

ICF 2 April 2009

Version 2.1

Medical Center for Mental Health [REDACTED]

Informed Consent Form

Title: MDMA- Assisted Psychotherapy in Twelve People with War- and Terrorism-Related Posttraumatic Stress Disorder.

Main Researcher: [REDACTED]

Work Phone No.: [REDACTED]

Patient's Initials:

Why was I asked to participate in this research and why is it taking place?

[REDACTED] and his colleagues are running a small scale, primary research in the experimental drug MDMA, taken by people who resist treatment (PTSD Posttraumatic Stress Disorder), when antidepressants and anti anxiety drugs are not effective enough or not effective at all. This new medication is taken during two special therapy session. A comparison between taking a full dosage and a lower dosage of the medication will be done. You were asked to participate in this research because you were diagnosed with PTSD and you experience symptoms related to this diagnosis. MDMA is an experimental drug and that means that this drug was not approved by the Ministry of Health for medical usage, except for usage during experiment.

MDMA is also a limited drug (it is illegal to use it outside the experiment), and when it is sold illegally, it's sometimes known as "Ecstasy". Ecstasy is supposed to contain MDMA, but often includes other drugs instead of MDMA or in addition to it. Please read carefully the information in this sheet. Please before you sign, don't hesitate to ask questions about the study. You'll be given an additional copy after you sign it.

How long will I participate in the research?

The research lasts about 54 weeks. Thirteen meetings will be held, including a screening meeting before you can participate in the research, and two visits which will require an overnight stay at the Medical Center [REDACTED].

How many people will participate in the research?

Twelve people in total.

Will everybody get the same treatment, and how will it be determined?

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All the people who will decide to participate in the research will receive MDMA, however, 33% (4 out of 12) will receive lower dosages and 66% (8 out of 12) will receive full dosages. A person will receive low or high dosage arbitrarily (by chance, as it is when you toss a coin). Participants who will receive low dosage will get the opportunity to receive a full dosage, if they are interested, two months after the second MDMA-assisted therapy session in a stage 2 open label administration of MDMA. This second stage is exactly the same as the first, except you will be guaranteed to receive the full dose.

Here are some important points about the research.

You will participate in seven psychotherapy session with the researchers. Every session will take near an hour. You will fill up questionnaires and participate in interviews during six sessions, 90 minutes each. One meeting which will include a questionnaire and an interview will be held at the beginning of the research, and the other five meetings will be held before a psychotherapy session or an experimental session.

Two experimental sessions will be held for 6-8 hours, a month apart from one another. In these sessions you will receive MDMA (low-dosage – 25 mg or experimental full dosage- 125 mg). You are not allowed to eat anything after midnight the day before the experimental session, nor you are allowed to drink alcoholic beverages after midnight, the day before the experiment.

You will receive one dosage of MDMA at the opening of every experimental session. If you and the researchers agree that it is safe to do so, and you feel well enough to do it, you will receive another dose of MDMA 2.5 hours after you received the first dose. The second dose will always contain half of the first dose. (62.5 mg)

A partner, a relative or a close friend is permitted to accompany you during the end of the experimental session, but it is not mandatory and is up to the therapists' discretion. Following every experimental session you will have to stay overnight at the Mental Health Center [REDACTED]. A therapy session will be set for the next day. You must not drive the day following an experimental session. You must arrange for a drive home, and if you don't have the option, the researchers will arrange it for you. There is a possible risk that MDMA might cause damage to certain parts of serotonin neural cells in your brain.

What will happen to me?

Screening (evaluation):

Before you could participate in the research, the researchers must make sure you are suitable for it. You have already given us your permission to go through a screening process that would include medical examination and anxiety index. The screening interview will include a semi-structured

psychiatric interview and questionnaires about anxiety, quality of life issues, your thoughts about your condition and about your mood. A urinalysis will take place to reveal drug abuse on that very day. The results must be negative to all drugs. In addition you will be asked to give a blood sample (about 2 spoonfuls) and urine sample to be examined in the laboratory for different hormones, such as thyroid hormone.

An EKG test will be done, to check the heart electric system.

If you are a woman and capable of child-bearing, we will give you a pregnancy test based on your urine sample. A negative result is a condition to your participation in the research.

Screening process will take 3-4 hours. If a participant gets pregnant during the research (unlikely given the precautions), she will be provided with suitable consultation including the option of termination of pregnancy. An HIV (AIDS) test will be held as well.

Enrollment:

If you qualify for the study and you are currently taking any psychiatric medications, the researchers will give you instructions for stopping the medication. With the exception of some medications approved by the researchers, all psychiatric medications and some other medications must be stopped until two months after the second experimental session. If you are enrolled in the study you will also be asked not to begin outside therapy or change the duration or frequency of current therapy. If you are currently in therapy with an outside therapist, you may continue seeing that person as you are now.

Psychotherapy Introduction Sessions:

You will meet with your two researchers one week prior to your first experimental session, for a psychotherapy introduction sessions. In this session you will talk about your PTSD symptoms, as well as other emotions related to your trauma. You will also learn more about the experimental sessions. Every patient will be directed arbitrarily (by chance, as it is with tossing a coin) to receiving a low dosage (“under threshold dosage”) of MDMA in the two experimental sessions or full or nearly full dosages (“experimental interference dosage”) of MDMA in the two experimental sessions.

At the opening of every experimental session you will receive one dose of MDMA. About two and a half hours later you will receive another dose of MDMA. The second dose will always be half of the first dose for all the patients in every experimental session, whether the first one was low or full. If you or one of the researchers notice any problem that arise after the first dose of MDMA was given, you might not be given the second dose.

Neither you nor the researchers know who receives the “**experimental intervention**” dosage (full or low) dosages, before the completion of the research. However, this information is available in case of an emergency.

Experimental Sessions:

Two experimental sessions will be held. In these sessions you will receive MDMA. The first one will be around the 14th day, and the second one will occur three to five weeks later. First you will discuss your goals and problems regarding PTSD with the researchers, so everybody knows what you would like to achieve throughout the experimental session. Researchers will answer other questions which might arise about the experimental sessions before they occur. Some of the tests that were taken before the experimental sessions and during them are meant to make sure that your participation in the research is still possible, and to discover problems during the experimental session.

You will be asked not to eat anything or drink alcohol from midnight on, the night before each session. You are allowed to have non-alcoholic beverages such as water or juice.

You are allowed to take non-steroidal anti-inflammatory, acetaminophin, birth control pills, or thyroid drugs as usual the week before the session, but any other medications must receive approval from the therapists. If you take a prescription drug, herbal supplement, or nonprescription medicine in the week prior to the experimental session without approval from the researchers, the researchers might decide to postpone the session or to reschedule it after talking to you.

Each one of the two sessions will take 6-8 hours. Despite that, the researchers will stay with you longer if there is a need. In addition to that, you will stay overnight at the Mental Health Center [REDACTED], and will stay there until the non-medicated psychotherapy session is over, in the next morning.

Before you receive the medication your temperature, blood pressure and pulse will be taken. Before the beginning of every session, you will give a urine sample to test wrong usage of drugs. If you are a woman in a child bearing age, a pregnancy test will be held as well. If one of these test results is positive, the session will be canceled or postponed. If you would like that, a significant person in your life, a close friend or a relative, will be allowed to stay with you during the end of the experimental session and following it.

To make sure that this person is indeed capable to function as your support, the researchers must meet with him before the experimental session date. You, that person and the researchers will determine when he or she would arrive. Either you or the researchers may decide not to allow this person into the session if they feel it would interrupt the process.

After the primary tests you will receive a capsule (at 11 a.m.) that will include “an under threshold” dosage of MDMA or higher “intervention” dosages. In the first experimental session the capsule will contain 125 mgs or 25 mgs MDMA and another dose that you may get 2 to 2.5 hours later that will be

half of the above mentioned dose. After taking the capsule you will sit or lay down in a comfortable position. If you would like we can supply you with an eye mask. You will listen to music with headphones during a major part of the experimental session. From time to time you will be asked to remove the headphones in order to talk to the researchers. You will be able to remove them by yourself when you like to talk to the researchers or if you choose a silence period. Lying down or sitting comfortably and listening to music are meant to encourage thoughts and emotional reactions, including thoughts and emotions about your trauma and PTSD. The two researchers will stay with you and help you if the need arise. They will talk to you or ask you to talk to them at least once an hour, but you are entitled to talk to them any time you like or remain silent. After you talk, there might be periods of time in which you'll be asked to stop talking for a while in order to notice your thoughts and emotions. There will be juices and other non- alcoholic beverages for you, and you will be encouraged to drink enough liquids. You may drink up to 12 cups (three liters) intermittently during the experimental session day.

Later on, you'll be given food, if you'd like that. Researchers will continue to measure blood pressure and pulse every set period of time, and your temperature will be taken automatically less often. Side effects will be observed and you will get medical treatment for them, if needed, with researchers' explanations about the treatment.

Staff will be accessible for possible emergencies. The next day a 60 minute psychotherapy session will be held with the researchers. You will have to arrange for a drive home after this session, because taking MDMA on the previous day might affect your ability to drive, and since there are people who report that they are tired, less alert or having difficulties focusing the day after they have taken MDMA.

You will have to arrange a drive back home prior to the session. If you can't find a person to drive you home, the researchers will pay for a cab. If you need more psychotherapy sessions with the researchers, aside the sessions that were planned as part of the research, you will be able to set them. There will be no further fees for additional appointments while you participate in the research.

Quitting the research during the first session or later, and a decision of the researchers not to include you in the research:

If you decide not to continue your participation in the research during one of the experimental sessions, you will still have to stay in the Mental Health Center [REDACTED] until the researchers agree that you are well enough to leave and that the psychoactive effects of the drug are gone.

If you experience very high blood pressure, a harsh or irregular emotional or physical reaction, or in case you have a significant on-going negative reaction after the first experimental session, you or the researchers might decide that you shouldn't participate in the second experimental session.

You are entitled to decide to end your participation in the research for any reason. The researchers will decide to end your participation, they will let you know about their decision and the reasons for preventing you from participating in the rest of the research.

If you end up your participation in the research at this point, whether due to the researchers' decision or to your own decision, the researchers will ask you to fill in a few ending questionnaires. These include questionnaires about your PTSD symptoms. The researchers would like to see whether there are any changes in your PTSD symptoms. You are allowed not to fill them up if you wouldn't like to do that.

Follow up:

There will be two kinds of follow up meetings: Psychotherapy sessions in which your experiences, thoughts and emotions during the experimental session will be discussed, and a research follow up (evaluation) to evaluate your answers before and after the experimental session.

One Psychotherapy follow up session will be held the day 24 hours after every therapy session and two further sessions will be held in the two to three weeks after each MDMA session. These sessions will be about an hour long. During these sessions you and the researchers will discuss your experiences during the experimental sessions and your thoughts and emotions regarding them afterwards. You will also discuss the ways to work with this information and use your experiences to help you cope better with PTSD and trauma. You will be asked to guess whether you received lower doses of MDMA or experimental intervention doses. This request allows the researchers to know more about the state you believed you experienced, and also if this thought changed the way you thought or felt regarding the experimental session.

More follow up sessions will be held two month, six months and twelve months after the last experimental session.

Your Requirements

If you are accepted to the research and agree to participate, you will be required to agree to the following:

1. Arrive to all the psychotherapy, evaluation and medicative sessions.
2. Avoid taking new medications from the beginning of the research to the last follow up session, unless they were approved by the researchers.

3. If you are seeing a psychotherapist right now, you are allowed to continue doing it. You are not allowed to start new psychotherapy or increase the frequency of sessions with your psychotherapist until the end of the last follow up session.
4. You must be capable of staying overnight after each experimental session at the Mental Health Center [REDACTED], in which the sessions will be held, and you must stay the following morning until the end of the psychotherapy follow up session.
5. If you are a woman and are capable of bearing a child you must use an effective contraceptive.
6. A major part of the processes, rules and tests that are required during the research are designed to reduce the odds of harm. It is highly important that you would fully describe your general medical history and your psychiatric history, as well as your medication usages, past and present. If you happen to break one of the research rules by mistake (as in taking a medication that was not approved by the researchers), it is very important that you would inform the research about it.
7. For your own safety, you must reveal all your diseases and allergies, past and present, to the research doctor, as far as you know. You are also obligated to inform the research doctor about all the medications you are taking, with or without prescription (such as cough syrup, vitamins, minerals etc.) as well as herbs (such as ginseng etc.) and food supplement (such as power bars etc.) you are using currently, since the reactions medications, supplements and herbs might cause are not fully established.
8. If you sense any of the above mentioned side effects, or any other irregular symptoms, you must inform the research doctor whose name is written in this form.

Do I have to participate in the research?

Participation in the research is on a voluntary basis alone. You are entitled to refuse to participate or quit at any given time, without risking your medical treatment. If you choose to quit the research, you will inform the research staff. The staff will encourage you to come back for a last follow up session and complete all the safety processes (blood and urine tests and physiological examination). In addition to that, the research staff may end your participation in the research at any time, if they determine that you or the research will benefit from ending it. For example, if you have a bad reaction to the research medication during the first experimental session, such as very high blood pressure or heart problems, or if you are too sick and need a medication which might react to the research medication, you will be asked to leave the research.

What are my rights as a participant of the research?

You are allowed to choose not to participate in the research, or, if you do agree to participate, you are allowed to leave any time. Your decision not to participate or quit the research does not involve any fine or losing rights to which you are entitled, and it will not harm your accessibility to medical treatment.

What do I benefit from my participation in the research?

Your direct benefits are: You will receive a psychiatric examination and other medical examinations during the screening process, as well as one physical examination during the research and at least six psychotherapy sessions.

There is no assurance that your PTSD symptoms will improve as a result of your participation in this research. The results of this research might be useful to patients that will be treated in the future with this experimental intervention. Your participation in the research will assist [REDACTED] and his colleagues to study the safety and efficiency of MDMA- assisted psychotherapy as a way to treat PTSD.

Will I be paid for my participation in the research?

You will not be paid for your participation in the research.

What are the costs?

You are not expected to have any costs in regard to this research. If there are any medical problems related to the research, these will be covered by the study sponsor.

What are the expected risks and the side effects of this research?

Participation in this research might include a number of additional risks or inconveniences, among them risks related to the screening process and to the medical examination, risks and inconveniences of psychotherapy and risks and inconveniences related to the experimental drug (MDMA). If you are currently taking any medications that you need to stop during the study, you may experience distress from not taking your medications.

Risks related to the screening process

The interviews you will have during the course of 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. A slight inconvenience, and rarely a small wound where the blood was drawn, a clot or an inflammation where the blood was taken. A weakness sensation is possible too, or even faintness.

A medical examination might take a long time, and part of the examination might involve some inconvenience. A psychiatric examination might take a long time and parts of it might cause distress or

inconvenience. Some people experience distress when they talk about previous exposure to a traumatic experience.

Risks related to psychotherapy

During psychotherapy people often talk about memories, events or thoughts that make them not-happy (feeling anger, fear or sadness). It is very likely that psychotherapy will make people feel these emotions. A conversation about sad thoughts or emotions might enhance anger, fear or sadness emotions during the therapy session or right afterwards. It also may be difficult to talk about your trauma and PTSD experiences and this may cause you emotional distress.

Risks related to the experimental drug (MDMA)

Up until now, MDMA was given in a clinical context to at least 400 people with no emotional disorders and to over 30 people with PTSD. Part of the observed risks will be detailed here. It's also possible that there are unknown risks or side effects to MDMA usage.

Slight Risks

Side effects during the MDMA experience that are less severe but more frequently reported, are:

- lack of appetite (70%)
- teeth grinding or tight jaw muscles 63%,
- dry mouth (57%)
- difficulty balancing or walking (44%)
- decreased concentration (42%),
- neck or back pains (50%)

Forty to 70% of subjects in previous studies and in a placebo-controlled study of MDMA-assisted psychotherapy in people with PTSD reported these side effects. Less commonly, 15% to 40% of research subjects reported feeling hot or cold, feeling that their heart was racing, sweating, dizziness, drowsiness, upset stomach, diarrhea, anxiety, tenseness, weakness, shaking, headache, or feeling faint (from most to least commonly reported). When any of these side effects occur, they usually last less than four hours, though some subjects report that some of these side effects can last for more than twenty-four hours, and rarely longer, but no more than four days.

Risks from MDMA

Changes in vision, hearing or other senses: In previous studies in which MDMA was given to

volunteers, including a total of about 365 subjects without emotional disorders and 21 with PTSD, most subjects reported experiencing minor changes in vision and hearing, such as sounds seeming closer or farther away than usual, or objects seeming brighter than usual, with these changes lasting 2 to 3 hours. People also reported unusual feelings in their bodies, such as tingling or numbness (12%-33%). These studies did not report exactly how many people experienced perceptual changes.

Blood pressure and heart rate. These effects of MDMA usually last 4 to 6 hours. At the dose in this experiment, the increases in blood pressure and heart rate are likely to be moderate.

Average increase in systolic blood pressure is 35 mmHg (measurement unit for blood pressure) and average diastolic blood pressure increase is 20 mmHg. Heart rate may increase by 20 beats per minute (BPM).

Blood pressure rose well above normal levels in a few subjects (a little less than 5%) after MDMA was given in previous studies, but these subjects did not report any discomfort and did not require any treatment. Although these increases in blood pressure are similar to what happens after heavy exercise, they could cause serious problems in individuals with preexisting heart or blood vessel defects. These serious problems could include heart attack or stroke. We will screen all potential subjects for preexisting heart problems before they are allowed to be in this study. This doesn't guarantee that no heart problems will occur, but it does greatly reduce the risk of this happening.

Anxious or jittery feeling: Some subjects in previous studies (16%) reported feeling overstimulated or anxious. It usually lasted less than 30 minutes. Due to your PTSD, you may be more likely to have severe anxiety or panic attacks. Letting yourself accept and feel those emotions deeply can be part of the psychotherapy. If you are not able to deal with these experiences in a way that helps you, the study doctors will work with you to deal with these feelings. It is possible that if such periods of heightened emotion do not clear up or grow weaker during the session, you could be at increased risk for suicide or other self-harm afterwards. You will be encouraged to ask the attendant to call the study doctors immediately if you have any thoughts about hurting or killing yourself so they can help you resolve them safely. If necessary, they may prescribe anti-anxiety medication or medication for sleep. If you are in immediate danger of hurting or killing yourself or hurting someone else, then the study doctors may require you to stay in a nearby hospital.

Serious problems and death: There have been some serious problems, and even deaths, associated with the use of Ecstasy outside of controlled clinical or laboratory settings. Serious problems

have included high fever, 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 against them). Since you will be receiving moderate amounts of uncontaminated MDMA in a controlled setting with trained therapists who will be closely monitoring your physical and psychological reactions, these problems are not expected to occur during or after the experimental session, but this does not guarantee that they could not occur. If they do occur, the study doctors are prepared to respond to these problems.

Insomnia & drowsiness: In previous studies, less than 40% (17%-23%) of subjects have reported insomnia (difficulty sleeping), and feeling tired, irritable, or drowsy for as long as 3 days after MDMA.

Mood: Some after-effects of MDMA may be noticeable up to 2 or 3 days later. While some subjects feel that their mood is better, 14% feel it is worse.

Immune System: You will probably have a less active immune system for 2 or 3 days after MDMA. This may make you more likely to become sick with a cold or other infection during this time. The study describing this finding did not say how many people in the study showed these changes.

Addiction: There is a small chance that you will become dependent on (addicted to) MDMA. One study found that up to 6% of people using Ecstasy for recreational purposes were dependent on it. However, a study of people who had received MDMA for the first time in a legal laboratory setting found that they did not want to try MDMA again outside of the laboratory.

People who have recently (in the last 60 days) had problems with drug abuse should not take part in this study.

There may be unknown side effects or risks from the use of MDMA.

Possible Brain Damage

Experiments in rats and monkeys show that high and repeated doses of MDMA can change brain cells that release a chemical called serotonin; in mice only, the affected cells release dopamine. The changes include loss of the part of the cell (called "axons") that connects 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 tests of memory. Recent studies in monkeys and rodents suggest that the doses in studies finding damaged axons are too high to reflect typical human doses of ecstasy or MDMA used in studies.

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 performed less well on tests of planning and impulse control. These differences are not great, but they have lasted for at least a 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. 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. 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 people without these problems.

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, and did not see any changes in the brain, 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 only saw one small change in the amount of blood found in a specific part of the brain, and did not see 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 changes in your brain, though this is not guaranteed. Studies of people receiving one or two doses of MDMA in a medical laboratory setting have not found any lasting changes in memory or planning. Studies comparing people before and after they decided to take a few ecstasy tablets 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. It is believed that the amount of MDMA you will receive will not produce any lasting changes in recall or planning ahead, though this cannot be guaranteed. You will not get a second dose of MDMA if they believe you are showing signs of memory problems.

Memory and organization were measured in people with PTSD before and after MDMA-assisted therapy and they showed no signs of memory problems afterwards.

Fertility damage:

Effects of MDMA on the growth and development of an unborn baby are not known. Birth defects could include physical deformities, mental retardation and premature birth; therefore you will not be allowed to enter the study if you are pregnant.

Women who are able to become pregnant must use one of the allowed birth control methods, such as birth-control pills or shots, IUDs, and diaphragms used along with spermicide and with partner use of condoms while they are in the study and for at least one month afterward. The study doctors 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.

You will be tested at the start of the study and again before each MDMA or placebo session to see if you are pregnant. 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 the researchers immediately. If you should become pregnant during the study, the study doctors will help you get proper advice and help you and your unborn baby get proper care while you are pregnant. If you prefer, this may include termination of the pregnancy.

Will I be informed about the findings?

If we will find new information about MDMA that will significantly change our understanding of its risks during your participation in the research, the researchers will inform you about it.

Am I covered in case of emergency?

A doctor is available 24 hours in case of emergency or in case you have thoughts about hurting yourself. You can call the on-duty doctor in the Mental Health Center [REDACTED] if you need to talk to him or her for any reason. You will receive a sheet with this phone number and other emergency numbers at the beginning of the research.

What about research-related damage?

If you will suffer any injuries as a result from participation in this research, your medical care will be covered by the sponsor. If you believe you have suffered a study related injury, please contact [REDACTED]. He will help you with an appropriate treatment plan for your condition. This study is insured by the sponsor and insurance will pay for all medical expenses and additional hospital expenses required for diagnosis and treatment of any negative effect of tests, medications, machine, laboratory work, or any research process required by the research protocol.

An explanation and an offer to answer your questions

██████████ research colleagues have explained the research to you and answered your questions. If you have further questions or problems related to the research, you may reach ██████████

What about the confidentiality of my information?

██████████ law requires the Mental Health Center ██████████ and the hospitals related to it, the researchers, medical care providers and the network of doctors to keep your identifying information that refers to your physical and mental health condition in past, present and future, confidential (“confidential medical information”). If you agree to participate in this research, research information (that does not include your identity) will be given to the sponsor of the research (MAPS), including its agents and contractors, the ethical team of this research as well as relevant legal authorities including the US FDA. Research information (that does not include your identity) might be published as well. Medical reports that contain your identity will be treated as confidential matter. These reports are kept in locked cabinets, and are identified by research numbers to keep them confidential. The only ways to release this information is by a written instruction from you referring to the part of the information that should be released, or by a court order.

Information achieved in this research will be used only for research needs, and your name will not be published. There will be no way to reveal your identity in any published material related to the research.

Video clips: Researchers and sponsor will watch recordings and listen to them, and no identifying information will be attached to these clips. **If you give your permission**, other staff member of the Mental Health Center ██████████ or other doctors will watch them for observation and studying purposes.

A written consent by the participant

A Study of MDMA- Assisted Psychotherapy in Twelve People with War and Terror Related Post Traumatic Stress Disorder.

You have received a copy of this written consent to keep.

You have read this form and you were given the opportunity to ask questions. ██████████ ██████████ or his colleagues answered your questions to your full satisfaction. You agreed to participate in this research on a voluntary basis. You are entitled to refuse to participate in this research or to end your participation at any given time. Your decision will not affect your present or future regular medical care, or any rights to which you are entitled in this site.

Participant: Signature, name, date

Researcher: Signature, name, date

Witness: Signature, name, date

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Video Clips of Research Participants

██████████ and his colleagues are running a small scale primary research on experimental drug, MDMA, which will be taken during special therapy sessions to participants who suffer from PTSD and do not respond to treatment [or therapy], in order to find out if this kind of therapy is safe, and if it would decrease the symptoms and improve quality of life. MDMA full dosage effects were compared to a very low dosage of this medication. In this research 33% of the participants will receive a very low dosage during the two experimental sessions while 66% of the participants will get the full dosage. Two experimental sessions of six to eight hours will be held, three to five weeks apart. In this research the experimental session will be video recorded, so that the researchers will have an accurate documentation of the session, and so that they can collect more data about drugassisted psychotherapy sessions. The researchers will document the whole experimental session, from the taking of the drug and during the six to eight hours of the experimental session. You can stop the recording any time, and you can ask to delete parts of the clip after they were recorded. You will be provided a copy of these clips (after editing that will remove periods of silence, lack of activity or parts you wish to delete). All the researchers involved in the research and the sponsor, are allowed to watch the clips in order to improve this experimental treatment. In addition to that, other staff members of the Mental Health Center ██████████ and/ or other doctors might watch parts of the recorded session for study and training purposes. Material that identifies the participant clearly would not be viewed by anybody aside from the researchers and the sponsor. You are allowed to ask that watching your clips will be limited to the researchers and the sponsor only. The clips will be stored in a locked cabinet in the Mental Health Center ██████████.

Written Consent by the participant

A study of MDMA- Assisted Psychotherapy in Twelve People with War and Terror Related Post Traumatic Stress Disorder.

You have received a copy of this written consent to keep.

You have read this form and you were given the opportunity to ask questions. ██████████

██████████ or his colleagues answered your questions to your full satisfaction. You agreed to participate in this research on a voluntary basis. You are entitled to refuse to participate in this

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research or to end your participation at any given time. Your decision will not affect your present or future regular medical care, or any rights to which you are entitled in this site. Do you request that the video clip watching will be limited for the researchers and the sponsor only? Please circle: yes/ no.

Participant: Signature, name, date

Researcher: Signature, name, date

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An Appendix for Informed Consent Form, MDMA Research

Functional MRI (Magnetic Resonance Imaging)

This is a most elaborate machine. Imaging using this machine allows discovering metabolic activity in brain tissue, i.e., which areas are active more or active less following different brain stimulations.

Imaging is achieved by energy release by oxygen nucleus, as oxygen concentration in a certain brain area serves as an indication for the amount of that brain area metabolism.

Previous examinations of people with PTSD found certain changes in the amygdale and back brain areas.

There might be a correlation between these changes and the existence of PTSD, and is very important scientifically to find out whether there is a correlation between the clinical change following the treatment and the brain changes that have occurred, or have not occurred, following it.

Objective of Study

This is a scientific experiment meant to find out the central nervous system site of the effect caused by the treatment. It might contribute in a major way to a better understanding of PTSD and its treatment in the future.

Patients Benefits

Functional MRI is a most elaborate examination that is done on the brain. If you suffer any brain problem, this examination will find it out.

Inconvenience

This examination requires lying down in a pipe shaped machine and hearing noises in your ears. It is known that people who have metal implants (screws, nails, platinum, pace maker etc) in their bodies are prohibited from it.

If you are suspected to have metal pieces in your body, you will be required to do an x-ray to negate this suspicion.

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If metal pieces will be discovered in your body, the functional MRI examination will not be performed.

Signing this appendix is a declaration saying that you don't have any metal parts in your body and that you agree to this imaging examination.

Side effects

Lying down in a closed space might cause headaches, inconvenience and anxiety.

This is a non invasive, non radioactive examination, with no antidotes injection.

The machine works on electromagnetic radiation but without any known side effects for the long run.

Note

I know that my consent to do or not to do this imaging examination is not a condition for my participation in the MDMA research, as detailed in the informed consent form attached to this appendix.

In any case, you can contact researcher: on phone no:

Participant name, signature, date

Researcher name, signature, date