

**Script for phone screening
MDMA/PTSD study, Michael Mithoefer, MD**

Version 1/20/03

Prospective subjects will be asked the following questions:

(The answers required for someone to continue to a screening visit are indicated in parentheses after each question.)

Before beginning the interview, the interviewer should say, "I would like to ask you a few questions to get a preliminary idea of whether or not you might be suitable for the study. Is that alright?" and "It's important that you give honest answers. If there is any question you do not feel comfortable answering on the phone please tell me, and we could arrange for you to come in to answer it in person. All your answers will be kept confidential."

How old are you? (21-65)

Have you been diagnosed as having PTSD? (yes)

Is the PTSD war-related (no)

Have you had treatment for it? (yes)

Has your treatment included

- 1) An antidepressant? If so, which one and for how long? (an SSRI for at least 3 months)
- 2) Psychotherapy? If so, what kind of psychotherapy was it, for how long and how many visits? (at least 6 months and 12 visits, see list of accepted psychotherapies at the end of this script. If the type of therapy is in doubt ask them if Dr. Mithoefer can call them back to clarify this)

Will you be able to be in Charleston much of the time for 3 1/2 months? (yes)

For women: Are you pregnant? (no) If you are able to get pregnant are you using birth control? (yes, or if no ask next question)

Would you be willing to use birth control? (yes)

Do you have any medical problems? (no - if yes ask them what and tell them Dr. Mithoefer will call them back to talk to them about whether or not this would exclude them)

Do you have high blood pressure? (no)

Do you weigh less than 110 or more than 230 pounds? (no)

Have you taken MDMA (“Ecstasy”) before? If so how many times? (no or no more than five times).

If the person has any disqualifying answers they will be told,

“This is a highly controlled and regulated scientific study. This means we are required to accept only subjects who fall within certain criteria. The fact that you are not eligible does not mean your problems are particularly bad or that you could not necessarily be treated successfully; it simply means you do not fall within the limits of this particular study group. If you would like to talk to Dr. Mithoefer about this and about other available treatment options, he will be glad to call you back.”

If the person does not have any disqualifying answers they will be asked,

“Would you like to make an appointment to learn more about the study? This would not necessarily mean you would be in the study. It will be a chance for you to get detailed information about what it involves. This will give you a basis for deciding whether or not you want to have additional evaluation to determine your eligibility. Making an appointment does not in any way commit you to being in the study. You will have much more information and all the time you need to decide whether or not you want to participate, and we will need more information from you before we can tell you whether you are eligible.”

List of Accepted Psychotherapy Treatments

1. Cognitive Behavioral Therapies

- A. Exposure therapies,
- B. Cognitive reprocessing,
- C. EMDR
- D. Anxiety Management approaches

2. Insight-Oriented Therapies

- A. Psychodynamic therapy
- B. Hypnotherapy.

3. Stress Inoculation Training