SerTRaline for AnxieTy in adults with a diagnosis of Autism (STRATA).
A randomised controlled trial.

Participant Information Leaflet

Chief Investigator: Associate Professor Helen Leonard

Principal Investigator: Professor Sergio Starkstein

We invite you to take part in the STRATA research study

Summary

- We are inviting **adults with a diagnosis of autism who experience anxiety** to take part in a research study, known as STRATA.
- We want to find out whether the medication sertraline is an effective treatment to reduce anxiety in adults with a diagnosis of autism.
- People who take part will receive **either sertraline, or a placebo (inactive) medication** in capsule form**.** They will be asked to take it for up to **one year**. Please note that the medication capsules may contain gelatine, which may not be suitable for vegans.
- Participants will be **contacted briefly** by trained study staff via video call, telephone, text or email (whichever you prefer) **at 1 to 2, 4, 8, 12 and 36 weeks** after you join the study, **to see how you are getting on with the medication.**
- Participants will be asked to **complete questionnaires at baseline (week 0), 16, 24 and 52 weeks** after you join the study. The questionnaires will ask about your anxiety, other symptoms, and healthcare usage. To thank you for your time, we will offer you a $20 gift voucher upon receipt of each completed questionnaire.
- By taking part in this study, **you will be helping to inform whether autistic adults who experience anxiety should be prescribed sertraline.**
- If you take part in the study, **you can withdraw at any time** without giving a reason.

Important things that you need to know

- **Before you decide to take part**, it is important that you understand what the study is about, why it is being done, and what will be involved.
- **Please take time to read this Participant Information Leaflet:**
  - PART A: explains why this study is being done.
  - PART B: describes what taking part involves.
  - PART C: provides further general information about the study and information about what will happen to your data if you decide to take part.
- Feel free to talk to family, friends, carers, or others about the study if you wish.
- Please contact the STRATA study team using the details below if there are any parts of this information leaflet that you do not understand, you have any questions, or you would like further information.
- Once you have read this leaflet, **if you are interested in taking part,** please complete the **online Expression of Interest form** www.tinyurl.com/STRATAEoI (or return the paper version of the form in the pre-paid envelope provided if applicable).
- **If we do not hear from you**, a member of the study team *may* contact you to discuss taking part and answer any questions you may have.

Please note: *(i) for the purpose of this information sheet, any reference to 'we' means the study sponsor (The University of Western Australia). (ii) Terms for the autistic population may also be used interchangeably throughout.*

Contact details – STRATA Study Team

Email: strata@uwa.edu.au **Tel:** (08) 9431 3978 **Website:** www.bristol.ac.uk/strata

Address: Fremantle Hospital, The University of Western Australia, Psychiatry,
T Block, Level 7, M704, Alma Street, Fremantle, WA 6160, Australia

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PART A: Why is the study being done?

1. What is the purpose of the study?

The STRATA study aims to find out whether the medication sertraline is an effective treatment for anxiety in adults with a diagnosis of autism.

We are interested to see whether sertraline reduces symptoms of anxiety, enhances quality of life, and is effective in the longer term.

We are also interested in understanding side effects of the treatment, what people think about being invited to the study, and their experiences of taking part in it.

2. Why is the study being done?

A lot of autistic adults experience anxiety and many find it to be very difficult to deal with. Medications like sertraline are often prescribed for anxiety in autistic adults but whether they work, and what their side effects are in the autistic population is not well known. Although such medications are well studied in the general population, those research findings may not apply to autistic adults. It is important that any medication prescribed to autistic adults is based on research evidence. Better research into treatments for mental health conditions in autistic people was recently identified as the "number one priority" by autistic people and other stakeholders. The National Health and Medical Research Council (NHMRC) identified this area as a major gap in the evidence and funded this study.

This study (STRATA) will be the largest of its kind and will therefore provide evidence to show whether the medication sertraline has a role in managing anxiety in autistic adults.

This study has been designed by experienced researchers and clinicians, with the help of an advisory group of five autistic adults.

We aim to enrol a total of 306 autistic adults to this study, in both Australia and the UK. Half will receive capsules containing the study medication sertraline and half will receive capsules containing a placebo (inactive medicine). We would like you to consider taking part.

To take part you need to:

- be aged 18 years or over and have a diagnosis of autism (including autism spectrum disorder/condition or other variations, Asperger syndrome or pervasive developmental disorder);
- experience anxiety for which you are willing to try treatment with medication;
- be able to complete online or paper-based questionnaires about things such as your anxiety, other psychological symptoms, and healthcare usage;
- be able to provide informed consent to take part.

The study *may* not be suitable for you to take part in if you are/have:

- currently taking certain medication(s) for depression and/or anxiety, or have taken them regularly in the past 8 weeks. (We will check this information with your doctor if you want to take part) or using St John's Wort.
- have a moderate or severe learning disability which means you may not be able to provide informed consent and/or understand and complete the study questionnaires.
- have/had a currently valid diagnosis of other mental health conditions such as bipolar disorder or psychosis.
- epilepsy that is not well controlled.
- current problematic use of alcohol or illicit drugs.
- allergies to sertraline or placebo.
- severe liver problems, bleeding disorders, some heart problems swallowing difficulties or are unable to take medication in capsule form.
- taking part in another clinical trial.
- pregnant, planning pregnancy during the study period, or breastfeeding.

If you have any questions about this, or would like further information, you can contact a member of the STRATA study team using the contact details on page 1.

PART B: What does taking part in the study involve?

3. Why have I been invited to take part?

You have been invited to take part in this study because you have a diagnosis of autism. You may also be looking for help for your anxiety.

You may have received this leaflet because one of your healthcare providers thought that you might be interested in taking part. Alternatively, you might have contacted our research team, volunteered to hear about research opportunities, or visited our website and requested more information.

4. Do I have to take part?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to.

- **If you are interested in taking part**, please complete the **online Expression of Interest form** www.tinyurl.com/STRATAEoI (or, if you prefer, complete and return the paper version of the form in the prepaid envelope provided).
- **If you decide to take part,** you are also free to leave the study at any time without giving a reason.
- **If you decide *not* to take part,** your usual care will not be affected in any way.
- **If you have any queries,** or you do not understand any part of this information leaflet, please contact us using the details on the front page.

5. What is involved if I take part?

The diagram on page 5 summarises what is involved, from being invited through to the end of the study. More information about what is involved shown below, and on the pages that follow.

a) Once you complete the Expression of Interest form

- **If your responses to the Expression of Interest form do *not* meet the requirements to take part:** the study is not suitable for you at this time. We will tell you promptly if you are completing the form online, or as soon as possible if you have completed the paper form.

- **If your responses to the Expression of Interest form meet the requirements to take part:** with your consent, a member of the research team will contact you and/or your doctor/GP to check that it is safe for you to take the study medication (capsules containing either sertraline or inactive placebo) if you decide to take part.

  A member of the study team will then contact you using your preferred method to let you know that the study is either not suitable for you at this time, or that you are eligible to take part. If you are eligible, we will answer any questions that you have and ask if you still want to take part.

- **If you are eligible and want to take part:** we will arrange the **first STRATA study appointment**. This appointment can be conducted via video call or in person* with a member of the study team; you can choose how and when.

  **In light of COVID-19, we realise that face-to-face appointments may not be feasible. STRATA therefore offers various contact methods. If face-to-face appointments are requested, research staff will check they are safe and follow the guidance at the time regarding face-to-face contact, including, for example, use of personal protective equipment and cleaning procedures. The safety of participants and staff are the priority, and you will not be asked to do anything that you feel uncomfortable with.*

b) First study appointment ("Baseline")

This appointment *may* take around 1-2 hours. At the appointment, the researcher will explain what taking part in the study involves, ask questions to check you are still eligible to take part, and answer any questions you may have. A clinically trained member of the research team will also check that it is safe and suitable for you to take part.

If you decide you want to take part in the 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.

Family or carers can help you decide if you would like to take part in the study. But you must give your own consent to participate in this trial.

If it is still suitable for you to take part in the study and you agree, you will:

- be asked to complete the **STRATA Baseline Study Questionnaires**, and other relevant questions about your diagnosis of autism, anxiety, and what medications you currently take.
- be allocated to receive either sertraline or a placebo (inactive) medication.

As we do not know if sertraline is an effective treatment for anxiety in autistic adults, the type of medication you will receive will be allocated through a process called **randomisation**. This means you will have an equal chance of receiving either sertraline or a placebo medication. A placebo is a medication with no active ingredients. It looks like the real thing but is not. Randomisation is used as it creates groups of participants that are similar except for the medication they are allocated. This will enable us to compare the two groups fairly so that at the end of the study we can reliably assess whether sertraline is an effective treatment or not. If you or someone in the study were allowed to choose the medication, then the groups of people being compared may not be sufficiently similar. You are participating in a double-blind study. This means, neither you, nor the research team will know which medication group you have been allocated to. This is important so that your, nor the research team's, perceptions about the medication can affect the results of the study. However, your safety comes first, and if there is a medical reason, to find out which medication you have been taking (ie either sertraline or inactive placebo), then this information will be available 24 hours a day, 7 days a week via the study pharmacy. 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. After you have been allocated the treatment, a study-specific prescription will be authorised, and the medication will be posted to your home (or other specified address) by the study pharmacy, or you can pick up after your appointment. ***At this point you are enrolled in the study.***

Please continue to next page.

6. Flow diagram about the STRATA study

Invitation to Take Part

- Read this Participant Information Leaflet. Ask any questions.

Expressions of Interest and Eligibility Screening

If you are interested in taking part in the STRATA study

- Complete the online Expression of Interest form (or return the paper version if preferred).
- Provide further information so the study team can contact you and/or your doctor/GP to complete essential participant safety checks.
- Once known, Study team will contact you to advise that it is either:
  - Not suitable for you to take part at this time; or
  - It is suitable for you to take part and to arrange your first STRATA appointment*

**can be conducted via video-call or in person; you choose how and when.*

First STRATA Appointment

During this appointment (*may* take around 1 to 2 hours)

- Discuss study and ask any questions. We will reconfirm it is still suitable for you to take part.
- Complete consent form.
- Complete study questionnaires and other relevant questions (e.g. about your diagnosis of autism, anxiety, and current medications). We will offer you a $20 voucher upon completion of this appointment.
- Be allocated (randomised) to receive either sertraline or a placebo (inactive) medication.

Brief Safety Checks

At 1 to 2, 4, 8, 12 and 36 weeks after you agree to take part

- Complete some brief questions about anxiety, mood and side effects.
- Member of the study team who is trained to monitor symptoms will contact to see how you are getting on with the study medication.
- Decisions about changes in medication dose will be taken by the local clinician prescribing you the study medication, taking into account your wishes and responses to the questions during the safety checks.

Follow Up Questionnaires

At 16, 24 and 52 weeks after you agree to take part

- Complete a questionnaire*. $20 voucher offered upon receipt of each completed questionnaire.
- The 52-week questionnaire is the final study questionnaire.

**online, postal copy, video-call with a researcher, or via telephone; you choose method of completion.*

Study Medication

- We will post you the study medication at regular intervals to your preferred address.
- **You will be asked to take the study medication capsules (containing either sertraline or inactive placebo) as instructed for up to 52 weeks after you agree to take part.**
- You can choose to stop the medication at any time, but you can carry on participating in the study by completing the questionnaires.

- The researcher will arrange dates and times of the **Brief Safety Checks** (see next page) to see how you are getting on with the medication.
- You will be provided with instructions on how to take the study medication, together with other supporting information

If you have informed us that you have a carer, with your permission, we would like to approach them about taking part in a separate study to explore how the treatment of anxiety for adults with a diagnosis of autism affects them as a carer. It is up to you to define who your carer is, but where possible, it would be someone who knows you well and is likely to continuing providing you with support throughout your involvement with this study. **If you agree for us to approach your carer**, then we will provide you with an information pack and ask you to provide it to them at the earliest opportunity. You are still able to take part in STRATA if your carer does not wish to take part, or if you do not have a carer. Similarly, if your carer does agree to take part, they can continue to be involved if you withdraw from the study at any point.

At the end of this first study appointment, we will send you a $20 gift voucher to thank you for your time, and cover any reasonable travel expenses.

c) At home, taking the medication

Receiving your medication. The medication will be posted to your home address or you can collect from the hospital pharmacy (or we *may* be able to send it to your GP practice or local pharmacy if preferred).

Taking the medication. You will receive separate information telling you all about how to take the medication each day and other important advice. The medication will be in the form of white capsules (that will contain either sertraline or an inactive placebo; see picture of capsule below). Please note that the capsules may contain gelatine which may not be suitable for vegans.

- **If you become pregnant while taking the study medication**, then you should inform a member of the study team using the contact details on page 1.
- **Diet**. In general, you do not need to make any changes to your diet when taking the study medication. However, it is advisable to avoid grapefruit juice when taking this medication as it can slow down the metabolism of the medication.

You will first receive a starter pack of the medication. **You will be asked to take:**

- **1 capsule of the medication (25mg) each day for 2-weeks**
- **then 2 capsules (25mg each) of the medication each day for the next 4 weeks**
- **after this you will be sent 50mg capsules of the medication.**

How do we decide which dose of medication you should take? To see how you are getting on with the medication, we will ask you to complete some brief questions. A member of the research team who is trained to monitor symptoms will arrange to contact you either by video call, telephone, text, or email (whichever you prefer), at 1 to 2, 4, 8, 12 and 36 weeks after you joined the study. These are the **Brief Safety Checks** mentioned on the page above.

During each of these follow up conversations, the researcher will ask you whether the medication is suiting you and whether you are having any side effects, and answer any questions you may have. They will then discuss which strength of medication you may be offered next. The dose can slowly go up to 200mg (4 x 50mg capsules per day) by week 12 of the study. Decisions about changes in the dose will be taken by the study doctor prescribing you the study medication, taking into account your wishes and replies to the questions during the safety checks. If you experience unpleasant side effects, we may advise you stay on the current dose, or go down to a lower dose.

Once you have reached the dose most suitable for you or the maximum dose allowed, you will be asked to carry on taking this dose of medication. You can arrange to discuss the medication with the clinical researcher at any time

including unpleasant effects or if you feel it is having a negative effect on your mental or physical health. *You may also decide to stop the medication earlier for any reason*. In total you will be taking the study medication for up to 52 weeks (one year).

d) Questionnaires

Before you start, and then at 16, 24, and 52 weeks after you join the study, you will be asked to complete a questionnaire. This can be completed online but can also be done via post, or with a researcher via video call or telephone. The questionnaire at 52-weeks is the final study questionnaire.

On each occasion you will receive a $20 voucher to thank you for your time spent completing these questionnaires and cover any reasonable travel expenses (up to $80 in total over the 52 weeks).

7. What is the medication being tested?

The active medication being tested is called sertraline. Sertraline is currently used for the treatment of depression, as well as several anxiety conditions including panic disorder with or without agoraphobia; obsessive compulsive disorder (OCD); social anxiety disorder, and post-traumatic stress disorder (PTSD). We therefore already know a lot about its safety, effectiveness, and side effects in the general population.

8. Does the medication have any side effects?

Like all medicines, sertraline can result in side effects for some people, but it is important to remember that not everybody encounters them.

Some common (happen in more than 1 in 100 people) known side effects of sertraline are:

- Nausea
- Dizziness
- Dry mouth
- Sleep problems
- Drowsiness/fatigue
- Headache
- Diarrhoea
- Sexual dysfunction (including ejaculation failure, erectile dysfunction, reduction in sex drive).

This is not an exhaustive list. If you require further details about the possible side effects of sertraline, they can be found in the Summary of Product Characteristics (SmPC) leaflet available on the STRATA website. You can also talk to the STRATA team if you have any queries or concerns.

You may see side effects more frequently when you start your medicine or increase the dose. In many cases, side effects gradually disappear as your body gets used to the medicine. Some people find their anxiety gets worse during the first few weeks of treatment, although this usually wears off after a few weeks. Some people may experience new suicidal thoughts after starting the medication. We suggest that you tell your family and/or carer about these possible side effects. *We will monitor any side effects you may experience carefully (see Section 6c).*

Some people are at higher risk of developing side effects from the medication used in this study. **If you have any of the following conditions your healthcare provider and the study team will talk about this before you agree to take part:**

- Some bleeding disorders
- Some heart conditions

If you decide to take part in the study, we will give you detailed information about the medication capsules including how to take them and what to do if side effects occur.

With your permission, we may tell your doctor/GP if we have concerns about your health or well-being. However, if there is a risk of harm to you or others, we may share such information without your consent.

One important aim of this study is to understand the side effects of sertraline in autistic adults. It is possible that the side effects experienced by autistic adults may be different from the non-autistic population. We will therefore be asking you about these at each point of contact (follow up).

9. What will happen if I get side effects?

You can discuss this with the clinical researcher prescribing you the study medication. They may suggest you:

- carry on with the medication and see if the symptoms resolve.

- seek treatment for the side effect e.g. from your doctor/GP.
- take a lower dose.
- stop the medication completely.

You do not have to wait for the next appointment before telling us if side effects are bothering you. You can contact a member of the study team when you need, using the contact details on page 1.

If you have severe side effects, significant worsening of your anxiety, or new symptoms such as suicidal thoughts, you should contact the clinical researcher as soon as possible. You can also make a free call to the Mental Health Emergency Response Line on 1300 555 788 (Metro) or 1800 676 822 (Peel) at any time, or speak to your GP. In an emergency, you should contact the emergency services (dialling 000) or attend a hospital Emergency Department.

You can carry on participating in the study even if you have to stop the medication because of side effects. Your responses to the questionnaires will still be valuable.

10. Will it affect other medications I take?

You will only be asked to join the study if you are not taking medications that the study medication may interfere with.

You can continue taking all your other medications as normal throughout the study. Your doctor/GP can prescribe most other medications normally. However, you cannot be prescribed sertraline or other similar medications used for treating depression or anxiety at the same time. We will let your doctor/GP know that you are taking part in this study, so they can take this into account when they prescribe any other medication to you.

If you were to need a general anaesthetic to undergo any operations, then it would be important to let the anaesthetist (the doctor who puts you to sleep for the operation) know that you are participating in this study.

11. What are the possible benefits of taking part?

Your anxiety symptoms may improve, but there is no guarantee. You may also benefit from the extra contact from being part of the study. However, please note that taking part in this study does not replace other services you may be receiving for any physical or mental health problems, and you should continue to seek support from your GP and any other services as you would usually do.

Even if you do not receive a direct benefit of taking part in this study, your involvement will help to improve future treatment recommendations for autistic adults who experience anxiety.

12. What are the possible risks and/or discomforts of taking part?

Study appointment

The first study appointment *may* last 1 to 2 hours. You may find it tiring to complete the questionnaires. We will try to ensure you are comfortable and you can take breaks as needed.

We estimate that it may take about an hour to complete each of the other study questionnaires, however this time will vary for each person; some people will take less time, and others may take longer. You will be able to complete these at a time, and by a method, convenient to you.

Possible side effects of medication

See Sections 8 and 9 above, for details.

13. What will happen when the study treatment stops?

At the end of the study treatment period (52 weeks) we will provide you with instructions on how to safely reduce and stop the study medication. We will do the same if you decide to stop taking the treatment before 52 weeks. You will also be given the option to know whether you received sertraline or the placebo medication. You can then use this information to discuss your future treatment options with your doctor/GP. Your doctor can continue to prescribe sertraline if they consider it appropriate.

If you withdraw from taking the medication before 52 weeks, you will be given the option of knowing which medication you have been taking at the time of withdrawal or at your 16 week follow up, whichever comes later. This information may be helpful if you are discussing further treatment options with your doctor.

14. What are the alternative treatments?

There are other treatments available for anxiety such as cognitive behaviour therapy or medications such as benzodiazepines. There is very little evidence on which treatments for anxiety work in autistic adults, which is why we are doing this study. **You can still have all other usual care** from your doctor/GP and any specialist services whilst taking part in the study including the above treatments if you are offered them.

15. What about expenses?

There are no additional costs associated with participating in this research project. All medication, tests and medical care required as part of the research project will be provided free of charge.

If you choose to complete paper questionnaires, the study team will provide you with prepaid envelopes.

16. If I take part, can I change my mind and leave the study?

Yes. If you decide to take part, **you are free to leave the study (withdraw) at any time**; please contact the study team using the details on page 1 to withdraw from the study. You do not have to give a reason for withdrawing, and your medical care and legal rights would not be affected.

If you just want to stop taking the study medication, please let us know so we can advise you on how to reduce and stop the medication safely. This is important because some people may experience unpleasant symptoms if they suddenly stop taking sertraline. If you wish to discontinue the medication in the first 16 weeks, we will remind you that it may take up to 16 weeks to notice improvements in anxiety with this medication, but that you can still stop the medication if you wish to.

If you decide to stop the medication, it will still be very valuable if you keep completing future questionnaires. It is **very important** that we try and get results from everyone who took part in the study, whether they continued with the medication or not.

If you withdraw from the study and do not wish to complete any further questionnaires, we will confidentially retain any information we have already collected about you to use in our analysis of the study results, and we will not contact you further.

PART C: Further information about the study and what will happen to your data if you decide to take part

17. What if new information becomes available during the study?

Sometimes we get new information about the treatment being studied. If this happens, the study team will tell you and discuss whether you should continue in the study. If you decide not to continue, you will be withdrawn from the study, and the study doctor will make arrangements for your regular health care to continue. If you do continue in the study, you may be asked to sign an updated consent form.

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

18. How long does the study last and what will happen to the results?

The study is expected to run through to March 2025. Once completed, overall results will be published in medical journals and presented at conferences attended by other healthcare professionals and specialists. The results will also be shared with the wider public using easy to understand summaries through our website and social media. **No one will be able to identify you from any of the study reports/publications.**

We will also send you, if you wish, a newsletter with the results of the study, which are expected in 2025.

19. Who funded this study, who is the sponsor, and who is managing this study?

The study is being funded by the National Health and Medical Research Council (NHMRC,

reference 1171206) and the National Institute for Health Research Health Technology Assessment programme (NIHR HTA, reference 127337). This study is not funded by any pharmaceutical company. The research is led by a team of experienced doctors and researchers who are responsible for managing the study and is sponsored by The University of Western Australia. This is an international collaboration with the University of Bristol, and the Bristol Trials Centre based in the UK. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

20. Will the information I provide be kept confidential?

Yes, we are committed to handling the information (data) used in the STRATA study securely and confidentially. Your data will be stored and used in compliance with the relevant, current data protection laws; Data Protection Act 2018 and General Data Protection Regulation 2018 (GDPR).

We will be using information from you and/or your medical records to undertake this study and the University of Bristol (UK) will act as the data controller. This means that they are responsible for receiving and looking after your information and using it properly. Personal information such as your name, date of birth, email address, and phone number will be stored on a secure database with the central research team (at the University of Bristol). The University of Bristol will keep identifiable information about you for at least 15 years after the study has finished; this is a legal requirement for clinical trials.

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.

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 Western Australia and the University of Bristol (UK), the institution relevant to this Participant Information Sheet, the South Metropolitan Health Service 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 study personnel and regulatory authorities as noted above.

Any information obtained for the purpose of this research project and for the future research described in Section 21 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.

21. Will my data be used in future research?

Other researchers *may* request to access anonymised data from this study in the future, for example to carry out a systematic review. If you take part in this study, anonymous data collected in this study *may* be used in future ethically approved studies; **this will never include names, dates of birth, or contact details, and it will not be possible to identify individual participants**.

22. How will we use information about you?

We will need to use information from you and/or from your medical records for this research project. This information will include your:

- Initials
- Name
- Gender
- Date of birth
- Contact details (for example: postcode, telephone number, email address)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

The Fiona Stanley Hospital Fremantle Group (FSHFG) is the organisation who will be providing you the medication from their pharmacy. They will be given your personal information so they can send you the correct medication (sertraline or placebo capsules). In an emergency, they will be the organisation who will be able to identify which medication group you are on (sertraline or placebo). The information provided to them will be kept securely; they must follow our rules about keeping your information safe.

"Sealed Envelope™" is the company who provide the randomisation software which helps to enable the process of treatment allocation. Your local researcher will provide "Sealed Envelope" with relevant information about you to enable their system to allocate which medication you will receive. The information provided to them will be kept securely.

23. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

24. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- our leaflet "How we use information from patients" available from: **www.bristol.ac.uk/strata/**
- at the University of Bristol website: **www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/**
- by asking one of the research team**: see contact details on front page**

25. Who has reviewed the study?

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 South Metropolitan Health Service 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.

An independent Trial Steering Committee, based in the UK, will monitor the study to ensure it is conducted according to good research practice.

26. What if there is a problem?

If you have a concern regarding your care as a participant, please discuss this with your doctor/GP or specialist.

You will be insured throughout the study period in accordance with the Product Liability Act for Pharmaceutical Research.

The same legal rights and insurance coverage will apply during the clinical trial as for any other medical treatment. Should you be injured as a result of your participation in the trial, you may receive compensation. In this case, it is essential that you inform your trial physician or researcher of such issues immediately, and they will assist you.

If you suffer any injuries or complications as a result 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.

27. What if I have a concern or complaint?

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

Clinical Contact person

If you have any questions (or concerns) about any aspect of this study, or your treatment or health whilst on the study, please speak to your local STRATA study team using the details on page 1.

Alternately, 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 principal study doctor Professor Sergio Starkstein on 0478 669 822 or email: sergio.starkstein@uwa.edu.au

Complaints Contact person

For matters relating to research at the site at which you are participating, please contact:

Manager, South Metropolitan Health Service Research Support and Development Unit

Phone: 08 6152 3214.

Email: smhs.rgo@health.wa.gov.au

Reviewing HREC approving this research

South Metropolitan Health Service Human Research Ethics Committee

Contact person: Ethics Coordinator

Phone: 08 6152 2064.

Email: smhs.hrec@health.wa.gov.au

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION.

PLEASE KEEP A COPY FOR YOUR RECORDS.

The authors and The University of Western Australia acknowledge funding from the National Health and Medical Research Council (Project Grant 1171206). The contents of the published material/website are solely the responsibility of the authors and do not reflect the views of NHMRC.

Australian Government
National Health and Medical Research Council

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FUNDED BY
NIHR | National Institute for Health Research

This study is funded by the National Institute for Health Research (NIHR) HTA Programme (Ref: 127337).The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.