

**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:** 4/04/2022

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

This form is 10 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 you and your child to take part in the research. Please read it carefully.

Before you decide if you want you and your child 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 and your child 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 them to take part, it will not affect the treatment and care they get at The Royal Children's Hospital.

#### **Signing the form**

If you want you and your child 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?**

The transition from primary school to secondary school comes with many new changes and can sometimes be challenging for adolescents. So, it is important for parents to learn more about how to better understand, support and connect with their children, particularly when their children are experiencing emotional difficulties.

Children can benefit from learning to understand and manage their emotions, and parents play an important role in supporting this development. As part of this research you will be involved in a parenting program called Tuning in to Teens (TINT), which aims to help you better understand your daughter's emotions and improve communication with her. The skills you will learn in the program will help you better support your daughter to manage any emotional difficulties she may be facing. Your participation in the Tuning into Teens' Brains (TINT-B) study more generally will help to increase our understanding of the impact of parents on their children's mental health and brain function.

Please note that fathers (and other caregivers) also play an important role in supporting their daughter's mental health. All caregivers are also important in supporting their son's mental health! While we are focusing on mothers and daughters in the current project, we hope to expand our research in future to include other family members.

If you choose to enroll in this study, you will be randomly allocated to one of two conditions: one condition will receive the parenting program right now and the other will receive the program in 8 months time. In addition to the program, we will ask you and your daughter to be involved in some activities and complete some questionnaires at 4 time points over 8 months.

## **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 and my child to take part?**

We are asking you and your child to take part in this project because you have a daughter in Year 6 (aged between 10 to 12) who may be experiencing difficulties with her emotions or mood.

## **4. What does we need to do in this research project?**

### **First time point: What will we be asked to do?**

First, we will discuss the study with you and your daughter, and explain the assessment procedures and the program. If you and your daughter agree to take part in the study, we will record your consent over the phone. Following this we will provide you and your daughter with a link to an online questionnaire. This questionnaire will ask about your daughter's mood, thoughts and feelings, and will take just a couple of minutes to complete. The questionnaire can be completed on a smartphone, tablet, or laptop, or we can send you a paper copy if preferred. The questionnaire is to determine if you and your daughter are eligible to take part in our study. If you are not eligible to participate in the study, we will provide you with alternative options for attending the TINT program or accessing other supports.

If you and your daughter are eligible to take part, we will then invite you and your daughter to come to the Royal Children's Hospital (RCH), where you will meet a member of our research team. Our researcher will ask you and your daughter to complete some more questionnaires, and they will help you to prepare for a brain scan that allows us to measure your daughter's brain function. Here is some more detail about what we do:

### Questionnaires

We will ask you and your daughter to complete some questionnaires at the beginning of the study (before you come into RCH). Questions on the questionnaires cover some topics such as your and your daughter's mood and family relationships. You can complete them via a smartphone, tablet, or laptop at home (or we can provide you with a paper copy if you prefer). These questions will take about 25 minutes for you to complete, and 15 minutes for your daughter to complete.

### MRI Scan

When you visit us at RCH we will invite your daughter to take part in an MRI scan.

#### *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 daughter's health. The pictures taken by the machine are called MRI scans. It is important for your daughter to lie very still in the scanner, so that the pictures turn out sharp and not blurry.*

The MRI scan will take approximately 30 minutes and during the scan we will measure your daughter's brain activity while she looks at some pictures of faces displaying different emotions. For some of the scan she will also be able to watch a short movie.

We will show you both a 'mock' scanner, which is a type of practice scanner, and an educational Virtual Reality (VR) simulation where they can experience the sights and sounds of the MRI before the actual scan, and practice staying still. We can send your daughter a 3D printed model 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.

### Hair Sample

At RCH we will also ask if we can collect a small hair sample from the back of your daughter's head near the scalp. Providing the hair sample is optional and you and your daughter can continue to take part in the study without providing the hair sample.

#### *Why are we asking for some of your daughter's hair?!*

*This is so we can measure the levels of some hormones in your daughter's 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 their hairstyle or appearance.*

After your RCH visit we will ask you and your daughter to complete a discussion task together at home:

### Mother-Daughter Discussion

We will invite you and your daughter to discuss some events and feelings with a set of guided questions. The conversations will take about 30 minutes and will place at home. We will help you to video record them with a tablet or laptop. The video recordings will be kept private and confidential.

### **TINT parenting program**

Depending on what group you are allocated to, we will invite you to take part in an 8-week x 1-hour one-on-one parenting program *EITHER soon after the mother-daughter discussion, OR 8 months later*. The program aims to help parents be aware of their own emotions while helping their children to understand and regulate their emotions. TINT has been shown to be effective in improving parenting, parent-child relationships, and children's emotional- and behavioural difficulties. The facilitator who will see you for these sessions will tailor the program to your unique needs and challenges. Sessions will be held at a time that is suitable for you and can be delivered in person at the Melbourne Neuropsychiatry Centre or online via Zoom. Please note that these sessions are just for you. Your daughter does not attend.

### **Second time point: What will I be asked to do?**

Two months after the first RCH visit, we will contact you again and ask you and your daughter to complete the same questionnaires and mother-daughter discussion as you did before. We will send you a link to complete the questionnaires on a smartphone, tablet or laptop in your own time. We will help you to video record the discussion with your daughter at home again.

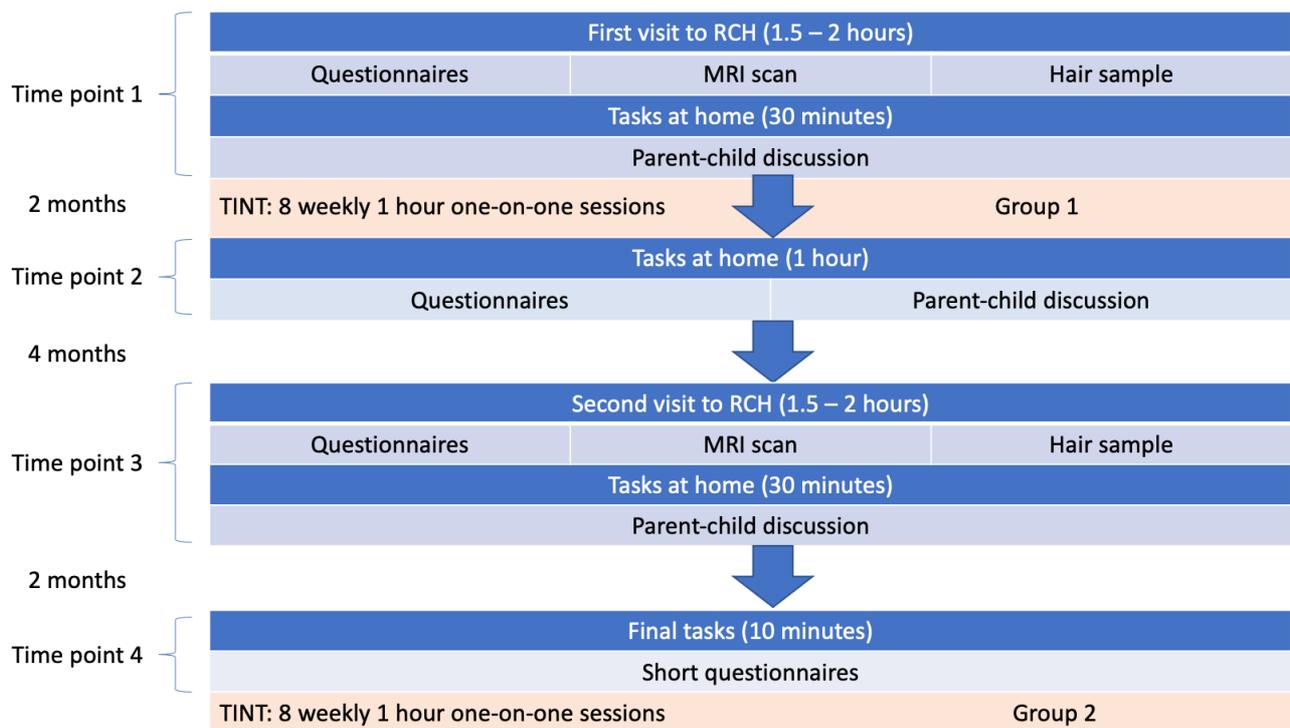
### **Third time point: What will I be asked to do?**

Six months later we will ask you and your daughter to come back to the RCH and complete exactly the same tasks as the first visit. These will include the questionnaires, MRI scan, and we will take another hair sample. We will also help you to video record the discussion with your daughter at home.

### **Fourth time point: What will I be asked to do?**

Eight months later we will contact you again and ask you and your daughter to complete some short questionnaires for the final time.

Here is a flowchart of how you will be involved in the study, including how long things take:



## 5. Can my daughter and I withdraw from the project?

Participation in a research project is voluntary. It is your and your daughter's choice to take part in this research. You and your daughter do not have to agree to participate if either of you do not want to, and your daughter is able to withdraw at any time.

If you give your consent and change your mind, or your daughter changes her mind, you can withdraw them from the project. You do not need to tell us the reason why you or your daughter want to stop being in the project. If you or your daughter 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.

## 6. What are the possible benefits for my child and other people in the future?

You will receive an 8-week one-on-one parenting program for free, and by participating in the parenting program, you may learn some new skills that will help you to communicate with your daughter about emotions and support her in managing emotional difficulties through the transition to secondary school. In addition, the study will lead to a better understanding of how parenting affects young people's mental health and brain function. This information may assist in the development of new interventions in the future.

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

### Possible risks

Virtual reality (VR)

Some individuals who try virtual reality may experience motion sickness or claustrophobia when using a VR headset. Although the risk is nominal, due to the visual display frame rate and the possibility of flashing lights to induce seizures, if your daughter has epilepsy or a history of seizures, we will not ask her to participate in the VR simulation. If you or your daughter do not wish for her to participate in the VR simulation, that's ok. If your daughter feels nauseous, dizzy or uncomfortable during the VR simulation it is important that she let us know so that we can stop the VR simulation.

#### 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 daughter 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 daughter goes into the MRI scanner.

While it is operating, the scanner can be noisy. We will give your daughter 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 daughter does not like confined spaces. Some people can feel anxious during the scan. If your daughter feels anxious it is important that they let us know so that we can stop the scan immediately.

#### Questionnaires:

You should be aware that some of the questions we will ask cover sensitive topics and could therefore cause some distress. For example, some questions ask about suicide and harsh parenting practices. These questionnaires, however, are widely used around the world and our research team has lots of experience with them. However, please note that you and your daughter do not have to answer any questions you do not want to. Like with any aspect of the research, if you or your daughter feel uncomfortable about the questionnaires, you can let someone from the research team know. Contact numbers are listed at the end of this document.

If you or your daughter 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 daughter raises significant 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.

#### Hair Samples:

Collecting the hair sample might make your daughter feel uncomfortable or concerned about her 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 daughter's hair is too short and it will be visible. If your daughter does not want to provide a hair sample, they do not have to.

### **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, 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 daughter'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 your daughter and may affect their ability to work in certain professions or get new life or other insurance cover. However, the discovery of a health risk may also help them get treatment.

An experienced pediatric radiologist will review your child's MRI scans. In the unlikely event that they find something that could be relevant to your child's health, your child will have the option of being referred to RCH Neurosurgery Research Clinic. The clinic will discuss your child's scan with you. There will be no cost to you.

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.

#### **Inconvenience**

Your daughter will be reimbursed with gift cards at a rate of \$20 per hour, and will additionally receive a 3D model of her brain. Her participation is likely to be approximately 5-6 hours.

You will be reimbursed for travel and parking expenses associated with the study visits.

### **8. How will you keep our information confidential?**

Any information obtained in connection with this research project that can identify you and your daughter 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.

Information collected from you and your daughter 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 sent to a commercial laboratory (in Australia) for processing.

All information you and your daughter provide will be re-identifiable. This means that we will remove your daughter's name and other identifying details and give the information an identification number. Only the named research team can match you and/or your daughter'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 daughter 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 and your daughter. 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 daughter'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 daughter's data before we share it. This means we will remove personal information such as your/your daughter's name, date of birth, and anything else that could identify you and your daughter. We will only share the data from the specific measures you and/or your daughter completed, such as questionnaires and MRI data. We will make sure that we only send data to ethically approved locations. However, any deidentified data and samples that we send overseas are not protected by Australian laws and regulations.

We will put security measures in place to protect your/your daughter'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 daughter 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 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 project 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 daughter.

## 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 what my child and I have to do to be involved in this project.
- I understand the risks my child could face because of their involvement in this project.
- I voluntarily consent for my child 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

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	I consent to my and my daughter's de-identified data being used in the future with other ethically approved research projects, databanks or biobanks, and medical journals.
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	I consent to be contacted for future ethically approved research projects that are suitable for me and/or my family members

\_\_\_\_\_  
Child's Name

\_\_\_\_\_  
Parent/Guardian Name

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

**Declaration by researcher:** I have explained the project to the parent/guardian who has signed above. I believe that they understand the purpose, extent and possible risks of their child's involvement in this project.

\_\_\_\_\_  
Research Team Member Name

\_\_\_\_\_  
Research Team Member Signature

\_\_\_\_\_  
Date

Note: All parties signing the consent form must date their own signature.