Developing EVIdence for AntidepreSsant ChoicE to Treat Depression in Huntington's Disease

Dose Escalation Information V1, 11/05/2026

SUMMARY

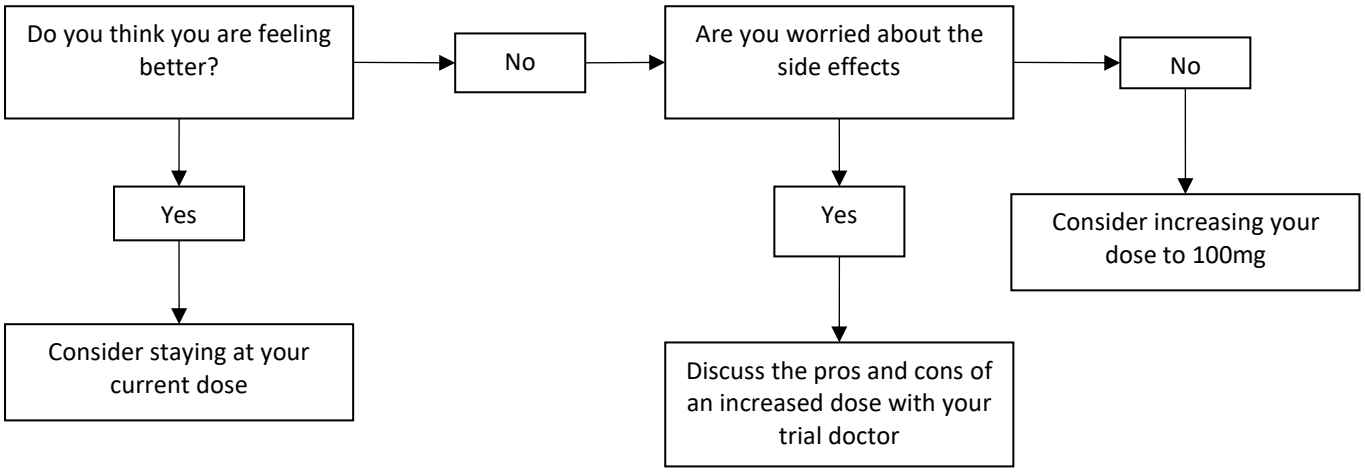
- We want to know how well anti-depressants do or don't work to improve depression in HD
- we want to understand whether it is possible to run a Randomised Control Trial (RCT) looking at the effect of anti-depressants in people with HD.
- You have been taking the anti-depressant Sertraline, or a version without the antidepressant medication (placebo).

YOUR ONGOING PARTICIPATION IN THE DEVISE-HD TRIAL

You have been taking 50mg of study medication daily. We know that for some people, they may need to take more than 50mg of the medication to feel better. You might have reported no improvement to how you are feeling, so we now want to increase your dose to 100mg. This will help to understand how much medication should be prescribed when we do a randomised control trial in the future.

The decision about the increased dose should be made by you and your trial doctor together. If you are feeling better or are very worried about the side effects, you don't have to have the increased dose. Your trial doctor can help you think about the potential benefits and side effects. You can stay in the trial if you don't want an increased dose. If you start taking 100mg and you don't like the side effects, you can return to taking 50mg dose.

You should tell your doctor about how you are doing emotionally and physically. It is possible you are not feeling better because you are taking the placebo. If you are very worried about your mental health, you and your trial doctor can discuss whether it would be better if you stop participating in the trial.



WHAT ARE THE POSSIBLE SIDE EFFECTS?

The side effects of Sertraline are well-known, and you may have experienced some of them already. It is possible you may experience more side effects with a higher dose of medication, but this is not always the case. We will monitor carefully for these but please tell the research team or your GP if you experience any of them or they get worse.

Common Side Effects:

- Nausea, vomiting, and constipation
- Fatigue
- Respiratory infections
- Changes in appetite and weight gain
- Difficulty sleeping
- Increased feelings of depression and anxiety
- Decreased libido and sexual dysfunction
- Menstrual irregularities
- Headaches
- Difficulty concentrating
- Abnormal heart rhythms and hot flushes
- Back pain

- Tremors, teeth grinding or difficulty moving
- rashes

Uncommon side effects

- Inflammation and pain of the stomach or intestines
- Ear infections and pain
- Tumour growths
- Swollen lymph nodes and low platelet count
- Increased allergic reactions
- Decreased thyroid activity, and increased hormone activity
- Changes in blood sugar levels and metabolisms
- Increased suicidal ideation and self-harm behaviour
- Sleepwalking, and night terrors
- Amnesia, migraines, dizziness, motor restlessness, or coma
- Vision difficulties
- Abnormal bleeding
- Difficulty breathing
- Mouth ulcers, irritation of the throat that leads to bleeding
- Difficulty going to the bathroom and incontinence
- Decreased drug tolerance
- Abnormal clinical laboratory tests
- Increased cholesterol tests

You can also reach out to Samaritans, SHOUT, or another organisation who can help you by talking through your thoughts and feelings

Samaritans by calling 116 123

Shout by texting 85258

[INSERT LOCAL TRUST SERVICES OR LOCAL SUPPORT ORGANISATIONS]

Please remember to tell your research nurse or doctor about any prescribed or other medications you are taking at any stage of the trial as there are some restrictions regarding other medications which might make you unsuitable for

this trial. Your Trial Doctor will remind you of these. When taking the treatment, it is important you do not eat grapefruit, or take St John's wort and take care when drinking alcohol. Grapefruit and St John's Wort can change how your body reacts to the medication. Sertraline can reduce your alcohol tolerance.

If you are pregnant or become pregnant during the trial, there is a small chance that anti-depressants can have a negative impact on your baby's development. This risk is low and anti-depressants are regularly given during pregnancy. During the trial, your baby's development and health will be closely monitored. You should make sure to discuss the risks and benefits to joining the trial with the treating physician before you make a decision.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON TAKING PART IN THE TRIAL?

Taking part in the trial is entirely voluntary. If you decide to take part you may withdraw from the trial, at any time, without affecting the standard of care you receive. You can withdraw from different parts of the trial, like withdrawing from trial treatment, or from provision of samples for future research, or from provision of questionnaires only. Your care team will go through these options with you.

If you wish to stop taking part in the trial completely you can tell anyone on the research team. We may need to see you one last time for an assessment and tests. The trial doctor will look to see if you were receiving the Sertraline or the placebo. **If you were receiving the Sertraline, you must not suddenly stop taking it.** Your trial doctor will discuss with you how to safely stop taking the medication if that is what you want. This will be for your own safety. We will need to monitor you while you gradually stop taking the medication to make sure you are not experiencing any significant side effects.

CONTACT

We understand that taking part in research can feel overwhelming. If you ever feel unsure or distressed, please speak to your trial team — your wellbeing matters.

<LOCAL SITE CONTACT DETAILS, including PI name>

Thank you for reading this information and considering taking part in this trial.