Clinical Supervision in MDMA Therapy Training: An Ethical Commitment

SHANNON CLARE CARLIN, M.A., MPBC MDMA THERAPY TRAINING PROGRAM MANAGER

Shannon Clare Carlin, M.A.

In 2016, the MDMA Therapy Training Program was redesigned to prepare dozens of therapists for working on the Phase 3 clinical trials that will soon be started by the Multidisciplinary Association for Psychedelic Studies (MAPS). Since, then the program has trained over 200 therapists and researchers, 80 of whom are co-therapists embarking on MAPS-sponsored MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) clinical trials in 2018.

Supervision is a primary focus of MAPS' current open-label Phase 2 trials, and will continue to be an important piece of the training program going forward. Amongst the 2016 program updates, we added clinical supervision as the final process of initiating new MDMA-assisted psychotherapy providers. In MAPS' MDMA clinical trials, therapy sessions are always conducted by two therapy providers, in a co-therapy pair. Clinical supervision (or just "supervision") entails close oversight and support of the first study participant treated by each co-therapy pair. There are many forms of study monitoring, including sponsor visits to study sites, data monitoring, medical monitoring, and adherence rating. These are all typical functions for conducting sound clinical research. Supervision adds an element of clinical support and oversight specific to the application of the therapeutic method, as outlined in the *Treatment Manual* (**maps.org/treatmentmanual**). Supervisors offer insight and feedback as therapy pairs put into practice the knowledge gained through their training.

Supervision is an ethical commitment to providing competent care to clients by supporting the development of practitioners, and an industry standard in the training of therapists. It is also a requirement for gaining licensure to practice psychotherapy in most jurisdictions, and a common practice in many certificate programs. MAPS and the MAPS Public Benefit Corporation (MPBC) are dedicated to ensuring the integrity of MDMA-assisted psychotherapy trials. As the number of study sites expands, currently 16 in the US, Canada and Israel, so do our efforts to maintain consistent and high-quality care across the sites.

The extra support that supervision provides allows newly trained providers to obtain guidance and ask questions during their first experiences treating clients in a new modality. The lived experience of a supervisor provides invaluable insight for supervisees. A senior practitioner has knowledge beyond the curriculum of the training program, and understands the practicalities of applying a therapeutic model in the real-world.

In MAPS-sponsored trials, the supervisor role is filled by lead therapists, researchers who are experienced in providing MDMA-assisted psychotherapy. They are intimately familiar with the therapy method and protocol. The current supervisors have all published results from MAPS-sponsored Phase 2 trials, and are the trainers in our MDMA Therapy Training Program. They currently include Annie Mithoefer, B.S.N., Marcela Ot'alora, L.P.C., and Michael Mithoefer, M.D.

Supervision in our current active open-label Phase 2 "lead-in" trials is closely linked to adherence rating. Adherence rating is the process of evaluating video-recorded therapy sessions according to specific criteria, assessing how closely co-therapy pairs adhere to the *Treatment Manual* and study protocol. Both adherence rating and supervision ensure a standardized therapeutic approach across many sites with dozens of providers. This standardized method increases data efficacy in clinical trials, as well as consistency and quality of care for study participants. The ratings serve as an internal cross-check, ensuring that the modality outlined in the protocol is indeed the same modality used at each study site. Adherence ratings also provide a feedback loop for training, highlighting areas where providers need more support, and where the training program can update its curriculum for future cohorts.

Examples of adherence criteria include such statements as "Therapists inquired about the participant's knowledge regarding PTSD and/or provided education about it as needed" and "Therapists created and communicated a setting of safety and support." Each criterion is rated "Yes" or "No." There are 24 adherence criteria for Preparatory Sessions, 20 for Experimental Sessions, and 12 for Integrative Sessions. Additionally, there are eight Competence Criteria for each session type. The *Adherence Rater Manual* is currently being updated, and will soon be available online.

Adherence raters undergo a six-month training to learn how to view and rate therapy sessions according to the adherence criteria. Adherence rater trainees are graduate students or professionals in the mental health field who are competent in patient confidentiality. Twelve Adherence raters are currently working on open-label Phase 2 trials in the US and Canada. Another 19 trainees are nearly complete with their six-month training for adherence rating of upcoming Phase 3 trials in the US and Canada. Additionally, a group of bilingual Adherence Raters will be trained to conduct ratings for future trials in Israel and across Europe.

To assist in the added function of supervision, adherence raters collaborate with supervisors to streamline the process of watching hundreds of recorded therapy sessions, rating therapist adherence and providing feedback for the co-therapy pair. While supervisors are the experts on the therapeutic modality, the adherence raters support them by pinpointing timestamps of interest and summarizing the activity of the session.

The technology required for adherence rating and supervision is elaborate. Audio-visual equipment at each study site records every moment of a therapy session and can be immediately uploaded to a secure video server only accessible to authorized users. Within 24 hours of the therapy session, the video is processed into a secure portal for adherence raters and supervisors to access through an encrypted link. Comments are made directly into the video portal, and adherence ratings are entered into the study database. Each piece of equipment and step of the process is supported by an MPBC staff member who closely monitors that everything is working properly and securely.

After successful upload of the video and completion of the adherence rating, the supervisor views the therapy session, reviewing the adherence ratings, timestamps, and comments from the adherence rater. The supervisor then makes their own assessment and adds their own comments to the video portal. Finally, the supervisor provides feedback to the co-therapy pair through regular supervision meetings via video conferencing. These supervision meetings take place before each experimental session so that therapists can make improvements and incorporate feedback before the next treatment.

At the time of this writing, nine co-therapy pairs have enrolled study participants in the US open-label Phase 2 trial, and are meeting regularly with their supervisor. In the coming weeks and months, dozens more co-therapy pairs will join them. The newly designed supervision process is effectively supporting co-therapy pairs in their growth and ability to conduct competent and compassionate treatment for participants enrolled in MDMA-assisted psychotherapy clinical trials.

Shannon Clare Carlin *is passionate about life and growth. She cares deeply about humankind and the natural world. Shannon is dedicated to working with people through addiction, trauma, relationship, and the body. She received her Master's Degree in Integral Counseling Psychology from the California Institute of Integral Studies in 2014, including a practicum working with youth on moderation management for drug and alcohol use. At MPBC Shannon serves as MDMA Therapy Training Program Manager, overseeing administration and program development to educate professionals and researchers to provide MDMA-assisted psychotherapy for PTSD in approved settings. Shannon is also committed to psychedelic harm reduction, and continues to provide integration services through the Zendo Project. Shannon served as co-therapist on the MAPS-sponsored Phase 2 trial researching MDMA-assisted psychotherapy for anxiety associated with life-threatening illness, and will be a co-therapist at the Phase 3 site in Los Angeles, researching MDMA-assisted psychotherapy for severe PTSD. She is a dancer and California native. An adventurer at heart, Shannon can be found running in nature or swimming in a body of water. She can be reached at shannon@mapsbcorp.com.*