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Ethical Safeguards

Safeguards currently in place include:

1) Potential legal repercussions for interactions that exploit a participant's vulnerable state.
2) Professional societies for psychiatrists, psychologists, and other mental health professionals have ethical guidelines that deter providers from having a sexual relationship with someone once a therapeutic relationship is established.
3) The Code of Ethics developed by MAPS also prohibits any practitioner of MDMA-AT to have an intimate relationship with a participant, including after termination.
4) The appropriate use of safe and respectful therapeutic touch is strictly emphasized in the months-long MDMA-AT Training Program and in the MAPS Code of Ethics.
5) Violation of the MAPS Code of Ethics is grounds for one's MDMA-AT certification to be irrevocably terminated.
6) MDMA-AT sessions are recorded for clinical and research purposes.
7) Supervision of recorded sessions is a core component of the training program.
8) After the completion of training and supervision, each therapist in the co-therapist pair continues to act as an intrinsic check to each other in maintaining ethical conduct throughout the course of treatment.

Despite these layers of safeguards that compound to further mitigate risk beyond traditional care, it may be impossible to ever eliminate the risk of unethical behavior completely. However, the ethical safeguards surrounding MDMA-AT are highly stringent given the prosocial and relational-oriented altered state of consciousness occasioned by MDMA administration, which lends itself to abuse by unscrupulous practitioners. This motivates the required multiple months of intensive training, recorded supervision, and two co-therapists, as well as certification programs and continuing education requirements designed to ensure high fidelity to the therapeutic model.

Therapeutic touch seems to have clinical benefits when implemented appropriately, but the benefits may not outweigh the risks in less regulated settings where risks remain unabated. Altogether, the benefits of therapeutic touch may indeed outweigh the risks when the risks can be optimally mitigated with intensive training, recorded sessions, rigorous supervision, ethical co-therapist pairs in a controlled clinical setting, and a robust system of professional accountability surrounding each treatment session as well as the treatment modality overall.

In 2007, the FDA initiated the Risk Evaluation and Mitigation Strategies (REMS) program, which necessitates an additional layer of medication-specific requirements be met for certain medications to be prescribed. There currently are approximately 75 medications with REMS in the United States. Most REMS require the prescriber be appropriately trained and certified, half require the dispenser be certified, and half require patient enrollment (1).

As of this writing, the REMS requirements tentatively proposed by the FDA specifically for MDMA-AT include: 1) The lead facilitator must be an independently licensed provider with clinical experience delivering psychotherapy either as a physician, psychologist, nurse

practitioner, or other masters-level therapist; 2) The assistant facilitator must have at least one year of clinical experience in a licensed mental health care setting as well as a bachelor's degree; 3) An on-call licensed physician must be able to reach the patient within 15 minutes in case of a clinical emergency. Considering the aforementioned REMS requirements are preliminary, the final REMS requirements are subject to change and may potentially deviate from those mentioned above.

Therapeutic Modality

Preparation Sessions & Intent

Three 90-minute preparatory sessions precede the first MDMA session. The primary purposes of the preparatory sessions are to educate the participant about the treatment, build a therapeutic alliance, and establish the participants therapeutic aim – or what is more commonly known in psychedelic medicine as setting one's *intent*. The intent is thought to be one of the most important aspects of psychedelic-assisted therapy (2). Establishing therapeutic intent is what in part differentiates MDMA-AT from taking MDMA in non-clinical settings where one's intent may be recreation.

In collaboration with the co-therapists, the participant will establish and refine an intent which is often solidified in writing prior to each dosing session. "To feel better" would be an example of an intent that may still be helpful but is likely less than ideal given its transient nature and being relatively open-ended. Whereas "to build trust in myself" would be an example of an intent that may be more helpful to the individual given its relative specificity while still maintaining an open-endedness for a patient-specific process to take place within the intent. Intents with even more specificity such as processing certain traumatic experiences are also viable and are common in MDMA-AT for PTSD.

While the therapists may assist the participant in establishing an intent, the therapists do not prescribe a particular intent. Rather, the therapists endeavor to establish and maintain a dynamic that the participant is truly the expert of their own experience and thus should be entrusted with determining the direction of the therapy. This therapeutic orientation is termed the "inner-directed approach" and is the fundamental construct underlying the Multidisciplinary Association for Psychedelic Studies (MAPS) manualized therapeutic approach to MDMA-AT (3). During the MDMA session, the participant may be reminded of their stated intent.

Establishing and maintaining a therapeutic intent also functions to further create a clear distinction between MDMA-AT versus MDMA used in non-clinical contexts for recreation. In contrast to recreational use of MDMA which is often externally-focused and enjoyable, the inner-directed experience of MDMA-AT tends to be more emotionally challenging and described by the patient as therapeutic "work."

MDMA Sessions

During each 6-8 hour MDMA session, the first dose of MDMA (80 or 120 mg) is administered shortly after beginning the session, and an optional supplemental dose at half of the initial dosage (40 or 60 mg) is offered after approximately 2 hours.

The therapeutic approach during the MDMA session, as mentioned previously, is derived fundamentally from elements of a person-centered, process-oriented approach that endeavors to establish a process of trust, respect, and supportive self-discovery. This is accomplished by providing non-directive support while also encouraging the participant to direct his or her attention to their inner process during the MDMA session. This may primarily involve encouraging the participant to put on their eye shades while listening to a predetermined playlist of music and laying supine on a couch, bed, or futon to ground them in an inner-directed experience. Encouraging the participant to use diaphragmatic breathing to "breathe into" emerging emotional obstacles is also often employed to assist in processing through those challenges while maintaining an inner-directed experience.

In most cases, participants maintain an inner-directed experience for the majority of the session while the co-therapists maintain an active mindfulness of the participant's needs as they arise. In some cases, the participant may have an entirely inward experience where the co-therapists may only converse with the patient in several sentences total throughout the 6-8 hour session. In other cases, a participant may prefer to have an externally-directed experience for most of the session, requiring more active engagement with the co-therapists. Regardless, the role of the therapist is to occasionally encourage the participant towards an inner-directed experience while also being supportive of any externally-directed experiences that are within the participant's therapeutic intent (3).

Notably, traumatic material may spontaneously emerge during dosing sessions without the therapists cuing the participant to focus on or discuss these experiences. Conversely, therapists may remind the participant of his/her intent to process a particular trauma if such processing has not yet occurred during the dosing session (3).

Integration Sessions

The three 90-minute integration sessions that follow each MDMA session are thought to be a critical component of MDMA-AT. New experiential knowledge, insights, and emotional shifts may have been catalyzed both during and after the most recent MDMA session. During the integration session, the participant is invited to share details of their MDMA experience, though this is not required.

Instead, the primary emphases of the integration sessions are to 1) attend to the potential changes that were catalyzed, 2) expand upon them through person-centered exploration, and 3) explore how to *integrate* these changes into daily life by refining one's thoughts and behaviors. The therapists rely less on prescribed manualized therapeutic techniques and instead prioritize establishing a supportive and validating stance of the individual's unique experience and needs.

In earlier studies, after each MDMA session, the participant would stay overnight with a trained night attendant to monitor for the emergence of any medical or psychiatric issues. In later studies, the participant was allowed to go home with a designated escort after each MDMA session and would return to the clinic the next morning for each of the first post-MDMA integration sessions. The latter approach is expected to continue as standard practice.

References

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