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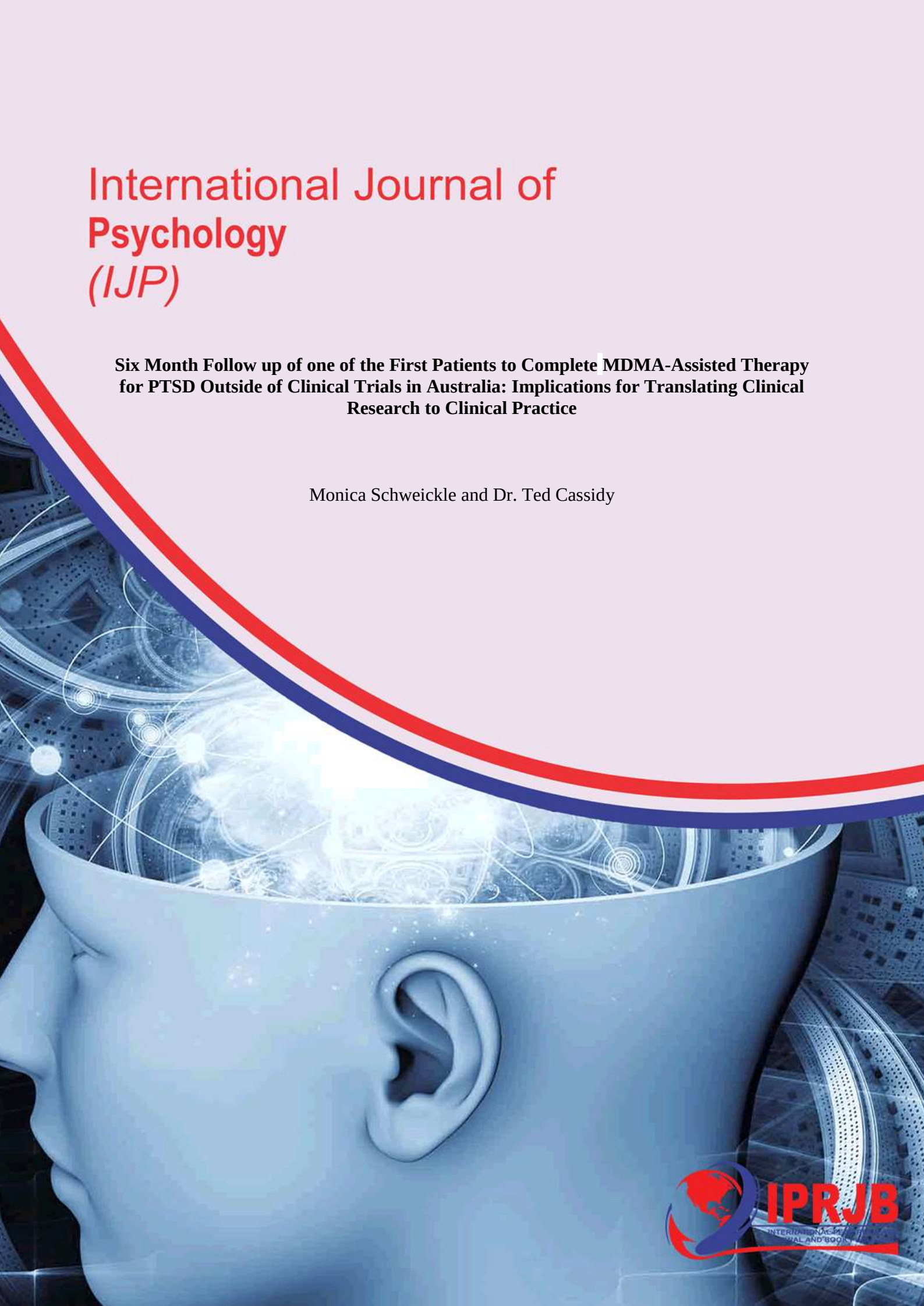

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Six Month Follow up of one of the First Patients to Complete MDMA-Assisted Therapy for PTSD Outside of Clinical Trials in Australia: Implications for Translating Clinical Research to Clinical Practice

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Abstract

Purpose: The goal of this case report is to illustrate the implementation of 3,4-methylenedioxymethamphetamine (MDMA)-assisted therapy for posttraumatic stress disorder (PTSD) and learning points for health professionals in the translation of psychedelic assisted therapy research into clinical practice. We present our key learnings and 6-month follow up data from one of the first patients to complete MDMA-assisted therapy for PTSD outside of clinical trials, in an Australian outpatient clinic setting.

Methodology: The patient described in this case report had chronic PTSD, depression and anxiety due to experiencing domestic violence, including sexual, physical, and psychological abuse in her adolescence. Treatment was informed by the Multidisciplinary Association of Psychedelic Studies (MAPS) MDMA-assisted therapy manual. After completing treatment, she enrolled in our weekly integration peer support group, including meditation workshops and family support sessions. Data was gathered using the Australian National University (ANU) Psychedelic-assisted therapy Australian national outcome database (https://medicine-psychology.anu.edu.au/research/research-projects/australian-interventional-pharmacotherapy-psychedelic-assisted-psychotherapy), which collates de-identified questionnaire data and outcomes from MDMA, psilocybin and ketamine assisted psychotherapy. Outcome data was gathered at baseline, the beginning of preparation, in the week after each dosing session, at the end of the program. Follow up data is collected at 3-, 6-, 9- and 12-months post-treatment. At the time of writing, she had completed 3 and 6 month follow up. Tables and figures are used to present the outcome data.

Findings: Our patient no longer met DSM-V criteria for PTSD or major depressive disorder at the end of treatment, and at 6-month follow up. Her Impact of Events Scale – Revised (IES-R) score was 61 at intake, reduced to 0 after the second dosing session and remained 0 at 3 and 6-months follow up. There were no adverse events, with the only side effect reported being loss of appetite in the first 24 hours after each dosing session. All scores on depression and anxiety measures reduced to the normal ranges after the second dosing session and remained in the normal ranges at her six month follow up. After the second dosing session reported having greater self-compassion and being less troubled by the trauma memories. After the third dosing session, she began to feel comfortable leaving her children with their father or trusted family member to run errands for the first time, and an increased sense of connectedness with herself and with others. All these gains were maintained at three- and six-months post-treatment, illustrating a case of safe and effective implementation of MDMA-assisted therapy for PTSD in an outpatient mental health service.

Unique Contribution to Theory, Practice and Policy: Our case study offers one model of clinical practice, contributing to Australian practitioner's implementation of safe and effective MDMA-assisted therapy in mental health services. We reflect on learning points for practitioners such as whether MDMA or psilocybin would be the most effective treatment, for a patient with both PTSD and treatment resistant depression. Recommendations for practitioners include the importance of working in a dyad, accessing ongoing supervision in the early stages of implementation, and the benefits of the having had legal experience with psychedelic medicines as part of therapist training.

Keywords: *MDMA, Posttraumatic Stress Disorder, PTSD, MDMA-assisted Therapy*

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INTRODUCTION

Posttraumatic stress disorder (PTSD) affects 11% of Australians in their lifetime (ABS, 2022) and is a significant public health concern associated with high social and economic costs (von der Warth, Dams, Grochtdreis & Konig 2020). While effective treatments are available, some individuals do not respond to or only have partial benefit (Koek & Schwartz et al., 2016). About 20 percent of participants drop out of PTSD treatment prematurely (Imel, Laksa, Jakupcak & Simpson, 2013). While psychological therapy and pharmacotherapy are beneficial for many, not everyone responds to these, warranting investigation into novel treatment approaches. This includes emerging therapies such as MDMA-assisted therapy for PTSD.

MDMA-assisted therapy combines 1-3 medically supervised MDMA dosing sessions within an intensive psychotherapy program, provided by two therapists prior, during and after the medicine dosing sessions (Mithoefer, 2015). Promising results of Phase III trials suggest that MDMA-AT might be a viable option for the treatment of PTSD, especially for those individuals who have not found benefit from existing treatments (Mitchell et al., 2023, Mitchell et al., 2021). This includes groups who may have poorer response to conventional treatments, including survivors of interpersonal violence, trauma which tends to be chronic and repeated.

MDMA works synergistically within an intensive psychotherapy program. As with other types of psychotherapy, a positive therapeutic alliance has shown to predict post-MDMA assisted therapy outcomes and symptom severity (Zeifman, Kettner & Ross et al., 2024). The therapeutic framework emphasizes the client's inner healing wisdom as the primary agent of change, facilitated by the therapeutic relationship and trauma-informed care principles (O'Donnell, Okano & Alpert et al., 2024). MDMA assisted therapy facilitates openness to experiences, which in turn, may enhance therapy effectiveness and alter personality structure post treatment (Wagner, Mithoefer & Mithoefer et al., 2017). MDMA also increases prosocial feelings and appears to reduce negative mood when participants think of a difficult memory (Cahart-Harris, Wall & Erritzoe et al., 2014). These mechanisms may facilitate trauma therapy, reduces avoidance of distressing memories, so trauma can be processed in psychotherapy sessions.

Building upon this work and others, in February 2023, the Australian Therapeutic Goods Administration (TGA) down-scheduled two psychedelic medicines, MDMA and psilocybin for use in PTSD and major depressive disorder, respectively. There are many uncertainties regarding how these therapies should be implemented and regulated (Hatfield, Thornton, Greenstein & Glozier, 2024). In this case report, we present the implementation of the first patient to complete MDMA assisted therapy in a community clinic in Australia, and contribute the lessons that we as a treating team learned.

METHODOLOGY

The case study described is "Addi", a woman in of Aboriginal background in her late 20's, who described a complex trauma history. She experienced several abusive relationships over her adolescence, including repeated physical, sexual and emotional abuse for a number of years. On several of these occasions she was close to losing her life. She had no history of mania, psychosis, or history of substance use problems. She had tried "ecstasy" once at a party in her teenage years, with no other history of psychedelic use or significant substance use. She did not present with suicidal ideation or risk, and identified several protective factors including her work, partner, and children. She described high anxiety, panic attacks and intrusive

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memories, and a fear of losing loved ones which impacted her parenting and relationships. She experienced distress when separated from her children to run day to day errands, due to these fears. She began experiencing complex trauma symptoms in her early 20's and had tried several courses of antidepressant medications, trauma-focused therapy and hypnosis with limited benefit.

Addi completed an initial screening assessment for eligibility to participate in MDMA-AT in November 2023. This involved psychological, medical, and psychiatric screening in line with the Authorised Prescriber's (TC) TGA approved clinical protocol. The screening process itself took approximately three weeks to complete, and comprised psychometric measures (see Table 1), a semi-structured psychological assessment, medical screening, and prescriber psychiatrist assessment. She reported good physical health and completed blood tests, an ECG, pregnancy test and urine drug screen. She completed the screening program with the authors, a clinical psychologist and an authorized prescriber psychiatrist, both of whom are trained in psychedelic assisted therapy. The nature of the treatment, including possible risks and benefits, was discussed as part of the informed consent process to participate. She was willing to engage in therapy to integrate what might emerge during the treatment.

A case conference was completed with her treating General Practitioner to corroborate the outcome of the assessment, which aligned with our opinion that she was a suitable candidate for MDMA-AT.

Differential Diagnosis

The Australian TGA rescheduling of MDMA and psilocybin is specific to two diagnoses: MDMA is able to be prescribed for PTSD, and psilocybin for "treatment resistant" depression. Because many people with difficult-to-treat depression also have a trauma history, and co-occurring depression is common among people who have a PTSD diagnosis, we reflected with our patient upon which medicine assisted therapy program would be ideal for her given she met criteria for both diagnoses. MDMA-AT for PTSD was chosen as the years of domestic violence she experienced predisposed her developing mental health symptoms and the secondary depression. Her preference was for MDMA-AT. We formed the view during our assessment, that her depression was "treatment resistant" because the effects of underlying relational trauma had not yet resolved. Addressing the impacts of trauma with MDMA-AT, we hoped would reduce depression, anxiety as well as PTSD symptoms. She met DSM-5 diagnostic criteria for severe, chronic PTSD and severe major depressive disorder.

Treatment

The MDMA-assisted therapy program utilised the MAPS MDMA assisted therapy for PTSD manual (Mithoefer, 2015), which has demonstrated promising results in clinical trials. The authors, a male psychiatrist and female clinical psychologist completed all aspects of the therapy as a dyad. There was an additional nurse on site for dosing sessions, who co-administered the MDMA with the prescribing psychiatrist. The patient's blood pressure and heart rate was checked before administering the medicine, then at regular intervals and before the additional half dose was administered, by the prescriber. The psychiatrist and psychologist otherwise had similar roles in the dosing session, providing inner-directed psychotherapeutic support as per the MAPS MDMA assisted psychotherapy manual (Mithoefer, 2015).

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Addi resides in a rural area of New South Wales, so the screening assessment and most of the preparation and integration sessions were completed via online video call. Addi travelled with a family member interstate to our Australian Council on Healthcare Standards (ACHS) accredited outpatient clinic in Victoria to participate in the MDMA dosing sessions. We were unable to provide the dosing sessions in our equivalent clinic in New South Wales, because regulations in New South Wales require the treatment be administered in a hospital setting only.

Preparation Sessions

There were 3 preparation sessions, with an additional in-person meeting in the clinic the day before dosing. Preparation sessions focussed on several themes, including building a trusting therapeutic alliance, exploring an intention for the dosing session, her hopes and fears, explaining the logistics of the dosing day, further elaborating on consent, and preferences for emotional support during the dosing session. This included discussion about therapeutic use of touch as a tool for support during the dosing session, as per the MAPS MDMA-AT manual (Mithoefer, 2015). It was explained that touch was entirely optional, only ever in service of the patient's process (e.g., providing support during times of distress) and that only touch consented to in preparation could be offered in the dosing session. She consented to having the therapists initiate holding her hand if she appeared distressed or she if she requested the supportive touch (hand holding, a hand on her forearm or shoulder). She ceased SSRI medication, 10Mg Lexapro, approximately one month prior to her first dosing day. She received outpatient Repetitive Transcranial Magnetic Stimulation (rTMS) for depression throughout the preparation phase, was able to continue work as usual and managed well. Her support network, husband, and mother were invited into the preparation phase where information was provided to them on what to expect and the nature of the treatment.

MDMA Dosing Sessions

There were three MDMA dosing sessions which occured in our Australian Council of Healthcare Standards (ACHS) accredited outpatient clinic. The initial dose was 120Mg followed by an optional half-dose of 60Mg after approximately 90 minutes. Heart rate and blood pressure were monitored by the prescriber at baseline then every half hour for the first three hours, including prior to the optional extra dose being offered. At each of her three dosing sessions, the patient had the full 180mg dose. The patient was supported by both therapists during the 8-hour dosing session. Rescue medications and a defibrillator were available on site however were not required, as there were no medical or psychological adverse events. The dosing sessions were video and audio recorded, with patient consent, for supervision and safety purposes. Supportive touch was provided as per participant's consented to preferences, in the form of both therapists sitting on either side of her on the couch to hold her hand. This support was provided at a moment when she was experiencing difficult memories, at her request, in the third dosing session.

After ingesting the medicine, the patient was invited to listen to a curated music playlist, sit with her intention and use optional eye shades to "go within". Each session began with a guided body scan meditation practice. Within about an hour, she would begin discussing her trauma experiences in a therapeutic manner and engaged with the therapists throughout most of the session. Body scan meditation exercises were offered at times of distress for grounding when needed, however she was mostly calm during these sessions. There were no adverse events,

with the only side effect reported being loss of appetite. This resolved within 24 hours after each dosing session.

She was accompanied by her mother to and from each dosing session, who was a trusted person aware of the nature of the treatment.

Integration Sessions

The focus of integration was to support Addi to make meaning of the MDMA session, process any challenging material that arose, and embed key insights into her life that may assist in ongoing recovery from complex trauma. Addi attended nine integration sessions in total, with three integration sessions occurring weekly, after each dosing session. The first integration always occurred the morning after dosing day.

Integration sessions explored themes such as expressing her needs, sitting with her emotions, and connection with loved ones. One of the authors (MS) is a level 1 trained Internal Family Systems (IFS; Schwartz, 2013; Morgan, 2020) therapist, and the integration sessions adopted an IFS approach. Sessions also focused on developing a daily meditation practice and anchoring new behaviours and actions that enhanced self-compassion.

After completing the program, Addi commenced an online peer support integration group which we established for participants of legal psychedelic assisted therapy trials or clinics to share and connect with others who have had this type of therapy. Our integration program also offered family support sessions, which her parents attended, to best support Addi in her ongoing recovery and understand the process of the treatment.

RESULTS

The patient consented to join the Australian National University Psychedelic-Assisted therapy Australian national outcome database

(https://medicine-psychology.anu.edu.au/research/research-projects/australian-interventional-pharmacotherapy-psychedelic-assisted-psychotherapy), which collates de-identified outcomes from MDMA, psilocybin and ketamine assisted psychotherapy. Outcome data was gathered at baseline, the beginning of preparation, in the week after each dosing session, at the end of the program. Follow up data is collected at 3-, 6-, 9- and 12-months post-treatment. At the time of writing, she had completed 3 and 6 month follow ups (Figures 1-4). She did not require any other medication during treatment which was maintained at 6 month follow up.

One week after the second dosing session, her IES-R (Weiss & Marmar, 1997) scores dropped from 49 (likely presence of PTSD) to zero, and remained at zero (no PTSD symptoms) as at six month follow up. In addition, her PHQ-9 (Kroenke, Spitzer & Williams 1999) depression ratings dropped from the moderately severe range, to the normal range after the second dosing session and remained in the normal ranges by six month follow up. Similarly, her GAD-7 (Spitzer, Kroenke, Williams & Lowe 2006) scores dropped from the severe ranges, to the normal ranges after the second dosing session, and remained in the normal ranges at six month follow up. After the third dosing session, she began to feel comfortable leaving her children with their father or trusted family member to run errands for the first time. After the second dosing session reported having greater self-compassion and being less troubled by the trauma memories. All these gains were maintained at three- and six-months post-treatment.

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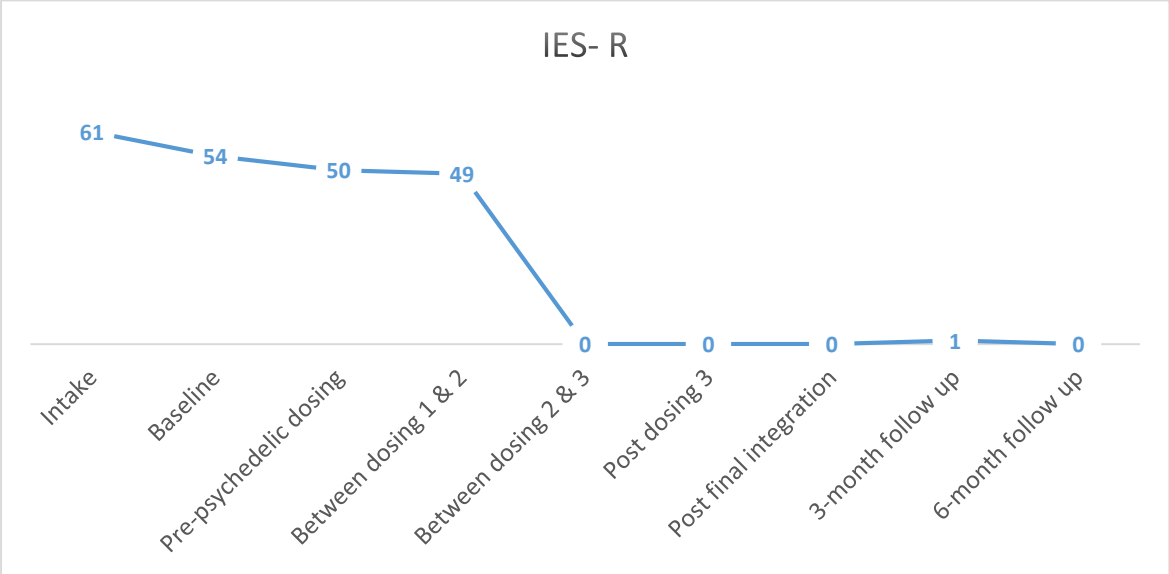

Figure 1: Impact of Events Scale – Revised (IES-R; Weiss & Marmar, 1997) Scores from Screening Assessment to Post-Treatment, Three and Six Month Follow Up. Scores over 33 Indicate the Likely Presence of PTSD, Up to a Theoretical Maximum Score of 88.

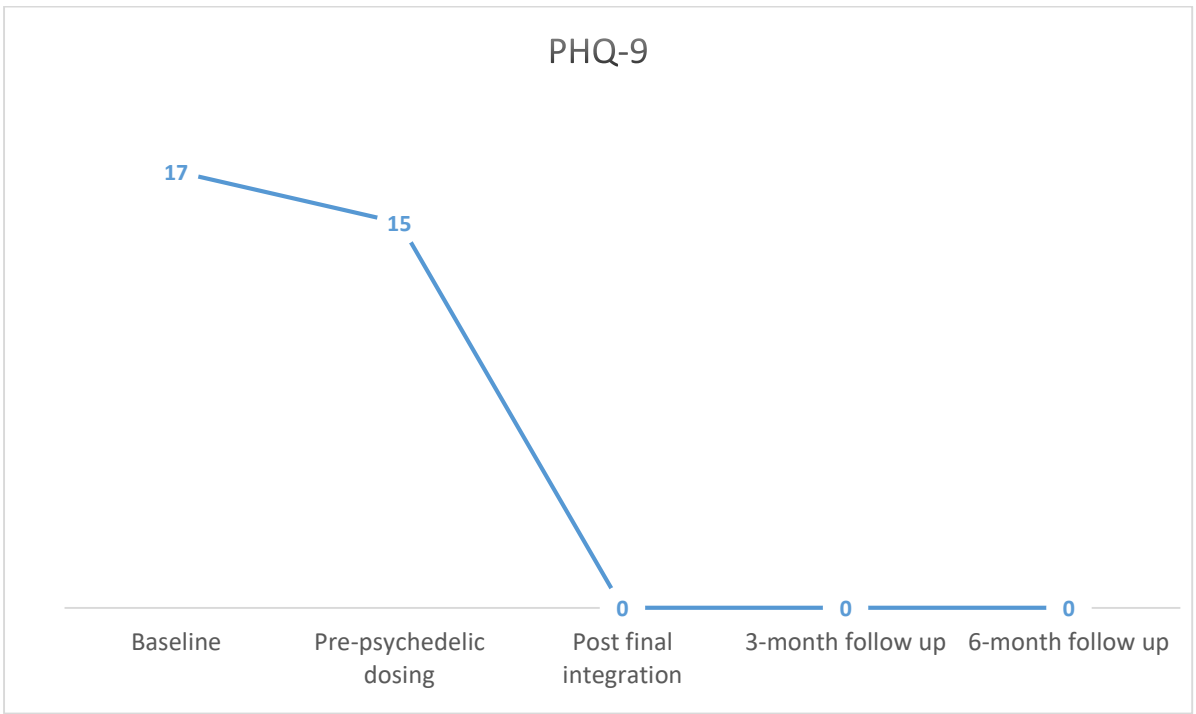

Figure 2: Patient Health Questionnaire – 9 (PHQ-9; Kroenke, Spitzer & Williams 1999) Scores from Screening Assessment to Post Treatment, Three and Six Month Follow Up. Scores Over 20 Indicate Severe Depression, Scores of 15-19 Indicate Moderately Severe Depression, 10-14 Indicates Moderate Depression, 5-9 Indicates Mild Depression and 0-4 None to Minimal Depressive Symptoms

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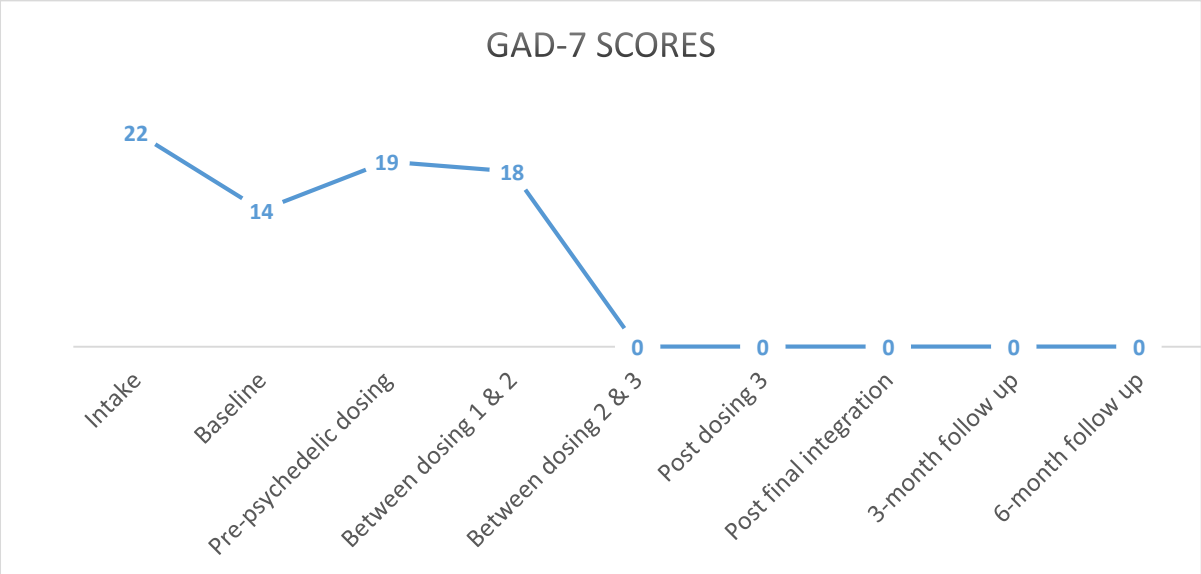

Figure 3: Generalized Anxiety (GAD-7; Spitzer, Kroenke, Williams & Lowe 2006) Scores from Screening Assessment to Post-Treatment, to Three and Six Month Follow Up. Scores Greater than 15 Indicate Severe Anxiety, Scores between 10-14 Indicate Moderate Anxiety, Scores between 5-9 Indicate Mild Anxiety and Scores 0-4 Indicate Minimal Anxiety.

CONCLUSION AND RECOMMENDATIONS

Conclusion

We present one of the first patients to complete a course of MDMA assisted therapy in the Australian community outside of a clinical trial, adapting our approach from the MAPS MDMA assisted therapy for PTSD manual. Our patient no longer met criteria for PTSD by the end of treatment, with gains maintained at six month follow up. We note that this is one person and expect medicine experiences and treatment trajectories to be highly variable. The limitations of this case study include that it is a single patient, of a specific demographic, and the treatment was tailored to her needs. The generalizability of these results is therefore limited.

Despite these limitations, our case study illustrates how psychedelic-assisted therapy might be implemented in clinical practice, in a community health setting. The majority of the preparation and integration sessions were via telehealth, and illustrate how MDMA-AT might be offered to patients in regional, rural, and remote areas of Australia to increase accessibility. While telehealth and travel for dosing sessions is not suitable for all patients, this case study illustrates how this session format may be an option for some patients.

Addi experienced both PTSD and major depression, and in deciding which therapy program would most likely be of benefit, we developed a case formulation to identify precipitating and maintaining factors in her present concerns. We noted that her depression was maintained by trauma-related beliefs and associated guilt, shame, and avoidance, that processing of the trauma would improve her depression and anxiety. We anticipate that other clinicians in the community will be faced with similar treatment planning decisions, given the high co-occurrence of trauma and depression; and that many individuals with difficult to treat depression have a history of trauma or intergenerational trauma.

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Cessation of contraindicated medications is a challenge for psychedelic assisted therapy participants, and prescribers in the community need to consider how to best support patients who are weaning off medications. Regarding the medication tapering prior to dosing, our patient concurrently engaged in outpatient Repetitive Transcranial Magnetic Stimulation (rTMS) for depression which supported her in this process. She was able to continue working as usual during the medication cessation process. In the future, research could investigate the use of rTMS during preparation, and whether this enhances the patient's engagement or outcomes of MDMA-AT.

Another reflection is on therapist training and professional development standards in learning psychedelic assisted therapy. The authors both have 20+ years of experience working in mental health settings and completed training in psychedelic assisted therapy. One of the therapists had taken MDMA legally as a participant in a "healthy participants" clinical trial, and felt this more adequately equipped her to support her first MDMA assisted therapy patient through the medicine sessions. We also received regular supervision from a psychiatrist who had experience working as a therapist in MDMA assisted therapy for PTSD trials, which was invaluable in the early stages of offering this therapy. As a dyad, we debriefed regularly about the patient and our learning process. We also felt that the dyad work enhanced our learning in this new area of mental healthcare, as were able to debrief and learn from each other as well as our supervisor.

Inclusion and representation of Aboriginal and Torres Strait Islander people in these early stages of establishing psychedelic assisted therapy clinics is essential (Sebben, Stone & Sarris et al., 2024). During the set-up of our service, we engaged with cultural consultants (Indigenous Psychedelic Assisted Therapy; IPAT). The social and emotional wellbeing framework (SEWB) for Aboriginal Australians (Gee, Dudgeon, Schultz, Hart & Kelly, 2013) highlights the importance of connection, to body; mind and emotions; family and kin; community; culture; country; spirituality and ancestors. Aligned with this, we established a peer support aftercare program, that included family system support groups. Addi described peer support as helpful in terms of maintaining progress and a sense of connection to other patients with similar experiences and challenges in recovery.

Addi's parents found the family support group beneficial and provided feedback that they would have benefited from more frequent family support groups earlier in the treatment process, which is notable for clinics considering setting up psychedelic assisted therapy programs. We have also amended the treatment protocols to have approval for an an Indigenous counsellor provide the treatment for increased cultural safety for future Indigenous participants.

Recommendations

We have described a case of MDMA-assisted therapy for PTSD, which was safely and effectively delivered in the community. Our key learning points regarding the implementation of MDMA-assisted therapy outside of clinical trials, include the importance of multidisciplinary teams delivering the therapy, the benefits of working in a dyad and accessing supervision in the early stages of implementation. We note that telehealth for preparation and integration sessions may be an option for suitable rural and regional patients to increase accessibility. Finally, we note the usefulness of adjunctive supports to MDMA-assisted therapy for our client, such as Repetitive Transcranial Magnetic Stimulation (rTMS), peer support

integration groups, and the education and involvement of family and carers before, during and after the treatment process.

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