Participant Information and Consent Form

Title	*The Silexan in the Treatment Of Posttraumatic stress disorder (STOP) trial: a phase 3, 12-week, multi-site, parallel-arm, randomised, placebo-controlled, double-blind trial*
Short Title	*STOP trial*
Project Number, Version and Date	The University of Melbourne HREC # 29307 V8, 28/11/25
Project Sponsor	Deakin University
Funding Body	The United States Department of Defense, Congressionally Directed Medical Research Programs' (CDMRP) Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP)
Coordinating Principal Investigator	Prof Michael Berk
Co-Investigators	Prof Richard Kanaan, Dr Rahul Khanna, Dr Greg Roebuck, Prof David Forbes, Prof Meaghan O'Donnell, Dr Mohammadreza Mohebbi, Prof Malcolm Hopwood, Assoc Prof Olivia Dean
Location	Deakin University, the University of Melbourne, Austin Health, Albert Road Clinic
Contact details	STOP Trial study team on 1800 292 969 or email stop-trial@unimelb.edu.au

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you may have a diagnosis of Posttraumatic Stress Disorder (PTSD). The research project is testing a new treatment for people experiencing PTSD. The treatment is a medication called Silexan. Silexan is an over-the-counter medication that contains lavender oil. It is already used to treat certain anxiety conditions, including a condition called Generalized Anxiety Disorder. There is evidence to suggest that it may also be useful in treating PTSD.

This Participant Information and 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 the

project with a relative, friend or your regular treating physician. One of our team will go through the information sheet with you and answer any questions you have.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. 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?

Current treatments for PTSD include talking therapy and medications. These treatments are very helpful for many patients. However, some patients do not complete talking therapy because they experience high levels of distress during it. Similarly, some patients experience unwanted side effects from medications that lead them to cease these medications. For this reason, it is important to investigate new treatments for PTSD that are effective and well tolerated by patients. This study will test if Silexan can improve the symptoms of PTSD. Silexan is a medication that contains lavender oil. It is produced from the lavender plant by a process called steam distillation. Lavender oil contains a number of different chemicals that occur naturally in the lavender plant. Silexan is produced in the form of capsules that are swallowed. It is available over-the-counter in Australia. It is used to treat certain anxiety conditions, including a condition called Generalised Anxiety Disorder. Previous research suggests that Silexan may be helpful in PTSD as well. In this study, we aim to test if Silexan can help to reduce the symptoms of PTSD.

In Australia, medications, drugs and devices must be approved for use by the Australian Federal Government. Silexan is approved in Australia to treat mild anxiety symptoms. However, it is not approved to treat PTSD. Therefore, it is an experimental treatment for PTSD. This means that it must be tested to see if it is a useful treatment for PTSD. Your participation in this trial will help to increase our understanding of whether Silexan can help persons suffering from PTSD.

As this is a randomised controlled trial, you may or may not receive active medication (Silexan) if you participate in the trial. Sometimes, we do not know which treatment is best for treating a condition, so to find out, we compare different treatments, putting people into groups and giving each group a different treatment. The results are compared to see if one treatment is better than the other. To try to make sure the groups are the same, participants are assigned to the groups by chance (randomly). In this study, you have equal chances (50%) of receiving Silexan or placebo (dummy pills).

This research has been initiated by the Coordinating Principal Investigator, Professor Michael Berk, and is being conducted at study sites at Deakin University, The University of Melbourne, Albert Road Clinic, and Austin Health.

3 What does participation in this research involve?

Consent

If you agree to participate in this research project, you will be asked to sign the consent form at the end of this document. The consent form will be signed prior to any study assessments being performed. It is essential that you are completely truthful regarding your health history and any symptoms or reactions you may experience during the research project. If you are not truthful, you may disadvantage yourself and other participants. It is important to understand that no guarantees or assurances can be made regarding the effectiveness of the trial medication that you receive during the study; the purpose of this study is to determine whether Silexan is useful in reducing symptoms of PTSD and your participation will help us investigate this You have equal chances of receiving Silexan or the placebo (dummy pills).

Initial steps

This study is recruiting individuals with PTSD, who are 18 years of age and older, and are fluent in English.
You are NOT eligible to participate if:

- You are currently serving in the Australian Defence Force
- You have experienced symptoms consistent with a current diagnosis of Alcohol or Substance Use disorder, or lifetime diagnosis of Psychosis, Bipolar disorder, Borderline Personality Disorder or Dissociative Identity Disorder
- You have an acute or unstable medical illness or other significant medical condition that would make participation in the trial unsafe or inappropriate
- You are pregnant, lactating, or unwilling to use an acceptable method of contraception
- You have commenced trauma-focussed psychotherapy in the past 3 months
- You have commenced or changed dose of a psychoactive medication in the past 4 weeks
- You have experienced a severe acquired brain injury
- There are safety issues that pose a risk to your own or another person's safety that may warrant alternative intervention
- You are not eligible for public mental health services in Australia, due to your visa status or for any other reason
- The study team have any other concerns for your well-being, or you have any other condition that in the study team's opinion make participation in the trial inappropriate or unfeasible.

The first interview will be over the telephone. It will involve a screening process to see whether you are likely to meet the criteria for participating in the study. We will also send you some online questionnaires to complete. We will ask you about your experiences with PTSD and other mental health symptoms that you might have experienced. If you appear to be eligible to participate in the study, we will arrange a baseline assessment session. You can choose whether to do this session in person at our research centre or via videoconference. In this baseline assessment session, we will start by asking you more detailed questions about your experiences of PTSD, and your current mental health. The baseline assessment will also involve completing further questionnaires on your own, which will ask about your demographics, as well as some questions about your life growing up, medical history, prescribed and over-the-counter medications, experience of mental health symptoms, functioning and quality-of-life. You will be asked about what gender you identify currently as well as your sex assigned at birth. You will also be asked about alcohol intake and substance use. If you served in the military, you will also be asked about this experience. The collection of this information will help us understand whether any of these factors affect whether someone may find Silexan useful for treatment of PTSD. If you do not provide this information, it may impact your ability to take part in the study and the study team may withdraw you from participating in the study. In order to participate in this study, it is also important you are not, or likely to become, pregnant during the trial. If you are not sure, the study team will provide you with a urine pregnancy test. The baseline assessment session will take approximately 2 hours. You will be randomised into the study during this session and will commence the trial medication the day after the session.

Procedures

Once randomised, you will be participating in a double-blind study. This means that there is an equal chance that you will receive Silexan or placebo capsules, and neither you nor the research team will know which treatment you are receiving. However, in certain circumstances the Principal Investigator can find out which treatment you are receiving. A placebo is a medication with no active ingredients. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids the research team or participants jumping to conclusions.

After being randomised, you will be asked to complete study visits at 2, 4, 6, 8, 12, and 16 weeks after your baseline assessment. You can choose whether to do these visits in-person or via videoconference, and you may do a mix of both. At each visit, you will complete several questionnaires. If you choose to complete these visits via videoconference, weeks 2, 4, 6 and 8 may be completed on

your own (without a researcher present) via an online questionnaire. However, a researcher may contact you if they have any concerns about your health or well-being. Generally, these visits will take up to one hour except for the week 12 visit, which may take up to 2 hours.

We will also ask you to wear an actigraphy watch (activity tracker) for the duration of the study, so that we can investigate whether the trial medication has an effect on sleep time or efficiency, or physiological measures such as heart rate, breathing rate, or activity. These activity trackers use an accelerometer to measure sleep activity and sleep/wake cycles, as well as step count. The accelerometer is also combined with a non-invasive light sensor to measure changes in blood pressure, respiratory rate and heart rate, and a gyroscope to measure gait. The activity trackers are developed by Actigraph and are designed for use in clinical trials. We will ask you to download the CentrePoint phone application (app) for the activity tracker, which is a secure, password-protected cloud software program also developed by Actigraph: data from the activity tracker will be stored locally on the activity trackers, and automatically uploaded to the CentrePoint app via Bluetooth at regular intervals. All activity tracker data will be associated with a de-identified code that the study team will assign you; no identifiable information will be input into the activity tracker or uploaded to CentrePoint. Only the study team will have access to the CentrePoint app and the data stored in the app. De-identified data will additionally be downloaded as .csv files onto secure, password-protected servers in study-specific folders at Phoenix Australia at regular intervals.

You can remove the activity tracker if it feels uncomfortable or you are doing an activity that might damage it (e.g. showering or swimming).

If you do not complete the visits at week 2, 4, 6, 8, and 12 of the study, the study team may withdraw you from participating in the study. The trial medication will be dispensed to you at the baseline assessment session. If you choose to complete the baseline visit via videoconference, the trial medication will be mailed to you. At the end of your study participation, a pre-paid return envelope will be provided to return the empty bottles. We will also ask that you return the activity tracker at the end of the treatment period using the same pre-paid envelope.

Table 1: Study Schedule

	Screening telephone call	**Baseline assessment Week 0**	**Visit 2 Week 2**	**Visit 3 Week 4**	**Visit 4 Week 6**	**Visit 5 Week 8**	**Visit 6 Week 12**	**Visit 7 Week 16**
Time commitment (hours)	0.5	2	< 1	1	< 1	1	2	1
Electronic consent	X							
Inclusion/exclusion criteria assessment	X							
Informed consent **Pregnancy test***		X X						
Questionnaires and assessments		X	X	X	X	X	X	X
Wearing an actigraphy watch			X	X	X	X	X	X
Dispensing of trial medication		X						

*For participants of child-bearing potential only

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge. You will be reimbursed for expenses associated with your participation in the study, including expenses associated with parking, transport, utilising a computer (if undergoing study visits via videoconference) and wearing and recharging the actigraphy watches. Reimbursement will be $50 AUD per visit which may take the form of a gift card. If you complete visits remotely, gift cards can be provided via email or mail.

You will be required to nominate your General Practitioner (GP) and we strongly recommend that you talk to them about your participation in this research project. By consenting to your participation in this trial, you also consent to providing the researchers with contact details of your doctor, who will be

contacted regarding your participation in the study. If you decide to participate in this research project, the study team will inform your regular treating physician.

You will be asked to keep the trial medication packs and return them to the research team. If you are attending a study visit via videoconference, you may need to send the medication packs by post to the research team. Postage fees will be covered by the trial.

Trial medication (Silexan or placebo):

During the trial, you will be asked to take two capsules each day in the morning for 12 weeks. If you are in the Silexan arm, these capsules will each contain 80 mg of Silexan for a total daily dose of 160 mg of Silexan. The recommended daily dose of Silexan, according to World Federation of Societies of Biological Psychiatry guidelines, is 80-160 mg (one to two tablets). In order to determine whether Silexan is useful in treating PTSD symptoms, the recommended dosage with the greatest probability of impact has been selected. If you are in the placebo arm, you will take two capsules each day with no active ingredients in them.

Other treatments

The trial medication you receive will be adjunct to your current treatment and medication. That means that, regardless of which group you are in, you will be able to remain on your current treatments. It is important to tell the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments or elective surgery. You should also tell the study staff about any changes to your treatments during your participation in the research project. Your safety is our first priority, and the study team want to ensure that any changes in treatment will not be negatively affected or compromised by the trial medication.

4 Other relevant information about the research project

A total of 278 participants will be recruited for the study (139 participants to receive Silexan and 139 participants to receive placebo). The study is being conducted as a collaboration between researchers at Deakin University, the University of Melbourne, Austin Health, and the Albert Road Clinic. The study is being funded by a clinical trial award (value of $2,031,972 USD) from the United States Department of Defense, through the Congressionally Directed Medical Research Programs' (CDMRP) Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP).

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

Participation in any research project is completely 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 any affiliated institute. If you choose to withdraw from the study, your incomplete data will be de-identified and retained in analyses of the study, unless specified otherwise. If you would like to withdraw from the study, and also withdraw your data provided to the study, you can request this by emailing the study team. Any data requested to be withdrawn from the study will be removed by electronic deletion, and not used in any way in study analyses.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, the results of the study may help people with similar problems of PTSD in the future.

The conduct and results of this study may also advance the academic standing of researchers involved; however, this is not an objective of the study. The researchers strive to advance their

knowledge and the knowledge of the PTSD research community on this topic and build additional expertise in the research group, particularly for early- to mid-career staff members.

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

Trial medication:

Medical treatments often cause side effects. You may have none, some or all the side effects listed below, and they may be mild, moderate, or severe. If you have any of these side effects or are worried about them, talk with the research team. The research team will also be looking out for side effects during your regular research assessments.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your trial clinician immediately about any new or unusual symptoms that you experience.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting, or permanent. If a severe side effect or reaction occurs, the Principal Investigator may need to stop your treatment. Your trial clinician will discuss the best way of managing any side effects with you.

We believe that about 6 in 100 people taking Silexan will experience side effects due to the Silexan. Your chance of experiencing side effects will not lessen if you take a smaller dose. These side effects are usually mild. Known potential side effects of Silexan include:

1. Burping
2. Feeling sick (nausea)
3. Indigestion

There are no known serious side effects of Silexan. However, it is possible that there are serious side effects that we do not know about.

If you notice any of the following symptoms, tell your doctor immediately or go to the nearest hospital Emergency Department:

- swelling of the face, lips, tongue, or throat
- swelling of the hands, feet, or ankles.
- harsh sounds when breathing
- rash, itching or hives
- yellowing of the skin and/or eyes
- easy bruising or bleeding more easily than normal
- extreme fatigue, tiredness or weakness
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- passing little or no urine
- vomiting, breathlessness, loss of appetite and weakness

These side effects require urgent medical attention.

Other Risks:

Mental distress
During the intake (screening) assessment and baseline assessment, you will be asked questions about previous traumatic experiences you have had, and any mental health symptoms. At all study sessions, you will be asked about your PTSD symptoms, other mental health symptoms, and general functioning. Participation at these visits may cause some distress, which is often mild and short-lived. If you experience prolonged distress and require further psychiatric assessment or treatment, the research team will refer you to the appropriate public mental health service and/or provide assistance in accessing appropriate care. At the end of this form, we will ask you to nominate your current treating GP. Should the research team have concerns for your immediate safety they will attempt to contact

your nominated treating GP and provide assistance in accessing appropriate (e.g. emergency or crisis) services.

As part of the intake assessment, we will also ask you about your current living arrangements, and for the contact details for a next of kin. We will contact your next of kin if we have concerns for your immediate safety.

In circumstances where you disclose risk of harm to yourself or others, and the treating clinician identifies this as significant, you may be withdrawn from the trial for your safety.

Conceiving during the trial
The effects of Silexan on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and childbearing is a possibility, you will be required to do a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least one month after the last dose of study medication.

Both male and female participants are strongly advised to use effective contraception during the research and for a period of one month after the last dose of study medication. You should discuss methods of effective contraception with your trial clinician.

For female participants: If you do become pregnant whilst participating in the research project, you should advise your trial clinician immediately. The researchers will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

For male participants: You should advise your trial clinician if you father a child while participating in the research project. The research team will advise on medical attention for your partner should this be necessary.

Legal risk
You will also be asked about any illicit recreational drug use at each research visit. This information will be stored in a de-identified way (coded under your participant number) for legal reasons. We will generally not disclose that information without your consent but there may be circumstances where we must do so for legal reasons. In that case, the information could potentially be used against you in legal proceedings or otherwise.

Online visits
You will have the option to complete study visits remotely, using a teleconferencing program (Zoom). These meetings can be run using your internet browser; no special equipment is needed, and no application needs to be downloaded. While Zoom is a secure teleconferencing program hosted by the University of Melbourne, there are inherent cybersecurity risks associated with any online tool. You may complete study visits in-person, remotely, or a mix of both.

8 Helplines

The questions at each interview will focus on the symptoms of PTSD and questions about your general functioning. This may cause psychological distress. Should you feel distressed at any time during the study, you may suspend or end your participation. Should you require further psychological assistance, you will be referred to the public mental health service for treatment.

Should you need additional support throughout the study, please consider using the following national helplines:

Suicide Call Back Service: 1300 659 467
Lifeline: 13 11 14
Open Arms – Veterans' & Families Counselling: 1800 011 046
Soldier On (veterans): 1300 620 380
1800 RESPECT: 1800 737 732

9 What if new information arises during this research project?

Sometimes during a research project, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the research project. 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 researchers might consider it to be in your best interests to withdraw you from the research project. If this happens, the researchers will explain the reasons and arrange for your regular health care to continue.

10 What if I withdraw from this research project?

You may decide to withdraw your consent and discontinue your participation in this study at any time for any reason. Your withdrawal will not jeopardise your medical care at this facility. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. We ask that if you do withdraw from the study that you attend a final interview to discuss any health risks or special requirements. As part of consenting to this study, you agree that the data you provide will be used for the study if you decide to withdraw. If you do not wish for your data to be used in the study, please let the study team know.

Your researcher may end your participation in this research program for any reason that they feel is appropriate. These may include but are not limited to an adverse event, injury, a medical condition which may place you at risk of further complications if you continue to participate, failure to take the medication as instructed, or termination of the study by the investigators or for other administrative reasons.

11 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The drug being shown not to be useful for PTSD
- The drug being shown to work and not need further testing

12 What happens when the research project ends?

Once the study has been completed by all participants, a notification letter will be sent to you revealing which group of the study (either the Silexan or placebo group) you were in. Additionally, once the data is analysed you will be sent a letter including the summary of the results of the study. The summary of results will be based on group data from all the participants. Individual data will not be provided.

Part 2 How is the research project being conducted?

1 What will happen to information about me?

By signing the consent form, you consent to the 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 so far as permitted by law. This will include de-identification of all documents relating to the trial by assigning you a random participant number that will identify you in terms of a data set and not an individual.

Any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data, as well as compliance with good clinical practice for human research studies) by the relevant authorities and authorised representatives of the Sponsor, Deakin University, including a Deakin University-employed clinical trial monitor and the Deakin University Research Governance office. Research investigators associated with the study, the Therapeutic Goods Administration, the University of Melbourne Human Research Ethics Committee, and the institution relevant to this Participant Information Sheet, the University of Melbourne, will also be able to inspect and access confidential data that identifies you by name. In addition, representatives from the United States Department of Defense (which is funding the trial) are also authorised to review research records that relate to your participation and identify you by name. 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. In accordance with relevant Australian and/or Victorian privacy and other laws, you have the right to request access to the information collected and stored by the study team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the study team if you would like access to your information.

By consenting to your participation in this trial, you also consent to the release of your relevant medical records to the above-named persons/bodies. 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. Information about your participation in this research project may be recorded in your health records.

The data collected in this research project will be entered directly by you, or directly or transcribed from hard copy records by the research team, into a highly secure online database called REDCap. Data obtained from your health records may be used to cross-check or validate data (for example, to accurately determine the nature of any side effects to Silexan, or confirm medication prescriptions) entered directly by you, or transcribed and entered by the research team, into REDCap. Accessing this data will require the use of passwords and user authentication details only possessed by approved members of the research team. Medical records, when in a digital format, will be stored in secure, password-protected folders on the Phoenix Australia server, identified using only your initials. Hard copy records, including a signed copy of this Participant Information and Consent Form, will be stored in locked cabinets in a dedicated research office at Phoenix Australia, at the University of Melbourne for the duration of the study. The keys for these cabinets will be held by approved members of the research team. The research office is locked and requires ID card access granted for approved personnel only. As outlined above, de-identified data from activity trackers will be stored on the activity tracker's secure, password-protected, cloud-based software program (CentrePoint), and downloaded as .csv files onto secure, password-protected, Phoenix Australia servers.

Following completion of the study, de-identified records relating to the results of the study will be kept by Deakin University for 15 years and you may access that information as it relates to you if required.

After the 15-year period, the data files on REDCap will be deleted and the hard copy records shredded. However, the data will remain in a de-identified form on the National Institute of Mental Health Data Archive.

2 Privacy and confidentiality

As we have noted above, any information obtained in connection with this project that can identify you will remain confidential. This will include de-identification of all documents by assigning you an anonymous and unique 'participant code identifier'. You will be assigned a unique code for the intake (screening) assessment, and a second unique code if you are eligible and consent to participate in the trial. A secure database on a password-protected Phoenix Australia server will contain the information which links your identifiable information with this unique code identifier. This database will only be accessible by the study team and regulatory agencies as outlined above.
De-identified data collected as part of this study – data that does not contain any identifiable information about you – will be uploaded to a large, online database in the United States for use by other researchers. Therefore, this form is requesting extended consent – consent to use data collected in this study, for this study, and to share your de-identified data as part of a larger dataset for use in other, future studies. Information about this database, including what to do if you do not want your data included in this database, is outlined in the next section (section 3).

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 as aggregate (i.e., grouped) data, and in such a way that you cannot be identified, except with your permission. Any analysis, interpretation and publication of the study results will remove all identifying details and cannot identify you.

3 Sharing data with online archive

Data from this study will be submitted to the United States National Institute of Mental Health (NIMH) Data Archive (NDA) at the National Institutes of Health (NIH). The NDA is a large database where de-identified study data from many NIH studies are stored and managed. Sharing your de-identified study data helps researchers learn new and important things about brain science more quickly than before.

De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number will be generated using software the study researchers have at the study site on their own computers; the personal information used to generate the code will not leave the study site. The code number cannot be used to identify you. The study researchers will never send your personal information to the NDA.

It is possible that you will participate in more than one study that sends data to the NDA. The NDA can connect your data from different studies by matching the code number on your de-identified data from each study. This data matching helps ensure that researchers who use NDA data only count you one time. It also helps researchers who use the NDA to better understand your health and behaviour without knowing who you are.

During and after the study, the study researchers will send de-identified study data about your health and behaviour to the NDA. Other researchers across the world can then request your de-identified study data for different research projects. Every researcher (and the institution to which they belong) who requests your de-identified study data must promise to keep your data safe and not try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are low; however, your study data could be accidentally shared with an unauthorised person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with the NDA. The study data provided to the NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. The NIMH will also report to the United States

Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to the NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in NDA, please tell the study researcher. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell the NDA to stop sharing your study data. Once your data are part of the NDA, the study researchers cannot remove the study data that was shared before they were notified that you changed your mind. If you would like more information about the NDA, it is available online at http://nda.nih.gov.

4 Will I hear about the results of this project?

Once the study has been completed by all participants, a notification letter will be sent to each participant revealing which group of the study (either the Silexan or placebo group) they were in. Additionally, once the data is analysed, participants will be sent a letter including the summary of the results of the study. The summary of results will be based on group data from all the participants, feedback on individual results (i.e. your data, or any other individual's specific data) will not be provided.

5 Who is organising the research?

This research project is being coordinated by Professor Michael Berk. If knowledge acquired through this research leads to discoveries that are of commercial value to Deakin University, the investigators 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).

6 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 University of Melbourne HREC (study #29307), and the U.S Army Medical Research and Development Command (USAMRDC) Office of Human Research Oversight (OHRO). The study has also been registered with other Australian ethics review bodies under processes for minimising duplication of ethical review in accordance with the National Statement.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

7 Complaints and compensation

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

Injuries or complications related to this research project
If you suffer any injuries or complications because of this research project, you should contact the study 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.

If you seek emergency care, or if hospitalisation is required, please alert the treating General Practitioner that you are enrolled in a research study being conducted by Professor Berk. You will be given a wallet insert which contains details of the study, please present this to the treating physician. In an emergency, please dial 000.

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 the STOP Trial study team on 1800 292 969 or email stop-trial@unimelb.edu.au

Complaints regarding the research project
This project has human research ethics approval from The University of Melbourne [study #29307]. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 1376 or Email: *research-integrity@unimelb.edu.au*. All complaints will be treated confidentially. In any correspondence, please provide the name of the research team and/or the name or ethics ID number of the research project.

This research project has also been approved by the U.S Army Medical Research and Development Command (USAMRDC) Office of Human Research Oversight (OHRO).

8 Emergency study contact

If you are experiencing severe physical side effects, which may be related to your involvement in the project, you may contact the study clinician on 03 9035 4749. This is a 24/7 line. In an emergency, call 000.

9 General Practitioner Details

The research team will contact your regular General Practitioner regarding your participation in the study. Contact may also be made to your regular General Practitioner regarding your safety or as deemed appropriate by the study team. Please provide their details for the research team.

GP's name	
Practice name	
Practice Address	