Longitudinal Adolescent Brain Study
Research Project Information Sheet

Ethics approval number: A181064

Investigators

The research project is being undertaken by a team of researchers, led by Professor Daniel Hermens (Principal Investigator) at the Thompson Institute, part of the University of the Sunshine Coast (UniSC).

Invitation to participate

Thank you for your interest in the Longitudinal Adolescent Brain Study. This *Research Project Information Sheet* provides information about the research project, participant involvement and how participant data is used.

Potential participants and their caregiver/s are invited to read this information sheet carefully before deciding whether, or not, they wish to participate in the Longitudinal Adolescent Brain study. Please feel free to contact the research team with any questions about this information sheet or the research project (contact details on page 3) and/or discuss the research project with family, friends or your health practitioner.

On deciding to participate in the research project, both the participant and their caregiver will be asked to sign electronic *Consent to Participate in Research* forms at the initial visit to the research project. At this visit, a research team member will ensure the participant and the caregiver have a clear understanding of the research project and are providing informed consent, prior to signing.

What is the research project about?

Adolescence is an important, exciting and dynamic period of one's life. It is a time when a young person undergoes significant physical changes, cognitive development (e.g. attention, memory), as well as emotional and social growth. For the brain, adolescence is one of its most dynamic phases, as there are significant changes in the structure and functioning of the brain as it becomes more and more efficient.

The Longitudinal Adolescent Brain Study is being undertaken to determine and track these changes occurring in the brain during adolescence. More specifically, researchers will look at changes in brain structure, chemistry and functioning as well as social, emotional and cognitive (e.g. concentration, attention, memory) changes. By tracking and mapping these changes through a participant's adolescence, researchers will gain greater understanding of how these changes relate to a range of factors. Such factors include thinking skills, bullying, resilience, connectedness, wellbeing, as well as onset and progression of mental and substance use disorders. The information collected in this study will inform future research and contribute to better mental health outcomes for young people.

Who can be a participant?

The research project is looking for participants who are aged 12-15 years and who are proficient in spoken and written English. Participants will be invited on an ongoing basis to engage with the research project until they turn 17 years to 17 years 11 months. The research project aims to have 500 young people taking part.

Young people who suffer from major neurological disorder, intellectual disability, major medical illness or who have sustained head injury (with loss of consciousness more than 30 minutes) will be unable to participate in the research project. If you have any metal in your body please tell us at first contact what kind and where in your body it is, as this will impact whether or not you can participate.

Participant Commitment – what's involved in being a participant?

The Longitudinal Adolescent Brain Study involves multiple neurocognitive activities and brain scans over a maximum 5 year period. All activities and scans (outlined below) will be conducted at the Thompson Institute, located at 12 Innovation Parkway, Birtinya.

Participants will be asked to attend 3 visits (every 4 months) per year. At each visit, participants will undertake 2 assessment blocks (outlined below). Participants can choose to split the assessment blocks over two days (with a maximum of 7 days between each assessment block).

Assessment Block 1 – Neurocognitive Activities (2.5 hours duration)

a. Short tour of the facilities
b. Self-report questionnaire on a touch-screen tablet (30 minutes): This will ask a range of questions about your thoughts, and feelings, and other things like your current behaviours and recent experiences.
c. Computerised cognitive tasks, with help from the research assistant (30-35 minutes): This will look at your thinking skills such as your concentration, attention and memory.
d. Face-to-face interview with a member of the research team (30 minutes): This will ask questions about your mental health, such as questions about whether there have been times in your life when you have experienced changes in your mood (for example, feelings of sadness or feelings of elation).
e. Debrief session: On completion of assessment block 1 a short debrief session will be conducted and appointment time for Assessment Block 2 confirmed.

BREAK (either 60-90 minutes if on same day or up to maximum of 7 days)

Assessment Block 2 – Brain Imaging (2.5 hours duration)

a. Short tour of the equipment and facilities
b. Magnetic Resonance Imaging (MRI) (1 hour): This is a non-invasive procedure that involves you lying in an MRI while images of your brain structure and activity are recorded. MRI obtains images using magnetic field and radio waves. (Please note: a non-invasive procedure means that it does not require the administration of any contrast dye and that it does not use radiation like x-rays and CT scans).
c. Neurophysiological Assessment (known as EEG) (1 hour): This is a non-invasive procedure that involves wearing a head cap to measure your brain activity while you complete a series of tasks.
d. Completion: You will receive $30 music or movie voucher. Your next visit times and dates will be booked.

Why so many visits?

As mentioned earlier, adolescence is a dynamic life phase for the brain. In terms of brain development, there are considerable changes that take place throughout adolescence. For this reason, it is important to be able to measure brain structure and chemistry at frequent intervals (i.e. every 4 months). By doing this frequent monitoring researchers will have more information to accurately map changes occurring in the brain, before and after major changes in, for example, one's mood or thinking skills.

Risks and Benefits to participating.

There may be some risks in taking part in this research project that should be considered.

Assessment Block 1 – Neurocognitive Activities

The self-report questionnaire and face-to-face interview asks some sensitive questions about your thoughts, feelings, and mental health and wellbeing. After the questionnaire and interview, there will be a short debrief session where you can talk about any issues or ask any questions about these assessments.

Assessment Block 2 – Brain Imaging

For some people, the cognitive and neurophysiological (EEG) assessments can cause mild anxiety (associated with following task instructions and performing in a 'test'). However, the anxiety usually lessens once these assessments commence. Researchers are trained to provide support during these situations and will ensure your comfort at all times. Some people also feel anxiety or claustrophobia when they lie in the MRI. If this occurs, the MRI will be discontinued. Again, researchers are trained to provide support during these situations. There are some medical conditions (e.g. heart pacemaker) or other difficulties (e.g. previous eye injuries due to metal objects) which can mean that someone may not be able to have an MRI.

It is also important to note that this research scan is not a clinical scan and therefore not able to diagnose disease. There will be no clear benefits to you from your participation in this study, therefore, we will not be actively looking for any abnormalities or pathology. Should a researcher coincidentally identify a potential anomaly, the Chief Investigator or senior delegate will (with your permission) contact you and inform you of this so that you can seek independent medical advice (such as from you GP). However, it is important to understand that you should not rely on the researcher to review the scan to find anomalies and that you should seek independent medical advice in the event you have any health concerns.

Participants will receive a $30 voucher from a set of pre-selected options as a re-imbursement at the completion of each visit (that is, after assessments 1 and 2 at each visit). Furthermore, participants will be given a picture (scanned image) of their own brain after each visit (up to 15 images). Participants will be regularly updated (via newsletters and our website) with group level findings as they are reported (for example in scientific publications), as well information about the latest research in the field of Youth Mental Health and Neurobiology. Participants will also be offered, annually, the opportunity to receive a cognitive (e.g. concentration, attention, memory) feedback report based on a single previous research battery, with the option to opt out of receiving this feedback at any time.

Participation is voluntary.

Participating in the research project is voluntary. If you agree to participate, you may withdraw at any stage, without explanation, by notifying Professor Daniel Hermens or the research team member conducting the assessment block. Contact details are on the last page of this information sheet or you can do this in person. You may withdraw from a single procedure or the entire research project. If you withdraw from a single procedure or assessment we will contact you for future assessments. If you withdraw from the study you will not be contacted for future assessments. Your previously collected data will remain confidential, only non-identifiable data will be used in analyses, and will be stored securely for the required length of time. If you and/or your caregiver request that your previous data is withdrawn from the study your re-identifiable data will be kept securely for the required length of time but will not be included in any analyses. There will be no consequences of any level of withdrawal, that is, if you withdraw from any aspect of the research project you will still receive compensation for your time and won't be biased in any way (e.g., in any future involvements that you may have with the Thompson Institute).

Consent

Consent to participate in this research project is indicated by signing the electronic *Consent to Participate in Research* form. Agreeing to consent will allow for the use of your results in this research project, as well as unspecified future projects. To clarify, the investigators in this study will use your results for analysis and report writing, which will not reveal your identity. The use of your data in unspecified future projects will be undertaken by the investigators as well as other researchers who will have access to a databank which will contain only non-identifiable data. That is, data that has had your personal details removed.

Results

Upon request, at completion of the research project, participants will receive a summary of the research findings.

Confidentiality

The information provided by the participant, will be held in a secure location and only the researchers directly involved in this study will have access to personal details. Any information that is obtained in connection with the research project that can be identified will remain confidential and will be disclosed only with the participant's permission. Please note that we may need to tell someone if you are in danger as required by law or if you tell us that you are at risk of serious harm to yourself or others. If we become aware of this, we might take steps to keep you and others safe which may involve speaking to family members about you. Participants will not be named in any reports or publications resulting from the research project, and no document containing your name will leave the research site. Any publications based on the research project will include only pooled results from all the participants, so an individual participant's results will not be singled out. The information given will be held in a secure location for 7 years after publications, after which time any identifying information will be destroyed.

Complaints

If a participant and/or their caregiver have any complaints about the way this research project is being conducted they can raise them with the Principal Investigator or, if preferred an independent person can be contacted. Please contact the Chairperson of the Human Research Ethics Committee at the University (c/- the Research Ethics Officer, Office of Research, University of the Sunshine Coast, Maroochydore DC 4558; telephone (07) 5430 2823; email humanethics@usc.edu.au).

Contacts

Professor Daniel Hermens
Principal Investigator
Thompson Institute
Phone: (07) 5456 5105
Email: dhermens@usc.edu.au

LABS Research Team
Thompson Institute
Phone: (07) 5456 3892
Email: LABS@usc.edu.au

The Researchers and the University of the Sunshine Coast would like to thank you for your interest in this project and appreciate the effort involved.

Longitudinal Adolescent Brain Study

Consent to Participate in Research

Ethics approval number: A181064

General Consent Information

I have read and understood the Research Project Information Sheet for the above research project and I have downloaded a copy or I know where to access this if I want to refer back to it in future.

I realise that this research project will be carried out as described in the Research Project Information Sheet.

Any questions I have about this research project and my participation in it have been answered to my satisfaction.

I agree to participate in the above research project.

I understand that I may withdraw my participation at any time, either for certain tasks or from the study as a whole, without consequence.

I give consent for data to be used in a confidential manner as described in the Research Project Information Sheet.

I also give consent for my non-identifiable data to be stored in a databank for unspecified future research undertaken by the investigators and other researchers.

Magnetic Resonance Imaging (MRI) Specific Consent Information

I understand that this is not a diagnostic scan and it will not be reviewed by a qualified radiologist.
A Radiologist is a Specialist Medical Practitioner who is qualified to identify abnormalities on MRI scans.

I understand that the research MRI scan I undergo is not designed to pick up abnormalities and that any potential abnormalities may not be identified from this scan.

If a researcher does coincidentally identify an abnormality that may require further investigation,
I consent to the Chief Investigator or senior delegate contacting and notifying my caregiver so that we may seek independent medical advice.

I agree that I will not rely on participating in this study or undertaking this MRI research scan to find an abnormality and that if I have health concerns I should seek independent medical advice.

Do you understand and want to take part in this research?

No, I do not want to take part

Yes, I understand and would like to take part

Do you wish to receive a cognitive report and feedback session, annually?

No, I do not want to receive feedback

Yes, I would like to receive feedback

Please type your name below to indicate agreement to participate in this study:

Auto-date/time stamp