Plain Language Statement

Department of Psychiatry, Faculty of Medicine, Dentistry and Health Sciences

Project: *The Emotional Learning and Memory (ELM) Study*

A/Prof Sarah Whittle (Responsible Researcher)
Tel: +61 3 83441958 Email: swhittle@unimelb.edu.au
Isabel Zwaan (PhD Student) Email: iszwaan@student.unimelb.edu.au
Sarah Manuele (PhD Student) Email: smanuele@student.unimelb.edu.au

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Introduction

Thank you for your interest in participating in this research project. The following pages will provide you with further information about the project, so that you can decide if you would like to take part.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time.

What is this research about?

Anxiety disorders are widespread and can be extremely debilitating. They are most likely to begin in childhood and adolescence, when significant changes in development and the brain occur. So, it is important to understand how individual differences in development and brain function might increase risk for anxiety, and especially in young people.

The Emotional Learning and Memory (ELM) study is investigating relationships between anxiety and brain function during emotional learning in three age groups: children, adolescents, and adults. We will also look at how developmental hormones influence brain function and emotional learning in these groups. We are also interested in the role of family environment in affecting anxiety in young people. This research will allow us to learn more about age differences in the expression of anxiety and will help create better interventions for people with anxiety disorders.

The three age groups we aim to include in the study are the following:

- Children: aged 8-10 years old
- Adolescents: aged 14-16 years old

- **Adults: aged 25-35**

What will I be asked to do?

First, we will discuss the study with you on the phone, and answer any questions you might have. If you agree to take part, we will record your consent on the phone, and then conduct a short screening interview with you, to make sure you are eligible. We may also ask some questions about your recent health, testing, isolation and any possible exposure to someone with COVID-19. We will ask about your health, behaviour, and height and weight. Because we wish to match diversity across our different groups, we will collect some basic demographic information about you, including age, gender, and the country where you and your parents were born. Based on age, gender and/or background, it is possible that you may not be able to take part in the study once certain numbers of participants in a particular group have been reached.

The rest of the study is made up of:
1) Tasks and interview to be done at home,
2) A visit to the University of Melbourne, and
3) A visit to the Royal Children's Hospital for a Magnetic Resonance Imaging (MRI) scan, on the day after your first visit.

When arranging the visits, we will try to schedule them at times that are convenient for you. We have included some information about the MRI scan below, as well as an explanation of the other components of the study. Should you agree to participate, we would ask you to do the following:

1. Tasks and interview at home

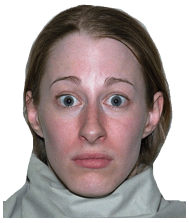
We will send you some questionnaires (via email) to do before we see you for your first appointment. If you have time to do this before you arrive this will make things go faster on the day. Questionnaires can be completed online, on a smartphone, tablet, or laptop, or we can send you paper copies if you prefer. This will take about 20 minutes of your time.

Within one week preceding your First Visit, we will ask you to participate in a short online interview (via Zoom, Webex, or phone) about your current and previous mental health. The interview will take about 30 minutes and is part of determining your eligibility for the study. It is possible that you may not be eligible to complete the rest of the study after this interview, however the initial telephone screening interview will make this unlikely. If that is the case, you will receive compensation for your time. You are still welcome to receive regular study updates if you are interested.

2. First Visit (University of Melbourne)

We will invite you to come to the Alan Gilbert building (Melbourne Neuropsychiatry Centre, Level 3, 161 Barry St, Carlton) at the University of Melbourne. This visit is expected to take around 1.5 hours of your time.

At this visit, we will first ask you to take part in a computer task. During this task, you will see faces displaying different expressions. We have included examples of these faces below. You will also sometimes hear short (1 second) scream sounds. Examples of faces:



We will attach a finger monitor, as this will allow us to measure your level of skin conductance (sweating) as a way of telling us how much you respond to the task. The task will take about 20 minutes in total, and we will give you a short break halfway through.

After the task, we will ask you to complete some questions that ask about anxiety, relationships and life experiences, and some thinking tasks. We will also measure your height and weight.

3. Second Visit (Royal Children's Hospital)

For the second visit, we will invite you to come to the Royal Children's Hospital. This visit is expected to take about 2 hours of your time.
During this visit, we will conduct an MRI scan of your brain while you lie in the scanner. In the MRI scanner, you will do a similar task as on the first day of the study, and we will again measure your skin conductance using a finger monitor. The scan will take approximately 30 minutes. If you are feeling nervous before going into the MRI, we will offer to show you a 'mock' scanner, which is a type of practice scanner where you can experience the sights and sounds of the MRI before the actual scan. We can send you a picture of your brain in the weeks following the MRI scan if you would like! Please note that this should not be used for medical purposes.

> What is an MRI Scan?
> MRI stands for magnetic resonance imaging. An MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. This means that MRI is very safe, and it should have no negative impact on your health. The pictures taken by the machine are called MRI scans. It is important for you to lie very still in the scanner, so that the pictures turn out sharp and not blurry.

Outside of the MRI scanner, we will ask you to complete some more questionnaires. These additional questionnaires cover topics such as your mood over the past few weeks.

4. Follow-up online survey

About a week after participating in the study, we will send you an online survey with a few questions about your experience in relation to the study. The survey will help us to monitor and improve our processes, and we would appreciate your feedback. For female participants, about one month after participating, we will send you a quick survey to ask you about your recent menstrual cycle.

What are the possible benefits?

There will be no direct benefit to you from participation in this research. However, the study will lead to a better understanding of brain function associated with emotional learning and memory in children, adolescents, and adults. This information may assist in the treatment of anxiety disorders for people in the future.

Inconveniences

You will be reimbursed for your time and travel expenses at $20 per hour at the end of each visit, with Coles/Myer gift vouchers. We can also reimburse parking costs for the visits. We estimate that participation will take approximately 4 hours, for which you would receive $80.

What are the possible risks?

MRI scan:

To date, there are no known long-term health risks associated with MRI scans. Undergoing an MRI scan is considered a safe procedure when performed at a centre with appropriate guidelines, such as The Royal Children's Hospital.

The MRI scanner has a strong magnet. The magnetic attraction for some metal objects can pose a safety risk. It is important that metal objects are removed and not taken into the scanner room. You must tell us if you have metal implanted in your body, such as a pacemaker or metal pins after being involved in an accident. We will ask you about metal implants multiple times before you go into the MRI scanner.

While it is operating, the scanner can be noisy. We will give you earphones to protect your ears against this noise. The scanner is shaped like a long tube, which may cause some people to feel cramped. Please let us know if you do not like confined spaces. Some people can feel anxious during the scan. If you feel anxious it is important that you let us know so that we can stop the scan immediately.

Emotional learning task:

This task has been used safely with children, adolescents and adults. However, the stimuli that you will see and hear during this task (on day 1 and 2) may be unpleasant. If you feel distressed during the task, you can let someone from the research team know at any point, and by doing so you can stop and either have a break or cease the task.

Questionnaires and interview:

You should be aware that some of the questions we will ask cover sensitive topics and could therefore cause distress. Our research team has lots of experience with the questionnaires and the interview used in this study. However, please note that you do not have to answer any questions you do not want to. If you feel distressed after completing the interview or the questionnaires, you should let someone from the research team know. You can also contact the principal investigators – their numbers are listed at the end of this document.

If you are experiencing emotional or mental health difficulties our research team is trained in this area and will discuss support options with you and help provide referrals to an appropriate clinical service, with your permission. For example, you could call Lifeline (13 11 14) or make an appointment with your GP.

Possible discovery of unexpected findings

MRI:

The brain scans conducted are for research purposes only. This means they are not designed to help diagnose, treat, or manage a particular medical condition. Very occasionally (in approximately 2% of cases), MRI images reveal unexpected things. Most of these findings have no negative implications for health. However, in some cases, the unexpected finding may represent a genuine health risk. In many instances, there are effective treatments available, but sometimes there are unexpected findings for which no effective treatment is currently available.

If your MRI images reveal an unexpected finding that may impact your health, as assessed by a clinical radiologist and neurosurgeon, you will be contacted. We will contact you immediately in the case of an urgent finding, and within two months for a non-urgent finding.

The discovery of a genuine health risk in these images could have consequences for you and may affect your ability to work in certain professions or get new life or other insurance cover. However, the discovery of a health risk may also help you get treatment.

If the radiologist identifies something that needs further examination, a referral to a local neurosurgeon will be made. The initial appointment with the neurosurgeon is free of charge, however, if any further appointments are required, you will need to discuss payment options with the neurosurgeon (including Medicare rebates, healthcare card discounts, etc.).

Please take time to consider the advantages and disadvantages of discovery of a health risk before deciding to take part in this research project. Please let us know if you have any questions or would like anything clarified.

Questionnaires:

One of the questions we will ask you is if you have (or someone close to you has) been a victim of crime, violence, or assault. We are asking this question because such experiences might influence brain function. *Please note that we are legally obligated to*

report suspected cases of child abuse or other situations that pose a risk to you or others. Please take the time to consider this before deciding whether you would like to answer these questions, or consent to take part in this research project.

Do I have to take part?

No. Participation in this research project is voluntary. It is your choice to take part in this research. You do not have to agree to participate if you do not want to, and you are able to withdraw at any time.

If you give your consent and change your mind, you can withdraw from the project. You do not need to tell us the reason why you want to stop. If you leave the project, we will use any information already collected unless you tell us not to.

Your decision will not affect your relationship with The University of Melbourne or the Royal Children's Hospital.

Will I hear about the results of this project?

Yes. We will send regular study newsletters to keep you updated of the study progress, as well as the results once the study is complete. Results from the study will be reported in journal articles, conference papers, and will also be made available to media outlets. No identifying or individual information will appear in any of this material. You can also contact one of the investigators listed at the end of this document to obtain a written plain English summary of the results of the study.

What will happen to information about me?

Any information obtained in connection with this research project that can identify you will remain confidential and securely stored. It will only be used for the purposes stated in this document, and will only be disclosed with your permission, except as required by law.

Information collected from you as part of this research study will be stored in locked filing cabinets at the Melbourne Neuropsychiatry Centre (MNC), Department of Psychiatry, The University of Melbourne, accessible only to the investigators involved in this research project. Data from the online questionnaires will be stored on a secure, electronic server on Qualtrics Premium, will regularly be downloaded as electronic data to save on the University servers, and then removed from the online Qualtrics server. Electronic data will be stored on a secure, password-protected server hosted by the University accessible only to the investigators involved in this research project. MRI images will be stored on a secure online database accessible only to the investigators involved in this research project, and then downloaded to the previously mentioned server.

All information you provide will be re-identifiable. This means that we will remove your name and other identifying details and give the information an identification number. Only the research team can match your details to the identification number, if it is

necessary to do so (for example, in case of a clinical issue arising where we needed to contact you, or if you contacted us to say you wanted your data removed from the study).

We will keep the information until 15 years after the last publication based on the data. The information you provide may be used in future projects that are closely related to this project, or in the same general area of research as this project. Any such projects would require approval from the relevant ethics committees, and your confidentiality would be maintained.

We plan to publish the results of this study. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access this information.

Data sharing

To advance science, medicine and public health, we may also need to share your **de-identified** data with other ethically approved research projects, databanks or biobanks, or medical journals. If we need to do this, we will de-identify your data before we share it. This means we will remove personal information such as your name, date of birth, and anything else that could identify you. We will only share the data from the specific measures you completed, such as questionnaires, MRI data, and task responses.

We will put security measures in place to protect your data if and when we give it to other people. We will send data using a secure application, encrypting the data while on that service and also while it is being transmitted online. This data will then be deleted from the service after it has been obtained by the people we share it with, or by a set expiry time.

Despite our best efforts, there is a small chance that you could be re-identified. In the unlikely event that this happens, someone from the research team will contact you. If, at any point, you think that you may have been re-identified, please let us know.

Who is funding this project?

This study is funded by the National Health and Medical Research Council (grant number: APP1163499).

Where can I get further information?

If you would like more information about the project, or if you need to speak to a member of the research team in an emergency, please contact:

Study email: elm-study@unimelb.edu.au
Study phone number: +61383443428

Name: A/Prof Sarah Whittle, telephone: 8344 1958, email: swhittle@unimelb.edu.au

Name: Dr Julian Simmons, telephone: 9035 8318, email: jgs@unimelb.edu.au

Who can I contact if I have any concerns about the project?

This research project has been approved by the Royal Children's Hospital Human Research Ethics Committee. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Director, Research Ethics and Governance
Tel: 03 9345 5044 Email: rch.ethics@rch.org.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.

Consent Form

Department of Psychiatry, Faculty of Medicine, and Health Sciences

The ELM Study

THE UNIVERSITY OF MELBOURNE

The Emotional Learning and Memory (ELM) Study

Responsible Researcher: A/Prof Sarah Whittle

Additional Researchers: Dr. Julian Simmons (Investigator), Dr Despina Ganella (Investigator), Dr Orli Schwartz (Investigator), A/Prof Benjamin Harrison (Associate Investigator), A/Prof Jee Hyun Kim (Associate Investigator), Prof Kim Felmingham (Associate Investigator), Isabel Zwaan (PhD Student), Sarah Manuele (PhD Student), Elena Pozzi (Research Assistant), Katherine Bray (Research Assistant)

Name of Participant: _____

1. I consent to participate in this project, the details of which have been explained to me, and I have been provided with a written plain language statement to keep.
2. I understand that the purpose of this research is to investigate relationships between anxiety and brain function during emotional learning in three age groups: children, adolescents, and adults. I understand that my participation in this project is for research purposes only.
3. I acknowledge that the possible effects of participating in this research project have been explained to my satisfaction.
4. In this project I will be required to complete several questionnaires, participate in an emotional learning task, participate in an MRI scan of my brain, have my body measurements collected, and complete several thinking tasks.
5. I have been given information regarding the possibility of incidental/adverse findings being identified as a result of the MRI scans, and consent to be notified of these.
6. I understand that my participation is voluntary and that I am free to withdraw from this project anytime without explanation or prejudice and to withdraw any unprocessed data that I have provided.
7. I understand that the data from this research will be stored at the University of Melbourne and will be destroyed 15 years after the last publication generated from this study.
8. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements;
9. I understand that my data will be password protected and accessible only by the named researchers.

10. I understand that after I sign and return this consent form, it will be retained by the researcher.

Participant Signature: _____ **Date:** _____

Optional:

1. I consent to my de-identified data being used in the future with other ethically approved research projects, databanks or biobanks, and medical journals.

Participant Signature: _____ **Date:** _____