***PACT Atlanta, LLC***
465 Winn Way, Suite 221
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Phone: 404-292-3810 Fax: 404-292-3848

# Deep Transcranial Magnetic Stimulation (dTMS) Information

*Below you will find a brief outline of frequently asked questions about dTMS. If you have any further questions, please do not hesitate to speak with your doctor or a member of our staff!*

## ➢ WHAT IS dTMS?

- dTMS stands for "deep transcranial magnetic stimulation." dTMS is a non-invasive, FDA-cleared medical procedure for the treatment of depression in adults.
- dTMS is a brain stimulation technique that relies on the generation of brief magnetic fields using an insulated coil that is placed over the scalp. These magnetic fields are the same type and strength as those used in Magnetic Resonance Imaging (MRI) machines. The magnetic pulses generate a weak electrical current in the brain that briefly activates neural circuits at the stimulation site.
- dTMS has been shown to be a safe and well-tolerated procedure that can be an effective treatment for adult patients with depression, who have not benefited from antidepressant treatment.
- The potential benefit of dTMS is that it may lead to improvements in the symptoms of psychiatric conditions.
- Not all clients respond equally well to dTMS. Like all forms of medical treatment, some patients recover quickly, others recover briefly and later relapse, while others may fail to have any response to dTMS therapy.

## ➢ ALTERNATIVES TO dTMS?

- There are alternative treatment options for many psychiatric conditions; including medications, psychotherapy, and electroconvulsive therapy (ECT). Please discuss with your personal doctor the risks and benefits of these other options.

## ➢ PROCEDURE

- dTMS therapy involves a series of treatments. For each dTMS session, there is a specially equipped room located within our facility. Clients are seated for the treatment.

- Before beginning the dTMS procedure, clients are asked to remove any and all metal or magnetic sensitive objects (e.g., jewelry, keys, credit cards, cell phones, etc.) and placed in a secure location which will be visible to the client at all times.
- dTMS produces a loud clicking sound with each pulse emitted, thus clients are asked to wear earplugs for comfort and safety.
- dTMS does NOT require any anesthesia or sedation, so clients are awake and alert during the entire procedure.
- A member of the dTMS treatment team will first position the clients head in the head support system. Next, the insulated magnetic coil will be gently placed over the side of the head. The dTMS staff member will then adjust the dTMS device by delivering a series of pulses until it gives just enough energy so that the right hand twitches slightly. The amount of energy required to make this hand twitch is called the "Motor Threshold." Everyone has a different motor threshold and the treatments are given at an energy level that is just above each individual's motor threshold.
- During the procedure, the client will hear a clicking sound and feel a tapping sensation on the scalp.
- Once the individual motor threshold is determined, the magnetic coil will be moved to the front side of the head, over a region of the brain that scientists think may be responsible for causing depression. The client will then receive the treatment as a series of "pulses," with a rest period between each pulse series.
- Treatment sessions typically last twenty (20) minutes. The longest session is the initial session, in which the Motor Threshold is determined..
- Trained staff will be monitoring each client at all times during the entire course of treatment.
- The procedure can be stopped at any time, for any reason. Decisions to receive the dTMS procedure are made on a voluntary basis and consent may be withdrawn and treatment may be discontinued at any time.

## ➢ NUMBER OF TREATMENTS

- The exact number of treatments received cannot be predicted ahead of time. The number of treatments received will depend on the psychiatric condition, the response to treatment, and the medical judgment of the treating psychiatrist. dTMS treatments are usually administered five (5) times per week, but the frequency of treatments may vary depending on my needs. Typically, clients who respond to dTMS experience results by the fourth ($4^{th}$) week of treatment. However, some clients may experience results in less time while others may take longer.
- A client may choose to end the treatments at any time.

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## ➢ RISKS

- As with any medical treatment, dTMS carries a risk of side effects. However, dTMS is generally well-tolerated and only a small percentage of clients discontinue treatment due to of side effects.
- During the treatment, the client may experience tapping, facial twitching, or painful sensations at the treatment site while the magnetic coil is turned on. These types of sensations are reported by about one third (1/3) of clients. Clients should inform a staff member if this occurs. The treatment staff may then adjust the stimulation settings or make changes to where the coil is placed in order to help make the procedure more comfortable for me. In addition, about half of the clients treated with dTMS experience headaches. *Both the discomfort and headaches tend to get better over time and the headaches generally respond very well to over-the-counter pain medications.*
- Because the dTMS device produces a loud click with each pulse, we require the use of earplugs during treatment to minimize the risk of hearing loss. *It is important to note that there have been no reported cases of permanent hearing loss with properly functioning hearing protection.* If the earplugs become loose or have fallen out, the treatment staff should be notified immediately.
- As with all antidepressant treatments, there is a small risk for the emergence of mania with dTMS therapy. Please discuss with your personal doctor any symptoms, so that they can be appropriately monitored and treated.
- *The most serious known risk of the dTMS is the production of a seizure.* Although there have been a few case reports of seizures with the use of dTMS devices, this risk is extremely small. Nonetheless, please let your doctor know if you have a personal or family history of seizure disorder, as it may influence the risk of developing a seizure with this procedure.
- The dTMS team at PACT Atlanta, LLC follow up-to-date safety guidelines for the use of dTMS that are designed to minimize the risk of seizures for this technique.
- dTMS therapy is not effective for all patients with depression, and there is a risk that depression may get worse. Any signs or symptoms of worsening depression should be reported immediately to the treating physician.
- The client may want to ask a family member or caregiver to assist in monitoring symptoms to help spot any signs of worsening depression.
- There are no known adverse cognitive (thinking and memory) effects associated with dTMS therapy.

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## ➢ PREGNANCY

- The risks of exposure to dTMS during pregnancy are unknown. Female clients of childbearing capacity may be asked to take a pregnancy test before starting treatment.

## ➢ LONG-TERM ADVERSE EFFECTS

- There are no known long-term adverse effects reported with the use of dTMS. However, as this is a relatively new treatment, there may be unforeseen risks in the long-term that are currently unknown.

## ➢ METAL IMPLANTS

- dTMS should not be used by anyone who has non-removable magnetic-sensitive metal in their head or within twelve (12) inches of the magnetic coil. ***Failure to follow this restriction or inform the staff of this could result in serious injury or death.***
- Objects that may have this kind of metal include:
  - Aneurysm clips or coils
  - Stents in neck or brain
  - Implanted stimulators
  - Cardiac pacemakers or implantable cardioverter defibrillator (ICD)
  - Cardiac stents
  - Electrodes to monitor brain activity
  - Metallic implants in ears or eyes
  - Shrapnel or bullet fragments
  - Facial tattoos with metallic or magnetic-sensitive ink
  - Other metal devices or objects implanted in or near your head

## ➢ FURTHER QUESTIONS

- Please feel free to ask your physician or a member of the dTMS team about dTMS at this time or any time during or after the course of treatment.
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***If you have further questions, please call PACT Atlanta, LLC's Director of Neuromodulation: Joshua Bailey at 404-292-3810, ext. 235.***

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## dTMS Treatment Consent

Client name: _____

Date of birth: _____

I, _____, have read (or have had read to me) the information contained in this consent packet, pages 1-5, about dTMS therapy and its potential

risks and benefits for the treatment of my diagnosis of _____

_____. I acknowledge that Dr. _____ Has explained the purpose of this procedure, the potential risks and the potential benefits of this procedure, as well as the alternatives to dTMS. All of my questions regarding the procedure have been fully answered to my satisfaction. I understand there are other treatment options for my condition available to me and this has also been discussed with me.

If during the course of treatment other conditions arise which, in the best judgment of the medical staff, require emergency treatment, I authorize and request the said treatment be performed. I further understand that no guarantee of any results have been made.

I agree to wear earplugs, ear buds, or similar hearing protection during treatment (these will be provided by PACT Atlanta, LLC).

I consent to the admission of medical students and other authorized observers during the treatments, in accordance with the ordinary practices of PACT Atlanta, LLC.

I understand that any changes from the standard treatment protocol used in research trials before approval of the dTMS device will be discussed with me. My doctor may make a recommendation for a modification in the stimulation amount or coil position, based on evidence of safety and efficacy that have been published in medical journals since the device was initially tested.

I have received and read the "Patient Information for Transcranial Magnetic Stimulation" document and the information contained in this consent form about dTMS therapy and its potential risks.

I therefore authorize and request the physicians and staff of PACT Atlanta, LLC to administer a course of dTMS treatments to me. I understand that treatment is voluntary and I have the right to withdraw from treatment at any time.

I have read carefully, and I understand, the foregoing.

Client Signature: _____

Witness Signature: _____Date: _____

Signature of healthcare provider: _____

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# Patient Health Questionnaire (PHQ-9)

Client Name: _____Date: _____

*Over the **last 2 weeks**, how often have you been bothered by any of the following problems?*

| | Not at all | Several days | More than half the days | Nearly every day |
|---|---|---|---|---|
| 1. Little interest of pleasure in doing things | *0* | *1* | *2* | *3* |
| 2. Feeling down, depressed, or hopeless | *0* | *1* | *2* | *3* |
| 3. Trouble falling or staying asleep, or sleeping too much | *0* | *1* | *2* | *3* |
| 4. Feeling tired of having little energy | *0* | *1* | *2* | *3* |
| 5. Poor appetite or overeating | *0* | *1* | *2* | *3* |
| 6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down | *0* | *1* | *2* | *3* |
| 7. Trouble concentrating on things, such as reading the newspaper or watching television | *0* | *1* | *2* | *3* |
| 8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so figety or restless that you have been moving around a lot more than usual. | *0* | *1* | *2* | *3* |
| 9. Thoughts that you would be better off dead, or of hurting yourself. | *0* | *1* | *2* | *3* |
| **For Office Coding:** | + | + | + | |

**Total Score:**

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
- Somewhat difficult
- Very difficult
- Extremely difficult

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# Transcranial Magnetic Stimulation Adult Safety Screening Questionnaire (TASS)

Name: _____ Date: _____

| | YES | NO |
|---|---|---|
| 1. Have you ever had an adverse reaction to dTMS? | | |
| 2. Have you ever had a seizure? | | |
| 3. Do you have a family history of seizures or epilepsy? | | |
| 4. Have you ever had a stroke? | | |
| 5. Have you ever had a head injury (including neurosurgery)? | | |
| 6. Do you have any metal in your head (outside of the mouth,) such as shrapnel, surgical clips, or fragments from welding or metalwork? | | |
| 7. Have you ever had an EEG? | | |
| 8. Do you have any implanted devices such as cardiac pacemakers, wires, medical pumps, or intracardiac lines? | | |
| 9. Do you suffer from frequent or severe headaches? | | |
| 10. Have you ever had any other brain-related condition? | | |
| 11. Have you ever had any illness that caused brain injury? | | |
| 12. Are you taking any medications? | | |
| 13. If you are a woman of childbearing age, are you sexually active, and if so, are you not using a reliable method of birth control? | | |
| 14. Are you pregnant? | | |
| 15. Do you consume alcohol? If so, how often? | | |
| 16. Have you had Aneurysm clips or coils? | | |
| 17. Have you had an Internal Cardioverter Defibrillator (ICD)? | | |
| 18. Have you had Carotid or Cerebral Stints? | | |
| 19. Have you had dental implants? | | |
| 20. Have you had a cochlear implant/ear implant? | | |
| 21. Have you had a SCF (cerebrospinal fluid) shunt? | | |
| 22. Have you had eye implants? | | |

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| | | |
|---|---|---|
| 23. Do you have any tattoo's on your upper torso? | | |
| 24. Have you had a blood vessel coil? | | |
| 25. Do you have an implanted insulin pump? | | |
| 26. Do you have a programmable shunt or valve? | | |
| 27. Do you have a hearing aid? | | |
| 28. Do you have any cervical fixation devices? | | |
| 29. Have you had a VeriChip microtransponder? | | |
| 30. Do you have a bone growth stimulator? | | |
| 31. Have you had a wearable infusion pump? | | |
| 32. Do you have a portable glucose monitor? | | |
| 33. Have you had a Tracheostomy? | | |
| 34. Have you had radioactive seeds? | | |
| 35. Do you use illicit drugs? | | |
| 36. Have you ever been a machinist, welder, or metal worker? | | |
| 37. Have you ever had a facial injury from metal and/or metal removed from your eyes? | | |
| 38. Have you ever had complications from an MRI? | | |
| 39. Do you have any medication or nicotine patches? | | |
| 40. Do you need further explanation of dTMS and its associated risks? | | |

*Note: A positive screen is any "yes" answer and indicates further investigation by the clinician (but not indicating exclusion from dTMS)*

Age: ____Weight (lbs): _____ Height: _____Last Menstruation: _____

Reviewed By: _____

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# Inventory of Depressive Symptomatology (Self-Report) (IDS-SR)

Name: _____Date: _____

*Please circle the one response to each item that best describes you for the past seven (7) days*

**1. Falling Asleep:**
- 0 I never take longer than 30 minutes to fall asleep
- 1 I take at least 30 minutes to fall asleep, less than half the time
- 2 I take at least 30 minutes to fall asleep, more than half the time
- 3 I take more than 60 minutes to fall asleep, more than half the time

**2. Sleep During the Night:**
- 0 I do not wake up at night
- 1 I have a restless, light sleep with a few brief awakenings each night.
- 2 I wake up at least once a night, but I go back to sleep easily
- 3 I awaken more than once a night and stay awake for 20 minutes or more, more than half the time

**3. Waking UP Too Early:**
- 0 Most of the time, I awaken no more than 30 minutes before I need to get up
- 1 More than half the time, I awaken more than 30 minutes before I need to get up
- 2 I almost always awaken at least one hour or so before I need to, but I go back to sleep eventually
- 3 I awaken at least one hour before I need to, and I can't go back to sleep

**4. Sleeping Too Much:**
- 0 I sleep no longer than 7-8 hours/night, without napping during the day
- 1 I sleep no longer than 10 hours in a 24-hour period including naps
- 2 I sleep no longer than 12 hours in a 24 hour period including naps
- 3 I sleep longer than 12 hours in a 24 hour period including naps

**5. Feeling Sad:**
- 0 I do not feel sad
- 1 I feel sad less than half the time
- 2 I feel sad more than half the time
- 3 I feel sad nearly all of the time

**6. Feeling Irritable:**
- 0 I do not feel irritable
- 1 I feel irritable less than half the time
- 2 I feel irritable more than half the time
- 3 I feel extremely irritable nearly all of the time

**7. Feeling Anxious or Tense:**
- 0 I do not feel anxious or tense
- 1 I feel anxious (tense) less than half the time
- 2 I feel anxious (tense) more than half the time
- 3 I feel extremely anxious (tense) nearly all of the time

**8. Response of Your Mood to Good or Desired Events:**

0 My mood brightens to a normal level which lasts for several hours when good events occur
1 My mood brightens but I do not feel like my normal self when good events occur
2 My mood brights only somewhat to a rather limited range of desired events
3 My mood does not brighten at all, even when very good or desired events occur in my life

**9. Mood in Relation to the Time of Day:**

0 There is no regular relationship between my mood and the time of day
1 My mood oten relates to the time of day because of environmentsl events (eg, being alone, working)
2 In general my mood is more related to the time of day than to environmental events
3 My mood is clearly and predictably better or worse at a particular time each day.

9A Is your mood typically worse in the morning, afternoon or night? (circle one)
9B Is your mood variation attributed to the environment? (yes or no) (circle one)

**10. The Quality of Your Mood:**

0 The mood (internal feelings) that I experience is very much a normal mood
1 My mood is sad, but this sadness is pretty much like the sad mood I would feel if someone close to me died or left
2 My mood is sad, but sadness has a rather different quality to it than than sadness I would feel if someone close to me died of left
3 My mood is sad, but this sadness is different from the type of sadness associated with grief or loss

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**Please complete EITHER 11 OR 12 (not both)**

**11. Decreased appetite:**

0 There is no change in my usual appetite
1 I eat somewhat less often or lesser amounts of food than usual
2 I eat much less than usual and only with personal effort
3 I rarely eat within a 24-hour period, and only with extreme personal effort or when others persuade me to eat

**12. Increased appetite:**

0 There is no change in my usual appetite
1 I feel a need to eat more frequently than usual
2 I regularly eat more often and/or greater amounts of food than usual
3 I feel driven to overeat both at mealtime and between meals

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**Please complete EITHER 13 OR 14 (not both)**

**13. Decreased Weight (Within the Last Two Weeks):**

0 I have not had a change in my weight
1 I feel as if I've had a slight weight loss
2 I have lost 2 pounds or more
3 I have lost 5 pounds or more

**14. Increased Weight (Within the Last Two Weeks):**

0 I have not had a change in my weight
1 I feel as if I've had a slight weight gain
2 I have gained 2 pounds or more
3 I have gained 5 pounds or more

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**15. Concentration/Decision Making:**

0 There is no change in my usual capacity to concentrate or make decisions
1 I occasionally feel indecisive or find that my attention wanders
2 Most of the time, I struggle to focus my attention or to make decisions
3 I cannot concentrate well enough to read or cannot make even minor decisions

**16. View of Myself**

0 I see myself as equally worthwhile and deserving as other people
1 I am more self-blaming than usual
2 I largely believe that I cause problems for others
3 I think almost constantly about major and minor defects in myself

**17. View of My future:**

0 I have an optimistic view of my future
1 I am occasionally pessimistic about my future but for the most part I believe things will get better
2 I'm pretty certain that my immediate future (1-2 months) does not hold much promise of good things for me
3 I see no hope of anything good happening to me anytime in the future

**18. Thoughts of Death or Suicide:**

0 I do not think of suicide or death
1 I feel that life is empty or wonder if it's worth living
2 I think of suicide or death several times a week for several minutes
3 I think of suicide or death several times a day in some detail, or I have made specific plans for suicide or have actually tried to take my life

**19. General Interest:**

0 There is no change from usual in how interested I am in other people or activities
1 I notice that I am less interested in people or activities
2 I find I have interest in only one or two of my formerly pursued activities
3 I have virtually no interest in formerly pursued activities

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**20. Energy Level:**

0 There is no change in my usual level of energy
1 I get tired more easily than usual
2 I have to make a big effort to start or finish my usual daily activities (for example, shopping, homework, cooking or going to work)
3 I really cannot carry out most of my usual daily activities because I just don't have the energy

**21. Capacity for Pleasure or Enjoyment (Excluding Sex):**

0 I enjoy pleasurable activities just as much as usual
1 I do not feel my usual sense of enjoyment from pleasurable activities
2 I rarely get a feeling of pleasure from any activity
3 I am unable to get any pleasure or enjoyment from anything

**22. Interest in Sex (Please Rate <u>Interest</u>, not activity):**

0 I'm just as interested in sex as usual
1 My interest in sex is somewhat less than usual or I do not get the same pleasure from sex as I used to
2 I have little desire for or rarely derive pleasure from sex
3 I have absolutely no interest in or derive no pleasure from sex

**23. Feeling Slowed Down:**

0 I think, speak, and more at my usual rate of speed
1 I find that my thinking is slowed down or my voice sounds dull or flat
2 It takes me several seconds to respond to most questions and I'm sure my thinking is slowed
3 I am often unable to respond to questions without extreme effort

**24. Feeling Restless:**

0 I do not feel restless
1 I'm often fidgety, wring my hands, or need to shift how I am sitting
2 I have impulses to move about and am quite restless
3 At times, I am unable to stay seated and need to pace around

**25. Aches and Pains:**

0 I don't have any feeling of heaviness in my arms or legs and don't have any aches or pains
1 Sometimes I get headaches or pains in my stomach, back or joints but these pains are only sometime present and they don't stop me from doing what I need to do
2 I have these sorts of pains most of the time
3 These pains are so bad they force me to stop what I am doing

**26. Other Bodily Symptoms:**

0 I don't have any of these symptoms: heart pounding fast, blurred vision, sweating, hot and cold flashes, chest pain, heart turning over in my chest, ringing in my ears, or shaking
1 I have some of these symptoms but they are mild are present only sometimes
2 I have several of these symptoms and they bother me quite a bit
3 I have several of these symptoms and when they occur I have to sop doing whatever I am doing

**27. Panic/Phobic Symptoms:**

0 I have no spells of panic or specific fears (phobia) (such as animals or heights)
1 I have mild panic episodes or fears that do not usually change my behavior or stop me from functioning
2 I have significant panic episodes or fears that force me to change my behavior but do not stop me from functioning
3 I have panic episodes at least once a week or severe fears that stop me from carrying on my daily activities

**28. Constipation/Diarrhea:**

0 There is no change in my usual bowel habits
1 I have intermittent constipation or diarrhea which is mild
2 I have diarrhea or constipation most of the time but it does not interfere with my day-to-day functioning
3 I have constipation or diarrhea for which I take medicine or which interferes with my day-to-day activities

**29. Interpersonal Sensitivity:**

0 I have not felt easily rejected, slighted, criticized or hurt by others at all
1 I have occasionally felt rejected, slighted, criticized or hurt by others
2 I have often felt rejected, slighted, criticized or hurt by others, but these feelings have had only slight effects on my relationships or work
3 I have often felt rejected, slighted, criticized or hurt by others and these feelings have impaired my relationships and work

**30. Leaden Paralysis/Physical Energy:**

0 I have not experienced the physical sensation of feeling weighted down and without physical energy
1 I have occasionally experienced periods of feeling physically weighted down and without physical energy, but without a negative effect on work, school, or activity level
2 I feel physically weighted down (without physical energy) more than half the time
3 I feel physically weighted down (without physical energy) most of the time, several hours per day, several days per week

**Which 3 items (questions) were the easiest to understand? _____**

**Any other concerns: _____**

**_____**

**Range 0-84**

**Score: _____ Scored By: _____**

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# dTMS Informed Consent
# Special Uses

I understand the risks of Deep Transcranial Magnetic Stimulation with my Vagal Nerve Stimulator (VNS) in place. I have given informed consent and have discussed all concerns directly with Dr. Todd M Antin and PACT Atlanta, LLC.

I understand that I have been instructed to deactivate my VNS prior to beginning treatment and failure to do so may result in damage to my VNS or injury to myself.

I understand that PACT Atlanta, LLC will not be liable if such injuries were to occur.

Client Name Printed: _____

Signature: _____

Date: _____