Participant Information Sheet/Consent Form

Interventional Study - *All participants*

Orygen

Title	A randomised, controlled trial of the RECOVER tailored psychological intervention for early stage bipolar disorder
Short Title	RECOVER
Project Sponsor	Orygen
Coordinating Principal Investigator	Professor Sue Cotton (Orygen)
Principal Investigator (Parkville)	Dr Aswin Ratheesh (Orygen)
Associate Investigator(s)	*Professor Greg Murray, Emeritus Professor Henry Jackson, Professor Andrew Chanen, Professor Michael Berk, Associate Professor Chris Davey, Professor Barnaby Nelson, Dr Melissa Hasty, & Dr Craig Macneil*
Location	Orygen Parkville 35 Poplar Rd Parkville VIC 3052 Sunshine 80B Harvester Rd Sunshine VIC 3020

Part 1. What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are being treated for early stage Bipolar Disorder. The research project is testing a new treatment for Bipolar Disorder. The new treatment is called RECOVER.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. 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.

2 What is the purpose of this research?

The aim of this research is to determine how effective the RECOVER intervention is in young people in the early stages of Bipolar Disorder (BD).

What is RECOVER?

RECOVER stands for REsearch into COgnitive and behavioural VERsatility early in the course of bipolar disorder. It is a new psychological therapy for young people with early stage BD and was developed by our experienced team with the input of young people with BD. This means that it is more appropriate for people at this stage of life and in the early stages of BD.

Why do we think RECOVER would help treat BD?

Medications are currently the most commonly used treatments for early stage BD. However, medications do not treat all aspects of the illness, and there is growing support for providing additional psychological therapy to help further reduce symptoms and improve outcomes. We would like to see if providing the RECOVER therapy in addition to usual treatment can help young people in the early stages of BD.

This research has been initiated by the Principal Investigator Professor Susan Cotton. Prof Cotton is employed at Orygen and the Centre for Youth Mental Health, The University of Melbourne.

This research has been funded by a National Health and Medical Research Council (NHMRC) Project Grant (#1128626).

3 What does participation in this research involve?

We are interested in how effective the psychological therapy RECOVER is when adding it on to usual treatment. This means that all participants will receive usual treatment but some will also receive the RECOVER therapy.

You will be participating in a randomised controlled research project. This type of project is carried out when we do not know which treatment is best for treating a condition. To find out we need to compare different treatments, so we put people into groups and give each group a different treatment. In the RECOVER trial, some participants will receive the RECOVER therapy plus usual treatment, whilst others will only receive their usual treatment. The results are compared to see how the groups differ. To try to

make sure the groups are the same, each participant is put into a group by chance (random). There is a fifty-fifty chance of being allocated to either the RECOVER group or the usual treatment group.
The RECOVER trial is an add-on intervention with no participant blinding, which means that you will know which group you have been assigned to. Sometimes just the knowledge that you are being observed for research can cause a change in behaviour. To help control for this, we will also have an Assessment Only (AO) group who will receive their usual treatment and will only meet with researchers once. Individuals who choose not to take part in the trial will be offered the AO option instead. The AO group will not be reimbursed for their time.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

To help us determine how effective the intervention is, you will meet with a research team member at various time points throughout the trial to provide information on your mental health and wellbeing. At each visit, there is an interview with a researcher and some questionnaires for you to fill out. Below is a more detailed description of each assessment, followed by a schedule of which assessments will be done and when over the course of the trial.

Consent and Screening Procedure
Before completing any of the study assessments or being allocated to a treatment group, you and a research team member will go through the consent process. This involves reading and talking about all the information included in this document to make sure you understand what is involved in participating in the study.

After signing the consent form you will then complete an interview with a researcher, who will ask you about your mental health history, demographic information (e.g., gender, age, living arrangements, educational level), and questions relating to your social and school life. You will also complete a brief questionnaire on attitudes and expectations, and a short test to measure your thinking skills. To be eligible for this study, you must have a diagnosis and be in the early stages of BD, have been receiving treatment at a specialist early intervention service (such as Orygen) for no more than 6 months, and have the ability to consent and comply with study procedures.

Once you have provided consent and the inclusion criteria requirements have been met, you will be randomly assigned into either the RECOVER plus usual treatment group, or the usual treatment only group.

Interviews
At each study visit, you will be asked to take part in an interview. The interviews will be conducted by a member of the research team who will ask you a number of questions regarding your symptoms, mood, and treatment, how you're going at work/school, home and socially, and alcohol and substance use. All interviews are audio recorded to ensure the researchers obtain accurate information. It is expected each interview will take around 2 hours to complete.

Self-report questionnaires
The self-report questionnaires involve answering some questions relating to your quality of life, social, work/school and home life, symptoms, activities of daily life, sleep, feelings and thoughts, and treatment. You will be given the option of completing the questionnaires before each study visit at a time convenient for you. The questionnaires will be given to you in either hard copy, or you will be sent a link to them via email. The self-report questionnaires will take between 30 minutes to 1 hour to complete.

Daily activity
You will be required to wear an actigraph device. The device resembles a wrist watch and measures time, how fast it's moving in three dimensions (forwards-backwards, left-right, and up-down), how light or dark

it is, if the button was pressed, and what temperature it is (up to 60°C). You will be asked to wear it continuously for one week at the baseline, 3-month, and 6-month time points.

Study Visits
Participants in the RECOVER plus usual treatment, and the usual treatment groups will be contacted by researchers at the following timepoints:

Baseline (Week 1), 3-month and 6-month follow-up
In the week leading up to beginning the trial and at the 3-month, and 6-month time points, you will complete an interview with a member of the research team, and some self-report questionnaires. You can choose to complete these prior to or during your meeting with the researcher. These assessments will take about 2.5 hours in total to complete. You will also be fitted with the actigraph device at this time.

9-month follow-up
A member of the research team will call you to check-in and see how you're going in general and how you're finding the treatment.

12-month and 18-month follow-up visits
You will meet with a research team member to complete an interview. You will also complete some self-report questionnaires. You can choose to complete these prior to or during your meeting with the researcher. This will take about 2.5 hours to complete including the self-report questionnaires.

There are no additional costs associated with participating in this research project, nor will you be paid. You will be reimbursed $20 for for completion of the first self-report assessment (at Baseline), in addition to $40 per face-to-face study visit (at Baseline, 3-months, 6-months, 12-months, and 18-months) to cover costs such as travel, parking, meals and other expenses associated with the research project visit.

Assessment Only group
Individuals who are part of the AO group, will complete a brief interview with a research team member at baseline. This will take about 10 minutes. Your medical record will be reviewed at baseline and 18-months to collect information related to your attendance at appointments, your diagnosis, your overall functioning and any substance use. You will not be paid nor reimbursed for your involvement in the study.

Collection of additional information
To assist us in collecting information related to how often participants (including AO group participants) are seen in the public mental health system, a request will be made to the Client Management Interface (CMI), to provide us with details of each participants' contacts during the study period. Information requested will include dates of contacts, who the contact was with and where the contact was (location/name of service).

We would also like to collect the contact details of a person you nominate (e.g., family member, close friend) to help us ensure that we can keep in contact with you throughout the study (in case your details change), or following the study, should we wish to have further contact with you. No information provided to us during the course of your involvement will be shared with them, except for letting them know that you have been involved in a study with us, and that you provided their details to assist us in contacting you.

4 What do I have to do?

Your participation in the study will involve attending regular therapy sessions, taking part in the study visit interviews, self-report questionnaires, and wearing the actigraph device.

You will be asked to attend your usual treatment throughout the course of the study trial and take any medication you have been prescribed by your treating clinician. If you have been allocated to the RECOVER plus usual treatment group, you will receive a minimum of 10 and up to a maximum of 18 sessions of RECOVER over a 6-month period. Each session will run for approximately one hour.

There are no significant lifestyle restrictions you must follow whilst taking part, we just ask that you do not enter into any other research projects over the course of the study without discussing with a member of the research team.

5 Other relevant information about the research project

We will aim to recruit a total of 122 people to take part in this research project, with an extra 61 people in the AO group. Participants will be current clients of Orygen, from both the Parkville and Sunshine clinics. It is expected that the results of this research project will be published and/or presented in a variety of ways, including by student researchers towards their degree. In any publication or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Orygen.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at Orygen. If you choose not to participate you will be offered standard clinical treatment which includes being prescribed medication, case management and psychosocial therapies as required. If you choose not to participate, you will be invited to be part of the AO group instead, which receives usual treatment and minimal contact with a researcher. This option is also completely voluntary and will not affect your treatment.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, the findings from this study may help us improve our understanding of Bipolar Disorder and lead to better treatments for other people experiencing Bipolar Disorder. There may be no clear benefit to you from your participation in this research.

9 What are the possible risks and disadvantages of taking part?

Risk of psychological distress

If you become upset or distressed as a result of your participation in the research, the study team 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. **Illicit drug use**

This research project involves the collection of information about participants' use of drugs. As part of the research interview, a researcher may ask you questions about whether or not you use drugs. This

information will be stored in a de-identifiable (or coded) format. In the event that Orygen is required to disclose that information, it may be used in legal proceedings or otherwise.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, a member of the study team will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw from the study, you will continue to receive usual care. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, the research team might consider it to be in your best interests to withdraw you from the research project. If this happens, a member will explain the reasons and arrange for your regular health care to continue.

11 Can I tell other people about the study?

You can tell other people about the study and treatment you are receiving, but you must not tell the researchers who interview you which treatment group you belong to (i.e. RECOVER plus usual treatment or usual treatment only group). This is to ensure that the researchers are blinded to the treatment groups and cannot bias the information they gather in any way.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you should continue to take any medications or treatments you have been taking for your condition or for other reasons. However, it is important to tell the research staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell researchers about any changes to these during your participation in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 What happens when the research project ends?

At the end of the study all participants will continue to receive their usual treatment. Participants will be able to seek psychological therapy from appropriate health professionals, but the specific RECOVER therapy will not be immediately available. The research team can assist in finding an appropriate health professional for you.

The participants of this research project will receive a summary of the project's findings at the completion of the study, should they indicate that this is their preference. A summary of group findings will be provided to participants by mail or via email. Individual results will not be made available.

Part 2. How is the research project being conducted?

15 What will happen to information about me?

By signing the consent form, you consent to the study doctor and 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.

The information obtained will be securely stored at Orygen so that only the researchers involved in this project will have access to the data. It will be kept for a minimum of 20 years after the results have been published. If the information is destroyed, it will be destroyed in a manner that protects the privacy and confidentiality of this information. The information obtained is classified as re-identifiable. This means that details that identify you have been removed from the information (by replacing this information with a unique code), but that it is possible to link the code back to you if necessary. The code will be stored separately from the data. The information collected from you in this project will be entered into a database, using the code rather than your personal identifiable details. Outside of the health service where you are seen, your information will only be identified by this code.

Information about you will be obtained from your medical records held at this service, and if you agree, may be obtained from other health services such as from your local doctor or other hospitals, for the purposes of this research project.

During the study we will endeavour to keep all the information that we collect in the assessments strictly confidential (including electronic or digital information kept on storage media or recording equipment, such as interview audiotapes). This means that only the investigators and research staff directly involved in this project will have access to them. The records will be kept in a locked office. Electronic copies of confidential information including your interview recordings will be password protected and accessed only by researchers involved in this project. There are some exceptions to this: 1) information from the assessments may be communicated with the case manager/clinician to ensure that you receive the best care possible; 2) if we are concerned about risk to you or to someone else, we may need to discuss this with your case manager/clinician and doctor at Orygen; 3) if as a result of the information you disclose in the interview relating to past trauma or abuse we believe that someone else may be at risk. In some cases we may contact The Department of Human Services (DHS) about risk to children under the age of 17 years. Mandatory reporting laws require clinicians to report to Child Protective Services any suspected cases of child abuse and neglect (Children, Youth and Families Act 2005 (Vic.)). In cases where abuse is reported, information gathered by researchers is passed on to the clinical team and the appropriate clinical procedures normally used within the mental health service are implemented. This may involve reporting abuse to DHS or other support services. We will try to the best of our ability to discuss this with you first.

All data collected from you may be kept indefinitely. This data may be used in other related research projects in the future.

<u>Cloud Storage</u>

Your study data will be stored in the Cloud. “In the Cloud” refers to servers in a data centre that are managed by a third party and accessible through the Internet. When storing your study data, we will replace your name with a unique code on all your study data. The coded data will be encrypted and stored on a secure Cloud server to prevent improper access.

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, Orygen, and the Melbourne Health Human Research Ethics Committee, or as required by law. By signing the consent form, you authorise release of, or access to, this confidential

information to the relevant research study personnel and regulatory authorities as noted above. Information about your participation in this research project will be recorded in your health records.
It is anticipated that the results of this research project will be published and/or presented in a variety of forums and may be used by student researchers towards their degree. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and/or Victorian 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 research team member named at the end of this document if you would like to access your information.

16 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the research team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the event of loss or injury resulting from study participation, the parties involved in this study agree to be bound by the Medicines Australia Guidelines for Compensation for Injury Resulting from Participating in a Clinical Trial. A copy of these guidelines is available from the research staff or can be accessed online at the Medicines Australia website.

17 Who is organising and funding the research?

This research has been initiated by the Principal Investigator, Professor Sue Cotton, of Orygen and The Centre for Youth Mental, University of Melbourne. The project is sponsored by Orygen. The research has been funded by the Australian government through a National Health and Medical Research Council project grant (APP1128626).

You will not benefit financially from your involvement in this research project even if, for example, your data, or knowledge acquired from analysis of your data, prove to be of commercial value to Orygen. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Orygen, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

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

18 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Melbourne Health Human Research Ethics Committee.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

19 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact any member of the research team on 9966 6100 or any of the following people:

Clinical contact person

Name	Aswin Ratheesh
Position	Consultant Psychiatrist
Telephone	(03) 9966 6100
Email	Aswin.ratheesh@orygen.org.au

Emergency 24-hour contact:

In an emergency, you can call the 24-hour Orygen clinical team (Youth Assessment Team) on 1800 888 320.

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

For Complaints:

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Name	Director Research Governance and Ethics
Position	Complaints Manager
Telephone	(03) 9342 8530
Email	Research@mh.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	Melbourne Health HREC
HREC Executive Officer	Manager HREC
Telephone	(03) 9342 8530
Email	Research@mh.org.au

Consent Form

Interventional Study - *All participants*

Orygen

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Short Title	RECOVER
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Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Orygen concerning my health status and treatment for the purposes of this project. I understand that such information will remain confidential.

I give permission for data regarding my service utilisation in the public mental health system to be collected from CMI.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that the data from this research will be stored at Orygen for a minimum of 20 years and may be used in other future research projects.

I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements; my data will be password protected and accessible only by the named researchers.

I freely agree to participate in this research project as described in the (please tick one):

- ☐ Randomised controlled group (RECOVER plus usual treatment, or usual treatment only); or
- ☐ Assessment Only (AO) group.

I understand that, if I decide to discontinue my study treatment, a request may be made for me to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I understand that I am free to withdraw at any time during the study without affecting my future health care.

I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

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

Form for Withdrawal of Participation

All participants

Orygen

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Location	Orygen Parkville 35 Poplar Rd Parkville VIC 3052 Sunshine 80B Harvester Rd Sunshine VIC 3020

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me, or my relationship with Orygen.

Name of Participant (please print)	_____
Signature _____	Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Researcher will need to provide a description of the circumstances below:

Declaration by Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher (please print)	_____
Signature _____	Date _____

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