MP18 Master Informed Consent Form
EudraCT # 2018-001718-13

ICF Version: Version 6, 22 November 2022

An Open-Label, Phase 2, Multicenter Feasibility Study of Manualized MDMA-Assisted Psychotherapy with an Optional fMRI Sub-Study Assessing Changes in Brain Activity in Subjects with Posttraumatic Stress Disorder

SPONSOR	MAPS Europe B.V.
SPONSOR DESIGNEE	Amy Emerson Chief Executive Officer MAPS Europe B.V. Email: amy@mapsbcorp.com
COORDINATING PRINCIPAL INVESTIGATOR	Prof. Dr. H.G.J.M. (Eric) Vermetten Leiden University Medical Center Email: e.vermetten@lumc.nl
MEDICAL MONITOR	Aurélien Viaccoz MAPS Europe B.V. Email: medicalmonitor@mapseurope.eu
USE	In conjunction with relevant regulatory and ethical guidance

Participant Information Sheet and Informed Consent Form

Study short title: MDMA-Assisted Psychotherapy for the Treatment of PTSD

Study official title: An Open-Label, Phase 2, Multicenter Feasibility Study of Manualized MDMA-Assisted Psychotherapy with an optional fMRI sub-study Assessing Changes in Brain Activity in Subjects with Posttraumatic Stress Disorder

Sponsor: MAPS Europe B.V.

Sponsor protocol number: MP18

Introduction

Dear Sir, Dear Madam,

You are being invited to take part in this medical research to find out if the experimental drug MDMA combined with psychotherapy (talk therapy) is safe and helpful for people who have posttraumatic stress disorder (PTSD). You have been asked to participate because you have been diagnosed with severe PTSD with symptoms lasting for at least six months. Please read this information carefully before you decide whether you want to participate in this study. Please ask the study doctor or research team for an explanation if you have any questions. You may also discuss it with your partner, friends, family or general practitioner (GP). Participation in this study is voluntary and you will need to give written consent in order to take part.

1. General information

MAPS Europe B.V. has prepared this study. MAPS Europe is owned by the Multidisciplinary Association for Psychedelic Studies (MAPS) a charity organisation that funds this study. MAPS Europe is the Study Sponsor. Approximately forty (40) participants from various research centres in Europe will be asked to be in this study and about [insert number of participants planned within the country] participants are expected to participate in [insert country].

The researchers involved in conducting this study do not receive any financial incentives for including you in this study and do not benefit financially from this study. However, the sponsor will pay the study doctor and/ or institution for his/ her expenses, time, and effort to conduct this study.

Ethics Committee [insert country Ethics Committee name and list other local bodies that will review and approve the study] has approved this study. The goal of the Ethics Committee is to protect the rights and welfare of study participants.

2. Purpose of the study

The purpose of this study is to find out if the drug MDMA combined with psychotherapy is safe and helpful for people who have PTSD. [Add for countries participating in the fMRI sub-study:
The study sponsor also wants to find out how MDMA affects brain function]. There have been many studies that suggest MDMA-assisted psychotherapy can have a positive impact on PTSD symptoms. How it helps is not yet fully understood. With the results from this study, we aim to better understand

the effects of MDMA-assisted psychotherapy on PTSD. [Add for countries participating in the fMRI sub-study: We aim to explore the effects of MDMA-assisted psychotherapy including two brain scans, before and after the course of therapy].

This study is open-label, meaning that you and the study researchers will know that you will get MDMA. During first MDMA-assisted psychotherapy session you will receive a dose of MDMA (80 milligrams (mg)) and possibly two hours later a second dose equal to half the size (40 mg) of the first dose. During the second session, about one month after your first session, you will receive either the same or a slightly higher dose (80 + 40 mg or 120 + 60 mg). Effects of MDMA usually last 6 to 8 hours after you take the capsule.

[Add for countries participating in the fMRI sub-study:
This study will also include two brain scans. During the brain scans, we will observe you as you complete different tasks. In one of the tasks we will observe how you respond to pictures of different faces and how you respond to a script of your own neutral and traumatic experience that you will prepare together with your study therapist. In other tasks you will be asked to close your eyes and be still. In between the tasks you will be asked how upset or bothered you are at the moment. Looking at your brain while you do these things will help us understand which regions of the brain are activated and how this effects things such as remembering positive and negative emotional memories].

3. Background of the study

MDMA is an experimental drug, which has not been approved by health authorities for medical use and can be used only within clinical studies. MDMA is similar to the stimulant methamphetamine, and a popular recreational drug, sometimes referred to as “Ecstasy” (which is supposed to contain MDMA, but often contains other drugs instead of or in addition to MDMA). The MDMA used in this study is produced by a pharmaceutical drug supplier licensed to manufacture the medicine under strict quality controls. MDMA is an illegal drug to use outside of research.

Before MDMA became illegal, some psychologists and psychiatrists combined it with psychotherapy to help people with psychological problems including PTSD. MDMA may increase positive mood and changes the way we see and think about the world around us, making it easier to think about and recall things that happened to us that are upsetting. People say they feel caring and forgiving toward themselves and others during the MDMA experience. It is possible that these drug effects, when combined with psychotherapy, help people work through thoughts, memories and emotions related to PTSD and other past experiences.

MAPS PBC has completed studies of MDMA-assisted psychotherapy in the United States, Canada, Israel and Switzerland; 358 participants have received MDMA across studies in the clinical development program, as of October 01, 2021. Data from six Phase 2 studies indicated that MDMA-assisted psychotherapy is safe and effective for patients with moderate to severe PTSD when administered in a controlled clinical setting, with 54.2% of participants (39 of 72) no longer meeting criteria for PTSD after two experimental sessions. In the long-term follow-up to Phase 2 studies, 67% (61 of 91) of participants still did not meet the criteria for PTSD at least 12 months after last exposure to MDMA.

[Add for countries participating in the fMRI sub-study: There have been a limited number of brain scanning studies exploring how MDMA affects the brain in people with PTSD. This study will address this knowledge gap by using the brain imaging technique known as functional magnetic resonance imaging (fMRI). A fMRI records a magnetic signal detected from blood flow in the brain, which is linked to changes in brain activity.]

4. What participation involves report

If you are enrolled into the study your participation will last at least 14 weeks and at most 27 weeks. Full screening may take 2 to 6 weeks after completing phone screening. Screening includes a visit to the study site where you will be asked to complete psychological questionnaires, have a physical examination, provide urine samples for drug and when appropriate pregnancy tests, undergo a heart test and provide a blood sample for laboratory tests. If your pregnancy test is positive, you cannot participate in the study. It is also possible that the study doctor may determine that it is necessary to include a Hepatitis C test at screening, or that you need additional tests of your heart (such as an exercise test to evaluate your heart function). Additional at-home tests, like checking your blood pressure, may also be requested. A urine drug test and pregnancy test (when appropriate) will be repeated before each MDMA-assisted psychotherapy session ("MDMA-therapy session"). You will need to tell your doctor about all the medications you are currently taking, as certain medications (including but not limited to antidepressants) will be slowly reduced and stopped before you can start the study treatment according to the plan with your study doctor. ***It is important that you do not stop any medication before the study doctor tells you to.***

Non-drug psychotherapy sessions begin after you pass initial screening. The duration of these sessions can be as brief as 2 weeks but can last up to 11 weeks depending on what medications you are currently taking. Enrollment confirmation for the treatment will happen after 3 initial non-drug psychotherapy sessions and, if confirmed, the treatment period will begin. Some participants complete the non-drug therapy sessions but then are not eligible to continue with the MDMA-therapy sessions. The research team can explain the reasons why this might happen.

The treatment period will last about 8 weeks with 2 MDMA-psychotherapy sessions including 2 over-night stays 3-5 weeks apart. The MDMA-psychotherapy sessions are always preceded by non-drug psychotherapy sessions. Your participation in the study will end about 8 weeks after your last MDMA session. Detailed information about types of visit and assessment duration is described in **Appendix A**. Please read this information carefully.

Your participation also involves audio and video recordings of your study visits and online evaluations, and written transcripts of these recordings, from now on called video recording. The purpose of video recording study visits and online evaluations is as follows:

- To verify that the assessments and evaluations are carried out properly, according to the research protocol, and ensure reliability of the measures and results

- To verify that the therapy is carried out according to the training manual and for your therapists to be able to review the videos with their supervisors to receive feedback and improve their delivery of MDMA-assisted therapy

You may ask to stop the video recording at any time. The therapy team will ask your permission to turn it back on when you are ready.

To be added for countries where companion presence during the therapy sessions is allowed following site specific SOPs: [If you would like, a companion (a friend or family member) may be present during part of the therapy sessions or part of MDMA- therapy sessions. Before the session, the therapy team will meet with you and your companion to discuss the most suitable arrangement. There must be mutual agreement between you and the therapy team concerning the presence of your companion.]

5. What is expected from you

In order to carry out the study properly and for your own safety, it is important that you follow the study instructions:

- Do not participate in another research study during the duration of this study.
- Stop taking those medications or recreational drugs that your study doctor has said are prohibited during this study.
- Report any changes to your health to the research team.
- Keep appointments and be flexible about taking the appointments offered.
- Agree not to begin a new form of mental healthcare during the study, without first speaking with the study team.
- Carry your participant card with you. This card states that you are participating in this study and who to contact in case of an emergency. Show this card if you visit any other doctor.
- You will need to give the therapy team the name and contact information (phone number or email) of a relative, spouse or close friend to contact in case of medical emergency, should you become at risk of hurting yourself or someone else, or if the study team cannot get in touch with you to let them know what is going on or find out if you are okay.
- Once you have swallowed the study medication on the dosing day, you will be required to remain in the clinical research facility at the hospital until the study team tells you that you can leave. You must understand that the study team may, in the least restrictive manner, prevent you from leaving the Clinical Research Facility if they think you would be a risk to yourself or others. Steps will be taken in your best interests, if necessary.

It is important that you contact the investigator as soon as possible:

- before you take any other medicines.
- if you are admitted to hospital or are going there for treatment.
- if you suddenly develop any health problems.
- if you no longer want to participate in the study.
- if your contact information changes.

6. Possible side effects and discomforts

MDMA has not been widely tested in humans. As of 01 October 2021, 1799 people have been given MDMA in clinical research settings, of which 358 were enrolled in the MAPS clinical development program.

The recently completed MDMA Phase 3 trial in the US shows the following frequent side effects related to MDMA:

- Muscle tightness (65%)
- Lack of appetite (52%)
- Nausea (30%)
- Sweating (20%)

Twenty percent or less of participants reported (from most to least common) the following effects: feeling cold, restlessness, big pupils, dizziness, jaw clenching, eye wiggling, increased blood pressure, feeling jittery, chest pain not related to heart issues, dry mouth, blurry vision, frequent urination, recurrent thoughts, vomiting, stress, muscle pain, increased body temperature, chills, substance use (cannabis use), urgent urination, muscle twitching, feeling sleepy, and nervousness. When these side effects occur, they usually last less than four hours. However, some effects have been reported to last for more than 24 hours and up to several days after the study drug session. In addition, there may be unknown side effects or risks from the use of MDMA.

Possible risks of MDMA may include:

Serious problems: There have been some serious problems, and even deaths, associated with the use of Ecstasy outside of controlled clinical or research settings. These problems have included high fever, brain swelling associated with drinking too much liquid, convulsions, and liver damage. Some recreational users of Ecstasy have become severely anxious, depressed or paranoid (thinking that other people are out to get them). These problems have not been observed in controlled clinical research settings. Since you will be receiving moderate amounts of research-grade MDMA in a controlled setting with a trained therapy pair who will be closely monitoring your physical and psychological reactions, these problems are not expected to occur either during or after the MDMA-therapy session. While this does not guarantee that they will not occur, it does mean that if they do occur, the study doctors are prepared to respond in a safe and professional manner. This may include transporting you to a hospital if necessary.

Other Risks

Blood pressure and heart rate: The effects of MDMA usually last 6 to 8 hours after the first dose, even if you take a second dose. At the dose in this clinical trial, the increases in blood pressure and heart rate are likely to be moderate. These increases are similar to what happens with moderate exercise. In past studies supported by MAPS, blood pressure rose well above normal levels in about one-third of participants after taking MDMA, but these participants did not report any discomfort and did not require any treatment. Although these increases in blood pressure are similar to what happens after moderate exercise, they could cause serious problems in individuals with pre-existing heart or blood vessel conditions. These serious problems could include an irregular heartbeat, heart attack or stroke.

We will evaluate you for pre-existing heart problems before you are allowed to be in this study. While this does not guarantee that no heart problems will occur, it does reduce the risk of this happening.

If you have stable hypertension (controlled blood pressure) that requires medication, or if you have stable chronic disease (for example, diabetes) which is a cardiovascular risk factor, you will be referred to a cardiologist for further investigation, such as a carotid ultrasound and an echocardiogram, or other non-invasive imaging, as recommended by the study doctor or cardiologist. You may continue with the study enrollment if the study doctor and Sponsor deem you at low risk of cardiovascular harm from taking MDMA.

Feeling Anxious: Participating in a clinical trial can cause you to feel anxious. In a recently completed Phase 3 trial of MDMA-assisted therapy for PTSD, approximately 37% of participants who received MDMA reported feeling anxious, and 41% of participants who received a placebo reported feeling anxious. These feelings usually lasted less than 30 minutes. Letting yourself accept and feel these emotions deeply can be part of the psychotherapy. If you are not able to process these emotions in a way that helps you, your study therapist will work with you to process these feelings. If needed, the study doctor may prescribe you anti-anxiety medication or medication to help you sleep.

It is possible that if such periods of heightened emotion do not decrease or pass during the session you could be at increased risk for suicidal thoughts or other self-harm afterwards. If you have any thoughts about hurting or killing yourself you should call the study doctor or therapy team immediately, so they can help you.
If you are in immediate danger of harming yourself or someone else, or ending your life, you may be required to be admitted to a hospital.

Driving Limitations: In past studies, participants have reported blurred vision (8.7%), eye wiggling (13%), pupil dilatation (15.2%), feeling tired/drowsy (13%) or dizzy (13%) after taking MDMA. ***You should not drive or use machinery immediately after MDMA-therapy session (up to 24 hours afterwards)****.*

Immune System: Studies have demonstrated changes in immune cells with MDMA, but a controlled study on change in infection risk in a patient population has not been published. It is currently not known whether MDMA impacts your body's ability to fight infections.

Pregnancy: Effects of MDMA on the growth and development of an unborn baby are not known. Therefore, if you are pregnant or breast-feeding you cannot participate in this study. People able to have children must not become pregnant during the study. It is important for you to tell your partner about your participation. The study doctor or researchers will talk to you about which contraceptives are approved for use in the study. If, at any time during the study, you think that you may be pregnant or are worried that you may become pregnant, you must tell your study doctor immediately. If you still become pregnant during the study, you must immediately inform the study doctor. If your partner becomes pregnant during the study, please ask her for permission to inform the study doctor. If you should become pregnant during the study, the study doctors will help you get proper advice. If you become pregnant, you will discontinue treatment but remain in the study for follow-up purposes.

You can find more information in **Appendix B**.

7. Side effects and discomforts of study tests

Blood tests: Taking blood may be painful or cause some bruising at the needle puncture site. In rare cases, you could get an infection. Fainting could also happen. In total, we will take 10 ml (approximately two teaspoons) of blood from you. This amount is small enough to not cause you any problems. To compare: a blood donation involves 500 ml of blood being taken each time.

Risks not related to the study drug

It is possible that you may experience some risks just from being in a research study, not related to MDMA. These potential risks are described below:

Emotional Discomfort

The medical tests done during screening for the study may show something abnormal that needs further evaluation by the study doctors or your general practitioner. Abnormal test results and additional evaluations may cause you some stress or emotional discomfort. The study doctors will explain all test results to you and refer you to the appropriate medical providers, as needed. You can decline any testing you do not want to complete, but you may not be able to enroll in the study.

Trauma Therapy

The treatment being tested in this study is a combination of a drug (MDMA) combined with psychotherapy. Any psychotherapy, including MDMA-assisted psychotherapy, can be a challenging process when it addresses emotionally painful experiences, and symptoms may become more pronounced at times. During the study (and/or after) you could experience increased anxiety, sadness, or other difficult feelings and thoughts, including the possibility of suicidal thoughts. Tell your therapy pair if you are having any new or worsening symptoms. If your experience does worsen, it does not necessarily mean that the study will not help you. The study is designed to give you support. It is important that you understand this possibility before deciding whether or not to participate.

COVID-19 Transmission

Study participation will involve a number of several hour in-person visits with the therapy pair, including 8-hour MDMA-psychotherapy session. This personal interaction may increase your risk of becoming infected with SARS-CoV-2 (coronavirus that causes COVID-19 disease). Some visits will be performed via teleassessment (online video meetings) and other precautions will be taken to try to reduce this risk such as screening for symptoms before in-person visits, using face masks, cleaning surfaces and washing hands. For your safety and the safety of study staff, we recommend that you follow the local safety guidelines for prevention of COVID-19, which may include wearing a face mask while in public, maintaining physical distance between yourself and others outside of your household, and other distancing guidelines in order to reduce the potential for COVID-19 infection. The Study Team will ask you about your habits prior to in person visits, and together you will agree a safe plan for reducing risk while attending in-person visits. This plan may include testing for the virus, isolating at home, or other changes to your habits.

Remote Visits

Some of the non-drug psychotherapy sessions and online evaluations may be able to happen remotely, via teleassessment, rather than at the study site. There may be benefits to remote visits, such as convenience and reduced risk of COVID-19 transmission. There may be risks, including potential breach of security and technological difficulties or interruptions. It is critical that you do not share the links to online meetings with anyone unauthorized to attend and that you have a private space where you will not be interrupted during the visit.

[Add for countries participating in the fMRI sub-study:

MRI scan: During the MRI scan you will be invited to lay on a table which is moved slowly into the MRI tunnel. The front and back of the tunnel are open. If you are claustrophobic, lying in the tunnel may feel unpleasant. You will not feel the magnetic waves but taking brain scans is associated with a loud thumping noise. Therefore, you will be given hearing protection, which is mandatory to wear.

It is important that you lie still. The researchers will try to make you as comfortable as possible, they will be monitoring and speaking to you throughout the scan session. If you experience anything unpleasant you can always reach the researcher by pressing an alarm button. The MRI scan will last approximately 1 hour.

Besides possible discomfort, there are no known harmful side-effects associated with temporary exposure to the strong magnetic field used by MRI scanners. However, there are important safety concerns to consider before performing or undergoing an MRI scan:

- The magnet may cause medical devices and implants that contain metal to malfunction or heat up during the session.
- Any loose metal object may cause damage or injury if it gets pulled towards the magnet.
- Dyes from tattoos or tattooed eyeliner can cause skin or eye irritation.
- Medication patches can cause a skin burn.
- Prolonged exposure to radio waves during the scan could lead to slight warming of the body.

Therefore, before lying down in the scanner, all participants will be screened for the above prior to MRI scanning.]

8. Possible advantages and disadvantages

It is important that you properly weigh the possible benefits and disadvantages before you decide to participate in this study.

Possible benefits:

Your symptoms of PTSD may improve while taking part in this study. Information obtained from this study may help doctors and researchers to improve treatment for PTSD in the future.

Possible disadvantages:

- Possible side effects/complications of the treatment
- Possible adverse effects/discomforts of the evaluations in the study
- There is no guarantee that you will benefit from taking part in this research study

- There may be side effects or risks from receiving MDMA that we are not yet aware of

[Add for countries participating in the fMRI sub-study:
- Incidental findings: for example, during the MRI scan, the investigator may find out about other illnesses that you may have.]

Participation in the study also means:
- Additional time you have to dedicate to the study
- Additional visits to the clinic and overnight stay
- Additional tests
- Instructions you need to follow

All these aspects have been described above under points 4, 5 and 6.

Media interest:
Because of the history of MDMA, it is quite likely that journalists will be interested in the trial. The media will not be informed that you are involved in the study. If somebody from the media approaches you, we ask that you do not talk to them. Please refer them to the Investigator [name, contact details].

9. Withdrawing consent - If you do not want to participate or you want to stop participating in the study

Participation in this study is voluntary. If you do not want to participate, you will be treated as usual for PTSD. There are approved medicines that may help treat your symptoms of PTSD and other forms of psychotherapy that you could try. If you are currently having psychotherapy and/or taking medicine, you could continue with those for a longer period of time. The therapy team can discuss the alternatives and the potential risks and benefits with you.

If you choose to participate in the study, you can always decide to stop at any time during the study. You can withdraw from treatment (stop treatment) or withdraw (take away) your consent to the use of your personal data at any time for any reason. You do not have to explain *why* you are stopping treatment or withdrawing consent, there will be no penalty or impact on your care if you decide to not participate or withdraw from the study after enrolling. But before withdrawing you must tell the study doctor or therapy team. This will allow your study doctor to let you know about any potential medical risks of withdrawal at that time. You may be asked to return to the study site for tests.

Also, the investigator can stop your study participation and discontinue treatment if it is judged as best for you, or if you cannot comply with parts of the study that are critical for your safety or for the purpose of the study. For example, if you become pregnant or require use of prohibited medications, you may be asked to stop MDMA treatment, but will be asked to remain in the study for the integration visits and/or other assessments.

The data collected until you stop participating (withdraw your consent) will still be used for the study.

During the study, you will be notified of changes to study procedures, newly discovered side effects or significant findings which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this study.

Right to erase data

Under the European data protection regulations (General Data Protection Regulation, or GDPR), you have the right to 'be forgotten', meaning to have the right to request the deletion of your personal data, including video recordings. The sponsor and the local research institute are obliged to consider your request and grant it, if it is appropriate according to the regulations.

You should understand that the sponsor and the local research institute may be subject to laws that require them to retain certain data. For example, the sponsor is typically required to retain data which is used to support the approval of a new medicine (marketing authorization) for up to 25 years after the end of the trial or for at least 2 years after the granting of the last approval. In those cases, deletion will only occur once those retention requirements have elapsed..

10.End of the study

Your participation in the study stops when:

- You have completed all the visits according to the schedule (**Appendix A**)
- You choose to stop
- The end of the entire study has been reached
- The investigator considers it best for you to stop (for example, if you become pregnant or if you experience unwanted side effects)
- The sponsor, the government or [enter name of the local Ethics Committee], decides to stop the study.

The study is concluded once all the participants have completed the study. The medication you have used during the study will not be available once the study has ended. Your therapy team will discuss the options for further medical care with you. After analyzing the data, the researchers will inform you about the most important results of the study.

11. Usage and storage of your data

Your personal data will be collected, used and stored for this study. This concerns data such as your name, address, date of birth, race, ethnic origin, marital status, data about your education, occupation/veteran status, employment, disability, income and data about your health. For this study, personal data is processed on the basis of your consent in accordance with the EU General Data Protection *(Regulation (EU) 2016/679 of the European Parliament and of the Council Directive 95/46/EC, (Art. 6 (1) (a) and Art. 9 (2) (a))*.

The organizations responsible for your personal data are MAPS Europe, MAPS PBC and the research institute where you will participate. You can contact them at any time if you have questions about how they are handling your data or wish to exercise your GDPR rights.

Sponsor's office for data protection, personal data and data privacy:
Email address: dataprivacy@mapseurope.eu or dataprivacy@mapsbcorp.com

Video recordings

The therapy sessions will be recorded and stored in a system called Valis, while the online evaluations will be recorded by and stored in a system called WebEx.

***Who is viewing these video recordings**:*

- The system administrators (only as needed)
- MPBC staff (only as needed)
- Senior Independent Raters and Lead Independent Raters (who specifically review the online evaluations to ensure reliability),
- the adherence raters (specifically for the psychotherapy recordings

the supervisors of the therapy pair (specifically for the psychotherapy recordings)..

Where are these video recordings located: The videos are stored for a limited amount of time in the Valis or WebEx servers, all of which are based in Europe.

How is the video data being transmitted: When the video recordings are being reviewed, the video data is encrypted and streamed from WebEx or Valis data centers (depending on storage location) to the viewer's browser, it is never downloadable.

The video recordings from your therapy sessions will be used for the purposes explained in section 4. The adherence raters, as well as the supervisors of the therapy team who may be viewing these video recordings will be selected by the Sponsor and will sign confidentiality agreements to ensure they do not share any identifying information, for example:

- Your physical appearance
- Your voice
- Your name (if it is spoken on the recording)
- Identifying situations from your life that might be discussed

Other data

The bodily material (blood and urine samples) collected from you during the screening period will be sent for the analysis to the central laboratory. Once samples are analyzed, the bodily material will be destroyed at the lab.

The collection, use and storage of your personal data is required to answer the questions asked in this study and to publish the results. It is also required to make the medication we are studying (MDMA) available on prescription to potential patients in Europe and abroad if these studies have positive results.

We therefore ask your permission for the use of your personal data and bodily material. By signing this consent form, you consent (agree) to the collection, access, use, sharing and storage of your

information in the data center as described above. You have the right to request information about what data is stored about you at any time.

Confidentiality of your data

To protect your privacy and confidentiality, your personal data and your bodily material will be given a code. Your name and other information that can directly identify you, will be removed. Data can only be traced back to you with the code key. The code will be stored securely in the local research institute. The data and bodily material that is sent to the sponsor or sponsor delegates will only contain the code, not your name. This process is known as “pseudonymization”, meaning no person can be identified from the coded information.

Study sponsor and other third-party companies working for the sponsor will take all reasonable measures to keep any information they receive confidential. The sponsor has agreements with the third parties to secure adequate protection of your data, biological samples and video recordings.

Electronic systems for recording audio and video data include measures to protect the confidentiality of your identity and data. Those systems were chosen as they are GDPR compliant. The data cannot be traced back to you in reports and publications about the study.

Site therapists, study doctors, investigators or other site staff may have to report abuse, for example child abuse or elder abuse if required by local law or professional code in your country. The sponsor and site staff will keep any information they receive to the same standard of confidentiality according to applicable local law.

Access to your data for verification

Some qualified and authorized people independent of the therapy team can access your data (including the data without a code) at the research location. This is necessary to check whether the study is being conducted in a good and reliable manner.

Study documentation that is copied will not have any information that could be used to identify you. If records are copied, only your participant number will identify you to the study. People who will have access to your directly identifiable data (medical records, including video and the consent form signed by you), are as follows:

- Auditors/data monitors working for the sponsor of the study
- National and international regulatory authorities, for example, European Medicines agency (EMA)

They will keep your data confidential. We ask you to consent to this access.

The results of this research study may be presented in meetings, presentations, or in publications, where your identity will not be disclosed.

Passing on to countries outside your country and outside the European Union (EU)

In this study, your encoded data will be sent in an encrypted way to countries outside the European Union where personal data protection laws might be less strict. These countries include the United States for coded data and health data. Other countries may receive coded data and health data as well, however, the study Sponsor will ensure that your personal information is protected at all times.

More information about your rights when processing data

For general information about your rights when processing your personal data, you can consult the local research institute's data protection officer or the Local Data Protection Authority. The Sponsor's data protection office will not know if you are a participant in the study or not, so if you have specific questions about the Sponsor's role, please ask the research institute's data protection office who will liaise with Sponsor as necessary at email address: dataprivacy@mapseurope.eu.

Retention period of your data

Study data and video recordings will be kept for only as long as necessary for the purposes for which the data is being collected. This generally means that non-video data will be retained for up to 25 years unless the Sponsor is legally required to retain it for longer. Video and audio recordings of both therapy sessions and IR assessments will be deleted within 90 days after a participant's last study visit, unless there is a concern noted through the supervisor review, in which case the video must be retained for the length of the investigation, or longer where legal privilege applies.

Information about unexpected findings

If, during this study, something is found by chance that is not important to the study but may be important for your health, you will be informed by the study doctor. You can then discuss with your doctor what needs to be done. You also consent to this by signing this form.

Registration of the study

A description of this clinical study, MP18 protocol, will be available on https://clinicaltrials.gov/ct2/show/NCT04030169 (identified by NCT04030169) and https://www.clinicaltrialsregister.eu/ctr-search/search?query=2018-001718-13 (identified by EudraCT Number 2018-001718-13).

These databases do not contain any information that can identify you. After the study ends, the website may display a summary of the results of this study.

12.Study participant insurance

Insurance has been taken out for everyone participating in this study. This insurance covers damage caused by the study. If you are injured as a direct result of a study related procedure or because you received the study drug, appropriate medical care for the treatment of the illness or injury will be discussed with you.

Appendix C contains more information about the insurance and the exclusions. It also tells you who to report potential claims to.

13. Will my GP and/or treating specialist and/or pharmacist be informed if I participate?

[Please update as per country specific regulations and check if it is required to inform GP] We will always send your General Practitioner (GP) and/or treating specialist a letter or email to let them know that you are participating in the study. This is for your own safety. If you do not agree to this, you cannot participate in this study. We may contact your GP/other doctor about your medical history or about the medicines you use, and in some cases, to discuss how best to stop certain medication prior to the MDMA-therapy sessions.

14. Costs and compensation

There will be no cost to you for participating in this study. The study sponsor will cover the costs that are directly related to the research. This includes the costs for all psychotherapy sessions, for the psychological and laboratory testing, for medical examinations to see if you can be in the study and for the study drug. You or your insurance company will remain responsible for on-going treatment not included in the study. You will not be paid for your participation in this study. You will be reimbursed for travel costs.

15. Questions or concerns

If you have any questions or if you have any unusual reaction while in the study, or in case of an emergency, you should contact the study doctor/research team.
If you have any complaints about the study, you can discuss this with the investigator. Contact Principal Investigator: [add email and phone here] Contact study doctor: [add email and phone here]

16. Signing the consent form

When you have had enough time to decide on participation in this study, we will ask you to give your consent in writing on the attached consent form (**Appendix D)**. By signing this consent, you indicate that you have understood the information and agree to participation in the study. You will receive a signed copy of the consent form to keep with you. Thank you for reading this document and considering taking part in the study.

17. Appendices to this information

A. Overview/description of study procedures
B. Additional Information on side effects
C. Insurance information
D. Informed Consent Form

Appendix A: Overview of study procedures

Please see the description of study procedures below.

Screening: Multiple visits at the study location, lab, and/or doctor's office, and teleassessments/phone calls.

Psychological and medical screening will be done by the study researchers and research site staff, doctors, and your therapy team. The tests will include the following:

- Questions about your medical history. This may include any previous medical, psychological or psychiatric problems or treatment and may include questions about difficult experiences you may have had during childhood, at other times of your life, or currently.
- Psychological questionnaires you fill out yourself and an interview about any psychological or psychiatric issues you may be experiencing, or that you have experienced in the past.
- A brief interview about thoughts you might have about hurting or killing yourself.
- A physical examination including measures of your blood pressure, pulse, temperature, height, and body weight and Body Mass Index (BMI). In addition, you may be asked to measure your blood pressure at home.
- An ECG (electrocardiogram) and rhythm strip, which are recordings of the electrical activity of your heart. If you have high blood pressure, or other cardiovascular risk factors, you may be asked to undergo additional tests of your heart. This may include a stress echocardiogram (an ultrasound of your heart during or after exercise or medication to make your heart beat quickly) and a carotid ultrasound (measurement of blood flow in your neck).
- A sample of your blood (about 2 teaspoons) and urine for laboratory testing, including tests of metabolism, liver function, and alcohol use. As part of the study, we may also test for the Hepatitis C virus (HCV).
    - If you have abnormal test results that could impact your health, we will notify you. If you do not want to know, you cannot participate in this study.
    - If you test positive for Hepatitis C you will only be able to participate if you currently don't have symptoms of Hepatitis C and have been previously treated for it.
- Urine drug tests will be done during screening and repeated before each MDMA-therapy session. We will not report findings of drugs to any authorities, but a positive drug test may impact your eligibility to continue in the study.
- A urine pregnancy test is required if you are able to get pregnant. This test must be negative for you to take part in the study and will be repeated before each MDMA-therapy session and again towards the end of the study.

The screening process continues after you start the preparatory session. At Visit 3, you will have additional psychological testing by an online video meeting. You will not know for sure whether you will get MDMA treatment until after Visit 3.

Beginning of Study (Visit 0): Once you have completed all screening procedures, your first preparatory psychotherapy session will be scheduled. You must let the therapy team know about any change in medicines or medical conditions or procedures, like surgery, within 48 hours of it happening. You should not stop taking your current medication until you are instructed by the study physician.

Preparatory Sessions (Visits 1 through 4): at the start of participation in the study, the first two preparatory sessions will last approximately 90 minutes and the last preparatory session will last about 3 hours, which includes completion of questionnaires and therapy session. Preparatory sessions are paced about one week apart.

During each session, you will talk about the traumatic incidents that led to your PTSD, the ways PTSD symptoms are affecting your life, and what you would like to achieve during the study. You will be asked questions about thoughts or feelings you might have about hurting or killing yourself and complete psychological questionnaires in the 3rd preparatory session. There will be four visits total during this period: three therapy visits and an online meeting with a researcher who will ask you questions about your PTSD symptoms. After the online video meeting (Visit 3), the staff will let you know whether you will continue to the treatment part of the study.

During this time, you may be asked to slowly stop taking certain medications, such as antidepressants or certain pain management medications. This "tapering plan" will be agreed between the study doctor, the doctor who normally prescribes your medications, and yourself. The length of time it takes to taper medications will be different for each study participant. Ask the study doctor if you are ever unclear about which medications to take, and when.

Please note, until you have completed all the Preparatory Sessions and tapered any required medications, the study team will not be able to confirm if you are eligible to participate in the MDMA-therapy session.

MDMA-assisted psychotherapy sessions (MDMA-therapy session) with overnight stay (Visits 5 and 10): (~8 hours plus an overnight stay): two visits about a month apart. You will be given MDMA during these visits along with psychotherapy. There will be two day-long MDMA-therapy sessions with overnight stays. These visits will happen 3-5 weeks apart. The first MDMA-therapy session will occur after you have had three preparatory sessions. During the day of your MDMA-therapy session, you will receive a dose of MDMA followed 1.5 to 2 hours later by a dose of half the first dose of MDMA. During the second MDMA-therapy session, you, the study doctor and therapy team can decide if you should take the same dose you took in your first MDMA-therapy session, or if you would like to try a higher dose. Your therapy team will discuss the optimal dose of MDMA with you for the second MDMA-therapy session.

You must not eat any food or drink any alcohol after midnight on the night before each MDMA-therapy session visit, though you can drink non-alcoholic liquids during this time, such as water or juice. There will be beverages available at the study site, including juices, and you will be encouraged to drink an adequate amount of fluid. You can drink it whenever you wish to do so, within the limits of the amount that is safe for your body. Later on, food will also be provided. You cannot use any psychoactive drug, with the exception of caffeine or nicotine, within 24 hours of each MDMA-therapy session (or longer depending on the specific drug – this should be discussed with the therapy team). You cannot use caffeine or nicotine for two hours before and six hours after you take the first dose during the MDMA-therapy sessions. For one week before each MDMA-therapy session, you cannot take any herbal

supplements, non-prescription medications, or prescription medications that have not been discussed with and approved by the study doctor and the therapy team.

If you are taking certain opioid medications for pain management, you can continue to take these medications during treatment, although we will ask you to reduce the dose before each MDMA-therapy session and stop taking them for 12 hours before and at least 24 hours after the first dose in each MDMA-therapy session. If your pain becomes too severe to handle during this period, you will be allowed to take your medication after talking with the study physician about it.

Before an MDMA-therapy session with overnight stay:

- Your urine will be tested for drugs of abuse, including stimulants, sedatives, opioids, and cannabis.
- If you can become pregnant, you will take a urine pregnancy test before each MDMA-therapy session.
- Answer questions about thoughts you might have about hurting or killing yourself (before and at the end of the MDMA-therapy session).

After urine testing, you will receive a capsule containing MDMA. After taking the capsule, you will sit or lie down in a comfortable position. You can ask for an eyeshade if you wish. You will listen to music during much of each MDMA-therapy session, either through headphones or room speakers. During the session there will be times when you will be asked to talk to the therapy team. If you are wearing headphones, you may remove them yourself if you want to talk to the therapy team or have times of silence. Lying or sitting in a comfortable position and listening to music are meant to bring out thoughts and feelings, including thoughts and feelings about past traumatic experiences. The therapy team will remain with you, and they will help you if you need them to. They will speak with you and ask you to talk to them at least once an hour, but you can talk to them whenever you wish. There may be times when the therapy team will suggest that you stop talking for a while in order to pay attention to your thoughts and feelings.

Approximately two hours after you take the first dose, you may take a second dose, after discussion with the study doctor and therapy team. The thought behind taking the second dose is that it is supposed to make the session last longer. If you, the study doctors or the therapy team notice you have problems after the first dose, then you will not get the second dose.

The therapy team will watch for any side effects (unwanted effects or health problems), which will be treated if necessary. If this happens, the therapy team will keep you fully informed about any concerns or treatment. Your blood pressure, temperature, and pulse will be measured before taking the first and second doses and at the end of the session. At the same time, you will be asked to complete a questionnaire about how you feel at that moment. If you have any symptoms including confusion, light-headedness, dizziness, chest pain or shortness of breath, please tell the therapy team. More frequent measurements may be needed if this happens.

If you are confused or upset 8 or more hours after the start of a MDMA-therapy session, the therapy team will stay with you until you have fully recovered. If the therapy team thinks you are at risk of hurting yourself or others, they will either remain with you all night or have you admitted to a hospital until you are no longer at risk. The therapy team will ask you how you feel at the beginning and end of the MDMA-therapy session and on several occasions during the phone follow-up period.

You will be spending the night in a room at the research facility with an attendant who will be staying in another room nearby. You can use the kitchen or may take a short walk around both outside of the room and into the immediate hospital grounds, if agreed and accompanied by your therapist or night attendant. If you find you need to talk with the therapy team or you are having problems and need to contact the therapy team, the attendant will contact them immediately.

The day after each MDMA-therapy session, you will have a non-drug therapy session (also known as an integration session, Visit 6 and Visit 11). After this session, you will need to have someone drive you (to home or wherever you are staying), because MDMA may affect your ability to drive. If you do not have anyone available to take you home, the therapy team will find someone to drive you.

After you return home from the therapy session, the therapy team will talk to you by phone four days out of the following week to ask how you are feeling and see whether you should see the therapy team before your next scheduled non-drug psychotherapy session. You and your therapy team can decide which days would be best to speak on the phone. The phone calls will take approximately 5 to 15 minutes, though they can be as long as you need them to be. The therapy team will ask you about thoughts about hurting or killing yourself during the second and seventh day of phone contact. You can call the therapy team at any time; except for a few times when they may be unavailable. At those times the study doctor or therapy team will be on call and can be called at the 24-hour number provided on this consent form. If there are delays in following the usual study schedule, the therapy team will call you at least once a week to talk about how you're doing. These calls will take about 15 minutes.

If you have very high blood pressure, get sick, or have an uncomfortable and strong lasting negative reaction (unwanted effect or health problem) during or after a MDMA-therapy session, you or the therapy team may decide that you should not have the next MDMA-therapy session. You may also make this decision to stop treatment in the study for any reason. If the therapy team decides to take you out of the study, they will let you know that they are doing this and their reason for doing it. They will help you find a therapist who can continue to help you with your PTSD, if needed. If you are taken out of the study or decide you do not want to receive treatment in the study, the study researchers will ask you to complete some final questionnaires about your PTSD symptoms. If you decide you do not want to continue in the study during a MDMA-therapy session, you will still have to stay in the office until the therapy team thinks that you are stable enough to leave and that all the short-lived effects of the drug have worn off. If this happens, you will also be asked to take part in some of the same interviews and questionnaires you completed at the beginning of the study.

Integration Visits (Visits 6, 7, 9, 11, 12, 13; ~90 minutes each): You will receive 3 psychotherapy sessions after each MDMA-therapy session. These visits will last about 90 minutes. These will usually be 1-3 weeks apart and will involve you talking to your therapists about your thoughts and feelings.
The day after each MDMA-therapy session, and 2-4 weeks afterward, you will have therapy visits to help you express, understand, bring together and connect any thoughts or feelings you may be having about your symptoms and their causes, and to think and talk about your experience during the MDMA-therapy session. The therapy team will ask you questions about thoughts about hurting or killing yourself at these sessions. At the last integration therapy visit you will also complete a psychological questionnaire and do a final pregnancy test if applicable.

Measuring the severity of your PTSD symptoms

Online Meetings (Visits 3, 8, and 14; 60-90 minutes each): There will be 3 online video meetings. During these meetings, the study researcher will ask about your PTSD symptoms and you will complete the same online interview about your PTSD symptoms. You will also be asked if you have had any thoughts about hurting or killing yourself.
During these meetings, you must be in a quiet place with a stable internet connection. Your device can be a phone, computer, or tablet. Your device must have a camera and you must be in a location in which you feel comfortable to discuss personal information. These meetings will be video recorded. If needed, we can arrange for these online visits to occur in the research facility.

Study Termination (Visit 15; 120 minutes): this final visit will take place after the online meeting at Visit 14. You will meet with your therapy team and the study physician to complete a physical exam (including weight, blood pressure, pulse and temperature). You will fill in the study questionnaires. The results from Visit 14 and 15 will help the therapy team to understand if your symptoms have changed or stayed the same during the study. Your therapy team will discuss the options for further medical care with you, including the possible restart of any medications that you stopped for this study.

Table 1 and **Figure 1** below shows the type of in-person visits and online sessions you will have. Time periods are counted from the first study visit after you are selected to participate in the study.

Table 1: Schedule of Events

	Screening (2-6 weeks)	Screening, Preparation (2-11 weeks)				Treatment Period 1 (about 4 weeks)					Treatment Period 2 (about 4 weeks)				Evaluation (±4 weeks)	Study Termination
Visit #		V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15
Participant Information and Consent at site	✓															
Medical Screening including weight, height	✓	✓	✓													
Blood Pressure, Pulse, Temperature	✓					✓					✓					✓
Medical tests (bloodwork, urinalysis, ECG)	✓															
Symptom-directed physical exam	✓					✓					✓					✓
Drug and/or Pregnancy Test	✓					✓					✓			✓		
Interview PTSD Symptoms				✓					✓						✓	
Psychological Testing and Questionnaires	✓			✓	✓				✓	✓				✓	✓	✓
Non-drug Psychotherapy		✓	✓		✓		✓	✓		✓		✓	✓	✓		
MDMA-therapy session with overnight stay						✓					✓					
Four phone calls during a week							✓					✓				
Overnight Stay						✓					✓					
Brain scan session [Add for countries participating in the fMRI sub-study]					✓ V4.1										✓ V14.1	

Figure 1: Overview Study Structure

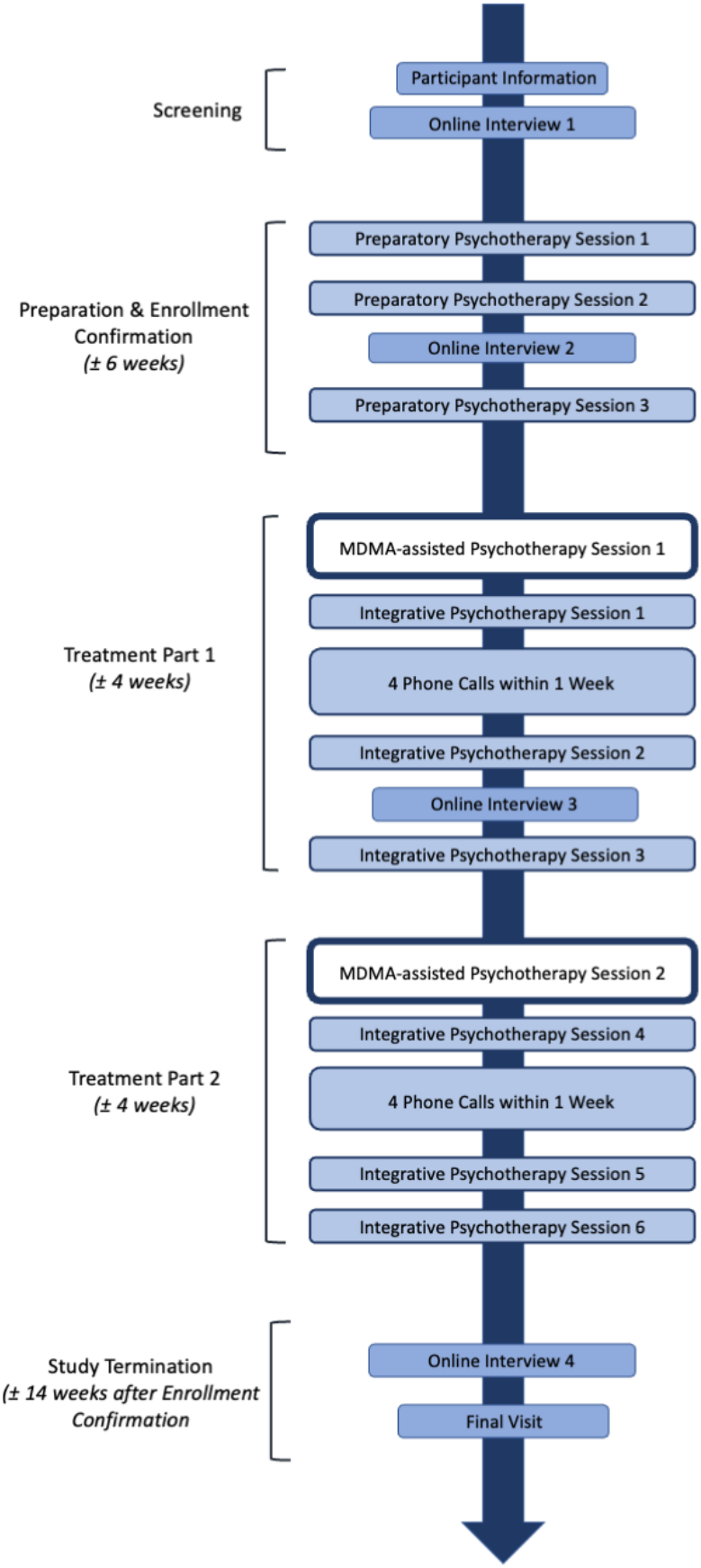
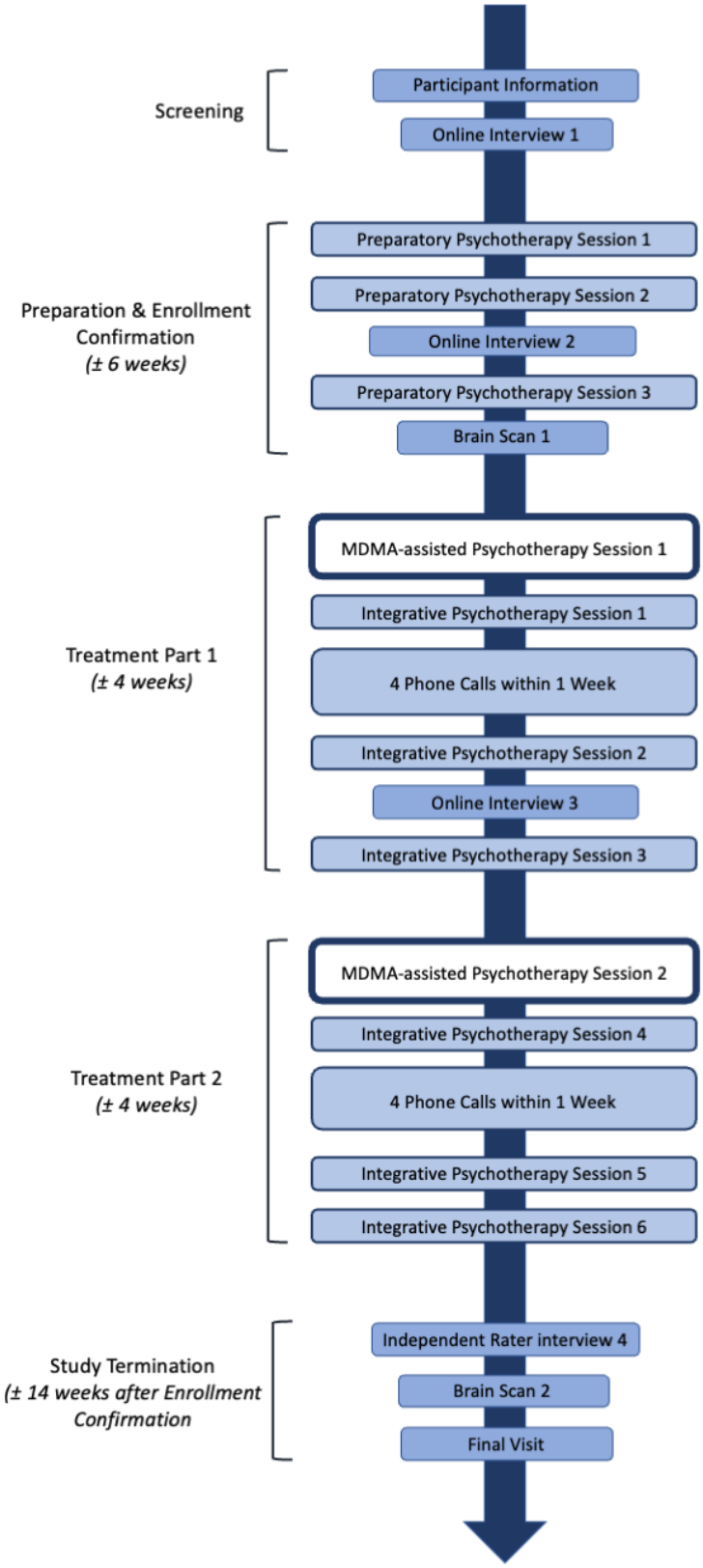


Figure 1: Overview Study Structure with fMRI Sub-study



Appendix B: Additional information on side effects

Possible Brain Damage

Experiments in rats and monkeys show that high and repeated doses of MDMA can change certain brain cells that release a chemical called serotonin. The changes include loss of the parts of the cell (called “axons”) that connect different brain areas. Rodents given repeated, high doses of MDMA are less sensitive to a later dose of MDMA, are more likely to become overheated when placed in a warm room, and some studies find they perform worse in difficult memory tests. Recent studies in monkeys and rodents suggest that the doses used in these studies are far higher than those typically taken by humans in either recreational or laboratory settings.

Many studies found that people who had used Ecstasy many times in recreational contexts were not able to recall words, pictures or patterns as well as people who did not use Ecstasy and they performed less well on tests of planning and impulse control. These differences are not great, but they have lasted for at least 1 year after people had stopped taking Ecstasy. Not all studies have found Ecstasy users to have difficulty recalling words or pictures or to have impulse control problems. At least two studies found that people who are anxious, depressed, or have psychological problems before taking any drugs are more likely to take Ecstasy than those who are not anxious, depressed, or without other psychological issues. When compared with people who do not use Ecstasy, studies found Ecstasy users were more likely to report feeling generally anxious or depressed. Many of these studies found that using alcohol or other drugs was also associated with feeling anxious or depressed.

Only one study has looked at brain scans of people before they got MDMA and then again after they have received one or two moderate doses of MDMA. This study did not show any changes in the brain following MDMA, though it is possible that there were changes that were too small to notice. Other studies looked at people before and after they decided to take a few tablets of Ecstasy in a recreational setting and found one small change in the amount of blood flow in a specific part of the brain but did not show signs of brain injury. The decrease in blood volume might be from temporary lowering of a type of brain receptor, or it might be a sign of reduced function in this area. Findings from these studies suggest that the amount of MDMA you will receive in this study will not produce any lasting negative changes in your brain, though this is not guaranteed.

Studies of people receiving one or two doses of MDMA in a laboratory setting have not found any lasting changes in memory or planning. Studies comparing people before and after they decided to take a few tablets of Ecstasy in a recreational setting with people who did not take them found less improvement in memory in the people who took ecstasy, and no other changes in thinking or planning ability. It is believed that the amount of MDMA you will receive will not produce any lasting changes in memory or planning ability, though this cannot be guaranteed.

Symptoms of Depression, Anxiety, or PTSD

It is possible that after you stop taking certain psychiatric medicines (for depression or anxiety) as part of the study, you may start to have symptoms again. There is also a risk that you may have thoughts of harming yourself or ending your life when you stop taking medicine, especially if you have had these thoughts before. If this happens, talk with your prescribing doctor, your therapist, and your study doctor. If you need to start taking medicine again, the study doctors will need to re-evaluate your eligibility and

there is a chance that you will not be able to continue in the study. Your safety takes priority over your continuation in the study. There are some allowable medicines on study; your doctors will discuss these with you if needed. Your pre-existing symptoms and diagnosis related to your PTSD may not improve and may become worse during the study or after.

Emotional Openness

MDMA is considered an “empathogenic” drug. This means people who use it may experience increased empathy and sociability. After taking the study drug, you may feel more emotionally open, friendly, extroverted, or talkative. You may also feel closer to your therapists or more trusting of them, or you may even feel love and sexual feelings toward your therapist(s). This can happen with any psychotherapy but may be heightened by MDMA. Your therapists are aware of the effects of the drug. They have been through training on how to appropriately care for someone who has taken MDMA and on a code of ethics that prohibits any sexual relations between therapists and participants, including after participation in the study has ended. All of your therapy sessions are recorded. One of the reasons for this is to ensure your safety. Videos are randomly reviewed by a group of adherence raters, who are trained to ensure the visits are conducted appropriately. Your therapists also have supervisors who continue to oversee and train them throughout the study.

Reproductive risks

Effects of MDMA on the growth and development of an unborn baby are not known; therefore, you will not be allowed to be in the study if you are pregnant. If you get pregnant after you have had at least 1 MDMA-therapy session, the study doctors and the sponsor, MAPS Europe B.V., will ask you about and keep track of your pregnancy and will need to know about the outcome of your pregnancy.

Those who are able to become pregnant and are engaging in penile-vaginal intercourse (male-female sex) must use one of the allowed birth control methods: intrauterine device (IUD), non-oral hormonal methods (injected, intravaginal, implanted, or transdermal [skin patch]),, oral hormones plus a barrier contraception (for example, condoms), or abstinence if this is your normal lifestyle. Condoms alone are not an acceptable form of contraception for this study. Not being able to become pregnant is defined as permanent sterilization or postmenopausal if no menses for more than 12 months or assigned male at birth. The therapy team will explain these methods to you and will help you decide which might be best for you, and they can suggest to you where you can get more information and advice.

Other risks

If you are tested for drugs of abuse within three days of each MDMA-therapy session, e.g., by your employer, you may test positive. The therapy team will provide you with an information card in case you are tested for drugs of abuse, and if you are tested for drugs of abuse while you are in this study, you can have the person(s) testing you call your therapy team to verify that you are in this study. We cannot guarantee that this card will protect you from discipline at work or loss of employment. The study doctors will discuss when and how to present the information card. The card will not prevent you from being stopped or cited if you are driving erratically or poorly.

The interviews you have during the study involve no specific risks or discomforts beyond those of a standard clinical interview situation. You may feel upset at the review of your emotional experiences, or you may feel boredom or fatigue. Answering questions about thoughts you might have of hurting or killing yourself may be upsetting.

Appendix C: Insurance information

Insurance has been taken out by sponsor for everyone participating in this study. The insurance covers damage due to participation in the study. [If needed by country specific regulations provide additional details]

In the event of damage please contact the insurance company directly.

The insurance company for the study is: Name: … Address: … Telephone number: … E-mail: … (Policy number: ...) (Contact person: …)

Appendix D: Participant Consent Form

Sponsor protocol number: MP18

Study short title: MDMA-Assisted Psychotherapy for the Treatment of Severe PTSD

- I have read the participant information form and understand the information it contains. I was able to ask questions. My questions have been answered to my satisfaction. I have had enough time to decide whether to participate.
- I know that participation is voluntary. I know that I may decide at any time not to participate or to withdraw from the study. I do not need to give a reason for this. I am also aware that withdrawing will not affect my medical care or legal rights or the continued processing of my coded data.
- I give permission for my GP / treating specialist(s) to be informed that I am participating in this study and I give permission for information to be requested from them about my medical history.
- I give permission to the Sponsor and its authorized representatives (such as monitors and auditors, governmental, regulatory health authorities, and ethics committee) to have direct access to my medical records for the purposes of the study.
- I give permission for the collection and use of my personal data / body material to answer the research questions in this study.
- I understand that my anonymized data may be used to support future scientific research in the public interest and may be shared with other researchers.
- I consent that my personal data as set out in this consent form, including data relating to my physical or mental health or condition, race or ethnic origin may be used by the sponsor and study center to answer the research questions of this study.
- I give permission to have my sessions video-recorded during this study, and for them to be stored for a limited amount of time in the data centers located in Europe, understanding that my personal information will be protected as mentioned above
- I agree that my GP and/or treating specialist will be informed of coincidental findings that (may) be of interest for my health. In relation to this, I also agree that the contact details I have provided may be used to contact me in order to provide this information about my health.
- I know that I should not become pregnant during the study.
- The investigator has discussed with me the most suitable contraception for me.
- I consent to being contacted again after this study for a follow-up study ☐ yes ☐ no
- I agree to take part in this study.

Name of Participant (Please print): _____

Signature of Participant: _____

Date (dd/MMM/yyyy): __ __ / __ __ __ / __ __ __ __ Time: __ __:__ __

Researcher taking consent:

I hereby declare that I have fully informed this study participant about this study and, to the best of my knowledge, they clearly understand the nature, risks and benefits of taking part in this study.

If information comes to light during the course of the study that could affect the study participant's consent, I will inform him/her of this in a timely fashion.

Name and signature of researcher taking consent:

Name: _____

Signature:_____

Date (dd/MMM/yyyy): __ __ / __ __ __ / __ __ __ __ Time: __ __:__ __

The participant will receive the full information sheet, together with a signed copy of the consent form. The second signed copy will be kept at the research site.