THE UNIVERSITY OF SYDNEY

Brain and Mind Centre

Participant Information Sheet

Study Title	Neurobiology Youth Follow-up Study: A Youth Mental Health longitudinal and prospective clinical cohort study.
Short Title	Neurobiology Youth Follow-up Study
Protocol Number	X20-0226
Principal Investigator	Professor Ian B. Hickie
Location	Brain and Mind Centre, University of Sydney

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1. Introduction

You are invited to take part in a research study that aims to identify and characterise specific clinical phenotypes of mental health treatment seeking youth (12-40 years). This study may enhance the identification and implementation of effective early interventions to provide young people maximal opportunity for full recovery.

This study is designed as a longitudinal and prospective cohort study. You have been invited to take part in this study as you are either a current or past mental health treatment seeking Patient of headspace, Camperdown, OR a current mental health treatment seeking patient of an external mental health service within the Sydney area.

To participate in the study you must meet the following criteria:

- 12 to 40 years of age at time of consent
- Current or past mental health treatment seeking Patient of headspace, Camperdown, or a current mental health treatment seeking patient of an external mental health service within Sydney.

You will ***not*** be able to participate in the study if you meet certain criteria including:

- Not fluent in English
- Withdrawal of consent
- Intellectual disability (at investigator's discretion)

This research project is being conducted by Professor Ian Hickie at The Brain and Mind Centre, the University of Sydney. Information generated by the trial will be owned by the University of Sydney.

This project is an investigator-initiated research study funded by several government sources including the National Health and Medical Research Council as well as various philanthropic funding sources.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

This study is not funded by commercial entities.

This Participant Information Sheet (PIS) will tell you what is involved in the study and help you decide whether or not you wish to take part. Please read this information carefully. If there is anything you do not understand, or if you feel you need more information about anything, please ask.

Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Student Involvement

Ms Sarah Gell is conducting activities within the study to contribute to the requirements of Masters in Brain and Mind Science, The University of Sydney, under the supervision of Professor Ian B. Hickie and Dr. Jacob Crouse.
Activities: Observing participant assessments and assisting with data analysis.

Ms Zitong Xi is conducting activities within the study to contribute to the requirements of Masters in Brain and Mind Science, The University of Sydney, under the supervision of Professor Ian B. Hickie and Dr. Jacob Crouse.
Activities: Observing participant assessments and assisting with data analysis.

Declaration of Conflicts of interest

Professor Ian B. Hickie is the Co-Director, Health and Policy at the Brain and Mind Centre (BMC) University of Sydney. The BMC operates an early-intervention youth services at Camperdown under contract to headspace. He is the Chief Scientific Advisor to, and a 3.2% equity shareholder in, InnoWell Pty Ltd which aims to transform mental health services through the use of innovative technologies.

Associate Professor Elizabeth Scott is Principal Research Fellow at the Brain and Mind Centre, The University of Sydney. She is Discipline Leader of Adult Mental Health, School of Medicine, University of Notre Dame, and a Consultant Psychiatrist. She was the Medical Director, Young Adult Mental Health Unit, St Vincent's Hospital Darlinghurst until January 2021. She has received honoraria for educational seminars related to the clinical management of depressive disorders supported by Servier, Janssen and Eli-Lilly pharmaceuticals. She has participated in a national advisory board for the antidepressant compound Pristiq, manufactured by Pfizer. She was the National Coordinator of an antidepressant trial sponsored by Servier.

2. Study Procedures

This study will primarily be conducted at The Brain and Mind Centre (BMC), The University of Sydney, 94-100 Mallett Street, Camperdown, NSW. You will be required to attend your local pathology lab to provide your blood samples.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form at the end of this document. You will then be asked to undergo the following study activities:

Baseline assessment (Visit 1)

You will be asked to take part in a series of assessments at baseline. The baseline assessments will include the following:

Clinical assessment

Time commitment: 45–60mins

- A clinical assessment where a research staff member will ask you a series of questions about your mental and physical health, family history of mental health concerns, and your treatment history for mental health concerns. This assessment will take place at the BMC.

Self-report assessment

Time commitment: 30–60mins

- You will be asked to complete a series of online self-report assessments that will include further questions about your mental health symptoms, physical activity & physical health, sleep, and the quality of your relationships and social supports. These questions will be answered using an iPad at the BMC. You will also have the opportunity to answer these questions via a secure online link using your PC or iPad at home if that is your preference.

Neuropsychological assessment

Time commitment: 45–60mins

- You will be asked to complete a series of neuropsychological assessments that will examine memory and other thinking functions. This is a computer based assessment and will be completed via iPad at the BMC.

Activity levels / sleep patterns

- You will be provided with an actigraphy device. Actigraphy is a non-invasive tool to measure your activity levels, skin temperature, and light exposure, and is used to estimate sleep and circadian patterns. It is worn around your wrist as you would wear a watch. You will be asked to wear the actigraphy device for a 2 weeks period. Clear instructions will be provided to you about when you will need to commence wearing the device and instructions for returning it to a research member at the BMC. A brief information sheet will also be provided that answers some common questions around wearing the actigraphy device.

Blood measures

- A blood test will be conducted to capture a series of metabolic, inflammatory and standard blood measures. The study doctor will generate a pathology

referral form. You will be asked to attend your local pathology collection centre for the collection of blood samples.

All blood samples and test results will be labelled with your study ID code only, and no identifying information. These samples will be sent to laboratories for analysis. Any remaining samples following analysis will be destroyed.

The following blood markers will be assessed as part of this study:

- Triglycerides
- Cholesterol (including total, High Density Lipoprotein (HDL), and Low Density Lipoprotein (LDL))
- Fasting glucose
- Fasting insulin
- Full blood count
- Urea
- Electrolytes
- Calcium, Magnesium, and Phosphorus (Ca, Mg, PO4)
- LFTs – liver function
- Vitamin B12, folate
- Iron Studies
- Thyroid Stimulating Hormone (TSH)
- Vitamin D
- C-Reactive Protein (CRP) – inflammatory marker
- ESR – inflammatory marker
- ANA (Antinuclear antibodies) – Positive ANA can be associated with autoimmune inflammatory diseases

Pupillometry Assessment

Time commitment: 30 minutes

- You will be asked to undergo a 30-minute pupillometry assessment to examine your pupil's response to light. You will be adapted to darkness for 10-minutes, sitting in a dark, quiet room. Two 1-second light pulses followed by brighter light pulse will be administered. A measure of baseline pupil size will be taken for 3 seconds before the onset of light pulses. You will be instructed not to wear contact lenses or eye makeup during the assessment.

Genetic analysis

- You will be asked to undergo saliva sample collection after informed consent. Saliva samples will be for the assessment of genomic risk markers. A saliva sample collection kit will be given to you at the Brain and Mind Centre where you will provide the saliva sample.

  Saliva samples collected will be labelled with your study ID code only and no identifying information.

  Saliva samples for genomic analysis will be sent to the Human Studies Laboratory at the Institute for Molecular Biosciences (IMB), St Lucia Campus at the University of Queensland, for processing, DNA extraction and preparation for downstream genomics

research. The samples will be used to generate genetic information from your DNA. The DNA is then analysed together with DNA from other research participants. Researchers are looking for similarities and differences between DNA within this group. Genetic researchers use this information to learn more about how specific genes can influence or reflect health or response to treatment. Your DNA and other de-identified information collected as part of this study may be made available to other investigators in the future, some of whom may have commercial interests. This will not include any identifying information. Your data can only be obtained and used by researchers who have their study approved by a Human Research Ethics Committee. Any scientists who wish to use your data must also agree to protect your privacy and store data securely.

This research is not intended for the purpose of treating any health problems you may have. Participation in this research study does not take the place of visits to a doctor or other health professionals. Your information will be used for research purposes. Your information will be analysed in combination with information from other participants in this study. The nature of the research means that the data is de-identified prior to analysis, and only results of a global (not individual) nature will be produced.

Follow-up assessments (6, 12, 24, 36 months)

You will be followed up and invited back to complete a similar series of assessments at each follow-up timepoint 6, 12, 24 and 36 months. The assessments at each of these follow-up timepoints include:

- A clinical assessment as per the baseline assessment
- Self-report assessment as per the baseline assessment
- Neuropsychological assessment as per the baseline assessment
- Actigraphy assessment as per the baseline assessment
- Pupillometry assessment as per the baseline assessment
- Blood tests will be conducted to capture a series of metabolic, inflammatory and standard blood measures as per the baseline assessment

3. Risks

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

Blood collection may involve some discomfort at the site from which the blood is taken. There is also a risk of some minor bruising at the site, which may last one to two days. If this happens, it can be easily treated.

Incidental Findings

This research involves the collection and analysis of blood samples, as outlined above in section 2 of this Participant Information Sheet. In line with the ethical principles outlined in the National Statement on Ethical Conduct in Human Research (2023), we acknowledge an ethical obligation to inform participants of any clinically significant and actionable findings from their individual blood results.

Your individual blood test results will be reviewed by the study doctor in a timely manner. If there are any clinically significant abnormalities identified in your blood results, as determined by the study doctor, you will be notified either by SMS, email, or a phone call from one of the research study staff members. You will then be asked to see your local treating GP for review. If a review of your blood test results is required, your blood test results will be made available to your treating GP.

You will only be informed of your individual blood test results when the results are considered clinically significant and actionable by the study doctor.

If your blood results do not meet these criteria, you will not be informed of your individual blood test results.

4. Benefits

This study aims to further medical knowledge and may improve future treatment of youth mental health disorders. We cannot guarantee that you will receive any direct benefits from being in the study.

5. Costs

Participation in this study will not cost you anything, nor will you be paid. All tests required as part of the research project will be provided to you free of charge.

You will be reimbursed for your time in this Study. Reimbursement will be as follows per timepoint:

- Providing a saliva sample: $50 Voucher.
- Having a blood sample collected at your local pathology centre and completing the online self-report questionnaire and wearing the actigraphy watch for 2 weeks: $50 Voucher

6. Voluntary Participation

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason by contacting a study staff member on Mb:0422 588 787; email: ymh.research@sydney.edu.au. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

You can continue other psychological and/or medical treatments throughout the duration of this research project.

If you decide that you want to take part in this research project, you will be asked to sign the consent form. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

If you decide to withdraw from the study, we will not collect any more study-related information about you.

Data collected up until the time you withdraw may be included in the study. If you do not want the researchers to do this, you must tell them at the time of your withdrawal. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

7. Confidentiality

By signing the consent form you consent to relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

With your consent, we may link your research data from this study, with your research data from any other study that is run as part of the Youth Mental Health Research Program led by Professor Ian Hickie. This may include studies you have participated in previously, or studies you consent to participate in, in the future.

Linking relevant research data between studies enables us to collect data in an efficient way. For example, certain standardised measures are repeated across a number of our research studies. By linking data between studies, we can capture these measures at one time point, and utilise this data for other relevant studies. In addition to this, linking data enables researchers to have access to a richer pool of relevant data that may contribute to research outcomes.

All data collected for the purposes of this study will be linked to unique study ID codes and will not contain identifying information. Data will be stored separately from any identifying information (e.g., signed consent forms). One senior research staff member at each site will have an electronic password protected file linking participant names and identification codes (i.e., data will be re-identifiable). This researcher will be responsible for any data linkage that may take place between studies. Individuals will not be named in any reports or publications resulting from the study, and no document containing identifying information will leave the study site. Any publications based on the study will include only pooled results from participants.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, The University of Sydney, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this research project may be recorded in your health records. In addition, we will provide you and your treating clinician, if you currently have one, with a brief summary of the results from the research assessments you take part in.

In accordance with relevant Australian and NSW privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project and for the future research that can identify you, will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

All study records will be stored for 15 years post study completion and then securely destroyed.

Hardcopies of data will be stored in a locked filing cabinet accessible only by authorised study staff at the Brain & Mind Centre. Electronic data (including the eCRF) will be stored in a password-protected folder accessible only by authorised study staff, on the University of Sydney's Research Data Store- an enterprise grade Network Attached Storage device.

Study data will be analysed at the Brain & Mind Centre by authorised members of the study staff.

With your consent, you may be contacted to be invited to participate in future lived experience workshops conducted at the Brain and Mind Centre. By consenting to this, you are consenting to being contacted to be invited to take part in the workshops. These workshops are voluntary and aim to explore the experience of young people taking part in research. The Lived Experience Working Group (LEWG) was established in February 2021 to ensure all research led by the Brain and Mind Centre's Youth Mental Health (YMH) and Technology team is conducted in consultation with young people with lived (or living) experience of mental illness. The LEWG members are viewed as experts in their experience, and thus are considered equal research partners. The LEWG conduct monthly workshops and will invite relevant BMC researchers and research participants to take part in these workshops to participate in the design of research projects.

8. Storage of Data

The University of Sydney software licence for REDCap (Research Electronic Data Capture will be used for to manage the collection and storage of research data. REDCap is a secure, web-based, non-commercial, data management tool designed for research purposes. Data collected by REDCap is stored on servers in the University of Sydney data centre. Data is secured and regularly backed-up to protect privacy and confidentiality.

9. Future use of Data

There may be future use of the study data for research purposes, this will always be conducted in a de-identified way. In addition to this there may be some sharing or pooling of data with future collaborators. Any new investigators/collaborators will be added as new personnel and notified to HREC.

You can indicate your agreement to this on the Participant Consent Form.

10. Further Information

When you have read this information, a research staff member will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact a research study staff member on Mb: 0422588787; email: ymh.research@sydney.edu.au

This information sheet is for you to keep.

11. Ethics Approval and Complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 9515 6766 and quote number X20-0226.