



A Pilot Study of MDMA-Assisted Therapy for the Treatment of Narcissism

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KEY INFORMATION ABOUT THIS STUDY

Purpose: The reason we are doing this study is to see if a medicine called MDMA (3,4-methylenedioxymethamphetamine) taken during three special therapy sessions (MDMA-Assisted Therapy, or MDMA-AT) can help people who have narcissism that is interfering with their quality of life (often called *narcissistic personality disorder*).

Study Duration: Participating in this study takes about 10 months total which includes 20 in-person visits

Types Of Activities You Will Do in This Study:

Before you start the therapy sessions with MDMA, there will be three (3) Prep Sessions ("Preparation Sessions") spread out over about four weeks. In these sessions, you'll talk about your past mental health, what you hope to get out of the therapy, what will happen during the sessions, and you'll answer some questionnaires that will help us understand where you're starting from (baseline responses). By the first of these three Preparation Sessions you will need to have finished any required tapering off drugs.

Following the three (3) Prep Sessions, you will have the first of 3 sessions with MDMA ("Experimental Sessions") which will take place in a comfortable space that is more like a living room than a clinic room and will each last 6-to-8 hours long.

After the first experimental session with MDMA, you will have three (3) weekly follow-up sessions, called "Integration Sessions," spaced about once a week. In these meetings, you'll talk about what you felt and thought during the therapy and share any new thoughts or insights that came to you.

Then you will have a second Experimental Session with MDMA, three (3) more Integration Sessions; then a third Experimental Session with MDMA, and three (3) final Integration Sessions.

At the last Integration Session of all three series, you will fill out one questionnaire. At your final Integration, you will also answer a set of open-ended questions. Once all treatments are done, you'll return for four (4) Follow-up visits after around one week, one month, three months, and six months. During these visits, you'll fill out the same questionnaires you did earlier during prep. This helps us track how you're doing over time. At your last Follow-up, you will again answer a set of open-ended questions.

This study also asks your therapist and a partner or family member who matters to you to also fill out questionnaires. They will fill out questionnaires at the same time that you fill out questionnaires, including at around one week, one month, three months, and six months after you finish your last therapy session with MDMA. You will not be able to see what they put on their questionnaires, and they will not be able to see what you put on your questionnaires.

During these activities, we will regularly check to make sure you are safe. This means we will look for any signs that you might want to harm yourself, and if you could have a baby we will have you take a pregnancy test. We will also check if you have been using any drugs that are not on your list of prescription or over-the-counter medications with a urine test. During the MDMA Sessions, your blood pressure, heart rate, and body temperature will be checked.

Reasons You May Want to Participate: You may want to join to help increase scientific understanding of MDMA-assisted therapy for narcissism. The effectiveness of this treatment is not yet known.

Reasons You May Not Want to Participate: You might prefer to wait for more information about how well this treatment works. You could also be worried about keeping your involvement private and other possible risks. If you are on antidepressant medication, you might not want to taper off it for this study. If you are a woman able to have children, you might not want to join because you'd have to make sure you don't get pregnant from the start of the study until after the last therapy session. You might not want to be in the study if you don't want to talk about past trauma and your mental health in a setting that is not with your own therapist and that involves use of an experimental drug. Unpleasant reactions are to be expected in these sessions. Taking MDMA in this study could lead to rare but serious health problems including cardiac problems (heart attack). You will need to *not* smoke or use nicotine for 24 hours before the MDMA Experimental Sessions (when you actually take the

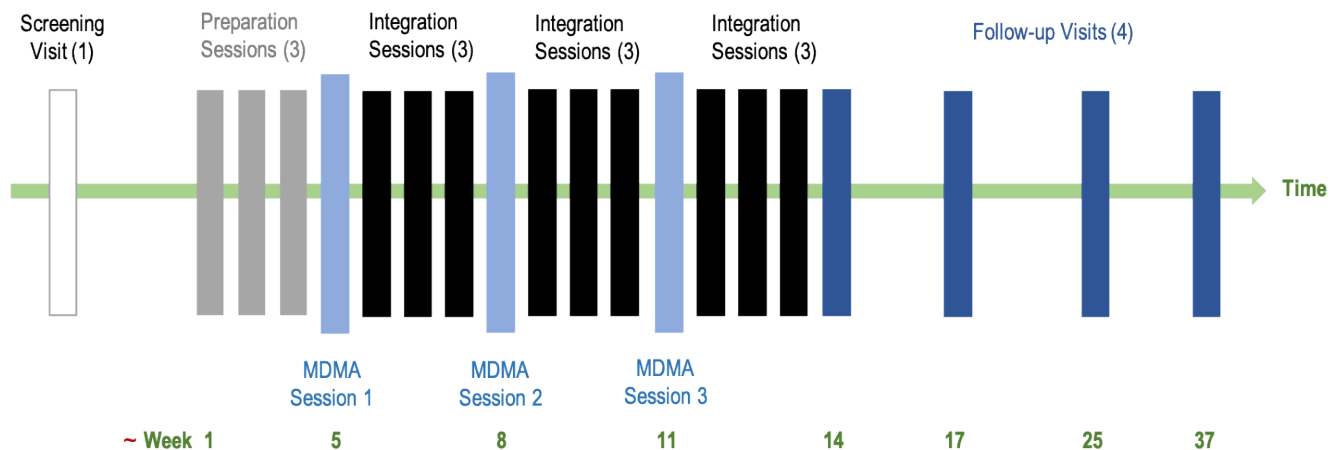
MDMA). If you smoke regularly, this amount of time without smoking could be very uncomfortable for you.

Other Treatment Options: There are alternative treatments like psychotherapy or medications for related conditions like depression or anxiety. You would need to be evaluated by a psychologist and/or psychiatrist to determine the range of options appropriate for you.

What is this study about and what will you be asked to do?

We're doing this study to find out if a new kind of therapy can help people who have narcissism that is interfering with the quality of their lives (often called *narcissistic personality disorder*). You've been invited to take part because you have been diagnosed with this condition and it's causing you problems.

In this study, you'll try an experimental drug called MDMA (3,4-methylenedioxymethamphetamine) during three therapy sessions in which you will guide the conversation. This treatment is known as MDMA-Assisted Therapy, or MDMA-AT. Being part of this study will take about 37 weeks, which is close to 10 months, and you'll come in for a total of 20 visits.



- Screening Visit:
 - One (1) visit to see if you are eligible for the study (Screening Visit).
 - This visit will last 90-to-120 minutes.
 - You will need to go to a separate clinic to get some tests done.
- Preparation Sessions:
 - Three (3) visits to prepare you for the study treatment (MDMA-AT) ("Preparation Sessions").

- Each of these visits will last 60-to-90 minutes.
- Experimental Sessions:
 - Three (3) visits where you will receive the MDMA (“Experimental Sessions”).
 - Each of these visits will last between 6-to-8 hours.
- Integration Sessions:
 - Three (3) visits after each Experimental Session to discuss your experience, for a total of nine (9) visits (“Integration Sessions”).
 - At the last Integration Session of all three series, you will fill out one questionnaire.
 - At your final Integration, you will also answer a set of open-ended questions.
 - Each of these visits will last 60-to-90 minutes.
- Post-Treatment Follow-Up Visits:
 - Four (4) visits to check in on any changes for you (“Follow-up Visits”). These will be at around one week, one month, three months, and six months following your last Integration Session.
 - At each Follow-up Visit, you will complete the same questionnaires to help us understand how you are doing over time.
 - Each of these visits will last about 60-to-75 minutes.
 - At your final Follow-up Visit, you will be asked a set of open-ended questions about your experience of this new treatment as well as any changes you have noticed about yourself. This is also when your participation in the study officially ends. We call this the “Study Termination Visit.”

<i>Reasons you might say “yes” to being in the study.</i>	<i>Reasons you might say “no” to being in the study.</i>
<p>Direct benefits to you:</p> <p>You'll get checked by a psychiatrist, have some extra medical tests to see if you fit into the study, and you'll go through nine (9) psychotherapy sessions. However, we can't promise that your condition or how you feel about your life will improve because you're a part of this study.</p> <p>Indirect benefits to you:</p>	<p>MDMA is being tested, which means the U.S. Food and Drug Administration (FDA) hasn't yet said it's okay to use for health reasons unless it's part of a study. MDMA is a Schedule I controlled substance under the Controlled Substances Act. On the streets, MDMA can be called "ecstasy," but illegal ecstasy might have other drugs in it, not just MDMA. Used in this way, MDMA is a drug of abuse and misuse.</p>

<p>By joining this study, you're helping add to what researchers know about MDMA-Assisted Therapy (MDMA-AT). This could help other people with the same mental health issues in the future. You're also aiding Drs. Albert and Back in understanding how well MDMA-AT works and if it's safe as a way to help people troubled by narcissism.</p>	<p>Even if the FDA decides to eventually approve psychedelic treatments like MDMA for medical use, their use may remain stigmatized in the eyes of some people which might affect how you feel.</p> <p>You won't get any money for being in this study. You might have to take time off work to be in the study.</p> <p>You might worry about keeping your part in the study private or confidential, and other possible risks.</p> <p>If you're a woman who can get pregnant, you'll need to make sure you don't get pregnant from when you join the study until it ends.</p> <p>You might choose to wait for more results about how well this treatment works before deciding to join.</p> <p>Taking MDMA in this study could lead to rare but serious health problems including cardiac problems (heart attack).</p> <p>You will need to <i>*not*</i> smoke or use nicotine for 24 hours before the MDMA Experimental Sessions (when you actually take MDMA). If you smoke regularly, this amount of time without smoking could be very uncomfortable for you.</p>
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Do I have options outside of this study?

Choosing not to join this study is completely up to you. If you decide not to take part, you won't face any penalties or lose any rights or benefits that you normally have. Not being in the study won't change how you can get healthcare at the University of Washington.

If you're not already doing so, other ways to help with feelings of depression, worry, or stress from past trauma might include certain medications. It's important to talk with your current doctor or therapist to figure out the best treatment for you.

What can you do if you want more information?

Learn More About the Study: The following pages have details about what will happen if you join the study and the changes you'll need to make in your daily life for about 10 months.

Speak with the Study Team: We're here to explain things and answer your questions – even those not mentioned in this form. Our job is to provide all the info you need to help you decide about joining. You can ask us anything before you make up your mind. Once you sign up, we'll give you a copy of this consent form for your records.

Discuss With Others: We're handing you this consent form before you sign it, so you have time to think and talk it over with your family, friends, your usual doctors, your therapist, or anyone else. This paper can help them understand the study, so you can all talk about it together.

Know Your Rights: If you wish to speak with someone not involved in the study about your rights as a participant, or if you have any issues or complaints, you can reach out to the UW Human Subjects Division at hsdinfo@uw.edu or call 206-543-0098.

What do the research procedures involve?

What Will Happen to Me? This part describes what you'll go through if you decide to join the study. Every time you come in for the study, you'll be in a room made to be comfy like a living room, not a typical clinic room. All study sessions will be recorded for your safety, and the recording is a requirement of being in the study. You can ask for the recorders to be turned off for a short time if you have something to say that you do not want to be recorded.

Screening Visit (1.5 to 2 hours):

- You'll re-read and ask questions about this Informed Consent Form. You have to agree and sign it before we do any health checks.
- We'll talk about why you want to be in the study.

- We'll ask about your health history and medicines to see if you can join.
- You'll get a physical exam to check:
 - Your vital signs (blood pressure, heart rate, and body temperature);
 - Your heart's health (a 1-minute rhythm strip and 12-lead ECG that record the electrical activity of your heart).
- We'll chat about your mental health to make sure of your diagnosis and check for any other mental health issues, including substance use disorders and suicidal thinking and behaviors.
- You'll need to let us talk to your current doctors so they can manage your medications safely for the study; to do this, you will need to agree and sign a "release of medical information."
- You'll need to give permission for:
 - A blood draw to check your liver, kidneys, and blood (about 4 tablespoons of blood).
 - Your urine for signs that you are pregnant (if you have the ability to get pregnant); and
 - Your urine for signs of any drugs in your body.

We'll tell you how to get these tests done. You will need to go to a separate clinic to get these tests done.

- We'll need the names and contact info of your therapist and a family member. They'll share their thoughts about you at the start and after the study. You won't see what they say; it's private and just for the Study Team.
 - You'll get a handout to give them, so they know how to talk to us through a video call.
 - Your family member must be:
 - 18 or older.
 - Able to speak and understand English.
 - Willing to be in the study and fill out a short computer questionnaire (5 minutes).
 - You must be willing to keep seeing your therapist while you're in the study.
- If everything looks good, we'll call you to officially join the study.
- You'll talk to your doctors about any meds you need to stop taking before the study. If there's a delay in stopping these meds, we might need to check you again before you start.

- Your next visits will be scheduled to get you ready for the main part of the study.
- These sessions will be audio-recorded.

Preparation Sessions (each 1 to 1.5 hours):

- At the start of your first prep visit, you'll fill out some questionnaires to see where you're at before the therapy sessions begin (called your "baseline"). We'll ask questions about things like whether you've ever been in jail or had an abortion.
- You'll get to know the two therapists who will be working with you. All study therapists are fully qualified healthcare providers and licensed to practice on their own. They'll be there through all your sessions - before, during, and after the drug is given.
- They'll explain what will happen when you take the medicine, including any usual side effects, and answer any questions you have.
- You'll discuss how your narcissism or narcissistic personality disorder has affected your mental health and well-being.
- On your second Prep Session, you'll answer a quick questionnaire about tough experiences that might've happened when you were younger. These questions will likely be the toughest (most sensitive) that you will be asked.
- You'll set some personal goals for what you hope to get out of the study.
- They'll check again to make sure it's still safe for you to take part in the study. This will include asking about any new health changes or medicines you're taking, and whether you're feeling very down or thinking about harming yourself (if that's the case, you'll be directed to appropriate evaluation and treatment).
- At your third prep visit, if you can have kids, they'll test to see if you're pregnant, and they'll test everyone to make sure there are no drugs in your body that could interfere with the study. If any test comes back positive, the next phase with the drug can't happen.
- These sessions will be audio-recorded.

Experimental Sessions (3 total, each 6-8 hours):

- Don't drink alcohol after midnight the night before your session.
- You will need to *not* smoke or use nicotine 24 hours before. Water and juice are fine.
- Please avoid solid foods for 3 hours before your session.

- You'll answer some questions to make sure it's safe for you to proceed with the session.
- You'll have two tests before taking MDMA:
 - If you might be pregnant, we'll do a pregnancy test.
 - We'll check for any drugs in your body with a drug test.

If you test positive for either, we can't go ahead with the session.

- You'll talk through what to expect in the session and revisit your goals.
- Your Therapy Team will be with you the whole time, except when they take a break.
- We'll check your vital signs before, during, and after the session.
- If you feel any side effects, we're ready to help right away.
- You'll take the first dose of MDMA and get comfy with music and eyeshades to help you focus inwardly.
- Every hour, you'll have a chance to chat with your therapists.
- Later, you might be offered a smaller second dose.
- Stay hydrated during the session, and we'll have snacks for you too.
- Arrange a ride home afterward; you can't drive yourself.
- When it's safe, you'll be ready to leave, no earlier than 6 hours after your first dose.
- If there's a risk of harm, you might be moved to the medical center for care.
- Take it easy after the session. Rest, reflect, and begin to integrate your experience. You can call us anytime (even overnight) if you need to talk.
- These sessions will be video-recorded using a camera in the corner of the room.
- **Your Therapy Team and study physician shall remain available to you overnight via a 24-hour cellular phone for any support or questions.**
- If you feel faint, have chest tightness or pain you should contact 911 and the study PI at the 24-hour emergency number.

Integration Sessions (total of 9; three after each of the 3 Experimental Sessions) (each 1.5 to 2 hours):

- You'll meet for the first one the next morning, and you'll have a total of three (3) of these over the span of four weeks.
- Have someone drive you to the first one. This is for your safety because some people feel tired, less alert, and/or have trouble concentrating the day after they have taken MDMA.
- Discuss your thoughts, feelings, and memories from the session, and what you thought and felt about them afterwards. Your Therapy Team will help you understand your experiences and what they might mean for you but they will not tell you what your experiences mean -- the interpretation is ultimately up to you.
- Your Therapy Team will help you to explore any distress you may have experienced so you are not left feeling residual psychological distress.
- You'll talk about any side effects and your well-being.
- Fill out three brief questionnaires at your first meeting and one quick questionnaire during your third meeting. At your final Integration Session, you will answer a set of open-ended questions.
- Plan for the next session and get support whenever you need it.
- These sessions will be audio-recorded.

Follow-up Visits (each 1 to 1.5 hours) (four sessions that take place after all Experimental and Integration Sessions are done):

- We'll catch up on any new changes with your health, medications, or side effects from the MDMA.
- You'll do more questionnaires over time to track any changes as well as answer a set of open-ended questions.
- Feel free to reach out to the Study Team for extra support between visits.
- Keep following the study's rules until your last check-up which is the last of the four follow-up visits shown as Week 37 on the study diagram. Then you're all done with the study.
- We'll give you a summary of what you've done and contact info if you have questions later.
- These sessions will be audio-recorded.

If I Agree to Be in this Study, What Will Be My Responsibilities? If you are accepted into the study, you must agree to the following lifestyle changes for the length of the study (~ 10 months):

1. You'll need to attend ALL study sessions including the visits that involve the drug, as well as all the preparation, integration, and follow-up visits.
2. Please don't sign up for any other research that involves treatments unless you check with us first.
3. At your first visit, it's essential to tell us about any health issues or medicines you're taking, including over-the-counter drugs, recreational drugs, vitamins, herbs, and supplements. We need this info to keep you safe.
4. From the start to the end of the study, avoid starting any new medications that we haven't okayed.
5. There might be certain medicines or substances you have to stop using while you're in the study because they could be dangerous with MDMA. We'll let you know what these are and talk about how to stop them safely.
6. If you're on psychiatric medicines like for depression or anxiety, you may have to stop these. Depending on what psychiatric medications you are on, you may have to stop them for 24 hours before your MDMA session(s) and/or for the duration of the study. If you need to start them again before the study is over, unfortunately, you'll have to leave the study.
7. It's important to stay away from any recreational drugs from the time you start the study until it's over.
8. Don't take any medications or supplements that we haven't approved for one week before each session where you'll get MDMA.
9. If you use pain medication, you might need to use less before your session. We'll guide you on this so that you won't take these meds on the day of and for 24 hours after the MDMA session.
10. If there's a chance you could get pregnant, you must use reliable birth control throughout the study and through 10 days after the last Experimental Session. The Study Team has given you information about appropriate birth control methods for use during the study. Reliable birth control methods include:
 - **IUD (Intrauterine Device):** A small device placed inside the uterus to prevent pregnancy.
 - **Hormonal Methods:** These include:
 - Injected hormones

- Implanted hormones
- Hormonal vaginal rings
- Hormonal skin patches
- **Abstinence:** Choosing not to have sex.
- **Oral Hormones Plus Barrier Contraception:** Taking birth control pills and also using condoms.
- **Vasectomized Partner:** Having a male partner who has had a surgery (vasectomy) to prevent pregnancy.
- **Double Barrier Contraception:** Using two types of barrier methods together, like condoms and diaphragms.

11. If you are male and planning to conceive a child after participating in this study, we want you to know that there is a possible risk that MDMA could affect your sperm, and we do not know how significant this possible effect is or how long this possible effect could last. We just do not have enough research yet. So, to be cautious, you might consider banking your own sperm prior to your first MDMA Experimental Session.
12. You will need to give us an emergency contact who we can reach if needed.
13. If you have any new health problems or medical treatments, tell us within two days.
14. You will need to stay at the MDMA dosing visits until the study therapists say it is safe for you to leave.
15. Please don't drive for at least a day after getting MDMA.
16. Always follow the study rules. If you slip up, it's important to tell us. It keeps you safe.
17. Be open to extra medical checks if we think they're needed to look after your health.
18. You may change your mind later and that's okay. But if you miss a visit, you won't be able to continue with the treatment visits.

What are the potential side effects and risks of the study?

Before you join the study, we'll collect all the necessary information to make sure it's safe for you to participate. If you have a health condition that isn't stable, or if your mental health could make being in the study unsafe for you, you won't be able to join.

Being in this study might have some risks and could be uncomfortable. These could be from the health checks we do, the therapy sessions, or the drug we're testing, which is MDMA.

Risks from Health Checks:

- Getting checked out for your mental health might be long and sometimes upsetting, especially if we talk about difficult things from your past.
- Physical check-ups could take a while, too. You might feel a bit of pain where we draw blood, or you might feel dizzy or even faint.

Risks from Therapy:

- In therapy, talking about bad memories or feelings can make you feel uncomfortable, and you may even feel worried or sad or irritated for a while. It's common and part of the therapy process.

Risks from the Drug (MDMA): The experiences you have during the study will differ greatly from one person to another and can't be predicted beforehand, but they may include:

Side Effects:

- Common side effects that you might experience include feeling less hungry, jaw clenching, dry mouth, feeling off-balance, or trouble focusing.
- Less commonly, you might experience feeling too hot or cold, your heart racing, becoming sweaty, dizzy, an upset stomach, or headaches.
- These side effects are generally short-lived, usually lasting a few hours to a day.

Changes in How You Perceive and Understand Things:

- You might notice temporary changes in how you perceive things around you during and after the sessions. Changes in how you see or hear things can last from a few hours to several months.
- In very rare cases, you might experience ongoing changes in how you perceive shapes and colors, a condition known as hallucinogen persisting perception disorder (HPPD). While these symptoms often improve over months or years, there is currently no cure, and they can be significantly disruptive. The risk of HPPD is lower when psychedelics are used in controlled settings, like during this clinical study.

Changes in Personality and Beliefs:

- You may experience changes in how you think and feel about yourself and the world. You might gain deep insights, become more open to new ideas, and see life's challenges from different perspectives. You may also feel a stronger sense of connection and openness with others.
- You might feel an increased sense of well-being, feel more social and outgoing, and feel more caring and understanding towards other people. You may experience a feeling of relaxation and/or an elevated mood.
- These experiences can be unexpected and confusing. They can be hard to explain and might make you feel both physically and emotionally tired.

Worsening of Psychological Symptoms:

- If you taper off antidepressant medications before you start the study, you may have increased symptoms such as a worsening mood or more anxiety.
- You may experience unpleasant feelings including psychological distress or panic. You may encounter strong emotions such as grief, rage, or fear.
- MDMA may intensify existing mental health issues, such as severe anxiety or thoughts of suicide.
- Because this study involves confronting and working through traumatic experiences, it is expected that you may experience some unpleasant feelings and psychological reactions as part of the therapeutic process.
- During the Preparation Sessions, you and your Therapy Team will discuss and agree on methods to help you manage distress or discomfort that you might experience during the study. These methods may include providing reassurance that difficult feelings will eventually pass, introducing emotional management techniques, talking with you about your experiences to enhance your understanding of them, and using self-calming and stress management strategies.
- Throughout the study, you will have access to support. You will have weekly check-ins with your Therapy Team throughout the 12-week treatment period, and your ongoing psychotherapy will continue outside the study with your therapist monitoring you for any signs of psychological distress.

Increased Vulnerability:

- Taking psychedelics like MDMA can leave you feeling very open and vulnerable during the treatment and afterwards. Unfortunately, there have been cases in the past where people were harmed by those supposed to help them who instead exploited and/or abused them. Our strict safety protocols are designed to protect and support you throughout the treatment and afterwards.

- Because psychedelics like MDMA can significantly affect your mental state and ability to make decisions, you will talk with your Therapy Team before starting the MDMA Sessions to establish clear rules about appropriate physical contact, such as comforting touches on the shoulder or holding hands. This is to make sure any touch is comforting and consensual, and necessary for safety. You will also set rules to stop any comforting touch quickly. This helps make sure you can easily communicate your needs to your Therapy Team so they can respect the limits you set.

Sleep:

- After the drug session, you might have trouble sleeping or feel tired or moody for a few days.

Your Immune System:

- Your body's defenses might be weaker for a couple of days after taking MDMA, just like if you'd had a few drinks.

Driving:

- MDMA could affect your driving even a few days later, so be careful.

Addiction:

- When people have taken MDMA that they have obtained illegally, they have sometimes gotten addicted. We'll talk about this risk if you're worried.

Brain Changes:

- Some research suggests repeated use of MDMA - much more than you would receive in this study - might harm the brain or affect memory but this isn't clear. In studies, people who take just a little bit, like in our study, usually don't have lasting problems.

Serious Risks:

- MDMA can raise your blood pressure and heart rate. It's usually not too bad but could be serious if you already have certain heart conditions.
- Outside of research studies and in other research studies like this one, some people have had serious issues or even died after taking drugs like MDMA. In other research studies like this one, some people have had serious issues after taking MDMA in a clinical trial. If you feel really bad and might hurt yourself or others, the Study Team might need to take you to the hospital.
- It's really important to tell us about all the medicines or drugs you use because they might not mix well with MDMA. MDMA increases a chemical in your brain called serotonin. You'll have to stop taking any medicine that does the same thing, like antidepressants (especially ones called MAOIs or SSRIs), some painkillers, cold medicines, and certain herbal supplements. If your

body has too much serotonin, you could develop a serious condition called serotonin syndrome and get very sick, feeling jittery, too hot, sweaty, have stiff or twitchy muscles, a fast heartbeat, or feel confused.

Serious Problems and Death:

- Outside of research studies and in other research studies like this one, some people have had serious issues or even died after taking drugs like MDMA. In other research studies like this one, some people have had serious issues after taking MDMA in a clinical trial.

If You're Pregnant:

- We don't know how MDMA affects unborn babies, so you can't be in the study if you're pregnant. We'll test you to make sure before you start and before each session.
- If, at any time during the study, you suspect that you may be pregnant or are concerned that you may become pregnant, you must advise Study Staff immediately. If you should become pregnant during the study, study researchers will help you get proper advice and help you and your unborn baby get proper care while you are pregnant. In the unlikely event that you become pregnant after using the study drug, maternal and infant outcomes will be tracked and reported to the sponsor.

Remember, we're here to make sure you're looked after during the study. If at any point you're worried about how you're feeling, let us know right away.

How will we protect the information you provide?

We will protect your confidentiality. Your privacy is a big deal to us. We'll keep everything we learn about you in the study private. Your name won't show up in any study reports or hospital records. After we're done with the study, we'll break the link between your name and the information we've gathered. We keep your data locked up or on password-protected computers. This includes video-audio recordings, if applicable. Even though we will do our best to keep your information safe and even though it's rare, data breaches can sometimes happen, and your private details could be seen by others.

During this study, it is possible that information about your health and safety will need to be shared with others to keep you safe. As a part of the safety plan for this study, you will pick an emergency contact person and provide us with their contact info. In the case of an emergency, we will coordinate with them about a local plan. If we learn that you intend to harm yourself or anyone else, we must report that to the authorities. The FDA can look at the study details if they need to, and so can PharmaAla Biotechthe drug company that is giving us the MDMA for the study.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

There are a few cases where we have to share what we know, like if the government asks for it to check on the study, or if someone else needs it to make sure we're doing things right, or if the FDA asks for it. If we find out about any harm to kids or elders or if someone might get hurt, we must report that.

The stuff we learn from you might be used in other studies down the road. We'll take your name off first, so no one will know it was you. If someone in the future wants to use that info in a way that could reveal who you are, they'll have to get special permission for that.

What if you want to stop being in this study, or if the researcher decides you should no longer participate?

If you decide to leave the study, please tell the research team right away. If you change your mind during a drug session, you will need to stay at the clinic for about 6 hours after taking MDMA. The team will make sure the drug's effects have worn off and that you're okay to go home. They'll check your health and ask how you're feeling to make sure you're not having a tough time because of the session.

If something happens during the first session that makes it unsafe for you to keep going, like if your blood pressure goes up a lot or you have a really hard time, your team might say it's best for you not to continue. They'll explain everything to you.

If you stop the study or if we have to stop your participation, we'll ask you to answer the questionnaires again to compare with your earlier answers. You can choose not to answer these if you don't want to.

Sometimes, if your situation changes and you don't fit the study rules anymore, we might have to end your participation. If this happens, we'll help you find the care you need outside of the study.

How will we test, store, and share your information and samples?

Can I Get Copies of My Results? You have the right to see and get copies of your health information. If there's anything important in your test results, like something not normal in your blood test, urine test, or heart check (ECG), we will share those results with you.

If you would like a copy of one of the recordings of your study sessions, please ask the Study Staff. While we can provide a copy of an individual session rapidly, it will take some time for us to create a copy of all the sessions.

Will you get to know your research results?

STATEMENT OF INFORMED CONSENT FOR PARTICIPANTS
Pilot Study of MDMA-Assisted Therapy for the Treatment of Narcissism

Will I Hear About New Findings? If we learn something new about MDMA that could change what we know about its risks, we'll let you know right away. This way, you can make an informed choice about whether you want to continue in the study.

Other information about this study.

Can I Choose Whether I Want to Be in This Study or Not? Yes, being in this study is completely voluntary. This means that you can refuse to sign up. It also means that if you do say yes, you can leave the study at any time without any trouble.

How Is This Study Being Funded? The study medicine, MDMA, comes from PharmAla Biotech, and Pivotal Ventures gave us the money to do the research. You won't have extra costs because of the study:

If you get hurt while in the study, call Dr. Anthony Back right away. If it's super serious, call 911 or go to the hospital fast. Once you're okay, call Dr. Back at 206-619-4367. If getting hurt is because of the study, you'll get care at a UW medical clinic or emergency department. You or your insurance will get the bill just like normal, unless UW's special program (HSAP) can help with the cost. The researcher may request HSAP coverage by following established procedures. If you want to ask for HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. Your insurance will be billed for any care you get for issues from your narcissism or regular care. If you don't have insurance or they won't pay, you'll get the bill.

Do the Researchers Have Any Conflicts of Interest? Members of the Study Team do not have any financial ties or other conflicts of interest with organizations or companies that could influence the results of our study. Our work is guided solely by the pursuit of scientific knowledge.

How Many People Will Be in the Study? We plan to enroll up to 12 people in this study.

Will Everybody Receive the Same Treatment, and How Will This Be Decided? All people who decide to take part in this study will receive the same visits and all will have a flexible dose of MDMA:

- In the 1st treatment session, everyone will get an 80 mg dose of MDMA.
- About 1.5-2 hours after your first dose, you might get a second, smaller dose of MDMA. This will only happen if your Therapy Team says it's okay and you feel alright to take it.

- For your second and third sessions with MDMA, the starting dose may be a bit more, up to 120 mg, if needed.
- You and your Therapy Team will decide together if you should stick with the first dose or change it, based on how you felt the first time.
- Your safety and how comfortable you feel are really important. So, the amount of MDMA you take can be changed to what you need.

What is the Purpose of the Live, Real-Time Video-Audio Recordings? We record these sessions to help the Study Team review your experience and how the therapists work with you. If you want, you can get a copy of these recordings. To keep your information private, we will label the recordings with a special study number and the date, not your name. We'll keep them safe in locked places or password-protected files that only the Study Team can access. We will keep the recordings until the study is done and any records retention requirements have been met. We'll need your okay to record the preparation and integration talks and to videotape the sessions with MDMA. There's a special place for you to sign for this at the end of this form.

A copy of the consent form will be emailed to you at an email address that you provide: We'll email you this consent form as a PDF file, which you can open, read, or print. If your computer can't open it, the email will have a link to get the free software you need. If you'd rather get a paper copy for free, just let the study people know.

Consent presenter statement

By printing my name on this form, I am attesting that I have provided the subject with information about this study. The participant has been given sufficient time to consider participation and I have answered any questions they had. The participant indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of Study Staff obtaining consent

Date

Subject's statement

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form. I give permission to the researchers to use my medical records as described in this form.

Printed name of subject

Signature of subject

Date

Video-Audio Recording Statement

By signing this consent form, I confirm that the purpose of the video-audio recordings has been explained to me. I understand that the recordings will be kept in locked offices in a locked file cabinet and secure on-line file system, accessible only by the research staff. I understand that the recordings are required to participate in the study.

Printed name of subject

Signature of subject

Date