Distribution Agreement

In presenting this thesis or dissertation as a partial fulfillment of the requirements for an advanced degree from Emory University, I hereby grant to Emory University and its agents the non-exclusive license to archive, make accessible, and display my thesis or dissertation in whole or in part in all forms of media, now or hereafter known, including display on the world wide web. I understand that I may select some access restrictions as part of the online submission of this thesis or dissertation. I retain all ownership rights to the copyright of the thesis or dissertation. I also retain the right to use in future works (such as articles or books) all or part of this thesis or dissertation.

Signature:

_____ _____

Zehra Khan Date

Assess the Effectiveness of Mindfulness Meditation (MM) Therapy in Women with Post-Traumatic Stress Disorder (PTSD) due to Childhood Sexual Abuse, and Comparison of Symptoms Reduction in both Women with PTSD who Utilize MM and those who do not Utilize MM in Georgia

By

Zehra Khan

Master of Public Health

Prevention Science

Rebecca Upton, Ph.D., M.P.H.

Committee Chair

Carolina M. Lecours, M.P.H.

Committee Member

Assess the Effectiveness of Mindfulness Meditation (MM) Therapy in Women with Post-Traumatic Stress Disorder (PTSD) due to Childhood Sexual Abuse, and Comparison of Symptoms Reduction in both Women with PTSD who Utilize MM and those who do not Utilize MM in Georgia

By

Zehra Khan

Bachelor of Medicine, Bachelor of Surgery (M.B.B.S.)

DOW Health Science University, Karachi, Pakistan

1995

Thesis Committee Chair: Rebecca Upton, Ph.D., M.P.H.

An abstract of

A thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of

Master of Public Health

in Prevention Science

2021

Abstract

Assess the Effectiveness of Mindfulness Meditation (MM) Therapy in Women with Post-Traumatic Stress Disorder (PTSD) due to Childhood Sexual Abuse, and Comparison of Symptoms Reduction in both Women with PTSD who Utilize MM and those who do not Utilize MM in Georgia

By

Zehra Khan

Childhood sexual abuse (CSA) is a pervasive, persistent, and pernicious problem worldwide, with reported prevalence rates ranging from 3-8 percent in women and 3-17 percent in men (Steine et. al.,2019). In the United States, the ratio for those who experience sexual abuse at least once in their childhood is 1 in 4 within females and 1 in 13 within males (Center of Disease Control and Prevention 2019). In Georgia, there were 26,952 victims of child abuse or neglect in 2015, an increase of 21.6 percent from 2014 (Child Welfare League of America Annual report 2017). Of these children, 3.4 percent were sexually abused (U.S. Department of Health and Human Services 2016). Childhood sexual trauma can lead to several mental health issues later in women's lives, including post-traumatic stress disorder (PTSD), which causes negative effects on women's quality of life. Due to PTSD's complex psychopathology, significant co-morbidities, and functional impairments, treatment may require a combination of psychotherapies and pharmacotherapies.

Although these conventional PTSD treatments showed improvement in PTSD patients, they have a high percentage of treatment resistance, non-adherence, and drop-out. This is because of the chronic patterns of avoidance and an inability to tolerate the intense emotions often experienced with the conventional PTSD treatment approaches. For this reason, CAM practices, mindfulness meditation (MM) in particular, are gaining popularity among patients with PTSD because of its nature of treating PTSD symptoms without trauma recall and absence of side effects.

In recent years, mindfulness meditation interventions have received increased clinical and scholarly attention for the treatment of PTSD. However, the evidence of the efficacy of these modalities for PTSD is limited. There were limited studies done, mostly with veteran populations, to address the role of mindfulness meditation modalities for patients with PTSD. MM serves as an important gateway treatment that increases patient motivation, willingness, and ability to engage in additional full-length treatment. Despite the widespread popularity of mindfulness meditation modalities for the treatment of PTSD, the exact extent of MM efficacy and potency in symptoms reduction is not well evaluate. Recently, MM therapies are more attractive to patients because they use an alternative approach to healing and usually do not have reported side effects. To date, there has been little research performed in women who were sexually abused in their childhood with the utilization of MM intervention to treat their PTSD. Although all previous studies showed promising results, a randomized controlled comparative effectiveness trial is needed to assess the efficacy of MM intervention relative to conventional PTSD treatments in CSA women with documented PTSD.

Assess the Effectiveness of Mindfulness Meditation (MM) Therapy in Women with Post-Traumatic Stress Disorder (PTSD) due to Childhood Sexual Abuse, and Comparison of Symptoms Reduction in both Women with PTSD who Utilize MM and those who do not Utilize MM in Georgia

By

Zehra Khan

Bachelor of Medicine, Bachelor of Surgery (M.B.B.S.)

DOW Health Science University, Karachi, Pakistan

1995

Thesis Committee Chair: Rebecca Upton, Ph.D., M.P.H.

A thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of

Master of Public Health

in Prevention Science

2021

ACKNOWLEDGEMENTS

First and foremost, praise and thanks to Allah, the almighty, for His showers of blessings throughout my journey to complete my master's degree in public health.

I would like to express my sincere gratitude to Dr. Rebecca Upton, the Chairperson for my thesis paper, for her guidance, patience, and support which kept me focused throughout this long process. I also want to thank Carolina Lecours, my Field Advisor who I consider a mentor and friend.

Finally, I am extremely grateful to my parents for their love and prayers. I am very much thankful to my family. My husband Azhar Khan, who has been extremely supportive of me throughout this entire process. My children (Zain, Hiba, Ali, and Maha) for always believing in me, encouraging me during the tough times and offering never ending love and support.

Table of Contents

Chapter I: Introduction

Childhood sexual abuse is a pervasive, persistent, and pernicious problem worldwide, with reported prevalence rates ranging from 3-8 percent in women and 3-17 percent in men (Steine et. al.,2019). In the United States, the ratio for those who experience sexual abuse at least once in their childhood is 1 in 4 within females and 1 in 13 within males (Center of Disease Control and Prevention 2019). In Georgia, there were 26,952 victims of child abuse or neglect in 2015, an increase of 21.6 percent from 2014 (Child Welfare League of America Annual report 2017). Of these children, 3.4 percent were sexually abused (U.S. Department of Health and Human Services 2016). Childhood trauma can lead to psychiatric disorders later in life, such as depression, anxiety, and post-traumatic stress disorder (PTSD), which can cause negative effects on women's quality of life. PTSD is a type of anxiety disorder, which may occur after exposure to traumatic events like sexual and physical abuse. Due to its complex psychopathology, significant co-morbidities, and functional impairments, PTSD treatment may require a combination of psychotherapies and pharmacotherapies.

Recently, a variety of integrative mind-body intervention modalities have emerged that are increasingly employed in the treatment of PTSD (Kim et al., 2013). Nearly 38 percent of U.S. adults use Complementary and Alternative Medicine (CAM) interventions, including mind-body practices to manage a range of physical and emotional health concerns (Barnes et.al.2011; Klap et.al. 2000). Mind body interventions fall under the umbrella of CAM, and include yoga, chiropractic, meditation, acupuncture, and relaxation techniques. Recently, mindfulness meditation practices have received increased clinical

and scholarly attention for the treatment of PTSD (Vujanovic et.al. 2016). However, the evidence of the efficacy of these modalities for PTSD is limited. There were limited studies done, mostly with veteran populations, to address the role of mindfulness meditation modalities for patients with PTSD. To date, there has been little research performed in women who were sexually abused in their childhood with the utilization of MM intervention to treat their PTSD. Although all previous studies showed promising results, a randomized controlled comparative effectiveness trial is needed to assess the efficacy of MM intervention relative to conventional PTSD treatments in CSA women with documented PTSD.

Problem Statement

Mindfulness meditation (MM) interventions, with the intent to reduce the duration and intensity of PTSD symptoms in women with PTSD secondary to childhood sexual trauma in the United States, are not well documented.

Purpose Statement

To assess the effectiveness of mindfulness meditation interventions utilized by women who have PTSD due to childhood sexual trauma in Georgia and to compare PTSD symptoms reduction in intensity and duration in abused women who utilize mindfulness meditation modalities to abused women who do not.

Proposed Research Question or Project

The specific aims of research project outlined in this proposal are:

Aim 1: To measure the therapeutic effects of using mindfulness meditation in women with childhood sexual trauma and PTSD.

Aim 2: To compare the reduction of PTSD symptoms in intensity and duration in women with childhood sexual trauma who use mindfulness meditation to those who do not use mindfulness meditation.

Aim 3: Assess patient motivation, willingness, and ability to incorporate mindfulness meditation interventions after the completion of the study into their traditional PTSD treatment.

Significant Statement

Although patients with PTSD utilize various pharmacotherapies and psychotherapies, a substantial proportion of patients continue to experience considerable residual symptoms. Moreover, most of these patients are reluctant to adhere/continue their conventional medical treatment because it may bring back their traumatic memories. MM serves as an important gateway treatment that increases patient motivation, willingness, and ability to engage in additional full-length treatment. Despite the widespread popularity of mindfulness meditation modalities for the treatment of PTSD, the exact extent of MM efficacy and potency in symptoms reduction is not well evaluated. Recently, MM therapies are more attractive to patients because they use an alternative approach to healing and usually do not have reported side effects. It is vital to investigate effectiveness, validity, and sustainability of MM when used by patients with PTSD, either alone or in conjunction with conventional PTSD treatments.

Definition of Terms

Complementary and Alternative Medicine: CAM is defined as "a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine" (National Center for Complementary and Integrative Health, 2016). Within this framework, "complementary" describes therapies used together with conventional medicine and "alternative" describes therapies used in place of conjunctional medicine (National Center for Complementary and Integrative Health, 2016).

Complementary Therapy: Complementary medicine is a group of diagnostic and therapeutic disciplines that are used together with conventional medicine (National Center for Complementary and Integrative Health, 2016).

Alternative Therapy: If a non-mainstream practice is used in place of conventional medicine, it is considered alternative (National Center for Complementary and Integrative Health, 2016).

Mind-Body Medicine: Mind body medicine uses a variety of techniques to enhance the mind's capacity to affect bodily function and symptoms (Wolsko et.al., 2004).

Mindfulness: Mindfulness is defined as "the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of an experience, moment by moment" (Kabat et.al., 2003).

Mindfulness Meditation: Mindfulness meditation represents a systematic framework and process for cultivating mindfulness in daily life by intentional and sustained practice (Black et.al., 2016).

Post-Traumatic Stress Disorder (PTSD): PTSD is defined as "a psychiatric disorder that can occur in people who have experienced or witnessed a traumatic event such as a natural disaster, a serious accident, a terrorist act, war/combat, rape, or other violent personal assault" (American Psychiatric Association 2013).

Childhood Sexual Abuse: Childhood sexual abuse is a form of child abuse in which the child is used for the sexual stimulation of the perpetrator or an observer (The National Child Traumatic Stress Network 2007).

Randomized Controlled Trial: In clinical research, randomized controlled trials (RCTs) are considered as a gold standard to study the safety and efficacy of new treatments. RCTs can determine the dominance of a new treatment over an existing standard treatment or a placebo. In RCT, participants are randomly assigned to either experimental group or control group. RCTs are used "to answer patient-related questions and are required by governmental regulatory bodies as the basis for approval" (Kabisch et.al., 2011).

Clinician-Administered PTSD Scale (CAPS): CAPS is a "structured diagnostic interview that assesses posttraumatic stress disorder (PTSD) diagnostic status and symptom severity" (Weathers et.al., 2018).

Quality of Life (QOL): World Health Organization defines Quality of Life as “an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (World Health Organization 2020).

Chapter II: Review of the Literature

Review of the Literature

This section discusses the statistics of childhood sexual abuse (CSA) and its consequences on the physical and mental health of women with CSA, including Post Traumatic Stress Disorder (PTSD). The neurobiology and different treatment interventions for PTSD will be discussed, along with the rationale of introducing Complementary and Alternative Medicine (CAM). This section highlights the research of PTSD patients utilizing CAM, as well as which forms of CAM have shown to be effective and popular in women with PTSD. Reasons for using Mindfulness Meditation (MM) interventions among women with Childhood Sexual Abuse (CSA) and PTSD, as well as efficacy of MM to treat PTSD symptoms, are discussed.

After a detailed research of the literature regarding MM practices and PTSD patients, the information presented provides a robust body of evidence that shows the important role of MM practices contributing to the treatment of PTSD patients, especially those who are reluctant to continue conventional treatment options. The literature was chosen based on the works of authors who have considerable experience in the study of MM interventions and PTSD. Though the study of MM practices in the treatment of PTSD in CSA women has not been extensively researched, it is an area that is beginning to gain attention as researchers are considering the potential benefits it could have on the quality of life of PTSD patients.

Early childhood sexual abuse is an important public health problem in the U.S. that affects 16 percent of women before their 18th birthday (Bremner et.al., 2002).

Although childhood sexual abuse is common in every gender, age, race, ethnicity, background, socioeconomic status and family structure, studies have shown that African American children have almost twice the risk of sexual abuse than other ethnicities (Sedlack et.al., 2010). In 2008, approximately 11,000 African American children were reported in cases of child sexual abuse (U.S. Department of Health and Human Services 2008). The city of Atlanta, the largest city of the state of Georgia, consists of a majority 52 percent African American population (U.S. Census Bureau, 2019), who are most at risk for childhood trauma, and have the most limited access to resources to deal with the effects of trauma. According to the Child Welfare League of America, 21,635 children were victims of abuse or neglect in Georgia in 2016, a rate of 8.6 per 1,000 children, of which, 4 percent were sexually abused (Child Welfare League of America 2016).

This childhood sexual trauma can lead to several health issues in women such as depression (Franklin et.al., 2001; Prigerson et.al., 2001), substance abuse (Kessler et.al.), dissociation (Putnam et.al.,1986; Bremner et.al.,1996), personality disorders (Battle et.al.,2004; Yen et.al.,2002), physical health problems (Bremner et.al.,1996), and most commonly PTSD (Bremner et.al. 2005). For many abuse victims, PTSD can be quite disabling, and symptoms are often persistent, at times lasting from childhood into adulthood (Burgess et.al., 1979; Armsworth, 1985). The neuropsychological effects of childhood sexual abuse have recently received increased attention. Studies have shown that child sexual abuse victims have a doubled risk for mental health conditions (Dube et. al., 2005), ranging from mild to moderate psychological and behavioral problems, with both short- and long-term consequences. Deficient inhibitory capacity (Mezzacappa et.al. 2001), problems with verbally mediated higher cognitive abilities (Palmer et.al., 1999),

distractibility, and impaired sustained attention (Beers et.al., 1999) have been observed in children shortly after abuse. Long term effects include deficits in short-term verbal memory (Bremner et.al., 1995), depression (Franklin et.al., 2001; Prigerson et.al., 2001), substance abuse (Kessler et.al., 1995; Bremner et.al., 1996), personality disorders (Battle et.al., 2004; Yen et.al., 2002), eating disorders, sexual disorders, and PTSD (Rodriquez et.al 1997). For many abuse victims, PTSD can be a life-long problem (Saigh et.al., 1999).

PTSD is a psychological disorder that may develop after experiencing a highly stressful event, like wartime combat, physical or sexual violence, natural disasters, etc. PTSD is characterized by specific symptoms, including intrusions (intrusive memories, flashbacks, feeling worse with reminders of the trauma, nightmares), avoidance (avoidance of thinking about the event, avoidance of reminders, decreased concentration, amnesia, feeling cut off from others, sense of foreshortened future), hyperarousal (increased startle), hypervigilance, and sleep deprivation (Bremner 2005). These symptoms are hypothesized to represent the behavioral manifestation of stress-induced changes in brain structure and function (Bremner 2005). Stress results in acute and chronic changes in neurochemical systems and specific brain regions (Bremner 2005), which result in long term changes to the brain's neurotransmitter response (Vermetten et.al., 2002; Bremner et.al., 2002). In PTSD, brain regions including hippocampus, amygdala, and medial prefrontal cortex play an important role (Bremner et.al., 1995). These brain areas play a major role in the experience of certain emotions (fear and anger), motivation, and memory (Bremner 2005). Similarly, dysregulation in central catecholamine neurons, which secret epinephrine, norepinephrine, and serotonin, play a

critical role in the level of alertness, vigilance, orientation, selective attention, memory, and fear conditioning in PTSD (Southwick et.al., 1999). Several studies have been conducted to see the effect of early stress on the neurochemical system in traumatized children and adults with PTSD. De Bellis and colleagues found increased levels of cortisol measured in 24-hour urine in traumatized children with PTSD (DeBellis et.al., 1999). Bremner's "Neural Circuits in Women with Abuse and PTSD" showed a decreased baseline cortisol based on 24-hour diurnal assessments of plasma and exaggerated cortisol response to stressors (Bremner et.al., 2002). In addition to mental health morbidities, PTSD has also associated with physical health issues such as chronic musculoskeletal pain, cardiovascular diseases, hypertension, obesity (McFarlane, 2010) which result in poor health-related quality of life (Green et.al., 2004).

Given the severity of the issues and related health problems, treatment is imperative. Several studies have been conducted to evaluate the efficiency of different treatment plans to reduce PTSD symptoms in affected adults. Medications like Paroxetine and Sertraline, which are selective serotonin reuptake inhibitors (SSRIs), reduce PTSD symptoms like depression and anxiety (Bremner et.al., 1996) in sexually abused women. Over the past 20 years, several therapies have been introduced for the treatment of psychological symptoms related to PTSD, like cognitive processing therapy, stress inoculation training, and prolonged exposure (Chard et.al. 2005). Number of studies have been conducted to evaluate the efficacy and efficiency of these PTSD treatment programs. For example, systemic desensitizing, cognitive therapy, and stress inoculation training significantly reduced PTSD symptoms in rape survivors (Frank and Stewart, 1983; Kilpatrick et.al.1982). A combination of exposure techniques and cognitive

interventions reduced PTSD symptoms in Vietnam War veterans (Frairbank and Keane 1982). Similarly, cognitive-behavioral therapy (CBT) has proven to be effective not only for the treatment of PTSD in battered women (Dutton 1992) but proven to be effective to cope with emotional discomfort and impaired functioning in everyday life (Echeburua et.al., 1996).

The above mentioned treatments have promising results for the treatment of this prevalent and devastating disorder, but there are around 50 percent patients who are non-compliant, and many patients still have lingering symptoms (Bradley, Greene, Russ, Dutra, & Westen, 2005; Kearney & Simpson, 2015; Schottenbauer, Glass, Arnkoff, Tendick, & Gray, 2008; Steenkamp, Litz, Hoge, & Marmar, 2015). Literature shows that the chronic pattern of avoidance and inability to tolerate the intense emotions often experienced with these treatments *(*Grunert et.al., 2007) leads to poor treatment response (Herman & Schatzow, 1984) and high dropout rates (Dye & Roth, 1991) among women with PTSD. Zayfert et.al. (2005) and Bank et.al., (2015) reported that there is a high rate of PTSD symptoms exacerbation such as dissociation, reexperiencing, anger, and suicidality with these treatments (Zayfert et.al., 2005; Bank et.al.,2015). Due to these detrimental treatment outcomes, many mental health practitioners are reluctant to use these treatments or may inconsistently use them (Becker, Zayfert, and Anderson, 2004). To address this issue, many researchers suggest introducing new complementary and alternative medicine (CAM) (Gallegos et.al., 2017), either to use alone or in conjunction with conventional treatments (Gallegos et.al., 2017).

In recent years, CAM modalities are becoming more attractive among patients with mental health issues including PTSD, as they engage the healing process with a non-

trauma focus (Wahbeh et.al., 2014). In 2007, a national study found that 38 percent of adults (estimated 83 million people) in the U.S. reported using CAM within the past twelve months, with an overall expenditure of $33.9 billion of out-of-pocket money on CAM modalities (Barnes, Bloom, & Nahin, 2008). To date, several literatures have supported the beneficial effects of complementary approaches for the treatment of PTSD (Kim et.al., 2013).

The National Center for Complementary and Integrative Health defines CAM as a group of diverse medical and health care systems, practices, and products typically used in conjunction with conventional medicine (National Center for Complementary and Alternative Medicine, 2008). CAM either blends conventional medicine (complementary) or substitutes non-mainstream practices (alternative) for healthcare practices outside of conventional Western medicine (National Center for Complementary and Integrative Health [NCCIH], 2017).

The most commonly used CAM approaches include natural products (herbal medicines, vitamins, minerals, and probiotics) and mind-body practices (Chan, 2019). The mind-body practices include acupuncture, mindfulness-based stress reduction, meditation, yoga, deep-breathing exercises, guided imagery, hypnotherapy, progressive relaxation, and tai chi. (Gallegos et.al., 2017). Among all, mindfulness meditation (MM) interventions are gaining more popularity in the United States among adults as well as military personnel for their mental health issues like PTSD (Gallegos et.al., 2017). Nearly 40 percent of adults and veterans in the U.S. are utilizing MM interventions for the treatment of PTSD (Gallegos et.al., 2017).

The practice of mindfulness meditation was first introduced by Jon Kabat-Zinn (1990) and his colleagues to treat chronic pain by developing mindfulness-based stress reductions that focused on mindfulness through meditation. Kabat-Zinn (2003) defined mindfulness as *"the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment," (Kabat-Zinn 2003).* Mindfulness meditation intervention involves present-focused, non-judgmental observation of sensations, thoughts, feelings, emotions, and environmental stimuli (Tan et.al., 2014). Later Segal and colleagues utilized MM in conjunction with cognitive-behavioral therapy for the treatment of depression (Segal et.al., 2002). Subsequently, several studies have shown the positive effects of using MM interventions for the treatment of bipolar disorders (Salcedo et.al., 2016), obsessive-compulsive disorder (Key et.al., 2017), generalized anxiety disorder (Evanset.al., 2008), eating disorders (Dunne 2018), and PTSD (Marina et.al., 2016). Among all these mental health disorders, MM practices gained considerable popularity among people with PTSD as many individuals preferred using such techniques to manage their symptoms (Lang et.al., 2012).

Literatures show that MM therapies for PTSD were equally efficacious when compared with trauma-focused treatments with significantly lower drop-out rates (Frost et.al., 2014; Boyd et.al., 2018). Among these MM interventions, some meditations trained practitioners to observe patients' thoughts, feelings, and sensation in a non-judgmental manner (Keng et.al., 2011), while others focused on patients to orient their attention to the present with interest, receptivity, and acceptance (Keng et.al.,2011). Gallegos, Cross, and Pigeon (2015) reported that MM interventions encourage

practitioners to address patients' distressing thoughts and feelings in a non-judgmental way, which can reduce cognitive distortions and avoidance – symptoms of PTSD.

There are different approaches to utilize MM in patients with PTSD. Some focus on just one stimulus like emotions (Baer, 2003), while others work on multiple stimuli including thoughts, feelings, emotions, and environmental stimuli (Bishop et.al., 2004). These approaches depend upon the patients' PTSD severity. Therefore, it is imperative to consider each patient's symptoms presentation and severity to determine which MM strategy would be most effective (Frewen and Lanius 2015; Follette, Briere, Rozelle, et.al.,2015).

Past literature has shown that mindfulness-based meditation is effective in reducing PTSD symptoms while improving mental health-related quality of life in veterans with combat-related PTSD (Khusid & Vythilingam, 2016). However, there is less literature available that addresses the usage and efficacy of MM interventions to treat depression and PTSD symptoms in childhood sexually abused victims (Kimbrough et.al., 2010).

To date, the efficacy of MM interventions in reducing PTSD symptoms among women with CSA has not yet been established because most of the research is conducted in military and domestic abuse populations (King, 2008; Dutton, 2008). Marzabadi and Zadeh (2014) performed a randomized controlled trial on warfare victims with PTSD to investigate the effectiveness of mindfulness training on their quality of life. Their study augmented the findings of previous studies and showed that MM training modified negative thoughts and behaviors, which lead to positive health-related changes, ultimately improving quality of life (Bishop 2002).

Kearney and colleagues (2013) randomized veterans with PTSD into treatment as usual (TAU) alone or mindfulness-based stress reduction (MBSR) plus TAU groups to assess safety, feasibility, and effects of mindfulness-based intervention. The study results suggested that mindfulness-based intervention not only reduced PTSD symptoms but also improved behavioral activation and mental health-related quality of life (HR-QOL) (Kearney et.al., 2013). In addition, Polusny et.al., (2015) compared MBSR and present-centered psychotherapy in a randomized controlled trial conducted in veterans with PTSD. They found improvements in depressive symptoms, mindfulness, and quality of life, with a low dropout rate in the MBSR group when compared with present-centered psychotherapy (Polusny et.al., 2015).

Kelly & Garland (2016) researched female survivors of interpersonal violence to investigate the effectiveness of mindfulness-based intervention. This study randomized women in mindfulness-based programs and exhibited significant improvement of PTSD symptoms, depressive symptoms, anxiety, and quality of life when compared to the wait-list control group. Similar results of improving PTSD symptoms have been found when comparing mindfulness meditations to psychoeducation therapy in veterans with PTSD (Niles et.al., 2012).

Sandra et.al., (2007) conducted a randomized control trial of mindfulness-based stress reduction (MBSR) in women suffering from depression secondary to fibromyalgia. The study supports the results of previous research showing mindfulness training ameliorates depression, PTSD, and quality of life of those experiencing stressful and traumatic situations (Simpson et.al., 2007; Vujanovic et.al., 2009; Mitmansgruber et.al., 2009). Diana and colleagues performed a qualitative study to research the efficacy of MM

in women with PTSD and history of intimate partner abuse. These women incorporated MM into their daily life. Researchers found that in the initial phase of study, these women experienced strong emotions of anger, sadness, confusion, fear, and numbness in relation to their past traumatic experiences. These symptoms gradually decreased in intensity with continuous MM practices, and they were more motivated to manage their PTSD symptoms while simultaneously improving the quality of relationships with their family, friends, and coworkers. Likewise, Banks, Newman & Saleem (2015), and Follette et.al. (2006) have demonstrated similar outcomes of reducing avoidance and negative cognition including self-blame, shame, and guilt among individuals with PTSD with mindfulness meditation interventions. Women who have PTSD secondary to CSA suffered from continuous intrusive thoughts and dreams of their sexual abuse. These intrusive memories could be controlled by MM, which helps these women shift their attention to coping strategies (Lang et.al., 2012). MM interventions train PTSD patients to orient their attention to the present with curiosity, openness, and acceptance while reducing cognitive distortions and avoidance (Gallegos, Cross, & Pigeon, 2015).

One of the most common symptoms in CSA women with PTSD is avoidance, which is predictive of PTSD's symptom severity (Boeschen, Koss, Figuerdo, & Coan, 2001; Marx & Sloan, 2005; Marshall et al., 2006; Orcutt, Pickett, & Pope, 2005). These CSA victims reported significantly higher rates of avoidance which included trying not to think or talk about the abuse and staying away from reminders of the abuse (Silva et.al., 1997). Because of these avoidance and intrusive thoughts of abuse (Bowen et.al., 2007), CSA victims may increase psychological distress, self-harm, and rate of dysfunctional behavior such as substance abuse and high-risk sexual behavior (Polusny & Follette, 1995).

These symptoms benefit from MM practices, as MM addresses these thoughts without judgment and reduces thought suppression (Bowen, Witkiewitz, Dillworth, & Marlatt, 2007).

Childhood sexual abuse causes long term devastating effects on the quality of women's lives. Due to repeatedly re-experiencing the trauma through flashbacks, dreams, and intrusive thoughts, these women show negative alterations in cognition, persistent negative beliefs, and markedly diminished interests in daily life (Wahbeh et.al., 2014). They also have trouble controlling their anger, expressing their emotions, and experiencing exaggerated startle responses (Wahbeh et.al., 2014) which cause negative influences on their marital relationship, reduces family performance, and leads to a lower quality of life (Azad et.al., 2014). These women also show significantly higher prevalence of sexual dysfunction, depression (Atlantis and Sullivan, 2012), and relationship difficulties (Metz & Epstein, 2002), negatively impacting their quality of life (Rosen and Bachmann, 2008; Stephenson and Meston, 2015). Several studies have been conducted in clinical, community, and college samples to find the rate of sexual dysfunction among women with CSA histories and PTSD. Laumann et al, using data from National Health and Life Survey, showed that among 1,749 women, 17% reported CSA histories and that 59% of those women reported with sexual difficulties. Najman et.al. found that among 898 women participating in a study, 35% reported CSA and among them, 57% reported sexual dysfunction. Gorcey and colleagues found in a community-based study that 58% women reported the history of CSA and among them, 85% reported sexual dysfunction. In conclusion, 55% to 85% of women with histories of CSA reported sexual dysfunction, nearly twice the rate reported by the general population of women (Pulverman, Kilimnik,

& Meston, 2018). It is essential to treat sexual dysfunction due to the negative impact it poses on women's relationship and their quality of life. Pharmacotherapies and psychotherapies showed minimal response in women with CSA and sexual dysfunction in several research studies when compared to women without CSA ((Berman, Berman, Bruck, Pawar, & Goldstein, 2001; van der Made et al., 2009). In contrast, women with CSA showed higher treatment response to mindfulness-based therapies ((Brotto, Basson, & Luria, 2008). Brotto and colleagues found out that women with CSA showed greater improvement in sexual function with mindfulness therapy when compared to cognitive behavioral therapy (CBT). The rationale behind this could be that MM interventions aids these women to cope with their symptoms (Ariapooran et.al.,2010) and provides a path towards the acceptance of thoughts, reducing sexual shame (Yalom, 1995).

Although there is sufficient literature available about the benefits of MM for the treatment of PTSD and several other mental health diseases, women with CSA are reluctant to use MM as well as other medical treatments. Several barriers were identified which hinder CSA women from seeking medical and non-medical help, including MM (Sawrikar et.al., 2017). These women do not see themselves as deserving (Sawrikar et.al., 2017) due to low self-esteem (Taylor & Norma, 2013) or because "they blame themselves for being a victim as a result of the power inequality between men and women, (so) do not feel empowered to seek help" (Smith, Bryant-Davis, Tillman, & Marks, 2010, p. 262). There are also cultural and religious barriers which may prohibit these women from getting treatment. In some cultures, seeking help to get treatment for their sexual trauma is considered as a weakness and shame (Elbedour et al., 2006; Futa, Hsu, & Hansen, 2001; Samms & Cholewa, 2014). A few studies have investigated that religious and spiritual

beliefs among women with CSA may prevent them from seeking MM interventions (Sawrikar et.al., 2017).

Despite the attitude shift towards the use of MM interventions among healthcare practitioners and people with PTSD, less evidence-based data is available to measure the effectiveness of MM interventions in women with CSA. Kimbrough and colleagues (2010) conducted a pilot study in adult survivors of CSA to measure the effect of weekly mindfulness-based stress reduction (MBSR) sessions for 8 weeks. The study results showed significant decreases in avoidance and depressive symptoms of PTSD in the participants by the end of the study. This study demonstrated that MBSR was feasible, safe, and acceptable in this patient population. However, there were several important limitations of this study. The most prominent limitation was the lack of a randomized control group; therefore, it is difficult to say whether these changes in symptoms were due to MBSR or not. The study was conducted with a relatively smaller sample size (28 participants), which may potentially cause susceptible outliers. The study participants of this study were under concurrent psychotherapy during the study period, which limited the validity of the study results. As a result, it is undetermined if the MSBR intervention of the psychotherapy was responsible for the changes observed, warranting further research to investigate the intervention in a randomized control trial, the gold standard for the effectiveness of research (Hariton and Locascio, 2018).

Even though previous research has shown that MM practices have positive effects on reducing PTSD symptoms, there is a lack of utilizing of MM as standard adjunctive tool by most clinicians (McGee, 2008), because they are either culturally unknown with the various meditative tradition, or they doubt the techniques used by MM to enhance

wellness and ease mental illness (McGee, 2008). There is a need for guidelines/data about the efficacy of MM interventions to treat PTSD either alone or to integrate MM in traditional PTSD treatments. MM practices are mostly conducted in a group setting which most of the CSA women are reluctant to attend because they do not feel comfortable talking about their trauma in the presence of other people (Wahbeh et.al., 2014). One-on-one sessions removes the social dynamic which may improve participant retention and allow scheduling flexibility (Wahbeh et.al., 2014). To date, there is no standardized individual format program to treat PTSD in CSA women with MM intervention. The proposed study will conduct individual MM sessions, which may eliminate the above mentioned limitation of doing MM sessions in a group setting.

This study will select participants from Atlanta, Georgia, where there is an increase of child abuse and neglect cases with no or limited access to resources to deal with effect of trauma. According to the Child Welfare League of America, 21,635 children were victims of abuse or neglect in Georgia in 2016, a rate of 8.6 per 1,000 children. Of these, 4 percent were sexually abused (Child Welfare League of America 2016). This study seeks to lay the groundwork for the potential integration of practice of MM in PTSD treatment and to develop MM as a tool for self-healing and self-care for CSA women survivors.

Chapter III: Methodology

Review of Funding Agencies

This section describes multiple sources of funding that support CAM and PTSD research. Each agency offers unique research opportunities in their respective fields. The funding source chosen best matches the topic, scope, and budget of the proposed research.

The National Center for Complementary and Integrative Health (NCCIH), formerly the National Center for Complementary and Alternative Medicine (NCCAM), funds and conducts scientific research on complementary and alternative health approaches (nccih.org, 2020). NCCIH is the part of National Institutes of Health (NIH). The aim of NCCIH is to support accurate scientific research to describe the effectiveness and safety of complementary and integrative health interventions and their role in improving health and health care (nccih.org, 2020). NICCH supports clinical trials to assess the safety, efficacy, and effectiveness of CAM approaches (nccih.org, 2020). One of the objectives of the NICCH is to advance the science and method development to improve care of treatment resistant symptoms (nccig.org,2020), which encase the investigation of using CAM for mental health issues like PTSD. The field of CAM and its relation to mental health comes under the umbrella of NICCH typically funds, which is research to help answer important scientific and public health questions about complementary and integrative health approaches (nccig.org. 2020).

National Institute of Mental health (NIMH) which is a part of National Institute of Health (NIH), funds and conducts biomedical and behavioral research and research training on mental health disorders. NIMH also plans and supports translation of mental health research into clinical practice, service delivery and policy making. The aim of NIMH is to support and promote the basic and clinical research to diagnose, prevent, and treat mental illnesses (nimh.nih.org, 2020).

Substance Abuse and Mental Health Service Administration (SAMHSA) is the agency work within the U.S. Department of Health Services (HHS) that supports public health efforts to improve mental and behavioral health of individuals and their families. SAMHSA provides leadership and resources in the form of programs, policies, information and data, funding, and personnel to develop advanced mental and substance use disorder prevention, treatment, and recovery services (samhsa.orh, 2020).

NCCIH is a Federal Government's lead agency for scientific research on the diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine (nccih.org, 2020). NCCIH support researchers to investigate strategies to integrate CAM interventions with conventional medical/clinical practice and to evaluate the effects of this integration. For this reason, it is chosen as the funding agency for the proposed project. NICCH offers several funding opportunities specifically for CAM, making the available option most suited to fit the proposed project.RFA-AT-01-001 or Integration of Complementary and Alternative Medicine: A Health Services Research Perspective is chosen as it provides the best opportunity to research integration of CAM interventions with conventional

medical/clinical practice for mental health issues like PTSD and to evaluate the effects of its integration, which is an area that has not been extensively studied.

Description of Grant Announcement

The requirements of RFA-AT-01-001 are described in the following paragraphs. The following section is taken directly from RFA, which can also be found in Appendix H. This proposal is in response to RFA-AT-01-001 and seeks funding under the National Institutes of Health (NIH) research project grant (R01) and exploratory/developmental grant (R21). This type of grant is selected because it is guaranteed to promote exploratory/development research that investigates strategies to integrate CAM interventions with conventional medical/clinical practice and to evaluate the effects of this integration. In addition, the proposed research will not require a long timeframe, thus making an R21 grant the best choice.

"The National Center for Complementary and Alternative Medicine (NCCAM) invites research applications that investigate strategies to integrate CAM interventions with conventional medical/clinical practice and to evaluate the effects of this integration.

For the purposes of this RFA, CAM is defined as healthcare practices that are not an integral part of conventional medicine. Integration is defined as the merging of CAM and conventional practice within a health care delivery system. The intent of the RFA is to 1) identify barriers and facilitators to the integration of CAM and conventional health care practices; 2) determine whether CAM research results obtained from studies conducted under ideal conditions (efficacy studies) can be translated to real-world settings (i.e., effectiveness) within an integrated model; and 3) support the evaluation of

currently planned or recently initiated programs, goals of which are to improve the outcomes, quality, effectiveness, and/or cost-effectiveness of health care through the integration of CAM and conventional health care.

Applications may be submitted by for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply.

This RFA addresses three main objectives:

1) identify barriers and facilitators to the integration of CAM and conventional health care practices;

2) determine whether CAM research results obtained from studies conducted under ideal conditions (efficacy studies) can be translated to real-world settings (i.e., effectiveness) within an integrated model; and

3) support the evaluation of currently planned or recently initiated programs, goals of which are to improve the outcomes, quality, effectiveness, and/or cost-effectiveness of health care through the integration of CAM and conventional health care.

It is anticipated that each application will address one or more of the following research questions:

a) The knowledge, attitudes, referral patterns and behaviors of both CAM and conventional practitioners.

b) Impact of CAM integration on health care quality.

c) Cost-effectiveness of CAM integration for specific health conditions; and

*d) Quantification of CAM cost offsets within care delivery systems or healthcare pl*ans.

It is anticipated that responses to this initiative will be multi-disciplinary, and may include collaborations between health services researchers, sociologists, medical anthropologists, clinical researchers, individual clinicians (CAM and conventional), and health care systems and organizations (e.g., purchaser groups, integrated health service delivery systems, academic health systems, managed-care programs including HMOs, practice networks, worksite clinics, etc.). These relationships will enable a rigorous evaluation of planned and ongoing integration efforts that may not otherwise occur. The presence of strong partnership arrangements is essential to determine the impact of CAM integration on clinical practice and patient outcomes in applied situations.

Qualitative methods may be valuable for identifying promising areas of research. Discussion should be devoted to analytic features of the study including primary endpoints, power estimates, randomization procedures, and statistical methods, as applicable. Study methods must be adequately rigorous to address the research question, implementation of similar interventions, and issues of validity (internal and external) and reliability. It is expected that studies involving clinical interventions will include concurrent comparison groups rather than historical controls. Strategies for addressing selection bias among participants, including randomization at the patient level, practice or other organizational unit, pseudo-randomization or matching must be included. Studies that are not amenable to randomization should address challenges to internal validity in some other manner."

This proposal is admissible to NCCIH which is the federal government's top agency for scientific research on diversified healthcare approaches, practices, and

products that are not commonly considered as part of conventional medicine. NCCIH focuses to develop and improve complementary health approaches and integrative interventions to address hard to manage symptoms. NCCIH strongly focuses on research projects which are feasible and scientifically plausible to treat disconcerting and prevalent health conditions to improve health, well-being, and quality of life. Among CAM, mindfulness meditation is one of the popular interventions utilizing for the management of mental health problems, including PTSD. Though there is an increasing trend of using MM practice, there has been fewer studies researching the effectiveness of mindfulness meditation as a treatment for PTSD in women with a history of childhood sexual abuse. An investigation of the impact of mindfulness meditation intervention in improving quality of life in PTSD patients is an area that is unique, and NCCIH is the most suitable given its existing research portfolio.

Review Criteria

RFA-AT-01-001 requires the applicant to develop a well-planned research plan approach that includes Significance, Approach, Innovation, Investigators and Environment. The following sections describe how the proposal is responsive to these criteria.

A. Significance

PTSD is an important public health problem caused by the exposure of trauma such as childhood abuse, sexual abuse, accidents, and life-threatening experiences (Basile et al., 2004; Harrison and Kinner, 1998; Hoge et al., 2004; Lowe et al., 2014; Neria et al., 2007; Punamaki et al., 2010). In the United States, there are about 8 out of every 100

people who may have PTSD at some point in their lives (ptsd.va.gov 2019). PTSD is more prevalent in women than men, about 10 of every 100 women (or 10%) develop PTSD sometimes in their lives as compared to 4 in 100 men (or 4%) (ptsd.va.gov 2019). PTSD is also very disabling and results in an inability to work or have close social relationships in many individuals. One of the most common causes of PTSD in women is childhood sexual abuse, which affects 1 in every 9 women at some time before their 18th birthdays and leads to chronic PTSD in 26.5% of cases (David et.al., 2014; Sharkansky, E 2019). Overall, PTSD result in poorer overall quality of life, health-related quality of life and functioning in Childhood Sexual Abuse (CSA) women (Anda et.al., 2004; Afifi et.al., 2007). These women reported difficulties with interpersonal relationships such as intimate relationship, female friendships, and difficulties with parenting (DiLillo, 2001). Based on these devastating consequences, it is imperative to treat PTSD to improve the quality of lives of CSA women. Several evidence-based treatments available for PTSD, including pharmacotherapy, cognitive processing therapy, and prolonged exposure therapy (Foa et.al., 1999; Resick et.al, 2002). These interventions have shown improvement in PTSD symptoms but on the other hand, they may also result in several unfavorable side-effects. PTSD medications like Paroxetine and Sertraline may cause nausea, constipation, dry mouth, sexual dysfunction, and insomnia, whereas PTSD psychotherapy may result in deterioration of PTSD symptoms, emergence of new symptoms or suicidality (Klatte et.al., 2018). Many of the women with PTSD are reluctant to pursue these treatment interventions.

In addition, women with PTSD secondary to the history of childhood sexual abuse have high percentage of treatment resistance, non-adherence, and drop-out from

the PTSD's conventional treatments. This is because of the chronic patterns of avoidance and an inability to tolerate the intense emotions often experienced with the conventional PTSD treatment approaches (Grunert et.al., 2007). For this reason, CAM practices especially mindful meditation are gaining popularity among patients with PTSD because of its nature of treating PTSD symptoms without trauma recall, and they barely have any side effects (Wahbeh et.al, 2014).

Little research has been done on the effectiveness and validity of MM practice in CSA women for the treatment of PTSD. There is very limited data available about the effect of MM interventions on the symptoms of PTSD and the quality of lives of CSA women with PTSD. Although most of the research has been done with veterans with PTSD, there are very few studies that utilize randomized controlled trials, which is a gold standard method of scientific evidence. For this reason, a randomized controlled comparative effectiveness trial is a need to assess the efficacy of MM intervention relative to conventional PTSD treatments in CSA women with documented PTSD.

B. Innovation

Sexual assaults in childhood may result in lifetime serious adverse effects on health, education, employment, and the economic well-being in women (WHO, 2010). One of the most common effect of CSA in women is PTSD. PTSD can be treated with both psychopharmacological and psychotherapeutic interventions which can be utilized either alone or in combination. Both have potential to improve symptoms of PTSD but at the same time there are a high rate of medication refusal and non-compliance (Rakofsky et.al., 2011). Women with PTSD secondary to the history of CSA comparatively have a

higher rate of these issues due to the nature of trauma and stigma of shame and guilt attached to it. To increase the rate of treatment adherence, there is a need to incorporate a treatment or technique which will reduce the PTSD symptoms in a non-judgmental, non-provoking method in CSA women. Among all CMA modalities, MM intervention would be the best choice. This project aims to understand and incorporate MM therapy into the clinical practice to treat PTSD in CSA women.

Clinicians' interest in considering MM practices to treat PTSD patients may be limited due to the lack of availability of resources and lack of familiarity of MM effectiveness in lowering PTSD symptoms. Further knowledge and research of these practices may encourage PTSD patients who either do not want to interact with psychiatry or who are reluctant to take medications.

The proposed study focuses on the feasibility and efficacy of MM practice as an alternative therapy to conventional PTSD treatments in CSA women diagnosed with PTSD. The project will utilize validated psychometric instruments, standardize procedure, control group, and appropriate follow-up to measure the validity of study outcomes. In addition, conducting research among CSA women, who are either taking PTSD conventional treatments or not taking any treatment to measure the effect of MM therapy, also adds to the project's innovation. The proposed research seeks to fill the gap between clinicians and patients by utilizing MM intervention in the clinical setting or non-clinical setting, as well as utilizing MM as the first line PTSD treatment in CSA women.

B. Approach

The investigator has selected a prospective randomized controlled trial (RCT) to assess the effectiveness of mindfulness meditation utilization by women with PTSD secondary to childhood sexual trauma. RCT, which is considered as the gold standard to measure the cause-effect relationship between an intervention and outcome (Hariton and Locascio, 2018), will validate the proposed research need. The study will also monitor the reduction of PTSD symptoms when using MM in conjunction with conventional PTSD treatments as well as its effect on people's quality of lives. In order to measure the effectiveness of MM therapy in reducing symptoms of PTSD, this study will utilize validated psychometric assessments tools and statistically analyzed data using IBM SPSS statistical software. In the study intervention, 120 women with childhood sexual abuse and PTSD, age 21 and above, will be randomized in one of the three groups: PTSD treatment group (PTSD_Rx), PTSD treatment plus mindfulness meditation group (PTSD_Rx+MM), and mindfulness mediation group (MM). Each group will consist of 60 participants. The research subjects will receive assessments including neuropsychological assessments of memory and behavioral assessments at baseline (pre-therapy) and post therapy. These assessments will also be performed at the three and six months follow up visit, post therapy.

Participants

We plan to enroll 120 participants in total, 60 participants for each of the study intervention groups (PTSD_Rx, PTSD_Rx + MM and MM). Participants will be women of age 21 and older with history of childhood sexual abuse and diagnosed PTSD**.** Subjects will be recruited through flyers, local news- papers, advertisements, Emory Clinic, and

Emory Department of Psychiatry. As the investigator has spent 10 years working on research at Emory's Department of Psychiatry, she has existing relationships with both psychiatrists and psychologists of the department. This will facilitate the recruitment process by alerting PI when there is a potential participant who meets the study criteria. All research activities will be reviewed and approved by the Emory University Institutional Review Board (IRB).

***Study Inclusion Criteria*:** Participants with PTSD that meet the following criteria will be included:

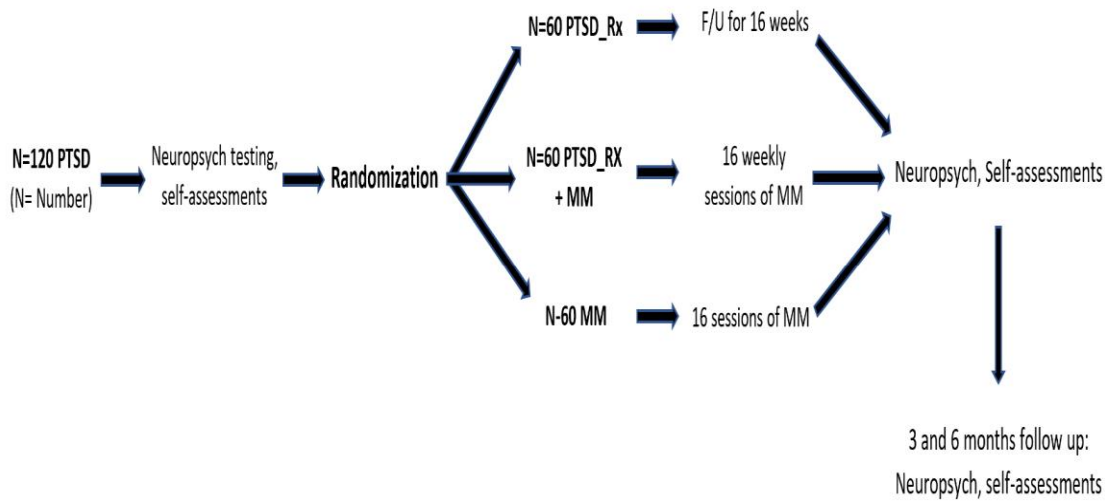
1. 21 years and older.
2. Meet criteria for current PTSD as determined by the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders lV (SCID) interview for PTSD (Spitzer et.al., 1987).
3. Clinical Administered PTSD Scale (CAPS; Weathers, Keane, & Davidson, 2001).
4. History of sexual abuse occurred before the age of 16, as assessed by the Early Trauma Inventory (ETI; Bryant et. al., 2005).
5. Ability to read and understand the study assessments.

***Study Exclusion Criteria*:** Women will be excluded if they have:

1. Traumatic brain injury (TBI)
2. Neurological disorder or organic mental disorder.
3. History of loss of consciousness.
4. Current alcohol or substance abuse.

5. Current or lifetime history of schizophrenia, schizoaffective disorder.
6. Current violence such as domestic abuse as measured by the ETI-lifetime.

FLOW CHART OF BASIC STUDY DESIGN



Measurements

The Mini International Neuropsychiatric Interview (MINI): M.I.N.I. is a short-structured interview for the diagnosis of major Axis I psychiatric disorders in DSM-IV and ICD-10 (Sheehan et. al., 1998). With a 15 minutes administration time, MINI is designed to meet the need for a short, but accurate structured psychiatric interview for clinical and epidemiologic research (Sheehan et.al., 1998).

Clinician-Administered PTSD Scale (CAPS): The CAPS, an interviewer-administered diagnostic instrument, will be used to measure current and lifetime DSM-IV diagnosis of PTSD (Weather et.al., 2001). Severity and frequency of PTSD symptoms will be calculated by adding CAPS severity and frequency rating on the following PTSD symptoms: reliving experiences, nightmares, avoidance of reminders and thoughts of the assault, impaired leisure activities (e.g., reduces socializing), sense of detachment, disturbed sleep, concentration difficulties, hyper-alertness, increased startle response, and feeling of guilt. CAPS will also measure the rate of social and occupational functioning, global PTSD symptoms severity, and the validity of the participant's responses (Resick et.al., 2002).

Early Trauma Inventory-Self Report-Short form (ETI-SR_SF): ETI-SR (Bremner et.al., 2007), a self- reported instrument (27 items), will be used for the measurement of childhood traumatic experiences. ETI will assess the presence of general trauma of childhood, physical, emotional, and sexual abuse before the age of 18 (Ana et.al., 2011). Severity scores for individual trauma domains and composite trauma severity scores are calculated.

PTSD Checklist for DSM-5 (PCL-5): The PCL-5 is a 20 item self-report measure that assesses the 20 DMS-5 symptoms of PTSD (American Psychiatric Association, 2013). It is widely used to monitor symptoms change during and after treatment. It also helps in making a provisional PTSD diagnosis

World Health Organization Quality of Life – Brief (WHOQOL-BREF) is a 26-item brief assessment of quality of life in four factor-analytically confirmed dimensions: Physical, Psychological, Social, and Environmental (Skevington et.al., 2004). The WHOQOL-BREF has good to excellent internal consistency reliability and has shown predicted relationships with health status, single items assessing quality of life, and demographic variables. WHOQOL-BREF which is a combination of qualitative and quantitative methods to assess CSA women's quality of life within the context of participants' culture, value systems, personal goals, standards, and concerns (Vahedi, 2010). This will be completed at baseline and at the end of study.

Procedure/Method:

If the patients express interest in participating in the study, the PI will meet the eligible women in the office at the Emory University's Department of Psychiatry. PI will then explain the study design, informed consent form, and Health Insurance Portability and Accountability Act (HIPPA) form. If the participants would like to take some extra time to read and share informed consent and HIPAA form with family, they could take these forms to home and bring back on the next appointment. After the informed consent and HIPAA forms are signed, an in-depth screening will be performed by PI that will cover all inclusion and exclusion criteria. All eligible participants will schedule for further in-depth

assessments. All the above-mentioned psychometric assessments will be performed by PI, and self-assessments will be completed by participants at baseline (at the beginning of the study) and post-treatment. After completing all baseline assessments, women will be randomly assigned to either PTSD treatment (PTSD_RX), PTSD treatment + MM intervention (PTSD_Rx + MM), or MM intervention groups for 16 weeks. Participants in the PTSD treatment group can have PTSD medications provided by their mental health physicians and psychotherapy provided by mental health clinicians (psychologists or clinical social workers). This group will be considered as the study control group. Participants in PTSD_RX + MM and MM groups will attend weekly in-person sessions of MM interventions. Mindfulness meditation will be conducted by a certified female instructor with expertise in mindfulness meditation therapy. The instructor will be trained to use the MM manual which specifies the agenda and treatment procedure for each session. The instructor will be closely supervised by the clinical investigator to ensure the integrity of the intervention procedure and all therapy sessions will be monitored by PI to assure fidelity to the protocol. PTSD_RX participants will encourage calling as needed, and the study clinician will routinely contact them during the 16 weeks period. Post-therapy reassessments will be performed to all groups. Three months and six months post-therapy follow up assessment will be conducted to all the three groups. Participants will receive compensation for their participation and adherence to the study intervention. Contact information of the PI will be given to participants and will encourage to report any significant exacerbation of symptoms or adverse effect to the MM intervention.

Drop out:

Drop out may be either due to the instructor or the participants may have experienced difficulties in the exposure process (imagination of trauma), or unmet expectations as MM progresses. To minimize risk of drop out, a well-experienced instructor who is specialized in MM will pose as a positive factor on participants' retention. To mitigate the effect of drop out on analysis, study will enroll more subjects than are needed for reliable statistical analysis.

Mindfulness Meditation Therapy:

Mindfulness meditation (MM) is a form of psychotherapy that combines mindfulness and experiential imagery (Peter strong, 2010). MM has demonstrated beneficial effects on reducing anxiety, depression, sleep disturbances, pain (Singh et.al., 2015), and PTSD in war victims (Khusid et.al., 2016).

Neuropsychological data recommend that meditation boost the skills to modulate cognition, emotion, and behavior (Hölzel et al., 2011). Skills learned in MM training may prepare participants to fully engage in evidence-based psychotherapies for PTSD. They train participants to form a non-reactive relationship with their traumatic memory and encourage them to adopt these techniques as a lifestyle change (Khusid et.al., 2016). Awareness of present experiences may facilitate improved client–therapist communication via enhanced open awareness.

Also, nonjudgmental acceptance can reduce shame and guilt, which is one of the main aspects of PTSD treatments (Vujanovic, Niles, Pietrefesa, Schmertz, & Potter, 2013).

Participants randomized to the PTSD_Rx + MM and MM groups will attend weekly 1 hour MM sessions for 16 weeks. Sessions will be held in the PI office located at Emory University. In the first session, participants will get the educational information about symptoms of PTSD, expectations, treatment rationale, and treatment planning. The next 15 sessions will be devoted to train the following skills:

a. Awareness, including being aware of and being able to recognize all things around (like light and sound), as well as things that are going on inside (like thoughts and feelings)

b. Focus on looking at the traumatic experiences in a nonjudgmental way

c. Being in the present moment instead of living in thoughts of the past (rumination) or the future (worry).

In every session, participants will review with the instructor about the past week – like issues with mediation, seeing changes, and difficulties. Participants will also be encouraged to practice mindfulness meditation as daily homework.

Recruitment and Retention of Subjects

Participants' recruitment will be an issue due to the time restriction (2 year) to complete study. To resolve this issue, PI will proactively request a HIPAA waiver for the purpose of recruitment at the time of initial IRB submission. The other challenge might be the retention of participants throughout the study period and adherence to study intervention. When a participant misses a MM session, investigator will contact the participant either by phone or email to re-establish contact and retain in the study. Study will give monetary compensation to all participants, based on the completion of study tasks.

Data Analysis

All psychometric data will analyze at baseline (pre-therapy) and compare their scores to the post-therapy data. For example, CAPS (Weather et.al., 2001), which is our study outcome measure, provide intensity and frequency of PTSD symptoms. By adding all frequency and intensity rating together, we will get the total severity score for PTSD. This score at pre-therapy will compare to the CAPS score at post-therapy assessment visit to measure any improvement in PTSD symptoms. Similarly, ETI, and WHOQOL scores will be added up and compared to post-therapy scores to determine any improvement of PTSD symptoms. Data will be quantitatively analyzed to respond to the objectives of this project by using univariate analysis with t-test or chi-square test in SPSS. Data analysis of all psychometric assessments will reveal any significant difference in improvement of PTSD symptoms among PTSD_Rx, PTSD_Rx + MM and MM groups.

Prior to analysis, all psychometric assessments will be entered in a secured database by PI. All entered data will be quantitatively analyzed by an experienced analyst, hired for this study. IBM SPSS software will be used to perform study analysis. IBM SPSS is an integrated collection of quantitative analysis software that can be used to perform many data management and statistical analysis tasks. Equivalence of MM group at baseline (pre-therapy) will be examined by using analysis of variance. To evaluate the long-term MM effect, we will conduct a three-level mixed effect linear regression repeated measures analysis for both pre-therapy to post-therapy, as well as post-therapy to 3-month and 6-month follow-up.

Result and dissemination

The outcome measure will be the severity of PTSD, depression symptoms, social adjustment, and anxiety symptoms. The other outcome measure will be the effect of MM practice on participant's quality of life. Analysis of the data will be used for non-medical treatment of PTSD in women with a history of childhood sexual abuse. Based on the analysis of the effectiveness or ineffectiveness of mindfulness meditation intervention in reducing symptoms of PTSD, PI will synthesize the conclusion and use these results to develop new therapy clinics for victims of childhood sexual abuse. Investigator will also share the study results with fellow psychiatrists to develop new research in PTSD prevention and treatment.

The analysis and results of the study will be submitted to the National Institute of Mental Health (NIMH), whose primary mission is "to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure" (nimh.nih.gov, 2020). Analyzed data and research outcome will be disseminated to Journal of Complementary and Alternative Medicine, American Psychiatric Association, American Psychological Association, and National Institute of Mental Health (NIMH) in the form of an article or report.

Investigators

The investigator has an extensive knowledge and experience in medicine and clinical research which makes her well suited for the role of primary investigator for this research project. She has completed her medical education from Dow University of Health Science, one of the oldest and most prestigious medical institutions in Pakistan.

Her experience in clinical research started with active participation in multiple community-based research projects, which included the public health issues of smoking, drugs, alcoholism, abuse, and AIDS. After moving to the USA, she continued her medical career as a clinical researcher in the Department of Psychiatry at Emory University School of Medicine, Atlanta Georgia. She started working as Research Associate in Emory University's Clinical Neuroscience Research Unit (ECNRU) on several NIH funded projects, including R01MH056120 Neural Circuits in Women with Abuse, R01HL088726-03 Mechanisms of Depression in Cardiovascular Disease, and Post-Traumatic Stress Disorder and Veteran's Affairs Clinical Science Research and Development, which sponsored A Multisite, Randomized, Controlled Trial of Mindfulness Meditation Therapy for PTSD. She performed as a key contributor to the progress made throughout the studies.

In ECNRU, she worked with the Principal Investigator J. Douglas Bremner on planning, designing, and executing investigator initiated translational and epidemiological study protocols. Her knowledge extends to the vital activities of any research project such as reviewing and comprehending study protocols, data collection, adherence to applicable federal and institutional regulations, grant and budget preparation, and maintaining regulatory documentations for the IRB submission. She worked as a point person to perform all the project related psychometric assessments as well as to conduct statistical analysis of the data collected as per study protocols. The investigator is a conscientious, efficient researcher who has provided quality research by her attention to detail and her ability to contribute novel and innovative solutions to the research team. She is also the co-author of published research articles such as "Brain

Correlates of Mental Stress-Induced Ischemia" (2018) and “Brain Mechanism of Stress and Depression in Coronary Artery Disease” (2019).

Dr. Bremner is a distinguished professor of Psychiatry and Radiology at Emory School of Medicine. He is also the Director of the Emory Clinical Neuroscience Research Unit (ECNRU) at Emory University School of Medicine. He is also Director of Mental Health Research at the Atlanta Veteran’s Affairs Medical Center in Decatur Georgia. Dr. Bremner’s research includes studies of neural circuits in abuse women, depression and cardiovascular disease, the neurobiology and assessment of PTSD, neural correlate of declarative memory and traumatic remembrance in PTSD. He is the author or co-author of more than 200 peer reviewed articles and book chapters such as “Psychometric properties of the adulthood trauma inventory” (Bremner JD. et al., 2020); “Diet, stress and mental health” (Bremner JD. et. al., 2020); “Traumatic stress: effects on brain” (Bremner JD. et.al.,2006); “Stress and brain atrophy. Current Drug Targets Central Nervous System and Neurological Disorders" (Bremner JD et.al.,2006); “Hippocampal volume reduction in major depression” (2000), and “The environment contributes more than genetics to smaller hippocampal volume in Post- Traumatic Stress Disorder” (Bremner JD. et.al., 2020).

In 2015, the investigator joined the Emory Trauma and Anxiety Recovery Program at Emory University School of Medicine as a Research Associate Scientist. She enhanced her research experiences by performing highly technical and complex research duties. She demonstrated increased technical, management, leadership, and professional expertise. Her role was to supervise all research activities from planning and designing to the execution of projects as per study protocols. The Investigator worked directly with the

Principal Investigator Dr. Barbara Rothbaum on several activities such as IRB submission, psychological assessments, data collection, developing guidelines and SOPs for proper data collection, and performing complex neuropsychiatric testing. She expanded her research experience working with patients with anxiety, depression, panic disorder, traumatic brain injury (TBI), and PTSD. Dr. Rothbaum is a renowned professor of Psychiatry and Associate Vice Chair of Clinical Research at the Emory University School of Medicine's Department of Psychiatry and Behavioral Sciences. She is Executive Director of the Emory Healthcare Veterans Program and Trauma and Anxiety Recovery Program. She specializes in research on the treatment of patients with anxiety disorders including PTSD using psychotherapies like cognitive behavioral therapy (CBT) and prolonged exposure (PE) psychotherapy. Dr. Rothbaum's work includes more than 300 scientific papers and chapters such as "Virtual Reality-Enhanced Extinction of Phobias and Post-Traumatic stress" (2017); "Psychotherapy for PTSD: An evidence-based guide to a theranostic approach to treatment" (Rothbaum et.al. 2018); "Treating the trauma of rape: Cognitive-behavioral therapy for PTSD" (Rothbaum et.al.,2001).

The investigator's interest in PTSD research, working with above mentioned, well-known principal investigators, produces an interest in PTSD patient's quality of life. Her clinical experience working directly with PTSD patients makes her well suited as the principal investigator of this study.

Institutional Environment

The grant proposal is responsive to the Institutional Environment as Emory University is exceptionally well qualified to carry out the proposed research. Emory

University is a distinguished university for its liberal arts college, professional schools and one of the leading healthcare systems in southeast America. Emory University Hospital, founded in March 1904, is equipped with the latest technology to provide the most advanced, compassionate patient care in Atlanta, Georgia. Emory University's mission is "to foster a culture that integrates leading edge basic, translational, and clinical research to further the ability to deliver quality health care, to predict illness and treat the sick, and to promote health of patients and community" (emory.edu 2018). Emory's clinicians and researchers conduct innovative and collaborative research and integrate their knowledge into practice of medicine to serve the needs of the community.

Embedded within Emory University, the Department of Psychiatry and Behavioral Neuroscience is well-known in the U.S. for its innovative methods of treatment and several neuroscience research programs. The department supports clinicians and researchers to develop and implement new models of behavioral health care. The Department of Psychiatry and Behavioral Sciences consists of many patient-focused centers, programs and services, come under the umbrella of Brain Health Center. There are more than 20 centers and programs within the Brain Health Center, including medical psychiatry unit, addiction psychiatry unit, general adult psychiatry unit, geriatric psychiatry unit and out-patients psychiatry clinics. It has more than 150 faculty members including psychiatrists, psychologists, and neuroscientists. It is currently (2010-2011) ranked #14 in NIH funding and #15 in "America's Best Hospitals" by *U.S. News and World Report* (psychiatry.emory.edu, 2020). Emory psychiatrists and psychologists perform several research projects in multiple areas of psychiatry and neuroscience such as depression, anxiety, PTSD, schizophrenia, autism, substance abuse and public health.

All of Emory hospital's psychiatrists, psychologists, social workers, and nurses offer compassionate care for patients with mental health conditions. More than 400 Emory researchers and clinicians from various psychiatric domains work in collaboration to diagnose, treat, and prevent devastating diseases or disorders of the brain.

The innovative technologies and facilities available to the PI at Emory University Hospital included everything needed to initiate and complete the proposed research project. The scholarly environment is rich with other investigators who are doing work that is correlative to what is proposed in this grant application. The proposed research would be strongly supported by this facility, which provides a well-equipped scientific environment, ensuring the success of the project. In addition, Emory university/Brain Health Center has established long-term relationships with Grady Health System, Atlanta Veterans Affairs Medical Center, and the Centers for Disease Control and Prevention (CDC).

Methodology of the Grant Review process

A copy of proposal was sent to the reviewers via email. The proposal included the following sections: Specific Aims, Research Strategy, Investigators, Institutional Environment, Recruitment and Retention of Subjects, Protection of Human Subjects, and Appendices. The proposal was distributed individually to each reviewer, along with an electronic copy of the RFA, instructions for the review process, a review evaluation scoring sheet, and a conflict of interest form, which are included in Appendices I, J, K, and L. Two week time were given to complete the review process. They were instructed to use the external review evaluation scoring sheet to evaluate each section for strengths,

weaknesses, and recommendations. Each evaluation criterion had a total number of points: Significance: 25; Innovation: 20; Approach: 30; Investigators: 15; Environment: 10. There was a section for “additional review criteria,” which included recruitment and retention of subjects; protection of human subjects; and inclusion of women and minorities. This section was not graded, only comments were encouraged, if applicable.

Reviewers sent their comments via email, and a thank you email was sent to each reviewer for their time and feedback. All the comments and feedback included strengths and weaknesses were reviewed thoroughly. Reviewers’ comments were copy and paste in a new Microsoft Word document in order to answer all the comments and recommendations provided by reviewers. Priority was given to edit the most challenging first as those required more time to resolve. After resolving all the comments, the proposal was edited according to the reviewer’s comments. After all the comments were reviewed and recorded, chapter 4 was completed. Chapter 4 consists of all the comments and how they were addressed. After that, the first draft of chapter 5 was completed. Chapter 5 is to be the final version of the proposal. Chapter 5 was sent out to the committee for review and after editing all the remaining commits, the final version of proposal was added to the thesis.

Description of Grant Reviewer

Rebecca Upton, Ph.D., M.P.H. is associate professor of sociology and anthropology at DePauw University and affiliated faculty at the Rollins School of Public Health at Emory University. She is working as a medical anthropologist and doing research in southern Africa on issues of gender, reproductive health, and the HIV/AIDS epidemic. As a

professor, she teaches classes on Qualitative Research Methods for public health graduate students in Emory University. Her education and experiences will be extremely beneficial to the review process. She serves as a Thesis Chair in thesis committee.

Carolina M. Lecours, M.P.H. is the Public Health Analyst and Project Officer for Lead Poisoning Prevention Program at Center of Disease Control and Prevention. Her previous experience includes acting as Quality management and Education coordinator at Emory Winship Cancer Institute. She is skilled in health policy, epidemiology, research design, and grant writing which make her suitable in the review process. She serves as Field Advisor on the thesis committee.

Donna Knutson, Ph.D. is the retired Deputy Director for the National Center for Environmental Health, Agency for Toxic Substances and Disease Registry at CDC. Her previous experience includes acting as the Fund Manager for the Working Capital Fund at CDC. She has a 25 + year career with CDC, and her vast experience in many areas of public health will be extremely useful in the review process.

Humama Khan, Ph.D. Is working as a clinical psychologist in a private practice as well as she is completing her Post-Doctoral Fellowship in Emory School of Medicine. She is specialized in depression, anxiety, transition/adjustment disorders, trauma, multicultural issues, and personality disorders. Her education and experience will make her suitable as reviewer.

Ebad Rahman, M.P.H. is working as a Senior Analyst in Payer Strategy and Contracting Department of Mass General Brighman MA. He has extensive experience in health policy making and analysis, grant writing, and data management/analysis. His education and experience make him suitable in the review process.

Protection of Human Subjects

Emory University is the proprietor of all institutional data. To maintain HIPAA compliance, the data will be completely de-identified and therefore the need of authorization from the individual is waived. HIPAA Privacy Rule covers all forms of patients' Protected Health Information (PHI), including paper, records, and electronic health information (ePHI). The Emory Office of Compliance will provide consultation and training for compliance with HIPAA and will serve as a point of contact for the research team.

Human Subject's Involvement, Characteristics, and Design

This is an investigator-initiated study. All research activities must be reviewed and approved by Emory University Institutional Review Board (IRB). The proposed study will enroll women with childhood sexual abuse-related PTSD based on specific criteria (outlined above). Women will be above the age of 21 who will be recruited through IRB-approved Flyers and Advertisements. Investigator will also reach out through Emory Clinic and Department of Psychiatry for PTSD patients who meet the study criteria.

Human Subject's Materials Collected

Data to be collected include participants self-assessments and psychometric assessments performed by PI. The research does not involve blood/tissue storage and banking. After enrollment, each participant will assign a unique identification number. The study ID will identify each individual case report form (CRF) so that data entered in the database will be de-identified. Personal identifying information will be kept in a separate location from the research records. Information connecting the study ID with the participant will be accessible only to study personnel. Study data will be entered into an access database. The access database will convert a SAS file for the analysis. The database will only be accessible via password protected computer to study personnel. The database will be saved on a computer which has the appropriate security safeguards such as encryption, anti-virus control, firewall configuration, and automatic backups to keep data safe from loss or theft. External hard drive will also be used for backup data.

Recruitment and Informing Subjects of Study or Program

Once the participants agree to be in the study, they will get a research consent form and HIPAA form to read. The investigator will go over the consent form and answer all the questions and concerns the participants may have. They also provide sufficient time to read and understand the consent form. Once participants sign the informed consent and HIPAA form, the investigator will review the study in detail and discuss any possible risk involved. The investigator will document the informed consent process by filling out the informed consent progress form, which is to be signed, dated and kept in

the participant record (see Appendix A: Informed consent; Appendix B: Informed consent progress form).

The informed consent form will explain the purpose and include a detailed description of the study, including randomization, blinding, study groups, intervention, and duration of participation. In addition, informed consent will also explain that participation is voluntary. Even if they decide to join the study, they have a right to withdraw themselves from the study at any point. Consent form will also explain how their study information will be stored, who will own the information, who will have access to this information, and how the data will be shared with other researchers. In addition, it will describe study risks and discomfort. The informed consent form will let the participants know that they will get monetary compensation for their time, travel, and inconvenience either at the end of the study or at the end of their participation. The study will pay $20.00 per session. They will receive a check at the end of all study sessions or if they stop participation in the study.

Potential Risks to Human Subjects

Mindfulness meditation therapies are considered low risk but there may be side effects from the study that are not known at this time. Participants' PTSD symptoms may not get better, or they may even get worse as a result of being in the study. There is a risk of having distress and discomfort while doing assessments such as SCID, CAPS, and ETI early life stress. To reduce this stress, the investigator will maintain a pleasant and professional attitude and will always be available to address any other side effects. The investigator will let the participants know that they can take breaks during the

assessments or reschedule assessments for completions at a later visit. Participants will also have access to the resources provided by Emory Department of Psychiatry (Emory Adult Intensive Outpatient Program and Emory Wesley Woods Hospital) if they need further support during and/or after the completion of study.

Benefits of the Research to Human Subjects and Society

The research participants may directly benefit from the intervention by having reduced PTSD symptoms. Improvement in psychiatric symptoms may result in improved quality of life and enhanced occupational, social, and interpersonal functioning. It is possible that the researchers will learn something new during the study about the benefits of being in it. If this happens, researchers will tell participants about it in detail. This study is designed to learn more about the effectiveness of mindful meditation therapy on PTSD symptoms in women with early childhood sexual abuse. Beside CSA women with PTSD, research will also benefit other PTSD patients by reducing their symptoms using MM interventions. The researchers are hoping to learn new things which may be beneficial to the population. The results obtained from this study will widen the scope of mindfulness meditation therapy in the treatment of PTSD in women with childhood sexual abuse.

Inclusion of Women and Minorities

Women from all racial/ethnic groups will be eligible for this study.

Chapter IV: Incorporation of Reviewer Comments

Thank you for agreeing to participate in the Assess the Effectiveness of Mindfulness Meditation (MM) Therapy in Women with Post-Traumatic Stress Disorder (PTSD) due to Childhood Sexual Abuse, and Comparison of Symptoms Reduction in both Women with PTSD who Utilize MM and those who do not Utilize MM in Georgia review. Your written review is critical as your comments and recommendations provide strength to the project.

Reviewer 1 comments

Comment 1: Are there significant concerns given an overall dearth of information about how well CAM approaches will address profound PTSD?

Response to comment 1: An additional paragraph was added to the Significance section, "Even though, previous researches have shown that MM practices have positive effects on reducing PTSD symptoms, there is a lack of utilizing of MM as standard adjunctive tool by most clinicians (McGee, 2008), because either they are culturally unknown with the various meditative tradition, or they have doubt about the techniques used by MM to enhance wellness and to ease mental illness (McGee, 2008). Given that there is a need to have a guideline/ data about the efficacy of MM interventions to treat PTSD either alone or integrate MM in the traditional PTSD treatments. To date, there is no standardized individual format program to treat PTSD in CSA women with MM intervention."

Comment 2: Are there human subjects concerns that need to be addressed at the outset of the proposal? Are there stigma related concerns?

Response to comment 2: An additional paragraph added in the Significance section, "Beside the availability of various types of treatment for PTSD, several barriers were identified which hinder CSA women to get medical and non-medical help (Sawrikar et.al., 2017). These women do not see themselves as deserving (Sawrikar et.al., 2017) due to low self-esteem (Taylor & Norma, 2013) or because 'they blame themselves for being a victim as a result of power inequality between men and women, (so) do not feel empowered to seek help' (Smith, Bryant-Davis, Tillman, & Marks, 2010, p. 262). There is also a stigma attached seeking mental health services for PTSD symptoms in women (Roeloffs et.al., 2003), especially if they belong to a low socioeconomic background (Dutton et.al., 2013) because of cost and inaccessibility of standard conventional PTSD treatments (USDHHS, 2001). MM interventions would be a good alternative for CSA women as it is cost-effective, acceptable, non-stigmatizing, and can be offered in non-mental health settings (Dutton et.al., 2013)."

Comment 3: The significance of the project is clear – the scope and goals are ambitious. Be sure to proofread – some citations are in lower case, be sure to capitalize references and in-text citations.

Response to comment 3: Document was proofread and edited for any discrepancy in style and font.

Comment 4: Will the study as designed be acceptable and utilized across demographic groups? Will there be potential for more willingness to accept these strategies by some groups over others? Could include much more discussion of demographics of participants particularly given the knowledge that PTSD from abuse such as that defined in the study may be significantly higher for Participants of Color (POC).

Response to comment 4: Additional data about the acceptability and utilization of MM by different demography was added in the innovation section, "CSA women who belong to low socioeconomic status/background are more susceptible to have prolonged and intensive PTSD symptoms due to facing other life stressors like poverty, racial injustice, and family instability (Gold, 2000). Accessibility of PTSD conventional treatment, either pharmacological or psychotherapy, could be difficult to these women due to several reasons including cost, geographically inaccessible (USDHHS, 2001), and stigma associated with mental health symptoms (Roeloffs et.al., 2003). These women need a cost-effective, community-based intervention which addresses their mental health issues in a non-judgmental environment, and which are more acceptable, easily accessible and less stigmatizing to them (Dutton et.al., 2013). Dutton et.al. (2013) reported that mindfulness meditation intervention to treat PTSD in low-income, predominantly African American women, showed promising results in terms of awareness and acceptability of utilizing MM for their trauma-related symptoms. Researches have shown that more

women utilize MM practices when compared to men (Clarke et.al., 2015; Barnes et.al., 2007). Among women, White women reported a higher rate of MM utilization than Black, Asian and Hispanic women (Upchurch et.al., 2019). Non-married women and women with high school and college degrees have higher prevalence of using meditation (Upchurch 2019)."

Comment 5: Stigma and privilege may play a significant role in acceptability and willingness to engage by various racial/age/ethnic groups – the researcher/s should state awareness and acknowledge that the treatment itself here may be subject to stigma.

Response to comment 5: Additional information was added in the innovation section about the stigma concern associated with MM interventions in the innovation section, "MM practices are mostly conducted in a group setting which most of the CSA women are reluctant to attend because they do not feel comfortable talking about their trauma in the presence of other people (Wahbeh et.al., 2014). Some women felt that they would be negatively judged by others if they engaged in group MM practices. Additionally, women from low socioeconomic status are also reluctant to participate in MM practice because they think that they are neglecting their responsibilities toward their family (Watson et.al., 2016). One-on-one sessions will remove the social dynamic which improves participant retention and allows for scheduling flexibility (Wahbeh et.al., 2014). The proposed study will conduct individual MM sessions, which eliminates the above mentioned limitations of doing MM sessions in a group setting while providing a more lenient schedule for women with familial responsibilities."

Comment 6: A suggestion in terms of the dissemination of information might be to pilot early results via conference presentations – are there particular journals the authors feel would be best? Most appropriate? Widest impact? Are these results intended for lay people – if so, how does the information and findings get pushed to wider audiences? More clarity would be good in terms of alternative tactics should initial protocols need adjustment.

Response to comment 6: Additional information was added in the section of Results and Dissemination, "Study Investigator will also expand the dissemination of study results to the American Journal of Psychiatry and JAMA Psychiatry, which are the most widely read psychiatric journals in the world. Study results will also be presented in the National Psychiatric and Psychological conferences as well as to the local community groups. The investigator will also conduct small educational talks in health fairs and schools to educate the lay people about the importance of CAM modalities especially MM intervention for the treatment of their PTSD symptoms."

Comment 7: While there are no reservations – it would be important to emphasize the need for cultural competence and how that will be essential to both conducting the work, debriefing and follow up.

Response to comment 7: Additional paragraph was added in the section of Investigator, "Moreover, the investigator has an extensive experience of working with a diverse patient population, including all racial and ethnic backgrounds. This experience will help the

investigator to understand, communicate and effectively interact with study participants. The research project aims to address a very sensitive issue with women which needs a strong relationship between investigator and participants based on trust, awareness, cultural knowledge, and cultural skills. Investigator has extensive experience working with sexually abused women with PTSD, making her a suitable principal investigator."

Comment 8: Care and attention to the long-term impact of healing through MM should be included. While difficult to anticipate, it will be important to anticipate any potential triggers and contextual factors in participants lives after study participation.

Response to comment 8: An additional information was added in the section of Institutional Environment, "The Emory Department of Psychiatry has several inpatient and outpatient programs which can be specifically helpful resources for study participants if they need further support and treatment at the end of the study. Emory Adult Intensive Outpatient Program has the resources to provide highest-level care to the patients seeking to learn effective coping and preventive awareness skills (Emory.edu 2021). Emory Wesley Woods Hospital provides inpatient care for patients seeking treatment for mental health crises. This hospital provides holistic patient care - body, mind, and spirit with the help of well-trained psychiatrist, therapists, nurses, counselors, and social workers".

Comment 9: Some of the wording in the 'Benefits of the Research to Human Subjects' is a bit awkward and convoluted – it should be clear as to what the researchers anticipate and if there are unknowns, make it succinct and clear as to how participants will be debriefed and supported. Is there a debriefing process for all?

Response to comment 9: Some sentences were re-worded in the section of Benefits of the Research or Program to Human Subjects and Society," It is possible that the researchers will learn something new during the study about the benefits of being in it. If this happens, researchers will tell participants about it in detail".

Comment 10: It will be interesting to know whether this project has relevance to cross-cultural contexts and cases. While that is not the emphasis in the call for proposals, it does raise the question as to how cultural, demographic, economic groups may vary.

Response to comment 10: A data added in the Innovation section about study intervention utilization among different demographics, "Researches have shown that more women utilize MM practices when compared to men (Clarke et.al., 2015; Barnes et.al., 2007), and among women, White women reported a higher rate of MM utilization than Black, Asian and Hispanic women (Upchurch et.al., 2019). Non-married women and women with high school and college degrees have higher prevalence of using meditation (Upchurch 2019). The proposed study plan to enroll women of all ethnicity and background to measure the acceptability and effectiveness of MM interventions."

Reviewer 2 comments

Comment 1: Results of MM studies, even if limited. results of the studies on veterans could further the significance of the proposed study.

Response to comment 1: An additional data was added in the section of Significance, “To date, there are several small, randomized studies of MM for veterans with PTSD have been published (Bormann et al., 2013;Kearney, McDermott, Malte, Martinez, & Simpson, 2013; Niles et al., 2012; Polusny et al., 2015; Seppälä et al., 2014) which reported in decrease in severity of PTSD symptoms when compared to patients in Treatment As Usual (TAU) and waitlist control groups. Kearney and colleagues (2013) randomized veterans with PTSD into treatment as usual (TAU) alone or mindfulness-based stress reduction (MBSR) plus TAU groups to assess safety, feasibility, and effects of mindfulness-based intervention. The study results suggested that mindfulness-based intervention not only reduced PTSD symptoms but also improved behavioral activation and mental health-related quality of life (HRQOL) (Kearney et.al., 2013). Similarly, Polusney et.al., (2015) found improvement in depressive symptoms, mindfulness, and quality of life when compared MBSR with present-centered psychotherapy in veterans with PTSD.”

Comment 2: Comment what it is about MM that makes it uniquely a better fit for PTSD in CSA, possibly include segments from the Mindfulness Meditation Therapy section to help the innovation section.

Response to comment 2: Additional data that describes the impact of MM on PTSD symptoms in the Innovation section, “MM showed positive impact on improving PTSD symptoms such as increased control of intrusive thoughts by increasing attentional control, reduce worry/ rumination using present-focus technique, and reduce avoidance by encouraging nonjudgmental stance (Lang et.al., 2012). Women with CSA reported

recurrent intrusive thoughts of their trauma, increased anxiousness, hypervigilance, and avoidance (Bremner et.al., 1999), which may be reduced by utilizing MM practices."

Comment 3: It is clear that the investigator is well aware of PTSD through her work but could display more motivation and associations with CAM practices if available.

Response to comment 3: A sentence about the investigator interest and experience working with patients using MM intervention for PTSD treatment is added in the Investigator section, "She had worked on a Randomized Control Trial of MM Therapy on Veterans with PTSD, which increased her interest to study MM intervention with other PTSD populations like CSA women. Her extensive clinical experience, working directly with PTSD patients, and understanding of mindfulness meditation makes her well suited as the principal investigator of this study."

Comment 4: Specific advantages of Emory to how it can advantage the Study. If there is specific technology or other advantages, such as having access to minorities or a student body, then that could cement the advantages of the environment.

Response to comment 4: An additional paragraph was added in the Environment section, "The Emory Department of Psychiatry has several inpatient and outpatient programs which can be specifically helpful resources for study participants if they need further support and treatment at the end of the study. Emory Adult Intensive Outpatient Program and Emory Wesley Woods Hospital have the resources to provide highest-level care to

the patients seeking to learn effective coping and preventive awareness skills (Emory.edu 2021)."

Reviewer 3 comments

Comment 1: Would mention what limited studies have already found, and how this study builds on that. For example, the document states that it has been used with Veterans – would comment on what was found there and how this study continues to build on the limited literature that exists.

Response to comment 1: This comment addressed with the response of reviewer 2 comments in the Significance section.

Comment 2: Since this is a foundational study and there is limited information, if possible, some qualitative questions would be helpful to better understand participant perspective. If possible, would encourage mixed methods design.

Response to comment 2: To validate the study's sustainability and strength, the study will use a mixed method, utilizing both quantitative and qualitative approaches. Study is utilizing World Health Organization Quality of Life – Brief (WHOQOL-BREF) which is combination of qualitative and quantitative methods to assess CSA women's quality of life within the context of participants' culture, value systems, personal goals, standards, and concerns (Vahedi, 2010).

Comment 3: Should make sure to mention who will be providing the Mindfulness Meditation psychotherapy (team etc.). Should be someone who is well-trained with a background in clinical psychology. Specifically, important because of the vulnerable population.

Response to comment 3: Information about the instructor who will conduct MM session was added in the Investigator session, "Mindfulness Meditation Instructor: All MM sessions will be conducted by a highly experienced female MM instructor, who received her training at the Center for Mindfulness at Emory University. The instructor has more than 15 years of experience in the development and facilitation of MM therapy sessions, individually and in groups."

Comment 4: Would include more on protections of client's mental health and resources available to them. PTSD and co-morbid disorders impact many facets of life, ensuring the participants understand the voluntary nature of the study at every step and to continuously monitor participants on their experience will be important and ethical.

Response to comment 4: Few lines are added under procedure/method about voluntary participation, "Informed consent clearly mentions that the participation is voluntary and participants can withdraw themselves from the study at any point". Another information added under Potential Risks to Human subjects about the available resources for study participants," Participants will also have access to the resources provided by Emory Department of Psychiatry (Emory Adult Intensive Outpatient Program and Emory

Wesley Woods Hospital) if they need further support during and/or after the completion of study."

Reviewer 4 comments

Comment 1: The effect of this study on the concepts or methods that drive this field are not entirely clear. The applicant should describe in more detail what the effect of this study will be on concepts or methods that drive this field.

Response to comment 1: Additional paragraphs were added in Significance and Innovation sections. These data and information were also the response of other reviewers. "Practicing mindfulness meditation not only physically train PTSD patients to cope with their trauma but it also effects on the neurobiology of PTSD (Creswell et.al., 2007). The components of MM technique like exposure, attention control, self-management, relaxation, and acceptance are all relevant to that of PTSD symptoms (Baer, 2003). Malinowski (2013) reported that MM practice increases patients' awareness of their trauma in a nonjudgmental way and strengthens their emotional and cognitive flexibility. Neurobiology of PTSD showed that there is dysregulation of some brain regions - prefrontal cortex and amygdala (Marina et.al., 2016). In PTSD, there is decrease prefrontal cortex activation and increased activity in amygdala, which result in PTSD symptoms of fear, hyperarousal, impulsiveness, intrusive thoughts, and avoidance (Marina et.al., 2016). Creswell, Way, Eisenberger, and Lieberman (2007) found that MM interventions increase activity of prefrontal cortex and decrease activity of amygdala,

resulting in improved PTSD symptoms. This will augment the need of current research projects for the treatment of PTSD in CSA women."

Comment 2: There are a few statements that could have used citations to back up statements. For example, citation would strengthen the statement "clinicians' interest in considering MM practices to treat PTSD patients may be limited due to the lack of availability of resources and lack of familiarity of MM effectiveness in lowering PTSD symptoms."

Response to comment 2: The sentence was reworded, and citation was added to the statement, "Clinicians' interest in considering MM practices to treat CSA women with PTSD may be limited due to the lack of training about meditation and lack of guidelines/ knowledge to effectively prescribe and monitor MM practices (Upchurch et.al., 2019)". The proposed project will help clinicians and other healthcare providers to understand and incorporate MM therapy into the clinical practice to treat PTSD in CSA women.

Comment 3: The applicant provides much background information and the need for this type of study instead of focusing on the study's innovation.

Response to comment 3: Additional information was added in the innovation section, "MM showed positive impact on improving PTSD symptoms such as increased control of intrusive thoughts by increasing attentional control, reduce worry/rumination using present-focus techniques, and reduce avoidance by encouraging a nonjudgmental stance (Lang et.al., 2012). Women with CSA reported recurrent intrusive thoughts of their

trauma, increased anxiousness, hypervigilance, and avoidance (Bremner et.al., 1999). This project aims to reduce these symptoms by utilizing MM practices."

"Some women felt that they would be negatively judged by others if they engaged in group MM practices. Additionally, women from low socioeconomic status are also reluctant to participate in MM practice because they think that they are neglecting their responsibilities toward their family (Watson et.al., 2016). One-on-one sessions will remove the social dynamic which improves participant retention and allows for scheduling flexibility (Wahbeh et.al., 2014). The proposed study will conduct individual MM sessions, which eliminates the above mentioned limitations of doing MM sessions in a group setting while providing a more lenient schedule for women with familial responsibilities."

"In addition, conducting research among CSA women, who are either taking conventional PTSD treatments or not taking any treatment to measure the effect of MM therapy, also adds to the project's innovation."

Comment 4: The applicant's plan to disseminate to more traditional medical/clinical journals and communities is unclear. Consider including dissemination of findings to traditional medical/clinical communities.

Response to comment 4: Additional information was added in result and dissemination section, "The investigator will also conduct small educational talks in health fairs and schools to educate the lay people about the importance of CAM modalities especially MM intervention for the treatment of their PTSD symptoms. Study Investigator will also expand the dissemination of study results to the American Journal of Psychiatry and JAMA

Psychiatry, which are the most widely read psychiatric journals in the world. Study results will also be presented in the National Psychiatric and Psychological conferences as well as to the local community groups."

Reviewer 5 comment

Comment 1: The short amount of time from study onset to the planned end of the grant period will be a limitation to recruitment of 120 participants, and with additional dropouts, the power of the cohorts may be diminished.

Response to comment 1: The duration of study was increased from 1 year to 2 years in order to enroll the desired number of participants (120 participants) and to complete data collection and data analysis.

Comment 2: A recommendation would be to provide incentives to the participants to encourage attendance at each session and to reduce the potential of dropouts.

Response to comment 2: Information about monetary incentive was added to encourage attendance and to reduce the potential dropouts in the Recruitment and Informing Subjects of Study section, "participants will be paid $20.00 per session in financial compensation for your time, inconvenience, and travel. All compensation will be paid at the end of the study or at the end of your participation. You will receive a check at the end of all study sessions or if you stop participation in this study."

Comment 3: This reviewer would recommend professional editing prior to submitting future proposals.

Response to comment 3: Thesis proposal was reviewed and proofread before submitting to the committee.

Comment 4: A recommendation would be to seek similar studies in other schools of public health as a way to benchmark Rollins against other schools if curious.

Response to comment 4: There are not many similar studies in other public health school that I can accurately create a benchmark to compare to Rollins to in this respective topic.

Summary of Grant Review Process

The review process provided comments and recommendations on aspects of the application that need to be strengthened. There were several comments about adding more information in Significance and Innovation sections. These issues were thoroughly addressed by adding more data and information in these sections. All reviewer comments about Institutional Environment and Investigator were addressed. These sections did not need to be included in the final proposal, but they were left as reviewers had commented on them, therefore they needed to remain. These two sections have been moved to the end of the proposal, as they are not part of the project plan specifically. After reviewing the recommendations brought up by the reviewers, the corresponding changes were made to address any problematic areas to provide a more thorough and clear proposal,

strengthening its attention to detail and considering its application in a real-world setting. Finally, a few changes were made to the literature review in chapter 2, with the addition of several new citations in order to keep it consistent with additions to the final proposal.

Chapter V: Final Version of Grant Proposal

Post-Traumatic Stress Disorder (PTSD) is an important public health problem caused by the exposure of trauma such as childhood abuse, sexual abuse, accidents, and life-threatening experiences (Basile et al., 2004; Harrison and Kinner, 1998; Hoge et al., 2004; Lowe et al., 2014; Neria et al., 2007; Punamaki et al., 2010). In the United States, there are about 8 out of every 100 people who have PTSD at some point in their lives (ptsd.va.gov 2019). PTSD is more prevalent in women than men, about 10 of every 100 women (or 10 percent) develop PTSD at some time in their lives as compared to 4 in 100 men (or 4 percent) (ptsd.va.gov 2019). PTSD is also very disabling and results in an inability to work or have close social relationships in many individuals. One of the most common causes of PTSD in women is childhood sexual abuse (CSA), which affects 1 in every 9 women at some time before their 18th birthdays, leading to chronic PTSD in 26.5 percent of cases (David et.al., 2014; Sharkansky, E 2019). PTSD results in poorer overall quality of life, health-related quality of life, and functioning in CSA women (Anda et.al., 2004; Afifi et.al., 2007). Due to its complex psychopathology, significant co-morbidities, and functional impairments, PTSD is usually treated with a combination of psychotherapies and pharmacotherapies.

Recently, a variety of integrative mind-body intervention modalities have emerged that are increasingly employed in the treatment of PTSD (Kim et al., 2013). Nearly 38 percent of U.S. adults use Complementary and Alternative Medicine (CAM) interventions, including mind-body practices, to manage a range of physical and emotional health concerns (Barnes et.al.2011; Klap et.al. 2000). Mind body interventions

come under the umbrella of CAM and include yoga, chiropractic, meditation, acupuncture, and relaxation techniques. Recently, mindfulness meditation practices have received increased clinical and scholarly attention for the treatment of PTSD (Vujanovic et.al. 2016). However, the evidence of the efficacy of these modalities for PTSD is limited. There were limited studies done, mostly with veteran populations, to address the role of mindfulness meditation modalities for patients with PTSD.

This proposal is in response to a request for application (RFA) -01-001 and seeks funding under the National Institute of Health (NIH) R21 award mechanism. This type of grant was selected because it promotes exploratory/development research that investigates strategies to integrate CAM interventions with conventional medical/clinical practice and to evaluate the effects of this integration.

The specific aims of research project outlined in this proposal are:

1. **To measure the therapeutic effects of using mindfulness meditation in women with childhood sexual trauma and PTSD.**

The study of mindfulness meditation in women with PTSD secondary to history of childhood sexual abuse has not been extensively researched. It is an area that needs more research to encourage clinicians to consider it for the treatment of PTSD. It is important to understand what role MM interventions could perform when it utilized with or without conventional PTSD treatment. To measure the effectiveness of MM therapy, the study will perform a psychometric assessment at the end of the study as well as after 3 and 6 months of treatment to measure the long-term effects of MM.

2. To compare the reduction of PTSD symptoms in intensity and duration in women with childhood sexual trauma who use mindfulness meditation and those who do not use mindfulness meditation.

There is a paucity of research studies that examine the PTSD symptoms reduction in CSA women utilizing MM intervention. In addition, very limited data is available which compare any symptoms reduction between MM intervention and conventional PTSD treatments. The proposed study is a randomized controlled trial which will compare the effectiveness of MM interventions in CSA women who either use MM with their conventional PTSD treatments or use MM alone. The study will measure the difference by utilizing the Clinician-Administered PTSD Scale (CAPS) and a PTSD checklist from the DSM-5 (PCL-5) before starting mindfulness meditation therapies and at the end of study.

3. To assess patient motivation, willingness, and ability to incorporate mindfulness meditation intervention after completion of study into their traditional PTSD treatment.

MM interventions are often used alongside with several mental health disorders including PTSD, yet CSA women are not utilizing this technique as often when compared to the other PTSD patients. It is important to investigate the reasons women do not utilize these non-invasive treatment modalities for PTSD symptoms. It is also vital to know the long-term effects of MM practices on women's quality of lives and ability to incorporate these techniques to reduce PTSD symptoms. The study will evaluate this by using the World Health Organization Quality of Life Questionnaire-26 (WHOQOL-26) before starting

mindfulness meditation and at the end of study. The findings of the proposed study will provide the recommended guidelines on how to incorporate MM to psychotherapy or psychopharmacology or both for CSA women with PTSD.

Research Strategy

RFA-AT-01-001 requires the applicant to develop a well-planned research plan approach that includes Significance, Approach, Innovation, Investigators, and Environment. The following sections describe how the proposal is responsive to these criteria.

A. Significance

Childhood sexual abuse is a pervasive, persistent, and pernicious problem worldwide, with reported prevalence rates ranging from 3-8 percent in women and 3-17 percent in men (Steine et. al.,2019). In the United States, the ratio for those who experience sexual abuse at least once in their childhood is 1 in 4 within females and 1 in 13 within males (Center of Disease Control and Prevention 2019). In Georgia, there were 26,952 victims of child abuse or neglect in 2015, an increase of 21.6 percent from 2014 (Child Welfare League of America Annual report 2017). Of these children, 3.4 percent were sexually abused (U.S. Department of Health and Human Services 2016). Although, childhood sexual abuse is common in every gender, age, race, ethnicity, background, socioeconomic status and family structure, studies have showed that African American children have almost twice the risk of sexual abuse than other ethnicities (Sedlack et.al., 2010). In 2008, approximately 11,000 African American children were reported for child

sexual abuse in U.S.A. (U.S. Department of Health and Human Services 2008). The city of Atlanta, the largest city of the state of Georgia, consists of a 52 percent African American population (Census 2019), who are most at risk for childhood trauma, and have the most limited access to resources to deal with the effects of trauma.

This childhood sexual trauma can lead to several health issues in women such as depression (Franklin et.al., 2001; Prigerson et.al., 2001), substance abuse (Kessler et.al.), dissociation (Putnam et.al., 1986; Bremner et.al., 1996), personality disorders (Battle et.al.,2004; Yen et.al., 2002), physical health problems (Bremner et.al., 1996), and most commonly PTSD (Bremner et.al. 2005). PTSD is characterized by specific symptoms, including intrusive thoughts, flashback, nightmare, avoidance, hyperarousal, hypervigilance, and sleep deprivation (Bremenr, 2005). For many abuse victims, PTSD can be quite disabling, and symptoms often persist, at times lasting from childhood into adulthood (Burgess et.al., 1979; Armsworth, 1985). These women also reported difficulties with interpersonal relationships such as intimate relationship, female friendships, and difficulties with parenting (DiLillo, 2001). Based on these devastating consequences, it is imperative to treat PTSD to improve the quality of lives of CSA women. Several evidence-based treatments are available for PTSD, including pharmacotherapy, cognitive processing therapy, and prolonged exposure therapy (Foa et.al., 1999; Resick et.al, 2002).

Despite the fact that these treatment modalities have showed improvement in PTSD patients, there are around 50 percent of patients who either refused treatment, are non-compliant, or still have residual symptoms (Bradley, Greene, Russ, Dutra, & Westen, 2005; Kearney & Simpson, 2015; Schottenbauer, Glass, Arnkoff, Tendick, & Gray, 2008;

Steenkamp, Litz, Hoge, & Marmar, 2015). Many of these CSA women with PTSD are reluctant to pursue these treatment interventions because of various unfavorable side-effects of these treatments. PTSD medications like Paroxetine and Sertraline may cause nausea, constipation, dry mouth, sexual dysfunction, and insomnia. Additionally, PTSD psychotherapy, such as prolonged exposure therapy may result in the deterioration of PTSD symptoms, with the emergence of new symptoms or suicidality (Klatte et.al., 2018).

In addition, women with PTSD secondary to a history of childhood sexual abuse have a high percentage of treatment resistance, non-adherence, and drop-out from conventional PTSD treatments. This is because of the chronic patterns of avoidance and an inability to tolerate the intense emotions often experienced with conventional PTSD treatment approaches (Grunert et.al., 2007). For this reason, CAM practices, especially mindfulness meditation (MM), are gaining popularity among patients with PTSD because of its nature of treating PTSD symptoms without trauma recall and absence of side effects (Wahbeh et.al, 2014). Practicing mindfulness meditation not only physically trains PTSD patients to cope with their trauma, but it also affects the neurobiology of PTSD (Creswell et.al., 2007). The components of the MM technique such as exposure, attention control, self-management, relaxation, and acceptance are all relevant to that of PTSD symptoms (Baer, 2003). Malinowski (2013) reported that MM practices increase patients' awareness of their trauma in a nonjudgmental way and strengthens their emotional and cognitive flexibility. The neurobiology of PTSD showed that there is a dysregulation of some brain regions - particularly the prefrontal cortex and amygdala (Marina etal., 2016). In PTSD, there is decreased prefrontal cortex activation and increased activity in amygdala, which

result in PTSD symptoms of fear, hyperarousal, impulsiveness, intrusive thoughts, and avoidance (Marina et.al., 2016). Creswell, Way, Eisenberger, and Lieberman (2007) found that MM interventions increased activity of prefrontal cortex and decreased activity of amygdala, resulting in improved PTSD symptoms. This will augment the need of current research projects for the treatment of PTSD in CSA women.

Despite the availability of various types of treatment for PTSD, several barriers were identified which hinder CSA women from seeking medical and non-medical help (Sawrikar et.al., 2017). These women do not see themselves as deserving (Sawrikar et.al., 2017) due to low self- esteem (Taylor & Norma, 2013) or because "they blame themselves for being a victim as a result of power inequality between men and women, (so) do not feel empowered to seek help" (Smith, Bryant-Davis, Tillman, & Marks, 2010, p. 262). There is also a stigma attached to seeking mental health services for PTSD symptoms in women (Roeloffs et.al., 2003), especially if they belong to a low socioeconomic background (Dutton et.al., 2013) because of cost and inaccessibility of standard conventional PTSD treatments (USDHHS, 2001). MM interventions would be a good alternative for CSA women as it is cost-effective, acceptable, non-stigmatizing, and can be offered in a non-mental health setting (Dutton et.al., 2013). MM interventions also showed promising results in racial/ethnic minority women such as African American, Native American, and Hispanics when used to treat substance abuse (Witkiewitz et.al., 2013), anxiety with an abnormal pap smear (Abercrombie et.al., 2007), and PTSD due to intimate partner abuse (Upchurch et.al., 2019).

The effectiveness and validity of MM practice in CSA women for the treatment of PTSD is an area where little research has been done. There is very limited data available

about the effect of MM interventions on the symptoms of PTSD and the quality of life of CSA women with PTSD. To date, several small, randomized studies of MM for veterans with PTSD have been published (Bormann et al., 2013; Kearney, McDermott, Malte, Martinez, & Simpson, 2013; Niles et al., 2012; Polusny et al., 2015; Seppälä et al., 2014) which reported a reduction in the severity of PTSD symptoms when compared to patients in Treatment As Usual (TAU) and waitlist control groups. Kearney and colleagues (2013) randomized veterans with PTSD into treatment as usual (TAU) alone or mindfulness-based stress reduction (MBSR) plus TAU groups to assess safety, feasibility, and effects of mindfulness-based intervention. The study results suggested that mindfulness-based intervention not only reduced PTSD symptoms but also improved behavioral activation and mental health-related quality of life (HRQOL) (Kearney et.al., 2013). Similarly, Polusney et.al., (2015) found improvement in depressive symptoms, mindfulness, and quality of life when comparing MBSR with present-centered psychotherapy in veterans with PTSD. Although most of the MM research has been done with veterans showing promising results, a randomized controlled comparative effectiveness trial is needed to assess the efficacy of MM interventions relative to conventional PTSD treatments in CSA women with documented PTSD.

Previous research has shown that MM practices have positive effects on reducing PTSD symptoms; however, there is a lack of utilizing of MM as standard adjunctive tool by most clinicians (McGee, 2008) because they are unaware of the various meditative tradition, or they doubt the effectiveness of the techniques used by MM to enhance wellness and to ease mental illness (McGee, 2008). Furthermore, since there is a lack of a clear guideline/data on how to utilize MM, clinicians are wary of integrating MM with

traditional PTSD treatments. To date, there is no standardized individual format program to treat PTSD in CSA women with MM intervention. Given that there is a lack of information, many patients are choosing not to utilize CAM methods. The proposed study will assess the efficacy of mindfulness meditation as an adjunct to conventional PTSD treatment. It will also compare the PTSD symptoms reduction in intensity and duration in women who utilize MM and women who do not utilize MM with PTSD conventional treatments. In addition, this project will evaluate the effects of MM practices in CSA women's quality of life.

B. Innovation

Sexual assaults in childhood may result in serious lifetime adverse effects on health, education, employment, and the economic well-being in women (WHO, 2010). One of the most common effects of CSA in women is PTSD. PTSD can be treated with both psychopharmacological and psychotherapeutic interventions which can be utilized either alone or in combination. Both have the potential to improve symptoms of PTSD, but at the same time, there is a high rate of medication refusal and non-compliance (Rakofsky et.al., 2011). Women with PTSD secondary to a history of CSA comparatively have a higher rate of these issues due to the nature of trauma and the stigma of shame and guilt attached to it. To increase the rate of treatment adherence, there is a need to incorporate a treatment or technique which will reduce the PTSD symptoms in a non-judgmental, non-provoking method. Among all the CAM modalities, MM intervention would be the best choice. MM showed a positive impact on improving PTSD symptoms

such as increased control of intrusive thoughts by increasing attentional control, reduced worry/rumination using present-focus techniques, and reduced avoidance by encouraging a nonjudgmental stance (Lang et.al., 2012). Women with CSA reported recurrent intrusive thoughts of their trauma, increased anxiousness, hypervigilance, and avoidance (Bremner et.al., 1999). This project aims to reduce these symptoms by utilizing MM practices.

CSA women who belong to low socioeconomic status/background are more susceptible to have prolonged and intense PTSD symptoms due to facing other life stressors such as poverty, racial injustice, and family instability (Gold, 2000). Accessibility to conventional PTSD treatments, either pharmacological or psychotherapy, could be difficult for these women due to several reasons including cost, geographic inaccessibility (USDHHS, 2001), and stigma associated with mental health symptoms (Roeloffs et.al., 2003). These women need a cost-effective, community-based intervention which addresses their mental health issues in a non-judgmental environment, and which are more acceptable, easily accessible, and less stigmatizing to them (Dutton et.al., 2013). Dutton et.al. (2013) reported that mindfulness meditation intervention to treat PTSD in low-income, predominantly African American women, showed promising results in terms of awareness and acceptability of utilizing MM for their trauma-related symptoms.

MM practices are mostly conducted in a group setting which most of the CSA women are reluctant to attend because they do not feel comfortable talking about their trauma in the presence of other people (Wahbeh et.al., 2014). Some women felt that they would be negatively judged by others if they engaged in group MM practices.

Additionally, women from low socioeconomic status are also reluctant to participate in MM practice because they think that they are neglecting their responsibilities toward their family (Watson et.al., 2016). One-on-one sessions will remove the social dynamic which improves participant retention and allows for scheduling flexibility (Wahbeh et.al., 2014). The proposed study will conduct individual MM sessions, which eliminates the above mentioned limitations of performing MM sessions in a group setting while providing a more lenient schedule for women with familial responsibilities.

Research has shown that more women utilize MM practices when compared to men (Clarke et.al., 2015; Barnes et.al., 2007), and among women, white women reported a higher rate of MM utilization than black, Asian and Hispanic women (Upchurch et.al., 2019). Non-married women and women with high school and college degrees have higher prevalence of using meditation (Upchurch 2019). The proposed study plans to enroll women of all ethnicity and background to measure the acceptability and effectiveness of MM interventions.

Clinicians' interest in considering MM practices to treat CSA women with PTSD may be limited due to the lack of training about meditation and lack of guidelines/knowledge to effectively prescribe and monitor MM practices (Upchurch et.al., 2019). The proposed project will help clinicians and other healthcare providers to understand and incorporate MM therapy into the clinical practice to treat PTSD in CSA women.

The proposed study focuses on the feasibility and efficacy of MM practice as an alternative therapy to conventional PTSD treatments in CSA women diagnosed with PTSD. The project will utilize validated psychometric instruments, standardized procedures, a control group, and appropriate follow-up to measure the validity of study outcomes. In addition, conducting research among CSA women, who are either taking conventional PTSD treatments or not taking any treatment to measure the effect of MM therapy, also adds to the project's innovation. This study provides vital insights regarding the extent of reducing PTSD symptoms when using MM either alone or with conventional treatments. The proposed research also seeks to fill the gap between clinicians and patients by utilizing MM interventions in a clinical setting or non-clinical setting, as well as utilizing MM as the first line PTSD treatment in CSA women. Further knowledge and research of these practices may encourage PTSD patients who either do not want to interact with psychiatry or are reluctant to take medications.

C. Approach

The investigator has selected a prospective randomized controlled trial (RCT) to assess the effectiveness of mindfulness meditation utilization by women with PTSD secondary to childhood sexual trauma. RCT, which is considered as the gold standard to measure the cause-effect relationship between an intervention and outcome (Hariton and Locascio, 2018), will validate the proposed research need. The study will also monitor the reduction of PTSD symptoms when using MM in conjunction with conventional PTSD treatments as well as its effect on people's quality of lives. To validate the study's sustainability and strength, the study will use a mixed method, utilizing both quantitative

and qualitative approaches. To measure the effectiveness of MM therapy in reducing symptoms of PTSD, this study will utilize validated psychometric assessments tools and statistically analyzed data using IBM SPSS statistical software. In the study intervention, 120 women with childhood sexual abuse and PTSD, age 21 and above, will be randomized into one of the three groups: PTSD treatment group (PTSD_Rx), PTSD treatment plus mindfulness meditation group (PTSD_Rx + MM), and mindfulness mediation group (MM). Each group will consist of 60 participants. The research subjects will receive assessments including neuropsychological assessments of memory and behavioral assessments at baseline (pre-therapy) and post therapy. These assessments will also be performed at the three and six months follow up visit, post therapy.

Participants

We plan to enroll 120 participants in total, 60 participants for each of the study intervention groups (PTSD_Rx, PTSD_Rx + MM and MM). Participants will be women of age 21 and older with a history of childhood sexual abuse and diagnosed PTSD**.** Subjects will be recruited through flyers, local newspapers, advertisements, Emory Clinic, and Emory Department of Psychiatry. As the investigator has spent 10 years working on research at Emory's Department of Psychiatry, she has existing relationships with both psychiatrists and psychologists of the department. This will facilitate the recruitment process by alerting the PI when there is a potential participant who meets the study criteria. All research activities will be reviewed and approved by the Emory University Institutional Review Board (IRB).

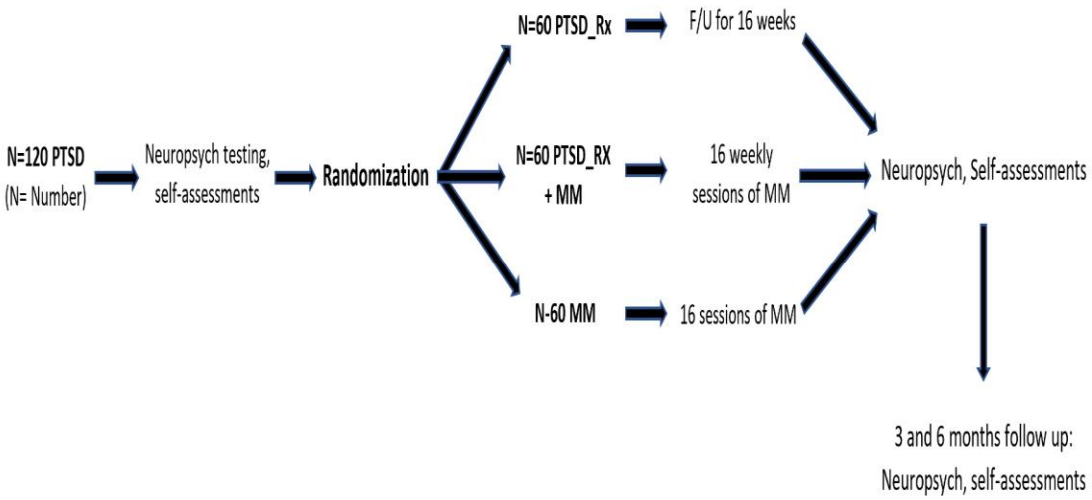
***Study Inclusion Criteria*:** Participants with PTSD that meet the following criteria will be included:

1. 21 years and older.
2. Meets criteria for current PTSD as determined by the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders lV (SCID) interview for PTSD
   (Spitzer et.al., 1987).
3. Clinical Administered PTSD Scale (CAPS; Weathers, Keane, & Davidson, 2001).
4. History of sexual abuse occurred before the age of 16, as assessed by the Early Trauma
   Inventory (ETI; Bryant et. al., 2005).
5. Ability to read and understand the study assessments.

***Study Exclusion Criteria*:** Women will be excluded if they have:

1. Traumatic brain injury (TBI)
2. Neurological disorder or organic mental disorder
3. History of loss of consciousness
4. Current alcohol or substance abuse
5. Current or lifetime history of schizophrenia or schizoaffective disorder
6. Current violence such as domestic abuse as measured by the ETI-lifetime

FLOW CHART OF BASIC STUDY DESIGN



Measurement

The Mini International Neuropsychiatric Interview (MINI): M.I.N.I. is a short, structured interview for the diagnosis of major Axis I psychiatric disorders in DSM-IV and ICD-10 (Sheehan et. al., 1998). With a 15 minute administration time, MINI is designed to meet the need for a short, but accurate structured psychiatric interview for clinical and epidemiologic research (Sheehan et.al., 1998).

Clinician-Administered PTSD Scale (CAPS): The CAPS, an interviewer-administered diagnostic instrument, will be used to measure a current and lifetime DSM-IV diagnosis

of PTSD (Weather et.al., 2001). The severity and frequency of PTSD symptoms will be calculated by adding CAPS severity and frequency rating on the following PTSD symptoms: reliving experiences, nightmares, avoidance of reminders and thoughts of the assault, impaired leisure activities (e.g., reduces socializing), sense of detachment, disturbed sleep, concentration difficulties, hyper-alertness, increased startle response, and feelings of guilt. CAPS will also measure the rate of social and occupational functioning, global PTSD symptoms severity, and the validity of the participant's responses (Resick et.al., 2002).

Early Trauma Inventory-Self Report-Short form (ETI-SR_SF): ETI-SR (Bremner et.al., 2007), a self- reported instrument (27 items), will be used for the measurement of childhood traumatic experiences. ETI will assess the presence of general trauma of childhood, physical, emotional, and sexual abuse before the age of 18 (Ana et.al., 2011). Severity scores for individual trauma domains and composite trauma severity scores will be calculated.

PTSD Checklist for DSM-5 (PCL-5): The PCL-5 is a 20 item self-reported measure that assesses the 20 DMS-5 symptoms of PTSD (American Psychiatric Association, 2013). It is widely used to monitor symptoms change during and after treatment. It also helps in making a provisional PTSD diagnosis.

World Health Organization Quality of Life – Brief (WHOQOL-BREF) is a 26-item, brief assessment of quality of life in four factor-analytically confirmed dimensions: Physical, Psychological, Social, and Environmental (Skevington et.al., 2004). The WHOQOL-BREF has good to excellent internal consistency reliability and has shown

predicted relationships with health status, single items assessing quality of life, and demographic variables. WHOQOL-BREF utilizes a combination of qualitative and quantitative methods to assess CSA women's quality of life within the context of participants' culture, value systems, personal goals, standards, and concerns (Vahedi, 2010). This will be completed at baseline and at the end of study.

Procedure/Method

If the patients express interest in participating in the study, the PI will meet the eligible women in the office at the Emory University's Department of Psychiatry. The PI will then explain the study design, the informed consent form, and the Health Insurance Portability and Accountability Act (HIPPA) form. If the participants would like to take some extra time to read and share informed consent and HIPAA form with family, they could take these forms to home and bring back on the next appointment. Informed consent clearly mentions that the participation is voluntary, and participants can withdraw themselves from the study at any point. After the informed consent and HIPAA forms are signed, an in-depth screening will be performed by the PI that will cover all inclusion and exclusion criteria. All eligible participants will schedule for further in-depth assessments. All the above-mentioned psychometric assessments will be performed by the PI, and self-assessments will be completed by participants at baseline (at the beginning of the study) and post-treatment. After completing all baseline assessments, women will be randomly assigned to either PTSD treatment (PTSD_RX), PTSD treatment + MM intervention (PTSD_Rx + MM), or MM intervention groups for 16 weeks. Participants in the PTSD treatment group can have PTSD medications provided by their mental health physicians

and psychotherapy provided by mental health clinicians (psychologists or clinical social workers). This group will be considered as the study control group. Participants in PTSD_RX + MM and MM groups will attend weekly in-person sessions of MM interventions. Mindfulness meditation will be conducted by a certified female instructor with expertise in mindfulness meditation therapy. The instructor will be trained to use the MM manual which specifies the agenda and treatment procedure for each session. Instructor will be closely supervised by the clinical investigator to ensure the integrity of the intervention procedure and all therapy sessions will be monitored by the PI to assure fidelity to the protocol. PTSD_RX participants will encourage calling as needed, and the study clinician will routinely contact them during the 16 weeks period. Post-therapy reassessments will be performed to all groups. Three months and six months post-therapy follow up assessment will be conducted to all the three groups. Participants will receive compensation for their participation and adherence to the study intervention. Contact information of the PI will be given to participants and encouraged to report any significant exacerbation of symptoms or adverse effect to the MM intervention.

Drop out

Drop out may be either due to the instructor, the participants (if they experienced difficulties in the exposure process such as the imagination of trauma), or unmet expectations as MM progresses. To minimize the risk of drop out, a well-experienced instructor who is specialized in MM will pose as a positive factor on participants' retention. In order to mitigate the effect of drop out on analysis, study will enroll more subjects than are needed for a reliable statistical analysis.

Mindfulness Meditation Therapy

Mindfulness meditation (MM) is a form of psychotherapy that combines mindfulness and experiential imagery (Peter strong, 2010). MM has demonstrated beneficial effects on reducing anxiety, depression, sleep disturbances, pain (Singh et.al., 2015), and PTSD in war victims (Khusid et.al., 2016). Neuropsychological data recommend that meditation boost the skills to modulate cognition, emotion, and behavior (Hölzel et al., 2011).

The skills learned in MM training may prepare participants to fully engage in evidence-based psychotherapies for PTSD. They train participants to form a non-reactive relationship with their traumatic memory and encourage them to adopt these techniques as a lifestyle change (Khusid et.al., 2016). Awareness of present experiences may reinforce improved client–therapist communication by increase open awareness. Also, nonjudgmental acceptance can reduce shame and guilt, which is one of the aspects of PTSD treatments (Vujanovic, Niles, Pietrefesa, Schmertz, & Potter, 2013). Participants randomized to the PTSD_Rx + MM and MM groups will attend weekly 1 hour MM sessions for 16 weeks. Sessions will be held in the PI office located at Emory University. In the first session, participants will get the educational information about symptoms of PTSD, expectations, treatment rationale, and treatment planning. The next 15 sessions will be devoted to train the following skills:

- Awareness, including being aware of and being able to recognize all things around (like light and sound), as well as things that are going on inside (like thoughts and feelings)
- Focus on looking at the traumatic experiences in a nonjudgmental way

- Being in the present moment instead of living in thoughts of the past (rumination) or the future (worry).

In every session, participants will review with the instructor about the past week – such as issues with mediation, seeing changes, and difficulties. Participants will also be encouraged to practice mindfulness meditation as daily homework.

Recruitment and Retention of Subjects

Participants' recruitment will be an issue due to the time restriction (2 years) to complete study. To resolve this issue, PI will proactively request a HIPAA waiver for the purpose of recruitment at the time of initial IRB submission. The other challenge might be the retention of participants throughout the study period and adherence to study intervention. When a participant misses a MM session, investigator will contact the participant either by phone or email to re-establish contact and retain in the study. Study will give monetary compensation to all participants, based on the completion of study tasks.

Data Analysis

All psychometric data will analyze at baseline (pre-therapy) and compare their scores to the post-therapy data. For example, CAPS (Weather et.al., 2001), which is our study outcome measure, will provide a rating on the intensity and frequency of PTSD symptoms. By adding all intensity and frequency ratings together, we will get the total severity score for PTSD. This score at pre-therapy will compare to the CAPS score at the post-therapy assessment visit to measure any improvement in PTSD symptoms.

Similarly, ETI, and WHOQOL scores will be added up and compared to post-therapy scores to determine any improvement of PTSD symptoms. Data will be quantitatively analyzed to respond to the objectives of this project by using a univariate analysis with a t-test or chi-square test in SPSS. Data analysis of all psychometric assessments will reveal any significant difference in improvement of PTSD symptoms among PTSD_Rx, PTSD_Rx + MM and MM groups.

Prior to analysis, all psychometric assessments will be entered in a secured database by the PI. All entered data will be quantitatively analyzed by an experienced analyst, hired for this study. IBM SPSS software will be used to perform the study analysis. IBM SPSS is an integrated collection of quantitative analysis software that can be used to perform many data management and statistical analysis tasks. Equivalence of the MM group at baseline (pre-therapy) will be examined by using analysis of variance. To evaluate the long-term MM effect, we will conduct a three-level mixed effect linear regression repeated measures analysis from pre-therapy to post-therapy, as well as post-therapy to 3-month and 6-month follow-up.

Result and Dissemination

The outcome measure will be the severity of PTSD, depression symptoms, social adjustment, and anxiety symptoms. The other outcome measure will be the effect of MM practice on participant's quality of life. Analysis of the data will be used for the non-medical treatment of PTSD in women with a history of childhood sexual abuse. Based on the analysis of the effectiveness or ineffectiveness of the mindfulness meditation intervention in reducing symptoms of PTSD, the PI will synthesize the conclusion and use

these results to develop new therapy clinics for the victims of childhood sexual abuse. The investigator will also share the study results with fellow psychiatrists to develop new research in PTSD prevention and treatment. The investigator will also conduct small educational talks in health fairs and schools to educate the lay people about the importance of CAM modalities, especially MM interventions for the treatment of their PTSD symptoms.

The analysis and results of the study will be submitted to the National Institute of Mental Health (NIMH), whose primary mission is “to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure” (nimh.nih.gov, 2020). Analyzed data and research outcome will be disseminated to Journal of Complementary and Alternative Medicine, American Psychiatric Association, American Psychological Association, and National Institute of Mental Health (NIMH) in the form of an article or report. Study Investigator will also expand the dissemination of study results to the American Journal of Psychiatry and JAMA Psychiatry, which are the most widely read psychiatric journals in the world. Study results will also be presented in the National Psychiatric and Psychological conferences as well as to the local community groups.

Investigators

The investigator has an extensive knowledge and experience in medicine and clinical research which makes her well suited for the role of primary investigator for this research project. She has completed her medical education from Dow University of

Health Science, one of the oldest and most prestigious medical institutions in Pakistan. Her experience in clinical research started with active participation in multiple community-based research projects, which included the public health issues of smoking, drugs, alcoholism, abuse, and AIDS. After moving to the USA, she continued her medical career as a clinical researcher in the Department of Psychiatry at Emory University School of Medicine in Atlanta, Georgia. She started working as Research Associate in Emory University's Clinical Neuroscience Research Unit (ECNRU) on several NIH funded projects, including R01MH056120 Neural Circuits in Women with Abuse, R01HL088726-03 Mechanisms of Depression in Cardiovascular Disease, and Post-Traumatic Stress Disorder and Veteran's Affairs Clinical Science Research and Development, which sponsored A Multisite, Randomized, Controlled Trial of Mindfulness Meditation Therapy for PTSD. She performed as a key contributor to the progress made throughout the studies.

In ECNRU, she worked with the Principal Investigator J. Douglas Bremner on planning, designing, and executing investigator initiated translational and epidemiological study protocols. Her knowledge extends to the vital activities of any research project such as reviewing and comprehending study protocols, data collection, adhering to applicable federal and institutional regulations, grant and budget preparation, and maintaining regulatory documentations for the IRB submission. She worked as a point person in performing all the project related psychometric assessments as well as conducting statistical analysis of the data collected as per study protocols. The investigator is a conscientious, efficient researcher who has provided quality research by her attention to detail and her ability to contribute novel and innovative solutions to the

research team. She is also the co-author of published research articles such as “Brain Correlates of Mental Stress-Induced Ischemia" (2018) and “Brain Mechanism of Stress and Depression in Coronary Artery Disease” (2019).

Dr. Bremner is a distinguished professor of Psychiatry and Radiology at Emory School of Medicine. He is also the Director of the Emory Clinical Neuroscience Research Unit (ECNRU) at Emory University School of Medicine. He is also the Director of Mental Health Research at the Atlanta Veteran’s Affairs Medical Center in Decatur, Georgia. Dr. Bremner’s research includes studies of neural circuits in abuse women, depression and cardiovascular disease, the neurobiology and assessment of PTSD, neural correlate of declarative memory and traumatic remembrance in PTSD. He is the author or co-author of more than 200 peer reviewed articles and book chapters such as “Psychometric properties of the adulthood trauma inventory” (Bremner JD. et al., 2020); “Diet, stress and mental health” (Bremner JD. et. al., 2020); “Traumatic stress: effects on brain” (Bremner JD. et.al.,2006); “Stress and brain atrophy. Current Drug Targets Central Nervous System and Neurological Disorders" (Bremner JD et.al.,2006); “Hippocampal volume reduction in major depression” (2000), and “The environment contributes more than genetics to smaller hippocampal volume in Post- Traumatic Stress Disorder” (Bremner JD. et.al., 2020).

In 2015, the investigator joined the Emory Trauma and Anxiety Recovery Program at Emory University School of Medicine as a Research Associate Scientist. She enhanced her research experiences by performing highly technical and complex research duties. She demonstrated increased technical, management, leadership, and professional expertise. Her role was to supervise all research activities from planning and designing to

the executing projects as per study protocols. The Investigator worked directly with the Principal Investigator Dr. Barbara Rothbaum on several activities such as IRB submissions, psychological assessments, data collection, developing guidelines and SOPs for proper data collection, and performing complex neuropsychiatric testing. She expanded her research experience working with patients with anxiety, depression, panic disorder, traumatic brain injury (TBI), and PTSD. Dr. Rothbaum is a renowned professor of Psychiatry at the Emory University School of Medicine's Department of Psychiatry and Behavioral Sciences. She is the Executive Director of the Emory Healthcare Veterans Program and Trauma and Anxiety Recovery Program at Emory School of Medicine. She specializes in research on the treatment of patients with anxiety disorders including PTSD using psychotherapies like cognitive behavioral therapy (CBT) and prolonged exposure (PE) psychotherapy. Dr. Rothbaum's work includes more than 300 scientific papers and chapters such as "Virtual Reality-Enhanced Extinction of Phobias and Post-Traumatic stress" (2017); "Psychotherapy for PTSD: An evidence-based guide to a theranostic approach to treatment" (2018); "Treating the trauma of rape: Cognitive-behavioral therapy for PTSD" (2001).

The investigator's interest in PTSD research, working with above mentioned, well-known principal investigators, produces an interest in PTSD patient's quality of life. She had worked on a Randomized Control Trial of MM Therapy on Veterans with PTSD, which increased her interest to study MM intervention with other PTSD populations like CSA women. Her extensive clinical experience, working directly with PTSD patients, and understanding of mindfulness meditation makes her well suited as the principal investigator of this study. Moreover, the investigator has extensive experience of working

with a diverse patient population, including all racial and ethnic backgrounds. This experience will help the investigator to understand, communicate, and effectively interact with study participants. The research project aims to address a very sensitive issue with women which needs a strong relationship between investigator and participants based on trust, awareness, cultural knowledge, and cultural skills. Investigator has extensive experience working with sexually abused women with PTSD, making her a suitable principal investigator.

Mindfulness Meditation Instructor: All MM sessions will be conducted by a certified and experienced MM instructor. The instructor has years of experience in the development and facilitation of MM therapy sessions, individually and in groups.

Institutional Environment

The grant proposal is well suited to be performed at Emory University as the Institutional Environment as Emory University is exceptionally well qualified to carry out the proposed research. Emory University is a distinguished university for its liberal arts college, professional schools and one of the leading healthcare systems in southeast America. Emory University Hospital, founded in March 1904, is equipped with the latest technology to provide the most advanced, compassionate patient care in Atlanta, Georgia. Emory University's mission is "to foster a culture that integrates cutting edge research, basic, translational, and clinical, to further the ability to deliver quality healthcare, to predict illness and treat the sick, and to promote health of patients and community"

(emory.edu 2018). Emory's clinicians and researchers conduct innovative and collaborative research and integrate their knowledge into practice of medicine to serve the needs of the community. Embedded within Emory University, the Department of Psychiatry and Behavioral Neuroscience is well-known in the U.S. for its innovative methods of treatment and several neuroscience research programs. The department supports clinicians and researchers to develop and implement new models of behavioral health care. The Department of Psychiatry and Behavioral Sciences consists of many patient-focused centers, programs, and services under the umbrella of Brain Health Center. There are more than 20 centers and programs within the Brain Health Center, including medical psychiatry unit, addiction psychiatry unit, general adult psychiatry unit, geriatric psychiatry unit, and out-patients psychiatry clinics. It has more than150 faculty members including psychiatrists, psychologists, and basic neuroscientists. It is currently (2010-2011) ranked #14 in NIH funding and #15 in "America's Best Hospitals" by U.S. News and World Report (psychiatry.emory.edu, 2020). Emory's psychiatrists and psychologists perform several research projects in multiple areas of psychiatry and neuroscience such as depression, anxiety, PTSD, schizophrenia, autism, substance abuse, and public health. All of Emory hospital's psychiatrists, psychologists, social workers, and nurses offer compassionate care for patients with mental health conditions. More than 400 Emory researchers and clinicians from various psychiatric domains work in collaboration to diagnose, treat, and prevent devastating diseases or disorders of the brain.

The Emory Department of Psychiatry has several inpatient and outpatient programs which can be especially helpful resources for study participants if they need

further support and treatment at the end of the study. Emory Adult Intensive Outpatient Program and Emory Wesley Woods Hospital have the resources to provide the highest-level care to the patients seeking to learn effective coping and preventive awareness skills (Emory.edu 2021). Emory Wesley Woods Hospital provides inpatient care for patients seeking treatment for mental health crises. This hospital provides holistic patient care - body, mind, and spirit with the help of well-trained psychiatrist, therapists, nurses, counselors, and social workers.

The innovative technologies and facilities available to the PI at Emory University Hospital include everything needed to initiate and complete the proposed research project. The scholarly environment is rich with other investigators who are doing work that is correlative to what is proposed in this grant application. The proposed research would be strongly supported by this facility, which provides a well-equipped scientific environment, ensuring the success of the project. In addition, Emory University/Brain Health Center has established long-term relationships with Grady Health System, Atlanta Veterans Affairs Medical Center, and the Centers for Disease Control and Prevention (CDC).

Literature Cited

Abercrombie, Priscilla D. PhD, RN, NP; Zamora, Anita BS, RN; Korn, Abner P. MD Lessons Learned, Holistic Nursing Practice: January 2007 - Volume 21 - Issue 1 - p 26-34.

About the National Institute of mental Health (NIMH). (2020). Retrieved March 06, 2021, from https://www.nimh.nih.gov/health/publications/about-the-national-institute-of-mental-health-nimh/index..

Afifi, T. O., Enns, M. W., Cox, B. J., de Graaf, R., ten Have, M., & Sareen, J. (2007). Child abuse and health-related quality of life in adulthood. The Journal of nervous and mental disease, 195, 797– 804.

Anda, R. F., Fleisher, V. I., Felitti, V. J., Edwards, V. J., Whitfield, C. L., Dube, S. R., & Williamson, D.F. (2004). Childhood abuse, household dysfunction, and indicators of impaired adult worker performance. Permanente Journal, 8, 30 –38. http://dx.doi.org/10.7812/TPP/03-089.

American Psychiatric Association. (2013). Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) Washington, D.C.: American Psychiatric Publishing.

Anna, P., Anna, T., Rocio, S., Bremner, J.D., 2011. Validation and Test-Retest Reliability of Early Trauma Inventory in Spanish Postpartum Women. J Nerv Ment Dis. 2011 April;199(4): 280-285.

Armswotth, M. W. (1984). Post-traumatic stress responses in women who experienced incest as children or adolescents. Doctoral dissertation, University of Cincinnati, 1984. Dissertation Abstracts International, 46. 1674-B.

Azad Marzabadi, E., & Hashemi Zadeh, S. M. (2014). The Effectiveness of Mindfulness Training in Improving the Quality of Life of the War Victims with Post Traumatic stress disorder (PTSD). Iranian journal of psychiatry, 9(4), 228–236.

Baer, R. A., (2003). Mindfulness training as a clinical intervention: a conceptual and empirical review. Clinical Psychology: Science and Practice, 10(2), pp. 125-143.

Banks K, Newman E, Saleem J. (2015) An Overview of the Research on Mindfulness-Based Interventions for Treating Symptoms of Posttraumatic Stress Disorder: A Systematic Review. Journal of clinical psychology, 2015, Vol.71(10), p.935-963

Basile KC, Arias I, Desai S, Thompson MP. (2004). The differential association of intimate partner physical, sexual, psychological, and stalking violence and posttraumatic stress symptoms in a nationally representative sample of women. Journal of Traumatic Stress. 2004;17(5):413–421.

Barnes, P. M., Bloom, B., & Nahin, R. L. (2008). Complementary and alternative use among adults and children: United States, 2007. National Health Statistics Reports,10(12), 1-23

Battle CL, Shea MT, Johnson DM, Yen S, Zlotnick C, Zanarini MC, Sanislow CA, Skodol AE, Gunderson JG, Grilo CM, McGlashan TH, Morey LC. (2004). Childhood maltreatment associated with adult personality disorders: findings from the Collaborative Longitudinal Personality Disorders Study. *J Personal Disord.* Apr 2004;18(2):193-211.

Becker, C. B., Zayfert, C., Anderson, E. (2004). A survey of psychologists' attitudes

towards and utilization of exposure therapy for PTSD. Behaviour Research and Therapy, 42, 277-292. doi:10.1016/S0005-7967(03)00138-4

Beers SR, De Bellis MD (2002): Neuropsychological function in children with maltreatment related posttraumatic stress disorder. Am J Psychiatry 2002; 159:483—486

Bishop SR. (2002) What do we really know about mindfulness-based stress reduction? [published correction appears in Psychosom Med 2002 May-Jun;64(3):449]. Psychosom Med. 2002;64(1):71-83. doi:10.1097/00006842-200201000-00010

Bishop, S. R. et al., (2004). Mindfulness: a proposed operational definition. Clinical Psychology: Science and Practice, 11(3), pp. 230-241.

Black, D. S., & Slavich, G. M. (2016). Mindfulness meditation and the immune system: a systematic review of randomized controlled trials. *Annals of the New York Academy of Sciences*, 1373(1), 13–24. https://doi.org/10.1111/nyas.12998.

Blake DD, Weathers FW, Nagy LM, Kaloupek DG, Gusman FD, Charney DS, Keane TM. (1995). The development of a clinician-administered PTSD scale. Journal of Traumatic Stress. 1995; 8:75–90.

Bormann, J. E., Thorp, S., Wetherell, J., Golshan, S., & Lang, A. J. (2013). Meditation-based mantram intervention for Veterans with post-traumatic stress disorder: A randomized trial. Psychological Trauma: Theory, Research, Practice, and Policy, 5, 259–267. 10.1037/a0027522

Boudewyns, P. A., Hyer, L. A., Woods, M. G., Harrison, W. R., & McCranie, E. (1990). PTSD among Vietnam veterans: An early look at treatment outcome using direct therapeutic exposure. Journal of Traumatic Stress, 3, 359-368.

Bowen, S., Witkiewitz, K., Dillworth, T. M., & Marlatt, G. A. (2007). The role of thought suppression in the relationship between mindfulness meditation and alcohol use. Addictive Behaviors, 32(10), 2324–2328. doi:10.1016/j. addbeh.2007.01.025

Boyd, J. E., Lanius, R. A., & McKinnon, M. C. (2018). Mindfulness-based treatments for posttraumatic stress disorder: a review of the treatment literature and neurobiological evidence. Journal of psychiatry & neuroscience : JPN, 43(1), 7–https://doi.org/10.1503/jpn.170021

Bradley R, Greene J, Russ E, Dutra L, Westen D. (2005). A multidimensional meta-analysis of psychotherapy for PTSD. American Journal of Psychiatry. 2005; 162:214–227. doi: 10.1176/appi.ajp.162.2.214.

Bremner JD, Narayan M, Staib LH, Southwick SM, McGlashan T, Charney DS. (1999). Neural correlates of memories of childhood sexual abuse in women with and without posttraumatic stress disorder. Am J Psychiatry. 1999; 156:1787–1795.

Bremner JD, Vermetten E, Mazure CM. (2000). Development and preliminary psychometric properties of an instrument for the measurement of childhood trauma: The early trauma inventory. Depress Anxiety. 2000; 12:1–12

Bremner JD., Vermetten E. (2002). Circuits and systems in stress. I. Preclinical studies. *Depress Anxiety.* 2002;15: 126–147.

Bremner JD, Vythilingam M, Vermetten E, Adil J, Khan S, Nazeer A, Afzal N, McGlashan T, Anderson G, Heninger GR, Southwick SM, Charney DS. (2002). Cortisol response to a cognitive stress challenge in posttraumatic stress disorder (PTSD) related to childhood abuse. *Psycho-neuroendocrinology.* 2002;(in press).

Bremner JD. (2005). Effects of traumatic stress on brain structure and function: Relevance

to early responses to trauma. J Trauma Dissociation 2005; 6(2):51-68.

Bremner JD, Randall P, Scott TM, Sandi Capelli, Richard Delaney, Gregory McCarthy, Dennis S. Charney (1995). Deficits in short-term memory in adult survivors of childhood abuse. Psychiatry Res 1995; 59(1-2):97-107.

Bremner JD, Southwick SM, Darnell A, Charney DS. (1996). Chronic PTSD in Vietnam combat veterans: Course of illness and substance abuse. *Am. J. Psychiatry.* 1996; 153:369-375.

Bremner JD, Bolus R, Mayer EA. (2007). Psychometric properties of the Early Trauma Inventory- Self-Report. J Nerv Ment Dis. 2007; 195:211–218.

Bryant RA, Felmingham KL, Kemp AH, Barton M, Peduto AS, Rennie C, Gordon E, Williams LM. (2005). Neural networks of information processing in posttraumatic stress disorder: a functional magnetic resonance imaging study. *Biol. Psychiatry.* Jul 15, 2005;58(2):111-118.

Brody AL, Saxena S, Stoessel P, et al. (2001). Regional brain metabolic changes in patients with major depression treated with either paroxetine or interpersonal therapy: preliminary findings. Arch Gen Psychiatry. 2001; 58:631-640.

Cahn, B. R. and Polich, J., (2006). Meditation states and traits: EEG, ERP, and neuroimaging studies. Psychological Bulletin, 132(2), pp. 180.

Chan, M. K. (2019). Mental Health Disorders, Health Behaviors, and Attitudes Toward and the Use of Complementary and Alternative Medicine among Graduate Students. UC Irvine. ProQuest ID: Chan_uci_0030D_15677. Merritt ID: ark:/13030/m5c87bp9. Retrieved from https://escholarship.org/uc/item/3jd5s5rt.

Chard, K. M. (2005). An evaluation of cognitive processing therapy for the treatment of

posttraumatic stress disorder related to childhood sexual abuse. *Journal Of Consulting And Clinical Psychology*, 73(5), 965-971. doi:10.1037/0022-006X.73.5.965.

Clarke TC, Black LI, Stussman BJ, Barnes PM, Nahin RL. (2015). Trends in the use of complementary health approaches among adults: United States, 2002-2012. Natl Health Stat Report. 2015 Feb 10; (79):1-16.

Cohen J., Mannarino A., Berliner L., Deblinger E. (2000). Trauma-focused cognitive behavioral therapy for children and adolescents: an empirical update. Journal of Interpersonal Violence 15(11),1202-1223. https://doi.org/10.1177/088626000015011007

Collinge, W., Kahn, J., & Soltysik, R. (2012). Promoting reintegration of National Guard veterans and their partners using a self-directed program of integrative therapies: A pilot study. Military Medicine, 177, 1477–1485. http://dx.doi.org/10.7205/MILMED-D-12-00121.

Creswell JD, Way BM, Eisenberger NI, Lieberman MD. (2007). Neural correlates of dispositional mindfulness during affect labeling. Psychosom Med 2007; 69(6): 560–5.

David Finkelhor, Anne Shattuck, Heather A. Turner, & Sherry L. Hamby, (2014). The Lifetime Prevalence of Child Sexual Abuse and Sexual Assault Assessed in Late Adolescence, 55 Journal of Adolescent Health 329, 329-333 (2014).

DiLillo, D. (2001). Interpersonal functioning among women reporting a history of childhood sexual abuse: Empirical findings and methodological issues. Clinical Psychology Review, 21, 553–576. http://dx.doi.org/ 10.1016/S0272-

7358(99)00072-0 Emory University School of Medicine (2020). Retrieved on January 1, 2021 from http://www.psychiatry.emory.edu/about/history.html.

De Bellis MD, Baum AS, Keshavan MS, Eccard CH, Boring AM, Jenkins FJ, Ryan ND. A.E. Bennett Research Award (1999). Developmental traumatology: Part I: Biological stress systems. *Biol. Psychiatry.* 1999; 45:1259-1270.

Dube SR, Felitti VJ, Dong M, Giles WH, Anda RF.(2003). The impact of adverse childhood experiences on health problems: evidence from four birth cohorts dating back to 1900. *Preventive Medicine.* 2003; 37:268-277.

Dunne J. J Am Psychiatry Nurses Assoc. (2018). Mar/Apr; Mindfulness in Anorexia Nervosa: An Integrated Review of the Literature. 24(2):109-117.

Dutton, M.A. (1992). Assessment and treatment of post-traumatic stress disorder among battered women. In D.W. Foy (Ed.), Treating PTSD: Cognitive-behavioral strategies (pp. 69-98). New Your, NY: Guilford Press.

Dutton, M. A., Bermudez, D., Matas, A., Majid, H., & Myers, N. L. (2013). Mindfulness-Based Stress Reduction for Low-Income, Predominantly African American Women with PTSD and a History of Intimate Partner Violence. Cognitive and behavioral practice, 20(1), 23–32.

Dye, E., & Roth, S. (1991). Psychotherapy with Vietnam veterans and rape and incest survivors. Psychotherapy, 28, 103-120.

Echeburúa, E., De Corral, P., Sarusua, B., & Zubizarreta, I. (1996). Treatment of acute posttraumatic stress disorder in rape victims: An experimental study. Journal of Anxiety Disorders, 10, 185-199. doi: 10.1016/0887-6185(96) 89842-2.

Elbedour, S., Abu-Bader, S., Onwuegbuzie, A. J., Abu-Rabia, A., & El-Aassam, S.

2006). The scope of sexual, physical, and psychological abuse in a Bedouin Arab community of female adolescents: 38 The interplay of racism, urbanization, polygamy, family honor, and the social marginalization of women. Child Abuse and Neglect, 30(3), 215–229

Evans S, Ferrando S, Findler M, Stowell C, Smart C, Haglin D.J. (2008, May); Mindfulness-based cognitive therapy for generalized anxiety disorder. Anxiety Disord 22(4):716-21.

Fairbank, J. A. & Keane, T. M. (1982). Flooding for combat-related stress disorders: assessment of anxiety reduction across traumatic memories. Behav.There.,13:499-510.

Foa, E. B., Dancu, C.V., Hembree, E.A., Jaycox, L.H., Meadows, E.A. & Stress, G.P. (1999). A comparison of exposure therapy, stress inoculation training, and their combination for reducing posttraumatic stress disorder in female assault victims. Journal of Consulting and Clinical Psychology, 67,194-200.

Follette VM, Briere J, Rozelle D, et al., editors. Mindfulness-oriented interventions for trauma: integrating contemplative practices. New York (NY): The Guildford Press; 2015.

Follette V, Palm KM, Pearson AN. (2006). Mindfulness and trauma: implications for treatment. J Ration-Emot Cogn-Behav Ther. 2006; 24:45–61.

Frank, E. & Stewart, B. D. (1983), Physical aggression: treating the victims. In:Behavior Modification with Women, ed.E. A.Blechman. New York: Guilford Press.

Franklin CL, Zimmerman M. (2001). Posttraumatic stress disorder and major depressive

disorder: Investigating the role of overlapping symptoms in diagnostic comorbidity. *J. Nerv. Ment. Dis.* 2001;189(8):548-551.

Frewen P, Lanius R. (2015). Healing the traumatized self: consciousness, neuroscience, treatment. New York (NY) and London (UK): WW Norton & Company; 2015.

Frost ND, Laska KM, Wampold BE, J Trauma Stress. (2014 Feb); The evidence for present-centered therapy as a treatment for posttraumatic stress disorder. 27(1):1-8.

Futa, K. T., Hsu, E., & Hansen, D. J. (2001). Child sexual abuse in Asian American families: An examination of cultural factors that influence prevalence, identification, and treatment. Clinical Psychology: Science and Practice, 8(2), 189–209.

Gallegos, A. M., Crean, H. F., Pigeon, W. R., & Heffner, K. L. (2017). Meditation and yoga for posttraumatic stress disorder: A meta-analytic review of randomized controlled trials. Clinical psychology review, 58, 115–124. https://doi.org/10.1016/j.cpr.2017.10.004

Georgia's Children (2012). Child Welfare League of America, found at http://www.cwla.org/advocacy/statefactsheets/2012/georgia.pdf (last visited June 22, 2012).

Gold SN. (2000). Not trauma alone: Therapy for child abuse survivors in family and social context. Brunner-Routledge; New York: 2000.

Goyal M, Singh S, Sibinga E, et al. (2015). Comparative effectiveness review: meditation

programs for psychological stress and well-being. Available at http://effectivehealthcare.ahrq.gov/ehc/products/375/1830/Meditation-report-140106.pdf; accessed August 25, 2015.

Green CA, Perrin NA, Polen MR. (2004). Gender differences in the relationships between multiple alcohol consumption and physical and mental health. Alcoholism: Clinical and Experimental Research. 2004;28(5):754–764.

Grunert, BK, Weis, JM, Smucker, MR, Christianson, HF. (2007). Imagery rescripting and reprocessing therapy after failed prolonged exposure for post-traumatic stress disorder following industrial injury. J Behav Ther Exp Psychiatry. 2007; 38:317–328

Harrison CA, Kinner SA. (1998). Correlates of psychological distress following armed robbery. Journal of Traumatic Stress. 1998;11(4):787–798.

Herman, J., & Schatzow, E. (1984). Time-limited group therapy for women with a history of incest International Journal of Group Psychotherapy, 34, 605-616.

Hoge CW, Castro CA, Messer SC, McGurk D, Cotting DI, Koffman RL. (2004). Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. New England Journal of Medicine. 2004;351(1):13–22.

Hölzel, B. K., Lazar, S. W., Gard, T., Schuman-Olivier, Z., Vago, D. R., & Ott, U. (2011). How does mindfulness meditation work? Proposing mechanisms of action from a conceptual and neural perspective. Perspectives on Psychological Science, 6, 537-559.

How Common is PTSD in Adults? (2019, October 16). U.S. Department of Veterans Affairs. https://www.ptsd.va.gov/understand/common/common_adults.asp.

Kabat-Zinn J. Mindfulness-based interventions in context: past, present, and future. Clin Psychol Sci Pract. 2003; 10:144–56.

Katie Witkiewitz, Brenna L. Greenfield, Sarah Bowen (2013). Mindfulness-based relapse prevention with racial and ethnic minority women, Addictive Behaviors, Volume 38, Issue 12, 2013, Pages 2821-2824, ISSN 0306-4603, https://doi.org/10.1016/j.addbeh.2013.08.018.

Keane, T., Caddell, J., & Taylor, K. (1988). Mississippi Scale for combat-related posttraumatic stress disorder. Journal of Consulting and Clinical Psychology, 56, 85-90.

Kearney DJ, Simpson TL. (2015). Broadening the approach to posttraumatic stress disorder and the consequences of trauma. JAMA. 2015; 314:453–455. doi: 10.1001/jama.2015.7522.

Kearney, D. J., Malte, C. A., McManus, C., Martinez, M. E., Felleman, B., & Simpson, T. L. (2013). Loving-kindness meditation for posttraumatic stress disorder: A pilot study. Journal of Traumatic Stress, 26, 426 – 434. http://dx.doi.org/10.1002/jts.21832

Kearney DK, McDermott K, Malte C, Martinez M, Simpson TL. (2013), Effects of participation in a mindfulness program for veterans with posttraumatic stress disorder: a randomized controlled pilot study. J Clin Psychol 2013; 69(1): 14–27.

Kearney, D. J., Malte, C. A., McManus, C., Martinez, M. E., Felleman, B., & Simpson, T. L. (2013). Loving-kindness meditation for posttraumatic stress disorder: A pilot study. Journal of Traumatic Stress, 26, 426–434. 10.1002/jts.21832.

Kelly, A., & Garland, E. L. (2016). Trauma-Informed Mindfulness-Based Stress Reduction

for Female Survivors of Interpersonal Violence: Results from a Stage I RCT. Journal of clinical psychology, 72(4), 311–328. https://doi.org/10.1002/jclp.22273.

Keng, S. L., Smoski, M. J., & Robins, C. J. (2011). Effects of mindfulness on psychological health: a review of empirical studies. Clinical psychology review, 31(6), 1041–1056. https://doi.org/10.1016/j.cpr.2011.04.006.

Kessler RC, Sonnega A, Bromet E, Hughes M, Nelson CB. (1995). Posttraumatic stress disorder in the national comorbidity survey. *Arch. Gen. Psychiatry.* 1995; 52:1048-1060.

Key BL, Rowa K, Bieling P, McCabe R, Pawluk EJ. (2017); Mindfulness-based cognitive therapy as an augmentation treatment for obsessive-compulsive disorder. Clin Psychol Psychother. 2017 Sep; 24(5):1109-1120.

Kevington, S. M., Lotfy, M., O'Connell, K. A., & WHOQOL Group (2004). The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation, 13(2), 299–310. https://doi.org/10.1023/B:QURE.0000018486.91360.00.

Khusid, M. A., & Vythilingam, M. (2016). The Emerging Role of Mindfulness Meditation as Self-Management Strategy, Part 1: Clinical Implications for Depression, Post-Traumatic Stress Disorder, and Anxiety. Military medicine, 181(9), 961–968. https://doi.org/10.7205/MILMED-D-14-00677.

Kilpatrick, D.G., Veronen, L. J. &Resick, P. A. (1982), Psychological sequelae to rape:

assessment in treatment strategies. In: Behavioral Medicine:Assessmentin Treatment Strategies, eds. D.M. Dolays & R.L. Meredith. New York:Plenum.

Kimbrough, E., Magyari, T., Langenberg, P., Chesney, M. and Berman, B. (2010), Mindfulness intervention for child abuse survivors. J. Clin. Psychol., 66: 17-33. doi:10.1002/jclp.20624.

Klatte, R., Strauss, B., Flückiger, C., & Rosendahl, J. (2018). Adverse effects of psychotherapy: protocol for a systematic review and meta-analysis. *Systematic reviews*, *7*(1), 135. https://doi.org/10.1186/s13643-018-0802-x.

Lai C, Daini S, Calcagni ML, et al. Neural correlates of psychodynamic psychotherapy in borderline disorders—a pilot investigation. Psychother Psychosom. 2007; 76:403-405.

Lang, A. J., Strauss, J. L., Bomyea, J., Bormann, J. E., Hickman, S. D., Good, R. C., & Essex, M. (2012). The Theoretical and Empirical Basis for Meditation as an Intervention for PTSD. Behavior Modification, 36(6), 759–786. https://doi.org/10.1177/0145445512441200.

Lee-Fan Tan, Zoltan Dienes, Ashok Jansari, Sing-Yau Goh,2014. Effect of mindfulness meditation on brain–computer interface performance, Consciousness and Cognition, Volume 23, Pages 12-21, ISSN 1053 8100, https://doi.org/10.1016/j.concog.2013.10.010.

Lowe SR, Galea S, Uddin M, Koenen KC. (2014). Trajectories of posttraumatic stress among urban residents. American Journal of Community Psychology. 2014;53(1-2):159–172.

Malinowski P. (2013). Neural mechanisms of attentional control in mindfulness

meditation. Front Neurosci. 2013 Feb 4; 7:8. doi: 10.3389/fnins.2013.00008. PMID: 23382709; PMCID: PMC3563089.

Marina A. Khusid, MD, ND, MSA, Meena Vythilingam, MD, (2016). The Emerging Role of Mindfulness Meditation as Effective Self-Management Strategy, Part 1: Clinical Implications for Depression, Post-Traumatic Stress Disorder, and Anxiety, *Military Medicine*, Volume 181, Issue 9, September 2016, Pages 961–968, https://doi.org/10.7205/MILMED-D-14-00677.

McDonagh, A., Friedman, M., McHugo, G., Ford, J., Sengupta, A., Mueser, K., & Descamps, M. (2005). Randomized trial of cognitive-behavioral therapy for chronic posttraumatic stress disorder in adult female survivors of childhood sexual abuse. *Journal of consulting and clinical psychology*, *73*(3), 515.

McGee M. (2008). Meditation and psychiatry. Psychiatry (Edgmont (Pa.: Township)), 5(1), 28–41.

McFarlane A. C. (2010). The long-term costs of traumatic stress: intertwined physical and psychological consequences. *World psychiatry: official journal of the World Psychiatric Association (WPA)*, *9*(1), 3–10. https://doi.org/10.1002/j.2051-5545.2010.tb00254.x

Mezzacappa E, Kindlon D, Earls F. (2001). Child abuse and performance task assessments of executive functions in boys. J Child Psychol & Psychiatry & Allied Disciplines 2001; 42:1041—1048

Mitmansgruber H, Beck TN, Höfer S, Schüßler G. (2009). When you don't like what you feel: Experiential avoidance, mindfulness and metaemotion in emotion regulation. Person and Individual Differences 2009; 46: 448–453.

Narimani M, Ariapooran S, Abolghasemi A, Ahadi B. (2012). Effectiveness of

mindfulness-based stress reduction and emotion regulation training in the Mental health of chemical weapons victims (Persian) Iran J Clinical Psychology. 2010; 4:61–72.

Narimani M., Ariapooran S., Abolghasemi A., Ahadi B. (2012). Effectiveness of mindfulness-based stress reduction and emotion regulation training in the affect and mood of chemical weapons victims (Persian) AMUJ. 2012; 15:107–118.

National Center for Complementary and Alternative Medicine (NCCAM) (2008). Complementary, alternative, or integrative health: what's in a name? 2008. http://nccam.nih.gov/health/whatiscam. Accessed February 11, 2014.

National Center for Complementary and Integrative Health. (2017). Complementary, alternative, or integrative health: What's in a name? Retrieved from https://nccih.nih.gov/health/integrative-health

Neria Y, Gross R, Litz B, Maguen S, Insel B, Seirmarco G, Rosenfeld H, Suh EJ, Kishon R, Cook J, Marshall RD. (2007). Prevalence and psychological correlates of complicated grief among bereaved adults 2.5-3.5 years after September 11th attacks. Journal of Traumatic Stress. 2007;20(3):251–262.

Niles, B., Klunk-Gillis, J., Ryngala, D., Silberbogen, A., Paysnick, A., & Wolf, E. (2012). Comparing mindfulness and psychoeducation treatments for combat-related PTSD using a telehealth approach. Psychological Trauma: Theory, Research, Practice, and Policy, 4, 538 –547. http://dx.doi.org/10.1037/a0026161.

Our vision and mission. (2018). Retrieved March 05, 2021, from https://med.emory.edu/about/mission/index.html.

Palmer LK, Frantz CE, Armsworth MW, et al. (1999). Neuropsychological sequelae of

chronically psychologically traumatized children: Specific findings in memory and higher cognitive functions, in Trauma & Memory. Edited by Williams LM. Thousand Oaks, Calif, Sage Publications, 1999, pp 229-244.

Polusny M, Erbes C, Thuras P, et al. (2015). Mindfulness-based stress reduction for posttraumatic stress disorder among veterans: a randomized clinical trial. JAMA 2015; 314(5): 456–65.

Prigerson HG, Maciejewski PK, Rosenheck RA. (2001). Combat trauma: Trauma with highest risk of delayed onset and unresolved posttraumatic stress disorder symptoms, unemployment, and abuse among men. *J. Nerv. Ment. Dis.* 2001;189(2):99-108.

Punamaki RL, Qouta SR, El Sarraj E. (2010). Nature of torture, PTSD, and somatic symptoms among political ex-prisoners. Journal of Traumatic Stress. 2010;23(4):532–536.

Putnam FW, Guroff JJ, Silberman EK, Barban L, Post RM. (1989). The clinical phenomenology of multiple personality disorder: A review of 100 recent cases. *J. Clin. Psychiatry.* 1986; 47:285-293.

Resick, P. A., Nishith, P., Weaver, T. L., Astin, M. C., & Feuer, C. A. (2002). A comparison of cognitive-processing therapy with prolonged exposure and a waiting condition for the treatment of chronic posttraumatic stress disorder in female rape victims. *Journal of consulting and clinical psychology*, *70*(4), 867–879. https://doi.org/10.1037//0022-006x.70.4.867.

Rodriguez, N., Ryan, S. W., Vande Kemp, H., & Foy, D. W. (1997). Posttraumatic stress disorder in adult female survivors of child sexual abuse: A comparison

study. *Journal of Consulting And Clinical Psychology*, *65*(1), 53-59. doi:10.1037/0022-006X.65.1.53

Roeloffs C, Sherbourne C, Unützer J, Fink A, Tang L, Wells KB. (2003). Stigma and depression among primary care patients. Gen Hosp Psychiatry. 2003 Sep-Oct; 25(5):311-5.

Saigh PA, Bremner JD. (1999). *Posttraumatic Stress Disorder: A Comprehensive Text.* Needham Heights, MA: Allyn & Bacon; 1999.

Salcedo S, Gold AK, Sheikh S, Marcus PH, Nierenberg AA, Deckersbach T, Sylvia LG J Affect Disord. (2016, Sep 1); Empirically supported psychosocial interventions for bipolar disorder: Current state of the research. 201():203-14.

Samms, K. M., & Cholewa, B. E. (2014). Exploring the context of child sexual abuse in Jamaica: Addressing the deficits. Journal of Child Sexual Abuse, 23(2), 115–127.

Sawrikar, P. & Katz, I. (2017). The treatment needs of victims/survivors of child sexual abuse (CSA) from ethnic minority communities: A literature review and suggestions for practice. Children and Youth Services Review, 79, 166–179.

Schottenbauer MA, Glass CR, Arnkoff DB, Tendick V, Gray SH. (2008). Nonresponse and dropout rates in outcome studies on PTSD: Review and methodological considerations. Psychiatry. 2008; 71:134–168. doi: 10.1521/psyc.2008.71.2.134.

Sedlack, A.J., Mettenburg, J., Basena, M., Petta, I., McPherson, K., Greene, A., and Li, S. (2010). Fourth National Incidence Study of Child Abuse and Neglect (NIS–4): Report to Congress, Executive Summary. Washington, DC: U.S. Department of Health and Human Services, Administration for Children and Families.

Segal ZV, Williams JMG, Teasdale JD. (2002): Mindfulness-Based Cognitive Therapy for Depression: A New Approach to Preventing Relapse. New York, Guilford Press, 2002.

Semmens-Wheeler, R. and Dienes, Z., (2012). The contrasting role of higher order awareness in hypnosis and meditation. The Journal of Mind-Body Regulation, 2(1), pp. 43-57.

Sephton, S.E., Salmon, P., Weissbecker, I., Ulmer, C., Floyd, A., Hoover, K. and Studts, J.L. (2007), Mindfulness meditation alleviates depressive symptoms in women with fibromyalgia: Results of a randomized clinical trial. Arthritis & Rheumatism, 57: 77-85. https://doi.org/10.1002/art.22478.

Seppälä, E. M., Nitschke, J. B., Tudorascu, D. L., Hayes, A., Goldstein, M. R., Nguyen, D. T., . . .Davidson, R. J. (2014). Breathing-based meditation decreases posttraumatic stress disorder symptoms in U.S. military veterans: A randomized controlled longitudinal study. Journal of Traumatic Stress, 27, 397–405. 10.1002/jts.21936.

Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R, Dunbar GC. (1998). The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. J Clin Psychiatry. 1998;59 Suppl 20:22-33; quiz 34-57. PMID: 9881538.

Silva C.,McFarlane J., Soeken K., Parker B., Reel S. (1997). Symptoms of Post-Traumatic Stress Disorder in Abused Women in a Primary Care Setting. Journal of Women's Health 1997 6:5, 543-552

Simpson TL, Kaysen D, Bowen S, MacPherson LM, Chawla N, Blume A, et al. (2007). PTSD symptoms, substance use, and vipassana meditation among incarcerated individuals. J Trauma Stress 2007; 20: 239-249.

Smith, K., Bryant-Davis, T., Tillman, S., & Marks, A. (2010). Stifled voices: Barriers to help-seeking behavior for South African childhood sexual assault survivors. Journal of Child Sexual Abuse, 19(3), 255–274.

Spitzer RL, Williams JBW, Gibbon M. (1987). Structured Clinical Interview for DSMIIIR. New York: New York State Psychiatric Institute; 1987.

Steenkamp MM, Litz BT, Hoge CW, Marmar CR. (2015). Psychotherapy for Military-Related PTSD: A Review of Randomized Clinical Trials. JAMA. 2015 Aug 4; 314(5):489-500. doi: 10.1001/jama.2015.8370.

Strong, P. (2010, December 10). Mindfulness Meditation Therapy for PTSD. Retrieved January 05, 2021, fromhttps://www.mentalhelp.net/blogs/mindfulness-meditation-therapy-for-ptsd/

Southwick SM, Paige S, Morgan CA, III, Bremner JD, Krystal JH, Charney DS. (1999). Neurotransmitter alterations in PTSD: catecholamines and serotonin. Semin. Clin. Neuropsychiatry. 1999; 4:242–248.

Substance Abuse and Mental Health Service Administration (SAMHSA), 2020; Retrieved November 10, 2020 from https://www.samhsa.gov/about-us/who-we-are

Synder, H.N. (2000). Sexual assault of young children as reported to law enforcement: Victim, incident, and offender characteristics, in A NIBRS Statistical Report. 2000, U.S. Department of Justice: Washington, D.C.

The National Center for Complementary and Integrative Health (NCCIH), 2020; Retrieved

September 10, 2020 from https://www.nccih.nih.gov/about/clinical-trials-utilizing-innovative-study-designs.

The National Center for Complementary and Integrative Health (NCCIH), 2020; Retrieved September 10, 2020 from https://www.nccih.nih.gov/about/nccihs-funding-priorities-and-research-focus.

Taylor, S., & Norma, C. (2013). The ties that bind: Family barriers for adult women seeking to report childhood sexual assault in Australia. Women's Studies International Forum, 37, 114–124.

U.S. Department of Health and Human Services, Administration for Children, Youth and Families. Child Abuse and Neglect Fatalities (2011): Statistics and Interventions. Retrieved from http://www.childwelfare.gov/pubs/factsheets.pdf

U.S. Department of Health and Human Services 2008 report on Child Maltreatment. Retrieved from http://www.acf.hhs.gov/programs/cb/pubs/cm08/cm08.

U.S. Department of Health and Human Services 2001: Mental health, culture, race, and ethnicity—A supplement to mental health: A report of the surgeon general. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services; Washington, DC: 2001.

United States Department of Commerce. U.S. Census Bureau: State and County quick facts, 2010. Retrieved from http://quickfacts.census.gov/qfd/states/13/1304000.html.

Upchurch, D. M., & Johnson, P. J. (2019). Gender Differences in Prevalence, Patterns,

Purposes, and Perceived Benefits of Meditation Practices in the United States. Journal of women's health (2002), 28(2), 135–142.

Urquiza, Anthony J., and Beth L. Goodlin-Jones. (1994). Child Sexual Abuse and Adult Revictimization with Women of Color. 9(3) *Violence and Victims* (1994): 223-232.

Vermetten E., Bremner JD. (2002). Circuits and systems in stress. II. Applications to neurobiology and treatment of PTSD, *Depression, Anxiety.* 2002; 16:14–38.

Vujanovic AA, Youngwirth NE, Johnson KA, Zvolensky MJ. (2009). Mindfulness-based acceptance and posttraumatic stress symptoms among trauma-exposed adults without axis I psychopathology. J Anxiety Disord 2009; 23: 297-303.

Vujanovic, A. A., Niles, B., Pietrefesa, A., Schmertz, S. K., & Potter, C. M. (2013). Mindfulness in the treatment of posttraumatic stress disorder among military veterans. Spirituality in Clinical Practice,1(S), 15–25. doi:10.1037/2326-4500.1.S.15.

Wahbeh, H., Senders, A., Neuendorf, R., & Cayton, J. (2014). Complementary and Alternative Medicine for Posttraumatic Stress Disorder Symptoms: A Systematic Review. Journal of Evidence-Based Complementary & Alternative Medicine, 19(3), 161–175. https://doi.org/10.1177/2156587214525403.

Watson, N.N., Black, A.R. & Hunter, C.D. African American Women's Perceptions of Mindfulness Meditation Training and Gendered Race-Related Stress. Mindfulness 7, 1034–1043 (2016). https://doi-org.proxy.library.emory.edu/10.1007/s12671-016-0539-3

Weathers, F. W., Keane, T. M., & Davidson, J. R. T. (2001). Clinician-Administered

PTSD Scale: A review of the first ten years of research. *Depression and Anxiety*, 13, 132–156.

West, Carolyn M. 2002. "Battered, Black, and Blue: An Overview of Violence in the Lives of Black Women". *Women and Therapy* 25 (3/4): 5-27.

World Health Organization (WHO), London School of Hygiene and Tropical Medicine. (2010). Preventing intimate partner and sexual violence against women. Taking action and generating evidence. Geneva: World Health Organization.

Yen S, Shea MT, Battle CL, Johnson DM, Zlotnick C, Dolan-Sewell R, Skodol AE, Grilo CM, Gunderson JG, Sanislow CA, Zanarini MC, Bender DS, Rettew JB, McGlashan TH. (2002). Traumatic exposure and posttraumatic stress disorder in borderline, schizotypal, avoidant, and obsessive-compulsive personality disorders: findings from the collaborative longitudinal personality disorders study. *J. Nerv. Ment. Dis.* Aug 2002;190(8):510-518.

Zayfert C, Deviva JC, Becker CB, Pike JL, Gillock KL, Hayes SA, J Trauma Stress. (2005 Dec); Exposure utilization and completion of cognitive behavioral therapy for PTSD in a "real world" clinical practice.18(6):637-45.

Appendix

Appendix A

EMORY UNIVERSITY | Institutional Review Board
Research Administration

Emory University
Consent to be a Research Subject

Title:

IRB #:

Principal Investigator:

Funding Source:

If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview
The purpose of this study is to…

Procedures

Risks and Discomforts

New Information
It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits
This study is not designed to benefit you directly. Y This study is designed to learn more about…. The study results may be used to help others in the future.

Compensation
You will not be offered payment for being in this study.

OR SOMETHING LIKE

You will get $____ for each completed study visit. If you do not finish the study, you will be paid for the visits you have completed. You will receive $____ total, if you complete all study visits. You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

Other Options Outside this Study

If you decide not to enter this study, there is care available to you outside of this research. [List the major standard care options and/or possibility of other studies] We will discuss these with you. You do not have to be in this study to be treated for [condition] OR to get [list services].

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include [the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance]. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

OR

Your data [and specimens] from this study will not be shared with anyone outside this study, even if we take out all the information that can identify you.

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

[No results returned to participants]

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

[Participants will receive aggregate results]

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

[Participants have option to receive individual results]

As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

[INSERT OTHER SECTIONS FROM MODULAR CONSENT DOCUMENT HERE]

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically:

- EXAMPLE-Imaging, lab work, etc.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

-

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study. [ADD ANY OTHER PURPOSES FOR WHICH PHI WILL BE USED/DISCLOSED]

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.

- _____ is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- [ADD ANY OTHERS].
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration; Veterans Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - ADD ANY OTHERS.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact [study contact person(s)] at [telephone number(s)]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

_____ _____

Signature of Legally Authorized Representative **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**

Appendix B

Informed Consent Documentation
Assess the Effectiveness of Mindfulness Meditation (MM) Therapy in Women with Post-Traumatic Stress Disorder (PTSD) due to Childhood Sexual Abuse

Subject ID:_____
Visit Date: _____

I have reviewed with _____ the opportunity to participate in the Assess the Effectiveness of Mindfulness Meditation (MM) Therapy in Women with Post-Traumatic Stress Disorder (PTSD) due to Childhood Sexual Abuse Study.

I have also reviewed with the subject, in detail, the risks and benefits associated with this protocol. I have provided the subject the opportunity to ask questions and have answered questions regarding the study.

The subject verbalized understanding of the study and all study related visits and procedures. The patient signed and received a copy of the Informed Consent form on _____
No study procedures were performed prior to obtaining informed consent.

Investigator conducting consent (print name): _____

Investigator conducting consent (signature): _____

Date: _____

Appendix C

HIPAA IDENTIFIERS

De-identified personal health information (PHI) does not fall under the HIPAA rule. Therefore, you can waive authorization for its use and disclosure.

To de-identify PHI these 18 identifiers must be removed:

1. Names
2. Geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial 3 digits of the zip code if, according to the current policy available from the Bureau of the Census
   - The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; AND
   - The initial 3 digits of the zip code for all geographic units containing 20,000 or fewer people is changed to 000.
3. Dates (except year) directly related to an individual (e.g., DOB, discharge date, date of death) and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security Number
8. Medical Record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic or code

Limited Data Sets

A “Limited Data Set” is a set of data that is not fully de-identified. You do not need authorization from the patient, nor do you need to seek a waiver, however you must have a “data use agreement” with Winship that describes the permitted uses and disclosures of the information received, and prohibits re-identifying or using this information to contact individuals. This plan must be reviewed by the IRB. Of the 18 identifiers listed above, the following MAY be used in a Limited Data Set

1. Dates
2. Geographic information (not street address)
3. Other unique identifying numbers characteristics, or codes that are not expressly excluded (The other 15 identifiers must be removed.)

Limited Data Sets

A “Limited Data Set” is a set of data that is not fully de-identified. You do not need authorization from the patient, nor do you need to seek a waiver, however you must have a “data use agreement” with Winship that describes the permitted uses and disclosures of the information received, and prohibits re-identifying or using this information to contact individuals. This plan must be reviewed by the IRB.
Of the 18 identifiers listed above, the following MAY be used in a Limited Data Set

4. Dates
5. Geographic information (not street address)
6. Other unique identifying numbers characteristics, or codes that are not expressly excluded (The other 15 identifiers must be removed.)

Appendix D

Baseline

National Center for PTSD

CLINICIAN-ADMINISTERED PTSD SCALE FOR DSM-IV

Name: _____ ID # :_____

Interviewer: _____ Date:_____

Study: _____

Dudley D. Blake, Frank W. Weathers, Linda M. Nagy,
Danny G. Kaloupek, Dennis S. Charney, & Terence M. Keane

National Center for Posttraumatic Stress Disorder

Behavioral Science Division -- Boston VA Medical Center
Neurosciences Division -- West Haven VA Medical Center

Revised July 1998

Criterion A. The person has been exposed to a traumatic event in which both of the following were present:
(1) the person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others
(2) the person's response involved intense fear, helplessness, or horror. Note: In children, this may be expressed instead by disorganized or agitated behavior

I'm going to be asking you about some difficult or stressful things that sometimes happen to people. Some examples of this are being in some type of serious accident; being in a fire, a hurricane, or an earthquake; being mugged or beaten up or attacked with a weapon; or being forced to have sex when you didn't want to. I'll start by asking you to look over a list of experiences like this and check any that apply to you. Then, if any of them do apply to you, I'll ask you to briefly describe what happened and how you felt at the time.

Some of these experiences may be hard to remember or may bring back uncomfortable memories or feelings. People often find that talking about them can be helpful, but it's up to you to decide how much you want to tell me. As we go along, if you find yourself becoming upset, let me know and we can slow down and talk about it. Also, if you have any questions or you don't understand something, please let me know. Do you have any questions before we start?

ADMINISTER CHECKLIST, THEN REVIEW AND INQUIRE UP TO THREE EVENTS. IF MORE THAN THREE EVENTS ENDORSED, DETERMINE WHICH THREE EVENTS TO INQUIRE (E.G., FIRST, WORST, AND MOST RECENT EVENTS; THREE WORST EVENTS; TRAUMA OF INTEREST PLUS TWO OTHER WORST EVENTS, ETC.)

IF NO EVENTS ENDORSED ON CHECKLIST: *(Has there ever been a time when your life was in danger or you were seriously injured or harmed?)*

IF NO: *(What about a time when you were threatened with death or serious injury, even if you weren't actually injured or harmed?)*

IF NO: *(What about witnessing something like this happen to someone else or finding out that it happened to someone close to you?)*

IF NO: *(What would you say are some of the most stressful experiences you have had over your life?)*

EVENT #1

What happened? *(How old were you? Who else was involved? How many times did this happen? Life threat? Serious injury?)*	*Describe (e.g., event type, victim, perpetrator, age, frequency):*
How did you respond emotionally? *(Were you very anxious or frightened? Horrified? Helpless? How so? Were you stunned or in shock so that you didn't feel anything at all? What was that like? What did other people notice about your emotional response? What about after the event -- how did you respond emotionally?)*	*A. (1)* *Life threat? NO YES [self other ___]* *Serious injury? NO YES [self other ___]* *Threat to physical integrity? NO YES [self other ___]* *A. (2)* *Intense fear/help/horror? NO YES [during ___ after ___]* *Criterion A met? NO PROBABLE YES*

EVENT #2

What happened? *(How old were you? Who else was involved? How many times did this happen? Life threat? Serious injury?)*	*Describe (e.g., event type, victim, perpetrator, age, frequency):*
How did you respond emotionally? *(Were you very anxious or frightened? Horrified? Helpless? How so? Were you stunned or in shock so that you didn't feel anything at all? What was that like? What did other people notice about your emotional response? What about after the event -- how did you respond emotionally?)*	*A. (1)* *Life threat? NO YES [self other ___]* *Serious injury? NO YES [self other ___]* *Threat to physical integrity? NO YES [self other ___]* *A. (2)* *Intense fear/help/horror? NO YES [during ___ after ___]* *Criterion A met? NO PROBABLE YES*

EVENT #3

What happened? *(How old were you? Who else was involved? How many times did this happen? Life threat? Serious injury?)*	*Describe (e.g., event type, victim, perpetrator, age, frequency):*
How did you respond emotionally? *(Were you very anxious or frightened? Horrified? Helpless? How so? Were you stunned or in shock so that you didn't feel anything at all? What was that like? What did other people notice about your emotional response? What about after the event -- how did you respond emotionally?)*	*A. (1)* *Life threat? NO YES [self other ___]* *Serious injury? NO YES [self other ___]* *Threat to physical integrity? NO YES [self other ___]* *A. (2)* *Intense fear/help/horror? NO YES [during ___ after ___]* *Criterion A met? NO PROBABLE YES*

For the rest of the interview, I want you to keep (EVENTS) in mind as I ask you some questions about how they may have affected you.

I'm going to ask you about twenty-five questions altogether. Most of them have two parts. First, I'll ask if you've ever had a particular problem, and if so, about how often in the past month *(week)*. Then I'll ask you how much distress or discomfort that problem may have caused you.

Criterion B. The traumatic event is persistently reexperienced in one (or more) of the following ways:

1. (B-1) recurrent and intrusive distressing recollections of the event, including images, thoughts, or perceptions. **Note:** In young children, repetitive play may occur in which themes or aspects of the trauma are expressed.

Frequency	*Intensity*	Past week
Have you ever had unwanted memories of (EVENT)? What were they like? *(What did you remember?)* [IF NOT CLEAR:] *(Did they ever occur while you were awake, or only in dreams?)* [EXCLUDE IF MEMORIES OCCURRED ONLY DURING DREAMS] **How often have you had these memories in the past month *(week)*?** 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day *Description/Examples*	**How much distress or discomfort did these memories cause you? Were you able to put them out of your mind and think about something else?** *(How hard did you have to try?)* **How much did they interfere with your life?** 0 None 1 Mild, minimal distress or disruption of activities 2 Moderate, distress clearly present but still manageable, some disruption of activities 3 Severe, considerable distress, difficulty dismissing memories, marked disruption of activities 4 Extreme, incapacitating distress, cannot dismiss memories, unable to continue activities *QV (specify)* _____	*F* ____ *I* ____ Past month *F* ____ *I* ____ *Sx:* Y N Lifetime *F* *I* ____ *Sx:* Y N

2. (B-2) recurrent distressing dreams of the event. **Note:** In children, there may be frightening dreams without recognizable content.

Frequency	*Intensity*	Past week
Have you ever had unpleasant dreams about (EVENT)? Describe a typical dream. *(What happens in them?)* **How often have you had these dreams in the past month *(week)*?** 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day *Description/Examples*	**How much distress or discomfort did these dreams cause you? Did they ever wake you up?** [IF YES:] *(What happened when you woke up? How long did it take you to get back to sleep?)* [LISTEN FOR REPORT OF ANXIOUS AROUSAL, YELLING, ACTING OUT THE NIGHTMARE] *(Did your dreams ever affect anyone else? How so?)* 0 None 1 Mild, minimal distress, may not have awoken 2 Moderate, awoke in distress but readily returned to sleep 3 Severe, considerable distress, difficulty returning to sleep 4 Extreme, incapacitating distress, did not return to sleep *QV (specify)* _____	*F* ____ *I* ____ Past month *F* ____ *I* ____ *Sx:* Y N Lifetime *F* *I* ____ *Sx:* Y N

3. (B-3) acting or feeling as if the traumatic event were recurring (includes a sense of reliving the experience, illusions, hallucinations, and dissociative flashback episodes, including those that occur on awakening or when intoxicated). **Note:** In young children, trauma-specific reenactment may occur.

Frequency	***Intensity***	***Past week***
Have you ever suddenly acted or felt as if (EVENT) were happening again? *(Have you ever had flashbacks about [EVENT]?)* [IF NOT CLEAR:] *(Did this ever occur while you were awake, or only in dreams?)* [EXCLUDE IF OCCURRED ONLY DURING DREAMS] **Tell me more about that. How often has that happened in the past month *(week)*?** 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How much did it seem as if (EVENT) were happening again?** *(Were you confused about where you actually were or what you were doing at the time?)* **How long did it last? What did you do while this was happening?** *(Did other people notice your behavior? What did they say?)* 0 No reliving 1 Mild, somewhat more realistic than just thinking about event 2 Moderate, definite but transient dissociative quality, still very aware of surroundings, daydreaming quality 3 Severe, strongly dissociative (reports images, sounds, or smells) but retained some awareness of surroundings 4 Extreme, complete dissociation (flashback), no awareness of surroundings, may be unresponsive, possible amnesia for the episode (blackout) ***QV (specify)*** _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx: Y N* ***Lifetime*** *F* *I* ____ *Sx: Y N*

4. (B-4) intense psychological distress at exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event

Frequency	***Intensity***	***Past week***
Have you ever gotten emotionally upset when something reminded you of (EVENT)? *(Has anything ever triggered bad feelings related to [EVENT]?)* **What kinds of reminders made you upset? How often in the past month *(week)*?** 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How much distress or discomfort did (REMINDERS) cause you? How long did it last? How much did it interfere with your life?** 0 None 1 Mild, minimal distress or disruption of activities 2 Moderate, distress clearly present but still manageable, some disruption of activities 3 Severe, considerable distress, marked disruption of activities 4 Extreme, incapacitating distress, unable to continue activities ***QV (specify)*** _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx: Y N* ***Lifetime*** *F* *I* ____ *Sx: Y N*

5. (B-5) physiological reactivity on exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event

Frequency	***Intensity***	***Past week***
Have you ever had any physical reactions when something reminded you of (EVENT)? *(Did your body ever react in some way when something reminded you of [EVENT]?)* **Can you give me some examples?** *(Did your heart race or did your breathing change? What about sweating or feeling really tense or shaky?)* **What kinds of reminders triggered these reactions? How often in the past month *(week)*?** 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How strong were (PHYSICAL REACTIONS)? How long did they last?** *(Did they last even after you were out of the situation?)* 0 No physical reactivity 1 Mild, minimal reactivity 2 Moderate, physical reactivity clearly present, may be sustained if exposure continues 3 Severe, marked physical reactivity, sustained throughout exposure 4 Extreme, dramatic physical reactivity, sustained arousal even after exposure has ended ***QV (specify)*** _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx:* *Y* *N* ***Lifetime*** *F* *I* ____ *Sx:* *Y* *N*

Criterion C. Persistent avoidance of stimuli associated with the trauma and numbing of general responsiveness (not present before the trauma), as indicated by three (or more) of the following:

6. (C-1) efforts to avoid thoughts, feelings, or conversations associated with the trauma

Frequency	***Intensity***	***Past week***
Have you ever tried to avoid thoughts or feelings about (EVENT)? *(What kinds of thoughts or feelings did you try to avoid?)* **What about trying to avoid talking with other people about it?** *(Why is that?)* **How often in the past month *(week)*?** 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How much effort did you make to avoid (THOUGHTS/FEELINGS/CONVERSATIONS)?** *(What kinds of things did you do? What about drinking or using medication or street drugs?)* [CONSIDER ALL ATTEMPTS AT AVOIDANCE, INCLUDING DISTRACTION, SUPPRESSION, AND USE OF ALCOHOL/DRUGS] **How much did that interfere with your life?** 0 None 1 Mild, minimal effort, little or no disruption of activities 2 Moderate, some effort, avoidance definitely present, some disruption of activities 3 Severe, considerable effort, marked avoidance, marked disruption of activities, or involvement in certain activities as avoidant strategy 4 Extreme, drastic attempts at avoidance, unable to continue activities, or excessive involvement in certain activities as avoidant strategy ***QV (specify)*** _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx:* *Y* *N* ***Lifetime*** *F* *I* ____ *Sx:* *Y* *N*

7. (C-2) efforts to avoid activities, places, or people that arouse recollections of the trauma

Frequency	***Intensity***	***Past week***
Have you ever tried to avoid certain activities, places, or people that reminded you of (EVENT)? *(What kinds of things did you avoid? Why is that?)* **How often in the past month *(week)*?** 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How much effort did you make to avoid (ACTIVITIES/PLACES/PEOPLE)?** *(What did you do instead?)* **How much did that interfere with your life?** 0 None 1 Mild, minimal effort, little or no disruption of activities 2 Moderate, some effort, avoidance definitely present, some disruption of activities 3 Severe, considerable effort, marked avoidance, marked disruption of activities or involvement in certain activities as avoidant strategy 4 Extreme, drastic attempts at avoidance, unable to continue activities, or excessive involvement in certain activities as avoidant strategy ***QV (specify)*** _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx:* Y N ***Lifetime*** *F* *I* ____ *Sx:* Y N

8. (C-3) inability to recall an important aspect of the trauma

Frequency	***Intensity***	***Past week***
Have you had difficulty remembering some important parts of (EVENT)? Tell me more about that. *(Do you feel you should be able to remember these things? Why do you think you can't?)* **In the past month *(week)*, how much of the important parts of (EVENT) have you had difficulty remembering?** *(What parts do you still remember?)* 0 None, clear memory 1 Few aspects not remembered (less than 10%) 2 Some aspects not remembered (approx 20-30%) 3 Many aspects not remembered (approx 50-60%) 4 Most or all aspects not remembered (more than 80%) ***Description/Examples***	**How much difficulty did you have recalling important parts of (EVENT)?** *(Were you able to recall more if you tried?)* 0 None 1 Mild, minimal difficulty 2 Moderate, some difficulty, could recall with effort 3 Severe, considerable difficulty, even with effort 4 Extreme, completely unable to recall important aspects of event ***QV (specify)*** _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx:* Y N ***Lifetime*** *F* *I* ____ *Sx:* Y N

9. (C-4) markedly diminished interest or participation in significant activities

Frequency	***Intensity***	***Past week***
Have you been less interested in activities that you used to enjoy? *(What kinds of things have you lost interest in? Are there some things you don't do at all anymore? Why is that?)* [EXCLUDE IF NO OPPORTUNITY, IF PHYSICALLY UNABLE, OR IF DEVELOPMENTALLY APPROPRIATE CHANGE IN PREFERRED ACTIVITIES] **In the past month *(week)*, how many activities have you been less interested in?** *(What kinds of things do you still enjoy doing?)* **When did you first start to feel that way?** *(After the [EVENT]?)* 0 None 1 Few activities (less than 10%) 2 Some activities (approx 20-30%) 3 Many activities (approx 50-60%) 4 Most or all activities (more than 80%) ***Description/Examples***	**How strong was your loss of interest?** *(Would you enjoy [ACTIVITIES] once you got started?)* 0 No loss of interest 1 Mild, slight loss of interest, probably would enjoy after starting activities 2 Moderate, definite loss of interest, but still has some enjoyment of activities 3 Severe, marked loss of interest in activities 4 Extreme, complete loss of interest, no longer participates in any activities ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx: Y N* ***Lifetime*** *F* *I* ____ *Sx: Y N*

10. (C-5) feeling of detachment or estrangement from others

Frequency	***Intensity***	***Past week***
Have you felt distant or cut off from other people? What was that like? How much of the time in the past month *(week)* have you felt that way? When did you first start to feel that way? *(After the [EVENT]?)* 0 None of the time 1 Very little of the time (less than 10%) 2 Some of the time (approx 20-30%) 3 Much of the time (approx 50-60%) 4 Most or all of the time (more than 80%) ***Description/Examples***	**How strong were your feelings of being distant or cut off from others?** *(Who do you feel closest to? How many people do you feel comfortable talking with about personal things?)* 0 No feelings of detachment or estrangement 1 Mild, may feel "out of synch" with others 2 Moderate, feelings of detachment clearly present, but still feels some interpersonal connection 3 Severe, marked feelings of detachment or estrangement from most people, may feel close to only one or two people 4 Extreme, feels completely detached or estranged from others, not close with anyone ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx: Y N* ***Lifetime*** *F* *I* ____ *Sx: Y N*

11. (C-6) restricted range of affect (e.g., unable to have loving feelings)

Frequency	***Intensity***	***Past week***
Have there been times when you felt emotionally numb or had trouble experiencing feelings like love or happiness? What was that like? *(What feelings did you have trouble experiencing?)* **How much of the time in the past month *(week)* have you felt that way? When did you first start having trouble experiencing (EMOTIONS)?** *(After the [EVENT]?)* 0 None of the time 1 Very little of the time (less than 10%) 2 Some of the time (approx 20-30%) 3 Much of the time (approx 50-60%) 4 Most or all of the time (more than 80%) ***Description/Examples***	**How much trouble did you have experiencing (EMOTIONS)?** *(What kinds of feelings were you still able to experience?)* [INCLUDE OBSERVATIONS OF RANGE OF AFFECT DURING INTERVIEW] 0 No reduction of emotional experience 1 Mild, slight reduction of emotional experience 2 Moderate, definite reduction of emotional experience, but still able to experience most emotions 3 Severe, marked reduction of experience of at least two primary emotions (e.g., love, happiness) 4 Extreme, completely lacking emotional experience ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	F ____ I ____ ***Past month*** F ____ I ____ Sx: Y N ***Lifetime*** F I ____ Sx: Y N

12. (C-7) sense of a foreshortened future (e.g., does not expect to have a career, marriage, children, or a normal life span)

Frequency	***Intensity***	***Past week***
Have there been times when you felt there is no need to plan for the future, that somehow your future will be cut short? Why is that? [RULE OUT REALISTIC RISKS SUCH AS LIFE-THREATENING MEDICAL CONDITIONS] **How much of the time in the past month *(week)* have you felt that way? When did you first start to feel that way?** *(After the [EVENT]?)* 0 None of the time 1 Very little of the time (less than 10%) 2 Some of the time (approx 20-30%) 3 Much of the time (approx 50-60%) 4 Most or all of the time (more than 80%) ***Description/Examples***	**How strong was this feeling that your future will be cut short?** *(How long do you think you will live? How convinced are you that you will die prematurely?)* 0 No sense of a foreshortened future 1 Mild, slight sense of a foreshortened future 2 Moderate, sense of a foreshortened future definitely present, but no specific prediction about longevity 3 Severe, marked sense of a foreshortened future, may make specific prediction about longevity 4 Extreme, overwhelming sense of a foreshortened future, completely convinced of premature death ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	F ____ I ____ ***Past month*** F ____ I ____ Sx: Y N ***Lifetime*** F I ____ Sx: Y N

Criterion D. Persistent symptoms of increased arousal (not present before the trauma), as indicated by two (or more) of the following:

13. (D-1) difficulty falling or staying asleep

Frequency	*Intensity*	*Past week*
Have you had any problems falling or staying asleep? How often in the past month *(week)*? When did you first start having problems sleeping? *(After the [EVENT]?)* 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day Sleep onset problems? Y N Mid-sleep awakening? Y N Early a.m. awakening? Y N Total # hrs sleep/night _____ Desired # hrs sleep/night _____	**How much of a problem did you have with your sleep?** *(How long did it take you to fall asleep? How often did you wake up in the night? Did you often wake up earlier than you wanted to? How many total hours did you sleep each night?)* 0 No sleep problems 1 Mild, slightly longer latency, or minimal difficulty staying asleep (up to 30 minutes loss of sleep) 2 Moderate, definite sleep disturbance, clearly longer latency, or clear difficulty staying asleep (30-90 minutes loss of sleep) 3 Severe, much longer latency, or marked difficulty staying asleep (90 min to 3 hrs loss of sleep) 4 Extreme, very long latency, or profound difficulty staying asleep (> 3 hrs loss of sleep) ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	F ____ I ____ *Past month* F ____ I ____ Sx: Y N *Lifetime* F I ____ Sx: Y N

14. (D-2) irritability or outbursts of anger

Frequency	*Intensity*	*Past week*
Have there been times when you felt especially irritable or showed strong feelings of anger? Can you give me some examples? How often in the past month *(week)*? When did you first start feeling that way? *(After the [EVENT]?)* 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How strong was your anger?** *(How did you show it?)* [IF REPORTS SUPPRESSION:] *(How hard was it for you to keep from showing your anger?)* **How long did it take you to calm down? Did your anger cause you any problems?** 0 No irritability or anger 1 Mild, minimal irritability, may raise voice when angry 2 Moderate, definite irritability or attempts to suppress anger, but can recover quickly 3 Severe, marked irritability or marked attempts to suppress anger, may become verbally or physically aggressive when angry 4 Extreme, pervasive anger or drastic attempts to suppress anger, may have episodes of physical violence ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	F ____ I ____ *Past month* F ____ I ____ Sx: Y N *Lifetime* F I ____ Sx: Y N

15. (D-3) difficulty concentrating

Frequency	***Intensity***	***Past week***
Have you found it difficult to concentrate on what you were doing or on things going on around you? What was that like? How much of the time in the past month *(week)*? When did you first start having trouble concentrating? *(After the [EVENT]?)* 0 None of the time 1 Very little of the time (less than 10%) 2 Some of the time (approx 20-30%) 3 Much of the time (approx 50-60%) 4 Most or all of the time (more than 80%) ***Description/Examples***	**How difficult was it for you to concentrate?** [INCLUDE OBSERVATIONS OF CONCENTRATION AND ATTENTION IN INTERVIEW] **How much did that interfere with your life?** 0 No difficulty with concentration 1 Mild, only slight effort needed to concentrate, little or no disruption of activities 2 Moderate, definite loss of concentration but could concentrate with effort, some disruption of activities 3 Severe, marked loss of concentration even with effort, marked disruption of activities 4 Extreme, complete inability to concentrate, unable to engage in activities ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx:* Y N ***Lifetime*** *F* *I* ____ *Sx:* Y N

16. (D-4) hypervigilance

Frequency	***Intensity***	***Past week***
Have you been especially alert or watchful, even when there was no real need to be? *(Have you felt as if you were constantly on guard?)* **Why is that? How much of the time in the past month *(week)*? When did you first start acting that way?** *(After the [EVENT]?)* 0 None of the time 1 Very little of the time (less than 10%) 2 Some of the time (approx 20-30%) 3 Much of the time (approx 50-60%) 4 Most or all of the time (more than 80%) ***Description/Examples***	**How hard did you try to be watchful of things going on around you?** [INCLUDE OBSERVATIONS OF HYPERVIGILANCE IN INTERVIEW] **Did your (HYPERVIGILANCE) cause you any problems?** 0 No hypervigilance 1 Mild, minimal hypervigilance, slight heightening of awareness 2 Moderate, hypervigilance clearly present, watchful in public (e.g., chooses safe place to sit in a restaurant or movie theater) 3 Severe, marked hypervigilance, very alert, scans environment for danger, exaggerated concern for safety of self/family/home 4 Extreme, excessive hypervigilance, efforts to ensure safety consume significant time and energy and may involve extensive safety/checking behaviors, marked watchfulness during interview ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx:* Y N ***Lifetime*** *F* *I* ____ *Sx:* Y N

17. (D-5) exaggerated startle response

Frequency	***Intensity***	***Past week***
Have you had any strong startle reactions? When did that happen? *(What kinds of things made you startle?)* **How often in the past month *(week)*? When did you first have these reactions?** *(After the [EVENT]?)* 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How strong were these startle reactions?** *(How strong were they compared to how most people would respond?)* **How long did they last?** 0 No startle reaction 1 Mild, minimal reaction 2 Moderate, definite startle reaction, feels "jumpy" 3 Severe, marked startle reaction, sustained arousal following initial reaction 4 Extreme, excessive startle reaction, overt coping behavior (e.g., combat veteran who "hits the dirt") ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx: Y N* ***Lifetime*** *F* *I* ____ *Sx: Y N*

Criterion E. Duration of the disturbance (symptoms in Criteria B, C, and D) is more than 1 month.

18. onset of symptoms

[IF NOT ALREADY CLEAR:] **When did you first start having (PTSD SYMPTOMS) you've told me about?** *(How long after the trauma did they start? More than six months?)*	_____ ***total # months delay in onset*** ***With delayed onset (≥ 6 months)?*** ***NO YES***

19. duration of symptoms

		Current	***Lifetime***
[CURRENT] **How long have these (PTSD SYMPTOMS) lasted altogether?** [LIFETIME] **How long did these (PTSD SYMPTOMS) last altogether?**	*Duration more than 1 month?* *Total # months duration* *Acute (< 3 months) or chronic (≥ 3 months)?*	***NO YES*** _____ ***acute chronic***	***NO YES*** _____ ***acute chronic***

Criterion F. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

20. subjective distress

		Past week
[CURRENT] **Overall, how much have you been bothered by these (PTSD SYMPTOMS) you've told me about?** [CONSIDER DISTRESS REPORTED ON EARLIER ITEMS] [LIFETIME] **Overall, how much were you bothered by these (PTSD SYMPTOMS) you've told me about?** [CONSIDER DISTRESS REPORTED ON EARLIER ITEMS]	0 None 1 Mild, minimal distress 2 Moderate, distress clearly present but still manageable 3 Severe, considerable distress 4 Extreme, incapacitating distress	____ ***Past month*** ____ ***Lifetime*** ____

21. impairment in social functioning

[CURRENT] **Have these (PTSD SYMPTOMS) affected your relationships with other people? How so?** [CONSIDER IMPAIRMENT IN SOCIAL FUNCTIONING REPORTED ON EARLIER ITEMS] [LIFETIME] **Did these (PTSD SYMPTOMS) affect your social life? How so?** [CONSIDER IMPAIRMENT IN SOCIAL FUNCTIONING REPORTED ON EARLIER ITEMS]	0 No adverse impact 1 Mild impact, minimal impairment in social functioning 2 Moderate impact, definite impairment, but many aspects of social functioning still intact 3 Severe impact, marked impairment, few aspects of social functioning still intact 4 Extreme impact, little or no social functioning	*Past week* ____ *Past month* ____ *Lifetime* ____

22. impairment in occupational or other important area of functioning

[CURRENT -- IF NOT ALREADY CLEAR] **Are you working now?** IF YES: **Have these (PTSD SYMPTOMS) affected your work or your ability to work? How so?** [CONSIDER REPORTED WORK HISTORY, INCLUDING NUMBER AND DURATION OF JOBS, AS WELL AS THE QUALITY OF WORK RELATIONSHIPS. IF PREMORBID FUNCTIONING IS UNCLEAR, INQUIRE ABOUT WORK EXPERIENCES BEFORE THE TRAUMA. FOR CHILD/ADOLESCENT TRAUMAS, ASSESS PRE-TRAUMA SCHOOL PERFORMANCE AND POSSIBLE PRESENCE OF BEHAVIOR PROBLEMS] IF NO: **Have these (PTSD SYMPTOMS) affected any other important part of your life?** [AS APPROPRIATE, SUGGEST EXAMPLES SUCH AS PARENTING, HOUSEWORK, SCHOOLWORK, VOLUNTEER WORK, ETC.] **How so?** [LIFETIME -- IF NOT ALREADY CLEAR] **Were you working then?** IF YES: **Did these (PTSD SYMPTOMS) affect your work or your ability to work? How so?** [CONSIDER REPORTED WORK HISTORY, INCLUDING NUMBER AND DURATION OF JOBS, AS WELL AS THE QUALITY OF WORK RELATIONSHIPS. IF PREMORBID FUNCTIONING IS UNCLEAR, INQUIRE ABOUT WORK EXPERIENCES BEFORE THE TRAUMA. FOR CHILD/ADOLESCENT TRAUMAS, ASSESS PRE-TRAUMA SCHOOL PERFORMANCE AND POSSIBLE PRESENCE OF BEHAVIOR PROBLEMS] IF NO: **Did these (PTSD SYMPTOMS) affect any other important part of your life?** [AS APPROPRIATE, SUGGEST EXAMPLES SUCH AS PARENTING, HOUSEWORK, SCHOOLWORK, VOLUNTEER WORK, ETC.] **How so?**	0 No adverse impact 1 Mild impact, minimal impairment in occupational/other important functioning 2 Moderate impact, definite impairment, but many aspects of occupational/other important functioning still intact 3 Severe impact, marked impairment, few aspects of occupational/other important functioning still intact 4 Extreme impact, little or no occupational/other important functioning	*Past week* ____ *Past month* ____ *Lifetime* ____

Global Ratings

23. global validity

ESTIMATE THE OVERALL VALIDITY OF RESPONSES. CONSIDER FACTORS SUCH AS COMPLIANCE WITH THE INTERVIEW, MENTAL STATUS (E.G., PROBLEMS WITH CONCENTRATION, COMPREHENSION OF ITEMS, DISSOCIATION), AND EVIDENCE OF EFFORTS TO EXAGGERATE OR MINIMIZE SYMPTOMS.	0 1 2 3 4	Excellent, no reason to suspect invalid responses Good, factors present that may adversely affect validity Fair, factors present that definitely reduce validity Poor, substantially reduced validity Invalid responses, severely impaired mental status or possible deliberate "faking bad" or "faking good"

24. global severity

ESTIMATE THE OVERALL SEVERITY OF PTSD SYMPTOMS. CONSIDER DEGREE OF SUBJECTIVE DISTRESS, DEGREE OF FUNCTIONAL IMPAIRMENT, OBSERVATIONS OF BEHAVIORS IN INTERVIEW, AND JUDGMENT REGARDING REPORTING STYLE.	0 1 2 3 4	No clinically significant symptoms, no distress and no functional impairment Mild, minimal distress or functional impairment Moderate, definite distress or functional impairment but functions satisfactorily with effort Severe, considerable distress or functional impairment, limited functioning even with effort Extreme, marked distress or marked impairment in two or more major areas of functioning	*Past week* ____ *Past month* ____ *Lifetime* ____

25. global improvement

RATE TOTAL OVERALL IMPROVEMENT PRESENT SINCE THE INITIAL RATING. IF NO EARLIER RATING, ASK HOW THE SYMPTOMS ENDORSED HAVE CHANGED OVER THE PAST 6 MONTHS. RATE THE DEGREE OF CHANGE, WHETHER OR NOT, IN YOUR JUDGMENT, IT IS DUE TO TREATMENT.	0 1 2 3 4 5	Asymptomatic Considerable improvement Moderate improvement Slight improvement No improvement Insufficient information

Current PTSD Symptoms

Criterion A met (traumatic event)? NO YES

_____ *# Criterion B sx (≥ 1)?* NO YES

_____ *# Criterion C sx (≥ 3)?* NO YES

_____ *# Criterion D sx (≥ 2)?* NO YES

Criterion E met (duration ≥ 1 month)? NO YES

Criterion F met (distress/impairment)? NO YES

CURRENT PTSD (Criteria A-F met)? NO YES

IF CURRENT PTSD CRITERIA ARE MET, SKIP TO ASSOCIATED FEATURES.

IF CURRENT CRITERIA ARE NOT MET, ASSESS FOR LIFETIME PTSD. IDENTIFY A PERIOD OF AT LEAST A MONTH SINCE THE TRAUMATIC EVENT IN WHICH SYMPTOMS WERE WORSE.

Since the (EVENT), has there been a time when these (PTSD SYMPTOMS) were a lot worse than they have been in the past month? When was that? How long did it last? *(At least a month?)*

IF MULTIPLE PERIODS IN THE PAST: **When were you bothered the most by these (PTSD SYMPTOMS)?**

IF AT LEAST ONE PERIOD, INQUIRE ITEMS 1-17, CHANGING FREQUENCY PROMPTS TO REFER TO WORST PERIOD: **During that time, did you (EXPERIENCE SYMPTOM)? How often?**

Lifetime PTSD Symptoms

Criterion A met (traumatic event)? NO YES

_____ *# Criterion B sx (≥ 1)?* NO YES

_____ *# Criterion C sx (≥ 3)?* NO YES

_____ *# Criterion D sx (≥ 2)?* NO YES

Criterion E met (duration ≥ 1 month)? NO YES

Criterion F met (distress/impairment)? NO YES

LIFETIME PTSD (Criteria A-F met)? NO YES

Associated Features

26. guilt over acts of commission or omission

Frequency	*Intensity*	*Past week*
Have you felt guilty about anything you did or didn't do during (EVENT)? Tell me more about that. *(What do you feel guilty about?)* **How much of the time have you felt that way in the past month *(week)*?** 0 None of the time 1 Very little of the time (less than 10%) 2 Some of the time (approx 20-30%) 3 Much of the time (approx 50-60%) 4 Most or all of the time (more than 80%) *Description/Examples*	**How strong were these feelings of guilt? How much distress or discomfort did they cause?** 0 No feelings of guilt 1 Mild, slight feelings of guilt 2 Moderate, guilt feelings definitely present, some distress but still manageable 3 Severe, marked feelings of guilt, considerable distress 4 Extreme, pervasive feelings of guilt, self-condemnation regarding behavior, incapacitating distress *QV (specify)* _____	*F* ____ *I* ____ *Past month* *F* ____ *I* ____ *Sx:* Y N *Lifetime* *F* *I* ____ *Sx:* Y N

27. survivor guilt [APPLICABLE ONLY IF MULTIPLE VICTIMS]

Frequency	*Intensity*	*Past week*
Have you felt guilty about surviving (EVENT) when others did not? Tell me more about that. *(What do you feel guilty about?)* **How much of the time have you felt that way in the past month *(week)*?** 0 None of the time 1 Very little of the time (less than 10%) 2 Some of the time (approx 20-30%) 3 Much of the time (approx 50-60%) 4 Most or all of the time (more than 80%) 8 N/A *Description/Examples*	**How strong were these feelings of guilt? How much distress or discomfort did they cause?** 0 No feelings of guilt 1 Mild, slight feelings of guilt 2 Moderate, guilt feelings definitely present, some distress but still manageable 3 Severe, marked feelings of guilt, considerable distress 4 Extreme, pervasive feelings of guilt, self-condemnation regarding survival, incapacitating distress *QV (specify)* _____	*F* ____ *I* ____ *Past month* *F* ____ *I* ____ *Sx:* Y N *Lifetime* *F* *I* ____ *Sx:* Y N

28. a reduction in awareness of his or her surroundings (e.g., "being in a daze")

Frequency	***Intensity***	***Past week***
Have there been times when you felt out of touch with things going on around you, like you were in a daze? What was that like? [DISTINGUISH FROM FLASHBACK EPISODES] **How often has that happened in the past month *(week)*?** [IF NOT CLEAR:] *(Was it due to an illness or the effects of drugs or alcohol?)* **When did you first start feeling that way?** *(After the [EVENT]?)* 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How strong was this feeling of being out of touch or in a daze?** *(Were you confused about where you actually were or what you were doing at the time?)* **How long did it last? What did you do while this was happening?** *(Did other people notice your behavior? What did they say?)* 0 No reduction in awareness 1 Mild, slight reduction in awareness 2 Moderate, definite but transient reduction in awareness, may report feeling "spacy" 3 Severe, marked reduction in awareness, may persist for several hours 4 Extreme, complete loss of awareness of surroundings, may be unresponsive, possible amnesia for the episode (blackout) ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	*Past week* *F* ____ *I* ____ *Past month* *F* ____ *I* ____ *Sx:* Y N *Lifetime* *F* *I* ____ *Sx:* Y N

29. derealization

Frequency	***Intensity***	***Past week***
Have there been times when things going on around you seemed unreal or very strange and unfamiliar? [IF NO:] *(What about times when people you knew suddenly seemed unfamiliar?)* **What was that like? How often has that happened in the past month *(week)*?** [IF NOT CLEAR:] *(Was it due to an illness or the effects of drugs or alcohol?)* **When did you first start feeling that way?** *(After the [EVENT]?)* 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How strong was (DEREALIZATION)? How long did it last? What did you do while this was happening?** *(Did other people notice your behavior? What did they say?)* 0 No derealization 1 Mild, slight derealization 2 Moderate, definite but transient derealization 3 Severe, considerable derealization, marked confusion about what is real, may persist for several hours 4 Extreme, profound derealization, dramatic loss of sense of reality or familiarity ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	*Past week* *F* ____ *I* ____ *Past month* *F* ____ *I* ____ *Sx:* Y N *Lifetime* *F* *I* ____ *Sx:* Y N

30. depersonalization

Frequency	***Intensity***	***Past week***
Have there been times when you felt as if you were outside of your body, watching yourself as if you were another person? [IF NO:] *(What about times when your body felt strange or unfamiliar to you, as if it had changed in some way?)* **What was that like? How often has that happened in the past month *(week)*?** [IF NOT CLEAR:] *(Was it due to an illness or the effects of drugs or alcohol?)* **When did you first start feeling that way?** *(After the [EVENT]?)* 0 Never 1 Once or twice 2 Once or twice a week 3 Several times a week 4 Daily or almost every day ***Description/Examples***	**How strong was (DEPERSONALIZATION)? How long did it last? What did you do while this was happening?** *(Did other people notice your behavior? What did they say?)* 0 No depersonalization 1 Mild, slight depersonalization 2 Moderate, definite but transient depersonalization 3 Severe, considerable depersonalization, marked sense of detachment from self, may persist for several hours 4 Extreme, profound depersonalization, dramatic sense of detachment from self ***QV (specify)*** _____ ***Trauma-related?*** *1 definite 2 probable 3 unlikely* *Current* _____ *Lifetime* _____	*F* ____ *I* ____ ***Past month*** *F* ____ *I* ____ *Sx: Y N* ***Lifetime*** *F* *I* ____ *Sx: Y N*

Appendix E

M.I.N.I.

MINI INTERNATIONAL NEUROPSYCHIATRIC INTERVIEW

English Version 6.0.0

DSM-IV

USA: **D. Sheehan[1], J. Janavs, K. Harnett-Sheehan, M. Sheehan, C. Gray.**
[1]University of South Florida College of Medicine- Tampa, USA

EU: **Y. Lecrubier[2], E. Weiller, T. Hergueta, C. Allgulander, N. Kadri, D. Baldwin, C. Even.**
[2]Centre Hospitalier Sainte-Anne – Paris, France

DISCLAIMER

Our aim is to assist in the assessment and tracking of patients with greater efficiency and accuracy. Before action is taken on any data collected and processed by this program, it should be reviewed and interpreted by a licensed clinician.

This program is not designed or intended to be used in the place of a full medical and psychiatric evaluation by a qualified licensed physician – psychiatrist. It is intended only as a tool to facilitate accurate data collection and processing of symptoms elicited by trained personnel.

M.I.N.I. 6.0.0 (October 10, 2010) (10/10/10)

Patient Name:		***Patient Number:***				
Date of Birth:		***Time Interview Began:***				
Interviewer's Name:		***Time Interview Ended:***				
Date of Interview:		***Total Time:***				

	MODULES	TIME FRAME	MEETS CRITERIA	DSM-IV-TR	ICD-10	PRIMARY DIAGNOSIS
A	MAJOR DEPRESSIVE EPISODE	Current (2 weeks)	☐			
		Past	☐			
		Recurrent	☐			
	MAJOR DEPRESSIVE DISORDER	Current (2 weeks)	☐	296.20-296.26 Single	F32.x	☐
		Past	☐	296.20-296.26 Single	F32.x	☐
		Recurrent	☐	296.30-296.36 Recurrent	F33.x	☐
B	SUICIDALITY	Current (Past Month) ☐ Low ☐ Moderate ☐ High	☐			
C	MANIC EPISODE	Current	☐			
		Past	☐			
	HYPOMANIC EPISODE	Current	☐			
		Past	☐	☐ Not Explored		
	BIPOLAR I DISORDER	Current	☐	296.0x-296.6x	F30.x- F31.9	☐
		Past	☐	296.0x-296.6x	F30.x- F31.9	☐
	BIPOLAR II DISORDER	Current	☐	296.89	F31.8	☐
		Past	☐	296.89	F31.8	☐
	BIPOLAR DISORDER NOS	Current	☐	296.80	F31.9	☐
		Past	☐	296.80	F31.9	☐
D	PANIC DISORDER	Current (Past Month)	☐	300.01/300.21	F40.01-F41.0	☐
		Lifetime	☐			
E	AGORAPHOBIA	Current	☐	300.22	F40.00	☐
F	SOCIAL PHOBIA (Social Anxiety Disorder)	Current (Past Month)				
		Generalized	☐	300.23	F40.1	☐
		Non-Generalized	☐	300.23	F40.1	☐
G	OBSESSIVE-COMPULSIVE DISORDER	Current (Past Month)	☐	300.3	F42.8	☐
H	POSTTRAUMATIC STRESS DISORDER	Current (Past Month)	☐	309.81	F43.1	☐
I	ALCOHOL DEPENDENCE	Past 12 Months	☐	303.9	F10.2x	☐
	ALCOHOL ABUSE	Past 12 Months	☐	305.00	F10.1	☐
J	SUBSTANCE DEPENDENCE (Non-alcohol)	Past 12 Months	☐	304.00-.90/305.20-.90	F11.2X-F19.2X	☐
	SUBSTANCE ABUSE (Non-alcohol)	Past 12 Months	☐	304.00-.90/305.20-.90	F11.1-F19.1	☐
K	PSYCHOTIC DISORDERS	Lifetime	☐	295.10-295.90/297.1/	F20.xx-F29	☐
		Current	☐	297.3/293.81/293.82/	293.89/298.8/298.9	
	MOOD DISORDER WITH	Lifetime	☐	296.24/296.34/296.44	F32.3/F33.3/	☐
	PSYCHOTIC FEATURES	Current	☐	296.24/296.34/296.44	F30.2/F31.2/F31.5	
					F31.8/F31.9/F39	☐
L	ANOREXIA NERVOSA	Current (Past 3 Months)	☐	307.1	F50.0	☐
M	BULIMIA NERVOSA	Current (Past 3 Months)	☐	307.51	F50.2	☐
	ANOREXIA NERVOSA, BINGE EATING/PURGING TYPE	Current	☐	307.1	F50.0	☐
N	GENERALIZED ANXIETY DISORDER	Current (Past 6 Months)	☐	300.02	F41.1	☐
O	MEDICAL, ORGANIC, DRUG CAUSE RULED OUT		☐ No	☐ Yes ☐ Uncertain		
P	ANTISOCIAL PERSONALITY DISORDER	Lifetime	☐	301.7	F60.2	☐

IDENTIFY THE PRIMARY DIAGNOSIS BY CHECKING THE APPROPRIATE CHECK BOX.
(Which problem troubles you the most or dominates the others or came first in the natural history?)

The translation from DSM-IV-TR to ICD-10 coding is not always exact. For more information on this topic see Schulte-Markwort. Crosswalks ICD-10/DSM-IV-TR. Hogrefe & Huber Publishers 2006.

GENERAL INSTRUCTIONS

The M.I.N.I. was designed as a brief structured interview for the major Axis I psychiatric disorders in DSM-IV and ICD-10. Validation and reliability studies have been done comparing the M.I.N.I. to the SCID-P for DSM-III-R and the CIDI (a structured interview developed by the World Health Organization). The results of these studies show that the M.I.N.I. has similar reliability and validity properties, but can be administered in a much shorter period of time (mean 18.7 ± 11.6 minutes, median 15 minutes) than the above referenced instruments. It can be used by clinicians, after a brief training session. Lay interviewers require more extensive training.

INTERVIEW:

In order to keep the interview as brief as possible, inform the patient that you will conduct a clinical interview that is more structured than usual, with very precise questions about psychological problems which require a yes or no answer.

GENERAL FORMAT:

The M.I.N.I. is divided into **modules** identified by letters, each corresponding to a diagnostic category.
•At the beginning of each diagnostic module (except for psychotic disorders module), screening question(s) corresponding to the main criteria of the disorder are presented in a **gray box**.
•At the end of each module, diagnostic box(es) permit the clinician to indicate whether diagnostic criteria are met.

CONVENTIONS:

Sentences written in « normal font » should be read exactly as written to the patient in order to standardize the assessment of diagnostic criteria.

Sentences written in « CAPITALS » should not be read to the patient. They are instructions for the interviewer to assist in the scoring of the diagnostic algorithms.

Sentences written in « **bold** » indicate the time frame being investigated. The interviewer should read them as often as necessary. Only symptoms occurring during the time frame indicated should be considered in scoring the responses.

Answers with an arrow above them (➡) indicate that one of the criteria necessary for the diagnosis(es) is not met. In this case, the interviewer should go to the end of the module, circle « **NO** » in all the diagnostic boxes and move to the next module.

When terms are separated by a *slash (/)* the interviewer should read only those symptoms known to be present in the patient (for example, question G6).

Phrases in (parentheses) are clinical examples of the symptom. These may be read to the patient to clarify the question.

RATING INSTRUCTIONS:

All questions must be rated. The rating is done at the right of each question by circling either Yes or No. Clinical judgment by the rater should be used in coding the responses. Interviewers need to be sensitive to the diversity of cultural beliefs in their administration of questions and rating of responses. The rater should ask for examples when necessary, to ensure accurate coding. The patient should be encouraged to ask for clarification on any question that is not absolutely clear.
The clinician should be sure that each dimension of the question is taken into account by the patient (for example, time frame, frequency, severity, and/or alternatives).
Symptoms better accounted for by an organic cause or by the use of alcohol or drugs should not be coded positive in the M.I.N.I. The M.I.N.I. Plus has questions that investigate these issues.

For any questions, suggestions, need for a training session or information about updates of the M.I.N.I., please contact:

David V Sheehan, M.D., M.B.A.
University of South Florida College of Medicine
3515 East Fletcher Ave, Tampa, FL USA 33613-4706
tel : +1 813-956-8437; fax : +1 813-974-4575
e-mail : dsheehan@health.usf.edu

Christian Even, M.D.
Centre Hospitalier Sainte-Anne
Clinique des Maladies Mentales de l'Encéphale
100 rue de la Santé, 75674 Paris Cedex 14, France
tel : +33 (0) 1 53 80 49 41; fax : +33 (0) 1 45 65 88 54
e-mail: even-sainteanne@orange.fr

A. MAJOR DEPRESSIVE EPISODE

(➡ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN ALL DIAGNOSTIC BOXES, AND MOVE TO THE NEXT MODULE)

A1	a	Were you ever depressed or down, most of the day, nearly every day, for two weeks?	NO	YES
		IF NO, CODE NO TO **A1b**: IF YES ASK:		
	b	For the past two weeks, were you depressed or down, most of the day, nearly every day?	NO	YES
A2	a	Were you ever much less interested in most things or much less able to enjoy the things you used to enjoy most of the time, for two weeks?	NO	YES
		IF NO, CODE NO TO **A2b**: IF YES ASK:		
	b	In the past two weeks, were you much less interested in most things or much less able to enjoy the things you used to enjoy, most of the time?	NO	YES
		➡ IS **A1a** OR **A2a** CODED YES?	NO	YES

A3 IF **A1b** OR **A2b** = YES: EXPLORE THE CURRENT AND THE MOST SYMPTOMATIC **PAST** EPISODE, OTHERWISE
IF **A1b** AND **A2b** = NO: EXPLORE ONLY THE MOST SYMPTOMATIC **PAST** EPISODE

Over that two week period, when you felt depressed or uninterested:

			Past 2 Weeks		Past Episode	
	a	Was your appetite decreased or increased nearly every day? Did your weight decrease or increase without trying intentionally (i.e., by ±5% of body weight or ±8 lb or ± 3.5 kg, for a 160 lb/70 kg person in a month)? IF YES TO EITHER, CODE YES.	NO	YES	NO	YES
	b	Did you have trouble sleeping nearly every night (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?	NO	YES	NO	YES
	c	Did you talk or move more slowly than normal or were you fidgety, restless or having trouble sitting still almost every day?	NO	YES	NO	YES
	d	Did you feel tired or without energy almost every day?	NO	YES	NO	YES
	e	Did you feel worthless or guilty almost every day?	NO	YES	NO	YES
		IF YES, ASK FOR EXAMPLES. THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA. Current Episode ❒ No ❒ Yes; Past Episode ❒ No ❒ Yes				
	f	Did you have difficulty concentrating or making decisions almost every day?	NO	YES	NO	YES
	g	Did you repeatedly consider hurting yourself, feel suicidal, or wish that you were dead? Did you attempt suicide or plan a suicide? IF YES TO EITHER, CODE YES.	NO	YES	NO	YES
A4		Did these symptoms cause significant problems at home, at work, socially, at school or in some other important way?	NO	YES	NO	YES
A5		In between 2 episodes of depression, did you ever have an interval of at least 2 months, without any significant depression or any significant loss of interest?			NO	YES

ARE **5** OR MORE ANSWERS (**A1-A3**) CODED **YES** AND IS **A4** CODED YES FOR THAT TIME FRAME?

SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.

IF **A5** IS CODED **YES,** CODE **YES** FOR RECURRENT.

NO	YES
MAJOR DEPRESSIVE EPISODE	
CURRENT	❒
PAST	❒
RECURRENT	❒

A6 a How many episodes of depression did you have in your lifetime? _____

Between each episode there must be at least 2 months without any significant depression.

B. SUICIDALITY

	In the past month did you:			Points
B1	Have any accident? This includes taking too much of your medication accidentally. IF NO TO B1, SKIP TO B2; IF YES, ASK B1a:	NO	YES	0
B1a	Plan or intend to hurt yourself in any accident either actively or passively (e.g. by not avoiding a risk)? IF NO TO B1a, SKIP TO B2: IF YES, ASK B1b:	NO	YES	0
B1b	Intend to die as a result of any accident?	NO	YES	0
B2	Feel hopeless?	NO	YES	1
B3	Think that you would be better off dead or wish you were dead?	NO	YES	1
B4	Think about hurting or injuring yourself or have mental images of harming yourself, with at least some intent or awareness that you might die as a result?	NO	YES	4
B5	Think about suicide (killing yourself)?	NO	YES	6

IF NO TO B5, SKIP TO B7. OTHERWISE ASK:

Frequency		Intensity	
Occasionally	❒	Mild	❒
Often	❒	Moderate	❒
Very often	❒	Severe	❒

B6	Have difficulty restraining yourself from acting on these impulses?	NO	YES	8
B7	Have a suicide method in mind (e.g. how)?	NO	YES	8
B8	Have a suicide plan in mind (e.g. when or where)?	NO	YES	8
B9	Intend to act on thoughts of killing yourself?	NO	YES	8
B10	Intend to die as a result of a suicidal act?	NO	YES	8
B11	Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die? This includes times when you were going to kill yourself, but were interrupted or stopped yourself, before harming yourself. IF NO TO B11, SKIP TO B12.	NO	YES	9
B11a	Take active steps to prepare to kill yourself, but you did not start the suicide attempt?	NO	YES	
B11b	Start a suicide attempt, but then **you stopped yourself** before harming yourself (aborted attempt)?	NO	YES	
B11c	Start a suicide attempt, but then **someone or something stopped you** before harming yourself (interrupted attempt)?	NO	YES	
B12	Injure yourself on purpose without intending to kill yourself?	NO	YES	4
B13	Attempt suicide (to kill yourself)?	NO	YES	10

A suicide attempt means you did something where you could possibly be injured, with at least a slight intent to die.

IF NO, SKIP TO B14:

Hope to be rescued / survive ❒
Expected / intended to die ❒

In your lifetime:

B14 Did you ever make a suicide attempt (try to kill yourself)? NO YES 4

"A suicide attempt is any self injurious behavior, with at least some intent (> 0) to die as a result or if intent can be inferred, e.g. if it is clearly not an accident or the individual thinks the act could be lethal, even though denying intent." (C-CASA definition). Posner K et al. Am J Psychiatry 164:7, July 2007.

IS AT LEAST **1** OF THE ABOVE (EXCEPT B1) CODED **YES**?

IF YES, ADD THE TOTAL POINTS FOR THE ANSWERS (B1-B14) CHECKED 'YES' AND SPECIFY THE SUICIDALITY SCORE AS INDICATED IN THE DIAGNOSTIC BOX:

MAKE ANY ADDITIONAL COMMENTS ABOUT YOUR ASSESSMENT OF THIS PATIENT'S CURENT AND NEAR FUTURE SUICIDALITY IN THE SPACE BELOW:

NO **YES**

SUICIDALITY CURRENT

1-8 points Low ❒
9-16 points Moderate ❒
≥ 17 points High ❒

C. MANIC AND HYPOMANIC EPISODES

(➡ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN MANIC AND HYPOMANIC DIAGNOSTIC BOXES, AND MOVE TO NEXT MODULE)

Do you have any family history of manic depressive illness or bipolar disorder, or any family member who had mood swings treated with a medication like lithium, sodium valproate (Depakote) or lamotrigine (Lamictal)? NO YES
THIS QUESTION IS NOT A CRITERION FOR BIPOLAR DISORDER, BUT IS ASKED TO INCREASE THE CLINICIAN'S VIGILANCE ABOUT THE RISK FOR BIPOLAR DISORDER .
IF YES, PLEASE SPECIFY WHO:_____

C1	a	Have you **ever** had a period of time when you were feeling 'up' or 'high' or 'hyper' or so full of energy or full of yourself that you got into trouble, - or that other people thought you were not your usual self? (Do not consider times when you were intoxicated on drugs or alcohol.) IF PATIENT IS PUZZLED OR UNCLEAR ABOUT WHAT YOU MEAN BY 'UP' OR 'HIGH' OR 'HYPER', CLARIFY AS FOLLOWS: By 'up' or 'high' or 'hyper' I mean: having elated mood; increased energy; needing less sleep; having rapid thoughts; being full of ideas; having an increase in productivity, motivation, creativity, or impulsive behavior; phoning or working excessively or spending more money. IF NO, CODE NO TO **C1b**: IF **YES** ASK:	NO	YES
	b	Are you currently feeling 'up' or 'high' or 'hyper' or full of energy?	NO	YES
C2	a	Have you **ever** been persistently irritable, for several days, so that you had arguments or verbal or physical fights, or shouted at people outside your family? Have you or others noticed that you have been more irritable or over reacted, compared to other people, even in situations that you felt were justified? IF NO, CODE NO TO **C2b**: IF **YES** ASK:	NO	YES
	b	Are you currently feeling persistently irritable?	NO	YES
			➡	
		IS **C1a** OR **C2a** CODED **YES**?	NO	YES

C3 IF **C1b** OR **C2b** = **YES**: EXPLORE THE **CURRENT** AND THE MOST SYMPTOMATIC **PAST** EPISODE, OTHERWISE
IF **C1b** AND **C2b** = **NO**: EXPLORE ONLY THE MOST SYMPTOMATIC **PAST** EPISODE

During the times when you felt high, full of energy, or irritable did you:

		Current Episode		Past Episode	
a	Feel that you could do things others couldn't do, or that you were an especially important person? IF **YES**, ASK FOR EXAMPLES. THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA. Current Episode ❒ No ❒ Yes Past Episode ❒ No ❒ Yes	NO	YES	NO	YES
b	Need less sleep (for example, feel rested after only a few hours sleep)?	NO	YES	NO	YES
c	Talk too much without stopping, or so fast that people had difficulty understanding?	NO	YES	NO	YES
d	Have racing thoughts?	NO	YES	NO	YES

		Current Episode		Past Episode	
e	Become easily distracted so that any little interruption could distract you?	NO	YES	NO	YES
f	Have a significant increase in your activity or drive, at work, at school, socially or sexually or did you become physically or mentally restless?	NO	YES	NO	YES
g	Want so much to engage in pleasurable activities that you ignored the risks or consequences (for example, spending sprees, reckless driving, or sexual indiscretions)?	NO	YES	NO	YES
C3	SUMMARY: WHEN RATING CURRENT EPISODE: IF C1b IS NO, ARE 4 OR MORE C3 ANSWERS CODED YES? IF C1b IS YES, ARE 3 OR MORE C3 ANSWERS CODED YES? WHEN RATING PAST EPISODE: IF C1a IS NO, ARE 4 OR MORE C3 ANSWERS CODED YES? IF C1a IS YES, ARE 3 OR MORE C3 ANSWERS CODED YES? CODE YES ONLY IF THE ABOVE 3 OR 4 SYMPTOMS OCCURRED DURING THE SAME TIME PERIOD. RULE: ELATION/EXPANSIVENESS REQUIRES ONLY THREE C3 SYMPTOMS, WHILE IRRITABLE MOOD ALONE REQUIRES 4 OF THE C3 SYMPTOMS.	NO	YES	NO	YES
C4	What is the longest time these symptoms lasted?				
	a) 3 days or less		❒		❒
	b) 4 to 6 days		❒		❒
	c) 7 days or more		❒		❒
C5	Were you hospitalized for these problems? IF YES, STOP HERE AND CIRCLE YES IN MANIC EPISODE FOR THAT TIME FRAME.	NO	YES	NO	YES
C6	Did these symptoms cause significant problems at home, at work, socially in your relationships with others, at school or in some other important way?	NO	YES	NO	YES

ARE **C3** SUMMARY AND **C5** AND **C6** CODED **YES**?

OR

ARE **C3** SUMMARY AND **C4c** AND **C6** CODED **YES** AND IS **C5** CODED **NO**?

SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.

NO **YES**

MANIC EPISODE

CURRENT ❒
PAST ❒

Is C3 SUMMARY **CODED YES** AND ARE **C5** AND **C6** CODED **NO** AND IS EITHER **C4b** OR **C4c** CODED **YES**?

OR

ARE **C3** SUMMARY AND **C4b** AND **C6** CODED **YES** AND IS **C5** CODED **NO?**

SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.

IF **YES** TO CURRENT MANIC EPISODE, THEN CODE CURRENT HYPOMANIC EPISODE AS **NO.**

IF **YES** TO PAST MANIC EPISODE, THEN CODE PAST HYPOMANIC EPISODE AS **NOT EXPLORED.**

HYPOMANIC EPISODE

CURRENT ❒ **NO**
❒ **YES**

PAST ❒ **NO**
❒ **YES**
❒ **NOT EXPLORED**

ARE **C3** SUMMARY AND **C4a** CODED **YES** AND IS **C5** CODED **NO**?

SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.

IF **YES** TO CURRENT MANIC EPISODE OR HYPOMANIC EPISODE,
THEN CODE CURRENT HYPOMANIC SYMPTOMS AS **NO.**

IF **YES** TO PAST MANIC EPISODE OR YES TO PAST HYPOMANIC EPISODE,
THEN CODE PAST HYPOMANIC SYMPTOMS AS **NOT EXPLORED.**

HYPOMANIC SYMPTOMS

CURRENT ❒ **NO**
❒ **YES**

PAST ❒ **NO**
❒ **YES**
❒ **NOT EXPLORED**

C7 a) IF MANIC EPISODE IS POSITIVE FOR EITHER CURRENT OR PAST ASK:
Did you have 2 or more of these (manic) episodes lasting 7 days or more (**C4c**) in your lifetime (including the current episode if present)? NO YES

b) IF MANIC OR HYPOMANIC EPISODE IS POSITIVE FOR EITHER CURRENT OR PAST ASK:
Did you have 2 or more of these (hypomanic) episodes lasting just 4 to 6 days (**C4b**) in your lifetime (including the current episode)? NO YES

c) IF THE PAST "HYPOMANIC SYMPTOMS" CATEGORY IS CODED POSITIVE ASK:
Did you have these hypomanic symptoms lasting only 1 to 3 days (**C4a**) 2 or more times in your lifetime, (including the current episode if present)? NO YES

D. PANIC DISORDER

(➡ MEANS : CIRCLE **NO** IN D5, D6 AND D7 AND SKIP TO E1)

D1	a	Have you, on more than one occasion, had spells or attacks when you **suddenly** felt anxious, frightened, uncomfortable or uneasy, even in situations where most people would not feel that way?	➡ NO	YES
	b	Did the spells surge to a peak within 10 minutes of starting?	➡ NO	YES
D2		At any time in the past, did any of those spells or attacks come on unexpectedly or occur in an unpredictable or unprovoked manner?	➡ NO	YES
D3		Have you ever had one such attack followed by a month or more of persistent concern about having another attack, or worries about the consequences of the attack - or did you make a significant change in your behavior because of the attacks (e.g., shopping only with a companion, not wanting to leave your house, visiting the emergency room repeatedly, or seeing your doctor more frequently because of the symptoms)?	NO	YES
D4		**During the worst attack that you can remember:**		
	a	Did you have skipping, racing or pounding of your heart?	NO	YES
	b	Did you have sweating or clammy hands?	NO	YES
	c	Were you trembling or shaking?	NO	YES
	d	Did you have shortness of breath or difficulty breathing?	NO	YES
	e	Did you have a choking sensation or a lump in your throat?	NO	YES
	f	Did you have chest pain, pressure or discomfort?	NO	YES
	g	Did you have nausea, stomach problems or sudden diarrhea?	NO	YES
	h	Did you feel dizzy, unsteady, lightheaded or faint?	NO	YES
	i	Did things around you feel strange, unreal, detached or unfamiliar, or did you feel outside of or detached from part or all of your body?	NO	YES
	j	Did you fear that you were losing control or going crazy?	NO	YES
	k	Did you fear that you were dying?	NO	YES
	l	Did you have tingling or numbness in parts of your body?	NO	YES
	m	Did you have hot flushes or chills?	NO	YES
D5		ARE BOTH **D3,** AND **4** OR MORE **D4** ANSWERS, CODED **YES**? IF YES TO D5, SKIP TO D7.	NO	YES *PANIC DISORDER LIFETIME*
D6		IF **D5** = **NO,** ARE ANY D4 ANSWERS CODED **YES**? THEN SKIP TO **E1.**	NO	YES *LIMITED SYMPTOM ATTACKS LIFETIME*

D7	In the past month, did you have such attacks repeatedly (2 or more), and did you have persistent concern about having another attack, or worry about the consequences of the attacks, or did you change your behavior in any way because of the attacks?	NO	YES *PANIC DISORDER CURRENT*

E. AGORAPHOBIA

E1	Do you feel anxious or uneasy in places or situations where help might not be available or escape might be difficult, like being in a crowd, standing in a line (queue), when you are alone away from home or alone at home, or when crossing a bridge, or traveling in a bus, train or car or where you might have a panic attack or the panic-like symptoms we just spoke about?	NO	YES

IF **E1** = **NO**, CIRCLE **NO** IN **E2**.

E2	Do you fear these situations so much that you avoid them, or suffer through them, or need a companion to face them?	NO	YES *AGORAPHOBIA CURRENT*

IS **E2** (CURRENT AGORAPHOBIA) CODED **YES**

and

IS **D7** (CURRENT PANIC DISORDER) CODED **YES**?

NO **YES**

PANIC DISORDER with Agoraphobia CURRENT

IS **E2** (CURRENT AGORAPHOBIA) CODED **NO**

and

IS **D7** (CURRENT PANIC DISORDER) CODED **YES**?

NO **YES**

PANIC DISORDER without Agoraphobia CURRENT

IS **E2** (CURRENT AGORAPHOBIA) CODED **YES**

and

IS **D5** (PANIC DISORDER LIFETIME) CODED **NO**?

NO **YES**

AGORAPHOBIA, CURRENT without history of Panic Disorder

F. SOCIAL PHOBIA (Social Anxiety Disorder)

(➡ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

F1	In the past month, did you have persistent fear and significant anxiety at being watched, being the focus of attention, or of being humiliated or embarrassed? This includes things like speaking in public, eating in public or with others, writing while someone watches, or being in social situations.	➡ NO	YES
F2	Is this social fear excessive or unreasonable and does it almost always make you anxious?	➡ NO	YES
F3	Do you fear these social situations so much that you avoid them or suffer through them most of the time?	➡ NO	YES
F4	Do these social fears disrupt your normal work, school or social functioning or cause you significant distress?	NO	YES

SUBTYPES

Do you fear and avoid 4 or more social situations?

If YES Generalized social phobia (social anxiety disorder)

If NO Non-generalized social phobia (social anxiety disorder)

EXAMPLES OF SUCH SOCIAL SITUATIONS TYPICALLY INCLUDE

- INITIATING OR MAINTAINING A CONVERSATION,
- PARTICIPATING IN SMALL GROUPS,
- DATING,
- SPEAKING TO AUTHORITY FIGURES,
- ATTENDING PARTIES,
- PUBLIC SPEAKING,
- EATING IN FRONT OF OTHERS,
- URINATING IN A PUBLIC WASHROOM, ETC.

NOTE TO INTERVIEWER: PLEASE ASSESS WHETHER THE SUBJECT'S FEARS ARE RESTRICTED TO NON-GENERALIZED ("ONLY 1 OR SEVERAL") SOCIAL SITUATIONS OR EXTEND TO GENERALIZED ("MOST") SOCIAL SITUATIONS. "MOST" SOCIAL SITUATIONS IS USUALLY OPERATIONALIZED TO MEAN 4 OR MORE SOCIAL SITUATIONS, ALTHOUGH THE DSM-IV DOES NOT EXPLICITLY STATE THIS.

SOCIAL PHOBIA
(Social Anxiety Disorder)
CURRENT

GENERALIZED ❒

NON-GENERALIZED ❒

G. OBSESSIVE-COMPULSIVE DISORDER

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE **NO** AND MOVE TO THE NEXT MODULE)

G1	In the past month, have you been bothered by recurrent thoughts, impulses, or images that were unwanted, distasteful, inappropriate, intrusive, or distressing? - (For example, the idea that you were dirty, contaminated or had germs, **or** fear of contaminating others, **or** fear of harming someone even though it disturbs or distresses you, or fear you would act on some impulse, **or** fear or superstitions that you would be responsible for things going wrong, **or** obsessions with sexual thoughts, images or impulses, **or** hoarding, collecting, **or** religious obsessions.) (DO NOT INCLUDE SIMPLY EXCESSIVE WORRIES ABOUT REAL LIFE PROBLEMS. DO NOT INCLUDE OBSESSIONS DIRECTLY RELATED TO EATING DISORDERS, SEXUAL DEVIATIONS, PATHOLOGICAL GAMBLING, OR ALCOHOL OR DRUG ABUSE BECAUSE THE PATIENT MAY DERIVE PLEASURE FROM THE ACTIVITY AND MAY WANT TO RESIST IT ONLY BECAUSE OF ITS NEGATIVE CONSEQUENCES.)	NO YES ↓ SKIP TO **G4**
G2	Did they keep coming back into your mind even when you tried to ignore or get rid of them?	NO YES ↓ SKIP TO **G4**
G3	Do you think that these obsessions are the product of your own mind and that they are not imposed from the outside?	NO YES obsessions
G4	In the past month, did you do something repeatedly without being able to resist doing it, like washing or cleaning excessively, counting or checking things over and over, or repeating, collecting, arranging things, or other superstitious rituals?	NO YES compulsions
	IS **G3** OR **G4** CODED **YES**?	➡ NO YES
G5	At any point, did you recognize that either these obsessive thoughts or these compulsive behaviors were excessive or unreasonable?	➡ NO YES
G6	In the past month, did these obsessive thoughts and/or compulsive behaviors significantly interfere with your normal routine, your work or school, your usual social activities, or relationships, or did they take more than one hour a day?	**NO** **YES** ***O.C.D. CURRENT***

H. POSTTRAUMATIC STRESS DISORDER

(➡ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

H1	Have you ever experienced or witnessed or had to deal with an extremely traumatic event that included actual or threatened death or serious injury to you or someone else? EXAMPLES OF TRAUMATIC EVENTS INCLUDE: SERIOUS ACCIDENTS, SEXUAL OR PHYSICAL ASSAULT, A TERRORIST ATTACK, BEING HELD HOSTAGE, KIDNAPPING, FIRE, DISCOVERING A BODY, WAR, OR NATURAL DISASTER, WITNESSING THE VIOLENT OR SUDDEN DEATH OF SOMEONE CLOSE TO YOU, OR A LIFE THREATENING ILLNESS.	➡ NO	YES
H2	Did you respond with intense fear, helplessness or horror?	➡ NO	YES
H3	During the past month, have you re-experienced the event in a distressing way (such as in dreams, intense recollections, flashbacks or physical reactions) or did you have intense distress when you were reminded about the event or exposed to a similar event?	➡ NO	YES
H4	**In the past month:**		
a	Have you avoided thinking about or talking about the event ?	NO	YES
b	Have you avoided activities, places or people that remind you of the event?	NO	YES
c	Have you had trouble recalling some important part of what happened?	NO	YES
d	Have you become much less interested in hobbies or social activities?	NO	YES
e	Have you felt detached or estranged from others?	NO	YES
f	Have you noticed that your feelings are numbed?	NO	YES
g	Have you felt that your life will be shortened or that you will die sooner than other people?	NO	YES
	ARE **3** OR MORE **H4** ANSWERS CODED **YES**?	➡ NO	YES
H5	**In the past month:**		
a	Have you had difficulty sleeping?	NO	YES
b	Were you especially irritable or did you have outbursts of anger?	NO	YES
c	Have you had difficulty concentrating?	NO	YES
d	Were you nervous or constantly on your guard?	NO	YES
e	Were you easily startled?	NO	YES
	ARE **2** OR MORE **H5** ANSWERS CODED **YES**?	➡ NO	YES

H6	During the past month, have these problems significantly interfered with your work, school or social activities, or caused significant distress?	NO	YES

POSTTRAUMATIC STRESS DISORDER CURRENT

I. ALCOHOL DEPENDENCE / ABUSE

(➡ MEANS: GO TO DIAGNOSTIC BOXES, CIRCLE **NO** IN BOTH AND MOVE TO THE NEXT MODULE)

			➡ NO	YES
I1		**In the past 12 months**, have you had 3 or more alcoholic drinks, - within a 3 hour period, - on 3 or more occasions?	NO	YES
I2		**In the past 12 months**:		
	a	Did you need to drink a lot more in order to get the same effect that you got when you first started drinking or did you get much less effect with continued use of the same amount?	NO	YES
	b	When you cut down on drinking did your hands shake, did you sweat or feel agitated? Did you drink to avoid these symptoms (for example, "the shakes", sweating or agitation) or to avoid being hungover? IF **YES** TO ANY, CODE **YES**.	NO	YES
	c	During the times when you drank alcohol, did you end up drinking more than you planned when you started?	NO	YES
	d	Have you tried to reduce or stop drinking alcohol but failed?	NO	YES
	e	On the days that you drank, did you spend substantial time obtaining alcohol, drinking, or recovering from the effects of alcohol?	NO	YES
	f	Did you spend less time working, enjoying hobbies, or being with others because of your drinking?	NO	YES
	g	If your drinking caused you health or mental problems, did you still keep on drinking?	NO	YES

ARE **3** OR MORE **I2** ANSWERS CODED **YES**?

* IF YES, SKIP I3 QUESTIONS AND GO TO NEXT MODULE. "DEPENDENCE PREEMPTS ABUSE" IN DSM IV TR.

NO	YES*
ALCOHOL DEPENDENCE **CURRENT**	

I3		**In the past 12 months:**		
	a	Have you been intoxicated, high, or hungover more than once when you had other responsibilities at school, at work, or at home? Did this cause any problems? (CODE **YES** ONLY IF THIS CAUSED PROBLEMS.)	NO	YES
	b	Were you intoxicated more than once in any situation where you were physically at risk, for example, driving a car, riding a motorbike, using machinery, boating, etc.?	NO	YES
	c	Did you have legal problems more than once because of your drinking, for example, an arrest or disorderly conduct?	NO	YES
	d	If your drinking caused problems with your family or other people, did you still keep on drinking?	NO	YES

ARE **1** OR MORE **I3** ANSWERS CODED **YES**?

NO	YES
	ALCOHOL ABUSE **CURRENT**

J. SUBSTANCE DEPENDENCE / ABUSE (NON-ALCOHOL)

(➡ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN ALL DIAGNOSTIC BOXES, AND MOVE TO THE NEXT MODULE)

Now I am going to show you / read to you a list of street drugs or medicines.

			➡	
J1	a	**In the past 12 months**, did you take any of these drugs more than once, to get high, to feel elated, to get "a buzz" or to change your mood?	NO	YES

CIRCLE EACH DRUG TAKEN:

Stimulants: amphetamines, "speed", crystal meth, "crank", "rush", Dexedrine, Ritalin, diet pills.

Cocaine: snorting, IV, freebase, crack, "speedball".

Narcotics: heroin, morphine, Dilaudid, opium, Demerol, methadone, Darvon, codeine, Percodan, Vicodin, OxyContin.

Hallucinogens: LSD ("acid"), mescaline, peyote, psilocybin, STP, "mushrooms", "ecstasy", MDA, MDMA.

Phencyclidine: PCP ("Angel Dust", "Peace Pill", "Tranq", "Hog"), or ketamine ("Special K").

Inhalants: "glue", ethyl chloride, "rush", nitrous oxide ("laughing gas"), amyl or butyl nitrate ("poppers").

Cannabis: marijuana, hashish ("hash"), THC, "pot", "grass", "weed", "reefer".

Tranquilizers: Quaalude, Seconal ("reds"), Valium, Xanax, Librium, Ativan, Dalmane, Halcion, barbiturates, Miltown, GHB, Roofinol, "Roofies".

Miscellaneous: steroids, nonprescription sleep or diet pills. Cough Medicine? Any others?

SPECIFY THE MOST USED DRUG(S): _____

WHICH DRUG(S) CAUSE THE BIGGEST PROBLEMS?: _____

FIRST EXPLORE THE DRUG CAUSING THE BIGGEST PROBLEMS AND MOST LIKELY TO MEET DEPENDENCE / ABUSE CRITERIA.

IF MEETS CRITERIA FOR ABUSE OR DEPENDENCE, SKIP TO THE NEXT MODULE. OTHERWISE, EXPLORE THE NEXT MOST PROBLEMATIC DRUG.

J2 **Considering your use of (NAME OF DRUG / DRUG CLASS SELECTED), in the past 12 months:**

	a	Have you found that you needed to use much more (NAME OF DRUG / DRUG CLASS SELECTED) to get the same effect that you did when you first started taking it?	NO	YES
	b	When you reduced or stopped using (NAME OF DRUG / DRUG CLASS SELECTED), did you have withdrawal symptoms (aches, shaking, fever, weakness, diarrhea, nausea, sweating, heart pounding, difficulty sleeping, or feeling agitated, anxious, irritable, or depressed)? Did you use any drug(s) to keep yourself from getting sick (withdrawal symptoms) or so that you would feel better?	NO	YES
		IF **YES** TO EITHER, CODE **YES**.		
	c	Have you often found that when you used (NAME OF DRUG / DRUG CLASS SELECTED), you ended up taking more than you thought you would?	NO	YES
	d	Have you tried to reduce or stop taking (NAME OF DRUG / DRUG CLASS SELECTED) but failed?	NO	YES
	e	On the days that you used (NAME OF DRUG / DRUG CLASS SELECTED), did you spend substantial time (>2 HOURS), obtaining, using or recovering from the drug, or thinking about the drug?	NO	YES
	f	Did you spend less time working, enjoying hobbies, or being with family or friends because of your drug use?	NO	YES
	g	If (NAME OF DRUG / DRUG CLASS SELECTED) caused you health or mental problems, did you still keep on using it?	NO	YES

ARE **3** OR MORE **J2** ANSWERS CODED **YES**?

SPECIFY DRUG(S): _____

* IF YES, SKIP J3 QUESTIONS, MOVE TO NEXT DISORDER.
"DEPENDENCE PREEMPTS ABUSE" IN DSM IV TR.

NO	YES *

SUBSTANCE DEPENDENCE
CURRENT

Considering your use of (NAME THE DRUG CLASS SELECTED), in the past 12 months:

J3	a	Have you been intoxicated, high, or hungover from (NAME OF DRUG / DRUG CLASS SELECTED) more than once, when you had other responsibilities at school, at work, or at home? Did this cause any problem? (CODE **YES** ONLY IF THIS CAUSED PROBLEMS.)	NO	YES
	b	Have you been high or intoxicated from (NAME OF DRUG / DRUG CLASS SELECTED) more than once in any situation where you were physically at risk (for example, driving a car, riding a motorbike, using machinery, boating, etc.)?	NO	YES
	c	Did you have legal problems more than once because of your drug use, for example, an arrest or disorderly conduct?	NO	YES
	d	If (NAME OF DRUG / DRUG CLASS SELECTED) caused problems with your family or other people, did you still keep on using it?	NO	YES

ARE **1** OR MORE **J3** ANSWERS CODED **YES**?

SPECIFY DRUG(S): _____

NO	YES

SUBSTANCE ABUSE
CURRENT

K. PSYCHOTIC DISORDERS AND MOOD DISORDER WITH PSYCHOTIC FEATURES

ASK FOR AN EXAMPLE OF EACH QUESTION ANSWERED POSITIVELY. CODE **YES** ONLY IF THE EXAMPLES CLEARLY SHOW A DISTORTION OF THOUGHT OR OF PERCEPTION OR IF THEY ARE NOT CULTURALLY APPROPRIATE. BEFORE CODING, INVESTIGATE WHETHER DELUSIONS QUALIFY AS "BIZARRE".

DELUSIONS ARE "BIZARRE" IF: CLEARLY IMPLAUSIBLE, ABSURD, NOT UNDERSTANDABLE, AND CANNOT DERIVE FROM ORDINARY LIFE EXPERIENCE.
HALLUCINATIONS ARE SCORED "BIZARRE" IF: A VOICE COMMENTS ON THE PERSON'S THOUGHTS OR BEHAVIOR, OR WHEN TWO OR MORE VOICES ARE CONVERSING WITH EACH OTHER.
THE PURPOSE OF THIS MODULE IS TO EXCLUDE PATIENTS WITH PSYCHOTIC DISORDERS. THIS MODULE NEEDS EXPERIENCE.

		Now I am going to ask you about unusual experiences that some people have.			BIZARRE
K1	a	Have you ever believed that people were spying on you, or that someone was plotting against you, or trying to hurt you? **NOTE**: ASK FOR EXAMPLES TO RULE OUT ACTUAL STALKING.	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do you currently believe these things?	NO	YES	YES →**K6**
K2	a	Have you ever believed that someone was reading your mind or could hear your thoughts, or that you could actually read someone's mind or hear what another person was thinking?	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do you currently believe these things?	NO	YES	YES →**K6**
K3	a	Have you ever believed that someone or some force outside of yourself put thoughts in your mind that were not your own, or made you act in a way that was not your usual self? Have you ever felt that you were possessed? CLINICIAN: ASK FOR EXAMPLES AND DISCOUNT ANY THAT ARE NOT PSYCHOTIC.	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do you currently believe these things?	NO	YES	YES →**K6**
K4	a	Have you ever believed that you were being sent special messages through the TV, radio, internet, newspapers, books, or magazines or that a person you did not personally know was particularly interested in you?	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do you currently believe these things?	NO	YES	YES →**K6**
K5	a	Have your relatives or friends ever considered any of your beliefs odd or unusual? INTERVIEWER: ASK FOR EXAMPLES. ONLY CODE **YES** IF THE EXAMPLES ARE **CLEARLY** DELUSIONAL IDEAS NOT EXPLORED IN QUESTIONS K1 TO K4, FOR EXAMPLE, SOMATIC OR RELIGIOUS DELUSIONS OR DELUSIONS OF GRANDIOSITY, JEALOUSY, GUILT, RUIN OR DESTITUTION, ETC.	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do they currently consider your beliefs strange?	NO	YES	YES
K6	a	Have you ever heard things other people couldn't hear, such as voices?	NO	YES	
		IF YES TO VOICE HALLUCINATION: Was the voice commenting on your thoughts or behavior or did you hear two or more voices talking to each other?	NO		YES
	b	**IF YES OR YES BIZARRE TO K6a:** have you heard sounds / voices in the past month?	NO	YES	
		IF YES TO VOICE HALLUCINATION: Was the voice commenting on your thoughts or behavior or did you hear two or more voices talking to each other?	NO		YES →**K8b**

K7 a Have you ever had visions when you were awake or have you ever seen things other people couldn't see? NO YES

CLINICIAN: CHECK TO SEE IF THESE ARE CULTURALLY INAPPROPRIATE.

b **IF YES:** have you seen these things in the past month? NO YES

CLINICIAN'S JUDGMENT

K8 b IS THE PATIENT CURRENTLY EXHIBITING INCOHERENCE, DISORGANIZED SPEECH, OR MARKED LOOSENING OF ASSOCIATIONS? NO YES

K9 b IS THE PATIENT CURRENTLY EXHIBITING DISORGANIZED OR CATATONIC BEHAVIOR? NO YES

K10 b ARE NEGATIVE SYMPTOMS OF SCHIZOPHRENIA, E.G. SIGNIFICANT AFFECTIVE FLATTENING, POVERTY OF SPEECH (ALOGIA) OR AN INABILITY TO INITIATE OR PERSIST IN GOAL-DIRECTED ACTIVITIES (AVOLITION), PROMINENT DURING THE INTERVIEW? NO YES

K11 a ARE 1 OR MORE « a » QUESTIONS FROM K1a TO K7a CODED **YES OR YES BIZARRE** AND IS EITHER:

MAJOR DEPRESSIVE EPISODE, (CURRENT, RECURRENT OR PAST)
OR
MANIC OR HYPOMANIC EPISODE, (CURRENT OR PAST) CODED **YES**? NO YES
↳ **K13**

IF NO TO K11 a, CIRCLE NO IN BOTH 'MOOD DISORDER WITH PSYCHOTIC FEATURES' DIAGNOSTIC BOXES AND MOVE TO K13.

b You told me earlier that you had period(s) when you felt (depressed/high/persistently irritable).

Were the beliefs and experiences you just described (SYMPTOMS CODED **YES** FROM **K1a** TO **K7a**) restricted exclusively to times when you were feeling depressed/high/irritable?

IF THE PATIENT EVER HAD A PERIOD OF AT LEAST 2 WEEKS OF HAVING THESE BELIEFS OR EXPERIENCES (PSYCHOTIC SYMPTOMS) WHEN THEY WERE NOT DEPRESSED/HIGH/IRRITABLE, CODE NO TO THIS DISORDER.

IF THE ANSWER IS NO TO THIS DISORDER, ALSO CIRCLE NO TO K12 AND MOVE TO K13

NO **YES**

MOOD DISORDER WITH *PSYCHOTIC FEATURES*

LIFETIME

K12 a ARE 1 OR MORE « b » QUESTIONS FROM K1b TO K7b CODED **YES OR YES BIZARRE** AND IS EITHER:

MAJOR DEPRESSIVE EPISODE, (CURRENT)
OR
MANIC OR HYPOMANIC EPISODE, (CURRENT) CODED **YES**?

IF THE ANSWER IS YES TO THIS DISORDER (LIFETIME OR CURRENT), CIRCLE NO TO K13 AND K14 AND MOVE TO THE NEXT MODULE.

NO **YES**

MOOD DISORDER WITH *PSYCHOTIC FEATURES*

CURRENT

K13 ARE 1 OR MORE « b » QUESTIONS FROM K1b TO K6b, CODED **YES BIZARRE**?

OR

ARE 2 OR MORE « b » QUESTIONS FROM K1b TO K10b, CODED **YES** (RATHER THAN **YES BIZARRE**)?

AND DID AT LEAST TWO OF THE PSYCHOTIC SYMPTOMS OCCUR DURING THE SAME 1 MONTH PERIOD?

NO **YES**

PSYCHOTIC DISORDER
CURRENT

K14 IS **K13** CODED **YES**

OR

ARE 1 OR MORE « a » QUESTIONS FROM K1a TO K6a, CODED **YES BIZARRE**?

OR

ARE 2 OR MORE « a » QUESTIONS FROM K1a TO K7a, CODED **YES** (RATHER THAN **YES BIZARRE**)

AND DID AT LEAST TWO OF THE PSYCHOTIC SYMPTOMS OCCUR DURING THE SAME 1 MONTH PERIOD?

NO **YES**

PSYCHOTIC DISORDER
LIFETIME

L. ANOREXIA NERVOSA

(➡ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

L1	a	How tall are you?	❑ ft ❑❑ in.	
			❑❑❑ cm	
	b.	What was your lowest weight in the past 3 months?	❑❑❑ lb	
			❑❑❑ kg	
	c	IS PATIENT'S WEIGHT EQUAL TO OR BELOW THE THRESHOLD CORRESPONDING TO HIS / HER HEIGHT? (SEE TABLE BELOW)	NO ➡	YES

In the past 3 months:

L2		In spite of this low weight, have you tried not to gain weight?	NO ➡	YES
L3		Have you intensely feared gaining weight or becoming fat, even though you were underweight?	NO ➡	YES
L4	a	Have you considered yourself too big / fat or that part of your body was too big / fat?	NO	YES
	b	Has your body weight or shape greatly influenced how you felt about yourself?	NO	YES
	c	Have you thought that your current low body weight was normal or excessive?	NO ➡	YES
L5		ARE 1 OR MORE ITEMS FROM **L4** CODED **YES**?	NO ➡	YES
L6		FOR WOMEN ONLY: During the last 3 months, did you miss all your menstrual periods when they were expected to occur (when you were not pregnant)?	NO	YES

FOR WOMEN: ARE **L5** AND **L6** CODED **YES**?

FOR MEN: IS **L5** CODED **YES**?

NO **YES**

ANOREXIA NERVOSA
CURRENT

HEIGHT / WEIGHT TABLE CORRESPONDING TO A **BMI THRESHOLD** OF **17.5** KG/M^2

Height/Weight														
ft/in	4'9	4'10	4'11	5'0	5'1	5'2	5'3	5'4	5'5	5'6	5'7	5'8	5'9	5'10
lb	81	84	87	89	92	96	99	102	105	108	112	115	118	122
cm	145	147	150	152	155	158	160	163	165	168	170	173	175	178
kg	37	38	39	41	42	43	45	46	48	49	51	52	54	55

Height/Weight					
ft/in	5'11	6'0	6'1	6'2	6'3
lb	125	129	132	136	140
cm	180	183	185	188	191
kg	57	59	60	62	64

The weight thresholds above are calculated using a body mass index (BMI) equal to or below 17.5 kg/m^2 for the patient's height. This is the threshold guideline below which a person is deemed underweight by the DSM-IV and the ICD-10 Diagnostic Criteria for Research for Anorexia Nervosa.

M. BULIMIA NERVOSA

(➡ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE **NO** IN ALL DIAGNOSTIC BOXES, AND MOVE TO THE NEXT MODULE)

M1	In the past three months, did you have eating binges or times when you ate a very large amount of food within a 2-hour period?	➡ NO YES
M2	In the last 3 months, did you have eating binges as often as twice a week?	➡ NO YES
M3	During these binges, did you feel that your eating was out of control?	➡ NO YES
M4	Did you do anything to compensate for, or to prevent a weight gain from these binges, like vomiting, fasting, exercising or taking laxatives, enemas, diuretics (fluid pills), or other medications?	➡ NO YES
M5	Does your body weight or shape greatly influence how you feel about yourself?	➡ NO YES
M6	DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA?	NO YES ↓ Skip to M8
M7	Do these binges occur only when you are under (____lb/kg)? INTERVIEWER: WRITE IN THE ABOVE PARENTHESIS THE THRESHOLD WEIGHT FOR THIS PATIENT'S HEIGHT FROM THE HEIGHT / WEIGHT TABLE IN THE ANOREXIA NERVOSA MODULE.	NO YES
M8	IS **M5** CODED **YES** AND IS EITHER **M6** OR **M7** CODED **NO**?	**NO** **YES** ***BULIMIA NERVOSA*** **CURRENT**
	IS **M7** CODED **YES**?	**NO** **YES** ***ANOREXIA NERVOSA*** *Binge Eating/Purging Type* **CURRENT**

M. BULIMIA NERVOSA

(➡ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE **NO** IN ALL DIAGNOSTIC BOXES, AND MOVE TO THE NEXT MODULE)

M1	In the past three months, did you have eating binges or times when you ate a very large amount of food within a 2-hour period?	➡ NO YES
M2	In the last 3 months, did you have eating binges as often as twice a week?	➡ NO YES
M3	During these binges, did you feel that your eating was out of control?	➡ NO YES
M4	Did you do anything to compensate for, or to prevent a weight gain from these binges, like vomiting, fasting, exercising or taking laxatives, enemas, diuretics (fluid pills), or other medications?	➡ NO YES
M5	Does your body weight or shape greatly influence how you feel about yourself?	➡ NO YES
M6	DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA?	NO YES ↓ Skip to M8
M7	Do these binges occur only when you are under (____lb/kg)? INTERVIEWER: WRITE IN THE ABOVE PARENTHESIS THE THRESHOLD WEIGHT FOR THIS PATIENT'S HEIGHT FROM THE HEIGHT / WEIGHT TABLE IN THE ANOREXIA NERVOSA MODULE.	NO YES
M8	IS **M5** CODED **YES** AND IS EITHER **M6** OR **M7** CODED **NO**?	**NO** **YES** ***BULIMIA NERVOSA*** **CURRENT**
	IS **M7** CODED **YES**?	**NO** **YES** ***ANOREXIA NERVOSA*** *Binge Eating/Purging Type* **CURRENT**

N. GENERALIZED ANXIETY DISORDER

(➡ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

N1	a	Were you excessively anxious or worried about several routine things, over the past 6 months? IN ENGLISH, IF THE PATIENT IS UNCLEAR ABOUT WHAT YOU MEAN, PROBE BY ASKING (Do others think that you are a "worry wart"?) AND GET EXAMPLES.	➡ NO	YES
	b	Are these anxieties and worries present most days?	➡ NO	YES
		ARE THE PATIENT'S ANXIETY AND WORRIES RESTRICTED EXCLUSIVELY TO, OR BETTER EXPLAINED BY, ANY DISORDER PRIOR TO THIS POINT?	NO	➡ YES
N2		Do you find it difficult to control the worries?	➡ NO	YES
N3		FOR THE FOLLOWING, CODE **NO** IF THE SYMPTOMS ARE CONFINED TO FEATURES OF ANY DISORDER EXPLORED PRIOR TO THIS POINT.		
		When you were anxious over the past 6 months, did you, most of the time:		
	a	Feel restless, keyed up or on edge?	NO	YES
	b	Have muscle tension?	NO	YES
	c	Feel tired, weak or exhausted easily?	NO	YES
	d	Have difficulty concentrating or find your mind going blank?	NO	YES
	e	Feel irritable?	NO	YES
	f	Have difficulty sleeping (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?	NO	YES
		ARE **3** OR MORE **N3** ANSWERS CODED **YES?**	➡ NO	YES
N4		Do these anxieties and worries disrupt your normal work, school or social functioning or cause you significant distress?	**NO**	**YES**

GENERALIZED ANXIETY DISORDER
CURRENT

O. RULE OUT MEDICAL, ORGANIC OR DRUG CAUSES FOR ALL DISORDERS

IF THE PATIENT CODES POSITIVE FOR ANY CURRENT DISORDER ASK:

Just before these symptoms began:

O1a	Were you taking any drugs or medicines?	❒ No	❒ Yes	❒ Uncertain
O1b	Did you have any medical illness?	❒ No	❒ Yes	❒ Uncertain
	IN THE CLINICIAN'S JUDGMENT: ARE EITHER OF THESE LIKELY TO BE DIRECT CAUSES OF THE PATIENT'S DISORDER? IF NECESSARY ASK ADDITIONAL OPEN-ENDED QUESTIONS.			
O2	**SUMMARY**: HAS AN ORGANIC CAUSE BEEN RULED OUT?	❒ No	❒ Yes	❒ Uncertain

P. ANTISOCIAL PERSONALITY DISORDER

(➡ MEANS : GO TO THE DIAGNOSTIC BOX AND CIRCLE NO)

P1 **Before you were 15 years old, did you:**

a	repeatedly skip school or run away from home overnight?	NO	YES
b	repeatedly lie, cheat, "con" others, or steal?	NO	YES
c	start fights or bully, threaten, or intimidate others?	NO	YES
d	deliberately destroy things or start fires?	NO	YES
e	deliberately hurt animals or people?	NO	YES
f	force someone to have sex with you?	NO ➡	YES
	ARE **2** OR MORE **P1** ANSWERS CODED **YES**?	NO	YES

DO NOT CODE **YES** TO THE BEHAVIORS BELOW IF THEY ARE EXCLUSIVELY POLITICALLY OR RELIGIOUSLY MOTIVATED.

P2 **Since you were 15 years old, have you:**

a	repeatedly behaved in a way that others would consider irresponsible, like failing to pay for things you owed, deliberately being impulsive or deliberately not working to support yourself?	NO	YES
b	done things that are illegal even if you didn't get caught (for example, destroying property, shoplifting, stealing, selling drugs, or committing a felony)?	NO	YES
c	been in physical fights repeatedly (including physical fights with your spouse or children)?	NO	YES
d	often lied or "conned" other people to get money or pleasure, or lied just for fun?	NO	YES
e	exposed others to danger without caring?	NO	YES
f	felt no guilt after hurting, mistreating, lying to, or stealing from others, or after damaging property?	NO	YES

ARE **3** OR MORE **P2** QUESTIONS CODED **YES**?

NO	YES
ANTISOCIAL PERSONALITY DISORDER **LIFETIME**	

THIS CONCLUDES THE

REFERENCES

Sheehan DV, Lecrubier Y, Harnett-Sheehan K, Janavs J, Weiller E, Bonara LI, Keskiner A, Schinka J, Knapp E, Sheehan MF, Dunbar GC. Reliability and Validity of the MINI International Neuropsychiatric Interview (M.I.N.I.): According to the SCID-P. European Psychiatry. 1997; 12:232-241.

Lecrubier Y, Sheehan D, Weiller E, Amorim P, Bonora I, Sheehan K, Janavs J, Dunbar G. The MINI International Neuropsychiatric Interview (M.I.N.I.) A Short Diagnostic Structured Interview: Reliability and Validity According to the CIDI. European Psychiatry. 1997; 12: 224-231.

Sheehan DV, Lecrubier Y, Harnett-Sheehan K, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R, Dunbar G: The Mini International Neuropsychiatric Interview (M.I.N.I.): The Development and Validation of a Structured Diagnostic Psychiatric Interview. J. Clin Psychiatry, 1998;59(suppl 20):22-33.

Amorim P, Lecrubier Y, Weiller E, Hergueta T, Sheehan D: DSM-III-R Psychotic Disorders: procedural validity of the Mini International Neuropsychiatric Interview (M.I.N.I.). Concordance and causes for discordance with the CIDI. European Psychiatry. 1998; 13:26-34.

Scientific committee for the MINI 6.0.0:

A. Carlo Altamura, Milano, Italy
Cyril Hoschl, Praha, Czech Republic
George Papadimitriou, Athens, Greece
Hans Ågren, Göteborg, Sweden
Hans-Jürgen Möller, München, Germany
Hans-Ulrich Wittchen, Dresden, Germany
István Bitter, Budapest, Hungary
Jean-Pierre Lépine, Paris, France
Jules Angst, Zurich, Switzerland
Julio Bobes, Oviedo, Spain
Luciano Conti, Pisa, Italy
Marelli Colon-Soto MD, Puerto Rico, United States
Michael Van Ameringen MD, Toronto, Canada
Rosario Hidalgo MD, Tampa, United States
Siegfried Kasper, Vienna, Austria
Thomas Schlaepfer, Bonn, Germany

Translations	**M.I.N.I. 4.4 or earlier versions**	**M.I.N.I. 4.6/5.0, M.I.N.I. Plus 4.6/5.0 and M.I.N.I. Screen 5.0:**
Afrikaans	R. Emsley, W. Maartens	
Arabic		O. Osman, E. Al-Radi
Bengali		H. Banerjee, A. Banerjee
Braille (English)		
Brazilian Portuguese	P. Amorim	P. Amorim
Bulgarian	L.G. Hranov	
Chinese		L. Carroll, Y-J. Lee, Y-S. Chen, C-C. Chen, C-Y. Liu, C-K. Wu, H-S. Tang, K-D. Juang, Yan-Ping Zheng.
Czech		P. Svlosky
Danish	P. Bech	P. Bech, T. Schütze
Dutch/Flemish	E. Griez, K. Shruers, T. Overbeek, K. Demyttenaere	I. Van Vliet, H. Leroy, H. van Megen
English	D. Sheehan, J. Janavs, R. Baker, K. Harnett-Sheehan, E. Knapp, M. Sheehan	D. Sheehan, R. Baker, J. Janavs, K. Harnett-Sheehan, M. Sheehan
Estonian		J. Shlik, A. Aluoja, E. Khil
Farsi/Persian		K. Khooshabi, A. Zomorodi
Finnish	M. Heikkinen, M. Lijeström, O. Tuominen	M. Heikkinen, M. Lijeström, O. Tuominen
French	Y. Lecrubier, E. Weiller, I. Bonora, P. Amorim, J.P. Lepine	Y. Lecrubier, E. Weiller, P. Amorim, T. Hergueta
German	I. v. Denffer, M. Ackenheil, R. Dietz-Bauer	G. Stotz, R. Dietz-Bauer, M. Ackenheil
Greek	S. Beratis	T. Calligas, S. Beratis, GN Papidimitriou, T Matsoukas CR Soldatos
Gujarati		M. Patel, B. Patel, Organon
Hebrew	J. Zohar, Y. Sasson	R. Barda, I. Levinson, A. Aviv
Hindi		C. Mittal, K. Batra, S. Gambhir, Organon
Hungarian	I. Bitter, J. Balazs	I. Bitter, J. Balazs
Icelandic		J.G. Stefansson
Italian	I. Bonora, L. Conti, M. Piccinelli, M. Tansella, G. Cassano, Y. Lecrubier, P. Donda, E. Weiller	L. Conti, A. Rossi, P. Donda
Japanese		T. Otsubo, H. Watanabe, H. Miyaoka, K. Kamijima, J.Shinoda, K.Tanaka, Y. Okajima

Appendix F

Early Trauma Inventory Self Report-Short Form (ETISR-SF)

J. Douglas Bremner, Emory University School of Medicine, Atlanta GA

Participant Name or ID:_____ DOB:_____ Age:____ Assessment Date:_____

Part 1. General Traumas. Before the age of 18

1. Were you ever exposed to a life-threatening natural disaster?..... YES NO
2. Were you involved in a serious accident? ..... YES NO
3. Did you ever suffer a serious personal injury or illness? ..... YES NO
4. Did you ever experience the death or serious illness of a parent or a primary caretaker? ..... YES NO
5. Did you experience the divorce or separation of your parents? ..... YES NO
6. Did you experience the death or serious injury of a sibling? ..... YES NO
7. Did you ever experience the death or serious injury of a friend? ..... YES NO
8. Did you ever witness violence towards others, including family members? ..... YES NO
9. Did anyone in your family ever suffer from mental or psychiatric illness or have a a "breakdown"? ..... YES NO
10. Did your parents or primary caretaker have a problem with alcoholism or drug abuse? ..... YES NO
11. Did you ever see someone murdered? ..... YES NO

Part 2. Physical Punishment. Before the age of 18

1. Were you ever slapped in the face with an open hand? ..... YES NO
2. Were you ever burned with hot water, a cigarette or something else? ..... YES NO
3. Were you ever punched or kicked? ..... YES NO
4. Were you ever hit with an object that was thrown at you? ..... YES NO
5. Were you ever pushed or shoved? ..... YES NO

Part 3. Emotional Abuse. Before the age of 18

1. Were you often put down or ridiculed? ..... YES NO
2. Were you often ignored or made to feel that you didn't count? ..... YES NO
3. Were you often told you were no good? ..... YES NO
4. Most of the time were you treated in a cold, uncaring way or made to feel like you were not loved? ..... YES NO
5. Did your parents or caretakers often fail to understand you or your needs?..... YES NO

Part 4. Sexual Events. Before the age of 18

1. Were you ever touched in an intimate or private part of your body (e.g. breast, thighs, genitals) in a way that surprised you or made you feel uncomfortable? ..... YES NO
2. Did you ever experience someone rubbing their genitals against you?..... YES NO
3. Were you ever forced or coerced to touch another person in an intimate or private part of their body? ..... YES NO
4. Did anyone ever have genital sex with you against your will? ..... YES NO
5. Were you ever forced or coerced to perform oral sex on someone against your will?. YES NO
6. Were you ever forced or coerced to kiss someone in a sexual rather than an affectionate way? ..... YES NO

If you responded "YES" for any of the above events, answer the following for the one that has had the greatest impact on your life. In answering consider how you felt at the time of the event.

1. Did you experience emotions of intense fear, horror or helplessness?..... YES NO
2. Did you feel out-of-your-body or as if you were in a dream? ..... YES NO

Revised on 3/09

Appendix G

PTSD Checklist for *DSM-5* (PCL-5)

Version date: 11 April 2018

Reference: Weathers, F. W., Litz, B. T., Keane, T. M., Palmieri, P. A., Marx, B. P., & Schnurr, P. P. (2013). *The PTSD Checklist for DSM-5 (PCL-5) – Standard* [Measurement instrument]. Available from https://www.ptsd.va.gov/

URL: https://www.ptsd.va.gov/professional/assessment/adult-sr/ptsd-checklist.asp

Note: This is a fillable form. You may complete it electronically.

PCL-5

Instructions: Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then circle one of the numbers to the right to indicate how much you have been bothered by that problem in the past month.

In the past month, how much were you bothered by:	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Repeated, disturbing, and unwanted memories of the stressful experience?	0	1	2	3	4
2. Repeated, disturbing dreams of the stressful experience?	0	1	2	3	4
3. Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?	0	1	2	3	4
4. Feeling very upset when something reminded you of the stressful experience?	0	1	2	3	4
5. Having strong physical reactions when something reminded you of the stressful experience (for example, heart pounding, trouble breathing, sweating)?	0	1	2	3	4
6. Avoiding memories, thoughts, or feelings related to the stressful experience?	0	1	2	3	4
7. Avoiding external reminders of the stressful experience (for example, people, places, conversations, activities, objects, or situations)?	0	1	2	3	4
8. Trouble remembering important parts of the stressful experience?	0	1	2	3	4
9. Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	0	1	2	3	4
10. Blaming yourself or someone else for the stressful experience or what happened after it?	0	1	2	3	4
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame?	0	1	2	3	4
12. Loss of interest in activities that you used to enjoy?	0	1	2	3	4
13. Feeling distant or cut off from other people?	0	1	2	3	4
14. Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?	0	1	2	3	4
15. Irritable behavior, angry outbursts, or acting aggressively?	0	1	2	3	4
16. Taking too many risks or doing things that could cause you harm?	0	1	2	3	4
17. Being "superalert" or watchful or on guard?	0	1	2	3	4
18. Feeling jumpy or easily startled?	0	1	2	3	4
19. Having difficulty concentrating?	0	1	2	3	4
20. Trouble falling or staying asleep?	0	1	2	3	4

Appendix H

THE WORLD HEALTH ORGANIZATION QUALITY OF LIFE (WHOQOL) -BREF

The World Health Organization Quality of Life (WHOQOL)-BREF

WHOQOL-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

_____

_____

[The following table should be completed after the interview is finished]

		Equations for computing domain scores	Raw score	Transformed scores*	
				4-20	0-100
27.	**Domain 1**	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
28.	**Domain 2**	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
29.	**Domain 3**	Q20 + Q21 + Q22 ☐ + ☐ + ☐	a. =	b:	c:
30.	**Domain 4**	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:

* See Procedures Manual, pages 13-15

Appendix I

NTEGRATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE: A HEALTH SERVICES
RESEARCH PERSPECTIVE

Release Date: October 25, 2000

RFA: AT-01-001

National Center for Complementary and Alternative Medicine

Letter of Intent Receipt Date: December 8, 2000
Application Receipt Date: January 24, 2001

THIS RFA USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS
THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS RFA

PURPOSE

The National Center for Complementary and Alternative Medicine (NCCAM) invites research applications that investigate strategies to integrate CAM interventions with conventional medical/clinical practice and to evaluate the effects of this integration. For the purposes of this RFA, CAM is defined as healthcare practices that are not an integral part of conventional medicine. Integration is defined as the merging of CAM and conventional practice within a health care delivery system. The intent of the RFA is to 1) identify barriers and facilitators to the integration of CAM and conventional health care practices; 2) determine whether CAM research results obtained from studies conducted under ideal conditions (efficacy studies) can be translated to real-world settings (i.e., effectiveness) within an integrated model; and 3) support the evaluation of currently planned or recently initiated programs, goals of which are to improve the outcomes, quality, effectiveness, and/or cost-effectiveness of health care through the integration of CAM and conventional health care.

Projects should focus on applied research with the objective of identifying and developing sustainable, reproducible strategies to
integrate CAM research effectively into practice and/or evaluation of integration programs using appropriate concurrent comparison groups, documentation of costs and resources associated with the programs,

identification of key model components and organizational conditions that have resulted in successful integration, and evaluation of transferability to other settings. It is important to note that this initiative is targeted toward investigating integration between CAM and conventional health care delivery systems. Efficacy studies and effectiveness studies that focus on specific treatment outcomes will not be considered responsive to this RFA.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA, Integration of Complementary and Alternative Medicine: A Health Services Research Perspective, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged toapply as Principal Investigators. Questions about eligibility may be addressed to the programmatic contact listed in the INQUIRIES section.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) research project grant (R01) and exploratory/developmental grant (R21)
mechanisms. The Principal Investigator will be responsible for the planning, direction, and execution of the proposed research project.
Awards will be administered according to the most recent NIH Grants Policy Statement.

Applicants without extensive preliminary data or prior experience with the NIH grant application process are urged to submit applications using the exploratory/developmental mechanism (R21). Applicants for R21s may request up to two years of support and up to a maximum of $125,000 direct costs per year. R21 grants are non-renewable and may not be used to supplement an ongoing project. Applicants who anticipate submitting an R21 grant application should review the NCCAM Web site (Research Grants, Application Guidelines) at http://nccam.nih.gov/research/instructions/r21/index.htm for
additional information on this mechanism.

This RFA uses the "MODULAR GRANT" and "JUST-IN-TIME" application procedures. They will apply to all applications submitted. Complete and detailed instructions and information on Modular Grant applications
can be found at https://grants.nih.gov/grants/funding/modular/modular.htm and in the NIH

Guide to Grants and Contracts, December 15, 1998 (https://grants.nih.gov/grants/guide/notice-files/not98-178.html).

FUNDS AVAILABLE

The NCCAM intends to commit approximately $3.0 M in FY 2001 to fund five R21 and four R01 new grants in response to this RFA. An R21 applicant may request a project period of up to two years and a budget for Direct Costs of up to $125,000 per year. An R01 applicant may request a project period of up to four years and a budget for Direct Costs of up to $350,000 per year. Modular applications will apply to all applications. Because the nature and scope of the research
proposed may vary, it is anticipated that the size of each award will also vary. Although the financial plans of the NCCAM provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. At this time, it is not known if this RFA will be reissued.

RESEARCH OBJECTIVES

BACKGROUND

Alternative medicine is increasingly popular among consumers in the United States, (Eisenberg et al. 1998) with 42.1% of adults reporting use in 1997. This figure represents an estimated 47% increase in visits to alternative practitioners since 1993. Extrapolation to the population of the United States suggests that Americans spent a total of $21.2 billion, $12.2 billion out-of-pocket, for CAM therapies in 1997. Despite widespread use and a growing interest in integration, CAM remains largely outside the mainstream healthcare system. Nearly two-thirds of CAM consumers say they have not discussed CAM use with their medical doctor. Third party reimbursement for CAM therapies is the exception rather than the rule, with CAM consumers reporting nocoverage nearly 60% of the time and complete coverage only 15% of the time (Eisenberg et al, 1998).

Barriers and Facilitators to CAM Integration
Several obstacles to integration of CAM with mainstream heath care have been acknowledged (Pellitier et al, 1999; Issues in Coverage for CAM Services, January 2000). The need for more research on the efficacy of CAM treatments has been identified. However, efficacy data does appear to translate readily into conventional practice. For example, although an NIH Technology Assessment Conference provided clear evidence that specific mind-body interventions relieved pain and insomnia, there appears to have been minimal incorporation of these interventions into routine practice. Similarly, an NIH Consensus Conference documenting he efficacy of acupuncture for management of certain types of acute pain, as well as for chemotherapy-related nausea and vomiting, does not appear to have impacted standard care as practiced by the conventional medical community

Managed Care Organizations (MCO's) have identified the following obstacles to CAM integration: economics; ignorance about CAM; provider competition; medical

establishment fear of change and the liability of making referrals to CAM practitioners, cultural bias and prejudice; and the lack of practice and license standards, CAM utilization data, consumer or employer demand, insurance reimbursement, and CAM provider networks (Pellitier et al, 1999). A multidisciplinary Clinician Workgroup on the Integration of CAM, initiated in the State of Washington by the Office of the Insurance Commissioner, similarly identified credentialing, care standards and professional liability as areas that require illumination (Issues in Coverage for CAM Services, January 2000). Other issues targeted by the Clinician Workgroup included the range of provider types that make up "integrated" practices and the juxtaposition of different health paradigms (condition versus whole person health care, and prevention).

Consumers appear to be the most powerful facilitator of the integration of CAM with conventional healthcare. In fact, consumer demand is a primary reason MCOs offer CAM coverage (Pelletier, Astin and Haskell, Am J Health Promot, 1999; Landmark Report II on HMOs and Alternative Care, 1999). Other facilitators include the development of professional relationships between CAM providers, conventional providers and payers; mutual respect and understanding regarding differences in philosophies, training and professional experience between CAM and conventional clinicians; objective valuation of the evidence base for both CAM and conventional treatments; and an appreciation for the differences in CAM and conventional patient care paradigms (Issues in Coverage for CAM Services, January 2000).

Strategies to Overcome Impediments and Facilitate Integration Research on how new conventional treatments are incorporated into standard medical care illustrates the difficulty in eliminating barriers to the integration of CAM therapies. For instance, the most common method to promote changes in practice patterns among conventional health professionals is the passive distribution of published or printed educational materials (eg: publication in the peer reviewed medical literature). Yet this method has been shown to produce little change in clinical practice and no change in health outcomes (Oxman et al., CMAJ, 1995; 153: 1423-1431; Chalmers, Clin Exp. Hypertens, 1999; 21: 647-657). Since the incorporation of innovative conventional medical practices is not accomplished through passive distribution, integration of CAM is not likely to be accomplished through this route.

Most research investigating methods to promote changes in clinical care has been plagued by inadequate methodology and lack of generalizability (Bero et al., BMJ, 1998; 317:465-468). Moreover, several factors impact significantly on the effectiveness of an approach towards change: 1) the characteristics of the message (Grilli and Lomas, Med Care, 1994; 32: 202-213); 2) recognition of external barriers to change (Davis et al., JAMA, 1995; 274: 700-705); and 3) readiness of the clinician to change (Grol, Qual Health Care, 1992; 1: 184-191). As outlined above, preliminary work has begun to identify barriers to CAM integration and indicates that both CAM and conventional clinicians are willing to make changes that facilitate integration. For instance, approximately 40% of conventional medical doctors report referring patients to CAM providers (Astin et al. Arch Intern Med

1998) and most medical schools in the U.S. include at least an introduction to CAM in the curriculum. In the
same vein, CAM practitioners have begun to recognize the usefulness of treatment guidelines (Issues in Coverage for CAM Services, January 2000). There is a need for studies focused on the outcomes and cost-effectiveness of evidence-based CAM treatment models that can be used in conjunction with conventional medical practice.

Current Initiatives for Integration Sixty-seven percent of Health Maintenance Organizations (HMO's) offer at least partial coverage for at least one therapy defined as CAM. However, coverage is limited primarily to chiropractic (65%) and acupuncture (31%), with four percent or fewer of plans including homeopathy, Tai Chi, Yoga, and Naturopathy (Landmark Survey, 1999). The level of coverage varies among plans and ranges from discount networks (negotiated discounts for enrollees but no reimbursement) to full coverage for specific clinical conditions. Advocates of CAM have argued that coverage of CAM by payors will reduce overall health care costs. Data to date are insufficient to support this belief (Pellitier et al, 1999), and health plans appear to be skeptical about financial benefit assertions. Of those plans that offer CAM coverage, eight percent cited
clinical effectiveness and twenty-one percent reported reduced total health care costs as the most important reasons for providing coverage (Landmark Survey, 1999).

Data are also insufficient on CAM utilization, the potential for cost offsets and determination of medical necessity, making it difficult for health plans to make coverage decisions regarding CAM using standard actuarial methods. However, there are several types of existing or readily obtainable data that could be used in the conduct of research on the integration of CAM and conventional health care that may already be available. Examples include: 1) enrollment data (including basic demographic data); 2) administrative claims or encounter-level data (e.g., diagnosis and procedure codes, charges); 3) more detailed data
on clinical (e.g., data on laboratory and diagnostic tests) and medication use; 4) survey data (e.g., satisfaction, health status etc.); and, 5) qualitative and quantitative data on characteristics of providers and organizations delivering care. The accuracy and completeness of these types of data and the extent to which they can be linked will influence their usefulness for research.

There is increasing interest in the integration of CAM by hospitals and multi-disciplinary clinics (Pelletier et al, Am J Health Promot 1997; Weeks, Integrator May 2000). Although many programs are too new to provide data on cost effectiveness or clinical outcomes, they are widely used by patients and therefore, can provide sites for future evaluation.

The issues delineated above will be relevant for studies that investigate the integration of CAM and conventional care. In addition, incentives and barriers to change among the conventional medical community, the legal stature of CAM and openness of policymakers within local areas will be important.

OBJECTIVES

This RFA addresses three main objectives: 1) identify barriers and facilitators to the integration of CAM and conventional health care practices; 2) determine whether CAM research results obtained from studies conducted under ideal conditions (efficacy studies) can be translated to real-world settings (i.e., effectiveness) within an integrated model; and 3) support the evaluation of currently planned or recently initiated programs, goals of which are to improve the outcomes, quality, effectiveness, and/or cost-effectiveness of health care through the integration of CAM and conventional health care. It is anticipated that each application will address one or more of the following research questions:

a) The knowledge, attitudes, referral patterns and behaviors of both CAM and conventional practitioners;
b) Impact of CAM integration on health care quality;
c) Cost-effectiveness of CAM integration for specific health conditions; and
d) Quantification of CAM cost offsets within care delivery systems or healthcare plans.

It is anticipated that responses to this initiative will be multi-disciplinary, and may include collaborations between health services
researchers, sociologists, medical anthropologists, clinical researchers, individual clinicians (CAM and conventional), and health
care systems and organizations (e.g., purchaser groups, integrated health service delivery systems, academic health systems, managed-care programs including HMOs, practice networks, worksite clinics, etc.). These relationships will enable a rigorous evaluation of planned and ongoing integration efforts that may not otherwise occur. The presence of strong partnership arrangements is essential to determine the impact of CAM integration on clinical practice and patient outcomes in applied situations.

Qualitative methods may be valuable for identifying promising areas of research. Discussion should be devoted to analytic features of the study including primary endpoints, power estimates, randomization procedures, and statistical methods, as applicable. Study methods must be adequately rigorous to address the research question, implementation of similar interventions, and issues of validity (internal and external) and reliability. It is expected that studies involving clinical interventions will include concurrent comparison groups rather than historical controls. Strategies for addressing selection bias among participants, including randomization at the patient level, practice or other organizational unit, pseudo-randomization or matching must be included. Studies that are not amenable to randomization should address challenges to internal validity in some other manner.

Applicants are expected to demonstrate that they either routinely collect and maintain data necessary for the conduct of research as described in this initiative or have the capacity to collect such data within the time and budget limits of the proposed project. The specific data required for any project will be determined by the study purpose. Applicants must be able to identify the specific data that will be collected and used for the project, demonstrate that the data are available or can be collected, and describe how the data can be cleaned, linked, and developed into an analytic file capable of
answering the study questions.

Timely sharing of information, instruments, and technology will build the knowledge base by permitting researchers access to sufficiently large and well-characterized data resources as quickly as possible. This sharing of data is essential to rapid progress and will help to avoid unnecessary duplication of large data collections. To ensure timely sharing of information and materials, applications should describe in detail how, when, and in what manner data and technology will be made available to the scientific and practice-based communities.

Applicants should consider taking advantage of other research projects (e.g., clinical trials about to be implemented) that could be expanded by adding a research component on integration. Such projects might provide access to subject populations or settings as well as reduce the costs of conducting research. A range of services (e.g., inpatient, acute, primary, or specialty care) delivered at a variety of sites (e.g. hospitals, outpatient clinics, worksite clinics, home health care, other community care sites) are all candidates for investigation.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

In studies with a clinical component, it is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for
Grants and Contracts on August 2, 2000 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html); a complete copy of the updated Guidelines are available at https://grants.nih.gov/grants/funding/women_min/guidelines_update.htm:
The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

NIH POLICY AND GUIDELINES ON THE INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects' research, conducted or supported by the NIH, unless there are scientific and ethical reasons to exclude them. (See NIH Guide to Grants and Contracts, March 6, 1998 or https://grants.nih.gov/grants/guide/notice-files/not98-024.html.)

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

LETTER OF INTENT

Prospective applicants are asked to submit, by December 8, 2000, a letter of intent that includes a descriptive title of the proposed
research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel (including research project collaborators and consultants) and participating institutions, and the number and title of this RFA. Although a letter of intent is not binding and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review.

The letter of intent should be sent to:

Dr. Christine Goertz
National Center for Complementary and Alternative Medicine
National Institutes of Health
6707 Democracy Boulevard, Suite 106
Bethesda, MD 20892-5475
Telephone: 301-402-1030
Fax: 301-402-4741
E-mail: goertzc@od.nih.gov

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) must be used in applying for these grants, with the modifications noted below. Applications kits are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301-710-0267, E-mail: GrantsInfo@nih.gov.

Applications are also available on the World Wide Web at https://grants.nih.gov/grants/forms.htm.

The MODULAR GRANT concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The JUST-IN-TIME concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and Institute staff.

MODULAR GRANT applications request direct costs in $25,000 modules. The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below: (a) PHS 398

o FACE PAGE: Items 7a and 7b should be completed, indicating Direct Costs (in $25,000 increments up to a maximum request of $350,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See
https://grants.nih.gov/grants/funding/modular/modular.htm for sample pages.) At the top of the page, enter the total direct costs requested for each year. This is not a Form page.

Under Personnel, List all project personnel, including their names, percent of effort, and roles on the project. No individual salary
information should be provided. However, the applicant should use the NIH appropriation language salary cap and the NIH policy for graduate student compensation in developing the budget request.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the Letter of Intent to establish a consortium.

Applicants are strongly encouraged to request the same number of modules for each year of funding. Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may beused for each person. A sample biographical sketch may be viewed at https://grants.nih.gov/grants/funding/modular/modular.htm.

Complete the educational block at the top of the form page;
List position(s) and any honors;
Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three
years.List selected peer-reviewed publications, with full citations;

o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of theindividual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

(b) Mailing Procedures

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title, and number, must be typed on Line 2 of the face page of the application form and the YES box must be marked. The sample RFA label available at:https://grants.nih.gov/grants/funding/phs398/label-bk.pdf has been modified to allow for this change. Please note this is in pdf format.

Submit a signed, original of the application, including the Checklist,and four (4) signed photocopies of the application in one package to:

CENTER FOR SCIENTIFIC REVIEW (formerly Division of Research Grants)
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, send one (1) additional copy of the application to:

Dr. Christine Goertz
National Center for Complementary and Alternative Medicine
National Institutes of Health
6707 Democracy Boulevard, Suite 106
Bethesda, MD 20892-5475

It is important to send this copy at the same time that the original and four copies are sent to the Center for Scientific Review (CSR).

Applications must be received by January 24, 2001. If an application is received after that date, it will be returned to the applicant without review. The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR and responsiveness by the NCCAM. Incomplete and nonresponsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCCAM in accordance with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit, generally the tophalf of applications under review, will be discussed, assigned a priority score, and receive a second level review by the NCCAM Advisory Council.

General Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) SIGNIFICANCE: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or

methods that drive this field? For Exploratory/Developmental (R21) Research Projects, what is the likelihood that the research will contribute to the development of interdisciplinary programs or more mature research endeavors?
o Degree to which the research will improve our understanding of how we can narrow the gap between what is proven efficacious and what is practiced in the real world of healthcare regarding CAM;

o Extent to which results will be transferable or reproducible in other healthcare systems;

o Likelihood that the research findings can be implemented and sustained for a variety of conditions and in a range of settings;

o Plans for dissemination and implementation of findings within and outside of the project's organization.

(2) APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

o Appropriateness of methods to address research hypotheses and needs of those who may be interested in applying the results of the study – in other words, how will scientific knowledge advance clinical practice.

(3) INNOVATION: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) INVESTIGATORS: Is each investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the Principal Investigator and other researchers (if any)?

o Incorporation of appropriate CAM expertise, including certified or licensed CAM practitioners;

o The integration of appropriate CAM, conventional medical and health services research expertise.

(5) ENVIRONMENT: Does the scientific environment in which the work will be done contribute to the probability of success of the project? Do the proposed studies take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

staff;

o Extent to which the project builds-on or establishes meaningful Demonstration of substantial commitment by the health care

organization/system to the CAM integration effort, including use of in-kind support and letters of support from clinical and administrative linkages between CAM practitioners, researchers and health care systems/organizations.

In addition to the criteria list below, the initial review group will examine: the appropriateness of proposed project budget and duration; the adequacy of plans to include both genders, minorities (and their subgroups), and children as appropriate for the scientific goals of the research, and plans for the recruitment and retention of subjects; the provisions for the protection of human and animal subjects; and the safety of the research environment.

Because the exploratory/developmental grant mechanism (R21) is designed to support innovative ideas, preliminary data as evidence of feasibility of the project are not required. However, the applicant does have the responsibility for developing a sound research plan approach, including appropriate statistical analyses and sample size calculations where appropriate. Innovation of the project and potential significance of the proposed research will be major considerations in the evaluation of this mechanism.

AWARD CRITERIA

The following will be considered in making funding decisions:

o The scientific merit of the proposed project as determined by peer review;

o Availability of funds; and

o The research priorities of the NCCAM.

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding specific PROGRAMMATIC ISSUES to:

Dr. Christine Goertz
National Center for Complementary and Alternative Medicine
National Institutes of Health
6707 Democracy Boulevard, Suite 106
Bethesda, MD 20892-5475
Telephone: 301-402-1030
Fax: 301-480-3621
E-mail: goertzc@od.nih.gov

Direct inquiries regarding FISCAL MATTERS to:

Ms. Victoria Putprush
Grants Administration Branch
National Center for Complementary and Alternative Medicine
National Institutes of Health
6707 Democracy Boulevard, Suite 106
Bethesda, MD 20892-5475
Telephone: 301-594-9102
Fax: 301-480-3621
E-mail: putprushv@od.nih.gov

AUTHORITY AND REGULATIONS

Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410), as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Appendix J

Instructions for Review Process

The function of this review is to impartially evaluate the merit of the enclosed application against the criteria published in the Request for Application (RFA). The review group serves to make recommendations to the student Principal Investigator, regarding the quality of the application against the criteria published in RFA-AT-01-001. These criteria are also listed on the review form you will complete. Please provide a score for each criterion and comment on strengths and weaknesses of each. If you have any general comments, note them under "Other Relevant Comments" section on the review form. Also note whether the applicant has addressed any Additional Review Criteria (Recruitment and Retention of Subjects, Protection of Human Subjects and Inclusion of Women and Minorities) that may be included in the announcement. **Comments on Additional Review Criteria are appropriate and welcome but please do not give scores for these items.**

Appendix K

Grant Proposal Thesis

Emory Executive Masters in Public Health Program
Student Investigator: Zehra Khan

EXTERNAL REVIEW EVALUATION SCORING SHEET

RFA-AT-01-001

Evaluation Criteria Score:

	POSSIBLE POINTS
A. Significance	25
B. Innovation	20
C. Approach	30
D. Investigators	15
E. Environment	10
F. Additional Review Criteria	N/A

Value totaling 100 points

FINAL SUMMARY OF CRITERION SCORES

Criteria	**Score**
A. Significance	
B. Innovation	
C. Approach	
D. Investigators	
E. Environment	
F. Additional Review Criteria (*Recruitment and Retention of Subjects; Protection of Human Subjects; Inclusion of Women and Minorities)*	

Strengths:

Weaknesses:

Recommendations:

Recommendation: (Mark one) Approve _____ Disapprove_____

Reviewer Name ———————————— Date_____

EVALUATION CRITERIA AND QUALITATIVE RATING TABLE

O=Outstanding
VG=Very Good
G=Good
F=Fair
P=Poor
U=Unsatisfactory

A. *SIGNIFICANCE (25 POINTS)*
   a. This study addresses an important problem.
   b. The application described how scientific knowledge will be advanced if the aims are achieved.
   c. The application demonstrates the degree to which the research will Improve our understanding of how we can narrow the gap between what is known and what is currently used as to treat PTSD in CSA women.

21-25	**16-20**	**9-15**	**5-8**	**2-4**	**0-1**
O	**VG**	**G**	**F**	**P**	**U**

Recommended Score: _____
Strengths:
Weaknesses:
Recommendations:

A. *INNOVATION (20 POINTS)*
   a. The project employs novel concepts, approaches or methods.
   b. The aims are original and innovative.

17-20	**13-16**	**9-12**	**5-8**	**2-4**	**0-1**
O	**VG**	**G**	**F**	**P**	**U**

Recommended Score: _____
Strengths:
Weaknesses:
Recommendations:

B. *APPROACH (30 POINTS*)

a. The conceptual framework, design, methods and analyses are adequately developed, well integrated, and appropriate to the aims of the project.
b. The applicant acknowledges potential problem areas and considers alternative tactics.
c. There is a robust plan for dissemination and implementation of findings within and outside the grantee's organization.

17-20	**13-16**	**9-12**	**5-8**	**2-4**	**0-1**
O	**VG**	**G**	**F**	**P**	**U**

C. *INVESTIGATORS (15 POINTS)*

a. The Principal Investigator is appropriately trained and well suited to carry out this work.
b. The work proposed is appropriate to the experience level of the Principal Investigator.

17-20	**13-16**	**9-12**	**5-8**	**2-4**	**0-1**
O	**VG**	**G**	**F**	**P**	**U**

Recommended Score: _____
Strengths:
Weaknesses:
Recommendations:

D. *ENVIRONMENT (10 POINTS)*

a. The scientific environment in which the work will be done contributes to the probability of success of the project.
b. The facilities are adequate to perform the proposed research, including clinical facilities and data management systems, when needed.

17-20	**13-16**	**9-12**	**5-8**	**2-4**	**0-1**
O	**VG**	**G**	**F**	**P**	**U**

Recommended Score: _____
Strengths:
Weaknesses:
Recommendations:

E. *ADDITIONAL REVIEW CRITERIA (NOT SCORED)*

a. Recruitment and Retention of Subjects
b. Protection of Human Subjects
c. Inclusion of Women and Minorities

Strengths:
Weaknesses:
Recommendations:

F. *OTHER RELEVANT COMMENTS:*

Appendix L

Conflict of Interest Form

PRE-REVIEW CERTIFICATION FORM REGARDING CONFLICT OF INTEREST, CONFIDENTIALITY, AND NON-DISCLOSURE OR REVIEWERS OF GRANT APPLICATIONS

Name [Last, First]_____
(Please print)

Other Employers (if applicable):_____

Funding Opportunity Number: RFA-AT-01-001

Date(s) of review:

Check only one (and provide any comments or explanations on reverse side):

- ❑ I have read the attached "Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers…" and have examined the list of applications/proposals to be reviewed, and hereby certify that, based on the information provided to me, I do not have a conflict of interest in any of them.

OR

- ❑ For grant application reviews only: I have read the attached "Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers…" and examined the list of applications to be reviewed and hereby certify that, based on the information provided, I have a conflict of interest in the specific applications listed below and hereby recuse myself from their review.

- ❑ For contract proposal reviews only: I have read the attached "Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers…" and examined the list of proposals to be reviewed and hereby certify that, based on the information provided, I have a conflict of interest in the specific proposals listed below and hereby recuse myself from their review. (Requires a waiver to participate in review meeting.)

I fully understand the confidential nature of the review process and agree: (1) to destroy or return all materials related to it; (2) not to discuss the materials associated with the review, my evaluation, or the review meeting with any other individual except as

authorized by the Scientific Review Administrator (SRA) or other designated official; (3) not to disclose procurement information prior to the award of a contract; and (4) to refer all inquiries concerning the review to the SRA or other designated official.

Signature: _____ Date: _____

I am in conflict with the following applications/proposals (identify applications by number and identify proposals by name of offer).

CONFLICT OF INTEREST, CONFIDENTIALITY, AND NON-DISCLOSURE RULES AND INFORMATION FOR REVIEWERS OF GRANT APPLICATIONS OR R&D CONTRACT PROPOSALS

A conflict of interest in scientific peer review exists when a reviewer has an interest in an application or a proposal that is likely to bias his or her review of it. A reviewer who has a real conflict of interest with an application or proposal may not participate in its review. Appearance of a conflict of interest should be avoided whenever possible but, if it is established that there is no real conflict of interest and the government official managing the review (i.e., the Scientific Review Administrator [SRA] or equivalent) determines that the integrity of the process would not be impaired, the individual in question may participate in the review.

As it is reviewers themselves who are most familiar with their own situation, it is their personal responsibility: (1) to bring to the attention of the SRA any conflict of interest situations that my pertain, whether real or apparent, and (2) on the pre-meeting and post-meeting Conflict of Interest Certification Forms associated with this information sheet to (a) identify any applications where they have a conflict of interest and (b) certify both that they will not be and have not been involved in the review of any application where their participation constitutes a conflict of interest and that they will not disclose any matters related to the review proceedings. Federal employees should be aware that federal conflict of interest statutes carry criminal penalties for violation.

The following guidance, derived from 42 CFR Part 52h and federal conflict of interest statutes, will assist you in determining whether you are faced with a real or an apparent conflict of interest. The guidance is not all-inclusive, due to the nature of the conflict of interest subject matter. Therefore, you should consult the SRA in charge when there is any question about your participation in a review.

BASES FOR CONFLICTS OF INTEREST

There are several bases for a real conflict of interest, employment, financial benefit, personal, or professional. If applicable, any one may serve to disqualify a reviewer from participating in the review of an application proposal.

EMPLOYMENT: Officers or employees of the U.S. government may not participate in the review of a specific grant application or contract project for which they have had or are expected to have any other responsibility or involvement in their role as an officer or employee of the United States. Reviewers who are Federal employees will also have a conflict of interest with organizations for which they conduct outside activities, with organizations they serve as officers, directors, trustees, or partner and with organizations for which they are seeking employment

FINANCIAL BENEFIT: Reviewers who are Federal employees will have a conflict of interest if they have an outside activity with an organization (even if that activity is unrelated to the application), if they serve as officers, directors, trustees, or partner in an organization, if they are seeking employment with an organization, and if they (their spouse and their minor children) own, in aggregate, more than $5,000 in stocks in a publicly traded company.

RELATIVES OR ASSOCIATES: Reviewers who are Federal employees will have a conflict of interest if their spouse submits an application or proposal. The impartiality of reviewers who are Federal employees will be questioned if a member of their household (other than their spouse, a close personal relative, a colleague with whom they have a business or other contractual relationship (e.g., co-author), the employer of their spouse, parent, or dependent child, or their former non-Federal employer) submits an application or proposal within the past year.

STANDING REVIEW GROUP MEMBERSHIP: When a scientific review group meets regularly, a relationship among the individual members exists; therefore, the group as a whole may not be objective about evaluating the work of one of its members. In such a case, the member's application or proposal will be reviewed by another review group to insure that an objective review is obtained.

REQUEST FOR APPLICATIONS (RFA) OR REQUEST FOR PROPOSALS (RFP): Persons serving as the principal investigator or as one of the key personnel or as a consultant on an application submitted in response to an RFA or on a proposal in response to an RFP are generally considered to have a conflict of interest with all of the applications or proposals submitted in response to the RFA or RFP.

Conflict of Interest, Confidentiality, and Non-Disclosure Information: For Federal Employees

However, if no other reviewer is available with the expertise necessary to ensure a competent review, a waiver may be granted by the agency head or his/her designee that will permit an individual to review only those applications or proposals with which he/she has no conflict but not those with which he/she has a conflict of interest. No contract may be awarded to an individual who has served as a reviewer of the proposals submitted in response to the RFP nor to that person's spouse or any organization in which the individual has a financial interest at the time of review. No contract may be awarded to a Federal employee or to an organization owned or controlled by one of more Federal employees. Reviewers who are Federal employees may not participate in the review of a proposal in which they have a conflict of interest.

MULTI-SITE OR MULTI-COMPONENT PROJECT: Persons serving as either the principal investigator, as one of the key personnel, or as a consultant on one component of a multi-site or multi-component project have a conflict of interest with all of the applications or proposals connected with the same project; and, they may have a conflict of interest with other applications or proposals submitted by the principal investigator, other key personnel or consultants of the same project.

LONGSTANDING DISAGREEMENTS: the impartiality of Federal reviewers may be questioned where the reviewer has longstanding scientific or personal differences with an applicant.

APPEARANCE OF CONFLICT OF INTEREST: Where the impartiality of a Federal reviewer may be questioned, the government official in charge of the review will authorize the reviewer's participation and document: (1) that there is no real conflict of interest; and (2) that, at the time of the review, no practical alternative exists for obtaining the necessary scientific advice if the reviewer with the apparent conflict were to be excluded from the review.

CONFIDENTIALITY AND NON-DISCLOSURE OF MATERIALS AND PROCEEDINGS

The applications and proposals and associated materials made available to reviewers, as well as the discussions that take place during the review meetings, are strictly confidential and must not be disclosed to or discussed with anyone who has not been officially designated to participate in the review process. Disclosure of procurement information prior to the award of a contract is prohibited by the Procurement Integrity

Act. Reviewers must certify that they will maintain the confidentiality of the review and not disclose this information to any other individual except as authorized by the official in charge of the review