Study Number:	77884		
Short Name of Project:	TINT-B		
Full Name of Project:	Tuning into Teens' Brains (TINT-B)		
Principal Researcher:	Prof Sarah Whittle, Responsible Researcher		
Version Number:	4	**Version Date:**	16/03/2022

Thank you for taking the time to read this **Participant Information and Consent Form**. We are inviting you to take part in a research project about parenting and adolescent brain development.

This form is 7 pages long. Please make sure you have all the pages.

What is an Information and Consent Form?

An Information and Consent Form tells you about the research project. It explains what the research project involves. This information is to help you decide whether or not you would like to take part in the research. Please read it carefully.

Before you decide if you want to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Taking part in the research project is up to you

It is your choice whether or not you take part in the research project. You do not have to agree if you do not want to. If you decide you do not want to take part, it will not affect the treatment and care you get at The Royal Children's Hospital.

Signing the form

If you want to take part in the research, please sign the consent form at the end of this document. By signing the form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to taking part in the project.

We will give you a copy of this form to keep.

1. What is the research project about?

Parents are very important figures in young people's lives. For example, parents can support their children during times of change, like the transition from primary school to secondary school, and help them manage their emotions.

In TINT-B we are particularly interested in understanding the relationship between **mothers and daughters** (although we know that fathers and other caregivers may also be very important!).

2. Who is running the project?

The project is being run by the University of Melbourne. It will take place at Melbourne Neuropsychiatry Centre and Royal Children's Hospital. It is funded by the National Health and Medical Research Council and is led by Prof Sarah Whittle.

3. Why are you asking me to take part?

We are asking you and your mother to take part in this project because you are aged 10 to 12, you may be experiencing some problems with emotions, your mood or anxiety, and your mother is interested in learning to better connect with you and support you during the transition to high school.

4. What do I need to do in this research project?

TINT-B is made up of two visits with us, and some tasks to do at home. The visits are at the **Royal Children's Hospital (RCH)**, and they will be 6 months apart.

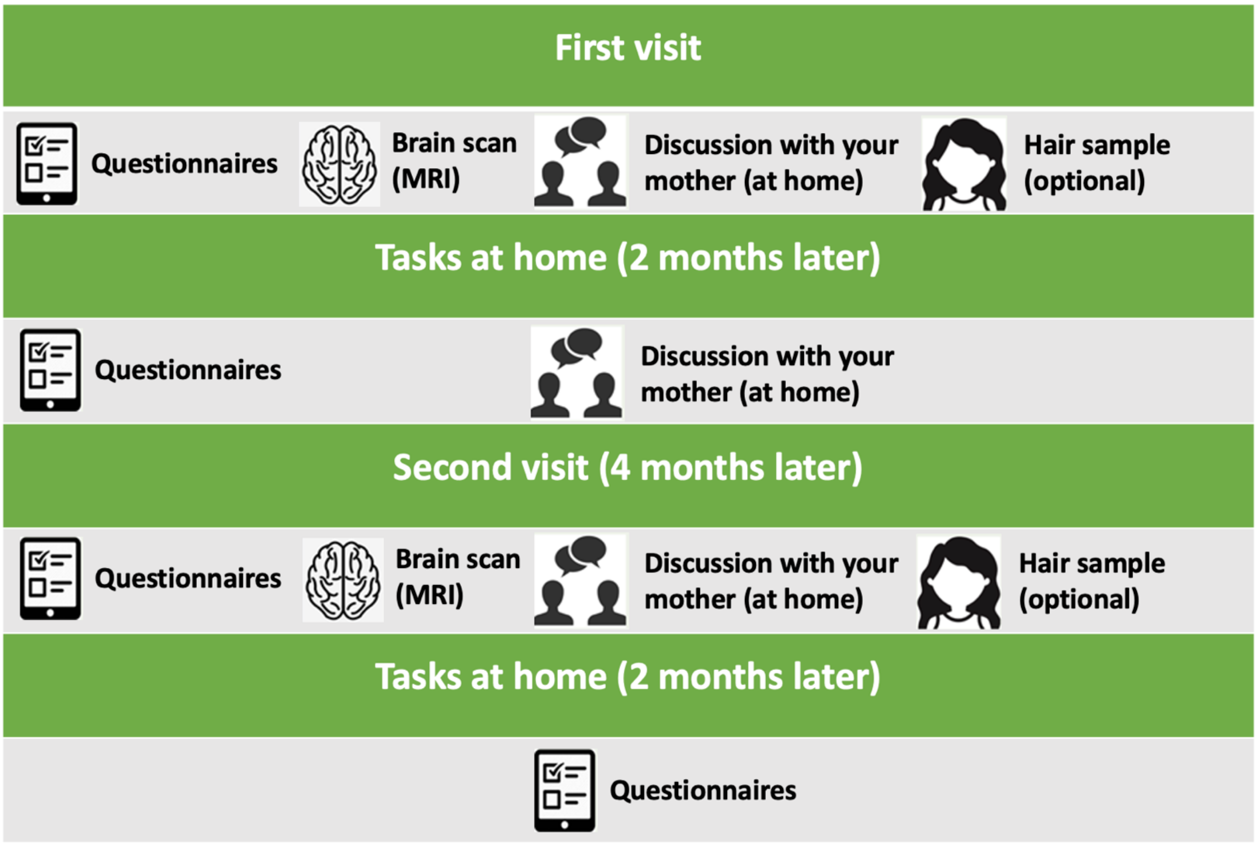
Your mother will also participate in a **parenting program** called Tuning in to Teens (either after the first visit or in 8 months time) that aims to help parents better understand their children's emotions and improve communication with them.

The skills your mother will learn in the program will help her better support you to manage any emotional difficulties you may be facing.

But before we start, we will discuss the study over the phone with you and your mother, so that you both can decide whether you want to take part.

Tuning
in to
Teens

The picture below shows you an overview of the activities included in TINT-B.



Below we explain each activity more in detail.

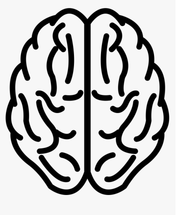
We will ask you to complete some **questionnaires** about some of your feelings and your relationships, at the beginning of the study, 2 months later, 6 months after, and then again 8 months later. The questionnaires will take about 15 minutes to complete, and you can use a tablet, smartphone or laptop to answer the questions. Important: you can skip any questions you do not want to answer.

We will ask you and your mother to **discuss** some events and feelings with guided questions, at the beginning of the study, 2 months later and again 6 months later. These conversations will take about 30 minutes, will take place at your home and we will help you record them.

We will ask if we can collect a small **sample of your hair** from the back of your head (near the scalp) at the beginning of the study and 6 months later. Providing hair samples is optional!

Why do we want some of your hair?!

This is so we can measure the levels of some hormones in your body, over the past few 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 hairstyle or appearance.



We will invite you and your mother to come to the Royal Children's Hospital for two **brain scans (MRI)**, one at the beginning of the study and one 6 months later. In the MRI scanner, you will watch a short movie and complete some tasks that involve looking at emotional faces and scenes. The scan will take approximately 30 minutes.

What is an MRI Scan?

MRI stands for magnetic resonance imaging. An MRI scanner is like a giant magnet that can take pictures of your brain. The MRI is a very safe procedure. 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.

We will offer you a practice scanner (called a 'mock' scanner) and a virtual reality game where you can experience the sights and sounds of the MRI before the actual scan, and practice staying still. You can also watch a short video about having an MRI scan at the Royal Children's Hospital here: https://www.youtube.com/watch?v=b073SYKrvP4

Sometimes the MRI makes funny noises that can get pretty loud, but we will give you headphones to help with this.

We can send you some pictures and a **3D printed model of your very own brain** in the weeks following the MRI scan if you would like, like the one in the picture here! We will also provide you with some **gift card** vouchers at the end of each visit.

5. Can I withdraw from the project?

your participation in TINT-B is completely **voluntary**! This means that you can stop participating at any time, even after you begin participating. And you do not need to tell us the reason why.

it's always okay to change your mind.

6. What are the possible benefits for me and other people in the future?

We are doing this study for research purposes. Our aim is to progress our knowledge of how parenting can influence brain function and mental health in young people. We cannot guarantee that you or your mother will get any benefits from this project. However, your mother will be involved in a parenting program (now or 8 months later) that will help them to better communicate and connect with you.

7. What are the possible risks, side effects, and inconveniences?

We will ask you some questions about your mood and your experiences, which might bring up some difficult feelings for some people. Some people can feel uncomfortable, dizzy or nauseous during the virtual reality game. We can stop the game at any time. The MRI brain scan may sound a little bit scary. While it is operating, the scanner is noisy. You will wear earphones to protect their ears. The scanner is shaped like a long tube and may cause some people to feel cramped. Some people can feel anxious during the scan. If you feel anxious we will stop the scan. Remember you can skip any question or task you do not want to complete, and please feel free to ask us if anything is unclear!

We will reimburse you with gift cards at a rate of $20 per hour for taking part in this project. You will also receive some pictures and a 3D printed model of your own brain at the end of the study.

8. How will you keep my information confidential?

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 or if we are concerned about harm to yourself or others.

You don't have to show your mother your answers to the questions. However, if your mother wants to, or there is something in your answers that worries us (for example, you let us know that something in your life is really upsetting you), we may ask your permission to talk about it with your mother.

Data sharing

To advance science, medicine and public health, we may also need to share your **de-identified** data with other research projects 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 and MRI data.

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 daughter may have been re-identified, please let us know.

9. How will I find out the project results?

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. At the end of the study we will send you a final letter including a summary of the results of the study. The letter will not have any information specifically about you or your mother.

10. Who should I contact for more information?

If you would like more information about the project, please contact:

Name:	Sarah Whittle
Contact telephone:	03 8344 2514
Email:	tint-brains@unimelb.edu.au

In case of a medical emergency, you should call 000 or attend your nearest hospital's emergency department.

For other urgent matters related to this project, please contact:

Name:	Sarah Whittle
Contact telephone:	03 8344 1958
Email:	swhittle@unimelb.edu.au

You can contact the Director of Research Operations at The Royal Children's Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.

Consent Form

Study Number: 77884

Short Name of Project: Tuning into Teens' Brains (TINT-B) Study

Version Number: 3 **Version Date:** 17/01/2022

- I have read this information statement and I understand its contents.
- I understand I have to do to be involved in this project.
- I understand the risks I could face because of my involvement in this project.
- I voluntarily consent to take part in this research project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

Optional Consent

☐ I do	☐ I do not	I consent to my data being shared in the future with other research projects and medical journals. The data will be de-identified (my personal details, like my name, will be removed), which means it will be very difficult to link it to me.
☐ I do	☐ I do not	I consent to be contacted for future ethically approved research projects that are suitable for me.

Participant Name Participant Signature Date

Declaration by researcher: I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name Research Team Member Signature Date

If you are signing this consent form you must also date your own signature.