

Using Drugs to Treat Drug Dependence: Exploring the Use of MDMA-Assisted Psychotherapy for Individuals with PTSD and Concurrent Substance Use

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Abstract: The importance of treating concurrent Post-Traumatic Stress Disorder (PTSD) and substance use with psychedelics is a controversial topic, hampered in part by a lack of empirical evidence and rigidity of substance scheduling. Traditional treatments for concurrent PTSD and substance use concerns are compartmentalized, with clinicians focusing on one condition over the other. In addition, traditional medication treatments are costly, requires significant time to take effect, and often come with debilitating side effects, resulting in decreased treatment retention and outcomes. Here, the aim of this manuscript is to explore the intricate mechanisms keeping concurrent PTSD and substance use in place and how traditional treatment methods are ineffective in treating the root cause of these conditions. The link between PTSD and substance use as a coping strategy is explored through the Self-Medication Hypothesis in combination with the prevalence of Adverse Childhood Events. The use of 3, 4-Methylenedioxymethamphetamine (MDMA)-assisted therapy is explored as a new and promising integrated treatment focusing on the safety, internal process, trust, and therapeutic rapport of the client and clinician. MDMA-assisted therapy consists of only a couple doses of a psychoactive substance administered in a controlled environment and under strict supervision. MDMA-assisted psychotherapy is more cost-effective than traditional treatments with virtually no adverse effects when compared to psychotropic medications. MDMA-assisted psychotherapy is shorter in length and more effective than traditional therapy with positive outcomes achieved within weeks, and lasting multiple years. Suggestions for future research include involving individuals who use substances and greater diversity and number in study samples. In addition, this manuscript contains recommendations for clinical practice for therapist training, an integrative treatment approach, and affordable access to MDMA-assisted treatment for PTSD and concurrent disorders. Finally, recommendations are made for the rescheduling of MDMA to allow for more significant research and clinical practice opportunities.

Keywords: Trauma, Substance Use, Adverse Childhood Experiences, MDMA-Assisted Psychotherapy, Psychedelic-Assisted Therapy, Concurrent Disorders

1. Introduction

Historically, 3, 4-Methylenedioxymethamphetamine (MDMA) has been utilized in psychotherapy and medical settings for various applications [1, 2] including enhancing therapeutic effects in neurosis, PTSD, interpersonal problems, and other psychotherapeutic concerns [3]. However, in 1985 MDMA became a schedule I substance [4] due to the increase in its recreational use in concert, rave, and festival scenes [1]. Since then, treatment for PTSD focused on a combination of psychotherapy and administration of

psychotropic medications.

In Canada, current systems meant to support individuals with either mental health or substance use concerns cannot efficiently handle concurrent disorders [5]. Treatment of concurrent post-traumatic stress disorder (PTSD) and substance use becomes complicated due to how these disorders interact on a biological and neurological basis [4]. Those engaging in prolonged exposure treatment explore difficult, traumatic experiences [6] and often experience increased psychological distress as a result. A small portion of individuals seeking treatment for concurrent disorders has

difficulty completing therapy due to various factors, including accessibility, treatment retention difficulties, and building a trusting therapeutic rapport with the clinician [7]. In addition, psychotropic medications often prescribed for individuals with PTSD have significant adverse side effects and may take a long time to take effect, further decreasing treatment adherence, medication compliance, and therapeutic outcomes [7]. Therefore, MDMA-assisted psychotherapy should be made available to individuals with PTSD unresponsive to traditional approaches with concurrent substance use as a way of coping.

This paper will explore the complex intersectionality of concurrent PTSD and substance use and discuss the importance of integrating MDMA-assisted therapy in trauma processing for this population. In addition, the paper will outline how Childhood Adverse Experiences (ACEs) and the Self-Medication Hypothesis (SMH) contribute to the complex presentation of concurrent disorders. Finally, current best practices will be explored and recommendations will be made for the utilization of MDMA-assisted psychotherapy.

2. Trauma and Resulting Psychological Concerns

2.1. Trauma and Substance Use

Approximately 70% of individuals worldwide will report experiencing a traumatic event at some point in their lifetime [8]. Such events may include natural disasters, accidents, exposure to neglect, abuse, bullying, or any other situation in which one perceives their life to be at risk [8, 9]. Stressful or traumatic situations are perceived and interpreted differently for each person, and the severity of this reaction may depend on the body's physiological response to the situation [8, 10]. Because of this, coping strategies to deal with such trauma varies across individuals and can include substance use.

2.1.1. Post-Traumatic Stress Disorder

Diagnostic criteria for PTSD include having witnessed or experienced a severe injury or potential threat to one's life resulting in symptoms such as flashbacks, nightmares, negative moods, changes in reactivity, or continued avoidance of related triggers [11]. These symptoms need to occur for a significant period following the traumatic event to meet diagnosis. While most people may experience a stressful or traumatic event at one point in their lives, it is important to note that only a small amount of those individuals (10%) develop a PTSD diagnosis as a result [4].

2.1.2. Substance Use

Substance use is almost a universal phenomenon amongst humans [4], and characteristics include the use of any substance affecting a person's current state of being [12]. Problematic substance use results in dysfunctional patterns or problems in social contexts and self-care [12]. To classify someone's use as a disorder, evidence of significant impairment in daily functioning, interpersonal relationships, and continued neglect of adverse effects of the substance use

need to be present [11]. Again, it is important to note that only a small fraction of individuals who use substances go on to develop problematic use resulting in substance use disorders [4]. Therefore, the focus of this paper will be on individuals using substances in general in conjunction with PTSD.

2.2. Concurrent Disorders

The Canadian Centre on Substance Abuse (CCSA) [12] indicates the term concurrent disorder applies when a mental health problem or illness presents alongside substance use or dependency. The severity of either condition influences the severity of the concurrent disorder. Mental health problems often arise when a person's ability to respond to daily stressors becomes difficult and they are unable to effectively cope with the situation or physiological response [12].

2.2.1. Link Between Trauma and Substance Use

There appears to be a common link between problematic substance use or disorders and traumatic experiences [8, 12] supported by empirical data [3, 10]. According to the CCSA [5], more than half of individuals attending treatment for substance use have a mental illness, while almost a fifth (15-20%) of those attending mental health therapy also use substances. Substances are often used after traumatic exposures to alleviate, escape, numb, or distract from resulting psychological distress and memories [8].

(i). Adverse Childhood Experiences

Events that occurred in childhood often affect the mental health of adults later in life. The Centre of Addiction and Mental Health [13] estimates 70% of adult mental health problems having started in childhood. When individuals do not effectively process traumatic events within their lives, either in early childhood or later in adult life, they may be susceptible to problematic substance use or disorders [12]. Traumas experienced in childhood are also known as Adverse Childhood Experiences (ACEs) [16, 17] and often affect the child's emotional and physical development into adulthood [17]. Significant associations were found between the number of adverse events the child was exposed to and the risk for premature death, with an average of 50.7% to 52% of the participants indicating having experienced at least one ACE in their lifetime [16]. Those who have experienced ACEs are more likely to suffer from anxiety, depression, emotional dysregulation [16], PTSD, self-esteem issues, behavioral dysfunction, poor social skills, and a poor self-image [17]. These arguably could contribute to risky behavior engagement such as substance use [16, 17].

(ii). Self-Medication Hypothesis

Many theories exist why a person may engage in substance use, mainly when other mental illnesses or psychological distress are present [12]. Trauma often precedes substance use [4, 9, 12], supported by the Self-Medication Hypothesis (SMH) theory. The SMH proposes individuals who experience significant psychological distress utilize substances to cope with resulting anxiety, loss, and physical or psychological pain [10, 18]. Individuals can recognize the short-term relief of

unmanageable or overwhelming symptoms such as depression, anxiety, and interpersonal conflict [16, 18], despite the risk of chronic use leading to substance dependence or problematic use [18], as described by one PTSD study participant:

[I was] probably just trying to self-medicate or something. I started drinking a lot in the Marines and it was just kind of this way of turning off from what was going on around me and in me and I think it was something that I kept doing for the same reasons. Just a way to disconnect, just to dull myself. [19].

Whether the desire for substances such as alcohol, tobacco, or marijuana following stressful or traumatic situations is a predictor for continued substance use or dependence is not clear [10]. However, those with previous struggles with substance use or mental illness may find these situations to be a catalyst for continued or increased use. Nevertheless, individuals without previous substance use struggles report significantly less problematic use following stressful situations, indicating those who haven't previously struggled with substances only to utilize them temporarily to balance their emotional regulation [10]. Although there are many reasons for concurrent disorders to present within a person, the most significant amount of data supports ACEs and the SMH as primary contributors [10, 16, 17, 18].

2.2.2. Cost of Concurrent Disorders

Concurrent disorders are challenging to diagnose often causing misdiagnosis or underdiagnosis and resulting in the mistreatment of the presenting problem [14]. In addition, concurrent disorders require specialized techniques [9], often resulting in decreased treatment adherence and outcomes [12]. This causes a significant burden in terms of cost on the individual, their families, and communities as longer, more frequent, and intense hospital visits are often required [9, 12, 20]. Adverse psychological effects of concurrent disorders can include problems in relationships, problems with the law, comorbid physical health problems [4, 12, 15], employment and housing issues, suicidal behavior [9], premature death [13], and negative stigma [14]. All these problems are also costly to the health care system. In 2014 alone, substance use cost Canada \$38.4 billion for healthcare, criminal justice, and lost productivity costs, while mental illness costs an average of \$51 billion annually [13].

3. Treatment for Concurrent Post-Traumatic Stress Disorder and Substance Use

3.1. Traditional Treatments

In accordance with the SMH, treatment for concurrent PTSD and substance use should focus primarily on the trauma response and symptomatology to alleviate the substance use in return [4, 21, 22]. However, even if treatment for PTSD is complete, the process of addiction may still take over, resulting in continued substance use or relapse after the PTSD symptoms have been resolved [4]. Traditionally, treatments for concurrent disorders have focused on either condition over

the other, creating a siloed style in therapy where individuals attend different service providers and health care facilities for separate concerns [14]. Most care systems are compartmentalized, and many clinicians are not cross trained in concurrent conditions, resulting in fragmented and disorganized care for individuals struggling [5, 14]. For example, individuals often experience unmet needs for substance use treatment as psychiatric professionals do not become involved with this type of treatment [14]. In contrast, substance use clinicians often refer individuals to other services for mental health concerns due to inexperience or lack of education with these concerns, creating a disconnect in treatment for concurrent individuals [14].

3.1.1. Psychotherapy

Cognitive Behavioral Therapy (CBT) is most appropriate to address ACEs in adults [17]. CBT interventions focus on coping skills to manage negative affect, psychoeducation, role-play, and self-efficacy enhancement [23]. However, CBT is highly structured, requires regular attendance, and focuses on written and verbal expressions of thoughts and feelings. These requirements make CBT less flexible for application with individuals from non-Western cultures by neglecting the need for relational and narrative processing and community-based healing practices [23]. Particularly for populations who have experienced historical assimilation and cultural appropriation within North America, forcing adherence to traditional CBT practices can be viewed as another form of assimilation leading to re-traumatization [23].

At this time, exposure treatments such as prolonged exposure and EMDR remain first-line therapies proven effective for concurrent PTSD and substance use [24]. Exposure therapy explores and challenges cues and triggers related to the individual's trauma without using substances until the physiological fight, flight, and freeze response is diminished [4]. While such treatments are proven effective, several individuals still do not respond to these treatments [7].

3.1.2. Medication

Psychotropic medications such as antipsychotics, anti-depressants, stimulants, anxiolytics, and mood stabilizers [7] are often used in the treatment of PTSD and substance use to reduce symptom severity [24]. However, medication administration for concurrent disorders becomes risky, convoluted, and complex due to substance interactions and side effects [5]. Physicians might utilize medications for substance use to mitigate withdrawal symptoms of certain substances; however, it is unclear whether substance use reduction results from the medication or PTSD symptom reduction [24]. These medications often result in adverse prolonged side effects, neurotoxicity risks, and may be insufficient in treating chronic and unrelenting symptoms [1, 7]. Individuals also often report the severe side effects of medication is not worth the minimal relief of PTSD symptoms they do provide [1, 7] and take a long time to take effect [20]. These problems often result in difficulty to engage in psychotherapy, and as a result, carry high drop-out rates and minimal positive therapeutic outcomes [7].

3.2. Treatment Adherence and Outcomes

Treatment of concurrent PTSD and substance use becomes complicated due to how these disorders interact [4]. In addition, substance use often exasperates PTSD symptoms, further complicating treatment adherence and outcomes [4, 9, 14, 15, 20]. For example, up to 20% of individuals drop out of therapy, and up to 58% still meet PTSD criteria after treatment [1]. Furthermore, 40-46% do not respond to PTSD treatment due to emotional detachment, tolerance, complex emotions, and inability to recall traumatic memories [25].

3.2.1. Limitations of Traditional Treatments

Individuals with higher levels of anxiety might have more difficulty managing internal experiences, such as maladaptive core beliefs or an ability to regulate anxiety-related symptoms, such as hyperventilation or an inability to focus [6]. In terms of abstinence after treatment, this was achieved for 55.6% of those who did not experience any abuse, compared to 13.3% of those with a history of childhood abuse [12]. In addition, psychotherapy often fails to address concerns in the therapeutic process due to mistrust, poor therapeutic rapport, or a history of minimal progress in treatment [7].

3.2.2. Therapeutic Relationship

Therapy is also enhanced by common factors in treatment, including patient characteristics, the Hawthorne effect, hope and positive expectations, therapeutic alliance, therapist variables, and extra therapeutic factors [2]. It is well known in the field that a positive therapeutic alliance between the individual and their therapist accounts for more favorable treatment outcomes than the treatment approach itself [2, 26]. Individuals with PTSD require a solid therapeutic relationship for the safety of trauma work [9]. Individuals who report a feeling of safety within the therapeutic alliance are more likely to attend treatment and have better outcomes than those who do not [26]. In such therapeutic alliances, the individual can trust that their therapist is empathetic, genuine, and responsive. In contrast, the therapist is confident in their ability to listen to the individual's trauma without judgment and understand underlying themes [26]. A positive therapeutic alliance is signified by collaborative and unified therapeutic goals and an emotional bond.

4. MDMA-Assisted Psychotherapy

4.1. MDMA Use

3,4-Methylenedioxymethamphetamine (MDMA) was first discovered in 1912 as an agent to stop bleeding [1, 2]. Since then, it has been utilized in medical and psychiatric settings in the USA and Europe [1]. In the 1980s, MDMA was also gaining popularity for recreational use in concert, rave, and festival scenes which caused authorities to have a closer look at its scheduling [1]. MDMA on its own, without additional therapeutic supports or considerations for the environment in which it is administered, has limited therapeutic effects [28].

4.1.1. Historical Use of MDMA in Treatment

Between 1970 and 1980, MDMA was used in psychotherapy to enhance therapeutic effects [1] for neurosis, interpersonal relationship problems, PTSD, and other psychological concerns [3]. Due to its popularity in the recreational realm, the FDA proclaimed MDMA as an illegal substance in 1985 [1, 7], preventing its use in research or clinical practices [1, 3, 7, 28]. Schedule I substances are considered to lack therapeutic properties, have abuse potential, and cause serious adverse side effects [20]. In 2000 the USA Multidisciplinary Association of Psychedelic Studies (MAPS) was approved for to conduct clinical studies using MDMA, with the first study published in 2010 [28, 29]. The FDA granted MDMA breakthrough therapy designation in 2017 [25, 30], indicating this type of treatment might be more beneficial than existing approaches [3] in end-of-life situations [20].

(i). Recreational Ecstasy

Recreational Ecstasy doses have anywhere from 0 to 245mg of MDMA per pill and often contain other substances or fillers [21, 31], including Ketamine, caffeine, or methamphetamine and others [27]. Those who use it only do so on weekends rather than daily [21]. Ecstasy's effects include euphoria, increased sensory awareness, and a feeling of closeness to others [21, 27]. Adverse side effects include nausea, teeth grinding, tremors, panic attacks, increased body temperature, seizures, and death [27]. However, it is important to note these are not direct results of MDMA within the Ecstasy. Rather, these are due to the other contaminants within the pill, dehydration, lack of nutrition, lack of sleep, excessive dancing, other substances consumed, or a result of the individual's perception and environment [28], and do not occur in clinical settings.

(ii). Set and Setting

The environment (setting) and individual's mind frame (set) in which someone takes Ecstasy differs significantly from clinical settings for MDMA [32]. For example, individuals use Ecstasy in the festival, rave, or concert settings with little control over the environment [28]. In this case, the individual is not able to control the weather, crowds, or find a place to regulate. In addition, they might experience anxiety in engaging in illicit substances, be unfamiliar with their effects, and experience a 'bad trip' [28]. Furthermore, there are no trained professionals available in these types of settings for support or to assist someone in such a state, which could result in a traumatic experience for the user. Even still, Ecstasy has incredibly low numbers of adverse effects and death [28].

4.1.2. Neurological Action of MDMA

MDMA affects neurochemicals such as serotonin, dopamine, and norepinephrine within the amygdala of the brain [7, 28, 33]. This results in enhanced fear extinction, stress reduction, and emotional regulation [1, 21, 25, 28, 33, 35]. The amygdala processes stimuli which might be perceived as dangerous or life-threatening and becomes overactive in those with PTSD [21]. Reduced activity at the amygdala allows individuals to rate their traumatic memories as less negative, attach more

positive emotions to the memory [25], and enable the individual to feel safer recalling the memories, without the need for numbing or avoidance with substances [28].

MDMA releases oxytocin, a neurochemical impacting social learning, attachment, empathy, bonding [25, 28], and connection with others [1, 21]. With the release of this neurochemical, individuals have less resistance in connecting with their therapist and increase the capacity for a positive therapeutic alliance. Psychological properties of MDMA and therapeutic interactions also widen the window of tolerance to allow traumatic content processing without becoming overwhelmed to the point of hyper- or hypo-arousal, allowing the individual to remain emotionally engaged in treatment [31, 35]. In addition, MDMA allows for more activity in the prefrontal cortex [7, 25, 31], responsible for decision-making, attention, impulse control, and emotional regulation [25].

Finally, MDMA increases the ability of the brain to produce synaptic plasticity, which creates new pathways within the brain [25]. Learning is based on synaptic plasticity, as it breaks old pathways and forms new ones for the brain to function on [25]. For example, when a traumatic memory is associated with new information, known as reconsolidation, and the fear becomes extinguished, the brain can relearn that certain cues and triggers no longer require the automatic physiological trauma response it once created [25].

4.1.3. MDMA-Assisted Psychotherapy for Trauma

MDMA utilizes in treating chronic and non-responsive treatment for PTSD indicates promising results to support the psychotherapeutic process [7, 31, 33]. PTSD is often the result of reoccurring real or perceived exposure to fear and trigger cues, causing automatic physiological fear responses, such as being startled, overwhelmed, and anxious [25, 31]. With the help of MDMA, these triggers and cues are explored in a safe and supportive manner, allowing the individual to reduce their physiological fear response through fear extinguishing [31]. This process also occurs in traditional therapies such as EMDR or prolonged exposure therapy; however, the main difference is that MDMA allows the individual to experience the cue with more positive emotions, empathy for self, and this often occurs more rapidly than in traditional therapies [31, 34]. The healing process of MDMA comes from the ability to work through the complex emotions, memories, and somatic sensations rather than avoiding or numbing these [34].

(i). Window of Tolerance and Memory Reconsolidation

During trauma-processing, it is ideal to have the individual remain within the optimal zone of arousal, according to the window of tolerance [1, 7, 31]. This zone of arousal decreases the individual's chance of becoming overwhelmed with emotions, which can result in emotional dysregulation, numbing, and dissociation [1, 3]. The optimal zone of arousal is widened by MDMA, allowing individuals to process their trauma with more emotional regularity [31]. In addition, MDMA allows for memory reconsolidation, a process in which memory is recalled, deconstructed and reconstructed with new and additional information, such as emotions and empathy for self [1, 25] with more imagination and creativity

[1]. For example, previously misplaced blame or responsibility for the event can be more appropriately or rationally assigned. In addition, recalling a memory in a supportive therapeutic space while under the influence of MDMA might allow the person to feel more empathetic and loving towards themselves and others, versus recalling memories with anxiety and fear attached [1]. This, in turn, will enable them to connect new meaning and information to the memory [1]. For example, one study participant explained this process:

One thing the MDMA facilitates is thinking about traumatic experiences in a neutral, safe manner. I could objectively think about them and talk about them. Then, it seemed those memories are put back in their place in the brain in a different configuration – a configuration that does not cause as many problems, such as bad dreams, intrusive thoughts all the time, or having horrible insomnia. This has continued to this day, a year and a half after the last MDMA session. [25].

(ii). MDMA and Treatment Adherence and Outcomes

In terms of attachment, MDMA decreases social fears and defensiveness, while increasing empathy, trust, connectedness, and openness [1, 28, 33]. In turn, the therapeutic alliance is increased, and the individual can learn to regain trust and connection within their interpersonal relationships [7, 25]. Additional MDMA effects include less resistance to therapy, and an increase in self-awareness, spiritual connection, cognitive flexibility [7], affect, [28], cognition, attachment, self-esteem [33], acceptance, interpersonal relationships, grounding, and release of muscle tension [1]. After one year, 83% of participants no longer met with criteria for PTSD, compared to 25% in the placebo group [28], and 74% achieved continued remission three to four years after treatment [7].

4.2. MDMA-Assisted Psychotherapy Process

MDMA-assisted psychotherapy is a non-directive approach allowing the inner healing process of the client to take place [21, 28, 30, 32, 34]. Therapists need to ensure individuals understand that there is no set agenda in therapy and lead the healing process through MDMA facilitation [34]. A total of nine to twelve psychotherapy sessions will occur in conjunction with the MDMA-assisted sessions to help integrate experiences and insights into the client's daily lives [1, 25, 30, 34]. This allows for debriefing the MDMA experience and trauma processing [1, 34]. Therapists may utilize other therapeutic approaches such as mindfulness, Internal Family Systems therapy, Somatic Processing, Cognitive Processing Therapy, cognitive restructuring [25], focused bodywork, breathwork, and metaphors [34]. Homework between sessions is meant to continue to integrate the client's experiences into their daily life and consists of drawing, painting, writing, physical movement such as yoga or somatic therapies, and spending time in nature [31, 32, 34].

4.2.1. Preparation for MDMA Sessions

Two or three 90-minute introductory sessions [25, 30] are held before MDMA-assisted sessions for the therapists to obtain the client's history, conduct assessments [34], and lay the groundwork for the therapeutic alliance. In addition, they introduce the process of the MDMA-assisted sessions [1] and discuss the safety of these [34]. During the preparatory sessions, grounding techniques such as deep breathing are taught to help the client remain calm during MDMA sessions [25].

Careful consideration of the therapeutic environment is essential to ensure client safety and comfort and ensure appropriate set and setting for the sessions [32]. The atmosphere is critical in psychedelic-assisted therapy as the client enters an altered state of consciousness [28]. Two therapists are present during the MDMA session [25], preferably a male and female team [1, 28]. Therapists remain nearby in the event the client wants to discuss certain aspects of their experience, to validate the client's experience, to redirect them back to their internal process, or to engage in reassurance and physical touch such as handholding [1, 25, 28, 34].

4.2.2. The MDMA Session

The MDMA-assisted session lasts about eight to nine hours [1, 7, 25, 30] and includes a follow-up period which can consist of spending the night at the clinic for continued monitoring for medical purposes [1]. MDMA-assisted sessions begin with the administration of 75mg [31] to 125mg [1] of MDMA, with a supplemental dose of up to 62.5mg given two to three hours into the session [1, 30]. The MDMA peaks between one to two hours and can last up to three hours [34].

Clients lay down on a sofa or bed and wear an eye mask and headphones, which play soft music to help induce a state of relaxation and euphoria [1, 25, 28, 31]. In addition, they are encouraged to keep their focus on the internal process allowing the MDMA to guide the therapeutic process [1]. Heart rate, blood pressure, and body temperature are monitored regularly throughout the MDMA sessions and afterward for a period to ensure there are no adverse physical reactions or cardiovascular risks [1, 28, 33].

4.2.3. Side Effects of MDMA in Therapy

No severe adverse reactions have been observed in MDMA-assisted therapy thus far [1, 7, 28], though short-term effects include jaw tightness, loss of appetite, poor concentration, impaired balance [28, 33], nausea, feeling cold, dizziness, and irritability [30]. In addition, increased blood pressure, body temperature, and heart rate may be observed [30]. However, these effects are temporary and wear off quickly after clinical use [21, 31]. In the week following MDMA-assisted therapy sessions, some clients struggle with sleep, low mood, irritability, and ruminations [30], reinforcing the need for psychotherapy sessions in between MDMA-assisted sessions. Twelve-month follow-up of phase 2 clinical trials indicated 67% of participants no longer carried a PTSD diagnosis, and follow-up data six years later indicated these results were maintained [30].

5. Ethical Considerations of MDMA-Assisted Psychotherapy

5.1. Legality of MDMA

It is difficult to break the stigma surrounding MDMA for clinical use given its illegal status in most countries, further complicating research and clinical practices [20, 32, 33]. MDMA is a Schedule I drug in Canada, placing it in the same category as opioids such as heroin, fentanyl, and morphine [36]. While some of these substances have been given therapeutic status, the Controlled Drugs and Standards Act (CDSA) has yet to consider the same for MDMA [36]. The CDSA provides legal guidance for the use of certain substances for medical and therapeutic purposes and allows for some exemptions for medical or scientific research purposes in end-of-life or terminal illness circumstances [36]. Health Canada's Special Access Program allows clinics to apply for exemptions of the CDSA only if traditional approaches have not worked, are not suitable for the individual, or are not available [37]. In addition to the restriction on research and access to treatment utilization, the legal status of MDMA could be considered a violation of human rights such as rights to science, highest attainable treatment, and to enjoy the benefits of scientific progress [20].

5.1.1. Ethics of MDMA Use

Individuals who suffer from treatment-resistant and chronic conditions, on average, attempt two different medications [20]. These can take up to three months to take effect [31] and often occur without benefit or have significant adverse side effects, prolonging the individual's suffering and adding to health care costs. In addition, it is unethical to make these individuals undergo unhelpful treatments before attempting MDMA-assisted psychotherapy. Ethically, therapists must avoid the risk of harm while maximizing the benefits of therapy for their clients, posing conflicting interests with unclear treatment opportunities for MDMA-assisted psychotherapy [28, 32].

Therapists need to remain professional and practice ethically to avoid negligence [38] which can be challenging given muddled clarity around the legality and practices of MDMA-assisted psychotherapy [32]. Suppose a therapist harmed a client during improper MDMA-assisted psychotherapy facilitation. In that case, it could leave the therapist open to lawsuits for failing to protect the client from harm, practicing a method without significant scientific evidence, or violating standards of care by not providing a standard practice [32]. In addition, licensing boards may view MDMA use in therapy as enabling or promoting illicit substance use and might not allow therapists to practice in a novice area without clear proof of knowledge or expertise on the subject [32]. Licensing boards will not allow their therapists to conduct in a manner that could leave a negative perception of the field to the public [32]. Let alone the potential to cause harm to a client, a therapist practicing MDMA-assisted psychotherapy illegally and without proper

authorization can cause great conflict for the entire field of psychotherapy.

5.1.2. Benefits of MDMA-Assisted Psychotherapy Use

Each year, ninety-thousand visits to the ER occur for adverse reactions to psychotropic medications, with a quarter of them for antipsychotic medications often used in PTSD treatment [3]. In addition, these individuals often experience other comorbid conditions, further decreasing their quality of life and increasing their suffering and health care interaction frequencies [20]. Minimal administration of MDMA under supervision in a controlled setting makes practice safer than other psychotropic medications used in therapy [7, 20, 31]. The therapeutic effects last months to years, making this type of treatment more cost-effective in general [20]. Furthermore, there is a low abuse potential [20, 21, 28, 33] due to the controlled setting and dosing. Most individuals in MDMA trials who report substance use such as alcohol or marijuana indicate decreased usage due to PTSD symptom relief [3, 20, 22].

Treatment adherence and outcomes would increase due to MDMA's safety and tolerability, preventing costs of unfavorable adverse effects, further hospitalization, and prolonged psychiatric care [20, 39]. Indeed, in the short-term, significant investments will need to be made to adjust the existing health care system with policies, procedures, training, and clinical facilities to support MDMA-assisted psychotherapy. However, in the long run, it would save the system significant money [20, 39]. MDMA-assisted psychotherapy was significantly more cost-effective than control groups, including psychotherapy only, in a cost-saving analysis [39]. This same study estimated net savings of \$103.2 million and 42.9 prevented deaths over the course of thirty years for chronic treatment-resistant PTSD [39]. In addition, some individuals with chronic, treatment-resistant PTSD could return to work due to symptom reduction, indicating MDMA-assisted treatment would ultimately lower disability payments and increase productivity [39].

5.2. Guidelines for Therapists

Limited training standards and availability for MDMA-assisted psychotherapy pose problems for therapists attempting to obtain sufficient training necessary for practice [32]. Therapists need to remain up-to-date with empirical support, legal status, and ethical guidelines for MDMA [32]. As individuals with PTSD require a strong therapeutic relationship for the safety of trauma work, therapists should not perform this type of work in a setting with a high turnover rate of clinicians [9].

5.2.1. Training

Therapists wanting to practice MDMA-assisted psychotherapy require expertise in trauma-focused work, such as EMDR, prolonged exposure, Internal Family Systems Therapy, or Cognitive Processing Therapy [34]. In addition, therapists are encouraged to have sound understanding and experience in somatic therapies such as breathwork, body-focused work, mindfulness, sensorimotor therapy, and

Hakomi [34]. Furthermore, therapists need to remain client-centered, empathetic, and put their own biases aside, letting the individual guide the session. MAPS provides training for MDMA-assisted psychotherapy in the USA, which is accepted for Canadian therapists as well [34]. However, this training can be costly and quite lengthy, with recommendations for the therapist to participate in an MDMA-assisted treatment session or two for themselves prior to practice [34]. While there are some training programs available for therapists in Canada, it is suggested interested therapists attend the MAPS program for actual certification.

5.2.2. Supervision

Concurrent PTSD and substance use is a complex presentation that requires adequate training and supervision of professionals conducted by clinicians who are well trained in concurrent disorders and trauma processing [9]. Therapists wanting to practice MDMA-assisted psychotherapy should receive supervision from those with significant experience and/or knowledge in MDMA-assisted therapy [32]. At this time, there are only a small number of clinical supervisors who could attain these qualifications to supervise MDMA-assisted psychotherapy, with most of them being located in the USA [34]. It is suggested for those who are interested in psychedelic-assisted treatment to obtain training and experience sooner rather than later to help the field grow effectively.

6. Future Recommendations

6.1. Limitations of MDMA's Legal Status

MDMA-assisted psychotherapy could ease the burden currently placed on the individual and health care systems with traditional, non-effective PTSD care facilitated with psychotropic medications. Rescheduling the legal status of MDMA to a status with lesser criminal implications would open doors for research and clinical opportunities. Trial sizes for MDMA-assisted psychotherapy have remained relatively small, with significant exclusion criteria such as substance use and other mental health concerns [32].

6.1.1. Trial Sample Size and Diversity

Generally, Caucasian individuals volunteer for and participate in, clinical trials for psychedelic treatments, leaving a gap in research and knowledge regarding the safety and efficacy of MDMA for people of color [29]. Reasons for this are often rooted in the historical and cultural stigma surrounding research practices for people of color, stigma, and fears surrounding illegal substance use and its consequences, and a lack of access to these types of studies in rural settings [3, 29]. These same individuals also experience a decrease in the accessibility of new treatments as they are often offered in urban settings and cost significant money due to a lack of insurance coverage. Furthermore, the majority of study participants are female [1], preventing proper generalization of study results to larger populations. Marginalized populations experience significantly higher rates of PTSD and substance

use, inaccessible care, and are more likely to experience chronic or multiple traumas, complicating treatment [29]. This is why it is imperative to expand study accessibility and sample sizes to ensure greater diversity in study participants [29].

Unfortunately, research studies for MDMA-assisted psychotherapy have excluded individuals who use substances, raising questions about whether substance use poses risks for this type of treatment [21]. Researchers find it difficult to discern whether the results are due to the psychiatric condition, substance use, or both [5]. If researchers continue to exclude individuals with concurrent disorders, the interaction of such complexities will remain misunderstood and can implicate clinical care negatively. More data is required to ensure the safety of individuals with concurrent disorders and to potentially open inclusion criteria for MDMA-assisted psychotherapy as PTSD and substance use often present together.

6.1.2. Control Substance

Further limitations to pilot studies include finding a control substance for double-blind trials which mimics the effects of MDMA observable to the participant and researcher, without inducing the same neurochemical changes as MDMA does. A low dose of 25mg of MDMA is an effective control dose, inducing a state of psychedelic euphoria, but not to the effect of therapeutic doses [1]. Further research is required to explore other options for control substances.

6.2. Clinical Practice

Training of clinicians and change in health care infrastructure has already lagged in keeping up with integrated concurrent treatment [29]. With the approval of MDMA-assisted psychotherapy, these will need a significant overhaul once again [29]. Currently, the health care system consists of a siloed approach for concurrent disorders, where individuals attend different service providers and health care facilities for separate concerns. These providers often do not communicate with each other, resulting in misinformation, significant gaps in treatment, or conversely, duplication of therapy [14]. For the health care system to best support MDMA-assisted psychotherapy practices, facilities need to be upgraded to support such practices. In addition, avenues for better communication, case conferencing, and treatment continuity need to be in place. Furthermore, training for clinical supervision of MDMA-assisted psychotherapy should be made available to those clinicians interested in this aspect of practice.

6.2.1. Cost of MDMA Therapy

Research indicates that over thirty years, MDMA-assisted therapy is more cost-effective than traditional treatments [39]. Unfortunately, MDMA-assisted therapy will likely be costly to clients, eliminating a significant number of vulnerable individuals who could benefit from such therapies [29]. Health care systems need to recognize MDMA-assisted treatment to allow insurance companies to offset high treatment costs. Large gaps in treatment accessibility and affordability result in large populations not receiving adequate care for their suffering, further implicating their quality of life

and increasing health care costs long-term.

6.2.2. Training

Clear guidelines for training and certification need to be put in place to allow those clinicians who choose to pursue MDMA-assisted therapy to obtain the correct type of training. This training should be available to tenure, rather than novice clinicians to avoid unethical and unsafe practices. In addition, health care systems need to remain focused and dedicated to integrated treatment for concurrent disorders to reduce costs and increase positive outcomes. Finally, more training opportunities need to be made available in Canada to allow for better access and affordability of training.

7. Conclusion

Traditional psychotherapy treatments for PTSD and substance use provide some symptom relief and indicate some reduction in substance use [25]. However, these treatments fail to address critical components of trauma-processing therapy, including safety, trust with the clinician, memory recall, and emotional regulation. In addition, psychotropic medications prescribed often come with adverse side effects [7] and take a long time to take effect [20].

Given the connection between childhood trauma and substance use, it would be beneficial to explore such treatment with the assistance of MDMA [28]. With MDMA increasing empathy of self and others, individuals who use substances might be able to confront the adverse effects their substance use has had on themselves and those around them, increasing potential to reduce their use [21]. In addition, this increased empathy may also reduce the denial often experienced with substance use problems. Compliance is often a barrier for substance use and PTSD treatment, and MDMA might assist with this given its effects on therapeutic rapport, empathy with self, trust, and self-confidence [28].

The first step in providing MDMA-assisted psychotherapy for PTSD and concurrent disorders is rescheduling the substance to allow more significant opportunities for research and clinical applications. In turn, the research could be conducted on a greater diversity of individuals, accounting for cultural, general, and age implications. Once this research is available, health care systems can enhance their facilities and clinicians can obtain the training necessary to carry out MDMA-assisted psychotherapy safely. MDMA-assisted psychotherapy as treatment may seem like a distant dream, however, with MDMA potentially becoming FDA approved in the USA in 2021, and 2024 in Europe [33], this innovative treatment could soon become a reality for the field.

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