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A PATIENT'S GUIDE TO

TMS THERAPY

nybsj.com

SECTION 1:
INTRODUCTION TO TMS THERAPY

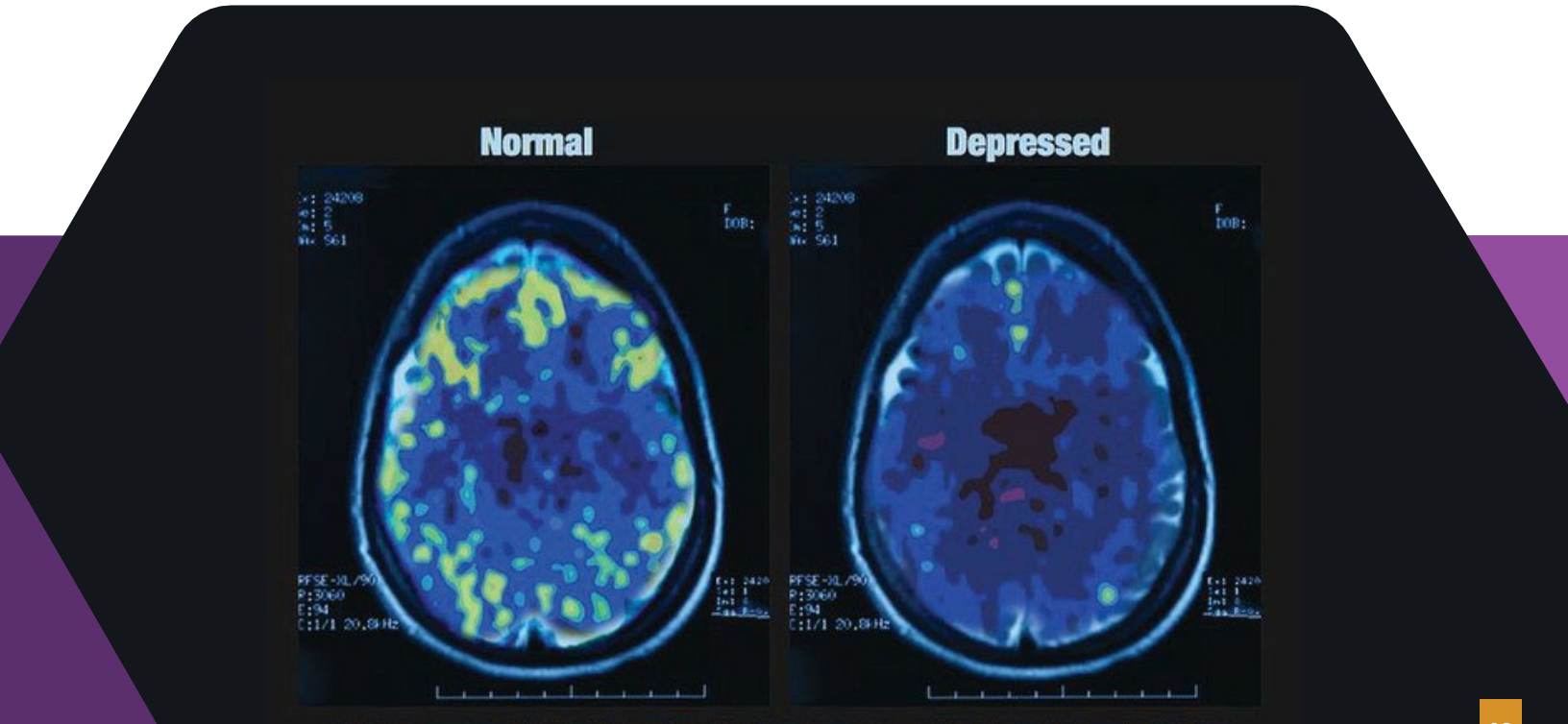
WHAT IS TMS?

- Definition of TMS (Transcranial Magnetic Stimulation):

Transcranial Magnetic Stimulation is a therapeutic intervention for depression that utilises magnetic fields to stimulate regions of the brain involved in mood regulation. The treatment involves the application of repeated magnetic pulses (often referred to as "rTMS" or "repetitive TMS") which aim to reactivate neuronal activity in patients experiencing depression.

HOW DOES TMS WORK?

- In individuals with Major Depressive Disorder, certain regions of the brain exhibit reduced activity. Transcranial Magnetic Stimulation (TMS) targets these areas, enhancing neural circuit activation and re-engaging circuits that may be underactive.
- TMS therapy for depressive disorders is typically focused on stimulating the left hemisphere of the brain, which research indicates is often less active in affected patients. This approach has been shown to alleviate symptoms and, in many cases, lead to significant recovery.
- Although the underlying science and methodologies are complex, this guide refers to the process broadly as neuroplasticity.



A PET scan measures vital functions such as blood flow, oxygen use and blood sugar (glucose) metabolism.

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HOW IS TMS PERFORMED?

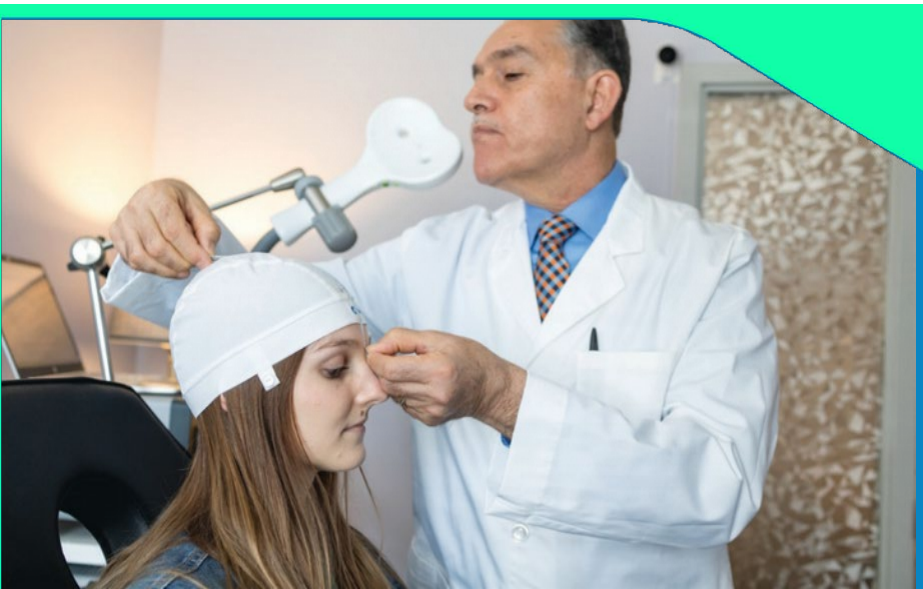
- A magnetic coil is positioned on the patient's forehead to deliver targeted magnetic pulses, which stimulate nerve cells within brain regions associated with mood regulation and depression.
- Transcranial Magnetic Stimulation (TMS) is conducted in an outpatient setting without the need for sedation. There are no activity restrictions before or after treatment, including operating a vehicle.

WHAT TO EXPECT DURING YOUR FIRST TMS TREATMENT SESSION?

- *Mapping:* The patient will be comfortably seated in a treatment room designed for relaxation. During the initial session, the TMS physician will conduct mapping and motor threshold determination. This process identifies the precise location for magnetic pulse delivery.
- *Motor Threshold Determination:* The physician will determine the appropriate treatment intensity by administering single pulses at the motor cortex to locate the area eliciting thumb movement. Additional pulses at varying intensities will be administered to establish the optimal magnetic dose.
- *Treatment Target Area:* Subsequently, the treatment target is identified, typically positioned 5.5 cm anterior to the site associated with observed thumb movement.
- *First Session:* The initial treatment session will follow the mapping process and will be the most extensive due to the preliminary procedures. Mapping is performed by a psychiatrist or medical doctor experienced in TMS therapy; subsequent sessions are conducted by a trained medical assistant under the doctor's supervision.

WHAT DOES IT FEEL LIKE?

- Patients often report experiencing a tapping sensation on the side of the head, sometimes described as a steady, pronounced drip or a woodpecker-like feeling. The majority of individuals acclimate to this sensation within the first few minutes of the initial session, and many cease to notice it thereafter.
- Approximately 5% of patients experience minor discomfort during treatment.



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WHAT DO I DO DURING THE TREATMENT SESSION?

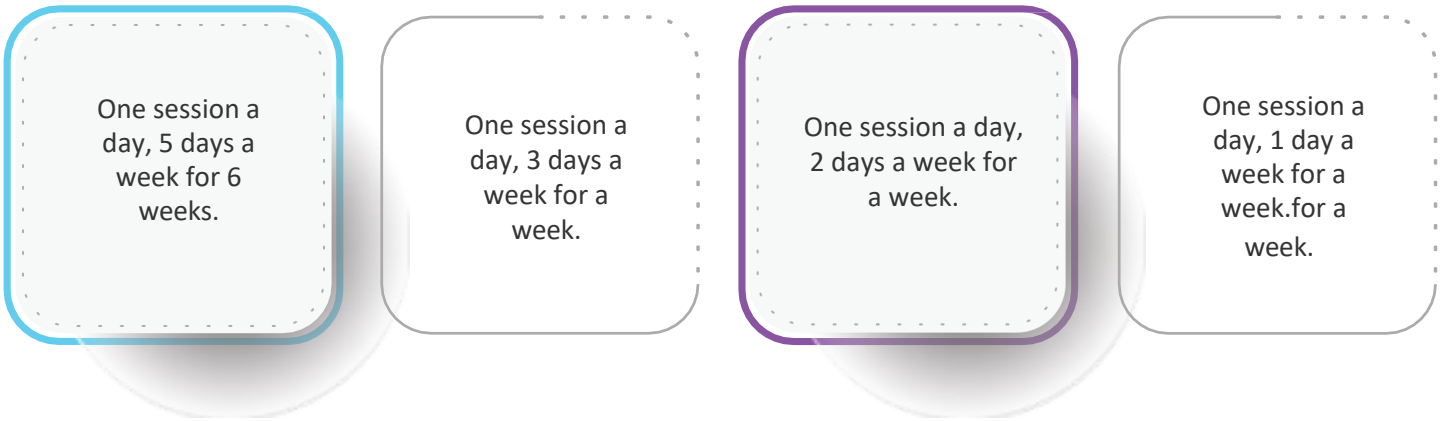
- Treatment sessions are conducted within 19 minutes or less, with some lasting as briefly as 3 minutes. During sessions, most patients choose to use their mobile devices or listen to music. Complimentary Wi-Fi and access to a high-definition 50-inch 4K television are provided, enabling you to enjoy programs on platforms such as Netflix, Hulu, or YouTube. We encourage selecting media that is pleasant and uplifting.

HOW MUCH TIME PER SESSION?

- The duration of each session *3-19 mins is determined by the specific therapy protocol and may vary accordingly.

HOW MANY SESSIONS DO I NEED?

- The total number of TMS sessions depends on the specific condition and protocol, with most patients receiving between 20 and 36 sessions.
- For the treatment of depression, the standard protocol is typically 30 sessions administered five times per week over a six-week period.
- A tapering period of approximately three additional weeks is commonly included following the initial course.
- Patients who self-pay and do not utilize health insurance may have the option to receive two sessions per day, potentially reducing the overall treatment duration by half (from six weeks plus tapering to three weeks plus tapering).



HOW LONG DOES THE THERAPY LAST AND WILL I HAVE TO DO IT AGAIN?

- Over 70% of patients sustain their response and remission for six to twelve months following TMS therapy.
- TMS is amenable to repetition; consideration for a second treatment round requires at least a 50% reduction in the depressive rating score. Response rates to a subsequent course of approved therapy remain high, ranging from 78% to 84%.
- Maintenance TMS therapy may be necessary for some individuals after the initial or subsequent treatment rounds, as it helps prevent relapse into depression. This maintenance can be administered weekly initially and potentially reduced to biweekly sessions.
- Recent research indicates that an intensive maintenance protocol—comprising two daily sessions over two or three consecutive days—yields excellent outcomes.

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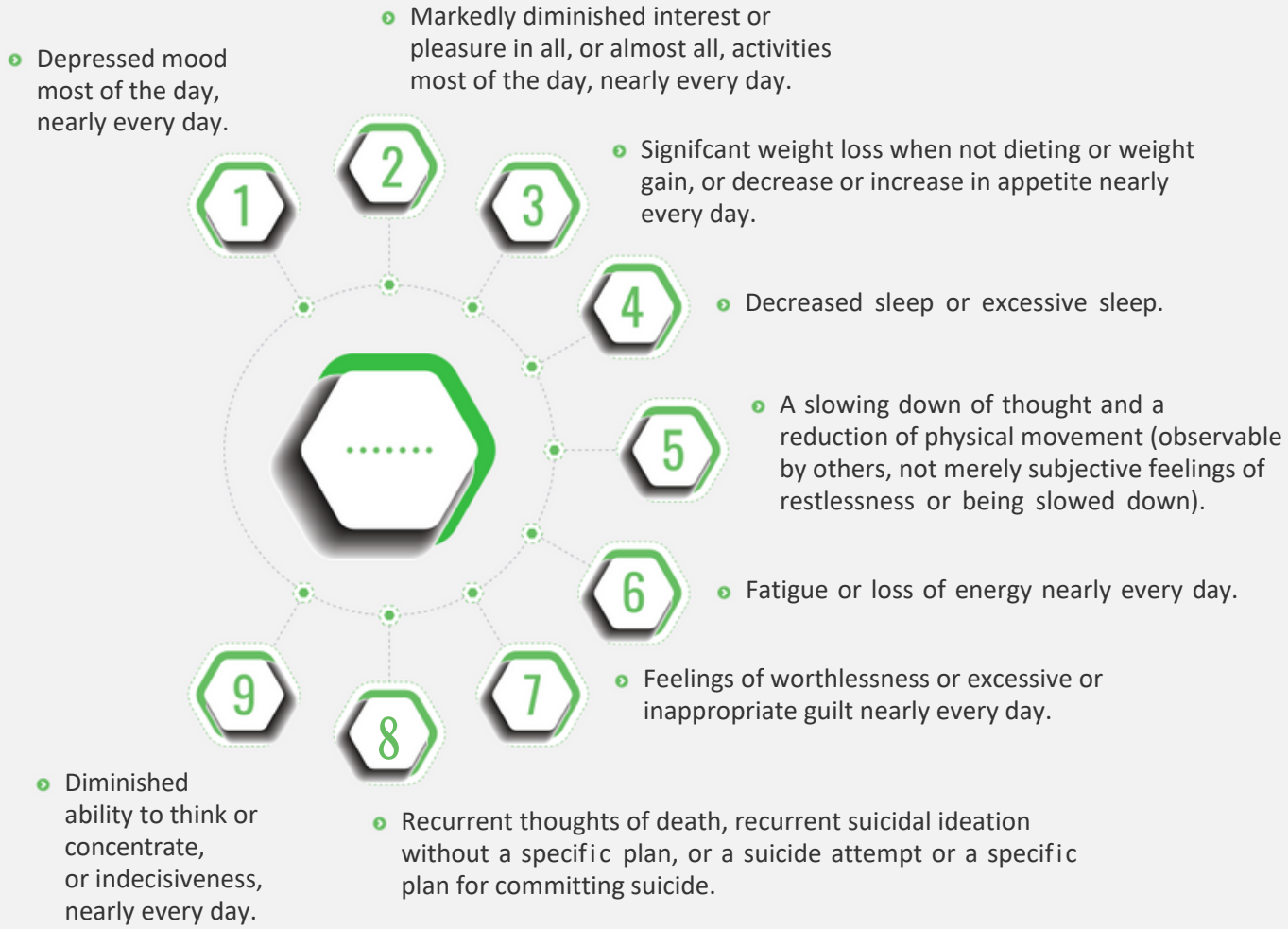
SECTION 2:

WHAT CONDITIONS DOES TMS TREAT?

TREATMENT RESISTANT DEPRESSION (TRD)

- Depression is a serious mental health condition affecting individuals' well-being; however, it cannot be identified through laboratory testing.
- According to the DSM-V criteria for major depressive disorder, diagnosis requires the presence of five or more symptoms within the same two-week period, with at least one symptom being either a depressed mood or a loss of interest or pleasure.



- TMS therapy was originally investigated as an alternative treatment for treatment-resistant depression (TRD) and is currently FDA-approved for depression, Anxious Depression, and OCD, with several other conditions pending approval.

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FDA APPROVED CONDITIONS

Depression

- Depression is the primary condition addressed by TMS therapy and was the first to receive FDA approval.
  - TMS therapy is typically indicated for adults with Major Depressive Disorder who have not achieved adequate improvement with previous psychotherapy and antidepressant medications.

OCD

- FDA approval was granted in 2020.
  - TMS therapy is authorized for use in patients with Obsessive-Compulsive Disorder who have not experienced sufficient benefit from prior treatments.

Smoking Cessation

- Received FDA approval in 2020.

OFF-LABEL TREATMENT

Bipolar

Bipolar is basically the combination of depression and mania. Many bipolar patients experience long bouts of severe depression. TMS is used during severe episodes when the patient does not respond to medication. However, there is the risk of inducing a manic episode. It is important for the treating physician to closely monitor the therapy.

In 2020 the FDA granted TMS therapy device breakthrough designation for bipolar depression.

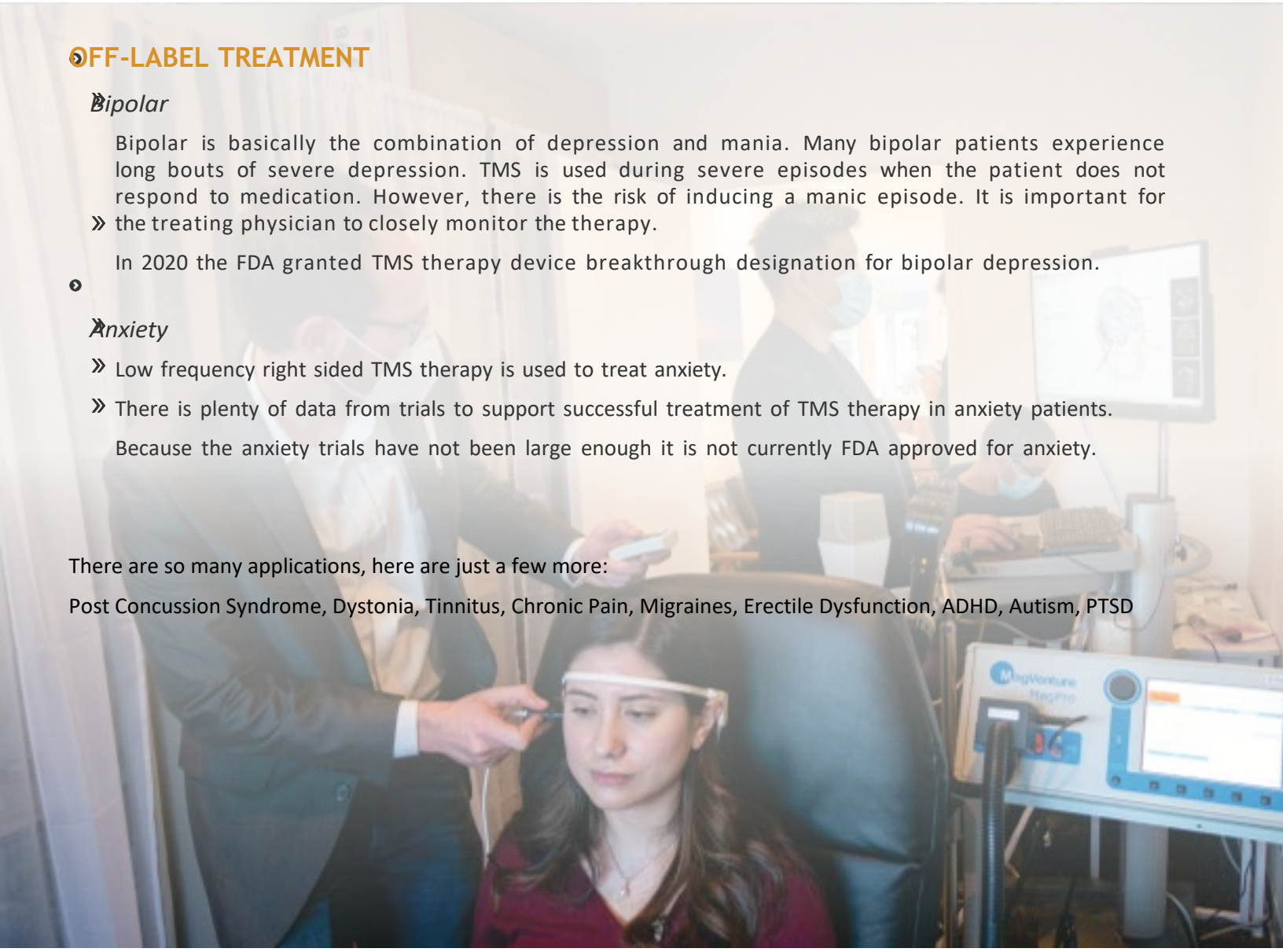
Anxiety

- Low frequency right sided TMS therapy is used to treat anxiety.
- There is plenty of data from trials to support successful treatment of TMS therapy in anxiety patients.

Because the anxiety trials have not been large enough it is not currently FDA approved for anxiety.

There are so many applications, here are just a few more:

Post Concussion Syndrome, Dystonia, Tinnitus, Chronic Pain, Migraines, Erectile Dysfunction, ADHD, Autism, PTSD

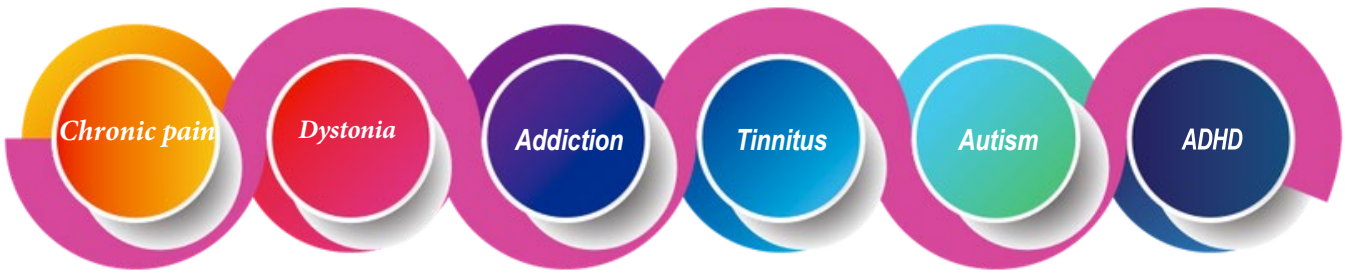


- *PTSD*
  - Currently TMS treatment for PTSD is not FDA approved. There were not large enough randomized controlled trials.
  - However, there are many studies that investigated the use of TMS to treat PTSD. Most showed good results and improvement.
  - Brain imaging studies have shown that PTSD patients have reduced brain activity in parts of the brain that control anxiety and distinguish between past and present.
  - TMS stimulates these areas and helps regulate cells in the brain and bring them back to normal activity, restoring balance and stability in your brain.

- *Post Concussion Syndrome/T.B.I*
  - Trauma-induced injuries to the brain, such as post-concussion syndrome and traumatic brain injuries (T.B.I.), have shown great results with TMS. The mechanism of action for TMS in these types of injuries is its ability to modulate neuronal activity and promote neuroplasticity. TMS encourages the brain to reorganize and form new neural connections. Additionally, TMS has been observed to affect neurotransmitter levels in the brain, such as increasing the release of certain chemicals like serotonin or dopamine, which contributes to its therapeutic effects, aiding recovery.
  -

- *Post-Partum and Pregnancy Depression*
  - TMS has successfully treated postpartum depression. There have been no adverse reactions from TMS in the postpartum phase or with breastfeeding mothers.
  - TMS can also be safely used during pregnancy to treat depression. The initial trials did not include pregnant women. Subsequent trials looked at the safety and efficacy of TMS during pregnancy and no adverse reactions were reported.

- *Other Conditions Being Studied*



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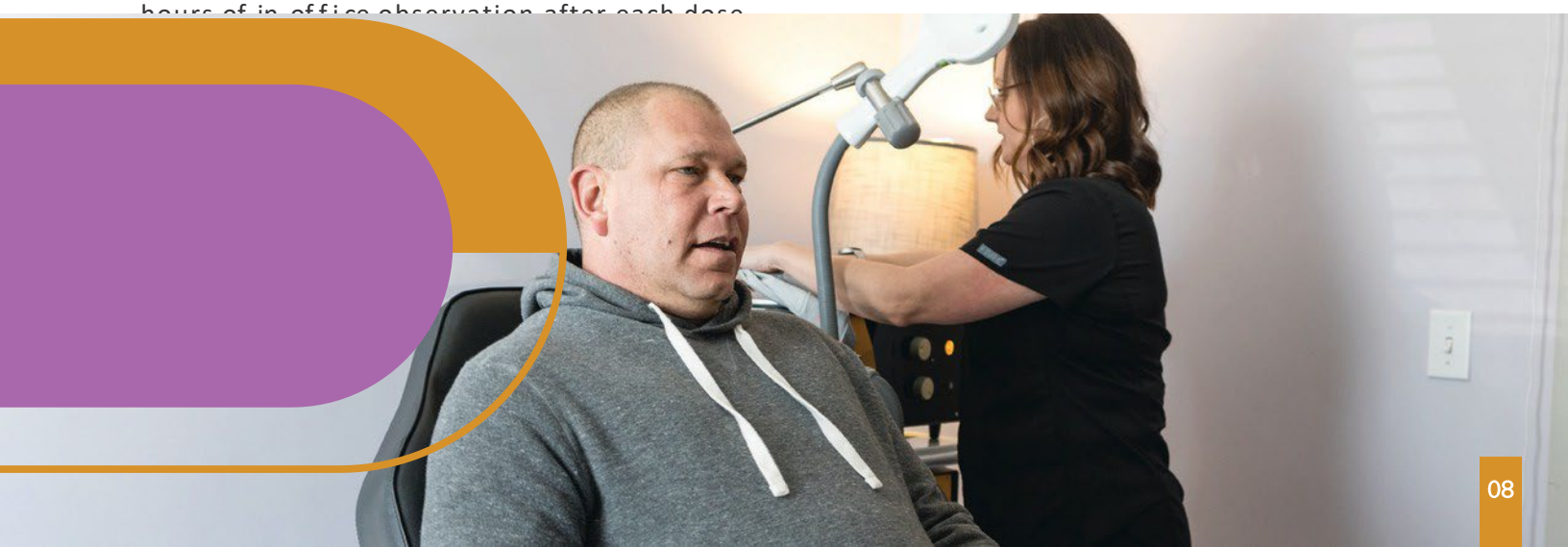
ALTERNATIVES TO TMS

- Beyond traditional antidepressants and talk therapy there are 2 alternatives to treat resistant depression besides TMS. These include Electro Convulsive Therapy (ECT) and EsKetamine or Spravato.
- ECT is commonly known as shock therapy.
  - TMS is not shock therapy.
  - In ECT, an electrical shock is delivered to the brain to induce a therapeutic brain seizure.
  - This is usually done in a hospital setting under sedation. TMS uses the law of induction using a magnetic eld to induce a microelectrical current.
  - A focused magnetic eld activates the brain cells by inducing these micro-electric currents.
  - TMS basically gives the end result from ECT without the side effects and need for sedation.
  - Unlike ECT, TMS does not cause memory loss which is a common side effect of ECT. Also, patients can drive to and from the TMS clinic and have therapy during their day without interrupting their schedule.
  - For depression without psychosis, both TMS and ECT are effective. For depression with psychosis, ECT is most likely the preferred treatment.
- Esketamine or Spravato.
  - Ketamine was a dissociative anesthetic that was used in anesthesia for humans (rarely now) and in veterinarian medicine. Recently Esketamine (Spravato) received FDA approval for TRD (Treatment Resistant Depression).
  - Esketamine is an intranasal spray administered under medical supervision. Patients need to be monitored for 2 hours after administration. It is given twice a week for 4 weeks and then weekly after that.
  - Common side effects include dissociation, nausea and vomiting. Some rare but high-risk side effects are hypertension and tachycardia.
  - TMS is almost always a better option than Esketamine. It is more effective and much safer. It is also much more convenient with no more than 20 minute sessions, while Esketamine requires at least 2 hours of in-office observation after each dose.



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SECTION 3:

INSURANCE COVERAGE

INSURANCE COVERAGE CRITERIA

- TMS therapy qualifications are set by insurance companies. Most insurance companies are slowly realizing the benefits of TMS therapy are superior to medications. In the past, insurance companies had very strict criteria to obtain coverage for TMS. That has been loosened recently and should continue to open more coverage for more conditions.

- Patients might have deductibles to meet and copays to pay. If paying privately the cost depends on the fee schedule for the clinic. If you want to see the average cost by zip code look to Fair Health Consumer using the CPT codes discussed in this guide. See *https://www.fairhealthconsumer.org/*

- Most insurance companies have at least the first 2 criteria:

  - *Criteria 1:* A diagnosis of severe depression in the current episode measured by a depression rating scale.
  - *Criteria 2:* Failure of medication antidepressants.
    - Insurance companies are always changing the amount of failed medications. They range from one to four. Medicare is now down to only one.
  - *Criteria 3:* Two classes of antidepressants.
    - Some insurance companies require the antidepressants to be from 2 different classes:
      - SSRI with Prozac; and an
      - SNRI like E exor.
  - *Criteria 4:* Augmentation treatment.
    - Some insurance companies require augmentation treatment.
      - 2 antidepressants; or
      - 1 antidepressant and 1 mood stabilizer.
  - *CriteFraiqilu5r:*e of Psychotherapy.

- What billing codes are used for TMS?
  - *CPT Code 90867:* Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery, and management. Should be reported only once in a treatment course.
  - *CPT Code 90868:* Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session. Typically reported up to 35 times in a treatment course.
  - *CPT Code 90869:* Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management. Typically reported 1-2 times in a treatment course. Should not be reported with CPT Codes 90867, 90868.

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- Insurance typically covers up to 36 sessions per treatment course. Most insurance companies want to see at least 2 months before subsequent treatment sessions, with other insurance companies requiring between 3 months to a year between courses.

INSURANCE COVERAGE FOR TMS IN NEW YORK

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INSURANCE COMPANIES ACCEPTED AT NYBSJ TMS; All Auto Insurance companies, and Workers Compensation claims for Depression.

TRICARE · BlueCross BlueShield · Humana · aetna · United Healthcare · Cigna · Medicare

TREATMENT WITHOUT INSURANCE COVERAGE

- Treatment is available for many o -label conditions without insurance coverage. Insurance covers
- mainly a diagnosis of Major Depressive Disorder while private pay patients can enjoy successful treatment of many more conditions.
- Health insurers are always behind the curve with state-of-the-art private treatments and TMS therapy is no different. It took years for health insurers to loosen the coverage requirements and there is no doubt coverage will continue to loosen as the efficacy data, as compared to medication, continues to improve.

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SECTION 4:

HOW EFFECTIVE IS TMS THERAPY?

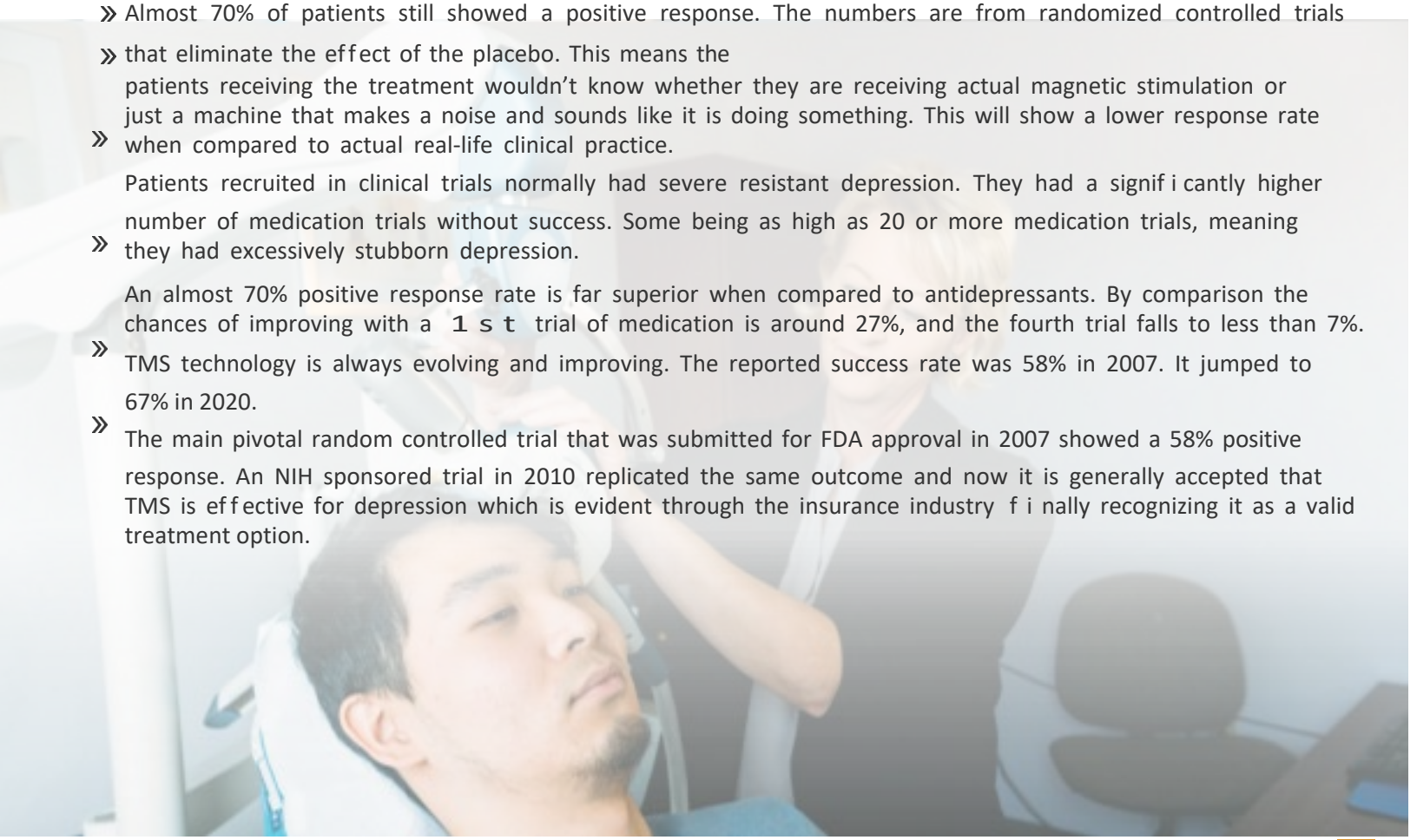
IS TMS EFFECTIVE?

- Yes. Transcranial Magnetic Stimulation (TMS) has been shown to be effective in the treatment of depression, anxiety, and obsessive-compulsive disorder (OCD), as evidenced by rigorous clinical trials.
- TMS is also considered effective for other off-label conditions discussed in this guide. Ongoing clinical research continues to develop, and it is expected that additional indications may receive approval in the near future.

WHAT IS THE SUCCESS RATE OF TMS?

- The success rate for TMS is excellent. It is important for anyone looking for an alternative to their antidepressant regiment to have con dence in TMS as a viable, non side-e ect option. Since TMS has been FDA approved for depression and now OCD and smoking cessation, the real-life clinical data (not the random trials) show how e ective TMS really is. When reviewing the clinical trials (not the real life clinical data) keep in mind the following:

  - Almost 70% of patients still showed a positive response. The numbers are from randomized controlled trials that eliminate the eff ect of the placebo. This means the patients receiving the treatment wouldn't know whether they are receiving actual magnetic stimulation or just a machine that makes a noise and sounds like it is doing something. This will show a lower response rate when compared to actual real-life clinical practice.
  - Patients recruited in clinical trials normally had severe resistant depression. They had a signif i cantly higher number of medication trials without success. Some being as high as 20 or more medication trials, meaning they had excessively stubborn depression.
  - An almost 70% positive response rate is far superior when compared to antidepressants. By comparison the chances of improving with a 1st trial of medication is around 27%, and the fourth trial falls to less than 7%.
  - TMS technology is always evolving and improving. The reported success rate was 58% in 2007. It jumped to 67% in 2020.
  - The main pivotal random controlled trial that was submitted for FDA approval in 2007 showed a 58% positive response. An NIH sponsored trial in 2010 replicated the same outcome and now it is generally accepted that TMS is eff ective for depression which is evident through the insurance industry f i nally recognizing it as a valid treatment option.



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- Accelerated TMS has a phenomenal success rates.
  - With the technology of accelerated TMS, the success rate is 90% and climbing in 2019.
  - In the SAINT-TRD trial the response rate was documented at 90%. See the CBS report on the issue at *https://www.cbsnews.com/video/apromising-new-treatment-for-depression/*
  - We provide and recommend the accelerated treatment not only for its efficacy but for the convenience of possibly getting your TMS therapy completed in much less time.
- Can You Try TMS Before Any Medication?

Insurance generally does not pay for TMS before trying medication. Not because of any danger, but because medication is the less expensive route in the beginning of any depression treatment plan.

The initial trials had patients who failed one or more antidepressants. Because of this, the FDA approved it for treatment resistant depression based on the data from 2007.

TMS could certainly work and be more effective than medication as a first line treatment.

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SECTION 5:
THE SIDE EFFECTS OF TMS

WHO CANNOT TRY TMS?

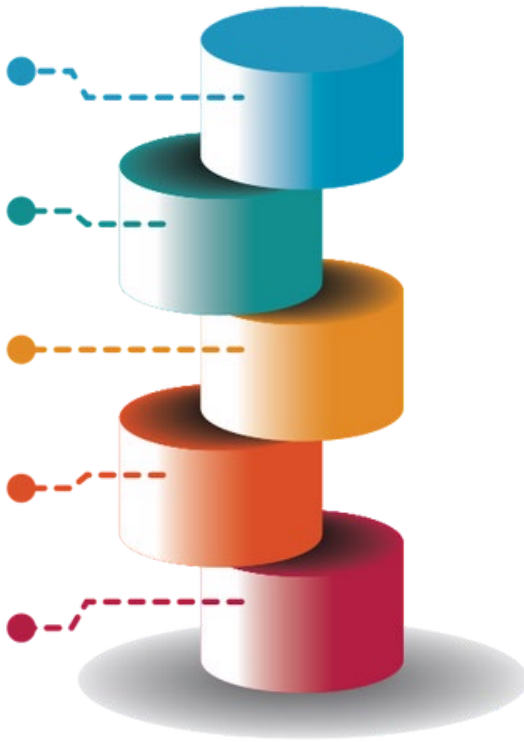
If someone has a brain stent, clip or stimulator they should not use TMS therapy.

Patients with a brain pacemaker should avoid TMS therapy.

Since TMS uses magnetic stimulation, the presence of any metal in the head of a patient could cause a problem.

WHO NEEDS TO BE CAREFUL WITH TMS?

- Patients with a history of seizure, head injury, brain surgery and any metal in the head (outside of the mouth) like shrapnel or fragments should be cautious or avoid TMS altogether. Regardless, a consultation with the TMS doctor is necessary.
- Alcoholics with a history of grand mal seizures need to be extra cautious.
- Epileptics with a history of seizures need to be cautious as well.
- Although rare, TMS can induce a seizure. This is documented in 1/10,000, not 30,000 sessions or about 0.1%.
- Some medications, like Wellbutrin are estimated to cause seizures in 0.4% of patients. Some medications have an increased risk of seizures as compared to TMS.



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IS TMS SAFE?

- Yes. Transcranial Magnetic Stimulation (TMS) is considered one of the safest treatments for depression beyond talk therapy. Numerous clinical trials have demonstrated its safety and efficacy.
- The most common side effect associated with TMS is scalp irritation or discomfort. This typically diminishes after the initial sessions and may be minimized by commencing treatment at a lower intensity and gradually increasing the power.
- No clinical evidence indicates that TMS causes chronic migraines, hearing loss, memory impairment, or insomnia.
- Please consult your physician or psychiatrist if you have the following conditions:
    - *Dental Implants:* TMS can generally be administered to patients with dental implants; however, it is essential to inform both your physician and the TMS clinic.
    - *Heart Pacemaker:* While TMS treatment is possible for individuals with heart pacemakers, notify your healthcare provider and TMS clinic, as additional precautions may be necessary. It is also advisable to obtain guidance from the device manufacturer regarding potential shielding recommendations.
    - *Spinal Cord Stimulator:* TMS has been performed on patients with spinal cord stimulators located in the thoracic or lumbar spine without adverse effects; nonetheless, this information should be communicated to your medical team.

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SECTION 6:

BACKGROUND OF TMS THERAPY

HISTORY OF TMS TREATMENT

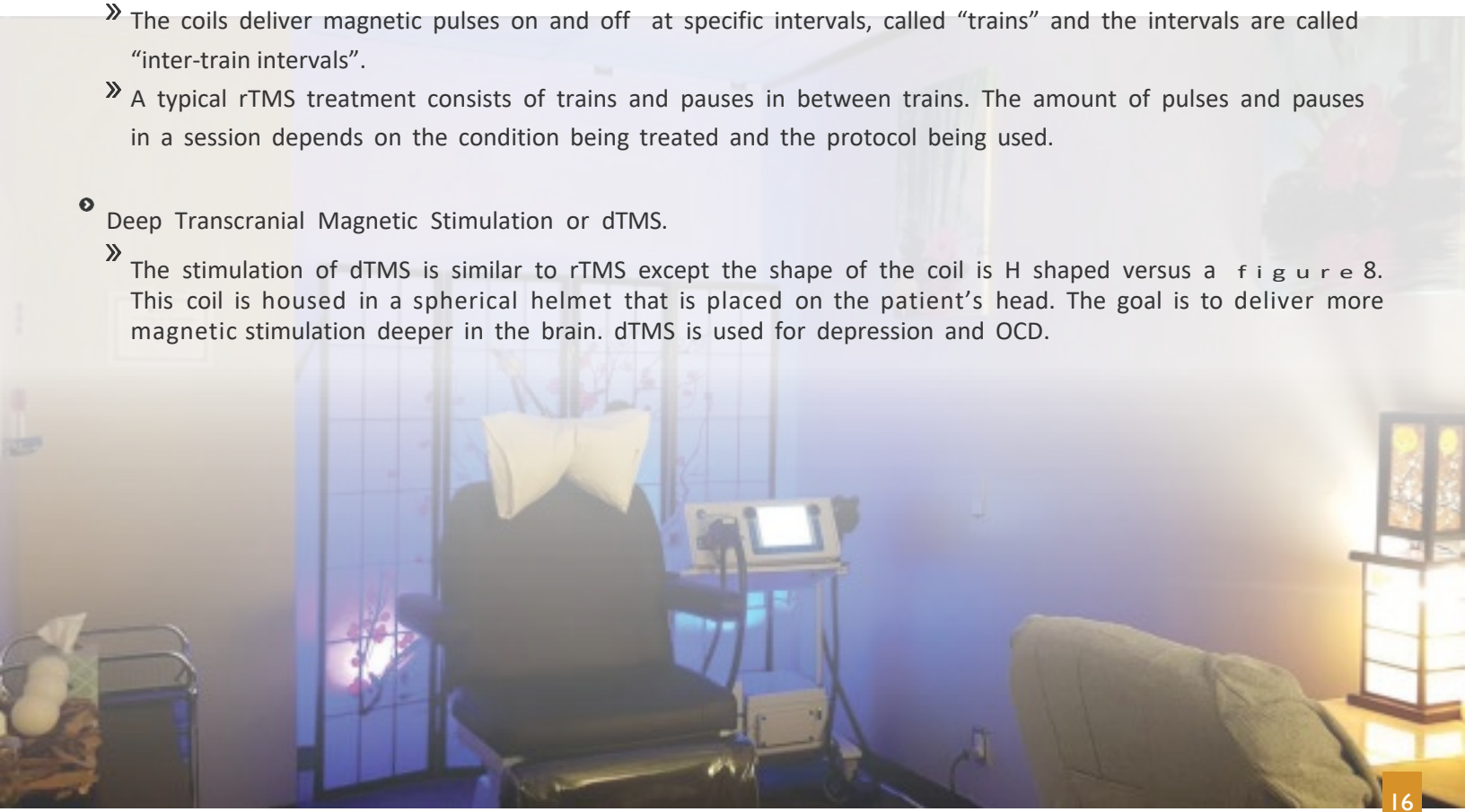
- Transcranial Magnetic Stimulation (TMS) was developed in 1985 in the United Kingdom. The first clinical TMS device was designed solely for single-pulse stimulation and featured a basic configuration. Initially, it was intended for the treatment of movement disorders and utilized by neurologists.
- Dr. Anthony Barker is credited with inventing TMS. Alongside Drs. Jalinous and Freeston, Dr. Barker conducted the inaugural demonstration of TMS, successfully eliciting hand movements by stimulating the motor cortex in the hemisphere controlling that muscle. Dr. Barker has been internationally recognized and awarded for his groundbreaking contributions to the field.
- In the United States, Dr. Mark George played a pivotal role in advancing TMS applications to psychiatric conditions and behavioral science. He remains a prominent leader in the field today.

https://www.bbrfoundation.org/about/people/mark-s-george-md

DIFFERENT TMS PROTOCOLS

- Repetitive Transcranial Magnetic Stimulation or rTMS.
  - This is the traditional TMS therapy as we know it today. It uses a " figure 8" looking coil and is placed on a specific area of the head.
  - The coils deliver magnetic pulses on and off at specific intervals, called "trains" and the intervals are called "inter-train intervals".
  - A typical rTMS treatment consists of trains and pauses in between trains. The amount of pulses and pauses in a session depends on the condition being treated and the protocol being used.

- Deep Transcranial Magnetic Stimulation or dTMS.
  - The stimulation of dTMS is similar to rTMS except the shape of the coil is H shaped versus a figure 8. This coil is housed in a spherical helmet that is placed on the patient's head. The goal is to deliver more magnetic stimulation deeper in the brain. dTMS is used for depression and OCD.



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INTERMITTENT THETA BURST STIMULATION OR ITBS

- Intermittent Theta Burst Stimulation (iTBS), also known as "Theta Burst," is administered using a figure-eight coil similar to that used in repetitive Transcranial Magnetic Stimulation (rTMS). The use of a helmet is not required, making this approach preferable for most patients.
- A primary advantage of Theta Burst is its significantly reduced treatment duration compared to rTMS. Theta Burst employs triplet pulses at a high frequency to deliver a distinctive, high-energy stimulus to neurons. Treatment consists of 20 stimulation trains, each lasting 2 seconds, with an 8-second interval between trains.
- Theta Burst sessions can typically be completed within approximately 3 minutes. Theta Burst has been demonstrated to be as effective as rTMS, according to evidence from a large clinical trial.

For further information, see https://pubmed.ncbi.nlm.nih.gov/29726344/.

WHY DOESN'T EVERYONE USE THE THETA BURST PROTOCOL?

- Accelerated Transcranial Magnetic Stimulation (TMS) utilizing the Theta Burst protocol represents a significant advancement in treatment delivery. This approach enables patients to undergo multiple TMS sessions within a single day, with the possibility of up to ten sessions daily, thereby reducing the total course of treatment to only five days.
- Notably, studies indicate that accelerated TMS and Theta Burst protocols demonstrate a remission rate approaching 90%. For further details, refer to Stanford researchers devise treatment that relieved depression in 90% of participants (SAINT Protocol). Achieving a 90% remission rate is considered exceptional in the context of treating complex disorders such as depression.
- When considering efficacy, evidence suggests that Accelerated TMS may offer advantages over traditional daily TMS. Both therapies are effective for depression; however, Accelerated TMS not only shortens individual session times and the overall treatment timeline but also yields improved outcomes (remission rates of 70% versus 90%). It is important to note that most health insurers currently reimburse for only one TMS session per day. Some clinics provide hybrid payment arrangements that combine insurance claims with private payments.

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SECTION 7:

TMS RESOURCES

CLINICAL RESOURCES

- Many of the resources online are meant for medical professionals, but there is no reason anyone cannot read and benefit from the material provided and keep abreast of new developments in the eld. Some of these resources include:
  Clinical TMS Society: https://www.clinicaltmssociety.org/
  »

BOOKS, TMS FORUMS AND REVIEWS

- "3000 Pulses Later" is a memoir written by Martha Rhodes and deals with her experience with TMS.
- "Transcranial Magnetic Stimulation TMS: My Mid Life Evolution" by Darcy Trumbo is a short but concise review of her experience with TMS.
- TMS+You (http://tmsyou.com/forum/forum/) is a forum where people share stories and experiences with TMS.
- TMS Facebook Groups.

» *Facebook Groups:*

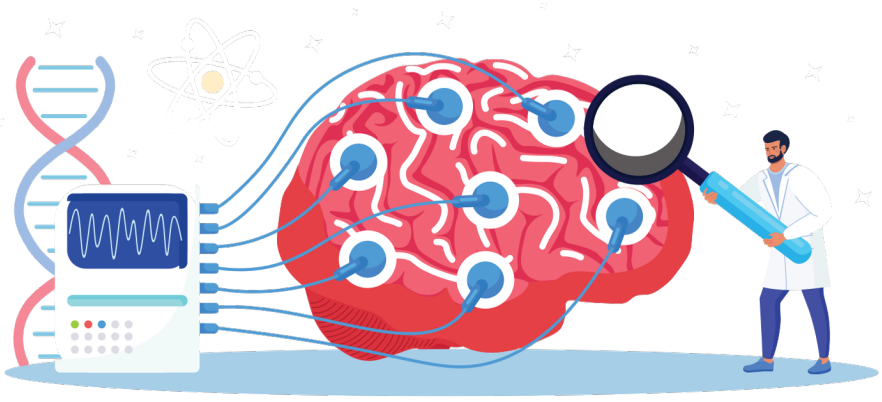
» Transcranial Magnetic Stimulation TMS Support" a private group.

» "TMS Therapy Support Group" a public group.

» "TMS Support Group", a public group.

» "TMS Therapy Support and Information" seems to have more genuine questions and answers.

» Regional Facebook Groups: there are also regional groups based on location, like "Sacramento TMS Support Group" if you search by a city or larger region.



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LET'S GET STARTED

TMS is a new and exciting treatment for depression and many other debilitating conditions. If you or someone you know is suffering and at a loss of where to turn, TMS is an excellent option. The lack of side effects, combined with increased success rates and the ability to use your health insurance make it a great choice. Schedule a free phone, or in person consultation now at:

631-600-9400

mlamantia@neurocaredx.com

www.nybsj.com