



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

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 might increase risk for anxiety, and especially in young people.

The Emotional Learning and Memory (ELM) study is investigating relationships between a number of psychological and external factors, and anxiety in youth. We are particularly interested in learning more about the role of the family environment in affecting anxiety in young people. This research will allow us to learn more about risk and resilience in youth, and will help create better interventions for people with anxiety disorders.

The participants we are seeking include:

- Adolescents: aged 12-16 years old inclusive.

- Their primary female *parent* (biological, adoptive or step parent, who has been in their life for at least the past 3 years, and spend at least 2 days per fortnight together).
- Their primary male *parent* (biological, adoptive or step parent, who has been in their life for at least the past 3 years, and spend at least 2 days per fortnight together).

Please note: We understand that families can be made up of a number of different parent and child variations; including same sex couples, grandparent or family member households, and more. For the purpose of our research, we wish to look at the role of male and female parental influences on child development. However, we acknowledge that families come in many wonderful and important shapes and sizes.

What will we be asked to do?

First, we will discuss the study with your child on the phone, and answer any questions that arise. If you and your child agree to take part, we will record both your and your child's consent on the phone. We will then email you and your child links for you both to complete a survey each. We will also email you and your child another brief description of the study (and link to a survey) for your child's other parent, which we will ask you to forward to them. The surveys can be completed online, on a smartphone, tablet, or laptop, or we can send paper copies if you prefer. These questions will take up to 20 minutes for you and the other parent to complete, and up to 30 minutes for your child.

The surveys will ask about:

- 1) Feelings, thoughts and moods;
- 2) Closeness and other aspects of relationships;
- 3) Parenting styles and behaviours; and
- 4) Conflict within the home.

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 risk and resilience factors in youth. This information may assist in the treatment of anxiety disorders for people in the future.

Inconveniences

Your child will be reimbursed with a \$20 gift voucher, and you will be reimbursed with a \$10 gift voucher, for your time. Your child's second parent will also be reimbursed with a \$10 gift voucher.

What are the possible risks?

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 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 questionnaires, you can 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. In the instance that they are not at risk of harm, we will provide links to online resources that can be helpful in dealing with these thoughts and feelings.

One of the questions we will ask you is if you or your child have witnessed or been a victim of crime, violence, or assault. We are asking this question because such experiences might influence anxiety. *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 you and your child are 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.

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 you or 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 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.

All information you and your child provide will be de-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 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, Dentistry and Health Sciences

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

Please read over the consent form. We will ask for your verbal and written consent if you choose to participate.

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).

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 psychological and external factors and anxiety in adolescents. 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 and I will be required to complete several questionnaires.
5. 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.
6. 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.

7. I have been informed that the confidentiality of the information we provide will be safeguarded subject to any legal requirements;
8. I understand that our data will be password protected and accessible only by the named researchers.
9. I understand that after I sign and return this consent form, it will be retained by the researcher.

Optional:

1. I consent to being contacted in the future for potential follow-up questionnaires as part of this research project.
2. I consent to our de-identified data being used in the future with other ethically approved research projects, databanks or biobanks, and medical journals.