



**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

- ☒ ☐ 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-judgement 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.