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

Version 1: 07 January 2013
Version 2: 24 January 2014
Version 3: 08 July 2015
Version 4: 23 October 2018
Version 5: 30 June 2020

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USE
In conjunction with the current version of the Treatment Manual,
“A Manual for MDMA-Assisted Psychotherapy in the Treatment of
Posttraumatic Stress Disorder,” in accordance with an approved
MAPS-sponsored Study Protocol

CONTRIBUTORS
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1.0 Background


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 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. The ideal background for an Adherence Rater would be someone eager to learn about MDMA-assisted psychotherapy, who is either a licensed mental health professional, or is in training to become a licensed mental health professional.

The following qualifications are deemed essential:

- Motivation for self-development in the therapeutic field
- Eagerness to learn about MDMA-assisted psychotherapy
- Formal, graduate-level training in psychology, social work, or psychiatry
- Licensed as a mental health professional, or in training to become one
- Psychotherapy internship or equivalent experience with direct patient contact

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• One year of experience working with trauma population or equivalent
• Training in the sensitive and confidential nature of the subject material
• Openness to feedback
• Discrete access to the Internet in a private setting on a personal computer
• Completion of Adherence Rater training (as described in Section 3.0)
• 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. Applicants accepted for training will receive access to training materials, any additional instructions, 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 4-month online program, consisting of 50 hours of training, including: 4 two-hour live meetings with a Gold Standard Adherence Rater, weekly homework assignments, required reading, and reliability ratings.

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

• Watch the Mithoefers’ Workshop videos (link for Parts 1-4 is below): “Principles of Psychedelic Psychotherapy-Lessons from MDMA Research for PTSD” filmed at Psychedelic Science 2017
  https://www.youtube.com/playlist?list=PL4F0vNTozFQq8pswXRa90XEpZt0ffS7T

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

1. Register for training
   a. Create account on online training portal (URL will be provided)
   b. Enroll in course
   c. Sign Confidentiality Agreement
2. Complete required reading and video (10 hours)
   a. Treatment Manual
   b. Adherence Ratings Manual
   c. Mithoefers’ Workshop videos
Month 1: Adherence Rating for Preparatory Sessions

3. Live Training Meeting #1: Adherence Rater Training Program Orientation and Rating Preparatory Sessions, 2-hour online call with a Gold Standard Adherence Rater
   a. Group Introductions
   b. Overview of MDMA-assisted psychotherapy for severe PTSD study design
   c. Overview of Adherence Rating process
   d. Orientation on online training portal, including discussion thread and submitting a rating form
   e. Review of training schedule
   f. Training on Adherence Criteria for Preparatory Sessions
   g. Self-care strategies and identifying sources of support

4. Preparatory Session Homework (8 hours)
   a. Six video assignments: watch video, take notes, submit rating form
   b. Complete assignments before due date, typically trainees are given 5 weeks to complete all Preparatory Session assignments
   c. Participate in discussion via discussion thread, email, and live calls

5. Reliability Rating for Preparatory Sessions

Month 2: Adherence Ratings for Experimental Sessions

6. Live Training Meeting #2: Adherence Ratings for Experimental Sessions, 2-hour online call with a Gold Standard Adherence Rater
   a. Group check-in
   b. Review Preparatory Session Ratings and Homework
      i. Reliability scores
      ii. Address discrepancies between Gold Standard and group or Inter-rater reliability
      iii. Remaining questions
   c. Training on Adherence Criteria for Experimental Sessions
   d. Check-out: self-care and support

7. Experimental Session Homework (16 hours)
   a. Six video assignments: watch video, take notes, submit rating form
   b. Complete assignments before due date, typically trainees are given 5 weeks to complete all Experimental Session assignments
   c. Participate in discussion via discussion thread, email, and live calls

8. Reliability Rating for Experimental Sessions

Month 3: Adherence Ratings for Integrative Sessions

9. Live Training Meeting #3: Adherence Ratings for Integrative Sessions, 2-hour online call with a Gold Standard Adherence Rater
   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. Remaining questions
c. Training on Adherence Criteria for Integrative Sessions

d. Check-out: self-care and support

10. Integrative Session Homework (8 hours)
   a. Six video assignments: watch video, take notes, submit rating form
   b. Complete assignments before due date, trainees are typically given 5 weeks to complete all Integrative Session assignments
   c. Participate in discussion via discussion thread, email, and live calls

11. Reliability Rating for Integrative Sessions

Month 4: Adherence Rater Training Program Review and Graduation

12. Live Training Meeting #4: Adherence Rater Training Program Review and Graduation, 2-hour online call with a Gold Standard Adherence Rater
   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. Remaining questions
   c. Next steps in preparation for Adherence Rating on active study protocol
      i. Study initiation timeline
      ii. Final evaluation and graduation
      iii. Contracts
      iv. Invoices
      v. Monthly Adherence Rater Meetings for active study
      vi. Points of contact
   d. Check-out: overall impressions of the training

13. Graduation!

14. Training Survey

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, which can 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 corresponding with a p value of less than .05 is demonstrative of a consistent Adherence Rater pool, meaning the group has strong internal agreement on the 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 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

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Average % Agreement with Gold Standard</th>
<th>% Agreement Gold Standard with Group Median</th>
<th>ICC p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful group reliability</td>
<td>75% or higher</td>
<td>75% or higher</td>
<td>&lt; .05</td>
</tr>
<tr>
<td>Successful group reliability, with outliers</td>
<td>75% or higher</td>
<td>75% or higher</td>
<td>≥ .05</td>
</tr>
<tr>
<td>Unlikely outcome, check gold standard</td>
<td>75% or higher</td>
<td>less than 75%</td>
<td>&lt; .05</td>
</tr>
<tr>
<td>Unlikely outcome, check gold standard</td>
<td>75% or higher</td>
<td>less than 75%</td>
<td>≥ .05</td>
</tr>
<tr>
<td>Unlikely outcome, check for outliers</td>
<td>less than 75%</td>
<td>75% or higher</td>
<td>&lt; .05</td>
</tr>
<tr>
<td>Unlikely outcome, check for outliers</td>
<td>less than 75%</td>
<td>75% or higher</td>
<td>≥ .05</td>
</tr>
<tr>
<td>Check gold standard</td>
<td>less than 75%</td>
<td>less than 75%</td>
<td>&lt; .05</td>
</tr>
<tr>
<td>Wide variability, retest on new assignment</td>
<td>less than 75%</td>
<td>less than 75%</td>
<td>≥ .05</td>
</tr>
</tbody>
</table>

The Supervisor 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 who is unable to establish reliability after two rounds of analysis must complete additional training in order to continue in the Adherence Rating 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 calibration checks will be conducted as described above. Feedback will be provided to ensure that individual Adherence Raters are learning how to apply adherence ratings consistently and additional meetings to discuss reliability will be scheduled on an as needed basis during the inter-rater reliability process.

5.0 Primary Adherence Rater Duties

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

Adherence Raters are tasked with the following roles and responsibilities:

- Watch and code video (as described in Section 8.0)
- Accurately complete Source Records containing ratings and relevant feedback by set deadline
- Be available for comments after Source Records submission, as needed
- Attend ongoing administrative Adherence Rater meetings and check-ins
- Work with other Adherence Raters as part of self-care team
• Ongoing cohesive communication with other Adherence Raters and the Adherence and Supervision Coordinator and Adherence and Supervision Program Manager
• Ensure technical set-up is maintained to privately and securely view videos

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 desktop logins on their computers. When possible, Adherence Raters are encouraged to use wired ethernet connections to their private home or work networks.

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 take time for regular debriefing with fellow Adherence Raters. 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, breathe. Consider a method for decompressing after rating a session, such as attending a yoga class, taking a shower, or cooking a meal.

This debriefing should 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.

Engagement in regular meetings with other Adherence Raters within the same study group for the purpose of regular self-care is required. 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 Roles and Responsibilities

The purpose of reviewing videos of study visits within MDMA-assisted psychotherapy 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 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

9.1 Adherence Rater Leadership Structure

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)

9.1.1 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 rating 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

9.1.2 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

9.1.3 Adherence and Supervision Coordinator

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

Specific roles and responsibilities include:

• Maintaining regular contact between the Sponsor and the Adherence Rater groups to ensure both 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 work load capacity of Adherence Raters
• Coordinating Adherence Rater assignment scheduling, tracking deadlines, invoice reminders
• Managing rating assignments to ensure timely completion
• Collaborating with video tech specialists and data security staff to assign protected video content for rating assignments
• Maintaining scheduling platforms for task assignment
• Facilitate Adherence Rater meetings (dyads, supervision, orientations, trainings, and check-ins)
• Collaborating with Gold Standard Adherence Raters on developing and providing training activities
• Evaluating qualifications of potential Adherence Rater Trainees and reviewing applications
• Supporting Adherence Rater Trainees through the training program, documenting progress
• Coordinate reliability testing, working with statistician contractors for reliability analysis
• Developing documentation of the training and rating procedures, including contributing to updates of the Adherence Manual and work instructions
• Compiling adherence ratings and written feedback for review by the Sponsor participating in the development of Adherence Criteria
• Critically reviewing completed trainings and incorporating participant feedback to ensure quality trainings
• 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

9.1.4 Gold Standard Adherence Rater

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 provide 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 Coordinator to develop and provide training activities
- Developing documentation of training and rating procedures
- Assisting with Adherence Rater meetings (dyads, supervision, and check-ins)
- Assisting in review of qualifications of potential Adherence Rater Trainees
- Participating in the development of Adherence Criteria
- Facilitating training modules for Adherence Rater Trainees
- Providing processes for self-care to Adherence Raters in clinical matters (countertransference, theoretical orientation, nuances of Adherence items, burnout, vicarious trauma, etc.)
- Critically reviewing completed trainings and incorporating participant feedback to ensure quality

9.1.5 Lead Adherence Rater

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
- Support communications with the rater pool and serve as a peer liaison with fellow Adherence Raters
10.0 Adherence Rating Data Workflow

The data workflow involves sharing recordings of experimental psychotherapy 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 Medrio database.

![Figure 2. Data Workflow](image)

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

11.0 Adherence Rating Instructions

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.

11.1 Adherence Rating Commentary for Training and Supervision

In addition to completing an adherence rating, Adherence Raters will write commentary for Sponsor Supervisors to review. Comments should include references to video segments that illustrate the performance of the Therapy Pair. Review should include moments in which deviation from the protocol is observed, or moments that may reveal a potential area of weakness. It should also include moments that illustrate the competence or strength of the Therapy Pair. Adherence Raters are encouraged to make note of all comments and feedback that may contribute to the improvement of the therapy being offered, even if the Adherence Rater is unsure about their judgment of the video or whether something is important enough to be documented. The Therapy Pair does not have direct access to commentary submitted by the Adherence Rater or know the Adherence Rater’s identity, except for select cases in which a Supervisor holds a dual role as both Supervisor and Therapist and will access commentary in
their supervisory role. If deemed appropriate, certain comments may be relayed via the Supervisor during check-ins with the Therapy Pair.

Time stamps are important references for assessment purposes. Please list time stamps in all comments, particularly for Adherence items with a “No” rating. Include the hour(s), minute(s), and second(s) for the time or range of time on the video to which each comment pertains.

11.2 Adherence 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 you think that the therapists did not demonstrate the behavior described in item 1a, then select “No”:

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

For items that contain conditional situations, follow the instructions outlined in the item. Select “Yes” if the condition did not exist. 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.
12.0 Adherence Criteria

Section A – Adherence in Preparatory Sessions

<table>
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<tr>
<th>Yes</th>
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**General Behaviors or Actions**

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

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.

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

**Discrete Behaviors or Actions**

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

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

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

7a. Therapists inquired about the participant’s knowledge regarding PTSD and/or provided education about it as needed.

8a. Therapists described the likely effects of MDMA.

9a. Therapists described typical procedures of Experimental Sessions.

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

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).

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

☐  ☐  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.

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

☐  ☐  16a. Therapists explained that they may inquire about participant’s bodily sensations and encourage release of pain, tightness, or energy in the body through movement in whatever way may feel appropriate to the participant.

☐  ☐  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 at the beginning of the session what they are comfortable with. Therapists clearly stated that all touch is nonsexual and if the participant becomes uncomfortable with any touch, the participant can say “Stop,” or use an agreed upon comparable alternative command.

☐  ☐  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.

☐  ☐  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.

☐  ☐  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.

☐  ☐  21a. Therapists inquired about whether the participant had learned a stress inoculation technique that worked well for them and if they had not, the therapists taught the participant a stress inoculation technique, such as diaphragmatic breathing.
Yes  No

☐  ☐  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.

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

☐  ☐  24a. Therapists discussed the possible involvement of the participant’s support person and invited them to a Preparatory Session, if appropriate.
Section B – Adherence in Experimental Sessions

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<tr>
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<th>Yes</th>
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<tr>
<td></td>
<td><img src="image1.png" alt="Image" /> □ □ 1b. Therapists created and communicated a setting of safety and support.</td>
<td><img src="image2.png" alt="Image" /> □ □</td>
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<td><img src="image3.png" alt="Image" /> □ □ 2b. Use of physical touch and/or physical space respected the participant’s boundaries.</td>
<td><img src="image4.png" alt="Image" /> □ □</td>
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<td><img src="image5.png" alt="Image" /> □ □ 3b. Therapists used communication that the participant could easily follow.</td>
<td><img src="image6.png" alt="Image" /> □ □</td>
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<td><img src="image7.png" alt="Image" /> □ □ 4b. Therapists encouraged and/or allowed the participant to have periods of inner focus balanced with periods of communication.</td>
<td><img src="image8.png" alt="Image" /> □ □</td>
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<td><img src="image9.png" alt="Image" /> □ □ 5b. Therapists used supportive language and conduct that encouraged the participant to stay present with their immediate experience, including difficult experiences, if they occurred.</td>
<td><img src="image10.png" alt="Image" /> □ □</td>
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<td><img src="image11.png" alt="Image" /> □ □ 6b. Therapists conveyed a non-judgmental attitude toward the participant’s experience and did not pathologize transpersonal experiences or multiplicity, if they occurred.</td>
<td><img src="image12.png" alt="Image" /> □ □</td>
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<td><img src="image13.png" alt="Image" /> □ □ 7b. Therapists validated positive, affirming experiences or insights as part of a process of healing, growth, or meaning-making.</td>
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<td><img src="image15.png" alt="Image" /> □ □ 8b. Therapists used a largely nondirective approach, being guided by the participant’s experience, offering support in service of an unfolding inner-directed process.</td>
<td><img src="image16.png" alt="Image" /> □ □</td>
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<td><img src="image17.png" alt="Image" /> □ □ 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.</td>
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<td><img src="image19.png" alt="Image" /> □ □ 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.</td>
<td><img src="image20.png" alt="Image" /> □ □</td>
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<td><img src="image21.png" alt="Image" /> □ □ 11b. Therapists treated all material that arose during the session as relevant to the healing process.</td>
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<td><img src="image23.png" alt="Image" /> □ □ 12b. Therapists used music to support the experience without being intrusive and allowed periods of silence, if requested by the participant.</td>
<td><img src="image24.png" alt="Image" /> □ □</td>
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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 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.
Section C – Adherence in Integrative Sessions

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**General Behaviors or Actions**

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

- **2c.** Therapists facilitated inquiry into the participant’s unfolding somatic experience.

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

- **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**

- **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.

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

- **7c.** Therapists facilitated exploration of any challenges the participant might be experiencing with regard to integration in the present moment, and not just as reflection about the Experimental Session.

- **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).

- **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.
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.

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).

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.