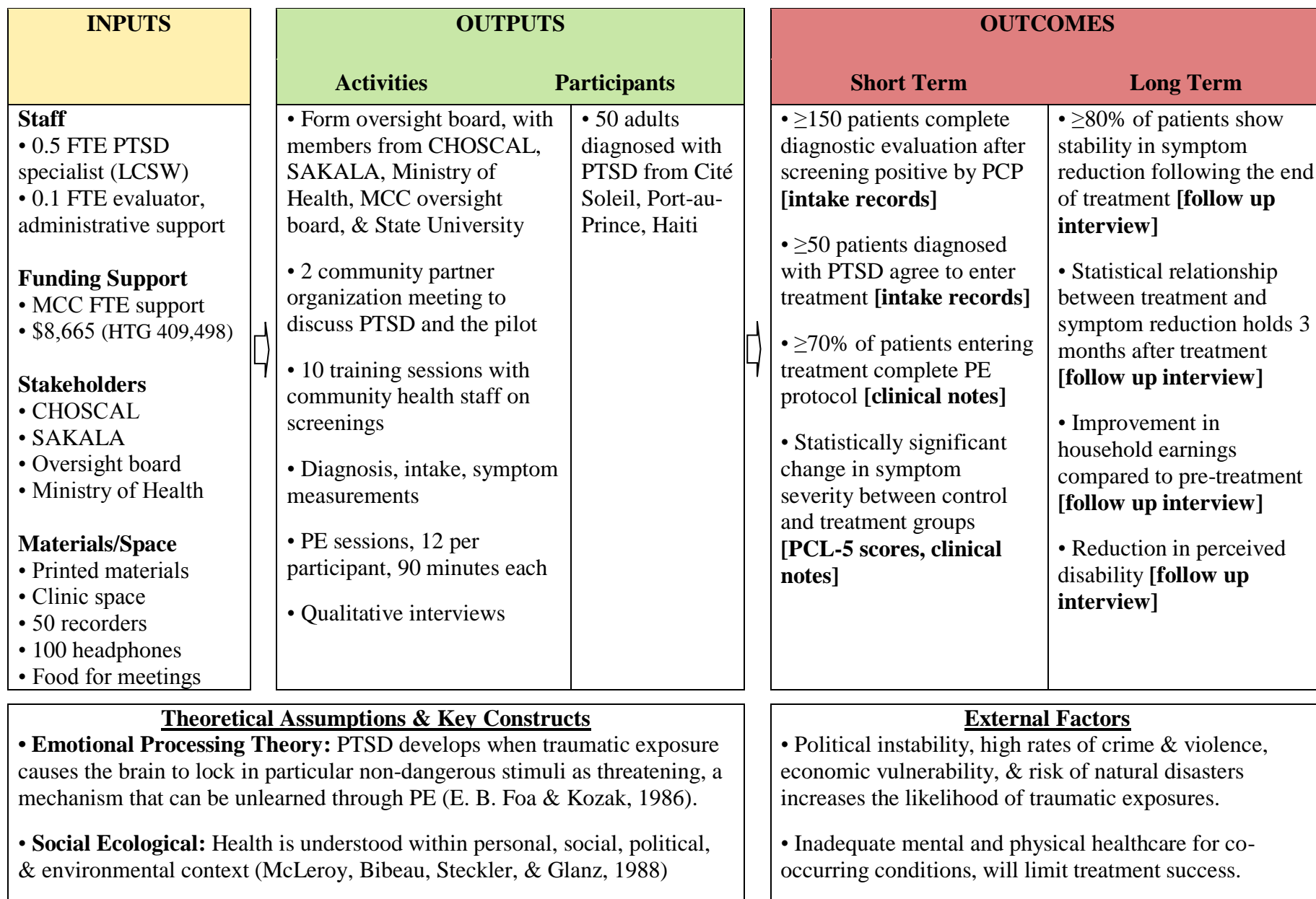


Figure 3: Program Logic Model

3.1 PROGRAM BUDGET

The budget for this two-year pilot program is \$8,665 plus salary support from MCC for the treatment and evaluation staff. The salary and benefit costs for the 0.5 Full Time Equivalent (FTE) LCSW PTSD Specialist and 0.1 FTE Program Evaluator are already budgeted and accounted for as Country Representatives under MCC's administrative budget for MCC Haiti. Office space for the clinical sessions represents the highest single program-budgeted cost, at \$100 per month for the 24 months of the program. This cost reimburses a partner organization (SAKALA or CHOSCAL) for a single room office within their organization's existing space. No internet, phone, or computer are required from the host agency. The costs of hosting oversight board and community partner meetings primarily covers the cost of food and refreshments for these events, a cultural necessity within the context, and a sign of respect for participants. Patients involved in treatment will receive travel and time reimbursement equal to \$2.00 per attended appointment. This cost was calculated at \$0.25 per way for public transport (*tap tap*) and an hourly reimbursement for their time of \$1.00 per hour for the session. As part of the PE protocol, each participant is provided with a simple digital recorder and headphones. These are used to record narratives during sessions, with patients listening to the recordings between sessions as *imaginal* homework. Printing costs cover educational materials for CHOSCAL healthcare staff, PTSD screening tools for CHOSCAL staff, and PCL-5 measurement tools for use and recording of symptom severity scores during sessions. Staff transport costs are calculated assuming the use of public transport (*tap tap*) between Cité Soleil and the MCC offices on clinic days.

| | Units | USD per Unit | Total USD | Total HTG (\$1 = 47.26 HTG) |
|------------------------------|-------|--------------|----------------|--------------------------------|
| Office Space | 24 | \$100.00 | \$2,400 | HTG 113,424 |
| Oversight Board Meetings | 8 | \$200.00 | \$1,600 | HTG 75,616 |
| Community Partner Meetings | 4 | \$350.00 | \$1,400 | HTG 66,164 |
| Travel Reimbursement | 600 | \$2.00 | \$1,200 | HTG 56,712 |
| Digital Voice Recorders | 60 | \$16.88 | \$1,013 | HTG 47,865 |
| Printing Education/Screening | 1700 | \$0.20 | \$340 | HTG 16,068 |
| Printing for Sessions | 1200 | \$0.20 | \$240 | HTG 11,342 |
| Staff Transportation | 300 | \$0.75 | \$225 | HTG 10,634 |
| Office Supplies | 1 | \$200.00 | \$200 | HTG 9,452 |
| Headphones | 50 | \$0.94 | \$47 | HTG 2,221 |
| Total Program Cost | | | \$8,665 | HTG 409,498 |

Figure 4: Program Budget

3.2 LOCATION AND COMMUNITY SUPPORT

The study will be conducted within the neighborhood of Cité Soleil, a slum on the outskirts of Port-au-Prince, Haiti. PTSD prevalence in the general adult population of Port-au-Prince has been estimated between 26-37% (Cénat & Derivois, 2014; Cerdá et al., 2013). As a neighborhood particularly hard hit by the 2010 earthquake, and with the city’s highest rates of poverty, crime, sexual violence, and gang activity, it is anticipated that Cité Soleil will have even higher rates of PTSD (Carlson et al., 2011; Cockayne, 2014; A. Gage, 2014). Due in part to its international reputation as one of the country’s most vulnerable neighborhoods, Cité Soleil is relatively well served by low-cost, accessible, and relatively high-quality basic healthcare services, including CHOSCAL healthcare system (Interuniversity Institute for Research and Development, 2011). This relatively wide availability of free or low-cost healthcare in a community of high need provides a nearly ideal referral source for a PTSD pilot. This referral stream is somewhat less likely to be biased by the patient’s socioeconomic status or other confounding variables, than might be the case in other neighborhoods within Port-au-Prince

where healthcare alternatives are more segregated by ability to pay. The initial stage of the project (prior to accepting referrals) will train community health workers from various health organizations in Cité Soleil on the basics of PTSD, the potential efficacy of evidence-based treatments, the purpose of the pilot program, how to screen patients for potential PTSD using a translated version of the PC-PTSD, and how to make referrals to the program. Participating community health workers will be asked to incorporate PTSD screening into their routine primary care screenings for all adults seen in their practice until the project has recruited at least 50 willing participants who receive a confirmatory diagnosis of PTSD by the project's clinical staff member.

The physical location of the clinic will be at one of two highly regarded community organizations, CHOSCAL or SAKALA. CHOSCAL (*Centre Hospitalier Sainte-Catherine Laboure*, St. Catherine Laboure Hospital) has the advantage of being the neighborhood's largest healthcare provider (and likely largest community referral source). Locating the clinic on CHOSCAL's campus would increase the opportunity for interaction and collaboration with referring healthcare providers, and lend significant medical credibility to this novel treatment modality in the community. Closer partnership with CHOSCAL would also facilitate relationships with the State University's Psychology Department, which may be helpful in scaling up the initiative at later stages. While not a direct healthcare provider, being based out of SAKALA (*Sant Kominote Alternatif Ak Lape*, Community Center for Peaceful Alternatives) has several advantages. SAKALA grew out of a community initiative for peace, justice, and alternative conflict resolution. SAKALA is a long-standing MCC partner, with strong ideological agreement with MCC's approach to person-centered resilience-based recovery from trauma, violence, and injustice. The theoretical perspective of PE is grounded in a similar belief in

building on an individuals' natural resilience by accompanying/bearing witness to and facilitating their healing after trauma. This philosophical foundation may prove a natural fit for the program. As a non-medical agency with deep community trust, SAKALA also offers the ability to engage the community around PTSD treatment without as much of the baggage associated with missionary medicine in Haiti (discussed in section 2.3, above). In either location (SAKALA or CHOSCAL), the clinic will operate out a private office, with clinic offered 2-3 days per week. Scheduling and all administrative functions will be handled directly by project staff and not rely on the hosting partner organization.

Community support for the project will be essential, particularly since PE requires a high level of trust from participants, and Haiti has an unfortunate history of public health initiatives imposed without community support (see section 2.3, above). Community support for the project will be gained through four primary mechanisms: 1) hosting the clinic at an established and well regarded community organization; 2) referral process through existing healthcare providers in the community; 3) hosting a series of 10 educational seminars for community health workers on PTSD, the efficacy of evidence-based treatments, the purpose and potential of the pilot program, and how to screen patients for possible PTSD using a translated version of the PC-PTSD; and 4) hosting two community partner meetings with existing MCC partner health organizations in Cité Soleil to educate staff from these organizations on PTSD, its causes, the consequences of non-treatment, the evidence of efficacy of existing treatment modalities from other contexts, the purpose and potential of the pilot program, and what the community can expect from the program in both the short and long run.

4. EVALUATION PLAN

The program's evaluation will test the following quantitative hypotheses:

1. The average reduction in PTSD symptom severity scores from baseline to immediately post-treatment will be significantly greater in the treatment group than in the control group. The reduction in symptom severity in the treatment group is expected to be statistically significant, and the size of effect is expected to be clinically significant (>10 point change).
2. A higher percentage of the treatment group will show total remission from PTSD symptoms (score <38) immediately post-treatment compared to the control group.
3. There will be no significant change in PTSD symptom severity scores in either the control or treatment groups between the immediate post treatment measurement and at the three-month follow up measurement, showing both the persistence of treatment effect in the treatment group and the continued failure of symptoms to abate without treatment in the control group.
4. Average change in family income between baseline and the three-month follow up will be significantly larger (and in a positive direction) in the treatment group when compared to the control group.
5. Average change in perceived disability between baseline and the three-month follow up will be significantly larger (and in a negative direction) in the treatment group when compared to the control group.
6. The control group will not have significant change in PTSD symptom severity, perceived disability, and family income between measurement periods.

The theory of the quantitative evaluation is that within the target population, a change in the independent variable of receiving a full course of individual PE will have a significant impact on the dependent variable of PTSD symptom severity as measured by the PCL-5. The study design will be a randomized, wait-list control, with a sample of 50 participants (25 receiving immediate treatment and serving as the treatment arm of the study, and 25 receiving delayed treatment and serving as the control arm for the study while on the waitlist). A qualitative component of the study will purposively sample 10 participants from the program for in-depth semi-structured one-on-one interviews. These interviews will aim to gather in-depth information on individual-level risk, resilience, and cultural factors that may influence PTSD development, explain differential treatment success, and inform future iterations of treatment to better adapt to Haiti's cultural context. During the intake process for both the waitlist control and immediate treatment groups, basic data, including age, gender, religious affiliation, family income, subjective level of disability, and education level will also be collected. During the follow up session three months after treatment (or six months after intake for the control group) family income and subjective level of disability will be collected again for comparison.

4.1 QUANTITATIVE STUDY DESIGN

The quantitative element of the study is a randomized, wait-list control design with a sample population of 50 (25 in the immediate treatment group and 25 in the waitlist control group). People eligible for inclusion in the program are referred from community health workers in Cité Soleil after screening positive for potential PTSD using the evidence-based PC-PTSD instrument. Referring providers are asked to screen all primary care patients for PTSD using this tool during the initial stage of the study period, until a sufficient number of participants are

reached. All referrals are then assessed by the program's LCSW, who will use DSM-5 criteria and the evidence-based CAPS-5 assessment to make a confirmatory PTSD diagnosis. All patients receiving a positive PTSD diagnosis will be offered inclusion in the study, until 50 participants have consented to participate. Of those selected, participants will be randomly assigned to either receive the treatment immediately or be placed on the waitlist for treatment (25 in each group). This waitlist will serve as the control arm of the study. Patients on the waitlist will be brought into treatment following 6 months on the waitlist at the conclusion of the study period. Patients will be informed prior to giving consent of the 50/50 probability of being brought into immediate treatment or being placed on the waitlist.

Quantitative data on symptom severity (the study's dependent variable) will be captured for both waitlisted and treatment groups at the same interval periods using the latest version of the evidence-based PTSD Checklist instrument (PCL-5), which measures patient-reported symptom severity scores (Ruggiero, Del Ben, Scotti, & Rabalais, 2003). Measurements from the PCL-5 will be collected upon entry into the study, at three months, and at six months. These periods align for the treatment group with pre-treatment, immediately post-treatment, and at a three-month follow up visit. For the waitlist control group, these periods correspond with intake into the study, at three months post-intake, and at six-months post-intake (which also marks their initiation into active treatment). Patients on the waitlist for treatment will serve as the control group for the study, and will receive no treatment during this period. Since no evidence-based PTSD therapies are currently offered in Haiti, this no-treatment condition represents the current community standard of care (World Health Organization, 2010). Collected data on PCL-5 scores, as well as all other treatment relevant notes will be input directly into the program's encrypted laptop following each session by the treating clinician. The data will be recorded under a

program-specific patient ID number, with no patient identifying information included in the notes. A reference sheet linking patients to specific ID numbers (but with no medical or treatment information) will be secured at the MCC offices, and destroyed once all treatment is complete. This approach minimizes the risk of patient-identifiable information being compromised as both access to the encrypted laptop and the reference sheet would be needed to connect information in the clinical notes to any one individual.

Based on established best practice in the field of PTSD research, the following values will be used to interpret PCL-5 symptom severity measurements. A clinically significant reduction in symptom severity is interpreted as a reduction of at least 10 points between pre and post treatment PCL-5 scores. Full PTSD symptom remission is interpreted as a final score below 38 (Blanchard, Jones-Alexander, Buckley, & Forneris, 1996; McDonald & Calhoun, 2010; Monson et al., 2008; National Center for PTSD, 2015; Ruggiero et al., 2003). Using these guidelines, and past research on the effectiveness of PE in reducing PTSD symptom severity, the effect size of the intervention is expected to be large and relatively easy to identify even in a small sample size. Most previous studies have seen about 85% of participants experiencing clinically significant improvements in symptom severity (reductions in 10 points on the PCL-5 compared to baseline), and about 45% experiencing full symptom remission (a final PCL-5 score below 38) (Tanielian & Jaycox, 2008). A meta-analysis of all published randomized trials testing PE's effectiveness found this consistent large effect size in similarly designed studies using a wait-list control group, with a Hedges's g of 1.51 ($SE=0.20$, 95% CI: 1.12 to 1.9, $p = .001$) (Powers et al., 2010). This large effect size, particularly, in the clinically significant reductions in symptom severity, is expected to provide sufficient power for the study with a sample of only 50

participants (25 in each group). An alpha of 0.05 will be used to establish significance of findings.

The study's primary statistical analysis will be conducted using Repeat-Measures Multivariate Analysis of Variance (MANOVA). Using this method will allow for testing variance both within groups (for example the treatment group at baseline vs. immediate treatment vs. three-month follow up), between groups (immediate treatment vs. waitlist control), and on multiple dependent variables (symptom severity, family income, and self-perception of disability) without the serious compromise to the study's power created by running multiple independent tests. All analyses will be conducted on an intent-to-treat basis, counting participants' data with their originally randomly assigned group, regardless of the actual course of treatment. Statistical analysis will be conducted in SPSS. Mauchly's sphericity test will be used to ensure the condition of sphericity is met for Repeat-Measures MANOVA before proceeding with the test.

4.2 QUALITATIVE STUDY DESIGN

The qualitative portion of the study will involve in-depth, one-on-one, semi-structured interviews with a purposive sample of 10 patients from the study who completed treatment. A program staff member other than the treating clinician will conduct the interviews to help reduce potential bias in the responses of participants. Selection of participants will be purposive, selecting participants representing a wide variety of clinical responses to treatment. Interviews will be conducted using a prepared interview guide, detailing topics and probes covering the following areas of interest:

1. Beliefs about PTSD symptoms, causes & consequences

2. Beliefs of how PE works to treat PTSD
3. Beliefs about the effectiveness of PE treatment
4. Beliefs about why some people do or do not develop PTSD
5. Potential cultural resources or barriers to PTSD treatment
6. Recommendations for adapting PE to the Haitian context

It is anticipated that a sample size of 10 for the qualitative portion will be sufficiently to begin seeing significant overlap in narratives and themes between respondents. Since the purpose of the qualitative portion is not generalizability, but depth of information, a random sample is not needed. Each interview is expected to take 90-120 minutes. All interviews will be conducted in Creole. Audio recordings will be made of the interviews. The recordings will be transcribed in Creole and coded using NVivo software. The coded data will be analyzed and triangulated with the quantitative data to see if patterns in the themes of interest emerge that could be used to improve the treatment method in future iterations. Recordings, notes, and data files from the qualitative portion of the study will be stored and accessed only at the MCC offices, by authorized project staff. All data will be de-identified before use, and all records will be coded under the same unique patient number used in the quantitative portion of the study so that these data elements can remain linked for future study even after the patient identifier reference sheet is destroyed.

4.3 ETHICS, OVERSIGHT, SAFETY, & CONSENT

Given the sensitive nature of the health issue in question, the novelty of the treatment for the community, and the long history of unaccountable healthcare in Haiti, it is essential that the project builds community support and establishes strong oversight, ethics, safety, and consent

policies. The plan for building community support is detailed in section 3.4, above. As a bi-national program, the project will seek IRB approval in both the US (at the institution associated with the principle investigator) and Haiti (through partnership with the State University, Université d'Etat d'Haïti). Following the most conservative recommendations of both IRB committees will help to ensure compliance with best practices and legal requirements in both countries. An in-country oversight committee will also be established, comprising representatives from the community of Cité Soleil, community partners SAKALA and CHOSCAL, MCC Haiti's local advisory committee, faculty from the State University's School of Psychology, and staff from the Ministry of Public Health and Population. The oversight committee will meet quarterly throughout the course of the project and receive updates on the project's progress and any issues that emerge.

A major ethical and safety consideration in the project is the treatment of people designated to the control group. The intervention protocol used with the treatment arm of the study likely represents a significant improvement over status quo treatment in the community (no targeted treatment). It would be unethical to burden diagnosed PTSD patients with symptom severity measurements as a control group without offering them access to this therapy. For this reason the study uses the program's waitlist as the control group. Waitlisted patients will be offered the same treatment protocol at the conclusion of the study period. In this way, all patients diagnosed with PTSD through the program will be offered the same level of treatment at no cost.

Other ethical and safety considerations include incidental findings and adverse events. Potentially serious mental or physical health issues may be discovered during assessment and treatment, representing incidental findings not within the scope of the project to treat. Patients with incidental findings will be referred for these conditions back to their referring primary care

provider with information on the incidental findings and suggested resources for follow up care in the community. With several options for quality, low or no cost medical care within Cité Soleil, ability to pay should not be a significant barrier to making this referral. This policy for incidental findings will be reviewed with referring providers and community health organizations during the training sessions conducted prior to the project's initiation, and with patients during the informed consent process.

Another potentially serious ethical consideration is adverse outcomes caused by, or happening concurrent with, participation in the study. Patients with untreated (or unsuccessfully treated) PTSD are at increased risk to themselves and others. While therapy can be difficult for patients, the current evidence in the literature does not show a significant increased risk during treatment with the proposed therapy when compared both to other talk therapy treatments and to a no-treatment control group (E. B. Foa et al., 2013; Powers et al., 2010; van Minnen, Harned, Zoellner, & Mills, 2012). In fact, according to the leading authorities in the field, “when one studies the results of large controlled trials, there is no evidence that PE is associated with a relative increase in adverse side effects” (E. B. Foa et al., 2013, p. 75). Additionally, a comprehensive review of clinical evidence of contraindications for PE treatment found that the therapy can be safely administered to patients suffering a wide variety of co-occurring conditions, including “dissociation, borderline personality disorder, psychosis, suicidal behavior and non-suicidal self-injury, substance use disorders, and major depression” (van Minnen et al., 2012, p. 1). PE was found both effective at treating PTSD in these populations as well as often producing reductions in symptoms of the co-occurring conditions as well (van Minnen et al., 2012). However, if patients become psychiatrically unstable during treatment, treatment will be discontinued and they will be referred to one of the city's major psychiatric facilities for follow

up care. While Haiti does not have a well-established mental health treatment system, what resources are available are highly concentrated in Port-au-Prince, making this an ideal location within the country for making such referrals. As an additional protection for patients, and following best practice in the field, patients will be screened for current and ongoing “Criterion A” traumatic stress exposure during intake. In the DSM-5 PTSD definition, Criterion A are traumatic stressors where “the person [is] exposed to: death, threatened death, actual or threatened serious injury, or actual or threatened sexual violence” (American Psychiatric Association, 2013, p. 271). Current exposure to Criterion A stressors means the patient’s protective flight-fight-or-freeze response will be, and should be, activated. A therapy actively attempting to lower these defense mechanisms in a situation of acute danger would be counterproductive and unethical (E. Foa et al., 2007).

The benefits and risks of treatment will be thoroughly discussed during all project meetings with the community and referring providers, and with patients prior to initiating treatment. Patients will be required to complete an informed consent that meets both US and Haitian legal standards and best practices prior to the initiation of treatment. Patients are free to discontinue treatment at anytime, and will be assisted in a referral to an alternate treatment provider of their choice. No children or adults incapable to providing consent will be included in this study.

4.4 FINDINGS

The findings from this study have the potential to significantly advance the treatment of PTSD in Haiti. While the literature has amply demonstrated the scope of the problem, no study to date has suggested a path forward for providing evidence-based care. This pilot study, despite the limitations of a highly targeted population and limited sample size, can begin building the

case for investing in more effective treatment for this important public health problem. The results of this study will be shared widely with four key groups: 1) members of the community where the study was conducted, largely through community forums on the topic; 2) members of the Haitian health sector, specifically providers and administrators of both physical and mental health care; 3) funders of healthcare services in Haiti, including governmental, nongovernmental, and private sector actors; and 4) academics in the fields of international mental health, PTSD, public health, and post conflict/disaster recovery. In this way, it is hoped that the results of the study can spur action at multiple levels: in the community demanding high quality effective services, within healthcare agencies wanting to lead with evidence-based care, within the funding community to be willing to support a scaled up intervention and population-wide evaluation; and among academics to push forward the literature on adapting evidence-based treatment for PTSD to the places that need it most

4.5 LIMITATIONS

A major limitation of this study is its narrow study population of one neighborhood in Port-au-Prince. Within this population, the study makes efforts to have a representative sample by utilizing a referral source less biased by ability to pay and that represents a broad swath of the community, and by randomly selecting participants from this referral source for the treatment and control arms of the study. However, it is not clear how generalizable the findings will be outside this neighborhood, including to more mixed-income communities or communities outside the capital city. The hope is that this pilot study, if successful, can serve as catalyst to secure funding for scaling the initiative and a larger clinical trial with a broader target population.

Another significant limitation is the small sample size. While the large expected effect size should give the study sufficient power at this sample size, it does limit the ability to parse the data more finely and explore variable effects on different subpopulations. An additional limitation of the study is the challenges associated with using translated tools and techniques. All the tools and protocols used in this study have been validated with well-designed studies in multiple cultures and contexts. The main two instruments used, PCL-C and CAPS-5, have been validated in the Haitian context prior to this study. The instrument yet to be validated in Haiti or in Haitian Creole is the PC-PTSD screening tool. Following best practices for translating mental health instruments, this tool will be translated by a group of bilingual subject matter experts recruited from the State University, with inter-translator reliability evaluated, and then re-translated back into English by a second group to assess for fidelity (Kaiser et al., 2013).

A fundamental limitation of this type of intervention is that it does not change the environmental causes of PTSD. While public health interventions prefer to work upstream and address root causes, in this case those causes (poverty, political instability, political violence, violent crime, domestic violence, natural disasters, etc.) are well outside the scope of one project, or one agency, to tackle effectively. MCC and many other agencies are actively pursuing programs to mitigate these dynamics and help improve the living conditions for the people most at risk. However, for the people already suffering from PTSD (those targeted by the program and study), there is no substitute for treatment. While new treatment methods should not be an excuse to avoid investments in prevention, neither should investments in prevention detract from the urgent and compelling need to provide treatment for those already impacted by the resulting condition.

5. DISCUSSION – SCALING UP THE INTERVENTION

The proposed pilot program and evaluation would represent the first time an evidence-based PTSD therapy was delivered and studied for effectiveness in the Haitian context. For over a decade, humanitarian organizations and academics have been suggesting high rates of PTSD in Haiti and calling for intervention (James, 2004; World Health Organization, 2010). In the last two years, two well designed studies have confirmed this extremely high prevalence among the general adult population of Port-au-Prince (Cénat & Derivois, 2014; Cerdá et al., 2013). However, to date, there are no studies demonstrating the effectiveness of a specific treatment in the Haitian context, and no program delivering the interventions that have demonstrated clinical success elsewhere. PE is particularly well suited to this first-of-its-kind study because of its demonstrated effectiveness across a wide variety of ethnic and cultural groups, literacy is not required on the part of the patient, it has been shown effective as a standalone service, the duration is short (12 sessions, 90 minutes each), symptom reduction has been shown to have lasting (usually permanent) effects, a documented high success rate for symptom reduction, and relatively low risk of adverse outcomes for patients who fail to respond to treatment (E. B. Foa, 2011). If effectiveness of an evidence-based treatment can be demonstrated in Port-au-Prince through a well-designed pilot study targeting a highly affected sub-population, the case can begin to be made for funding to scale-up the intervention and run a large-scale clinical study.

MCC's comparative advantage as an implementing agency is as a flexible innovator with deep community trust and an established track record in-country of launching and testing new programs before turning them over to local partners. The proposed pilot program is aimed at establishing the field of evidence-based PTSD therapy in Haiti, and providing a “proof of

concept.” The goal would be to then work with MCC’s partners in-country, many of which are major health care providers, to scale up the intervention and initiate an ongoing clinical program. Potential partnerships for MCC to consider would include Partners in Health, the Haitian Ministry of Public Health and Population, CDC’s Haiti Program, the Clinton Foundation’s Haiti Program, and Hôpital Albert Schweitzer. Each of these organizations has the capacity to deliver, fund, or promote the expansion of evidence-based PTSD services to the Haitian population.

Scaling up the clinical delivery of treatment would rely on training Haitian staff in the evidence-based protocol. Following best practice from the United States, a training program could be established with the State University’s Department of Psychology as a capstone course and paid practicum after graduation. The course would consist of a semester long study of trauma theory, evidence-based therapies, and the PE protocol. Students in the capstone could compete for the opportunity to complete a three-month paid practicum, with individual and group supervision by a trained PTSD specialist, as they each took 10-15 patients with PTSD through the full protocol of individual PE. Available funding would determine the number of psychology students that could be trained each year with this approach. This cohort of trained practitioners could then be recruited by the agency aiming to scale-up the intervention in the community. Once individual PE is available and scaled in-country, practitioners could begin testing more experimental, but potentially more cost effective, versions of treatment including group-based therapy implemented by trained community health workers. While this type of approach may prove useful in the long-run, there is currently insufficient evidence in the literature to support this being the sole form of PTSD therapy offered in country.

6. CONCLUSION

Post-Traumatic Stress Disorder (PTSD) is a significant and untreated public health problem in Haiti. While Haiti is well known for its poverty (World Bank, 2014a), weak public health system (Farmer, 2012), and poor health outcomes (Pan American Health Organization, 2012), it is also suffering significant public health consequences from high rates of untreated PTSD. The public health consequences of untreated PTSD include: depression and anxiety, substance use (Brady et al., 2000), suicide (Kessler et al., 2005), premature mortality (Boscarino, 2006), medical complications (Beckham et al., 1998), homelessness, unemployment (Tanielian & Jaycox, 2008), sexual-risk-taking behaviors (Holmes et al., 2005), domestic violence (Jordan et al., 1992), and second generation mental and physical health problems in children of parents with untreated PTSD (Davidson et al., 1989). Despite these severe consequences of untreated PTSD and documented rates of PTSD in the general adult population of Port-au-Prince at over five times those found in the United States, there have been no published studies adapting evidence-based PTSD therapy to Haiti or any programs attempting to deliver these interventions in country. PTSD is unlikely to resolve without intervention (Zohar et al., 2011), but is highly responsive to the evidence-based treatments (Forbes et al., 2010). Of treatments currently available, PE has the longest track record of success, and is generally considered the gold standard of PTSD treatment in the United States and Europe. The proposed program aims to fill this gap in the literature by conducting a pilot study of the effectiveness of individual PE therapy delivered by a trained clinician to adults diagnosed with PTSD in Cité Soleil, Port-au-Prince, Haiti.

MCC is a well-positioned agency to lead this innovative program. As a well established and highly-regarded organization in Haiti, with a proven track record of launching innovative

programs that are successfully turned over to local partners to sustain and scale, MCC has the organizational reputation, and competence necessary to implement this program. With minimal additional funding (less than \$9,000), and the use of existing staff resources, MCC is in a position to make a substantial contribution to the field of mental health and trauma recovery in Haiti, while also providing a desperately needed clinical intervention to the program's direct participants. The proposed program builds on MCC's approach of people-centered, resilience based, trauma recovery, and working with and through local partners to support long-lasting changes while addressing immediate needs.

This pilot study represents a critical next step in improving the lives of the estimated 375,000-534,000 people in Port-au-Prince alone suffering from this debilitating but highly treatable condition (Cénat & Derivois, 2014; Cerdá et al., 2013). The findings from this study have the potential to significantly advance the treatment of PTSD in Haiti. While the literature has amply demonstrated the scope of the problem, no study to date has suggested a path forward for providing evidence-based care. This pilot program represents the first attempt to demonstrate the effectiveness of PTSD treatment in the Haitian context, laying the foundation for future studies to refine treatment and scale up the intervention to reach the hundreds of thousands of Haitians currently suffering from untreated PTSD.

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