

OFFICIAL TITLE OF STUDY: Attention Bias Modification Training for Child Anxiety CBT Nonresponders

NCT NUMBER: 01819311

DATE: 1-12-2017

PARENTAL CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Attention Bias Modification in Anxious Children

PURPOSE OF THE STUDY

You are being asked to give your permission for your child to be in a research study on a new treatment for childhood anxiety problems. This new treatment, which is administered via computer, has research evidence showing that it is effective in reducing anxiety in adults and in some children with anxiety. The purpose of this study is to examine whether this new treatment leads to reductions in anxiety among children who have already received “talk therapy” and continue to experience some symptoms of anxiety.

This study will compare the effects of the new computer treatment with the effects of a computer “placebo” task. The computer placebo task looks like the computer treatment, but it is not expected to produce large decreases in anxiety. This is a randomized, controlled trial. That means your child has a 50% chance of receiving the computer treatment and a 50% chance of receiving the computer placebo. Whether your child receives the computer treatment or the computer placebo will be decided by chance, as with flipping a coin. During the study, you, your child, and the researchers will not know whether your child is receiving the computer treatment or the computer placebo.

NUMBER OF STUDY PARTICIPANTS

If you agree for your child to participate, your child will be one of 70 children in this research study.

DURATION OF THE STUDY

This study consists of 11 visits to our clinic over a period of 12-14 weeks. After an initial evaluation, your child will be asked to attend two treatment visits a week until your child has completed eight treatment sessions. After that, you will come to the clinic for a post-treatment evaluation, and eight weeks later, you will come in for a final evaluation. The total time commitment for the entire study is about 16 hours.

PROCEDURES

Evaluation Visits (Visit #1 and Visit #10)

At the initial evaluation and then again at the post-treatment evaluation, we will interview you about how nervous or scared your child feels in various situations. We will ask you to complete two forms that asks questions about your child’s anxiety symptoms and one form that asks about any treatments your child has received for anxiety. Your child will also be interviewed about how nervous or scared he or she feels in various situations and will be asked to complete some forms about his or her anxiety and mood symptoms. The interviews, combined, will take about two hours, and the forms typically take parents and children about 15 minutes to complete. Your child also will complete a computer task that takes about 20 minutes to complete. These two visits will each take about four hours to complete.

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- In the computer task, your child will see faces and symbols on the computer screen. Your child will be asked to click different buttons on a mouse depending on what symbols appear on the screen. This task measures your child's attention to emotional expressions.

Treatment Visits (Visit #2 – Visit #9).

Your child will be given either the computer treatment or the computer placebo at Visits #2-#9. The treatment and the placebo computer tasks are very similar to the one your child will complete at the evaluation visits. Your child will view pictures of faces and symbols on a computer screen and will respond to them by clicking a mouse button as quickly as possible. The task takes about 20 minutes to complete. Your child will complete the same computer task at all eight treatment visits. Altogether, these eight visits will take about four hours.

Follow-Up Evaluation (Visit #11)

Eight weeks after Visit #10, you will come in for a Follow-Up Evaluation (Visit #11). At this visit, we will be conducting the same interviews and asking you and your child to complete the same forms and computer task as we asked you to complete during Visits #1 and #10. This visit will take about four hours.

Information obtained from all measures and tasks will be kept by the investigators of the study even if you and your child decide to stop coming to the treatment.

POTENTIAL RISKS AND/OR DISCOMFORTS

Your child may not feel comfortable answering some of the items on the questionnaires or during the interviews. He/she may skip any questions that he/she is not comfortable answering.

Although the treatment has been found to be effective in reducing anxiety problems in adults and in some children, the success of treatment cannot be guaranteed for any particular individual. If any new findings that may affect your child's willingness to continue in this study are developed during the time that he or she is in this study, you will be informed as soon as possible.

POTENTIAL BENEFITS

The computer treatment may help your child overcome or reduce problems with anxiety. Research suggests that the computer placebo also may help reduce problems with anxiety but that it may have a weaker effect than the computer treatment. At the end of the study, you and your child will be told whether he or she received the computer treatment or the computer placebo. If your child received the computer placebo, he or she will be offered computer treatment at that time and/or referral information for other types of treatment.

ALTERNATIVES

There are no known alternatives available to your child other than not taking part in this study.

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CONFIDENTIALITY

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any report we publish, we will not include information that will make it possible to identify you or to identify your child as a participant. Research records will be stored securely and only the research team will have access to the records. You should also be aware that we may need to release information about your child if: (1) he/she discloses that he/she intends to harm him/herself or others; (2) information is obtained revealing that your child is abused or neglected; or (3) we are ordered to do so by a judge. In such cases, parents will be informed and, if necessary, proper authorities will be contacted. Your child's records may also be reviewed for audit purposes by authorized University or other agents who will be bound by the same provisions of confidentiality.

COMPENSATION & COSTS

There is a cost for metered parking that you must pay at each visit. There are no other costs to participate in this study. As thanks for your participation in the assessments, you will receive a \$125 Target gift card for each of the three evaluation visits that you and your child complete (Visit #1, Visit #10, and Visit #11). In total, you will receive \$375 in Target gift cards if you complete all of the assessments in this study.

RIGHT TO DECLINE OR WITHDRAW

Your child's participation in this study is voluntary. You and your child are free to withdraw consent at any time during the study. A decision not to take part in this study or to stop being a part of this study will not affect any benefits to which your child is otherwise entitled. The investigators reserve the right to remove your child from the study without your consent at such time that they feel it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Jeremy W. Pettit, Ph.D., at Center for Children and Families, AHC I Rm 239, Florida International University, 11200 SW 8th Street, Miami, FL 33199, Phone: (305) 348-1671.

IRB CONTACT INFORMATION

If you would like to talk with someone about your child's rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

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PARENTAL CONSENT

I have read the information in this consent form and agree to allow my child to participate in this study.
I have had a chance to ask any questions I have about this study, and they have been answered for me. .
I understand that I will be given a copy of this form for my records.

Signature of Parent/Guardian

Date

Printed Name of Parent/ Guardian

Printed Name of Child Participant

Signature of Person Obtaining Consent

Date

ASSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Attention Bias Modification in Anxious Children

WHY ARE YOU DOING THIS STUDY?

We would like you to be in a research study. A research study is a way to learn information about something. Sometimes children who have received treatment at the Child Anxiety and Phobia Program continue to feel anxious and have fears. This study will look at a new computer task that may help such children with fears and anxieties.

HOW MANY OTHERS WILL BE IN THIS STUDY?

If your parent gives permission for you to participate and you agree to participate, you will be one of about 70 children in this research study.

HOW LONG WILL THE STUDY LAST?

If you decide to be in the study, you and your parent will come to our clinic 10 times over a period of four to six weeks and one more time eight weeks later to answer some interview questions, fill out four forms and do some tasks on a computer. The total time it will take to complete the entire study is about 16 hours.

WHAT WILL HAPPEN IN THIS STUDY?

At the first visit (#1), the visit after the eight computer tasks (Visit #10) and at the last visit (#11), we will be asking you questions about how nervous or scared you feel in certain situations. You will also fill out some short forms about your mood and anxious feelings. After that, you will do a computer task. The computer task is like a game. You will see pictures of faces and dots, and you will be asked to click a computer mouse to tell the direction in which the dots on the screen line up. In total, each of these two visits will last about one hour.

At the other visits (#2 - #9), you will complete a computer task like the game described above. There are two different computer tasks in this study, and you will complete only one of them. You might complete the computer task that has been found to help some children's problems with anxiety get better. We call this the treatment task. If you don't complete the treatment task, then you will complete a different computer task that we don't think helps anxiety get better. We call this the placebo task. The task you complete will be decided by flipping a coin, so you have an equal chance of completing the treatment task or the placebo task. The treatment task and the placebo task look almost the same, so nobody will know which task you are completing until the end of the study. In total, these eight visits will take about four hours.

CAN ANYTHING BAD HAPPEN TO ME?

A risk is a problem that might happen. A risk of this study is that you may feel funny or nervous answering some of the questions. You can skip any questions that make you feel uncomfortable and you can stop filling out forms at any time. You can also choose not to answer a question in an interview, and you can stop the interview at any time. Another risk is that all of your problems

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may not go away after you finish the treatment.

CAN ANYTHING GOOD HAPPEN TO ME?

A benefit is a good thing that might happen. A benefit of this study is that your problems with anxiety may get better. At the end of the study, we will tell you if you completed the treatment computer task or the placebo computer task. If you completed the placebo task, then we will allow you to complete the computer treatment task if you want to do it and if your parent wants for you to do it.

DO I HAVE OTHER CHOICES?

If you decide not to take part in this study, we will give you and your parent a list of other places that may help you with fears and anxieties.

WILL ANYONE KNOW I AM IN THE STUDY?

What you tell the people in this study will only be used to help you and other children with fears and anxieties. This means that what you tell people in this study is “secret.” The only times that what you tell people in this study will not be kept a “secret” is if you say that a) you want to hurt yourself or someone else and b) if someone else is hurting you. In cases like these, your parent will be told and, if necessary, others who will be able to help you will also be told.

WILL I BE GIVEN ANYTHING FOR PARTICIPATING?

There is a cost for metered parking that your parent must pay at each visit. There is no other cost to be in this study. As thanks for taking part in the interviews and computer task, your family will receive \$125 Target gift cards for each of these three visits that you complete. In total, your family will receive \$375 in Target gift cards if you complete all of the visits in this study.

WHAT IF I DO NOT WANT TO DO THIS?

You do not have to be in this study if you don’t want to and you can quit the study at any time. If you don’t like a question, you don’t have to answer it. No one will get mad at you if you decide you don’t want to participate.

WHO CAN I TALK TO ABOUT THE STUDY?

If you have any questions about this study now, or at any time, you may contact Dr. Jeremy Pettit. The phone number is 305-348-1671 and the email address is jpettit@fiu.edu. If you would like to talk with someone about your rights of being a participant in this research study, now, or at any time, you may contact the FIU Office of Research Integrity. The phone number is (305) 348-2494. The email address is ori@fiu.edu.

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PARTICIPANT AGREEMENT

You have read all of the information above. You have had a chance to ask any questions you have about this study, and they have been answered for you. You know what it means and you agree to take part in the study.

Signature of Participant (Child)

Date

Printed Name of Parent/ Guardian

Signature of Person Obtaining Consent

Date