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

**Carer Study: Participant Information Leaflet**

**Chief Investigator:** Associate Professor Helen Leonard **Principal Investigator:** Professor Sergio Starkstein

**We would like to invite you to take part in the STRATA Carer Study. Someone that you care for (as a paid carer, or as a family carer) has agreed to take part in the STRATA study and has identified you as their carer. They have passed this information to you on our behalf.**

**SUMMARY**

* A team of researchers, led by the University of Bristol (UK) in collaboration with The University of Western Australia, are conducting a study called **STRATA** (**S**er**TR**aline for **A**nxie**T**y in adults with a diagnosis of **A**utism), which aims to find out whether the medication sertraline is an effective treatment to reduce anxiety in adults with a diagnosis of autism.
* Within the STRATA study, we would also like to explore **how the treatment of anxiety for adults with a diagnosis of autism affects their carer,** hence this invitation for you to take part in the “STRATA Carer Study”.
* **If you take part, you will be asked to complete a questionnaire three times; when the person you care for starts taking part in the STRATA study (now; week 0), and then at 16 and 52 weeks.** The questionnaires will ask about your care giving responsibilities and how these may impact upon you and your wellbeing, as well as some questions about any support you receive, and about the person you care for.
* By taking part in this study, you will be helping us to understand about whether treatment for anxiety in autistic adults influences the wellbeing and any perceived burden of their carers.
* If you take part in the study, **you can withdraw at any time without giving a reason**.
* The person you care for is still able to take part in the main STRATA study even if you do not wish to take part in this carer study. Similarly, if you agree to take part, you can continue your involvement if they decide not to continue taking part in the main STRATA study.

***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

**IMPORTANT THINGS 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 the time to read this **Participant Information** **Leaflet,** whichexplains the carer study.
  + **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.
* Please feel free to talk to family, friends, or others about the study before deciding, if you wish.
* **If there are any parts of this information leaflet that you do not understand, you have any questions, or would like further information**, please contact the STRATA study team using the details on the front page.

**IF YOU ARE WILLING TO TAKE PART**

Once you have read this leaflet, **if you are willing to take part, please complete and return the two following documents using the pre-paid envelope, which are enclosed in this invitation pack** (please note that you do *not* need to use stamps, or to take this to a Post Office – the pre-paid envelope can be put straight into a post box):

1. Consent Form (we enclose two copies; please keep one for your records and return the other)
2. Baseline Questionnaire (week 0, now)

**If you would prefer to complete the consent form and/or questionnaire online,** please contact the STRATA team using the contact details on the front page so we can arrange this for you promptly. At the end of the Baseline Questionnaire, you will be asked how you would like to complete your future questionnaires (e.g. online, via video-call or telephone, or via paper (postal) copy).

**IF YOU DO NOT WISH TO TAKE PART**

**If you do not wish to take part in the carer study**, please let us know using the contact details on the front page so that we do not send additional correspondence.

# PART A:Why is the study being done?

1. **What is the purpose of the STRATA Carer Study and why is it being done?**

The STRATA study aims to find out whether the medication sertraline is an effective treatment for anxiety in adults with a diagnosis of autism. Anxiety is common in autistic adults and many find it to be very disabling. Medications like sertraline are commonly prescribed for anxiety in autistic adults but whether they work, and what their side effects are in the autistic population is not well known. We aim to enrol 306 autistic adults to STRATA, making it the largest study of its kind, providing evidence to inform the management of anxiety in adults with a diagnosis of autism.

Anxiety in adults with a diagnosis of autism, and its treatment, may also impact upon the wellbeing of the people who care for them. Therefore, we are also exploring **how the treatment of anxiety in this population affects their carer;** the “STRATA Carer Study”.

We aim to enrol one carer for each person who agrees to take part in the main STRATA study.

**To take part you need to be:**

* aged 18 years or over
* a paid or family carer of a person taking part in the main STRATA study, and know them well
* able to provide informed consent to take part
* able to complete three questionnaires (over 12 months) about things such as your care giving responsibilities, your wellbeing, and any support you receive, as well as some questions about the person you care for. You will be able to complete these online, via a video call/ telephone call with a researcher, or on a paper copy.

# Why have I been invited to take part?

We are inviting you to take part in the STRATA carer study because someone that you care for has agreed to take part in STRATA and has identified you as their carer.They have agreed to contact you with this information on our behalf.

# PART B: What will I need to do?

# 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 decide to take part,** you are free to leave the study at any time without giving a reason. This will not affect whether the person you care for can continue to participate in the STRATA study.
* **If you decide *not* to take part**, the care of the person you care for and their participation in STRATA will not be affected in any way. Please let us know so that we do not contact you again about this study.
* **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.

# What is involved if I 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 research that is described
* Consent to the use of your personal and health information as described.

The **diagram on page 4** summarises what is involved, from being invited to taking part (now), through to the end of the study.

**In brief, you will be asked to complete a questionnaire three times; first when the person you care for starts taking part in the main STRATA study (now; week 0), and then at 16 and 52 weeks.** The questionnaires will ask about your care giving responsibilities, your wellbeing, and any support you receive, as well as some questions about the person you care for. Each questionnaire may take around 15 – 20 minutes to complete.

**Additional information about what is involved is detailed here and on the pages that follow.**

**Week 0 (now)**

**If you would like to take part, the next step is to complete and return the following two documents using the pre-paid envelope provided in this invitation pack:**

1. Consent Form (we enclose two copies; please keep one for your records and return the other)
2. Baseline Questionnaire (week 0, now)

**Alternatively, if you would prefer to complete the consent form and/or questionnaire online,** please contact the STRATA team using the contact details on the front page so we can arrange this for you promptly. At the end of the Baseline Questionnaire, you will be asked how you would like to complete your future questionnaires (e.g. online, via video-call or telephone, or via paper (postal) copy).

**Week 16**

You will be asked to complete the **Week 16 Carer Study questionnaire**. This questionnaire will be sent to you via the preferred method that you indicated at Week 0.

**Week 52**

You will be asked to complete the **Week 52 Carer Study questionnaire.** This is the final questionnaire and marks the end of your participation in the STRATA Carer Study.

The questionnaires will be sent to you via the preferred method that you previously indicated. At any time if you cannot remember or would like to change the way you complete the questionnaire, you can contact the STRATA study team who will update your records.

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.

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# Flow diagram about the Carer Study

**Invitation to take part**

Read this **Carer Study Participant Information Leaflet**. Contact us using the details on the front page to ask any questions.

**If you choose to take part in this carer study, you should now complete and return:**

1. Consent Form (we enclose two copies; please keep one for your records and return the other)
2. Baseline Questionnaire (week 0, now)

If you would prefer to complete the consent form and/or questionnaire online, please contact us using the details on the front page so we can arrange this for you.

**Consenting to take part and starting the study**

**At 16 weeks** after the person you care for joined the STRATA study, you will be asked to complete another questionnaire. This can be completed online, or with a researcher via video call or telephone, or on a paper questionnaire returned using a pre-paid envelope.

**Week 16**

**Week 52**

**At 52 weeks** after the person you care for joined the STRATA study, you will be asked to complete another questionnaire. Again, this can be completed online, or with a researcher via video call or telephone, or on a paper questionnaire returned using a pre-paid envelope.

**This is the final questionnaire and marks the end of your participation in the carer study.**

**End of your involvement in the Carer Study**

# What are the possible benefits of taking part?

You may benefit from further understanding about the STRATA study that the person you care for is taking part in. Even if you do not receive a direct benefit of taking part in this study, your involvement will inform future recommendations regarding the wellbeing of people who care for adults with a diagnosis of autism who experience anxiety when they are taking part in a trial.

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

The questionnaires will be brief, and take around 15-20 minutes each, although we appreciate this will vary for each person. You can complete the questionnaires at your own pace, and via a method that suits you (online, via telephone/video call with a researcher, or via paper (postal) copy). Some questions will ask about your own experiences or feelings. This may feel intrusive but please be assured that we will treat the information that you give us confidentiality. **You will never be personally identifiable in any research outputs.** The information you provide will not be disclosed to the person you care for.

# What about expenses?

You will not incur costs by taking part in this questionnaire study. You can complete them online, telephone/video call with a researcher, or via paper (postal) copy. If you choose to complete them via video/telephone calls with a researcher, this will be at a time suitable to you. Alternatively, if you choose to complete paper questionnaires, you will be provided with prepaid envelopes to return the questionnaires.

# 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 STRATA study team using the details on the front page 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. This will not affect whether the person you care for can continue to participate in the STRATA study. We would confidentially retain any information we had already collected about you to use in our analysis of the study results, however we would not contact you further.

# PART C: Further information about the study and what will happen to your data

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

The study is expected to run through to September 2023 (dates are subject to change), although your participation would last 52 weeks. Once the study is completed, overall results will be published in scientific journals and presented at conferences attended by healthcare professionals, academics, and specialists. The results will also be disseminated to the wider public using accessible 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 2024 (date is subject to change).

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

In Australia, this study is funded by the National Health and Medical Research Council (NHMRC; reference 1171206). In the UK, this study is being funded by 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 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).

# Will the information that I provide be kept confidential?

Yes, we are committed to handling the information (data) used in the 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 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.

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 13 below 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.

# 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 from this data**.

# How will we use information about you?

We will need to use information from you for this research project. This information will include your:

* Initials
* Name
* Gender
* Ethnicity
* 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.

# 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.

# 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**

# 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.

# What if I have a concern or complaint?

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

A close up of a sign

Description automatically generated

**Clinical Contact person**

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

Alternately, if you want any further information concerning this project 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.**

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