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

**Carer Study: Participant Information Leaflet**

**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 (University of Bristol) (ii) Terms for the autistic population may also be used interchangeably throughout.*

**Contact details – STRATA Study Team**

**Email:** strata-takepart@bristol.ac.uk **Website:** www.bristol.ac.uk/strata

**Tel:** 0117 428 3001

**Address:**  Centre for Academic Mental Health, University of Bristol, Oakfield House, Oakfield Grove, Bristol, BS8 2BN

**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 (freepost) 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 videocall/ 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?

No. It is your choice whether you take part in this study, or not.

* **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?

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. 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.

**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.

This questionnaire will be sent to you via the preferred method that you previously indicated. 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.

*Please continue to the next page.*

# 

# 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 videocall 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 videocall 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/videocall 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 and travel?

You will not incur costs by taking part in this questionnaire study. You can complete them online, telephone/videocall 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 (freepost) 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 from October 2019 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 the UK, this study is being funded by the National Institute for Health Research Health Technology Assessment programme (NIHR HTA, reference 127337). In Australia, this study is funded by the National Health and Medical Research Council (NHMRC; reference 1171206). 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 Bristol (UK). The Bristol Randomised Trials Collaboration, as part of the Bristol Trials Centre (UK), are responsible for managing the study.

# 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 we are responsible for 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 (UK Sponsor) will keep identifiable information about you for at least 5 years after the study has finished; this is a legal requirement for clinical trials.

It is a requirement that your records in this research can be looked at by authorised staff working for the Sponsor or the Regulatory Authorities. Their job is to check that research is properly conducted and the interests of those taking part are adequately protected.

# 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:

* at **www.hra.nhs.uk/information-about-patients/**
* 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**
* by sending an email to **strata-takepart@bristol.ac.uk**, or
* by ringing us on 0117 428 3001

# Who has reviewed the study?

All research in the National Health Service (NHS) is looked at by independent group of people, called a Research Ethics Committee (REC) to protect your safety, rights, wellbeing, and dignity. This study has been reviewed and approved by the Health Research Authority (HRA), University of Bristol and NHS Research Ethics Committee (Ref: 21/FT/008). An independent Trial Steering Committee will monitor the study to ensure it is conducted according to good research practice.

# What if I have a concern or complaint?

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.

Alternatively, you can contact the STRATA Trial Manager (email: strata-rct@bristol.ac.uk, phone: 0117 428 3001), who will do their best to answer and resolve your queries. If you remain unhappy with any aspect of the study, please email the sponsor ([research-governance@bristol.ac.uk](mailto:research-governance@bristol.ac.uk)).

If you are still concerned and wish to complain formally about your health care or any aspects of this study, you can do this through the NHS Complaints Procedure, either by post, telephone, or email.

**Post:** NHS England, PO Box 16738, Redditch, B97 9PT. **Telephone:** 0300 311 22 33. **Email:** england.contactus@nhs.net *(Please state: ‘For the attention of the complaints team’ in the subject line).*

You can visit their website for further information: **https://www.england.nhs.uk/contact-us/complaint /complaining-to-nhse/**

**THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION.**

**PLEASE KEEP A COPY FOR YOUR RECORDS.**

A close up of a sign

Description automatically generatedThis 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.

The authors and 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.

