

# NeuroModulation Technique (NMT) Autism Study Announcement

## Purpose

1. The purpose of this study is to determine whether NeuroModulation Technique (NMT) is effective in reducing maladaptive behaviors and increasing adaptive behaviors in children diagnosed with autism.
2. Hypothesis: Children in the experimental group will show significant improvement over the control group as measured by the ATEC, ABC and the PDDBI. Children in the control group will show significant improvement over their baseline measures after receiving NMT treatment.

Study Type: Interventional treatment trial

Study Design: Treatment, Randomized, Wait-list Control

Phase I Study

Official Title: A Study of the Efficacy of NeuroModulation Technique with Children Diagnosed with Autism

Primary Outcomes: Global functioning

Expected Total Enrollment: 58

Study start: September 2007; Expected completion: December 2007

## Eligibility:

Fifty-eight male and female children between the ages of 5 through 10 years of age will be recruited from 24 different study sites in the United States, Canada and Mexico.

## Inclusion Criteria:

Qualified participants are those who have received a formal diagnosis of autism from a physician or psychologist using DSM-IV, DSM-IV-TR or ICD-9-CM diagnostic criteria. Parents and/or legal guardian must supply proof of autism diagnosis. Autism (DSM-IV, DSM-IV-R or ICD-9-CM 299.0) **must** be diagnosed – any other diagnosis such as Pervasive Developmental Disorder (PDD), Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) or Asperger Syndrome is **not** sufficient for inclusion in this study. Children must have had their diagnosis of autism for at least one year prior to the date of the application for participation in this study. Children must not have started any new therapies or stopped any ongoing therapies designed to treat their autism such behavior therapy, speech therapy, physical therapy, sensory integration, dietary modification or dietary supplementation, or any alternative or experimental therapies not mentioned in the 6 months prior to the date of the application for participation in this study. The purpose of this requirement is to ensure that improvement in autistic symptoms during the course of this study is not due to stopping a therapy that may have caused a worsening of symptoms in the child, and to make sure that improvement seen during the course of this study was not due to a therapy that was recently started prior to receiving NeuroModulation Technique. During the course of this study, children will be required to continue with any therapies they have been receiving prior to starting the study, and they will be required to not start any new therapies besides NeuroModulation Technique during the course of this study. Children in the study

will be allowed to make any medication changes during the course of the study if required by their treating pediatrician.

### **Exclusion Criteria:**

Excluded from participating will be children with any of the following medical conditions: cerebral palsy, Down's syndrome, traumatic brain injury, encephalitis, Lyme disease, cancer, any active infectious disease, endocrine disorder, other mental disorders such as psychotic disorders or other mood disorders including bipolar disorders, or any acute, chronic or unstable medical condition (such as a seizure disorder, Crohn's disease, asthma, bronchitis, etc.) other than autism for which the child has been receiving treatment, medication and/or therapy. Also excluded from the study are children who have or are undergoing chelation therapy, and children who have displayed significant self-injurious behavior (children who have caused visible harm to themselves.) Children with a history of mild to moderate food or airborne allergies, sensitivities, or mild digestive problems are eligible to participate in the study. If you are not sure whether or not your child is eligible due to a medical condition that is not listed above, please have your participating NMT researcher contact the Study Chair, Dr. Robert Weiner, to see if your child will qualify to be in the study.

In order to participate in the study, children must not have received any previous NeuroModulation Technique treatment.

Parents and/or legal guardians of children in the study must be fluent in English and complete all forms and questionnaires in English (for U.S. and Canadian research sites only).

Based on the clinical judgment of the researchers or Study Chair, parents and/or legal guardians may be asked to withdraw their children from the study should the child miss two or more NeuroModulation Technique sessions, or should the parents and/or legal guardians fail to complete in a timely manner (more than one week late) required symptom checklists or behavioral inventories. If a child misses an NMT session due to illness or any other reason, he or she must make up that session the same week or the following week.

### **Procedure:**

Parents and/or legal guardians who are interested in having their children participate in this study will contact an NMT research participant to receive an application to participate in the study. This application will include an application form, consent form including a videotape release, and the Autism Treatment Evaluation Checklist (ATEC). Parents will return these completed forms to the NMT research participant by a deadline specified in the application form. The names of all children at each research site who meet the selection criteria for the study will be placed in a selection pool. Two names will be drawn at random from this selection pool at each research site for inclusion in the study. The first child drawn from the selection pool ("Child 1") will receive 12 sessions of NMT, 2 sessions a week for 6 weeks. The second child drawn from this selection pool ("Child 2") will serve as the wait-list control, and will not receive any NMT until 2 weeks after the first child has completed his or her 12 NMT sessions. At this time, the second child will receive 12 sessions of NMT, 2 sessions a week for 6 weeks.

Week 1: Once two names are drawn from the selection pool, parents of Child 1 and Child 2 will complete the Symptom Questionnaire for Children (Part 1 & 2), ATEC, ABC and the PDDBI.

Week 2: Child 1 receives sessions 1 & 2 of NMT

Week 3: Child 1 receives sessions 3 & 4 of NMT

Week 4: Child 1 receives sessions 5 & 6 of NMT

Week 5: Parent of Child 1 completes the ATEC and the ABC prior to the start of session 7. Child 1 receives sessions 7 & 8 of NMT.

Week 6: Child 1 receives sessions 9 & 10 of NMT

Week 7: Child 1 receives sessions 11 & 12 of NMT

Week 8: Parent of Child 1 completes ATEC, ABC, PDDBI and Symptom Questionnaire for Children (Part 2). Parent of Child 2 completes ATEC, ABC, PDDBI and the Symptom Questionnaire for Children (Part 1 & 2).

Week 9: Child 2 receives sessions 1 & 2 of NMT.

Week 10: Child 2 receives sessions 3 & 4 of NMT.

Week 11: Child 2 receives sessions 5 & 6 of NMT.

Week 12: Parent of Child 2 completes ATEC and ABC prior to session 7. Child 2 receives sessions 7 & 8 of NMT.

Week 13: Child 2 receives sessions 9 & 10 of NMT

Week 14: Child 2 receives sessions 11 & 12 of NMT

Week 15: Parent of Child 2 completes ATEC, ABC, PDDBI, and Symptom Questionnaire for Children (Part 2).

## **Location and Contact Information**

### **CALIFORNIA**

1. Fresno, CA
22. Hemet, CA
10. Los Angeles, CA
14. Sacramento, CA
13. San Leandro, CA
15. Sherman Oaks, CA

### **COLORADO**

21. Greenwood Village, CO

### **IOWA**

16. Bettendorf, IA

## ILLINOIS

4. Evanston, IL
6. Peru, IL

## MARYLAND

2. Olney, MD

## NEW JERSEY

11. Bloomfield, NJ
3. Holmdel, NJ
5. Mountain Lakes, NJ

## NEW YORK

24. Brooklyn, NY

## OREGON

20. Eugene, OR
7. Hermiston, OR

## PENNSYLVANIA

18. Fountainville, PA
17. Lansdale, PA
9. West Chester, PA

## TEXAS

23. Dallas, TX

## WASHINGTON

12. Richland, WA

## CANADA

8. Ontario N1H 3Y2, Canada

## MEXICO

19. Naucalpan, Edo. Mexico

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### **Principal Investigator**

Roger L. Greene, Ph.D., Palo Alto, California

### **Study Chair**

Robert H. Weiner, Ph.D., Dallas, Texas

### **Additional Information**

<http://nmt.md/autismstudy/>