Brain Stimulation Treatments for Mental Health

Parents' Guide

American Academy of Child & Adolescent Psychiatry
www.aacap.org

American Psychiatric Association

Brain Stimulation Treatments for Mental Health: Parents' Guide Workgroup

CHAIR:
Paul E. Croarkin, DO, MS

MEMBERS:
Adrian Jacques H. Ambrose, MD, MPH, MBA
Raman Baweja, MD, MS
Christine Conelea, PhD
Neera Ghaziuddin, MD
Stephanie Hartselle, MD
Ernest V. Pedapati, MD, MS
Robyn Thom, MD

STAFF:
Sarah Hellwege, MEd, Director, Research, Grants, & Workforce

CONSULTANTS:
Glennon Floyd, Medical Science Writer
Azra Jaferi, PhD, Medical Science Writer

With special thanks to Teri Brister, PhD, LPC, NAMI Senior Advisor, for a thoughtful review of the guide.

The American Academy of Child and Adolescent Psychiatry promotes the healthy development of children, adolescents, and families through advocacy, education, and research. Child and adolescent psychiatrists are the leading physician authority on children's mental health.

The purpose of this guide is to provide a broad overview of available brain stimulation treatments. It is not meant to provide medical advice or to encourage any particular form of treatment. Instead, we hope this guide will provide sufficient information in lay terms to allow patients and families to have meaningful discussions with their physicians about brain stimulation treatments.

Table of Contents

Introduction

Two important areas to consider are the safety of the treatment and whether the treatment is likely to improve your child's symptoms and quality of life.

This guide will help you approach decisions about the use of brain stimulation treatments that may be available for your child. It provides an overview of how brain stimulation treatments can help your child, the potential side effects, and the potential risks. There is a lot of information to consider, and research on these treatments continues. Brain stimulation treatments are usually provided along with psychotherapy (talk therapy) and psychiatric medications. Although brain stimulation treatments are also sometimes referred to as "neuromodulation" or "neurotherapeutics," this guide will use the term "brain stimulation" to describe these treatments.

Brain stimulation treatments use electric or magnetic fields to change how the brain works. Research shows these treatments can help brain cells and circuits work better, which can improve mood, thinking, anxiety, and focus.

There are two types of brain stimulation treatments: noninvasive and invasive. The main difference is that invasive treatments involve surgery, while noninvasive treatments do not. Invasive treatments are not used as often as noninvasive treatments in youth. Examples of invasive treatments are deep brain stimulation (DBS) and vagal nerve stimulation (VNS), which are used to treat seizures (epilepsy) and severe movement disorders.

Nonsurgical Brain Stimulation Treatments

- Electroconvulsive therapy (ECT)
- Transcranial magnetic stimulation (TMS)
- Transcranial electrical stimulation (TES)
- Transcutaneous vagal nerve stimulation (tVNS)
- Trigeminal Nerve Stimulation (TNS)

A randomized controlled trial (RCT) is a form of scientific experiment used to control factors that are not under direct experimental control. The placebo appears to be similar to the treatment but does not contain the active ingredients of the treatment. The patients, parents, and researchers doing the study do not know which one the patients are receiving—the treatment or the placebo—making the trial double-blind.

Noninvasive brain stimulation treatments include electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), transcranial electrical stimulation (TES), and transcutaneous vagal nerve stimulation (tVNS). These treatments do not involve surgery and are usually done in a clinic while the patient is awake. ECT is an exception because it involves a needle stick (for an IV) and general anesthesia before the treatment, but it still does not involve surgery. Noninvasive brain stimulation treatments are used to treat youth with severe psychiatric symptoms.

When deciding on these treatments, it is important to think about several factors: the potential benefits, risks, and side effects; how these treatments might improve your child's quality of life; the costs of the treatment both in money and time; and your family's values.

When you are considering any new treatment for your child, it is important to speak with

your child's healthcare team and ask questions. All treatment approaches have relative positives and negatives. Two important areas to consider are the safety of the treatment and whether the treatment is likely to improve your child's symptoms and quality of life. To learn about whether a new treatment is safe and effective, researchers examine the treatment in a type of gold-standard study called a *randomized, double-blind, controlled trial*. In these studies, many patients with the condition are assigned randomly (as if a coin was flipped to decide) to either the new treatment or a placebo. If the active treatment improves symptoms more than the placebo, the treatment is said to be effective (or to have *clinical efficacy*). If the active treatment and the placebo have similar side effects, this suggests that the treatment is safe. Sometimes, lower levels of evidence are taken into consideration when randomized trials are difficult to conduct because the condition being studied is very severe and/or there are ethical issues (for example, when giving a placebo to sick patients could cause more harm or carries a high risk of a negative outcome).

The U.S. Food & Drug Administration (FDA) reviews evidence from research studies to decide if a new treatment should be approved (if the treatment is a medication) or cleared (if the treatment is a device) for commercial marketing. FDA approval or authorization is needed for the new treatment to be marketed for the special purpose of treating a certain condition. It is important to know that not all treatments that healthcare professionals provide to children and adolescents are approved or authorized by the FDA. When an FDA-approved treatment is used for a condition or an age group other than what the approval specifies, it is known as an "off-label" use of the treatment. This is accepted medical practice, if supported by research and clinical experts.

Types of Brain Stimulation Treatments

During the ECT procedure, a very small amount of electricity is passed through two electrodes that are applied to the scalp with gel.

Electroconvulsive Therapy (ECT)

ECT is a form of therapy used for severe depression, bipolar disorder, and catatonia. Catatonia is a disorder that affects a patient's awareness, speech, movement, and thinking, and it can be life-threatening. For initial ECT treatments, your child might be admitted to the hospital and receive anesthesia for each treatment so that they are asleep during the procedure. These treatments are administered once every 1–3 days. Once your child's psychiatric condition has been stabilized with ECT, your child may have the remaining treatments as an outpatient and may go home right after the procedure.

During the ECT procedure, a very small amount of electricity is passed through two electrodes that are applied to the scalp with gel. This electric stimulation causes a very brief seizure that is thought to be helpful for the brain. This kind of controlled seizure is safe and carefully managed by the doctors. It is thought that the seizure provides a "reset" for the brain and that chemicals are released during the seizure that help treat your child's condition. Based on clinical practice, ECT appears to be as effective, and possibly more effective, than all medications.

For some disorders , improvement with ECT may need booster sessions called "maintenance ECT." Maintenance ECT is usually done weekly for one month and then less often for weeks or months following, before stopping. The number and timing of both initial and maintenance treatments is discussed with the treatment team and tailored based on the diagnosis and severity of the illness, along with how well your child's symptoms respond.

The major risks of ECT are related to anesthesia used to put a child to sleep for the procedure. The frequency of these anesthesia-related incidents is exceedingly low. Patients treated with ECT may have side effects related to thinking and memory, but there are ways your treatment provider can reduce this risk. Current studies suggest that for most patients, these possible side effects go away within 2–3 months after ECT. Rarely, patients may have longer-lasting cognitive effects.

Patients and parents may have worries about treatment with ECT, especially because of the way it is sometimes portrayed in the media. In general, ECT is a safe and effective treatment. It is so safe that it is a treatment of choice for patients with severe symptoms who are unable to tolerate medications, patients who are medically compromised, elderly, or pregnant. Of all the treatments described in this guide, ECT has been used and studied much more and for longer than the other forms of brain stimulation.

Transcranial Magnetic Stimulation (TMS)

TMS is a form of brain stimulation that does not involve anesthesia. It uses a magnetic pulse to stimulate the brain while the patient is awake. It is now commonly used to treat adults who have treatment-resistant major depressive disorder. Researchers have safely used TMS in studies to treat adolescent patients with a variety of conditions, such as depression, attention-deficit/hyperactivity disorder (ADHD), tic disorders, obsessive

compulsive disorder (OCD), and autism spectrum disorder. TMS can be provided in many settings including a TMS center, a physician's office, or a hospital. During a session, your child will sit in a comfortable chair with a magnetic coil above their head. After a TMS session, a child can typically return to school or play.

The length and number of TMS sessions can vary depending on the symptoms being treated. The TMS stimulation session lasts between 5 and 40 minutes. Some treatments involve daily sessions over 4–6 weeks, while some new approaches deliver more than one treatment in a day over 1–2 weeks.

Several forms of TMS that are approved by the FDA for use in adults can also be used in children and adolescents as an "off-label" treatment. An off-label treatment is not specifically authorized by the FDA for use in this age group, but doctors may still offer it if they believe it is the best treatment option for your child. In 2024, the FDA cleared TMS treatment to add on to antidepressant medication in adolescents (aged 15–21 years) with major depressive disorder. Currently, other uses of TMS in children and adolescents are "off-label."

Common side effects of TMS include headaches, scalp discomfort, tingling, and twitching. These symptoms are usually mild and do not last long. Hearing protection must be worn during TMS, because the magnetic pulses make a tapping or clicking sound that may damage hearing. In very rare cases, TMS can cause a seizure; however, the seizure risks have been shown to be quite small and are more likely to occur in patients who already have seizure risks, such as head injuries or brain infections. The effects of TMS are not always long-lasting.

Transcranial Electrical Stimulation (TES)

TES provides mild electrical stimulation to the scalp while the patient is awake. In most cases, patients do not feel any uncomfortable sensations. Different

An off-label treatment is not specifically authorized by the FDA for use in this age group, but doctors may still offer it if they believe it is the best treatment option for your child.

TES procedures are thought to help the brain in different ways. Procedures like transcranial direct current stimulation (tDCS) and transcranial random noise stimulation (tRNS) are thought to help the brain's building blocks, called cells or neurons, work in a healthier way. Other forms, such as transcranial alternating current stimulation (tACS), are thought to help make brain waves healthier.

Trigeminal Nerve Stimulation (TNS)

TNS is a type of TES that stimulates the trigeminal nerve (a nerve involved in feelings like pain, touch, and temperature on the face). It is authorized by the FDA to treat children (ages 7–12 years) with ADHD who are not taking medications at the same time. TNS comes in the form of an electronic device named the Monarch eTNS® System. Studies have shown that TNS is relatively safe. It is delivered when the patient is sleeping. In most studies, TNS treatment is delivered daily for 4 weeks. Symptoms may improve gradually over the course of 4–8 weeks.

To use TNS, the parent places an electrode patch on the child's forehead that is connected to a stimulator by thin wires. It is placed right before bedtime, worn for 7–9 hours during sleep, and taken off after waking up in the morning. Children usually tolerate TNS well, with the most common side effects being skin rash or discoloration under the areas where the patch was placed. For rashes, washing the area after the patch is removed and applying cortisone cream usually help. Discoloration of the skin improves by approximately two weeks after stopping the TNS and with normal exposure to sun.

Vagal Nerve Stimulation (VNS)

VNS uses a surgically implanted stimulator to send electrical pulses to the vagus nerve, a nerve with important brain connections. It has been studied in both epilepsy (seizure disorder) across the lifespan and for treatment-resistant depression in adults . VNS is used for children with difficult-to-treat seizures. Many of the patients who have been treated with VNS for epilepsy also have mental health problems. It is not known if VNS helps pediatric mental health problems like ADHD, anxiety, and depression. Large studies that have examined side effects and risks when used to treat seizures have found that, in general, VNS is relatively safe and well-tolerated. Common side effects include hoarseness of voice, difficulty swallowing, difficulty speaking, stomach upset, and problems with the device hardware. There have been rare accounts of aspiration (accidentally inhaling through your vocal cords into your airway, instead of swallowing through your food pipe, or esophagus, and into your stomach) and heart problems called arrhythmias. In rare cases, patients with epilepsy treated with VNS have had sudden unexplained death, but this was not proven to be due to the VNS. There are also risks and side effects related to the initial surgery. There is another form of VNS, called transcutaneous VNS, that is delivered without the need for surgery.

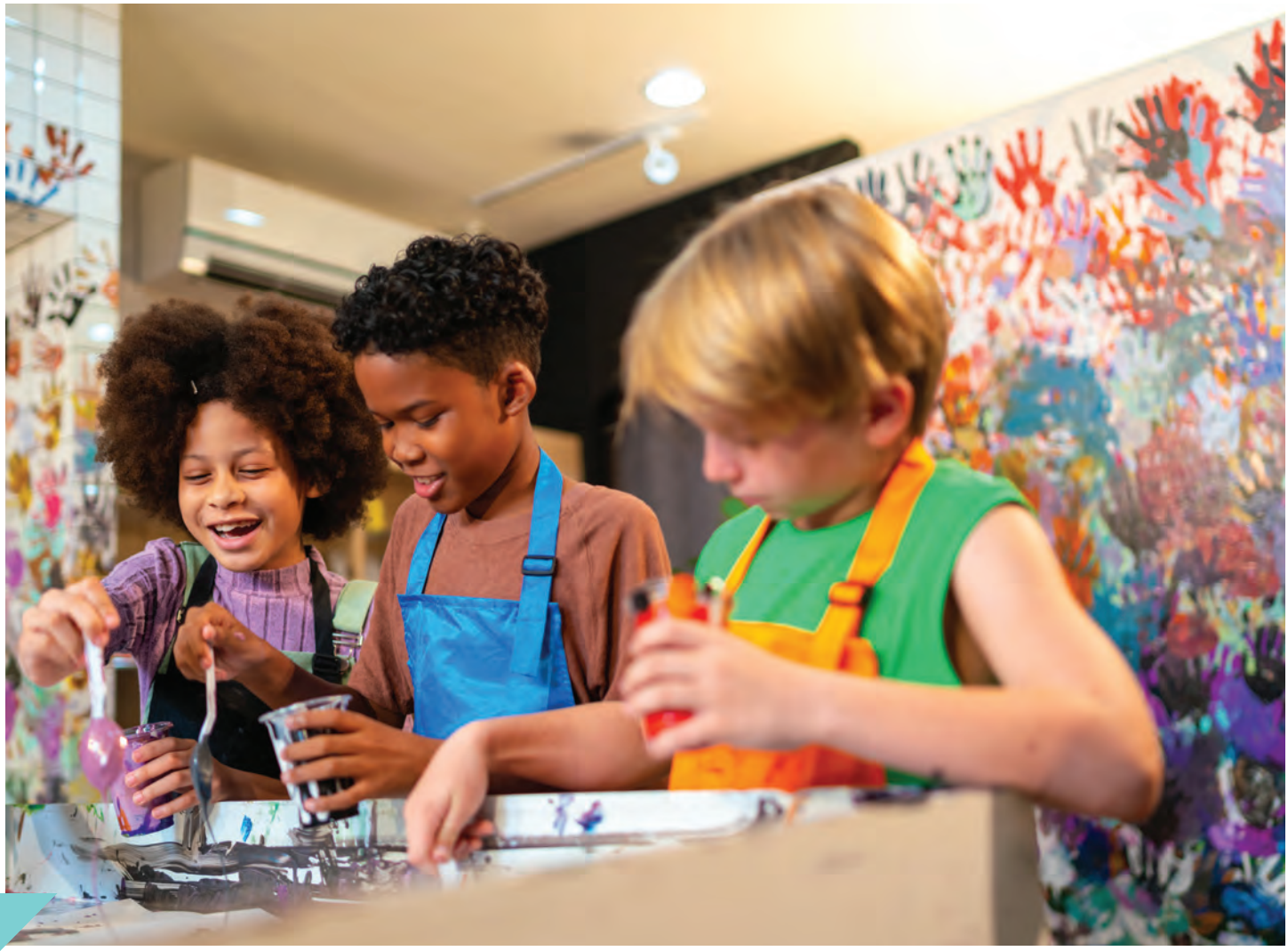
Large studies that have examined side effects and risks when used to treat seizures have found that, in general, VNS is relatively safe and well-tolerated.

Deep Brain Stimulation (DBS)

DBS has been studied and used since the 1960s. DBS treatment requires surgery to implant electrodes in the brain and a stimulator under the skin of the chest. DBS is used to treat Parkinson's disease (a disorder that affects movement) and essential tremor (a neurological condition that causes your hands to shake). DBS is an add-on treatment for hard-to-treat focal epilepsy. DBS has been used in some circumstances for OCD in adults and dystonia (involuntary muscle contractions that cause repetitive or twisting movements). There is research in progress that has been studying DBS in adults with very hard-to-treat depression. In children and adolescents, DBS is primarily used for dystonia. Patients with dystonia often have other mental health problems, but it is not known if DBS is helpful for mental health symptoms. The side effects and risks of DBS mainly relate to the initial surgical procedure and implanted hardware. These can include pain, brain swelling, infection, and seizures. Over time, patients with DBS can have dizziness, problems with focus, behavioral problems, and other types of changes in behavior.

Summary

While some research evidence about pediatric brain stimulation treatments is clear, there are still many unknowns. There is ongoing research focused on helping us learn more about these treatments. Most likely, doctors will have new ways of providing brain stimulation treatments in the future, such as customizing the treatment to each patient's own brain and symptoms. Brain stimulation treatments may also be combined with talk therapy and medications. More research evidence is needed and important to guide clinicians, parents, and patients.



Frequently Asked Questions

Brain stimulation treatments can be helpful, but the decision to use these in children and adolescents is complicated because there is not as much research on these treatments for children and adolescents as there is for adults.

What are brain stimulation treatments and are they the best treatment option for my child?

Brain stimulation is a type of treatment that uses magnetic fields or electricity to either directly or indirectly improve how the brain works. Most forms of brain stimulation treatments are noninvasive, meaning they do **not** require surgery. Brain stimulation treatments can be helpful, but the decision to use these in children and adolescents is complicated because there is not as much research on these treatments for children and adolescents as there is for adults. It is important to discuss your questions with your child's treatment team and to consider the pros and cons, side effects, risks, potential benefits, and practical factors such as the time and costs of treatment.

How do I know if brain stimulation treatments are safe and effective?

Some brain stimulation treatments or devices have been authorized by the FDA for certain disorders. The FDA gives authorization only after carefully reviewing studies showing that the device is safe, and then gives permission to companies to legally market a device for the "approved" diagnosis such as depression or ADHD. It is also important to talk to your treatment team about any research that could inform your decision. As with medications that are prescribed for children and adolescents, some brain stimulation treatments are used as an "off-label" treatment, meaning that even if those particular treatments have not been authorized by the FDA for the condition that your child has, the treatments are still available to doctors to prescribe if they feel they are the best treatment option for your child.

Table 1. Questions to Ask Your Child's Healthcare Team

- How has this treatment been studied in children or adolescents?
- How will we know that the treatment helps my child?
- Has the FDA reviewed this new treatment?
- Are there other treatments with more evidence?
- What are the risks and side effects of the treatment?
- How many child and adolescent patients have you treated with this? How many had no benefit with this treatment? How many had side effects from the treatment?
- What is the total cost of this treatment if it is not covered by our insurance?
- What are the chances of success of this treatment?
- If the treatment helps my child, will more treatments be needed in the future?
- What would you choose if your own child needed a treatment for this condition?

Are brain stimulation treatments covered by health insurance? What are the costs?

It is best to speak to your insurance carrier and treatment team about this before starting treatment. ECT is covered by insurance under certain circumstances. Your child's doctor will be able to provide you with the appropriate diagnosis and Current Procedural Terminology (CPT®) codes to use if you submit claims to your insurance plans.

Do patients continue with talk therapy and medication if they have brain stimulation treatments?

It is very important that you discuss your child's treatment plan with your child's doctor. In most cases, this will involve continuing talk therapy and medications during treatment with a brain stimulation therapy. In some cases, you may be asked to not give a medication on the day of treatment in order to improve its safety or positive effects. It is important to know

that if the brain stimulation treatment is helpful, the effects may last for only days, weeks, or months. More treatment with the brain stimulation or other treatments may be needed in the future.

What are the side effects and risks of brain stimulation treatments?

The side effects and risks vary with the form of the brain stimulation used. ECT requires anesthesia, so the risks of ECT involve the same risks of any surgery with anesthesia. It is important to have your child's physical health evaluated before starting treatment. With other forms of brain stimulation in which your child would be awake, there may be scalp pain or discomfort during the treatment. Other common side effects include headaches or fatigue after the treatments. Sometimes, more serious but rare side effects may include seizure and temporary confusion. If your child already has risk factors that increase the likelihood of side effects, your treatment team can work with you to help improve the safety and tolerability of the treatment for your child.

I did not know that electroconvulsive therapy (ECT) was still used. Is it really a good treatment for youth?

Yes, ECT is still used and can be very effective in the treatment of children and teenagers. Although ECT is more often used in adults, it often can be a very useful and life-saving treatment for patients under 18 years old who have severe depression, suicidal thoughts and behaviors, neuroleptic malignant syndrome (a life-threating reaction to antipsychotic drugs), or catatonia (a severe neurological disorder affecting movement and behavior) that does not improve with other treatments.

I heard that we could buy a home version of transcranial direct current stimulation (tDCS) on the internet. Is this a good idea?

Brain stimulation treatments for mental health symptoms should be administered and monitored only by an appropriately trained clinician and their healthcare treatment team. Administering brain stimulation treatments yourself without monitoring from a healthcare team could have many risks and side effects for your child.

Table 2. Summary of Brain Stimulation Treatments

Type of treatment	What it is used for	Side effects and risks
Electroconvulsive Therapy (ECT)	• Bipolar disorder, catatonia, and treatment-resistant depression (both unipolar and bipolar)	• Memory problems and headache • Risks related to general anesthesia
Transcranial Magnetic Stimulation (TMS)	• Major depressive disorder, anxiety, obsessive compulsive disorder (OCD)	• Discomfort, headache, dizziness • Rare (less than 1%) risk of brief seizure during treatment
Trigeminal Nerve Stimulation (TNS)	• Attention-deficit/hyperactivity disorder (ADHD)	• Skin rash or discoloration under the electrode site, and headache
Transcranial Electrical Stimulation (TES) Including: transcranial direct current stimulation (tDCS), transcranial alternating current stimulation (tACS), and transcranial random noise stimulation (tRNS)	• ADHD, anxiety, autism spectrum disorder, psychosis, and neurodevelopmental disorders	• Skin rash or discoloration under the electrode site, and headache
Vagus Nerve Stimulation (VNS)	• Intractable (hard to control) epilepsy • Partial-onset seizures that are hard to control with seizure medications • Off-label or investigational for psychiatric indications	• Coughing, hoarseness, voice change, neck pain, throat pain, throat itching, difficulty speaking, difficulty swallowing, headache, and worsening behavioral problems • Risks associated with anesthesia and surgery for implantation of stimulator under chest skin with connection to the vagus nerve in the neck
Deep Brain Stimulation (DBS)	• Hard-to-control dystonia for patients aged 7 years and older • Off-label or investigational for psychiatric indications	• Seizure, infection, headache, confusion, difficulty concentrating, stroke, complications with implanted device, pain and swelling at location of implantation, activation, and worsening behavioral problems • Risks associated with anesthesia and surgery with implantation of stimulator under chest skin with electrodes implanted in the brain

Links and Resources for Additional Information

- Ghaziuddin N, Kutcher SP, Knapp P, Bernet W, Arnold V, Beitchman J, Benson RS, Bukstein O, Kinlan J, McClellan J, Rue D, Shaw JA, Stock S, Kroeger Ptakowski K, AACAP Work Group on Quality Issues. Practice parameter for use of electroconvulsive therapy with adolescents. *Journal of the American Academy of Child & Adolescent Psychiatry* 2004 Dec;43(12):1521-39.
- McGough JJ, Sturm A, Cowen J, Tung K, Salgari GC, Leuchter AF, Cook IA, Sugar CA, Loo SK. Double-blind, sham-controlled, pilot study of trigeminal nerve stimulation for attention-deficit/hyperactivity disorder. *Journal of the American Academy of Child & Adolescent Psychiatry.* 2019 Apr 1;58(4):403-11.
- Michigan Medicine. ECT: Disrupting the Stigma Around an Essential Treatment Option. YouTube; February 24, 2022. Available from: https://www.youtube.com/watch?v=qk_FjhitKDI. Accessed May 24, 2024.
- National Alliance on Mental Illness. ECT, TMS and Other Brain Stimulation Therapies. https://www.nami.org/about-mental-illness/treatments/ect-tms-and-other-brain-stimulation-therapies/
- National Institute of Mental Health. Brain Stimulation Therapies. https://www.nimh.nih.gov/health/topics/brain-stimulation-therapies/brain-stimulation-therapies. Updated March 2024. Accessed May 24, 2024.
- U.S. Food & Drug Administration. FDA In Brief: FDA takes action to ensure regulation of electroconvulsive therapy devices better protects patients, reflect current understanding of safety and effectiveness. https://www.fda.gov/news-events/fda-brief/fda-brief-fda-takes-action-ensure-regulation-electroconvulsive-therapy-devices-better-protects. Published December 21, 2018. Accessed May 24, 2024.

Medication Tracking Form

Use this form to track your child's medication history. Bring this form to appointments with your clinician and update changes in medications, doses, side effects and results.

Date	Medication	Dose	Side Effects	Reason for keeping/stopping

Author Disclosures

ADRIAN JACQUES H. AMBROSE, MD, MPH, MBA
Chief Clinical Integration Officer, Department of Psychiatry
Senior Medical Director, ColumbiaDoctors
Columbia University Irving Medical Center

Advisor/Consultant: Johnson & Johnson

RAMAN BAWEJA, MD, MS
Professor
Penn State College of Medicine
Associate Chief, Child and Adolescent Psychiatry
Penn State Health

Advisor/Consultant: Ironshore

Research Funding: Cardinal Health Foundation

CHRISTINE CONELEA, PHD
Associate Professor
University of Minnesota

In-kind Services: Tourette Association of America

Research Funding: Minnesota Masonic Charities; Minnesota Robotics Institute; National Institute of Mental Health; National Institute of Neurological Disorders and Stroke; National Science Foundation

Science Advisory Board Member: Tourette Association of America

PAUL E. CROARKIN, DO, MS
Ervin A. and Margaret C. Mueller Director
Mayo Clinic Children's Research Center
Chair, Division of Pediatric Research, Department of Pediatric and Adolescent Medicine
Mayo Clinic

Advisor/Consultant: Engrail Therapeutics; Meta Platforms, Inc.; MindMed; Myriad; Procter & Gamble Company; Sunovion Pharmaceuticals, Inc.

In-kind Services: Neuronetics, Inc.; MagVenture, Inc.; Myriad

Research Funding: Innosphere; NeoSync, Inc.; Neuronetics, Inc.

NEERA GHAZIUDDIN, MD
Professor
Director, Pediatric Electroconvulsive Therapy Clinic
University of Michigan

No financial disclosures to report.

STEPHANIE HARTSELLE, MD
Chief Executive Officer
Hartselle and Associates
Clinical Associate Professor
Brown University

No financial disclosures to report.

ERNEST V. PEDAPATI, MD, MS
Associate Professor
Cincinnati Children's Hospital Medical Center
Associate Professor of Clinical-Affiliate
University of Cincinnati College of Medicine

Books, Intellectual Property: Springer

Honorarium: AACAP

Research Funding: National Institutes of Health; Tetra Therapeutics

ROBYN THOM, MD
Co-Director
Massachusetts General Hospital Williams Syndrome Program
Assistant Professor
Harvard Medical School

Books, Intellectual Property: Oxford University Press; Springer

Honorarium: AACAP; Neuroscience Education Institute; Society for Developmental and Behavioral Pediatrics

In-kind Services: Neuroscience Education Institute; Society for Developmental and Behavioral Pediatrics

Research Funding: AACAP; Jerome Lejeune Foundation; National Institute of Mental Health; Piton Therapeutics; Williams Syndrome Association

AMERICAN ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY

WWW.AACAP.ORG

3615 Wisconsin Avenue, NW | Washington, DC 20016-3007 | www.aacap.org