



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 to take part.

Please note that your parents or guardian will also need to participate, and agree for you to take part. We will provide them with a separate document to read.

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. Please discuss the project with one of your parents or guardians.

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

What is this research about?

Anxiety disorders are very common and can significantly impact your 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 for us to understand how individual differences in development might increase risk for anxiety, especially in young people.

The Emotional Learning and Memory (ELM) study is investigating relationships between a number of internal 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.
- Your primary female *parent* (biological, adoptive or step parent, who has been in your life for at least the past 3 years, and spend at least 2 days per fortnight together).
- Your primary male *parent* (biological, adoptive or step parent, who has been in your 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 parents, grandparent or other family member carers, and more. For the purpose of our research, we wish to look at the role of male and female parents on adolescent development. However, we acknowledge that families come in many wonderful and important shapes and sizes.

What will I be asked to do?

First, we will discuss the study with you and one of your parents/caregivers, and answer any questions you have on the phone. If you both agree, we will record both you and your parent's consent on the phone.

The rest of the study is made up of questionnaires for you and your parents to complete online.

We will send you a link to a questionnaire. Questions can be answered on a smartphone, tablet, or laptop, or we can send paper copies if you prefer. These questions will take up to 30 minutes for you to complete, and up to 20 minutes for your parents. You can take as many breaks as you like along the way.

Parent/guardian involvement

We will also ask your parents/guardians to be involved by filling in a questionnaire. We will send you two links for these, one for your female parent and one for your male parent. These questionnaires ask about your health and behaviour, as well as their own health and behaviour, and some things about your family.

What are the possible benefits?

There will be no direct benefit to you or your parents from participation in this research. However, the study will lead to a better understanding of environmental and family factors which influence anxiety and mood in young people. This information may assist in the treatment of anxiety disorders for people in the future.

Inconveniences

You will be reimbursed for your time with a \$20 gift voucher of your choice at the end of the study.

What are the possible risks?

You should be aware that some of the questions we will ask are about sensitive topics and could cause distress. Our research team has lots of experience with the questionnaires 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 questionnaires, you should let your parents and/or someone from the research team know. You can contact the principal investigators – their numbers are listed at the end of this document.

If you are experiencing sadness, or emotional or mental health difficulties, please let us know and we will discuss support options with you (and your parents, if you agree) 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.

Please note that your answers to the questionnaire and anything you discuss with us will remain confidential, and we will not share that information with anyone, including your parent/guardian, unless you provide information that indicates you or someone else may be at risk of harm.

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 agree and then change your mind, you can withdraw from the project at any time. 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.

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 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 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. 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 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

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



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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, 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 family environment. 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 a questionnaire online.
5. 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.
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 I provide will be safeguarded subject to any legal requirements;
8. I understand that my 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 my de-identified data being used in the future with other ethically approved research projects, databanks or biobanks, and medical journals.