

Attention Training to Modify ERN and Risk for Anxiety in Adolescence

WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

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WHAT IS THE PURPOSE OF THIS RESEARCH:

You are being asked to allow your child to be a volunteer in a research study understand how your child's brain and body respond to thinking and feeling. Adolescence is a time when people begin to think and feel differently, and we are interested in understanding those changes.

Approximately 300 participants will be included at San Diego State University.

These are the reasons that you/your child might want to participate:
by participating you are you are helping to provide information which may benefit science and society.

These are the reasons you/your child might not want to participate:
You may get tired or uncomfortable from completing the questionnaires, performing the tasks, and thinking about sad memories. During the EEG recording, there is a small possibility of temporary mild skin irritation (redness) where the electrode contacts the skin. There may be some discomfort from wearing the EEG cap as it may put some pressure on the forehead or chin (chin strap).

HOW LONG WILL I BE IN THIS RESEARCH?

If you allow your child to be in this study, your child's participation will involve two lab visits, which will be separated by about two years. After your first visit, your child may be asked to complete some tasks at home on a computer or mobile device and return for another visit 8 weeks later. You can decide not to participate in the additional training or the second visit.

Each session will last approximately 4 hours on average.

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Approved
15-May-2018
Expires
14-Nov-2018

WHAT WILL HAPPEN IN THIS RESEARCH?

If you allow your child to be in this study, your child's participation will involve two lab visits, which will be separated by about two years. After your first visit, your child may be asked to complete some tasks at home on a computer or mobile device and return for another visit 8 weeks later. You can decide not to participate in the additional training or the second visit. At each lab visit, you will complete some/all of the following:

1. *Physiology Recording Session:* We will record you and your child's brain activity and muscle activity, while you are making decisions about things we show on a computer screen, playing some games on a computer, hearing sounds, or just looking at pictures. We record brain activity using an EEG. To do this, we will use a specialized lycra cap that contains 32 recording disks (electrodes) that you and your child will wear on your head. In order to record the brain's activity, these disks need to be filled with a gel, which helps the sensors accurately record brain activity at the scalp. Therefore, your hair may need to be cleaned after the task. The gel washes off completely and easily. Other recordings will be made using sensors around your left eye and behind your ear. All of these recordings are completely painless, non-intrusive, and safe. They are similar to heart rate recordings (i.e., electrocardiogram or EKG) that are typical during routine physical exams—the only exception is that EEG records electrical activity generated by the brain rather than the heart.
2. *Surveys:* Your child will be asked to fill out surveys or questions about his/her mood (for example screenings for child anxiety and depression), personality, development questions (e.g., hormonal questions), and relationships.
3. *Interview:* You and your child will participate in a comprehensive interview about each of your feelings, thoughts, activities, and relationships with others. We will also ask questions about the general well-being of your immediate family. We will also ask questions about the general well-being of your immediate family. With your permission and your child's assent, these interviews will be video or audio-taped to allow us to monitor the reliability of our ratings. You will be afforded the option to conduct these interviews either in our lab, or if more convenient for you, using a HIPPA-compliant video chat and telehealth platform (VSee; <https://vsee.com>). Please note that to use the latter option you will have to download VSee onto your computer. Those who are found to be at risk of suicide and who are referred to care will be withdrawn from the study by Dr. Amir as they no longer meet study eligibility criteria.
4. *Additional Training:* Your child may be asked to complete additional tasks at home following the initial visit. This training is computerized (i.e., like playing a game) and designed to change the way your child responds to threat. Your child would be asked to complete two (2) sessions per week for eight (8) weeks. She/he could be randomized to either an active or control condition; the difference is that in the active condition, the computer trains your child's attention away from threat—which has been shown to reduce anxiety in previous studies. If your child completes these exercises at home, they will be paid up to an additional \$100, plus \$5 for every 100 levels gained in the program, which is allotted as \$5 for every session (for all 16 sessions completed, this is \$80) and if your child completes all 16 training sessions, they will receive a bonus of \$20. If your child does this training, we would also ask that he or she come back for an additional lab visit afterwards. This visit will be much like the first—and you will get paid \$20 for each hour, plus a \$40 bonus for coming back.

Depending on how many of the tasks (listed above) your child is selected for and decides to participate in, the study will take approximately 4 hours on average. Your family will receive \$20 per hour for your participation, and will get frequent breaks.

During each visit, you (the parent) will be asked to fill out surveys about your child's mood, personality, development, and relationships while you are in the lab with your child. Participation in these tasks is voluntary. In addition, you will participate in an interview about your child's temperament, behavior, and adjustment. You will also answer some questions about yourself and your child's immediate family. With your permission, these interviews will be video or audio-taped to allow us to monitor the reliability of our ratings.

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	<i>All participants</i>	<i>Some participants</i>	<i>Some participants</i>	<i>All participants</i>
	<i>Visit 1 Day 1</i>	<i>At home sessions 2x per week for 8 weeks</i>	<i>Visit 2 8 weeks after initial visit</i>	<i>Visit 3 2 year follow-up</i>
<i>Questionnaires</i>	X		X	X
<i>Interview</i>	X		X	X
<i>Task completion and EEG recording</i>	X		X	X
<i>Computer Activities</i>		X		
<i>Total time</i>	<i>4 hours</i>	<i>20 minutes per session (5 hours, 20 minutes total)</i>	<i>4 hours</i>	<i>4 hours</i>

WHAT ARE THE RISKS OR DISCOMFORTS INVOLVED IN THE RESEARCH?

Potential risks include getting tired or uncomfortable from completing the questionnaires, performing the tasks, and thinking about sad memories. You and your child will be welcome to take short breaks between the various tasks. During the EEG recording, there is a small possibility of mild skin irritation (redness) where the electrode contacts the skin. However, this is rare and temporary. There may be some discomfort from wearing the EEG cap as it may put some pressure on the forehead or chin (chin strap).

There is a small chance that you or your child may feel uncomfortable answering questions about some aspects of your personal life. If you or your child prefer not to answer certain questions, you are both free not to do so.

There may be new findings developed during this research which may relate to your willingness to continue to have your child participate in this study. These new findings will be shared with you.

ARE THERE ANY BENEFITS TO PARTICIPATION?

There may be some potential benefit from receiving our prevention program that may help with the development of anxiety. Also, by participating you are helping to provide information which may benefit science and society.

ARE THERE ANY ALTERNATIVES TO PARTICIPATION?

An alternative is to not participate.

WILL MY INFORMATION BE PRIVATE?

Confidentiality will be maintained to the extent allowed by law. However, the study team members are required by California law to report suspected child or elder abuse to the appropriate authorities.

The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you.

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We will take steps to help make sure that all the information we get about your child, from your child, and from you is kept private. We will do this by not writing down your child's name, your name, or any identifying information except for a study code (i.e., your child's data and your data will be assigned a subject number) on the forms that contain information you or your child gives us for our study. The code can only be linked to your name with a list of code numbers and corresponding names that will be kept in the study computer and will be encrypted. If any papers and talks are given about this research, your child's name and your name will not be used.

We want to make sure that this study is being done correctly and that your child's rights and welfare are being protected. For this reason, we will share the data we get from him/her and you in this study with the study team, San Diego State University's Institutional Review Board, applicable Institutional officials, and certain federal offices. However, if your child tells us they are going to hurt him/herself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

This study requires that we collect very private information about you and your child. While you and your child are in this study we will get data about you and your child's health from some of the tests each of you will have done in this study. You have a right to privacy but the data we get about you and your child's health in this study can be shared with the people referenced above (the study team, the sponsor of this study, those who work for the sponsor, San Diego State University's Institutional Review Board, applicable institutional officials, and certain federal offices).

Your and your child's health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure you and your child's rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission. For example, the sponsor of this study, the National Institutes of Health, does not have to make the same promise under the law to protect your health data. However, they follow other policies that require all government officials to respect the privacy of research subjects.

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

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

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

You may decide now or later that you do not want to share your information with either NDA or with the researchers of the study. You can do this at any time by writing to Dr. Nader Amir. You may also choose not to share your information with NDA but continue sharing it with the researchers of this study. We will then contact

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NDA and they will stop sharing your data. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at <http://data-archive.nimh.gov>. If you choose not to share your information with the researchers of this study, we will stop collecting any new data from you and your child and will not use the data collected.

In a lawsuit, a judge can make us give him the information we collected about your child.

If your child is paid \$600 or more a year as a research subject, your child's social security number will be reported to those in charge of taxes. You may have to pay taxes on this money.

DO I HAVE TO PARTICIPATE?

You and your child do not have to participate in this research study. If you choose not to participate there is no penalty or loss of benefits to which you are otherwise entitled. Additionally, you and your child may choose to stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.

WILL I BE TOLD ABOUT THE STUDY RESULTS?

We will not contact you with results of this study after this study is completed.

There may be new findings developed during this research which may relate to your willingness to continue to participate in this study. These new findings will be shared with you.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no direct cost to participate. You may incur transportation-related costs in coming to the clinic.

WILL I BE PAID FOR MY PARTICIPATION IN THE RESEARCH?

Your family will receive \$20 an hour for participation in the study, at each visit. If you (the parent) choose to complete the EEG session during your visit, you will receive \$25. In addition, you and your child will receive between \$0.00 and \$10.00 based on your performance in the EEG guessing task. If your child is selected to complete additional tasks at home, your family will receive up to \$100 for completing the tasks plus \$5 for each 100 levels gained in the program. You will then be asked to return for the post- assessment, your family will also receive \$20/hour, a \$40 bonus for returning and money earned during the guessing task (\$0-\$10). If you participate in the second lab visit two years later, we will also give your family \$20/hour and a \$40 bonus for returning.

One of the tasks is a guessing game. In this game, you will be shown doors on the screen and asked to choose a door. There is money behind some doors, and there is nothing behind other doors. On this task you can make between \$0.00 and \$10.00, depending on how many correct guesses you make.

Conflict of interest: Dr Amir is a part owner of Cognitive Retraining Technologies, a company that markets anxiety relief products. Dr Amir has declared this COI to SDSU is COI committee who has plan in place to manage this COI.

WHAT IF I HAVE QUESTIONS REGARDING THIS STUDY?:

If you have any questions about the research now, please ask. If you have questions later about the research, you may contact Nader Amir, Ph.D. (619) 229-3740. If you have any questions about your rights as a participant in this study, or in the event of a research related injury, you may contact the Division of Research Affairs at San Diego State University (telephone: 619-594-6622; email: irb@mail.sdsu.edu). At any time during

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the research you can contact the IRB for questions about research rights, to discuss problems, concerns, or suggestions, or to offer input.

CONSENT TO PARTICIPATE:

The San Diego State University Institutional Review Board has approved this consent form, as signified by the Board's stamp. The consent form must be reviewed annually and expires on the date indicated on the stamp.

Your signature below indicates that you have read the information in this document and have had a chance to ask any questions you have about the study. Your signature also indicates that you agree for your child to be in the study and have been told that you can change your mind and withdraw your consent for your child to participate at any time. The investigator or a member of his/her research team has provided you with a copy of this consent form with information about who to contact in the event you have questions.

Child's Name (please print)

Name of Parent/Guardian of Participant (please print)

Signature of Parent/Guardian of Participant

Date

Signature of investigator/authorized study personnel

Date