

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

Contact details – STRATA Study Team

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Participant Information



Useful words

You – you, if you decide to be in this STRATA study

We – the STRATA study team

Sertraline – a medication capsule that may help you feel calmer and less anxious

Placebo – a capsule that looks the same as the **sertraline** capsule, but has no active medication

Randomisation – a way to make two similar groups of people with the same chance of getting **sertraline** or **placebo**

Blinding - you and the researcher will not know whether you are taking sertraline or placebo

Informed consent – learning about a study so that you understand it fully. Then, you can decide if you want to take part

Summary



- We are inviting adults with a diagnosis of autism who experience anxiety to take part in research.



- We want to know if a medicine called **sertraline** helps reduce anxiety.
- We know sertraline can help with anxiety in non-autistic adults. It is very commonly prescribed to non-autistic and autistic adults.
- This study will test whether it can also help with anxiety in adults with a diagnosis of autism.
- We also want to learn about which side effects sertraline may have in autistic people.



- If you take part in this study, you will take **either sertraline, or a placebo (inactive) capsules** for up to **1 year**.
- The capsules you are offered will be decided by a process called **randomisation**.
- This is done so that everyone has the **same chance of getting sertraline or placebo**. This means that comparing the groups will be fair.



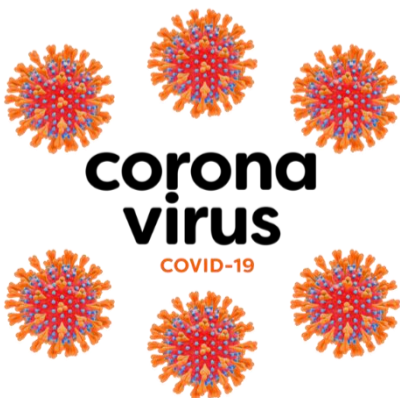
- You and the researcher will **not know** whether you are taking sertraline or placebo.
- This is called **'blinding'**. It is needed so that this is a **fair test** of the effect of the medication.



- We will **check how you are getting on with the medication** 4 times in the first 4 months, and after 9 months.



- We can talk to you **in person, on the phone, or by video call**.



- **Coronavirus rules** might mean that how we talk to you has to change.
- For example, **meeting online or talking on the phone** instead of meeting in-person.



- You will **answer questions about your anxiety and other symptoms** at the start of the study, and after 4 months, 6 months, and 1 year.
- You will get a £10 gift voucher for answering these questions.
- We will pay for your travel costs if you have to come and see us.



- **You can stop being in the study at any time**, and you don't have to tell us why.
- If you stop being in the study, it will not affect your medical care or legal rights.

If you want to take part, you need to:

- be aged 18 years or over;
- have a diagnosis of autism;
- experience anxiety;
- be willing to try taking medication for anxiety;
- be able to swallow capsules of medication;
- be able to complete forms with questions online or on paper;
- be able to give **informed consent** to take part.

We will also ask your doctor to confirm it is safe for you to have this medication.

Please continue to the next page

If you want to take part, this is what would happen:



You should now **ask us for the full Participant Information Leaflet**. You can do this by:

- emailing us on: strata-takepart@bristol.ac.uk
- calling us on 0117 428 3001
- or writing to us at: STRATA Study, Oakfield House, Oakfield Grove, Bristol, BS8 2BN



It is up to you if you want to take part in this study, or not. You can **ask us any questions** before deciding.

If you want to, you can also talk to family, friends, carers, or your doctor about the study before deciding.



Next, we would ask you to **complete an Expression of Interest form**. We will give this form to you.



Then, **we would talk to your GP** to check it is safe for you to be in the study.

Your GP would know if you took part in the study, and if you stopped taking part.



If your GP says the study is suitable for you to take part, you can be in the study.



You would get **either sertraline or placebo capsules**.

You will be asked to take the medication for up to **1 year**.

The medication can be stopped earlier if it does not suit you.



Throughout the year, we will talk to you **4 times in the first 4 months**, and **after 9 months** to check how you are feeling when taking the medication.



We will send you **forms with questions** to answer after **16 weeks and 24 weeks, and 1 year**.

You will get a £10 gift voucher for answering these questions.



At the end of the study, you can **discuss your future treatment with your GP**.

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