

Plain Language Statement

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

Project: The Emotional Learning and Memory (ELM) Study

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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 for you and your child to take part in this research.

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. If you are interested, we would like you to discuss the project with your child. We will provide them with a separate document to read.

Please note that participation for you and your child is voluntary. If either of you don't want to take part, you don't have to. If you begin participating, and then either of you change your mind, you can stop at any time.

What is this research about?

Anxiety disorders are widespread and can significantly impact quality of life. 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. 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 we be asked to do?

First, we will discuss the study with you and your child, and answer any questions you might have on the phone. If you both agree to take part, we will record your consent on the phone, and then conduct a short screening interview with your child, to make sure they are eligible. We will ask about their health, behaviour, and height and weight.

Because we wish to match diversity across our different groups, we will collect some basic demographic information about your child, including age, gender, and the country where they and their parents were born. Based on age, gender and/or background, it is possible that your child 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 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 both. We have included some information about the MRI scan below, as well as an explanation of the other components of the study. Should you both agree to participate, we would ask your child to do the following:

1. Tasks at home

We will send you both some questionnaires. If you have time to do these before you arrive, this will make things go faster on the day. Questions can be answered on a smartphone, tablet, or laptop, or we can send paper copies if you prefer. These questions will take about 20 minutes to complete.

We will also ask your child to provide saliva samples.

For biologically female children: this will consist of five samples at wake, taken over the course of four weeks before your child's visits. We will ask for the first sample exactly three, two, and one weeks before the MRI visit, as well as the morning of both visits. For example, if your child's MRI (second) visit is scheduled on a Saturday, we would like for your child to collect samples for the three Saturday mornings before their first visit, as well as on the mornings of the visits.

For biologically male children: this will consist of three samples at wake, taken over the course of one week before your child's visits. We will ask for the first sample exactly one week before the MRI visit, as well as the morning of both visits. For example, if your child's MRI (second) visit is scheduled on a Saturday, we would like for your child to collect a sample on the Saturday morning before their visits, as well as on the mornings of the visits.

We will write down the dates your child should collect saliva on an instruction sheet, and send you text message reminders, so that it's easy for you both to remember when to collect the samples. Samples should be collected when your child first wakes up and we'd like you to write down the time it was collected. Each sample will take approximately 10 minutes of your child's time. We'll provide collection tubes, gloves, and storage bags to make this as clean as possible, and we will send out this collection kit in the mail beforehand.

2. First Visit (University of Melbourne)

We will invite you both 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 about 2 hours of your time.

At this visit, we will first ask your child to participate in a short interview about their mental health, now and in the past. The interview will take about 30 minutes and is part of determining your child's eligibility for the study. It is possible that your child may not be eligible to complete the rest of the study after this interview, however the telephone screening interview will make this unlikely. If your child is ineligible after the interview, you and your child will receive compensation for your time, and you are still able to receive regular study updates, if you would like.

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



We will attach a finger monitor to their non-dominant hand, which will allow us to measure the level of skin conductance (sweating) as a way of telling us how much they respond to the task. The task will take about 20 minutes in total, and we will give them a short break halfway through.

After the task, we will measure your child's height and weight, and collect a small hair sample (this is described in detail below). We will then ask your child to complete a few questionnaires that ask about anxiety, relationships and life experiences and some thinking tasks.

Why are we asking for some of your child's hair? This is so we can measure the levels of various hormones over the past months. We only need to collect a very small hair sample, which is less than 1/10th of a gram (lighter than a small feather!). We will cut it in a way that should not alter your child's hairstyle or appearance.

3. Second Visit (Royal Children's Hospital)

For the second visit, the day after the first, we will invite you and your child 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 child's brain while they lie in the scanner. In the MRI scanner, they will do a similar task as on the first day of the study, and we will again measure their skin conductance using a finger monitor. They will also do a short task that involves thinking about themselves and a close friend. The scan will take approximately 45 minutes.

If your child is feeling nervous, or would just prefer, we will show you both a 'mock' scanner before going into the MRI, 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 your child a picture of their brain in the weeks following the MRI scan if they 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 child's health. The pictures taken by the machine are called MRI scans. It is important for your child 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 your child to complete some more questionnaires. These additional questionnaires cover topics such as their mood over the past few weeks.

Parent/Guardian involvement:

We will also ask you to be involved by filling in a few questionnaires. These questionnaires ask about your child's pubertal development, their life experiences, your own mental health and your family's demographics. You will be able to complete these questionnaires at your child's appointments, on a tablet or a laptop that we will provide,

or on your own internet accessible device. This should take approximately 1 hour of your time. We will also give you the option of completing several of the questionnaires prior to the visits on your own internet accessible device.

4. Follow-up online survey

About a week after participating in the study, we will send you an online survey with a few questions for you and for your child, 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. If your child has begun their menstrual cycle, about one month after participating, we will send them a quick survey to ask them about their recent menstrual cycle.

What are the possible benefits?

There will be no direct benefit to you or your child 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 both 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 provide parking vouchers for the visits.

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 your child has metal implanted in their body, such as a pacemaker or metal pins after being involved in an accident. We will ask you about metal implants multiple times before your child goes into the MRI scanner.

While it is operating, the scanner can be noisy. We will give your child earphones to protect their 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 your child does not like confined spaces. Some people can feel anxious during the scan. If your child feels anxious it is important that they 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 your child will see and hear during this task (on day 1 and 2) may be unpleasant. If your child feels distressed during the task, they can let someone from the research team know at any point, and by doing so they can 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 types of questionnaires and interviews used in this study. However, please note that you and your child do not have to answer any questions you do not want to. If you or your child 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 or your child 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 general medical practitioner (GP). If your child raises emotional or mental health difficulties with us, we will first discuss it with them, and discuss support options. We will recommend that they inform you, or let us do so. However, in consideration of their age, we will not pass this information on to you without their consent. The exception to this is if they or someone else is at risk of harm.

Saliva samples:

Collecting the saliva samples at home poses a small risk if someone else was to come in contact with your child's saliva and they were unwell, as there is a small risk of infection. This risk would be similar to sharing a cup or kissing. We will provide gloves and instructions on how to minimise this risk, such as not touching things until they have washed your hands. Please let us know if your child is unwell and we can determine if the collection should proceed.

Hair Samples:

Collecting the hair sample might make your child feel uncomfortable or concerned about impact on their appearance. We have lots of experience collecting these samples, and we are experienced in removing a small amount of hair in a way that won't impact their appearance. We can show them before and after photos from other participants. We'll also discuss with you both if your child's hair is too short and it will be visible. If they do not want to provide a hair sample, they do not have to.

Other measures:

We will also collect several measurements of your child's body. When we measure height, weight, and waist circumference, we will follow a well-established protocol. The measurements will be taken while you are present in the room, they can be taken while

your child is fully-clothed, and a male or female researcher can be requested if that would make your child feel more comfortable.

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 child's MRI images reveal an unexpected finding that may impact their 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 your child and may affect your child's ability to work in certain professions or get life or other insurance cover. However, the discovery of a health risk may also help your child get treatment.

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

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

Saliva and Hair samples:

The saliva and hair samples may reveal the presence of health concerns such as endocrine or immune anomalies. In circumstances where health concerns are indicated, results will be reviewed and, where required, you will be contacted and advised to seek medical follow up with your child's preferred GP. Please note that these results will not become available until the end of the study. Please speak with your child's GP if they have current health concerns.

Questionnaires:

One of the questions we will ask is if you or your child have (or someone close to them 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, your child, 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 my child and I have to take part?

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

If you give your consent and change your mind, or your child changes their mind, you can withdraw them from the project. You do not need to tell us the reason why you or your child want to stop being in the project. If your child leaves 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 we hear about the results of this project?

Yes. We will send regular study newsletters to keep you and your child 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 my child?

Any information obtained in connection with this research project that can identify your child 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 and your child 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. Other electronic data, including MRI images, will be stored on a secure, password-protected server hosted by the University, accessible only to the investigators involved in this research project. Hair samples will be stored in locked cabinets in restricted access areas at MNC, and subsequently shipped to a commercial laboratory for processing. Saliva samples will be stored at the Murdoch

Children's Research Institute (MCRI) and The University of Melbourne, and will be processed at MCRI. All biological samples will be stored de-identified.

All information you and your child provide will be re-identifiable. This means that we will remove your child's name and other identifying details and give the information an identification number. Only the named research team can match you and/or your child's details to the identification number, and only 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. We plan to publish the results of this study. In any publication and/or presentation, information will be provided in such a way that your child 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 your child. 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/your child's **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/your child data before we share it. This means we will remove personal information such as your/your child's name, date of birth, and anything else that could identify you and your child. We will only share the data from the specific measures you and/or your child completed, such as questionnaires, MRI data, and task responses.

We will put security measures in place to protect your/your child's 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 and/or child 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 and/or your child 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

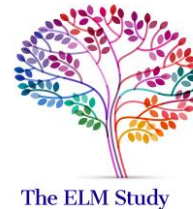
Who can I contact if I have any concerns about the project?

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 Emotional Learning and Memory (ELM)

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), Elena Pozzi (Research Assistant), Katherine Bray (Research Assistant)

**Name of
Parent/guardian:**

Name of child:

1. I consent to participate in this project *myself*, and I consent for *my child* to participate in this project, the details of which have been explained to us, and we 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 and my child's 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 my child will be required to complete several questionnaires, have samples of their saliva and hair collected, participate in an emotional learning task, participate in an MRI scan of their brain, have their body measurements collected, and complete several thinking tasks. I will be required to complete several questionnaires.
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 and my child's participation is voluntary and that we are free to withdraw from this project anytime without explanation or prejudice and to withdraw any unprocessed data that we 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 we provide will be safeguarded subject to any legal requirements;
9. I understand that our 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 our de-identified data being used in the future with other ethically approved research projects, databanks or biobanks, and medical journals.

Participant Signature: _____ **Date:** _____