

ASSENT

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Project Title: Attention Training to Modify ERN and Risk for Anxiety in Adolescence

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Who are we?

I am one of the Research Assistants that works here. You may also meet some other people such as Dr. Amir or other workers. We all work here at the Anxiety Clinic.

Why am I here?

Here at the Anxiety Clinic, we do studies and so that we can learn how to help people who are feeling nervous, scared, or sad to feel better. You are being asked to be in a research study.

These are the reasons that you might want to participate: Anxiety is a problem for many children and adults. Because of this, it's important to figure out what causes it and how it can be prevented. Your participation in this study will help us figure this out.

These are the reasons you might not want to participate: You might get upset answering questions that about your feelings, but if you are ever too uncomfortable to answer a question, you can decide not to. Some of the visits are long, and you might feel like the EEG preparation is uncomfortable - if you are ever feeling uncomfortable just let us know.

Purpose

The purpose of this study is to understand how your 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. Around 300 adolescents (ages 11 to 14) will be included in this study.

What will be done

If you agree to be in this study, we will ask that you come in for two lab visits, about two years apart. After your first visit, you may be asked to complete some tasks at home on a computer or a 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. *Recording Session:* We will record your behavior, 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 will ask you to wear a cap that contains recording disks filled with gel. 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 and safe. 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.

2. *Surveys*: You will be asked to fill out surveys about your how you feel, how you think, your body, and your relationships.
3. *Interview*: You will participate in an interview about your feelings, thoughts, activities, and relationships with others. With your permission, this interview will be video or audio-taped to allow us to monitor the reliability of our ratings.
4. *Additional Training*: You may be asked to complete additional tasks at home following your initial visit. This would be a computerized training, much like a video game. You would be asked to complete two (2) 20-minute sessions per week for eight (8) weeks. If you do this training, we would also ask that you come back for an additional lab visit afterwards. This visit will be much like the first.

Depending on how many of the tasks you are chosen for and want to complete, the study visit will take approximately 4 hours to complete.

Risks/ Discomforts

You may get tired or uncomfortable from doing the study. You are welcome to take short breaks. There is a small chance of getting mild skin irritation (redness) where the sensors contact the skin. However, this is rare and temporary. The EEG cap may feel uncomfortable on your head as it may put some pressure on your forehead or chin.

Do my parents know about this?

Please talk to your parents about this research study before you decide whether you want to do it. We will also ask your parents if it is all right with them for you to take part in this treatment. If your parents say that you can, you can still decide not to participate.

Benefits

There is no direct benefit to you, but we expect that people in general will benefit from more information about how the brain and body respond to thinking and feeling.

Costs to you

You will not have to pay anything to be in this study.

Payment to you

Your family will be paid \$20 an hour for your participation in this study. Also, you will be paid up to \$10.00 as a bonus based on your guesses in the guessing task (\$0-\$10). If you are selected to complete additional tasks at home, your family will receive \$100. You will then be asked to return for the post-assessment, for which your family will receive \$20/hour and money earned during the guessing task (\$0-\$10). If you participate in the second lab visit two years later, we will also give you a bonus of \$40, in addition to \$20/hour and money earned during the guessing task(\$0-\$10)..

Confidentiality

All the information we get from you will be kept private. We will not write down your name on our forms. All your responses, physical recordings, will only have your subject number on them, not your name. All papers and talks are given about this research, your name will not be used.

Your Rights

Taking part in this study is up to you. No one will be upset if you don't want to participate. If you decide to participate, you can also change your mind and stop any time you want.

Questions

You can ask me any questions that you have about this study and I will try to answer them for you. If you have questions that you think of later, you can call Dr. Amir at 619-229-3740.

If you have any questions about whether you have to be in this study, or about other things about this study that you don't want to talk over with your parents or the study director, you can contact the Division of Research Affairs San Diego State University (Telephone: 619-594-6622; email: irb@mail.sdsu.edu).

If you sign below, it means that you have read this form and you would like to be in this study.

Printed Name of Minor Subject

Signature of Minor subject

Date

Signature of investigator/authorized
study personnel

Date