



MAPS
Public Benefit
Corporation

**A Manual for Adherence Ratings of
MDMA-Assisted Therapy for Treatment of Posttraumatic Stress Disorder**

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USE

In conjunction with relevant regulatory and ethical guidance

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1.0 Background

The Treatment Manual, [*A Manual for MDMA-Assisted Therapy in the Treatment of Posttraumatic Stress Disorder*](#), offers practical guidance for conducting MDMA-assisted therapy sessions in accordance with a MAPS-sponsored Study Protocol. The Treatment Manual facilitates standardization of the therapy method through an emphasis on adherence to the Study Protocol. The role of this Adherence Ratings Manual is to outline procedures that establish and maintain congruence to the Treatment Manual.

Adherence is a significant effort toward fulfilling the Sponsor's greater responsibility to ensure a certain standard of care and guarantee the quality of study data. By overseeing the implementation of the study methodology, the Sponsor is able to ensure that the application of treatment is as intended, which serves to enhance the quality of care for Participants, and also that the application of treatment is consistent, so that the Sponsor can pool data across studies for meta-analyses.

Adherence is fundamentally a data quality assurance (QA) and standardization process. By administering Adherence Rater reviews of therapy session video, based on Adherence Criteria, the Sponsor aims to implement QA across the entire treatment process. By further establishing and maintaining reliability between individual Adherence Raters, the Sponsor aims to validate the Treatment Manual Adherence process. Inter-rater Reliability measures are designed accordingly to standardize the QA process.

Figure 1: The QA and Standardization Approach (arrow indicates the role of oversight)

Sponsor – *Inter-rater Reliability* → Adherence Raters – *Adherence Protocol* → Treatment

To establish Inter-Study Reliability, Adherence Raters review video sessions and rate them for Adherence to the Treatment Manual based on this Adherence Ratings Manual. To establish Inter-Rater Reliability, multiple Adherence Raters review the same video sessions and generate ratings. These ratings are compared statistically to measure reliability.

2.0 Adherence Rater Qualifications

Due to the specialized and sensitive nature of the work that is involved, it is important for an Adherence Rater to have the proper qualifications. Adherence Raters are either licensed or in training to become licensed mental health professionals.

The following qualifications are deemed essential:

- Motivation for self-development in the therapeutic field
- Eagerness to learn about MDMA-assisted therapy
- Formal, graduate-level training in psychology, social work, or psychiatry
- Licensed as a mental health professional, or in training to become one
- At least one year of psychotherapy internship experience or equivalent experience with direct patient contact
- At least one year of experience working with trauma population or equivalent
- Training in the sensitive and confidential nature of the subject material
- Openness to feedback
- Ability to review session videos in a private setting, on a personal computer from a secure internet server
- Completion of Adherence Rater training (as described in Section 3.0)

- Strong self-care habits and emotional support resources

When recruitment for Adherence Raters is open, applicants may submit their CV to the Sponsor; the Sponsor will assess qualifications for essential requirements. Only those applicants meeting the requirements will be accepted for training. Applicants may be asked to show proof of completed patient confidentiality coursework, such as Law and Ethics or HIPAA training. Applicants accepted for training will receive access to training materials and an invitation to an upcoming instructional session. Participation in the Adherence Rater Training Program is not guarantee of a paid position conducting adherence ratings; performance will be evaluated upon successful completion of training.

3.0 Adherence Rater Training Program

Once an applicant has been accepted into the Adherence Rater Training Program, they will be provided with instructions to register for the online training. The Adherence Rater Training Program is a 5-month online program consisting of approximately 65 hours of training, including: five 2-hour live meetings with a Gold Standard Adherence Rater, required reading, rating assignments, and reliability ratings.

The following are required to be completed before the first training meeting:

- Submit documentation of prior coursework completion in patient confidentiality
- Review and sign a Confidentiality Agreement
- Read the current version of the Treatment Manual, [*A Manual for MDMA-Assisted Therapy in the Treatment of Posttraumatic Stress Disorder*](#)
- Read the Adherence Manual (this document), *A Manual for Adherence Ratings of MDMA-Assisted Therapy for Treatment of Posttraumatic Stress Disorder*
- Review training materials on Adherence Rating and MDMA-Assisted Therapy for PTSD
- Review training materials on self-care, cultural awareness, and inclusion

The Adherence Rater Training Program follows the outline below, with live training calls to be scheduled according to Sponsor and Adherence Rater Trainee availability. Training calls typically occur once a month.

Pre-Training

1. Training Registration
 - a. Create account on online training portal (URL will be provided)
 - b. Sign Confidentiality Agreement
2. Pre-Training Assignments (5 hours)
 - a. Read Treatment Manual
 - b. Read Adherence Ratings Manual
 - c. Review training materials on Adherence Rating and MDMA-Assisted Therapy for PTSD
 - d. Review training materials on self-care, cultural awareness, and inclusion
 - e. Participate in discussion via online training portal discussion board

Month 1: Orientation & Adherence Rating for Preparatory Sessions

3. Live Training Meeting #1: Adherence Rater Training Program Orientation and Rating Preparatory Sessions (2-hour online call)
 - a. Introductions
 - b. Review of training schedule

- c. Overview of Adherence Rating process
 - d. Cultural awareness and inclusion
 - e. Training on Adherence Criteria for Preparatory Sessions
 - f. Self-care strategies and identifying sources of support
4. Preparatory Session Homework (8 hours)
- a. Five video assignments: watch video, take notes, submit rating form
 - b. Reading assignments
 - c. Participate in discussion via online training portal discussion board

Month 2: Adherence Ratings for Experimental Sessions

5. Live Training Meeting #2: Adherence Ratings for Experimental Sessions (2-hour online call)
- a. Group check-in
 - b. Review Preparatory Session Rating Assignments
 - i. Reliability scores
 - ii. Address discrepancies between Gold Standard and group or Inter-rater reliability
 - iii. Questions and discussion
 - c. Training on Adherence Criteria for Experimental Sessions
 - d. Check-out: self-care and support
6. Experimental Session Homework (18 hours)
- a. Six video assignments: watch video, take notes, submit rating form
 - b. Reading assignments
 - c. Participate in discussion via online training portal discussion board

Month 3: Adherence Ratings for Integrative Sessions

7. Live Training Meeting #3: Adherence Ratings for Integrative Sessions (2-hour online call)
- a. Group check-in
 - b. Review Experimental Session Ratings and Homework
 - i. Reliability scores
 - ii. Address discrepancies between Gold Standard and group or Inter-rater reliability
 - iii. Questions and discussion
 - c. Training on Adherence Criteria for Integrative Sessions
 - d. Check-out: self-care and support
8. Integrative Session Homework (8 hours)
- a. Six video assignments: watch video, take notes, submit rating form
 - b. Reading assignments
 - c. Participate in discussion via online training portal discussion board

Month 4: Adherence Rater Comments and Best Practices

9. Live Training Meeting #4: Adherence Rater Comments and Best Practices (2-hour online call)
- a. Group check-in
 - b. Review Integrative Session Ratings and Homework
 - i. Reliability scores
 - ii. Address discrepancies between Gold Standard and group or Inter-rater reliability
 - iii. Questions and discussion
 - c. Training on Adherence Rater comments
 - d. Panel Discussion and Q&A with experienced Adherence Raters
10. Calibration Rating Homework (14 hours)
- a. Three video assignments: watch video, write rating commentary, submit rating form
 - b. Reading assignments
 - c. Participate in discussion via online training portal discussion board

Month 5: Adherence Rater Training Program Review and Graduation

11. Live Training Meeting #5: Adherence Rater Training Program Review and Graduation (2-hour online call)
 - a. Group check-in
 - b. Review Calibration Rating assignments
 - i. Reliability scores
 - ii. Address discrepancies between Gold Standard and group or Inter-Rater reliability
 - iii. Questions and discussion
 - c. Questions and training feedback
 - d. Graduation celebration
12. Training Survey
13. Training Certificate of Completion sent to Adherence Rater Training Program graduates

4.0 Assessing Reliability and Calibration

A process of rating calibration involving Adherence Raters' watching and coding the same video sessions is designed to standardize the assignment of the adherence ratings themselves. In order to ensure that individual Adherence Raters are applying the rating method consistently, calibration video sessions will be selected by the Sponsor Supervisor and then scored by all available Adherence Raters in the pool. Over the course of the Adherence Rater Training Program, at least three video sessions, one of each type, will be rated for calibration and reliability testing (at least one preparatory, one experimental, and one integrative session).

The gold standard for adherence ratings represents an expert opinion, intended to reflect the standard for rating. To establish reliability compared to the gold standard, the rating responses given by an individual Adherence Rater will be compared to the ratings made by the gold standard, and a percentage score will be calculated, representing how closely the individual Adherence Rater agreed with the ratings of the gold standard on a particular video. A score of 75% or higher is considered sufficient agreement with the gold standard. The group average score will also be assessed, by calculating an average of all of the individual scores from the pool of Adherence Raters. The percentage score an individual Adherence Rater receives is intended to indicate that Adherence Rater's ability to rate accurately according to the gold standard.

To help determine the validity of the gold standard on a given video, the gold standard's ratings can be compared to the group median. A percentage score will be calculated, representing how closely the gold standard agreed with the ratings of the group median on a particular video. A score of 75% or higher is considered an effective gold standard. An effective gold standard would be unlikely to have strong disagreement with the group median, although this may happen if there is a very small pool of Adherence Raters, an error in data entry, the Gold Standard Adherence Rater makes a rating that doesn't align with the standards of this manual or the Adherence Rater Training Program, and/or when a given criterion, or an entire video, is particularly difficult to rate. In these cases, the video assignment should be reassessed; if there are one or two problematic criteria, those may be removed from the analysis and reliability testing would be repeated without them. If there are more than two problematic criteria on a given video assignment, the entire assignment should be replaced with a new one, the Gold Standard Adherence Rater and pool of Adherence Raters should rate the new assignment, and reliability can be reassessed. Gold Standard Adherence Raters, when not producing the gold standard for a given video assignment, will participate in the pool of Adherence Raters during routine reliability and calibration testing to maintain their ability to rate as a gold standard.

To establish *inter-rater* reliability, the intraclass correlation coefficient (ICC) will be analyzed. The rating responses of individual Adherence Raters within the pool are compared to each other and not the gold standard. An ICC value of 0.75 or higher is demonstrative of a consistent Adherence Rater pool, meaning the group has strong internal agreement on the ratings. In instances in which more than 80% of group median scores are the same (e.g., more than 80% of ratings are “Yes” ratings), half of the items will be reverse coded before ICC calculation to account for instability of the ICC calculation when there is a lack of variation in ratings.

The gold standard reflects the expertise of one Gold Standard Adherence Rater, intended to represent the standard for rating, while the ICC reflects the robustness of an entire pool of Adherence Raters. In some cases, a pool of Adherence Raters may disagree with the ratings made by the gold standard. This may be reflected by a group average score, compared to the gold standard, that is much lower than 75%. During training periods, it may be common for the group average to start low and increase with additional training. If the group average score is low and the ICC is also low, this may be a sign of the need for additional training for the group, in which case a training plan will be implemented, and another round of calibration will be set. If the group average score is low and the ICC is high, that may be a sign of a weak gold standard for that particular video, in which case the assignment should be reviewed, and a replacement assignment should be considered.

Table 1: Determining Outcomes of Reliability Process

Outcome	Average % Agreement with Gold Standard	% Agreement Gold Standard with Group Median	ICC
Successful group reliability	75% or higher	75% or higher	0.75 or higher
Unlikely outcome, check gold standard	75% or higher	less than 75%	less than 0.75
Unlikely outcome, check for outliers	less than 75%	75% or higher	less than 0.75
Check gold standard	less than 75%	less than 75%	0.75 or higher
Wide variability, retest on new assignment	less than 75%	less than 75%	less than 0.75

The Sponsor will examine the variability in the data to identify any items that need to be discussed with the Adherence Rater pool. This process of reliability and calibration can be repeated, on an individual basis or by the whole group, as many times as necessary, until each Adherence Rater is reliable. Any Adherence Rater trainee who is unable to establish reliability after two rounds of analysis must complete additional training in order to graduate from the Adherence Rater Training Program.

In order to maintain inter-rater reliability, the pool of Adherence Raters will complete a group calibration test and refresher training every six months that a protocol is active. A gold standard will be set, and tests of validity of the gold standard and of reliability compared to the gold standard will be calculated as described above; average agreement with the Gold Standard and group median agreement with the Gold Standard scores of 75% or higher and an ICC of 0.75 or higher will be considered sufficient agreement. Feedback will be provided to ensure that individual Adherence Raters are learning how to apply adherence ratings consistently, and additional meetings to discuss reliability or assignments to retest for reliability will be scheduled on an as-needed basis during the calibration process. Any Adherence Rater

who is unable to establish reliability after two rounds of analysis must complete additional training in order to continue in the Adherence Rating Program.

5.0 Roles and Responsibilities

5.1 Adherence Rater Role and Responsibilities

Adherence Raters complete the Adherence Rater Training Program, establish reliability, maintain confidentiality, and report to the Adherence and Supervision Coordinator, as assigned.

Adherence Raters are tasked with the following roles and responsibilities:

- Review session video (as described in Section 11)
- Accurately complete Source Records containing ratings and relevant feedback by set deadline
- Be available for comments after Source Records submission, as needed
- Attend ongoing, monthly Adherence Rater meetings and check-ins
- Proactively engage in self-care, seeking support from other Adherence Raters as needed
- Ongoing cohesive communication with other Adherence Raters and the Adherence and Supervision Team
- Ensure technical set-up is maintained to privately and securely view videos

5.2 Adherence Rating Program Leadership Structure

The purpose of reviewing videos of study visits within MDMA-assisted therapy clinical trial protocols is to ensure conformity of clinical study visits with the most recent version of the Treatment Manual. Accordingly, the Sponsor delivers Adherence Ratings that include summarized feedback to the Clinical Supervisor and Medical Monitor for distribution to the study team. The Sponsor will manage the data workflow (as described below) and provide oversight of ratings activities, acting in a supervisory capacity with regard to adherence activities.

The Sponsor is tasked with the following roles and responsibilities:

- Establish qualifications of Adherence Rater Trainees
- Facilitate training for Adherence Rater Trainees
- Assess availability of Adherence Raters
- Manage rating assignments to ensure timely completion
- Collect, compile, and oversee QA on the Adherence data
- Ensure validity of Adherence data
- Maintain an accurate database of Adherence Source Records

In order for the Sponsor to effectively administer the Adherence Ratings process, an intermediate leadership structure has been created between the Sponsor and Adherence Rater teams to provide a layer of support, in the form of supervision, management, and training of Adherence Raters.

Five specific leadership roles are designated:

- Director of Training and Supervision
- Adherence and Supervision Program Manager

- Adherence and Supervision Coordinator
- Gold Standard Adherence Rater(s)
- Lead Adherence Rater(s)

5.2.1 Director of Training and Supervision

The Director of Training and Supervision provides oversight and guidance to the Adherence Rating Program. The Director of Training and Supervision manages the Adherence and Supervision Program Manager, Adherence and Supervision Coordinator, and Video Team, advising on administrative structure, training activities, and reliability analysis. The Director of Training and Supervision reports directly to the Sponsor Executive Director.

Specific roles and responsibilities include:

- Formulating a vision for the Adherence Rater group structure and processes in line with other rating groups used in the clinical program
- Guiding the Adherence and Supervision Program Manager and Adherence and Supervision Coordinator to actualize the vision
- Ensuring timely completion of tasks assigned to the group within timelines set by the Director of Clinical Research
- Providing thorough, objective feedback based on knowledge of standards in the field
- Approving final documents and ratings criteria
- Programmatic review and strategic planning

5.2.2 Adherence and Supervision Program Manager

The Adherence and Supervision Program Manager provides oversight to daily operations of the Adherence and Supervision program.

Specific roles and responsibilities include:

- Supervising the Adherence and Supervision Coordinator and providing oversight to adherence activities
- Developing and maintaining systems to support Adherence Rater trainings and ensure quality Adherence data collection
- Interacting with the Director of Training and Supervision to ensure the adherence team is run in line with other rater groups and the expectations of the Sponsor
- Collaborating with Gold Standard Adherence Raters on developing and providing training activities
- Evaluating qualifications of potential Adherence Rater Trainees and reviewing applications
- Critically reviewing completed trainings and incorporating participant feedback to ensure quality trainings
- Overseeing reliability testing and analyses
- Documenting Adherence Rating and Training rating procedures
- Reviewing ratings data and feedback and refining ratings criteria as needed

5.2.3 Adherence and Supervision Coordinator

The Adherence and Supervision Coordinator attends to the operation of the adherence rating program.

Specific roles and responsibilities include:

- Maintaining regular contact between the Sponsor and the Adherence Rater groups to ensure all parties are kept abreast of timelines, availability, and task completion
- Coordinating trainings and inter-rater calibrations for Adherence Rater Trainees and Adherence Raters
- Assessing availability and workload capacity of Adherence Raters
- Coordinating Adherence Rater assignment scheduling, tracking deadlines, invoice reminders
- Managing rating assignments to ensure timely completion
- Collaborating with Sponsor staff to assign protected video content for rating assignments
- Maintaining scheduling platforms for task assignment
- Co-facilitating Adherence Rater meetings
- Supporting Adherence Rater Trainees through the training program, documenting progress
- Coordinating Adherence Rater calibration
- Compiling adherence ratings and written feedback for review by the Sponsor participating in the development of Adherence Criteria
- Interacting with the Adherence and Supervision Program Manager and Director of Training and Supervision to ensure the adherence team is run in line with other rater groups and the expectations of the Sponsor

5.2.4 Gold Standard Adherence Rater Role and Responsibilities

Experienced Adherence Raters who demonstrate excellent performance, leadership, and high reliability scores may be recruited to serve as Gold Standard Adherence Raters. Training and thorough familiarity with the Treatment Manual and the Adherence Ratings process is an essential prerequisite. At least one year of adherence rating experience in a MAPS protocol, with more than one study participant, is required to qualify as a Gold Standard Adherence Rater. Gold Standard Adherence Raters act as trainers in the Adherence Rater Training Program and set the gold standard ratings for testing reliability and calibration. Gold Standard Adherence Raters typically participate in Adherence Rating for active study protocols, in addition to their role as a trainer and setting the gold standard. Gold Standard Adherence Raters report to the Adherence and Supervision Coordinator directly and may occasionally correspond with the Adherence and Supervision Program Manager or Director of Training and Supervision.

Specific roles and responsibilities include:

- Maintaining regular contact with the Sponsor and the Adherence Rater group to ensure both parties are kept abreast of timelines, availability, and task completion
- Setting the gold standard to establish and maintain reliability across the rater pool during Adherence Rater trainings and calibration
- Providing Adherence ratings and drafting written feedback for review by the Sponsor
- Collaborating with the Adherence and Supervision Team to develop and provide training activities
- Developing documentation of training and rating procedures
- Supporting processes for self-care in clinical matters (countertransference, theoretical orientation, nuances of Adherence items, burnout, vicarious trauma, etc.) amongst Adherence Raters
- Assisting in review of qualifications of potential Adherence Rater Trainees
- Facilitating training modules for Adherence Rater Trainees
- Critically reviewing completed trainings and incorporating participant feedback to ensure quality

5.2.5 Lead Adherence Rater Role and Responsibilities

Adherence Raters who demonstrate excellent performance, leadership, and high reliability scores may be recruited to serve as Lead Adherence Raters. Training and thorough familiarity with the Treatment Manual and the Adherence Ratings process is an essential prerequisite. Lead Adherence Raters participate in Adherence Rating for active study protocols. Lead Adherence Raters report to the Adherence and Supervision Coordinator and Adherence and Supervision Program Manager directly and may occasionally correspond with the Director of Training and Supervision.

Specific roles and responsibilities include:

- Maintaining regular contact with the Sponsor and the Adherence Rater group to ensure both parties are kept abreast of timelines, availability, and task completion
- Collaborating with the Adherence and Supervision Coordinator and Adherence and Supervision Program Manager to co-facilitate monthly Adherence Rater calls
- Supporting communications with the rater pool and serving as a peer liaison with fellow Adherence Raters
- Supporting processes for self-care in clinical matters (countertransference, theoretical orientation, nuances of Adherence items, burnout, vicarious trauma, etc.) amongst Adherence Raters

6.0 Confidentiality

Study videos and other research data may contain identifying information and are confidential. All Adherence Rater Trainees and active Adherence Raters must have a signed copy of the Video Confidentiality Agreement on file with the Sponsor. Adherence Raters shall not use or share confidential information other than for the purposes of its business with the Sponsor. Adherence Raters will not disclose, publish or otherwise reveal any of the confidential Information received from the Sponsor to any other party whatsoever except with the specific prior written authorization of Sponsor. Adherence Raters shall not download or duplicate any confidential information provided to them by the Sponsor, unless explicitly requested by the Sponsor. Adherence Raters must return all confidential information upon request, alternatively the Sponsor may request the destruction of such information, within ten days of request. Adherence Raters will not discuss any of the reviewed material with anyone not involved with MAPS studies. Adherence Raters should always check with their Supervisor if in doubt when contacted by anyone regarding the study.

Adherence Raters and Adherence Rater Trainees must commit to internet security measures by accessing video and other confidential information only on secure internet connection on a private computer. Adherence Raters are prohibited from conducting ratings for MAPS-sponsored studies over public networks. These networks include, but are not exclusive to, universities, libraries, coffee shops, airports, restaurants, and other public settings. Permissible networks must be secured private home or work networks. All network users must be known to the Adherence Rater, and the network must be configured with WPA encryption, which is standard with most password-protected wireless network routers. If Adherence Raters connect to the network wirelessly, they must disable network sharing on their machines. Adherence Raters must use password-protected logins on their computers.

Adherence Raters should not access video or audio in the vicinity of others, where non-staff might see or hear protected content. Adherence Raters should log out when they complete online work and must never share their login information or passwords with anyone. If an Adherence Rater becomes aware of a breach in confidentiality, they must immediately notify the Sponsor.

Adherence Raters who are Mandated Reporters should reference the Mandated Reporting Guidelines for MAPS staff members, a document provided by the Sponsor. Adherence Raters must fulfill the legal duties of their profession and must report any safety or reporting concerns immediately to the Sponsor.

7.0 Conflict of Interest

Adherence Raters are expected to make all reasonable attempts to reduce bias when rating study video sessions. Adherence Raters should not view or rate videos of Participants with whom they have a pre-existing relationship. Additionally, if an Adherence Rater has a personal relationship with one of the therapy providers in the video, beyond an acquaintance, they should immediately notify the Sponsor to assess for reassignment. If an Adherence Rater is unable to view or rate a therapy session due to the content of the session, such as personally triggering material, they may request reassignment. As soon as an Adherence Rater or Adherence Rater Trainee becomes aware of a conflict of interest, real or potential, they should immediately notify the Sponsor.

8.0 Adherence Rater Self-Care

Adherence Raters should engage in regular self-care to prevent emotional burnout and vicarious trauma that could result from interacting with trauma content. Because of the emotional intensity of trauma therapy and the remote nature of Adherence Rating, it is especially important that Adherence Raters take breaks, engage in their support networks, continue doing their own personal work, and participate in regular debriefing with fellow Adherence Raters during the monthly Adherence Rater calls. Some suggestions include setting up the workspace with comforting objects, such as a candle, picture of a beautiful landscape, favorite blanket, cup of tea, or aromatherapy. Especially when rating Experimental Sessions, plan to take breaks, step away from the video for a little while, drink water, eat a snack, get outside, take a short walk, breath. Consider a method for decompressing after rating a session, such as attending a yoga class, taking a shower, or cooking a meal.

Engagement in regular meetings with other Adherence Raters is required. Adherence Rater calls include an opportunity for Adherence Raters to process their own emotional responses from working with Participants, as well as peer supervision and discussion about the optimal application of the ratings method in specific situations. Meetings will be held remotely, once a month during active study protocols. Adherence Raters will be provided with additional resources for self-care and are encouraged to reach out for support.

For the sake of validity, it is very important that Adherence Raters never change ratings based on discussions with fellow Adherence Raters. If any questions, concerns, or validity issues arise before, during, or after a meeting, please compile them and request clarification from the Sponsor.

9.0 Adherence Rating Data Workflow

The data workflow involves sharing recordings of experimental therapy sessions from the clinical study site, to the Sponsor, then onto remote Adherence Raters who complete Adherence Ratings. Videos of the sessions are uploaded from the clinical study site to the Sponsor's remote server. The Sponsor grants access to the assigned Adherence Raters to remotely stream session videos for rating purposes only. Data generated by the Adherence Raters is submitted to the Sponsor via electronic Source Records in the Valis database.

Figure 2: Data Workflow

Investigator (Site) —*Video stream*→ **Sponsor remote server**→ **Assigned Adherence Rater (Remote)** —*Ratings forms on Valis database*→ **Sponsor (MAPS)**

Once Adherence Raters receive an assignment from the Sponsor, they should complete their assignment within the given deadline. Rating turnaround times vary depending on the study protocol. Any expected delays should be brought to the immediate attention of the Supervisor so that the task can be reassigned.

10.0 Adherence Rating and Comments

Adherence ratings will be used to determine to what extent the delivered treatment adheres to the Treatment Manual. Adherence should be scored for the joint Therapy Pair, not for each Therapist individually. In some cases, an adherence criterion need only be addressed by the Therapy Pair during one session out of a series of sessions; ratings should be conducted based on observation of the assigned video and not previous videos or unrecorded content.

If a video or audio recording is incomplete and the video support staff cannot recover the lost content, the Adherence Rater should rate the session based on observable content. If more than 15% of the therapy session is missing from the recording, then an accurate rating cannot be achieved, and the video should not be rated. In this case the Sponsor may request an alternative session, or sessions, be rated from the same Therapy Pair.

10.1 Adherence Commentary Instructions

In addition to completing an adherence rating, Adherence Raters will leave qualitative commentary in the web-based portal. Adherence Raters' comments are intended to provide additional context to ratings and to support supervision of Therapy Pairs. Adherence Raters are encouraged to make note of anything they feel important for the Sponsor to review, including areas of strength and potential weakness.

Participant names, initials, or other identifying information should not be included in commentaries. Adherence Raters should use the following abbreviations:

- Participant = P
- Therapist 1 = T1
- Therapist 2 = T2

Commentary should include a key indicating which therapist is abbreviated as T1 and which as T2 (typically identified by the color of their clothing or other distinguishable visual characteristics).

Commentary should include an overall summary of the session and specific comments and observations.

Specific comments should include relevant quotes, time stamps, and rating criteria. Adherence Raters are encouraged to consolidate comments regarding the same topic, for example listing two timestamps that support the same adherence rating together in one comment.

Commentary should be focused on the following topics (see example comments in section 10.1.1 below):

- Overall summary of the session (providing a sense of the arc of the session, including the sequence of major themes/events in the session, and overall impressions of the session)

- A/V Issues (e.g., issues with audio or camera, such as being unable to see/hear the participant, music too loud, audio crackling, camera angle off, etc.)
- Logistical issues (e.g., timing issues, feedback on room setup, extended absence of one of the therapists from the room, etc.)
- Moments in which deviation from the adherence criteria/protocol are observed
- Areas of ambiguity about whether or not adherence criteria were met (e.g., moments in which an adherence criterion was touched upon but may not have met the full criterion)
- Moments that may reveal a potential area of weakness or missed opportunity
- Moments that illustrate the competence or strength of the Therapy Pair
- Examples and feedback about the tenor of participants' interaction with the therapists
- Dynamics or tensions between the therapists
- Body language and positioning
- Use of music
- Red flags/anything that feels "off"
- *For protocols with placebo:* discussions regarding condition assignment (active MDMA vs. therapy-only)

Adherence Raters should bear in mind the following:

- Not all instances in which a theme/issue was observed should be listed – a few key examples are sufficient.
- Quotes or observations should not be included without an accompanying comment explaining their importance (e.g., "5:28.61- there is a lot going on"; "1:15:05- P went inward; 1:29:40- went back inward")
- Adherence Raters should never include comments about whether or not they perceive the participant received placebo, as this compromises the integrity of study data (e.g., "1:50: It became clear that the participant got the placebo")

10.1.1 Examples of Adherence Comments

Overall summary (providing a sense of the arc of the session, including the sequence of major themes/events in the session, and overall impressions of the session)

- This prep session not only gave the information, but also embodied the information, in a really experiential way. So, not only did they explain "non-direction", they showed it to her and allowed her to feel what that was like. Not only did they explain what it means to go into her body, they had many moments where they had her go into her body to have that felt experience. There was a lot of silence in this session - it became really obvious that they were creating an experience for her during this session, and that the vibe of the experimental was actually brought into the preparatory. Through the participant's own feedback, this was incredibly valuable. (1:05:50-1:08:00) They slowed her WAY down and her system responded really favorably. Her normal defense mechanisms of intellectualizing and talking a lot were drastically and positively impacted by the container that they provided. They created an atmosphere that really established the tone, the container, the relationship, and the way that the experimental was going to go. I thought this session was really special.
- This session seemed to be a solid starting point, and there were no observed problems. The therapists give an overview of what's ahead, and they mention the importance of the prep sessions as a relationship-building opportunity. T2 explains that in this first prep session they may not go very deeply into trauma history and that they want to address P's concerns and expectations. They spend the fair amount of time acknowledging the healing journey she has already been on and her experience of anxiety and coping, eliciting some relevant history, and they discuss the possibility

of placebo. There are several criteria that are not yet discussed (12a, 13a, 15a, 17a, 18a, 19a, 20a, 24a).

- This session was delivered with high adherence to the protocol. The therapists were warm, authentic, affirming, supportive, and gentle. P is clearly very well-read on PTSD and its treatment. He had a lot of specific questions that they answered thoroughly. His difficulties trusting others, intellectualizing, and emotional avoidance were apparent, but the therapists were sensitive to all of it. They (particularly T2, who tended to be a bit more active here) were exemplary in how they covered many of the topics, including those that are subjective and difficult to convey in words, like inner-directiveness. In fact, I can see several exemplary parts of this session being used for training. I have never seen such a thorough discussion about the role of music and touch either.
- This is a solid and effective integrative session. Therapists are not faced with any real problems/barriers, and client readily reflects and talks about her process, insights, and gains/growth. The bulk of the session notes I made pertained to items 5c, 6c, and 7c... therapists demonstrating active listening and validation of insights and affirming experiences. Therapists do not meet every single criterion in this session, but near the session end they remember to touch on a couple more key integrative points/criteria. The therapists' role in this session seems primarily about being reflective of observations and insights the participant is making about her own process. And rather than simply parroting the client (which sometimes can seem vapid), their comments are incisive and helpful at facilitating or inviting client to expand and go deeper. Their words seem measured and thoughtfully chosen and serve to help client with deepening and connecting ideas.

A/V Issues (issues with audio or camera, such as being unable to see/hear the participant, music too loud, audio crackling, camera angle off, etc.)

- Video froze at 7:25:10
- Unfortunately the participant is off most of the screen so it is impossible to gauge non-verbal responses. T2 is partly off the screen as well.
- The camera is set up high, so it is looking down on the therapists and participant from a bird's eye view. The participant is in full view, though a little far away and kind of blurry, so it's hard to see her facial expressions. T1 is cut off and I can only see the back of her head and body from the top down. T2 is more in full view, but I can only see his profile when he is facing the client. The audio is clear most of the time. There was some outside noise that sometimes interfered with being able to understand what was being said.

Logistical issues (e.g., timing issues, feedback on room setup, extended absence of one of the therapists from the room, etc.)

- Showed visit number and participant number, but the marker was so faint as to be pretty much unintelligible.
- Set up of room feels good. Good lighting, intention, gentle music already playing. Everything is within comfortable reach of participant.
- At the beginning of the session they were unsure about appropriate administration of MDMA, which is concerning. They were able to contact someone for clarification. At 0:32:00 it is determined that they had only given the participant half the dose, and they contacted a supervisor and were instructed to give the other half dose.
- 3:21:00 The participant was asking therapists to hold her. They discussed what would feel safe for all given COVID precautions. They settled on T1 holding her feet to ground her, and it seemed she felt well held/cared for.

Moments in which deviation from the adherence criteria/protocol are observed

- 20b: At 2:51:20 she gets up to go to the bathroom. Neither Therapist has her pause before standing and did not closely escort her to the restroom.
- 17a, touch: There was no discussion about touch. At 0:14:21, the P joked about getting back massages, and this would have been a great opportunity to cover this item, but T2 only said, “Sure, we can do some bodywork.”
- 4b: There were some points where the therapist encouraged inner focus. This was great. On the other hand, the subject also was not allowed to have periods of silence. At one point the male therapist even interrupted the subject’s inner focus period with a question (3:19:57).

Areas of ambiguity about whether adherence criteria were met

- 4b (inner focus balanced with communication): At 1:31:26 she explains “I think I just needed to be heard. I’m sitting here and I’m like I should be going inside, but I spend so much time going inside guys! no one’s really listened to me no one really knows my life.” T1 gives her permission: “Talk, we would like for you to feel seen and heard and validated.” At this point she starts talking about her sexual trauma. At no point from here onward do either therapist make the suggestion to her to go inside, which seemed like good exercise of clinical judgement. At 1:50:10, she reports, “I’m very afraid that y’all are mad at me for not going inside. We need to talk about this.” The therapists help her explore her fear of not being liked, and remind her that they might make suggestions but that it’s all up to her and her inner healer to decide what to do... Although a close call, I decided they met this criterion because the effort was made on several occasions to invite her to go inside, and when it became apparent that she needed to be verbally processing for pretty much the whole session, this was allowed.
- 8a, MDMA effects: The therapists slightly touched on this at one point (0:28:30) when saying that it affects everyone differently and everything she experiences will have an arc. The P also talked about how the MDMA she used in the past affected her (palpitations, jaw clenching), so it seems like she already knows the effects of MDMA, but I would have liked to see a more active explanation from the therapists here, especially since most of what she described was quite aversive.
- I struggled with rating item 17b (processing regrets/self-judgment). Although the therapists definitely provided a safe space for the P to bring up several regrets and self-judgment (mainly not having “solved the problem” of his PTSD, but also feeling like a failure compared to his friends and not having self-compassion), I feel like they could have been more explicit in the second part: framing these issues as part of the ongoing process of healing.

Moments that may reveal a potential area of weakness or missed opportunity

- Several things came up that to me seemed like they should’ve been addressed in the prep. P seemed to have questions about what the point of the session was (0:37:00), identified feeling like she had to talk about the trauma and force herself into very uncomfortable conversation (instead of being encouraged to let her inner healer take the lead with a beginner’s mind) (1:42:00), didn’t know she didn’t have to talk to the night attendant (7:32:20), and wasn’t sure what the next morning’s session would be for (5:24:15).
- 4:32:41: P: “I simultaneously feel comforted and safe here and at the same time, tension” (which by the way was exactly the way I felt about these parts. The therapists were so nice and directing her towards loving feelings but there was something else she needed as well). What was striking to me was when she would speak of anger or fear of her anger or any negative emotion, (like tension in the above example) which she always had the impulse to inhibit T1 would then ask her, not about the emotion, but about how she felt towards that little girl in the story. This would invariably steer her away from that emotion rather than helping her to both deepen and normalize the experience so she could allow herself a fuller range. The result was always sweet and she

always felt nurturing and sympathetic towards her feeling self but took her away from the deeper experience in the present moment. (See also timepoints 3:45:00, 4:12:20, 4:25:10)

- 0:27:45 – Asked her if she knew what MDMA does. Therapist said “Everyone experiences it somewhat differently. We see a whole range of experience and nothing will be concerning to us.” This was a nice way to show support and let participant know that they wouldn't judge her experience (1a), but this might have been a missed opportunity to just go over the likely effects of the medicine (8a).

Moments that illustrate the competence or strength of the Therapy Pair

- T1 was very good at slowing down her story-telling to bring her deeper into her own experience. E.g., in this moment, what's this sense of that? Is it familial or is it personal, or is it something we haven't considered? (1:23:00), Yeah, can I stop you for a second? Just stay with what's happening with your body right now. This shakiness in your voice and yeah trust that experience to the best of your ability (1:37:20), So in this moment can you allow the hurt? (3:51:22).
- 7:27:35.37 – T2 closes by guiding P through a breath mindfulness exercise, which is beautifully done. There is something energetically special here, because she has a kind, soothing, gentle, maternal voice. He seems to like the exercise. Perhaps this is maternal nurturing that he never received. The music is absolutely perfect here.

Examples and feedback about the tenor of participants' interaction with the therapists

- 00:55:49 When P lays down and gets settled in she says “it's nice to be cared for,” indicating T1 & T2's bond with her, and making her feel safe and held.
- 1:18:00 (While attempting to stay clear of being "parental") T2 reiterates concerns about the client's safety. P appears to take this somewhat defensively (kind of underscoring a level of transference or judgment about herself). I am concerned with how these therapists kind of freeze up or shut down in response to the client's somewhat unusual lifestyle. I worry that their judgment over her lifestyle will become much more evident to the client during the experimental session which could get in the way of the client fully embracing her true self and accessing her inner healing intelligence.
- T1 showed indications of frustration by asking a host of questions about P's trauma as if doing an initial psychiatric interview (1:28:00, 3:19:20, 3:45:00). T2 was more receptive. Neither approach worked. Everyone looked exhausted by hour 6.

Dynamics or tensions between the therapists

- I don't think the therapy pair worked especially well together early in the session. T1 interrupts T2, and she also critiques his choice of words at 35:00 min in. There's a bit of tension or awkwardness that could be felt, but it's subtle. Later in the session, the therapy pair seem to work much better together and more as a team.
- 2:43:05 – T1 has a tendency to glance at T2 but she does not really respond; it seems like he is looking for assurance perhaps? It comes off as a tentativeness or lack of confidence.
- The therapists worked well together, creating a good balance of how much each one spoke, since the patient had a good rapport and positive transference towards them both, and seemed to value the contributions of each in different ways. At one point T1 recognized a misunderstanding the participant was having in trying to comprehend T2's point, and quickly stepped in to explain the confusion and clear it up so the two could continue (03:19:00).

Body language and positioning

- P asks to hold someone's hand after having been inside for a while (02:35:00 -02:37:45). Instead of moving closer to her, T1 leans way forward in an uncomfortable position that she is aware of. His position makes her uncomfortable and she withdraws her hand.

- From the outset the atmosphere seemed awkward. P took a position sitting on couch with her back against the wall which she maintained for the next 6+ hours and waited. P burrowed under her blanket and kept it on her for 6 hours despite the therapists complaining that the room was stuffy and getting hotter.

Use of music

- This participant really hated the music. I think the therapists did a good job attempting to use it as a vehicle for bringing up what it reminded her of, and skipping the songs she absolutely hated. But it ended up being a pretty big thing throughout the session, and I wonder if picking different music or not turning it back on would have let more processing happen.
- 3:20:21 - This music sounds almost like dance music and does not feel quite appropriate for where the P is right now.

Red flags/anything that feels “off”

- I don't know how I feel about T1 knitting during an experimental session. It feels disengaged when talking about trauma.
- 04:34:15 P appears to be texting. I'm surprised they are allowing this.
- 07:52:12 When T2 left the room at the end to bring in the night attendant (whose gender pronoun is “they”), T1 makes a comment about the night attendant to the participant, refers to them as “he,” and corrects himself in the following sentence by switching to “they.” T1 then makes a comment to the participant about how he doesn't “like” the gender pronoun “they.” This was incredibly culturally insensitive and clinically inappropriate, and initiated a conversation where the participant went on to share her feelings about people who use “they” as a pronoun.

Discussions regarding condition assignment (active MDMA vs. therapy-only)

- 1:49:47- P says, “My body feels weird and it makes me anxious to focus on it. My hands feel clammy and my head is hot.” T2: “those are all feelings consistent with the medicine.” (I don't think this is appropriate, even if true, because therapists should not make assumptions about if they have gotten medicine/placebo.)
- 1:36:10, 2:34:20 P states he doesn't think he got placebo; therapists validated his feelings but did not state their own opinion or further discuss this topic.
- 2:27:18 - P expresses anger to therapists about saying that they can't know if he's on MDMA: “It's fucking bullshit and it feels patronizing.” He was pretty caustic but they did not get defensive. Later, at 3:54:57 – T2 gets dangerously close to agreeing with P that he got placebo, but he did rather paint the therapists into a corner with that by getting mad at them earlier for saying that they can't be sure (in his mind it is obvious and a catastrophe). At 5:15:58, P says he was hoping for a breakthrough with the MDMA; T2 says “that's still a possibility, later on,” which implies that she agrees that this is placebo.

10.2 Adherence Rating Instructions

When reviewing a therapy session, adherence to the treatment protocol is determined by recording the occurrence or absence of “adherence items,” a predetermined set of specific actions and behaviors. For each adherence item, Adherence Raters assess whether or not the therapy team demonstrated the behavior described and make the appropriate selection, either Yes or No.

For example, if the therapists fulfilled the requirement of item 1a, then “Yes” would be selected:

Yes No

- 1a. Therapists created and communicated a setting of safety and support.

Likewise, if the therapists did not demonstrate the behavior described in item 1a, then “No” would be selected:

- Yes No
 1a. Therapists created and communicated a setting of safety and support.

For items that contain conditional situations, all instructions outlined in the item should be followed. If the condition did not exist, the item should be rated “Yes.” For example, in item 17b for experimental sessions, if regrets or self-judgment did not occur, then “Yes” would be the appropriate response:

- Yes No 17b. Therapists facilitated processing of any regrets or self-judgment by putting them
 in perspective as part of the ongoing process of healing. If regrets or self-judgment
did not occur, select Yes.

Adherence items do not have to be accomplished in any specific order. Within the list of adherence items, a distinction is made between general and discrete behaviors or actions. General behaviors or actions correspond to overall approach and conduct. General behaviors or actions items might require that the entire session be reviewed before assigning a rating. Discrete behaviors or actions correspond to specific episodes, events, or moments. Discrete behaviors or actions items can be rated as soon as the specified behavior or action is observed.

11.0 Adherence Criteria

11.1 Adherence Criteria in Preparatory Sessions: Definitions and Examples

1a. Therapists created and communicated a setting of safety and support.

- Therapists should be observed to be helping the participant feel a sense of safety and comfort in the therapeutic setting through comments or actions that communicate presence, acceptance, attunement, validation, support, and/or kindness.
- This item is expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists discuss confidentiality, explain that the participant’s agency is essential throughout treatment and that they never want her to feel things are being done to her, and discuss their role in supporting the participant. The participant seems to resonate with what’s being said and to feel comfortable with the therapists.
 - **Yes:** Throughout the session, the therapists make small, supportive comments that communicate presence, attunement, support, connection, validation, kindness, and acceptance.
 - **No:** The participant states several times that although she feels ok talking about her trauma with her therapist, she is uncomfortable talking with two new therapists at once. The therapists acknowledge her discomfort but spend the majority of the session reviewing history and logistical points, and the participant seems uncomfortable throughout, sitting with arms crossed and not making eye contact with the therapists.

2a. Therapists nurtured an attitude of trust in the healing properties of the therapeutic process and introduced the concept of the participant’s inner healing intelligence.

- Therapists do not have to use the specific terminology of “inner healing intelligence,” but they should be observed to introduce the concept of inner healing intelligence (the innate ability to heal and grow) and convey their trust in the participant's process.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapist says, “The body knows how to heal itself. If someone goes to the ER with a cut, a doctor can stitch the wound together, but they don’t direct or cause the healing that ensues. The body initiates a remarkably sophisticated healing process and spontaneously moves toward healing. The psyche, too, exhibits an innate healing intelligence and capability.”
 - **Yes:** The therapists say, “We trust in your inner healer” and go on to explain what this means.
 - **No:** The therapists say, “We trust in your process,” but do not further elaborate.

3a. Therapists elicited, explored, or addressed the participant’s expectations, fears, or concerns.

- Therapists should be observed to explore or address the participant’s expectations, fears, or concerns about treatment. If these spontaneously arise and the therapists explore or address them, this item can be considered met.
- If discussion of the participant’s expectations, fears, or concerns does not spontaneously arise, the therapists must be observed to inquire about them for this item to be met.
- This item is expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The participant mentions that she is nervous about sleeping at the site after Experimental sessions. The therapists provide an explanation of what will happen after an Experimental session, discuss the night attendant’s role, and specify that the participant can reach out at night if needed.
 - **Yes:** The participant brings up her concerns about getting placebo. The therapists further explore and normalize her fears, and provide information about how the therapy-only assignment can potentially provide healing.
 - **No:** The therapists are not observed to elicit expectations, fears, or concerns.
 - **No:** The participant mentions some expectations she has of the study. The therapists listen but do not respond, and go on to describe the typical procedures of the experimental session without connecting their description to the expectation, fears, and concerns brought up by the participant.

4a. Therapists validated the importance of positive, affirming experiences as part of the process of healing, growth, or meaning-making.

- This item is specific to the therapists' validating the importance of positive, affirming experiences in the context of the Experiential sessions (treatment). The therapists should be working to prepare the participant to know that having positive experiences in an Experimental session can be just as important/healing as negative ones.
- Although not covered by this item, the therapists’ validation of positive, affirming experiences overall in the participant’s life is also important. Raters are encouraged to look for and comment on the therapists’ general attitude, namely whether they are going beyond looking at the pathology of the participant; searching for positive experiences/parts of the self; encouraging positive practices that come from within the client; and/or encouraging positive practices for integration and self-care.
- This item is not expected to be met in each Preparatory session.

- *Examples:*
 - **Yes:** The participant talks about how dance and song have been healing for her. The therapists validate this and say, “Just like some of these moments have helped you in your healing journey, there may be very affirming moments in the medicine sessions that help you in your healing.”
 - **Yes:** The therapists state that positive feelings may arise during the Experimental session, and that they will encourage the participant to sit with any positive emotion that arises as part of the process.
 - **No:** The participant talks about how dance and song have been healing for her. The therapists validate this but do not tie it into the context of treatment.

5a. Therapists validated the importance of negative, difficult experiences as part of the process of healing, growth, or meaning-making.

- This item is specific to the therapists' validating the importance of negative, difficult experiences in the context of the Experimental sessions (treatment). The therapists should be working to prepare the participant for challenging experiences should they arise in an Experimental session.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapist makes an analogy of wound-cleaning when talking about difficult experiences that may arise in an Experimental session, saying sometimes there is a painful process in service of healing.
 - **Yes:** The therapist says, “There may be times when the MDMA magnifies the experience of wanting to hide or of disappearing. We trust that however that comes up will be part of the healing process.”
 - **Yes:** The therapist states that healing isn't linear and that during the Experimental session, if negative or challenging emotions arise, they are coming up for healing.
 - **No:** The therapists are not observed to mention the possibility of encountering difficult experiences in an Experimental session.
 - **On the fence:** The therapists say, “Sometimes the medicine will bring painful thoughts or memories to the surface. We will help you to deal with that.” If the therapists go on to explain that they will help the participant to process difficult experiences in order to heal, this item is met. If they do not further explain or tie challenging experiences to the healing process, this item is not met.

6a. Therapists elicited significant historical information, especially that which was related to trauma history.

- Therapists should be observed creating an opportunity for the participant to share personal history. Because details about the participant's trauma are collected extensively in the source record, therapists do not need to go deeply into history or speak about it at length for this criterion to be met. For example, the therapists might ask, “Is there any more about your experiences that you'd like us to know at this point?”
- Raters should bear in mind whether the therapists have created opportunities for the participant to share, as well as whether (in conjunction with the information that will be received from the Source document) it seems that the therapists have enough information about the participant and their situation to be supportive.
- This item is not expected to be met in each Preparatory session.
- *Examples:*

- **Yes:** The participant spontaneously begins to discuss their trauma history; the therapists listen actively and ask appropriate clarifying questions.
- **Yes:** The therapists ask the participant how it was for him to complete the CAPS assessment. They say, “You don’t have to describe all of what happened – we can review the records. But is there anything about the trauma that came up during that interview that you’d like to talk about here with us?”
- **No:** The therapists are not observed to ask about the participant’s history, and the participant does not volunteer any details about it.
- **On the fence:** The therapists ask, “Is there any more about your experiences that you’d like us to know?” and the participant declines. If it seems the therapists are building a safe container where it seems that the participant feels able to share if/when desired, this item is met. If it seems there is not enough information or trust in the dynamic for the participant and therapists to feel adequately prepared for the Experimental session, this item is not met.

7a. Therapists assessed the participant’s knowledge of PTSD and its impact on their life; therapists provided education about PTSD if needed.

- Therapists should be observed:
 - Assessing the participant's knowledge of PTSD
 - Identifying how PTSD symptoms manifest in the participant’s life
 - If needed, providing information that is tailored to the participant's needs. Often education is provided through normalizing effects of PTSD that the participant is experiencing.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapist asks, “What are some of the ways that PTSD shows up in your life?” and, if any areas where additional psychoeducation would be warranted arise, provides further education about them.
 - **Yes:** The participant shares some details about their experience of dealing with trauma. In response, the therapists tie the participant’s experiences to some of the common symptoms of PTSD. They ask, “Is there anything you’d like to know about PTSD?”
 - **Yes:** The participant appears to be quite knowledgeable about PTSD, using several academic terms related to her PTSD symptoms.
 - **No:** The participant does not describe the impact of PTSD in their life, and the therapists do not inquire.

8a. Therapists described the likely effects of MDMA.

- Therapists should be observed:
 - Stating that each person experiences the effects of MDMA in different ways, and a range of effects may arise
 - Describing at least 2 of the most common physiological and at least 2 of the most common psychological effects of MDMA.
- This prepares participants for some of the experiences that may arise, as well as for knowing that people have different experiences of MDMA. If the therapists do not describe common effects or do not state that experience of effects is variable, this item is not met.
- Common physiological effects of MDMA:
 - Dizziness while rising
 - Jaw tightening

- Temperature change
- Loss of appetite
- Change in pulse
- Intense bodily sensation
- Heightened sensation and perceptual changes
- Common psychological effects of MDMA:
 - Increased feelings of intimacy or closeness
 - Reduced fear when confronting emotionally threatening material
 - Enhanced positive mood
 - Novel thoughts about meaning of objects, events, or memories
 - Increased access to distressing thoughts and memories
 - Reduced anxiety
 - Decreased self-blame and judgment
 - Changes in the meaning or significance of perceptions
 - Altered perceptions of time
 - Waves of intense emotion or experiencing
 - Magnification/spotlight on things in the participant's life
 - Challenging experiences
 - Blissful experiences
 - Resource richness
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapist says, “Everyone experiences the medicine in different ways, but some of the common effects can include feelings of connection or closeness, and intense waves of emotion. Physically, it can sometimes cause people to have intense bodily sensations or changes in body temperature.”
 - **No:** The therapist states that MDMA may facilitate experiencing intense emotions in a new way, but does not provide other common psychological or physiological side effects or state that the effects of MDMA are variable.
 - **No:** The participant states that she has done Ecstasy in the past and experienced a lot of teeth grinding. The therapists state that “nothing will surprise us,” but do not elaborate further. Because they do not touch on the most common effects of MDMA, this item is not met.

9a. Therapists described typical procedures of Experimental Sessions.

- Therapists should, at minimum, describe the following elements of Experimental sessions:
 - How the room will be set up;
 - Tests that will be conducted prior to beginning the session;
 - Collecting vitals;
 - Description of medication administration and onset of medication;
 - When they will have food;
 - What will happen at the end of the session (e.g., that there will be a night attendant or that the participant's support person may pick them up or stay with them).
- If these elements of an Experimental session are covered, this item is met; if there was not enough of a walkthrough for the participant to be prepared for what to expect or only a few of the elements of an Experimental session are described, this item is not met.
- Often this item is met in Preparatory Session 3, when the therapists tie the elements together to provide a comprehensive picture of what the participant can expect in the subsequent Experimental session. Ideally this description of a typical Experimental session is delivered as a

standalone description, unless delivering this information all at once is not appropriate to the participant's situation.

- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists provide a standalone description of the Experimental session flow.
 - **Yes:** Due to the flow of discussion with the participant, the therapists describe the different elements of the Experimental session over the course of the session; it is not a standalone description but covers all of the listed elements.
 - **No:** The therapists mention some of the elements of the Experimental session but do not cover all aspects.

10a. Therapists explained that this model of therapy uses a largely inner-directed approach and elaborated on the meaning and implications of this approach.

- Therapists should be observed:
 - Describing the inner-directed approach (often discussed as different from goal-oriented therapy in that it follows the participant's internal wisdom, is frequently somatic, and includes a good deal of time spent inside)
 - Conveying their trust in the participant's inner healer and its direction
 - Conveying that they are there to support the participant throughout whatever comes up
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapist says, "We really trust this process and trust the person's inner wisdom to bring up the content that is needed in each session. Especially during the medicine session, we encourage you to focus inward and work with whatever comes up. We are here to support you in that process."
 - **No:** The therapist says, "We take a non-directive approach in these sessions – we really trust in your inner healer," but do not convey that they are there to support the participant.

11a. Therapists explained that, in Experimental Sessions, they will encourage the participant to set aside expectations and remain open to whatever emerges (beginner's mind).

- Therapists should be observed to encourage non-directedness in the participant's relationship with their own process – for example, by setting aside expectations and holding intentions lightly. This differs from 10a, which is regarding therapists' introduction of the therapeutic approach.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapist says, "We encourage you to approach whatever comes up as part of your healing process. We trust that your inner healing intelligence will bring you what you need for healing and that that's much more reliable than anything you or we could figure out ahead of time with our rational minds."
 - **No:** The therapist says, "Just be open to whatever happens" but does not further explicate.

12a. Therapists explained that, during Experimental Sessions, they will encourage the participant to have periods of inner focus balanced with periods of verbal communication, which either the therapists or the participant may initiate.

- The therapists should be observed describing that in Experimental sessions there will be a combination of inner-directed time and time spent interacting together, which any party may initiate.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapist says, “We’ll encourage you to have alternating periods of going inside, using eye shades and listening to music if you want to, and then talking to us when you feel like it.”
 - **Yes:** The therapist says, “Sometimes if we’ve been talking for a while we may suggest you bring your attention inside, or you may just get the sense that you need to do this.”
 - **No:** The therapist says, “Sometimes you’ll talk with us, and sometimes we’ll have you go inside” without communicating that the participant can initiate either communication or inner focus.

13a. Therapists and the participant agreed that at some time during each Experimental Session, the therapist may bring up the trauma, if the participant has not spontaneously done so.

- An agreement should be observed between the therapists and participant that if the participant’s traumatic experiences do not come up spontaneously, the therapists may inquire about them at some point in the Experimental sessions.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists say, “If you haven’t mentioned trauma at all in the session, we ask for permission to ask about it, but that doesn’t mean you need to go there.”
 - **No:** The therapists state that they will bring up the trauma during the Experimental session; it is not posed as an option to which the participant could agree or disagree.
 - **No:** The therapists do not mention that they may bring up the trauma at some point during the Experimental session.

14a. Therapists explained that in this model of therapy, they will provide support and encouragement for staying present with difficult experience.

- The therapists should be observed to convey that they will encourage and support the participant to welcome difficult emotions, operating as much as possible from the assumption that whatever arises is being presented at that moment by the inner healing intelligence as an opportunity for healing.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists say, “We want to reaffirm our commitment to be present for you. We will make this a safe place for you to have whatever experience comes up. If difficult things come up, try to stay with them and fully experience them and use your breath to move into them as much as you can. And ask us for anything you need.”
 - **Yes:** The therapists say, “We are going to be following your lead and inviting you to explore what your internal experience is.” The participant says that this is hard for her, and they say, “We will be here to support you in that, and we can titrate if it is challenging or too much and assist you in getting grounded.”
 - **No:** The therapists say, “Sometimes the medicine will bring painful thoughts or memories to the surface. We will help you to deal with that” but do not explain that they will support the participant to stay present with their experience.

15a. Therapists explained that if thoughts or feelings of wanting to leave should arise during Experimental Sessions, it is important to express them and work with them as part of the inner process rather than to act on them. Therapists explained that, at the beginning of each Experimental Session, they will ask for an agreement that the participant will not leave the clinic until the next morning.

- The therapists must explicitly state the importance of not leaving during Experimental sessions and state they will ask for the participant’s agreement at the beginning of each Experimental session that they will not leave the site until the next day.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists say, “Sometimes people have feelings of wanting to leave partway through the session. If this comes up for you, we encourage you to bring it to our attention, and we will work through these feelings together. We will ask for your commitment at each medicine session not to leave until after the session and overnight stay are complete.”
 - **No:** The therapists say, “Sometimes people have feelings of wanting to leave partway through the session. If this comes up for you, we encourage you to bring it to our attention, and we will work through these feelings together.” They do not say that they will ask for the participant’s agreement not to leave until the next morning.

16a. Therapists explained that during treatment, they may inquire about participant’s bodily sensations and encourage exploration of the body through movement or whatever way may feel appropriate to the participant.

- Therapists should be observed saying that they will inquire about bodily sensations and that they will encourage exploration of bodily sensations and awareness of what’s happening in the body during the Experimental session. Frequently therapists will describe this using terms such as “somatic,” “in your body,” or “sensation.”
- This does not have to be a lengthy discussion in order for the item to be met, simply enough that the participant is not surprised when it comes up in an Experimental session.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists mention that different bodily sensations may arise during the Experimental session and state that they will encourage the participant to feel into any bodily sensations or movement that feels right to them.
 - **No:** The therapists briefly mention that they will ask the participant to pay attention to their body, but do not provide additional explanation about what this means, what it may look like, or why they are doing it.

17a. Therapists discussed the optional use of physical touch during Experimental Sessions and Integrative Sessions. Therapists made it clear that physical space and participant boundaries will be respected and that the participant will be asked before the first Experimental session what they are comfortable with. Therapists communicated that touch happens only with the participant's consent and can be discontinued at any time by the participant's saying “Stop” or another comparable agreed-upon command. Therapists clearly stated that all touch is nonsexual.

- Therapists should be observed to cover each of the following points:
 - They will respect the participant’s physical space and boundaries
 - They will ask the participant about their boundaries around touch

- Touch only happens with the participant's consent
- The participant can discontinue touch at any time
- All touch is nonsexual
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists say, "During the sessions, we may offer touch, like holding your hand or offering bodywork, if it is appropriate and wanted. We will ask you before the medicine session what you are comfortable with. It's always up to you. Touch is never sexual, and it is always optional and up to you. If there is ever a time when you don't want touch, you can say 'Stop' or another word you'd like to use, and it will stop immediately."
 - **No:** The therapists state that they will ask about and respect the participant's physical space and boundaries and agree upon a word the participant may say if they are uncomfortable with touch, but do not state that all touch is nonsexual.

18a. Therapists explained that they will use music to support the experience without being intrusive and will allow periods of silence, if requested by the participant.

- Therapists should explain:
 - That music is used to support emotional experience in the Experimental sessions
 - That periods of silence will be allowed
 - This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists say, "We find that music can help people go further into their experience, and we'll be offering headphones and music to you at some points in the session. If you prefer for it to be silent at points during the session, you can always ask for that."
 - **No:** The therapists explain the use of music in Experimental sessions but do not state that it is optional and periods of silence are allowed.

19a. Therapists discussed the rationale for using eyeshades and headphones at times during the Experimental Session to increase inner focus. The therapists made it clear that eyeshades and headphones are optional.

- Therapists should be observed to say:
 - That eyeshades and headphones are used at times in the Experimental sessions in order to support participants to go inside and open to their unfolding experience
 - That eyeshades and headphones are optional
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapist explains that headphones and eyeshades can help participants to go inside during internal processes, and adds that their use is at the participant's discretion.
 - **No:** The therapists describe the use of eyeshades and headphones, but do not state that they are optional.
 - **On the fence:** The therapists describe the use of eyeshades and headphones, and the participant says that she is worried about using eyeshades around other people but will challenge herself. The therapist says they will support her to try to use them and encourage her to hold curiosity around what the eyeshades bring up. If they then say that

the participant can decline to use them, this item is met. If they imply that it's preferred that the participant use the eyeshades, this item is not met.

20a. Therapists explained that they will ensure the participant's physical safety in various ways, for example, by asking them to sit on the edge of the futon before rising, protecting the participant from falling when walking, and ensuring adequate fluid intake by asking the participant to drink periodically.

- Therapists should be observed to state:
 - That they will ask participants to sit on the edge of the futon before rising
 - That they will protect the participant from falling when walking – this may bring up a discussion of when a participant's boundaries around touch cannot be maintained
 - That they will ensure adequate fluid intake
- In addition, they may discuss other ways that they will ensure safety, for example, that they may prevent participants from hurting themselves by discouraging movement that feels unsafe.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists say, “We will make sure you are safe throughout the session, including asking you to wait a moment before standing up during the session, preventing you from falling, and encouraging you to stay hydrated.”
 - **No:** The therapists state that they will ensure that the participant has adequate fluid intake, but they do not state that they will ask the participant to sit on the edge of the futon before rising or that they will protect them from falling.

21a. Therapists identified a stress inoculation technique that worked well for the participant and/or taught the participant a stress inoculation technique, such as diaphragmatic breathing.

- The goal of this item is for the therapists to identify or teach tools that can be used in Experimental and Integrative sessions if needed. If the therapists and participant discuss only stress inoculation techniques that cannot be practiced in the context of a session (e.g., walking on the beach), this item is not fulfilled.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The participant is talking about his meditation practice and about how counting breaths has helped him tremendously when he feels triggered.
 - **Yes:** The therapists say, “Part of the approach we're going to use in the sessions is to support you in staying present with whatever feelings come up. It's a paradox that breathing into feelings rather than moving away from them can lead to healing, moving through them, instead of away.” They then teach a breathing technique for stress inoculation.
 - **No:** The therapists inquire about how the participant works with stress, and the participant says that they go for long hikes or call their cousin. Because these are not stress inoculation techniques that can be applied in a session, this item is not fulfilled.

22a. Therapists invited the participant to talk about their experience of anxiety, including triggers and defenses, and discussed ways that the therapists can help the participant through anxiety states if and when they occur.

- Therapists should be observed both eliciting information about the participant’s experience of anxiety and discussing ways that they can help the participant through such experiences. If both aspects of this item are not covered, this item is not met.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists inquired about the participant’s experience of anxiety, eliciting that she tends to mask her anxiety and alertness, making it difficult for others around her to notice it. They discussed ways to identify if she is experiencing anxiety and ways that they can help her through these states if they notice them arising.
 - **No:** The therapists inquire about how the participant experiences anxiety, but do not explore ways that they will help the participant through anxiety states.
 - **On the fence:** The participant is actively experiencing anxiety in the Preparatory session. The therapists actively work to help the participant through their anxiety state. If there is an acknowledgement that they have just worked to help the participant through an anxiety state, this item is met. If there is no discussion of this, the item is not met.

23a. Therapists and the participant discussed the nature of the participant’s support system.

- Therapists should be observed to elicit information about the participant’s support system (who knows about the study in the participant’s life; who can they talk to about emotional issues). If the therapists explore the topic but find the participant does not have a strong support network, this would be rated Yes.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** The therapists and participant discuss the participant’s partner, family, and friends as possible sources of support, and explore the qualities of support that each is able or unable to offer.
 - **No:** The therapists ask about the participant’s support system, and the participant says, “I have some friends I can talk to.” They do not elaborate, and the therapists do not inquire further.

24a. Therapists discussed the possibility of including a support person in a study session(s), including discussion about the conditions that would need to be met for the support person to participate in a session.

- Therapists should be observed:
 - Discussing if the participant would like to invite someone to join in at a future session.
 - Explaining that they would like to meet and speak with the support person prior to their joining the close of an Experimental session.
 - Extending an invitation for the support person to join, if the participant desires.
- The intention behind this item is to assess whether these elements are discussed; it is not asking for an assessment of whether or not it was appropriate for the therapists to invite a support person.
- This item is not expected to be met in each Preparatory session.
- *Examples:*
 - **Yes:** After discussing the participant’s support network, the therapists say, “If you’d like, your sister could be invited to join at the end of one of the medicine sessions. We would want to meet her during a Preparatory visit beforehand. Would you be interested in having her involved?”

- **No:** The participant's support person is present in the session being rated. They discuss how the support person will be involved in the Experimental session. Presumably this item was met in a prior Preparatory session, but it is not considered met in this session.
- **No:** The therapists state that the participant can invite their support person to join in at the end of the Experimental session, but do not state that they would like to meet the support person in advance of the Experimental session.
- **No:** The therapists ask if the participant would like their support person to be involved in a session, and the participant immediately says no. The therapists do not describe what involvement would entail.
- **On the fence:** The therapists state that the participant can invite a support person to a Preparatory session and answer the participant's questions about what would happen if the partner were to attend part of a Preparatory session. Although they do not discuss the support person's possible involvement in a subsequent Experimental session, they are covering all of the requirements for the support person to be involved, and this item is met.

11.2 Adherence Criteria in Experimental Sessions: Definitions and Examples

1b. Therapists created and communicated a setting of safety and support.

- Therapists should be observed to be helping the participant feel a sense of safety and comfort in the therapeutic setting through comments or actions that communicate presence, acceptance, attunement, validation, support, and/or kindness.
- *Examples:*
 - **Yes:** The therapist says, "I know a lot of your tendency can be to tough it out. Today is an invitation and encouragement to let go of as much of that as possible. This is a whole day for you to have all the support you need, all the support you are able to accept, and allow yourself to feel and work with whatever comes up rather than pushing it away or sucking it up."
 - **Yes:** As the participant puts on her eye shades, she says, "It's nice to feel taken care of."
 - **No:** Although the therapists worked hard to establish rapport, the participant appeared uncomfortable, wary, and disengaged throughout the session.
 - **No:** The therapist is very quiet throughout the session, mostly writing notes. They sit down to eat together in complete silence. The participant asks him several questions, trying to engage, but he is brief in his responses, and they return to silence.

2b. Use of physical touch and/or physical space respected the participant's boundaries.

- Therapists must be observed to respect the participant's physical space and boundaries at all times. All touch is nonsexual. If the participant asks for touch to stop at any time, the therapists should be observed to do so immediately. If the participant seems to be uncomfortable with the touch offered or given at any point in the session, this item is not met.
- Ideally, therapists should be observed to ask the participant about their boundaries around touch at the beginning of the Experimental session. If they do not initiate this discussion but do respect the participant's boundaries, this should be noted in Adherence Comments, but the item can be considered met.
- *Examples:*
 - **Yes:** The participant begins to cry; the therapist checks in first and then provides supportive touch.

- **No:** The participant is having an emotional experience, and the therapist reaches out to touch their shoulder. The participant is startled; they do not say anything, but the touch does not seem to be comforting to them. Later the participant moves away and covers up with a blanket.

3b. Therapists used communication that the participant could easily follow.

- Therapists should be observed to use language and non-verbal communication that is clear to the participant. If the therapists are using terminology or talking in a way that seems unclear to the participant, this item is unmet.
- *Examples:*
 - **Yes:** The therapists speak clearly, using metaphors that the participant can relate to easily.
 - **No:** The therapist talks extensively about IFS and ancestral work, using many theoretical terms. The participant did not seem to be engaged or following this discussion.
 - **No:** The therapists use a lot of therapy terms (boundaries, container) and lengthy interpretations that the participant has to ask them to repeat to understand.
 - **On the fence:** The therapists generally communicate in ways that the participant is able to follow, but a few times in the session, the therapist goes on theoretical monologues that the participant does not seem to be following. If important concepts are repeatedly lost during the session due to a communication gap, this item is unmet. If the therapists recognize that their communication has been unclear and clarify their meaning, this item is met.

4b. Therapists encouraged and/or allowed the participant to have periods of inner focus balanced with periods of communication.

- Therapists should be observed to interweave periods of interaction with periods of silent witnessing. Depending on the participant's process, therapists may be observed to inquire about the participant's experience after periods of silence or encourage the participant to focus on their inner experience.
- *Examples:*
 - **Yes:** After some discussion, the therapist says, "If it feels like it's the time to talk through that now, we can help you do that, but it might be better at this point to first go inside and, as much as you can, relax into the way the experience will unfold. Sometimes talking can get in the way of the experience. We can talk more later."
 - **No:** The therapist repeatedly interrupts the participant's periods of inner focus with a question or comment that seems to pull her out of her inner experience.
 - **On the fence:** The participant is having an inward experience for the vast majority of the session. If the therapists check in periodically (roughly every 45-90 minutes) and are present for any communication the participant might want to initiate, this item can be considered met. If the participant is inward and the therapists do not check in with the participant periodically, this item is unmet.
 - **On the fence:** Each time the participant attempts to go inward, she closes her eyes for a few minutes and pops out to continue communication. If the therapists suggest several times that the participant go inward, this item can be considered met (even though the participant does not choose to remain in inner focus). If the therapists readily engage with the participant in conversation and do not suggest that she go inward, this item is unmet.

5b. Therapists used supportive language and conduct that encouraged the participant to stay present with their immediate experience, including difficult experiences, if they occurred.

- Therapists should be observed to support the participant in surrendering to the process rather than trying to direct it. They may provide verbal reassurance when needed, and nurturing touch when requested.
- Therapists should demonstrate an ability to be present without needing to intervene.
- If a participant touches upon a difficult experience and tries to move away from it, therapists should be observed to encourage them to stay with the experience (though not forcing them to do so), or to help them to resource themselves in order to remain present in the experience.
- *Examples:*
 - **Yes:** The therapist says, “We’re right here with you. Use your breath and stay with it as much as you can. We know that this is difficult, but we also know from experience that it is an important part of the healing. Fully experiencing and expressing this, moving through it instead of away from it, is the way to really heal it.”
 - **Yes:** The therapist says that everything that is coming up is for healing. They encourage the participant to be present with and not try to push it.
 - **No:** The participant is struggling with their experience and makes a distracting statement that pulls attention away from their difficult experience. The therapist focuses on that statement and allows it to pull the participant away from their experience.
 - **No:** The participant reports feeling anger about events that happened in her childhood. Instead of encouraging the participant to stay present with her feelings, the therapist takes her out of feelings and into mind by asking her specific questions about her childhood experiences.

6b. Therapists conveyed a non-judgmental attitude toward the participant’s experience and did not pathologize transpersonal experiences or multiplicity, if they occurred.

- Therapists should be observed overall to convey non-judgment toward the participant’s experience.
- If the participant experiences transpersonal experiences or multiplicity, the therapists should convey a respect for and openness toward the participant’s experience and view.
- *Examples:*
 - **Yes:** The therapist is open and non-judgmental as the participant describes dark or uncomfortable impulses or responses. The therapist normalizes and validates and communicates an attitude that this is all a part of the healing process.
 - **No:** The therapist appears uncomfortable with the content the participant is sharing and either challenges, invalidates, or dismisses the participant’s experience.
 - **No:** The participant reports that when he went inward, he had a vision of an angel whose light poured into him and dissolved tension he was holding in his body. The therapist has a skeptical look on her face and says, “I doubt that was an angel you were experiencing. I believe that was your inner healing intelligence.”

7b. Therapists validated positive, affirming experiences or insights as part of a process of healing, growth, or meaning-making.

- Fulfillment of this item is a demonstration of the therapists’ ability to see and remark upon the participant’s positive aspects and experiences. If therapists are not observed to validate any positive experiences or insights, this item is not fulfilled.
- Missed opportunities where there was a positive, affirming experience or insight that might have been validated by the therapists should be noted in rater comments.

- *Examples:*
 - **Yes:** The participant is largely having what he describes as a “peaceful and beautiful experience” during the session. They state that not much trauma-related information is coming up, but that they feel more relaxed and safe than ever in adulthood. The therapists reassure the participant that feeling good is an important part of the healing process and encourage going into and exploring that feeling of safety and calm.
 - **Yes:** The participant describes some insights that came through some lyrics in the music, which helped him to reframe some things and make meaning out of a challenging experience. The therapists his insights and acknowledge the power that music can have on one's ability to make meaning and heal.
 - **No:** The participant mentions positive experiences with her sister and ways she feels she has grown; the therapists do not validate these areas of growth and healing.

8b. Therapists used a largely nondirective approach, being guided by the participant’s experience, offering support in service of an unfolding inner-directed process.

- Therapists should be observed to follow, rather than guide, the participant’s process. The pace of the session should allow for the participant’s own process to unfold spontaneously. Therapists should allow for silence and hold off on interventions, encouraging the participant’s inner healing intelligence to take the lead.
- For this item to be met, therapists must be observed to respect the participant as the authority of their consciousness and healing, and to offer guidance only to support the participant in moving through their process. If direction or intervention is offered, it should be done in the spirit of collaborative inquiry and invitation, ultimately leaving decisions to the participant.
- If the therapists largely follow the participant’s lead but there are moment(s) of directiveness that are highly disruptive of the participant’s process or threaten to break the therapeutic container, this item is unmet.
- *Examples:*
 - **Yes:** The therapist says, “Try to see what direction the medicine gives you. Instead of trying to control your thoughts, trust the medicine will unravel these knots in some way and take on direction. As much as you can, let go of worrying about how you are going to heal. Breathe into the process and trust your own inner healing intelligence with the help of the medicine.”
 - **No:** The therapists suggest repeatedly that the participant use art to try to express herself; the participant agrees the first time, and then says no three times.
 - **No:** The therapists leave the participant in inward focus for long periods of time (2 hours, 1.5 hours) without checking in; then, in periods of communication, they are over-directive in their questions and lead the participant to specific topics.

9b. If the participant repeatedly avoided trauma-related material, the therapists gently encouraged collaborative exploration. If the participant did not repeatedly avoid trauma-related material, select Yes.

- If the participant seems to be avoiding trauma-related subjects, the therapists should be observed to allow time for the participant to acknowledge and address the avoidance themselves. If avoidance persists, the therapists should be observed to bring it up in a spirit of collaborative inquiry, ultimately leaving the decision of whether or not to follow their suggestions up to the participant.
- *Examples:*

- **Yes:** The participant spontaneously brings up trauma-related material, and the therapists engage in the exploration
- **Yes:** The participant is avoiding trauma-related material throughout the first half of the session, stating that she doesn't feel that talking about her trauma will be productive for her and will just put her back into feeling like a "victim," which she doesn't want to feel anymore. The therapists respect this. The participant later starts talking about sleep issues. After some discussion, the therapist asks her if she has nightmares. The participant shares a recurring nightmare she has, which then leads into her processing the traumatic event.
- **No:** The therapists attempt to bring up trauma-related material once; a brief conversation ensues but quickly moves to other topics. The therapists do not bring up trauma-related material again.

10b. If the participant was having a largely inward process, therapists did not interrupt this process to discuss traumatic material. If the participant was not having a largely inward process, select Yes.

- If the participant is having a largely inward-facing process, therapists should not be observed to disrupt their process to engage in interactive processing.
- *Examples:*
 - **Yes:** The participant is having a largely inward process; the therapists check in with her every 30-45 minutes but do not attempt to engage her in discussion.
 - **Yes:** The participant is not having an inward process.
 - **No:** The therapist repeatedly interrupts the participant's periods of inner focus with a question or comment that seems to pull her out of her inner experience.

11b. Therapists treated all material that arose during the session as relevant to the healing process.

- Therapists should be observed to engage with all material that arises during the Experimental session as important to the participant's process.
- *Examples:*
 - **Yes:** The therapist says to the participant, "If you have an experience today that is restful, softening, letting go, an experience of well-being, that is just as healing as working through something that might show up as more difficult and emotionally challenging. Everything is going to be exactly as it's supposed to be."
 - **Yes:** The participant said she brought a book and asks if she can read. The therapist explored what is coming up for her that is causing her to want to read a book.
 - **No:** The participant expresses happiness about an experience of oneness he was having while inward and listening to the music. The therapist validate his feelings, but go on to say that the session is really about processing trauma and asks for permission to circle back to some trauma-related material that was brought up earlier in the session.

12b. Therapists used music to support the experience without being intrusive and allowed periods of silence, if requested by the participant.

- Therapists should be observed to use music to support the participant's staying present in their experience. Music selections should be culturally appropriate and fitting to the general mood and flow of the session.
- Participants may ask for a change in music or for periods of silence; however, if it seems they are attempting to control the process or distract from feelings, therapists may encourage them to

explore their tendency to want to control the music or other aspects of the setting as part of their inner process.

- *Examples:*
 - **Yes:** As the session begins, the therapist states that there can be silence or a change of music if desired, but that they invite the participant to be curious about anything they are feeling in relation to the music.
 - **No:** The therapists are playing music that feels very out of sync with the participant's experience, including very activating electronic music during the start of the session.
 - **On the fence:** The participant states repeatedly that she doesn't like the music – it reminds her of Catholic church and makes her feel "awful." The therapists change the song when this comes up, but her discomfort with the music continues to arise. If this leads to a deepening of the process (e.g., the therapist asks, "Is it ok for you to have different feeling about music aside from being relaxed by it?") and a discussion ensues) this item may be considered met. If it seems the music is disrupting the process or the participant's ability to feel safe and supported, this item is not met.

13b. Both therapists were present in the room for the entire session, with the exception of one therapist at a time taking breaks for the bathroom, short meal breaks, medical needs, or nursing.

- Both therapists should be observed in the room for the entirety of the session, except for short (<30 minute) breaks as needed. At no time should the participant be alone in the room.
- *Examples:*
 - **Yes:** Both therapists are present in the room, aside from short breaks.
 - **No:** T2 is out of the room for over an hour near the end of the session.

14b. Therapists worked effectively as a team and respected any therapist preference from the participant.

- Therapists must be observed to work respectfully and cohesively together in service of the participant.
- If there is a participant preference observed, the therapist who is not preferred should not be seen to insert themselves into the dynamic.
- *Examples:*
 - **Yes:** The therapists have a good rapport and work well together throughout the session. The participant does not appear to have a preference between therapists.
 - **No:** The therapists do not appear to be working together as a team - they seem to be working separately and each trying to lead the session, rather than building off one another's efforts.

15b. Therapists encouraged the participant to go inward for an extended period of time, within twenty minutes after MDMA was ingested. If participant went inward on their own, select Yes.

- Therapists should be observed to encourage the participant to go inward within 20 minutes of ingesting the medicine.
- *Examples:*
 - **Yes:** About 15 minutes after the initial dose, the therapist suggests that the participant listen to music with the eyeshades on.
 - **No:** About 15 minutes after the initial dose, the therapist asks how the participant is feeling, initiating a discussion; the participant does not go inward until 30 minutes after the initial dose.

16b. Therapists brought the participant’s attention to bodily sensations and, when appropriate, encouraged exploration of any pains, tightness, or energy in the body through movement, bodywork, emotional processing, or in whatever way felt appropriate to the participant.

- Therapists should be observed bringing attention to the body. If the participant seems to be holding back from bodily expression, the therapists should be observed to encourage its exploration for this item to be fulfilled.
- If the participant spontaneously engages in exploration of their bodily sensations, therapists should be observed to be engaged and attuned (verbally or nonverbally) with the participant’s experience, but they do not necessarily need to verbally interject into it for this item to be fulfilled.
- *Examples:*
 - **Yes:** The therapist asks, “Where do you feel that fear in your body?”
 - **Yes:** The participant appears restless and is moving her legs a lot. The therapist asks, “If your legs could say something, what would they say?”
 - **Yes:** The participant is describing a core belief of not feeling good enough. The therapist suggests she sink into the feeling of not feeling good enough and go into her body with it.
 - **No:** The participant wanted to lie down because his back felt tight; the therapists encouraged him to lie down but did not explore his bodily sensations further (aside from seeming to treat it as pain management).
 - **No:** The therapists processed cognitively during the whole session, never bringing the participant’s attention to bodily feelings or sensations.

17b. Therapists facilitated processing of any regrets or self-judgment by putting them in perspective as part of the ongoing process of healing. If regrets or self-judgment did not occur, select Yes.

- If the participant expresses regrets or self-judgment, the therapists should be observed to normalize these feelings and reframe them in the perspective of healing. This does not need to be addressed every time a regret or self-judgment arises in the session but should be substantially addressed at some point(s) during the session to be considered met.
- *Examples:*
 - **Yes:** After the participant describes self-judgments, the therapist validates how difficult those things might feel but provides reassurance that going toward them and exploring them is part of the ongoing process of healing, and that meeting those harder things with curiosity and kindness can help with the process.
 - **Yes:** The therapists assist the participant with her regret and judgment about leaving her kids with her former partner to focus on getting better herself. The therapists support the participant to work through a deep inner conflict. They articulate the bind and help her stay with her ambivalence as the participant finds compassion for herself and connects more deeply with herself.
 - **No:** The therapist says, “Self-judgment is not what’s needed for healing” and argues with the participant’s statement that she is a horrible person.

18b. If the participant expressed that they were overwhelmed during the onset of MDMA effects, the therapists reassured the participant about safety, encouraged them to use diaphragmatic breathing or other relaxation techniques, and/or reminded them that feelings of intensity would be

experienced in waves. If the participant did not express that they were overwhelmed during the onset of MDMA effects, select Yes.

- During the start of the session, if the participant expresses or appears overwhelmed, therapists should be observed to support them through techniques such as reassuring safety, encouraging use of relaxation techniques, and/or reminding them that the feelings of intensity will come and go.
- If a participant does not express overwhelm at the onset of MDMA effects, this item may be considered met.
- *Examples:*
 - **Yes:** One hour after ingesting the medicine, the participant reported feeling overwhelmed and nauseous. The therapists provided her with a container to throw up in if needed and sat beside her, asked for permission to put a hand on her back (which participant consented to), and encouraged her to use diaphragmatic breathing to help move through waves of nausea.
 - **No:** One hour after ingesting the medicine, the participant was showing signs of physical distress, appearing restless and fidgety. He was talking a lot; the therapists engaged him in conversation and didn't inquire about or address the restless and fidgety body movements that were indicating some feelings of overwhelm.

19b. If the participant expressed that they were overwhelmed by difficult experiences later in the session, the therapists encouraged the participant to “breathe into” the experience and feel and express it as fully as possible. (Other expressions encouraging focusing awareness may be substituted for “breathe into.”) If the participant did not express that they were overwhelmed by painful feelings later in the session, select Yes.

- After the initial onset of MDMA effects (~1.5-2 hours after ingestion of the medicine), if the participant expresses overwhelm, therapists should be observed to support the participant to stay with their experience.
- If a participant does not express overwhelm at painful feelings, this item may be considered met.
- *Examples:*
 - **Yes:** The therapist says, “Use your breath to help you stay as present as you can with this experience.”
 - **No:** The participant is talking about their relationship with his mother and becomes overwhelmed; the therapist attempts to calm him down by using distraction or humor.
 - **On the fence:** The participant states that he is feeling overwhelmed, and the therapist asks, “Where is that showing up in your body?” If this leads to the participant’s deepening into their feelings, this item can be considered met. If it seems to distract the participant from being present with their feeling, this item would be unmet.

20b. Therapists ensured the participant’s physical safety by asking them to sit on the edge of the futon before rising, protecting the participant from falling when walking, and ensuring adequate fluid intake by asking the participant to drink periodically, if necessary.

- Overall, the therapists should be observed to be watching for and actively ensuring safety. Specifically, the following three behaviors should be observed:
 - When possible, therapists ask the participant to sit on the edge of the futon before rising: If there was not enough time for the therapists to ask the participant to pause before rising, but the therapists were immediately responsive (standing to be able to catch the participant if needed), this can be considered met. Ideally if this happens, the therapists remind the participant to pause before standing next time – if they don’t do so, please

mention this in your comments. If there was enough time for the therapists to ask the participant to pause but they did not, if the participant stands suddenly and the therapists are not responsive, or if the participant repeatedly stands without pausing during a session, this is not met.

- Therapists protect the participant from falling: The therapists must be close enough to steady the participant if necessary. Although ideally therapists are touching the participant, there are times when a participant does not want touch. If the therapists are walking close by and available to catch or steady the participant, this can be considered met. If a participant is standing or walking without therapists nearby, this is not met.
- Therapists ensure adequate fluid intake: If the participant does not drink fluids and the therapists never offer fluids over the course of the entire session, this is not met.
- *Examples:*
 - **Yes:** The participant stated she had to use the bathroom; the therapist asked her to sit up slowly and pause before standing. Each time the participant stood during the session, one of the therapists stood nearby and walked closely behind her. They leave a bottle of water close to where she is seated, and she sips water periodically.
 - **No:** The participant returns from the bathroom and remains standing and stretching for about 30 minutes, while both therapists sit across the room from him.
 - **No:** The participant is not observed to drink fluids at any time during the session, and the therapists do not encourage them to drink fluids.
 - **On the fence:** The therapists adhere perfectly to safety protocol for the first seven hours of the session. Near the end of the session, they relax their attention, not noticing when the participant stands suddenly to go to the bathroom. Ideally one or both therapists should rise when they notice the participant has stood up, even at the end of the session. If they do not, but have otherwise adhered to the criterion (except in the final hour of the session), this item can be considered met, but the deviation should be noted in comments.

11.3 Adherence Criteria in Integrative Sessions: Definitions and Examples

1c. Therapists facilitated discussion of the participant's emotional and cognitive response to the sessions.

- Therapists should be observed to initiate or actively engage in a discussion of the participant's treatment experience and intellectual/emotional processing around it.
- This item is expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The therapist asks, "Is anything that needs more attention from what unfolded yesterday?"
 - **Yes:** The therapist says, "So yesterday was a long day – lots of deep processing. How was that for you?"
 - **Yes:** The therapist invites the participant to reflect on themes that arose in the experimental session and therapists help to facilitate discussion. Therapists also highlight other themes that arose during the experimental session.
 - **No:** The therapists don't inquire about participant's emotional and cognitive response to the sessions, and the participant doesn't talk about it either. Instead, they discuss other topics totally unrelated to and not tied into the sessions.

2c. Therapists facilitated inquiry into the participant's unfolding somatic experience.

- Therapists should be observed to facilitate or encourage exploration of the participant’s current bodily processes or processes that have occurred since the Experimental session. If they touch on the topic only briefly or only in relationship to the Experimental session (rather than tying it into the present moment), then this item is unmet.
- If the participant is experiencing emotional or somatic distress that they cannot move through spontaneously or through talk and the therapists introduce focused bodywork, this item is met.
- If therapists attempt to inquire into unfolding somatic experience but the participant does not respond, this item is met.
- This item is expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** During a discussion of anxiety the participant was feeling during the Experimental session, the therapist asks, “Where do you notice that in your body right now?” and facilitate an exploration of their bodily experience.
 - **Yes:** The participant is experiencing back pain and neck tightness during the Integrative session; the therapists connect the participant’s pain with the experience of being taken over by their critical voice.
 - **No:** The participant mentions they had a headache after the last Exp session, but they do not further discuss it.
 - **On the fence:** The participant and therapists talk about the physical side effects from the prior Experimental session. If this leads to discussing changes in the participant’s somatic exploration since the session, as opposed to simply talking about the side effects in isolation, this could be rated a Yes. If it is only focused on listing symptomology without discussion or exploration of its implications, the item is not met.

3c. Therapists followed the participant’s lead regarding how much to talk about the Experimental Session or its sequelae.

- Therapists should be observed to take their topical cues from the participant.
- Sometimes participants would rather allow their inner experience to continue unfolding without attempting to put it into words. If this is the case, therapists should validate that choice, but ask for enough information for them to be aware of the participant’s emotional state and any difficult feelings or thoughts that should be addressed before the participant leaves the office.
- If therapists are perceived as pushing the participant to discuss the Experimental session, this item is not met.
- This item is expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The participant says that he was trying to remember the experimental session, but that it was like trying to remember a dream, like “grasping at smoke.” He asks if the therapists can remind him of what he said to trigger memories, so the therapists review what the participant talked about from their notes.
 - **No:** The therapists are clearly forcing the participant to discuss the Experimental session or what happened afterwards more than the participant seems to want to.
 - **On the fence:** The therapists begin by following the participant’s lead in talking about the Experimental session but become focused on giving advice around a particular theme that the participant does not seem engaged in. If they spend the majority of the session following the participant’s topical cues, this can be rated a Yes. If they spend the majority of the session pushing their topical agenda on the participant, this can be rated a No.

4c. Therapists facilitated processing of any emotional distress or cognitive dilemmas that arose for the participant, including regret and self-judgment, by putting them in perspective as part of an ongoing process of healing and growth. If emotional distress or cognitive dilemmas did not arise, select Yes.

- Therapists should be observed putting any emotional distress or cognitive dilemmas that arise in the perspective of part of the process of healing or growth. If they validate or explore issues without reinforcing the perspective that they are part of the healing process, this item is unmet.
- This item is expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The therapists normalize the participant’s process and describe it as healing or growth (“That you’re feeling this way is part of the process of healing”; “It makes sense you’re feeling that way given your history. You might be starting to notice that in a different way now that the medicine has been working with your inner healer.”)
 - **No:** The therapists validate the participant’s feelings without putting them into the perspective of a healing process (“It makes sense that you’re feeling that way.”)
 - **On the fence:** The participant brings up a recent panic attack, and the therapist asks how it feels in her body and how it resolved. If there are cues from the therapist that this is part of the healing process (e.g., “sometimes these things arise as the medicine is helping us to process old hurt”; “you are learning how to meet the anxiety in new ways”), this item can be rated Yes. If this is not tied into the perspective of healing, the item is not met.

5c. Therapists invited the participant to talk more about the Experimental Session, or any sequelae. If the participant does this spontaneously, then active listening constitutes appropriate encouragement.

- Therapists should be observed to invite discussion of the Experimental session or related experiences or feelings that have arisen related to the Experimental session, or to listen actively if initiated by the participant.
- This item is expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The participant has her hand on her chest and states several times that she feels like she is still processing from the session; the therapists engage actively in her exploration.
 - **Yes:** The therapists ask if there’s a general feeling the participant is taking away from the experimental session.
 - **Yes:** The therapists acknowledge the participant’s concerns about her life changing a lot due to the experimental session and inquire about how she feels now.
 - **No:** The participant only talks about their physiological reactions to the drug during the Experimental session, and the therapists do not facilitate a deeper discussion of the session or what has transpired since then.

6c. Therapists validated affirming experiences or insights that occurred during or since the Experimental Session and, if necessary, helped the participant learn to re-connect with and continue to gain from these experiences. If affirming experiences or insights did not occur, select Yes.

- Therapists should be observed to encourage the participant in remembering and reconnecting with positive aspects of their experience during or following the MDMA-assisted sessions.
- If therapists inquire and affirming experiences or insights did not occur for the participant, this item is not applicable and should be marked as met.

- This item is expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The participant discusses feeling more compassion since the experimental session – they say, “I just didn’t have the tools and awareness before.” The therapists validate this, saying, “That was beautiful, you just turned it to that place where you had compassion toward yourself, to say I just didn’t have those tools.”
 - **Yes:** The therapist acknowledges the participant’s main goal of being more in touch with their feelings and validates how this has occurred more since the experimental session.
 - **Yes:** The participant discusses insight about letting herself degrade physically as a method of controlling the part of herself that enjoys aggression and physicality. The therapist acknowledges that this is a powerful insight.
 - **No:** The participant brings up affirming experiences or insights that occurred during or since the Experimental session, but the therapists don’t validate, or invalidate, these experiences or insights.
 - **On the fence:** The participant says he is more self-reflective and slower to anger now. The therapist asks a question about something unrelated. Later in the session, the participant mentions again that he feels more self-reflective now. The therapists nod. If the therapists are validating other affirming experiences/insights during the Integrative session, this item may be met. If they do not validate any affirming experiences/insights aside from nodding, this item is not met.

7c. Therapists inquired about whether there were any challenges the participant was experiencing with regard to integration that would benefit from further exploration or support.

- Therapists should be observed to engage in an exploration of present experiences. If therapists inquire and the participant is not experiencing challenges with regard to integration, this item can be considered met. If the participant spontaneously brings up challenges and the therapists facilitate exploration, this item can be considered met. If the therapists inquire about challenges related to integration but do not then facilitate an exploration of them, this item is not met.
- This item is expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The therapist discusses insights the participant had about his mother during the Experimental session and reminds him that he said, “I wish she could have seen me happy.” There is a pause, and then the therapist asks him what feelings are coming up around that. The participant says he feels sad. He goes on to share how his mother just wanted him to be happy and healthy, and that if this treatment is successful, she will have just missed seeing it. He is tearful. The therapists further assist him with processing his feelings about his mother.
 - **No:** The participant brings up the upcoming holiday and talks about how they will be lonely and feel cut off from their family. The therapists don’t facilitate exploration of her challenges and instead ask what she plans to do over the holiday weekend.
 - **No:** The participant doesn’t mention any challenges with integration and the therapists don’t inquire about these either.

8c. Therapists reminded participant that the experience would continue to unfold over time and communicated that waves of intense emotion or new experiencing, whether difficult or affirming, are part of the dynamically shifting healing process (therapists facilitating a wave during the session would also be appropriate).

- Therapists should be observed conveying to the participant that waves of intense or difficult experience may recur for some time as part of the healing process. This item may be fulfilled by therapists' either talking about this or demonstrating it in real time. If therapists facilitate a wave (an intense emotional experience that takes the participant out of their normal state or defenses) during the session, they must be observed to affirm and convey a trust in the unfolding moment for this item to be met.
- This item is not expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The therapists say, "It is very common for the MDMA experience to continue to unfold for days after the session. Often it unfolds in an easy, reassuring way, but sometimes it can be more difficult. Sometimes working with traumatic experiences can stir things up so that symptoms may temporarily get worse. These feelings may come in waves of emotion or memories. When this happens, it is part of the healing process and we're here to help you work with anything that comes up for you."
 - **Yes:** The therapist says, "You're identifying the lay of the land; you've brought tools with you that you may not have used, and now you're using them. And there's still obstacles and potential hazards, but there's also beauty out there. You're figuring that all out and recognizing it – there's a ways to go, but you're on your way."
 - **No:** The therapists don't mention anything about waves of intense emotions or new experiencing as being part of the healing process.

9c. Therapists reinforced activities, such as journaling or other creative expression, meditation, yoga, use of breath, body awareness, or other activities that support ongoing healing, self-awareness, and integration.

- Therapists should be observed to encourage the participant to make time in their daily life to reflect on the MDMA-assisted sessions and their sequelae through activities that help the participant in continued processing, integration, and self-exploration. The specific activities that are suggested or reinforced will vary by participant and do not have to be specifically creative or physical for this item to be met.
- This item is not expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The therapists say, "It may be helpful to write about your experience and your thoughts and feelings since the session."
 - **Yes:** The participant spontaneously describes running as beneficial to her healing process and the therapists reinforce this.
 - **No:** Therapists don't mention anything about the use of activities that support ongoing healing, self-awareness, and integration, nor do they ask or explore what types of self-care activities they engage.
 - **On the fence:** The therapists conduct breathwork with the participant during session. If they do not tie this to activities that the participant can continue to do over the course of integration, this item is not met. If they do mention that the participant can use these skills, or the participant spontaneously states they will do so, this item is considered met.

10c. Therapists re-emphasized their commitment to support the participant during the integration period by addressing follow-up or on-call provision in the case of any difficulties or concerns.

- Therapists should ensure that the participant feels supported through the course of their study participation through describing their follow-up steps (including upcoming check-in calls)

following the first Integrative session after an Experimental session) or confirming that the participant knows how to connect with the therapists.

- This item is not expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The therapists confirm that the participant has their contact numbers and remind them of when they will be calling to check in.
 - **No:** The therapists don't mention anything about their commitment to support the participant during the integration period and do not discuss follow-up or on-call provision in the case of any difficulties or concerns.
 - **On the fence:** The therapists and participant schedule phone check-in calls together, but one therapist begins by listing several days when she will not be available, and the other therapist mentions some days he will be out of town. If there is no other discussion of the therapists' commitment to support the participant, this is not met. If they then affirm their availability to the participant at any time (making sure there is coverage for the days one or the other is not available), this item may be rated as met.

11c. On the day after Experimental Sessions, therapists encouraged the participant not to engage in strenuous, stressful, or over-stimulating activity for the remainder of the day; in later integrative sessions, therapists emphasized the continued importance of gentleness, rest, or relaxation.

- Therapists should be observed to explicitly encourage that the participant refrain from over-exertion in the day after an Experimental session or to explicitly emphasize the importance of rest in subsequent Integrative sessions.
- This item is expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The therapist encourages the participant to be mindful and gentle with himself for the remainder of the day and for the next few days.
 - **No:** In a session occurring the day after an Experimental session, the therapists ask what the participant has planned for the rest of the week, but do not make any comment about avoiding over-stimulating activity or continued gentleness when the participant states that she plans to go hiking and have a difficult conversation with an estranged friend.
 - **On the fence:** In a session occurring the day after an Experimental session, the therapists ask what the participant has planned for the rest of the week, but do not make any comment about avoiding over-stimulating activity or continued gentleness when the participant states that he plans to take it easy and process by journaling. If the therapists do not reinforce this, the item is not met. If the therapists do reinforce or validate this, the item is met.
 - **On the fence:** On the day after an Experimental session, the therapists encourage the participant not to engage in over-strenuous activity for the coming week but do not specify this for the remainder of that day. This item can be considered met.

12c. Therapists encouraged the participant to feel connected with their support system, but cautioned the participant that other people may not understand the depths of their experience and insights.

- Although they do not have to discuss either of these elements extensively, therapists should be observed discussing both parts of this item in order for it to be met. Therapists should be supporting the participant to consider their support network and identify safe places for them to reach out for support.

- If therapists do not caution the participant to use discretion in reaching out for support, this item is not met, unless it is clear that the potential support person would be understanding and supportive.
- This item is not expected to be met in every Integrative session.
- *Examples:*
 - **Yes:** The therapists say, “Since the MDMA experience is so unique, it can be hard to explain to other people. It can be painful if such an important experience is misunderstood or judged by other people in your life. It may be important to exercise judgment about how and when you talk about your experience,” and help the participant to identify support people they feel comfortable reaching out to.
 - **No:** The therapists encourage participant to reach out to their family members; they do not suggest that the participant use discretion in deciding whom to reach out to for support.
 - **On the fence:** At one point in the session, the participant talks about her boyfriend as a source of support and the therapists reinforce this, but in another point, she suggests he sometimes is not supportive or understanding. This could be rated a No if there were no further discussion, or a yes if the therapists provided the appropriate caution or helped her identify someone else who would be more consistently supportive and understanding.
 - **On the fence:** The therapists inquire into the participant’s sources of support, and the participant states that her family would not be understanding but that she has been feeling very supported by her dog. Because exercising caution to be sure that her support figure (the dog) is not applicable, this item may be rated as met.

12.0 Adherence Rating FAQ

Will giving a therapy pair too many “No” ratings hurt them?

No, giving a therapy pair “No” ratings will not hurt them! Please do not hold back from rating “No” when warranted – the aim is to provide support to the therapists so that they can provide treatment that is as efficacious as possible and in alignment with the therapeutic model.

Adherence ratings and comments help to ensure that this is the case. Therapy pairs will not be penalized for “No” ratings; rather, the ratings will help them to recalibrate as needed and help MAPS PBC to ensure treatment quality. This is invaluable feedback for therapy pairs and an essential responsibility of adherence raters.

When rating “No,” please provide specific examples in your rater comments about what issues or missed opportunities for the criterion to be met you observed.

What if I’m on the fence between a Yes vs. No rating?

First, check in with yourself. Do you truly feel 50/50 about this criterion? If you have any leaning toward rating one way vs. the other, trust your gut in the rating. If it is truly 50/50, rate Yes. Any time you are on the fence in rating an item, please include an explanation in your comments (e.g., “I was on the fence on item 8a. I rated No because...”) so that the Supervisor knows that there is still room for improvement in how this item is being met by the therapists. This is especially helpful when the rater experiences any hesitation or ambiguity before deciding on their response.

How much is enough for the item to be fulfilled?

When considering whether a criterion is sufficiently met, a good rule of thumb is to consider whether or not, if you were the participant or therapist, the information or support that has been

provided would feel sufficient to you. For example, if you were the participant in a Prep session, did the therapists provide enough information related to the criteria for you to feel prepared for the Experimental session? If you were the therapist, was enough information gathered to feel comfortable moving forward, or are there pieces you feel are missing?

What is enough is often specific to the participant's individual needs. For example, participants may have varying levels of need, interest in, and tolerance for PTSD psychoeducation (item 7a). Please bear individual needs in mind and comment on any instances in which it feels they are not being met, due to therapists' either missing a criterion or meeting it at the expense of maintaining connection and attunement to the participant.

Another rule of thumb is to think about quality and quantity. For example, if an item is observed to be addressed multiple times with high quality/clarity, it should be considered met. If it is addressed only once, but very thoroughly and with very high quality, it is likely met. If it is addressed multiple times with low quality, it is likely unmet, depending on your assessment of the situation. If it is addressed once and with low quality, it is likely unmet. Finally, if the opposite of the item is observed (e.g. the therapists create a setting that feels unsafe rather than one that feels safe (1a); the therapists explicitly state that they will not ask about a participant's trauma during the Experimental session rather than that they may do so (13a)), the item should be considered unmet.

What if an item is spontaneously covered by the participant, as opposed to initiated by the therapists?

If a participant spontaneously covers an item and the therapists adequately reinforce it or ensure that the main points of the item are covered, the item can be considered met. For example, if a participant spontaneously engages in somatic exploration during an Experimental session (16a) or describes their ongoing somatic experience in an Integrative session (2c), and the therapists engage in active listening or otherwise support the participant's exploration, these items are met. If the therapists do not reinforce or support the participant in their exploration/discussion, these items are not met.

If I have viewed prior sessions between a therapy pair and participant, should I rate them in relation to one another?

No, sessions should always be rated independently of one another. You are rating a specific session recording for specific observed adherence. For example, if item 24a is met in Preparatory Session 1 and not met in Preparatory Session 2, you would rate it as a Yes for Preparatory Session 1 and a No for Preparatory Session 2, even though you know it was previously covered.

How are Preparatory and Integrative session ratings evaluated?

Raters should always rate sessions independently of one another (see Question 5). When evaluating session ratings, the sponsor staff assess the following Preparatory and Integrative adherence criteria as met if they were rated as a Yes at least once across the series of affiliated Preparatory or Integrative sessions: 2a, 4a, 5a, 6a, 7a, 8a, 9a, 10a, 11a, 12a, 13a, 14a, 15a, 16a, 17a, 18a, 19a, 20a, 21a, 22a, 23a, 24a, 8c, 9ac, 10c. Preparatory items 1a and 3a, and Integrative items 1c, 2c, 3c, 4c, 5c, 6c, 7c, and 11c are expected to be met in each session and evaluated accordingly by sponsor staff.

Appendix A – Adherence Criteria in Preparatory Sessions

Yes No

General Behaviors or Actions

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 1a. Therapists created and communicated a setting of safety and support. |
| <input type="checkbox"/> | <input type="checkbox"/> | 2a. Therapists nurtured an attitude of trust in the healing properties of the therapeutic process and introduced the concept of the participant’s inner healing intelligence. |
| <input type="checkbox"/> | <input type="checkbox"/> | 3a. Therapists elicited, explored, or addressed the participant’s expectations, fears, or concerns. |

Discrete Behaviors or Actions

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 4a. Therapists validated the importance of positive, affirming experiences as part of the process of healing, growth, or meaning-making. |
| <input type="checkbox"/> | <input type="checkbox"/> | 5a. Therapists validated the importance of negative, difficult experiences as part of the process of healing, growth, or meaning-making. |
| <input type="checkbox"/> | <input type="checkbox"/> | 6a. Therapists elicited significant historical information, especially that which was related to trauma history. |
| <input type="checkbox"/> | <input type="checkbox"/> | 7a. Therapists assessed the participant’s knowledge regarding PTSD and its impact on their life; therapists provided education about PTSD if needed. |
| <input type="checkbox"/> | <input type="checkbox"/> | 8a. Therapists described the likely effects of MDMA. |
| <input type="checkbox"/> | <input type="checkbox"/> | 9a. Therapists described typical procedures of Experimental Sessions. |
| <input type="checkbox"/> | <input type="checkbox"/> | 10a. Therapists explained that this model of therapy uses a largely inner-directed approach and elaborated on the meaning and implications of this approach. |
| <input type="checkbox"/> | <input type="checkbox"/> | 11a. Therapists explained that, in Experimental Sessions, they will encourage the participant to set aside expectations and remain open to whatever emerges (beginner’s mind). |
| <input type="checkbox"/> | <input type="checkbox"/> | 12a. Therapists explained that, during Experimental Sessions, they will encourage the participant to have periods of inner focus balanced with periods of verbal communication, which either the therapists or the participant may initiate. |

- | Yes | No | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 13a. Therapists and the participant agreed that at some time during each Experimental Session, the therapist may bring up the trauma, if the participant has not spontaneously done so. |
| <input type="checkbox"/> | <input type="checkbox"/> | 14a. Therapists explained that in this model of therapy, they will provide support and encouragement for staying present with difficult experience. |
| <input type="checkbox"/> | <input type="checkbox"/> | 15a. Therapists explained that if thoughts or feelings of wanting to leave should arise during Experimental Sessions, it is important to express them and work with them as part of the inner process rather than to act on them. Therapists explained that, at the beginning of each Experimental Session, they will ask for an agreement that the participant will not leave the clinic until the next morning. |
| <input type="checkbox"/> | <input type="checkbox"/> | 16a. Therapists explained that during treatment, they may inquire about participant's bodily sensations and encourage exploration of the body through movement in whatever way may feel appropriate to the participant. |
| <input type="checkbox"/> | <input type="checkbox"/> | 17a. Therapists discussed the optional use of physical touch during Experimental Sessions and Integrative Sessions. Therapists made it clear that physical space and participant boundaries will be respected and that the participant will be asked before the first Experimental Session what they are comfortable with. Therapists communicated that touch only happens with the participant's consent and can be discontinued at any time by the participant's saying "Stop" or another comparable agreed-upon command. Therapists clearly stated that all touch is nonsexual. |
| <input type="checkbox"/> | <input type="checkbox"/> | 18a. Therapists explained that they will use music to support the experience without being intrusive and will allow periods of silence, if requested by the participant. |
| <input type="checkbox"/> | <input type="checkbox"/> | 19a. Therapists discussed the rationale for using eyeshades and headphones at times during the Experimental Session to increase inner focus. The therapists made it clear that eyeshades and headphones are optional. |
| <input type="checkbox"/> | <input type="checkbox"/> | 20a. Therapists explained that they will ensure the participant's physical safety in various ways, for example, by asking them to sit on the edge of the futon before rising, protecting the participant from falling when walking, and ensuring adequate fluid intake by asking the participant to drink periodically. |
| <input type="checkbox"/> | <input type="checkbox"/> | 21a. Therapists identified a stress inoculation technique that worked well for them and/or taught the participant a stress inoculation technique, such as diaphragmatic breathing. |

Yes **No**

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 22a. Therapists invited the participant to talk about their experience of anxiety, including triggers and defenses, and discussed ways that the therapists can help the participant through anxiety states if and when they occur. |
| <input type="checkbox"/> | <input type="checkbox"/> | 23a. Therapists and the participant discussed the nature of the participant's support system. |
| <input type="checkbox"/> | <input type="checkbox"/> | 24a. Therapists discussed the possibility of including a support person in a study session(s), including discussion of the conditions that would need to be met for the support person to participate in a session. |

Appendix B – Adherence Criteria in Experimental Sessions

Yes No

General Behaviors or Actions

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 1b. Therapists created and communicated a setting of safety and support. |
| <input type="checkbox"/> | <input type="checkbox"/> | 2b. Use of physical touch and/or physical space respected the participant's boundaries. |
| <input type="checkbox"/> | <input type="checkbox"/> | 3b. Therapists used communication that the participant could easily follow. |
| <input type="checkbox"/> | <input type="checkbox"/> | 4b. Therapists encouraged and/or allowed the participant to have periods of inner focus balanced with periods of communication. |
| <input type="checkbox"/> | <input type="checkbox"/> | 5b. Therapists used supportive language and conduct that encouraged the participant to stay present with their immediate experience, including difficult experiences, if they occurred. |
| <input type="checkbox"/> | <input type="checkbox"/> | 6b. Therapists conveyed a non-judgmental attitude toward the participant's experience and did not pathologize transpersonal experiences or multiplicity, if they occurred. |
| <input type="checkbox"/> | <input type="checkbox"/> | 7b. Therapists validated positive, affirming experiences or insights as part of a process of healing, growth, or meaning-making. |
| <input type="checkbox"/> | <input type="checkbox"/> | 8b. Therapists used a largely nondirective approach, being guided by the participant's experience, offering support in service of an unfolding inner-directed process. |
| <input type="checkbox"/> | <input type="checkbox"/> | 9b. If the participant repeatedly avoided trauma-related material, the therapists gently encouraged collaborative exploration. If the participant did not repeatedly avoid trauma-related material, select Yes. |
| <input type="checkbox"/> | <input type="checkbox"/> | 10b. If the participant was having a largely inward process, therapists did not interrupt this process to discuss traumatic material. If the participant was not having a largely inward process, select Yes. |
| <input type="checkbox"/> | <input type="checkbox"/> | 11b. Therapists treated all material that arose during the session as relevant to the healing process. |
| <input type="checkbox"/> | <input type="checkbox"/> | 12b. Therapists used music to support the experience without being intrusive and allowed periods of silence, if requested by the participant. |

Yes **No**

- 13b.** Both therapists were present in the room for the entire session, with the exception of one therapist at a time taking breaks for the bathroom, short meal breaks, medical needs, or nursing.
- 14b.** Therapists worked effectively as a team and respected any therapist preference from the participant.

Discrete Behaviors or Actions

- 15b.** Therapists encouraged the participant to go inward for an extended period of time, within twenty minutes after MDMA was ingested. If participant went inward on their own, select Yes.
- 16b.** Therapists brought the participant’s attention to bodily sensations and, when appropriate, encouraged exploration of any pains, tightness, or energy in the body through movement, bodywork, emotional processing, or in whatever way felt appropriate to the participant.
- 17b.** Therapists facilitated processing of any regrets or self-judgment by putting them in perspective as part of the ongoing process of healing. If regrets or self-judgment did not occur, select Yes.
- 18b.** If the participant expressed that they were overwhelmed during the onset of MDMA effects, the therapists reassured the participant about safety, encouraged them to use diaphragmatic breathing or other relaxation techniques, and/or reminded them that feelings of intensity would be experienced in waves. If the participant did not express that they were overwhelmed during the onset of MDMA effects, select Yes.
- 19b.** If the participant expressed that they were overwhelmed by difficult experiences later in the session, the therapists encouraged the participant to “breathe into” the experience and feel and express it as fully as possible. (Other expressions encouraging focusing awareness may be substituted for “breathe into.”) If the participant did not express that they were overwhelmed by painful feelings later in the session, select Yes.
- 20b.** Therapists ensured the participant’s physical safety by asking them to sit on the edge of the futon before rising, protecting the participant from falling when walking, and ensuring adequate fluid intake by asking the participant to drink periodically, if necessary.

Appendix C – Adherence Criteria in Integrative Sessions

Yes No

General Behaviors or Actions

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 1c. Therapists facilitated discussion of the participant’s emotional and cognitive response to the sessions. |
| <input type="checkbox"/> | <input type="checkbox"/> | 2c. Therapists facilitated inquiry into the participant’s unfolding somatic experience. |
| <input type="checkbox"/> | <input type="checkbox"/> | 3c. Therapists followed the participant’s lead regarding how much to talk about the Experimental Session or its sequelae. |
| <input type="checkbox"/> | <input type="checkbox"/> | 4c. Therapists facilitated processing of any emotional distress or cognitive dilemmas that arose for the participant, including regret and self-judgment, by putting them in perspective as part of an ongoing process of healing and growth. If emotional distress or cognitive dilemmas did not arise, select Yes. |

Discrete Behaviors or Actions

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 5c. Therapists invited the participant to talk more about the Experimental Session, or any sequelae. If the participant does this spontaneously, then active listening constitutes appropriate encouragement. |
| <input type="checkbox"/> | <input type="checkbox"/> | 6c. Therapists validated affirming experiences or insights that occurred during or since the Experimental Session and, if necessary, helped the participant learn to re-connect with and continue to gain from these experiences. If affirming experiences or insights did not occur, select Yes. |
| <input type="checkbox"/> | <input type="checkbox"/> | 7c. Therapists inquired about whether there were any challenges the participant might be experiencing with regard to integration that would benefit from further exploration or support. |
| <input type="checkbox"/> | <input type="checkbox"/> | 8c. Therapists reminded participant that the experience would continue to unfold over time and communicated that waves of intense emotion or new experiencing, whether difficult or affirming, are part of the dynamically shifting healing process (therapists facilitating a wave during the session would also be appropriate). |
| <input type="checkbox"/> | <input type="checkbox"/> | 9c. Therapists reinforced activities, such as journaling or other creative expression, meditation, yoga, use of breath, body awareness, or other activities that support ongoing healing, self-awareness, and integration. |

Yes **No**

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 10c. Therapists re-emphasized their commitment to support the participant during the integration period by addressing follow-up or on-call provision in the case of any difficulties or concerns. |
| <input type="checkbox"/> | <input type="checkbox"/> | 11c. On the day after Experimental Sessions, therapists encouraged the participant not to engage in strenuous, stressful, or over-stimulating activity for the remainder of the day; in later integrative sessions, therapists emphasized the continued importance of gentleness, rest, or relaxation. |
| <input type="checkbox"/> | <input type="checkbox"/> | 12c. Therapists encouraged the participant to feel connected with their support system, but cautioned the participant that other people may not understand the depths of their experience and insights. |