INFORMED CONSENT FORM

Official title: Confirmatory Efficacy and Safety Trial of Magnetic Seizure Therapy for Depression (CREST – MST)

NCT number: NCT03191058

IRB Approved Document date: 10-28-22

The University of Texas Southwestern Medical Center

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: Confirmatory Efficacy and Safety Trial of Magnetic Seizure Therapy for Depression: CREST-MST

Funding Agency/Sponsor: National Institute of Mental Health

Study Doctors:

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Shawn M. McClintock, Ph.D.
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You may call these study doctors or research personnel during regular office hours at 214-633-3800 or 214-648-2806. At other times, you may call them at 214-633-0580 or call the Psych Link number at 214-630-7285.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?
This study is being done to investigate the safety and efficacy of Magnetic Seizure Therapy (MST), a recently developed treatment, compared to Electroconvulsive Therapy (ECT) for the treatment of depression.

Why is this considered research?
This is a research study because:

- Magnetic Seizure Therapy is investigational and has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of depression outside of research studies, it remains an experimental treatment..
- Magnetic Seizure Therapy (MST) is being compared to the standard procedure Electroconvulsive Therapy (ECT). The researchers are interested in learning which procedure is more effective and/or safer in treating your depression.

The following definitions may help you understand this study:

- Double-blind means that neither you nor the research personnel who interact with you, except for those providing treatments, will know the type of treatment you receive. This is the case for the duration of your study participation.
- Randomization means you will be placed by chance (like a flip of a coin) in one of the study groups.
- Standard medical care means the regular care you would receive from your personal doctor.
- Researchers means the study doctor and research personnel at the University of Texas Southwestern (UT Southwestern) Medical Center at Dallas and its affiliated hospitals.

Why am I being asked to take part in this research study?

You are being asked to take part in this study because you have a diagnosis of Major Depressive Disorder and are interested in pursuing a brain stimulation therapy (ECT or MST), as prescribed by your clinical physician.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

Principal Investigator

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Carol Tamminga MD, Department of the Department of Psychiatry at the University of Texas Southwestern Medical Center.

How many people will take part in this study?

Approximately 130 people will take part in this study at UT Southwestern. This study is also taking place at two additional facilities: in Canada, the Centre for Addiction and Mental Health (CAMH), and in California, the University of California San Diego (UCSD). There will be a total of 260 people taking part in this research study at the three sites in the United States and Canada.

What is involved in the study?

If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. Some of the procedures may be part of your standard medical care, while others are being done solely for the purpose of

this study.

While you are taking part in this study, you will be asked to attend up to approximately 40 visits with the researchers or study staff.
It may be necessary for you to return to the hospital/clinic three times per week.

Screening Visit:
To help decide if you qualify to be in this study, the researchers will ask you questions about your health. This includes medications you take or any medical conditions and surgical procedures you have had.

You will also be asked to complete an assessment visit at the UT Southwestern Psychiatry Clinic where you may also have to fill out certain forms or have the following exams, tests or procedures:

- Physical exam and medical history;
- Vital signs;
- Blood tests;
- Electrocardiogram (EKG), a tracing of the electrical activity of the heart;
- Demographic information (age, sex, ethnic origin);
- Diagnostic and depression rating scales.

The above procedures are considered standard of care and will be covered by either yourself, your guarantor or your insurance provider. Once your full study eligibility has been confirmed, all further procedures will be covered as part of the research trial and you will not be charged for subsequent visits. **The study will not be covering procedures related to your standard care or any procedures required to determine your eligibility for ECT or MST treatment.**

Baseline Visit:
Upon confirmation of full study eligibility, you will take part in several baseline visits. At these visits, you will have some interviews and fill out questionnaires regarding your symptoms. You will also complete about one and a half hours of cognitive assessments that will assess your memory and executive functioning. After testing, subjects will be randomly assigned to either the ECT or MST treatment group at the ratio of 1:1 (like a flip of a coin). Every subject has a 50% chance of being in either treatment group. Medication history will be asked. Subjects are required to continue their antidepressant medications without any changes in the dosages throughout the course of the study.

Treatment Visits 1-21:
During the treatment phase, subjects will receive 2-3 treatments per week usually on a Monday, Wednesday and Friday. To maintain blinding, the treatment room will have both the ECT and MST machines ready for treatment for every subject. The same medication regimen will be used in both treatment groups to manage anesthesia and any other treatment related adverse effects. Subjects in both groups will receive a maximum of 21

treatments over a period of approximately 7 weeks, unless they reach remission or if their condition worsens from baseline, requiring changes in the management plan for safety.

In the ECT treatment group, you will be provided treatment using either the MECTA spectrum 5000Q or the MECTA Sigma devices. These machines are FDA approved for providing standard-of-care clinical ECT treatments.

The MST treatment will be administered using the MagPro MST machine with a twin coil over the frontal cortex in the midline position. An example of the coil can be seen below:

MagPro MST Twin coil for placing on the frontal cortex

The treatment procedure is approximately 10 minutes, followed by a recovery period of approximately 30 minutes until you are stable and feeling well enough to be escorted home by your dedicated family or friend.

If you miss more than 2 scheduled treatment sessions, your treatment as part of the study may be stopped. Missing treatment sessions compromises the effectiveness of the treatment.

Subject Monitoring Procedure during Acute Treatment Phase:
The study team will follow your progress with additional monitoring visits after every 3-4 treatments. It should take around 30-45 minutes to complete this monitoring visit.

Post-Acute Treatment Subject Monitoring Procedures:
After your final treatment, you will take part in the same interviews, questionnaires, and neurocognitive testing as in your baseline visit. Once the final data has been collected, you will be referred back to your treating psychiatrist for treatment as usual. This visit will take 2.5-3 hours.

In addition to this, the William P. Clements Jr. University Hospital Team will complete standard of care follow-up post treatment. This is **not related** to the study and therefore

will be covered by either yourself, your guarantor or your insurance provider.

6 Month Follow-up:
You will have a 6-month follow-up visit to identify any symptoms of depression, suicidality, quality of life, or side effects from the treatment regimen. Long-term effects on thinking and memory will be tested through neurocognitive assessments. This visit will be approximately 3 hours long.

If for any reason you should stop the treatment prior to completing the full course, we aim to continue to follow you at the regularly scheduled time points described above. This allows us to collect more complete, unbiased data about these treatments and their effects.

Optional Sessions to Measure Brain Physiology:
Transcranial magnetic stimulation (TMS) is a method used to measure changes in brain activity. TMS excites nerves over the area of the brain involved in moving your hand muscles. When the nerves are stimulated, this causes the muscles in your hand to move, which will be recorded and later analyzed. Brain activity and inhibition during TMS will be measured using electroencephalography (EEG) and electromyography (EMG).

- You will be seated in a comfortable chair and we will attach soft foam electrodes to the skin surface over your hand muscles; these electrodes will then be connected to a recorder that will record the activity of your hand muscles.
- It takes approximately 30 minutes to put on the EEG cap and get it ready for recording. The cap contains many recorders that record your brain activity. There is gel on the inside of the cap that may be sticky. It can easily be washed off after testing.
- A magnetic coil will be held on the surface of your scalp.
- When the magnetic stimulation is applied, you will feel a twitch or small movement in your hand, but there should be no pain.
- The TMS measures of brain physiology will be taken from your motor cortex (the part of the brain that controls movement) and the prefrontal cortex (the part of the brain that controls thinking).

If you choose to participate in these sessions, there will be one scheduled before your first treatment and one after your treatment course is complete. Each session lasts around 3 hours. An example of the EEG cap worn during the treatment can be found below:

EEG CAP

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If the TMS-EEG sessions are being offered and you would like to take part in these additional sessions, please initial "Yes" below. If you are not interested, please initial "No" below. ***(Choosing NO does not impact your participation in the overall CREST study.)***

Yes_____ initials No_____ initials

Optional Magnetic Resonance Imaging (MRI) Sessions:
Magnetic Resonance Imaging (MRI) is a technology that uses strong magnetic fields ("magnetic") and radio frequency fields ("resonance") to produce detailed pictures of soft tissues in the body, including the brain. For this study, we will be using MRI to take pictures of your brain's structure and function. Each brain scan will take around 45-60 minutes, is done for research purposes only, and will not be used to guide your medical care.

Because MRI uses strong magnetic fields, we need to make sure you do not have certain metal objects in your body or with you when you enter the MRI room. You will be asked to change into hospital pants and gown when you arrive at the MRI facility. Your clothes and all personal items (e.g., watch, jewelry, wallet, cell phone) will be stored securely. The MRI technologist will talk with you before the scanning session to answer any question and to make sure it is safe for you to go into the MRI machine.

The MRI machine looks like a big doughnut, and you will lie down on a bed with your head and shoulders in the tunnel made by the "doughnut hole". We will put some pillows around your head and ask you to stay very still while we scan your brain. Movement will not be dangerous to you in any way, but will blur the picture of your brain. You will be able to contact the MRI technologist at any time during the scan session for any reason.

You will hear moderately loud knocking or beeping sounds when the MRI machine is scanning. You will be given ear protection to wear in the scanner. Different types of scans will make different sounds, which is normal for MRI. There will be a mixture of very short scans and some longer scans (up to 7 minutes each). While you are in the MRI machine, we will ask you to rest, but not fall asleep. This will allow us to measure and visualize your brain's activity.

If you choose to participate in these MRI sessions, there will be one scheduled before your first treatment, one during your first or second week of treatment, and one after your treatment course is completed.

If the optional MRI sessions are being offered and you would like to take part in these sessions, please initial "Yes" below. If you are not interested, please initial "No" below. ***(Choosing NO does not impact your participation in the overall CREST study.)***

Yes_____ initials No_____ initials

Calendar of Visits:

Boxes marked with an X show what would happen at each visit:

Visit	Interview and Questio-nnaires	Cognitive Assessmen-ts	TMS-EEG[e] (optional)	MRI (optional)	Clinical Lab[d]/ Consult	Treatment (MST or ECT)	Time
Screening Visit	X				X[d]		1 – 1.5 hours
Baseline Visit 1	X	X		X			2 - 2.5 hour
Baseline Visit 2			X (2 - 2.5 hours)				2 - 2.5 hours
Visits1-21[a]				X[e]	X	X	
Visits 4, 7, 10, 13, and 16,19[c]	X					X	30 - 45 minutes[b]
Post-treatment Monitoring Visit	X	X	X (2 - 2.5 hours)	X			4 - 5 hours
6 month post-treatment Monitoring Visit	X	X					2 – 2.5 hours

[a]For these visits, we cannot provide an exact estimate of the total duration of time, as this will be affected by wait times at the facility on a given day.
[b]The time duration listed for visits 4, 7, 10, 13, 16 and 19 only accounts for the interview and questionnaire portion.

[c]There is some flexibility with the interview and questionnaire monitoring visits, as they may be rescheduled to facilitate treatment scheduling.
[d]Clinical labs may be completed at a time point other than the Screening Visit, but this information should be available for review before Baseline Visit 1 to confirm eligibility.
[e]The mid-point MRI scan can occur between treatment visits 3 and 8 to facilitate scheduling.

Planning for Treatment Visits

Because you will be receiving a general anesthetic you cannot have anything to eat after midnight the night before your treatment. In addition, you must have nothing to drink, but clear liquids, no more than 6 ounces, 6 hours before your appointment time.

You MUST have an escort to take you home after each of your treatments. An escort may be a relative, friend, neighbor, caseworker, etc.

Prior to treatment start you will be seen by a brain stimulation physician, during this visit you may be asked to change a medication that could interfere with the MST or ECT procedure. The limiting or discontinuation of any medications prior to treatment start is a clinical decision and all risks associated with this will be reviewed with the brain stimulation physician or your clinical physician.
Taking a benzodiazepine (lorazepam, Xanax, Valium etc.) at a dose greater than lorazepam 2 mg or equivalent or, taking a non-benzodiazepine anticonvulsant medication is not permitted in the study as it could interfere with the MST or ECT procedure.

Should you be required clinically to start any new medication, please ensure to inform the research team. We also ask you to, please refrain from starting any new “over the counter” or “as needed” medications without talking about this with the research team first. This includes medication to treat anxiety or insomnia such as lorazepam or clonazepam.

After each treatment, you will spend some time in the recovery room where your vitals will be measured, nursing staff will monitor your status and you will be asked some questions by study staff to check your orientation (e.g. name, DOB, place, etc.). There will be other patients in this space who will be at various stages of recovery and reorientation. Current practice standards aimed at maintaining confidentiality will be applied throughout this process.

Group Assignment:
If the researchers believe you can take part in this study, you will be assigned randomly (like a flip of a coin) to receive either ECT or MST. Subjects are randomized to one of the two treatment arms at baseline before cognitive assessment.

How long can I expect to be in this study?
The study has a maximum of 21 treatments (2 - 3 per week until subjects reach remission), stop due to adverse events, or complete the maximum of 21 treatments in approximately 7 weeks.

You can choose to stop taking part for any reason at any time. However, if you decide to stop taking part in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

What are the risks of the study?

Risks associated with ECT:
ECT is a standard therapy that is routinely and widely used for the treatment of depression. You will be asked to sign both this consent form and the routine clinical consent form for ECT, which specifically outlines the risks of the treatment. ECT carries with it both the risk of medical complications and the risk of memory impairment.

The potential risks of ECT include the risks of anesthesia (including the very remote possibility of mortality), the possibility of headache and nausea, and general systemic complications. The most common adverse effect of ECT is cognitive side effects.
You will be given a detailed description of the cognitive changes with ECT, particularly the better-established immediate effects following each treatment and the effects that should decrease in the immediate weeks following the treatment course. Right unilateral electrode placement is used exclusively in this study in order to decrease the extent of cognitive effects, while maximizing efficacy. There is also a small risk of feeling difficulty breathing after each treatment. If this happens, we will adjust the doses of the medications administered during the treatment to ensure that this does not happen again. The risks of ECT are discussed in depth in the clinical ECT consent form.

Risks associated with MST:
MST is an investigational therapy for treatment of depression. There are potential risks related to anesthesia (including very remote possibility of mortality), the possibility of headache and nausea, and general systemic complications due to seizure activity as result of therapy. The data available from earlier human trials suggests that MST does not cause any significant decline in cognitive functioning or memory. There is also a small risk of experiencing difficulty breathing after each treatment. If this happens, we will adjust the doses of the medications administered during the treatment to ensure that this does not happen again.

Risks associated with TMS
TMS may cause some, all, or none of the side effects listed below.

<u>Frequent (10-25%)</u>
- Headache including migraine
- Local site pain

<u>Occasional (1-9%)</u>
- Facial pain
- Toothache
- Skin pain

Rare (1.25-3%)

- Facial numbness
- Manic or hypomanic symptoms

Serious/Rare (1.25-3%)

- Worsening of Depression which may lead to hospitalization
- Suicidal thinking which may lead to a suicide attempt
- Seizure
- Some hearing loss

Headache/Pain:
The treatment may cause local pain, dental pain, toothache, headaches, facial pain, and skin pain. These are usually temporary side effects and clear up within a short period. Some people may experience mild headache or shoulder stiffness after testing but these symptoms will usually go away in 24 hours. Typically, acetaminophen is enough to get rid of these symptoms. If you experience pain, you may be treated with pain medication, as appropriate. If you have further concerns, you may contact your study doctor at any time.

There is a rare risk that treatment may cause temporary facial numbness. Subjects in this study will be monitored closely due to the frequent visits during the treatment course. You will be asked about adverse events.

Hearing Loss:
The device makes noise, but hearing damage or problems are not expected. You will be asked to wear earplugs and the study staff will make sure that the earplugs are properly inserted in place during the treatment. If they loosen or come out you should tell the study staff and the treatment will be stopped. There is a risk of permanent hearing loss if an earplug should loosen or fall out. If you have hearing loss or history of hearing loss, you will not be allowed in the study.

Seizures:
There is a risk of having an epileptic seizure when using TMS. Repetitive TMS (rTMS) has been reported to cause seizures in some people. Patients with epilepsy and/or patients who have had a stroke may be more vulnerable to potential seizures. There are safety guidelines for rTMS that minimize this possible seizure risk. We intend to follow these guidelines and control stimulation so that it is well below the maximum limits of the safety guidelines.

Discomfort:
When the stimulation (TMS) is applied to your head, you will hear a short click from the machine. If this is an inconvenience, you will be offered earplugs, which partly mutes the sound.

At certain positions on the head, the stimulation may cause eyes to blink or a brief twitch of the scalp, neck, trunk or upper arm muscles. You may find these twitches annoying,

but they should not be painful.

Risks associated with MRI:

There are no known risks from exposure to magnetic fields. You may experience nervousness and/or anxiety due to the loud noise made by the machine while it is taking pictures and from confinement in a tight space (claustrophobia). If you become anxious, you can stop the procedure at any time. You may also experience some discomfort and fatigue from lying still during the MRI scan.

If you have a history of an implanted device or clips in your pelvis (involving your uterus or fallopian tubes) or under your skin, acting as a contraceptive to prevent pregnancy, the MRI technologist will obtain specific information about the make and model of your implanted device to determine if it is safe for you to receive the MRI examination.

If you have any metal clips or plates in your body, you should tell the investigator. MRI may not be appropriate if you are pregnant or are trying to become pregnant. MRI may not be appropriate if you have permanent eyeliner or eyebrows or any pieces of metal in your body, such as the following:

- heart pacemaker, heart valve replacement, or aortic clips
- metal fragments in your eyes, skin, or elsewhere in your body
- brain clips or pieces of metal used in aneurysm surgery or intracranial bypass
- venous umbrella
- pieces of metal in the body resulting from work as a sheet-metal worker or welder
- clips placed in an internal organ
- prosthetic devices, such as middle ear, eye, joint, or penile implants
- joint replacement
- hearing aid that cannot be removed
- neurostimulator
- insulin pump
- intrauterine device (IUD)
- shunts or stents
- metal mesh or coil implants
- metal plate, pin, screws, or wires, or any other metal implants

What if the researchers find something unusual on my brain scan?

The MRI scans in this study are designed for research, not for medical purposes. Even though the researchers are not looking at your brain to find or treat a medical problem, you will be informed if they notice something unusual and may receive a CD with de-identified images of your MRI brain scans. You and your doctors can decide together whether to follow up with more tests or treatment. Because the MRI scans done in this study are not for medical purposes, the research results will not be automatically sent to

you or your doctors. However, if you wish to disclose the MRI images of your brain obtained in this study to your doctor, you may request researchers to do so and sign Authorization to Release Information for your doctor.

Risks associated with Treatment Resistant Depression (TRD):

There is a possibility that you may experience a worsening of your symptoms or suicidality during the course of the study.

Risks associated with clinical interviews:
During the clinical interviews or neuropsychological testing, you may become tired or upset about the questions. If this happens, you should tell the interviewer/study personnel and he/she will stop the examination. Depending upon how you feel, you may then 1) take a rest period and resume later, 2) reschedule the appointment or 3) decide not to finish the exam.

Risks associated with EEGs:
There are no adverse reactions reported or expected with the use of electroencephalographic monitoring of patients during therapy. All patients will be monitored by digitized EEG data capture to confirm quality & adequacy of treatments.

Psychological Stress:
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time.

Loss of Confidentiality:
Any time information is collected, there is a potential risk for loss of confidentiality.
Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks of Blood Drawing:
Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting also are possible, although unlikely. You will have the same amount of blood collected whether you receive standard medical care for your health problem or take part in this research.

Risks to Sperm, Embryo, Fetus or Breast-fed Infant:

Males: Being in this research may damage your sperm, which could cause harm to a child that you may father while on this study. If you take part in this study and are sexually active, you may use medically acceptable forms of birth control, which include:
(1) Surgical sterilization (vasectomy), or
(2) A condom used with a spermicide (a substance that kills sperm).

Females: If you are part of this study while pregnant or breast-feeding an infant, you may expose the unborn child or infant to risks. For that reason, pregnant females cannot participate in the study. A urine pregnancy screen will be completed and it must be negative before you participate in this study. If you take part in this study and you are sexually active, we also ask that you not actively try to become pregnant while participating in this trial. You may use medically acceptable forms of birth control (contraceptives) which include:
(1) Surgical sterilization (such as hysterectomy or "tubes tied"),
(2) Approved hormonal contraceptives (such as birth control pills, patch or ring; Depo-Provera, Implanon),
(3) Barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or
(4) An intrauterine device (IUD).
If you do become pregnant during this study, you must tell the researchers immediately.

Other Risks:
There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

How will risks be reduced or prevented?
Your clinical physician and the research team perform a thorough evaluation to determine if you are a suitable candidate for this study. You will be monitored by the study personnel for the duration of the study. You will be encouraged to maintain adequate fluid intake and to not drink alcohol during your participation in study related procedures.

The study personnel (study psychiatrists, study coordinator, clinical rater) are trained in evaluating symptoms of depression in a structured manner to evaluate response to treatment. You will be asked at each visit about any depressive symptoms and suicidal thoughts you may have. If the study doctors have concerns about your safety, steps may be taken to ensure your safety, including hospitalization. You will be withdrawn from the study if the study doctors think that continuing is not in your best interest. If this happens, the referring psychiatrist will be consulted for other possible treatment options.

What will my responsibilities be during the study?
While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Store study materials in a secure place at home away from anyone who is unable to read and understand labels, especially children.

- Tell the researchers before you take any new medication, even if another doctor for a different medical problem prescribes it or something purchased over the counter.
- Tell your regular doctor about your participation in this study.
- Report to the researchers any injury or illnesses while you are on study even if you do not think it is related.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

What are the possible benefits of this study?
If you agree to take part in this study, there may or may not direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others with Treatment Resistant Depression in the future. Information gained from this research could lead to better treatment of TRD.

What options are available if I decide not to take part in this research study?
You do not have to participate in this research to receive care for your medical problem. Instead of being in this study, you have the following options:

- Medication only
- ECT without medication
- ECT with Medication
- Psychotherapy
- Another type of brain stimulation

Please talk to the researchers or your personal doctor about these options.

Will I be paid if I take part in this research study?
No, you will not be paid for being part of this study**.**

Should you choose to take part in the **optional MRI portion of this study**, you will be compensated for your time and inconvenience at a rate of $50 for each MRI scan, for a total of $150 for the completion of all three MRI scans.

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. You will also receive instructions on how to use the card. Compensation will be credited to the card after completion of each MRI scan.
Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. Your social security number is needed to process your payments. Study payments are considered taxable income and are reportable to the IRS. Should you decide not to provide your social security number, or your social security number does not match the name on file with the IRS, your study participation payment will be decreased in accordance with the current IRS tax rate. All information will be stored in a secure fashion.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

This information will remain confidential unless you give your permission to share it with others, or if we are required by law to release it.

UT Southwestern, as a State agency, will not be able to make any payments to you for your participation in this research if the State Comptroller has issued a "hold" on all State payments to you. Such a "hold" could result from your failure to make child support payments or pay student loans, etc. If this happens, UT Southwestern will be able to pay you for your taking part in this research 1) after you have made the outstanding payments and 2) the State Comptroller has issued a release of the "hold.

Additionally, at your request, we can provide you with a copy of the anatomical MRI scan (a picture of your brain), including a digital hard copy picture of what your brain looks like and/or the imaging files collected as part of the initial MRI.

You will be given a parking voucher in amount of $5 at each visit to the research group offices. You will not be reimbursed for parking at William P. Clements Jr. University Hospital as part of your ECT/MST treatments. Parking tickets will not be required in order to get a parking voucher. There are no funds available to pay for transportation to and from the research center, lost time away from work and other activities, lost wages, or childcare expenses.

Will my insurance provider or I be charged for the costs of any part of this research study?

No, neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the cost of ECT/MST therapies, MRI scans or anesthesia fees).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care. **This includes any consultations, tests or laboratory work required to determine your eligibility to receive ECT/MST treatments, and any required post-ECT/MST care.**

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if:

- Your medical problem remains unchanged or becomes worse.
- The researchers believe that participation in the research is no longer safe for you.

- The researchers believe that other treatment may be more helpful.
- The sponsor or the FDA stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

Will my information be kept confidential?
Research policies require that private information about you be protected, and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:
- Patient's current medical records.
- History of symptoms and current medications.
- Current medical, health, and psychiatric problems.
- Results of physical and psychiatric exam.
- Results of neuropsychological tests (pen and paper tests).
- Results of depression rating tests (pen and paper tests).
- Side effects or complications subjects have with the study intervention.
- Questionnaires regarding subject's experience with the study interventions.

We will get this information by asking you, asking your doctor, by looking at your electronic medical records at UT Southwestern Medical Center.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study (Recipients) including:

- The Sponsor, National Institute of Mental Health, funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health

information to assure the quality of the information used in the research.

- Representatives of government agencies, like the U.S. Food and Drug Administration (FDA), Health Canada or other health regulatory agencies, involved in overseeing drug or device research.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center.
- Representatives of the Centre for Addiction and Mental Health (CAMH), This is the other research facility that is working with UT Southwestern on the Research Project.
- Ontario Brain Institute and CAMH Center for Bioinformatics: these sites will collaborate and analyze data collected at the sites.
- The committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

<u>If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.</u>

Parts of your PHI may be photocopied and sent to a central location, or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

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

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of UT Southwestern for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Whenever possible your health information will be kept confidential as required by law. Federal privacy laws may not apply to other institutions, companies or agencies collaborating with UT Southwestern Medical Center on this research project. There is a

risk that the Recipients could share your information with others without your permission. UT Southwestern cannot guarantee the confidentiality of your health information after it has been shared with the Recipients.

Why is my personal contact being used?
Your personal contact information is important for the UT Southwestern Medical Center research team to contact you during the study. However, your personal contact information will not be released without your permission.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior and in some cases, your genetic information, to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.
After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter

to:
Carol Tamminga, M.D.
UT Southwestern Medical Center,
5323 Harry Hines Blvd,
Dallas, TX 75390-9127,
Phone number: 214-648-2806.

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends, and all required study monitoring is over.

Are there procedures I should follow after stopping participation in this research?
If you, the researchers, or the sponsor stops your participation in the research, you may be asked to do the following:

- Let the researchers know immediately that you wish to withdraw from the research.
- Return to the research center for tests that may be needed for your safety.
- Discuss your future medical care, if any, with the researchers and/or your personal doctor.

Whom do I call if I have questions or problems?
For questions about the study, contact Carol Tamminga, M.D. at 214-648-2806 or 214-633-3800 during regular business hours and at 214-633-0580 after hours and on weekends and holidays. You can call National Suicide Prevention Hotline number at 1-800-273-8255.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.

_____

Name of Participant (Printed)

_____ _____ _____ AM / PM

Signature of Participant Date Time

_____

Name of Person Obtaining Consent (Printed)

_____ _____ _____ AM / PM

Signature of Person Obtaining Consent Date Time