UMASS CHAN MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: AlPHA Follow Up: Assessing VisuaL Perception in High Anxiety

STUDY00001087

Sponsor: National Institute of Mental Health K01 MH117290 NCT04187326

Investigator: E. Kale Edmiston, PhD

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Consent Version: Version 2

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

KEY INFORMATION

You are being invited to participate in a research study because you are between the ages of 18 and 30 years old and meet the inclusion criteria of this research study.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main question this study is trying to answer is how the brains of people with anxious personalities function. We will compare the brain function and behavior of people with anxious personalities with those of people without anxious personalities. We hope this will further our understanding of anxiety symptoms and inform new therapies.

You have already completed the first portion of this study. This additional portion consists of:

-one remote (web-based) visit, approximately 30 minutes

-a brief web-based survey approximately six months from today, approximately 15-20 minutes

If you join this research, you will be asked to complete some surveys as well as a computer-based task where we will ask you to look at faces and identify emotional expressions. The web-based surveys will include questions about your mood and emotions.

You may not want to be in this study if you are uncomfortable with:

-Sharing your private information with researchers

Risks: There is a risk of discomfort when answering questions about yourself. We will take steps to protect your personal information. However, there is a risk of breach of confidentiality. There may also be risks that we do not know yet. There is also a risk of boredom or frustration while completing the surveys or the task. You will be able to stop study procedures at any point if you choose to do so.

Benefits: You will receive no direct benefit from taking part in this research. The findings may, however, lead to better understanding of brain function and other contributors to psychiatric disorders. We hope that the results from this research study will help us to increase our knowledge and find better ways to diagnose and treat psychiatric disorders in the future.

STUDY DETAILS

Why is this research being done?
The primary purpose of this research is to gather scientific information about how people with anxiety process social and emotional information. We will compare the behavior of people with anxious personalities with those of people without anxious personalities. We hope this will further our understanding of anxiety symptoms and inform new therapies.

How many people will take part in this research?

About 16 people will take part here at UMass Chan Medical School.

How long will I be in this research?

You have already completed the first portion of this study. For this second portion, you will be in this research study for approximately six months. You will be asked to complete an additional web-based survey in approximately six months, as well as a brief phone call with a member of the study team. You will be randomly assigned to complete a behavioral task either at your six month post-scan appointment or at a 12-month post scan appointment. The web-based survey and phone call should take approximately 15-20 minutes, and up to 45 minutes to complete. The behavioral task will take approximately 30 minutes to complete.

What happens if I say yes, I want to be in this research?

If you agree to be in this second portion of the study, you will be asked to complete an additional web-based survey approximately 12 months after your scan visit. At either 6 months post scan or 12 months post scan, you will also complete a computer-based behavioral task remotely over Zoom with a member of the study team.

Web-Based Survey:
This survey includes questions about your current mood, as well as questions covering themes such as lifetime history of mood concerns, stressful events, and personality. These measures will be sent to you via a secure, web-based form that you will receive via email or text. You will also be scheduled for a brief telephone call with a member of the study team to update any changes to your medication usage reported at your first visit in the earlier portion of the study.

Behavioral Task:
This computer task will ask you to look at pictures of faces and identify emotions. It includes a brief pre-test, training, and then a post-test.

Will you be collecting any specimens from me?
We will not be collecting any speciments from you.

Could being in this research hurt me?
You may feel emotional discomfort (e.g., embarrassment or anxiety) because of the surveys. You may stop the survey at any time if you feel uncomfortable.

Risks of Confidentiality: Please be aware that even with all procedures in place to prevent it, there is still a risk of breach of confidentiality. We will follow strict procedures for record keeping to maintain information that is related to you as private as possible.

Will I be given any money or other compensation for being in this study?

You may be paid up to a total of $35. Your compensation will be broken down as follows:

- You will receive $15 for completing the behavioral task, and $20 for completing the second survey. Compensation will be provided in the form of a gift card issued by a major bank.
- In order to receive a stipend for study participation, you will need to give us private information like your name, address and phone number. We will then share this information with the business offices and companies that need it to process the payment. Once this information is provided to the business office – it will be destroyed by the study personnel.

You will need to provide your social security number and complete a W-9 (tax form) if you receive:

- $300 or more from a single study within a single calendar year at Umass Chan, or
- $600 or more in a calendar year across multiple research studies at Umass Chan.

The Medical School may report the payment to the IRS and send you a 1099 form for tax purposes. The business offices and companies will keep the information as part of their financial records. The research team will destroy this information no later than six years after study closure.

What happens if I am injured because I took part in this research?

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

The Umass Chan Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

What are my responsibilities if I take part in this research?

If you take part in the research, it is important for your safety that you:

- Follow the directions of the study doctor and research staff.
- Call the study doctor or staff at (508) 856-2998 if you have any questions.
- Do not consume unprescribed drugs or alcohol prior to each study phone call or remote visit.

What happens if I say yes, but I change my mind later?

You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research.

However, you can ask us to destroy any information that identifies you so that no one can tell the data belonged to you. Our contact information is below.

Can I be removed from the research without my approval?
It is possible that you may be removed from the research study by the researchers if, at any point, you meet exclusion criteria (e.g.: you have a chronic medical condition). You may also be removed from this study if you do not meet, or you no longer meet, the inclusion criteria (e.g., your present state makes your participation unhealthy for you such as being too anxious, depressed, etc.). There are also times when you could be removed from the study owing to your own actions, whether overt, aggressive, or passive in terms of study participation or with study staff, including being dishonest in reporting, actively threatening, or non-compliant with study procedures. If you are removed from participation in this study at any point, all usable data previously collected will be retained.

How will my information be stored and when will it be destroyed?

We will remove your name and any other information that could directly identify you from your data. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data.

We will keep paper documents under lock and key. We will keep research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data. We will destroy the master list of identifiers six years after the completion of the study, which is the minimum retention period for the consents.

It is possible that we might use the research data in other future research. We may also share data with researchers that are not part of Umass Chan Medical School. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for yourconsent.

Who has access to my information?
Your research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with

- The research sponsor
- Federal and state government agencies, such as state auditors
- The UMass Chan Medical School, including its Institutional Review Board (IRB) and research, billing, and compliance offices
- People and companies who work with UMass Chan on activities related to the research

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy. In unusual cases, the investigators may have to release identifiable information related to your participation in this research study in response to an order from a court of law. We are also legally required to disclose information about child abuse, abuse of the elderly or disabled, and you potentially harming yourself or others. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they have to inform the appropriate agencies, as required by Massachusetts law.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. Secondary investigators (those not directly involved in the conduct of this study) may have access to data to aid in study analyses, and for other research related to various disorders. Data released to secondary investigators will be released in format that does not readily identify you (i.e., without your name, address, etc.).

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing your identifiable sensitive information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify you, as part of a court, legislative, administrative, or other proceeding.

Identifiable sensitive information includes specimens gathered during the research if there is a small risk of being able to identify you from those specimens, if they are combined with other information.

There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or Food and Drug Administration (FDA). The Certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

Will you share any results with me?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
  You want to get information or provide input about this research.

Signature Block

Your signature documents your permission for you to take part in this research.

Printed Name of Research Participant	
Signature of Research Participant	Date
Printed Name of Person obtaining consent	
Signature of Person obtaining consent	Date