



The SATURN Study:

Stimulant Medication for ADHD and Tics – Understanding Response versus Non-stimulants

Why are we doing the study?

At the moment, we do not know the best way to manage symptoms in children and young people who have both ADHD and tics. This study will look at two medications currently being used in the UK to see which is more effective for children and young people with ADHD and tics

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most common mental health conditions affecting children and young people. Doctors estimate one in five children and young people with ADHD also experience tics - sudden, repetitive and uncontrollable movements or sounds. These can include blinking, throat clearing, or head jerking.

The most prescribed medicine for ADHD is a stimulant medication called methylphenidate. However, some experts are concerned that stimulant medication may make tics more frequent or intense. Another widely used medication for ADHD is a non-stimulant, such as guanfacine, and some experts think this is a better option to treat ADHD without worsening tics.

Our SATURN study is looking at both medications to see which is better suited to manage symptoms of ADHD and tics for children and young people.

Who can take part?

Children and young people **aged 6-16** can take part if they:

- Show tic symptoms
- Have a diagnosis - or be on the waiting list for one - of ADHD. If currently undiagnosed, assessments can be carried out by qualified doctors from participating NHS trusts.
- Do not have signs of an intellectual disability, psychosis or mania
- Are not at risk of harming themselves or others
- Have a parent or carer willing to participate with them and complete questionnaires
- Have not taken ADHD medication before OR are looking to change medication (your child or young person will need to stop taking this medication before taking part)

What are tics?

Tics are sudden, repetitive and uncontrollable movements or sounds like blinking, throat clearing, or head jerking

What if I don't know if my child has tics or some of the conditions above?

Don't worry - doctors will check your child is suitable for the study before starting any medication





Joining the SATURN study

Finish completing the Consent to Contact form to give permission for the local research team to contact you. These are doctors and research assistants hired by participating trusts to conduct the SATURN study.

Your local research team will call you to discuss the Development and Wellbeing Assessment (DAWBA), book an appointment to carry out an ADHD assessment (if needed), and provide you with a patient information sheet

The patient information sheet explains the study. There is one for you and one for your child or young person.

You will be sent a link and a password to login and complete the DAWBA online. This helps the research doctor assess if your child or young person is suitable for the study.

The DAWBA can take a while to complete. You can:

- Save and come back to finish later
- Ask for help from the researchers
- Skip sections if you aren't sure

Once your DAWBA is completed and an ADHD assessment appointment (if needed) is confirmed, the team will call you to discuss next steps.

If your child or young person is not eligible you, and their usual care team, will be told and any assessment outcomes shared.

If your child or young person is suitable, you and their doctors will be told. You then decide if you want to continue

If Yes: the research team call you to arrange a baseline visit

If No: The research team notify your child or young person's health team to continue treatment, any assessment outcomes shared.



Children and young people currently on an ADHD waitlist

If you complete this consent to contact form, your child or young person will need to be assessed for ADHD by a specialist doctor before they can take part.

This assessment may be done by a doctor who is not part of their usual care team.

You might need to travel for these diagnostic appointments, and unfortunately, the study does not cover these travel costs.

The results and observations of any tests to assess if your child or young person has ADHD will be shared with their usual care team. If your child or young person is found not to have ADHD, their usual care team will be informed, and they will decide on the next steps for your child or young person's care.



Your Data

What will happen to collected screening data?

Researchers, including the local care team, the SATURN research team and the Nottingham Clinical Trials Unit (NCTU, part of the University of Nottingham) will need to use information from you and your child or young person and their medical records for this research project.

The information collected will be stored on the trial database. The trial database is a secure password-protected database, accessible only to your local research team (the doctors and research assistants at your local hub and the NCTU trial staff).

Any data shared between NHS trusts will be done either through a secure document sharing service or secured email.

Storage of your data will comply with the UK Data Protection Act 2018 and any new laws in relation to data protection in the UK and Europe.

If your child or young person is not eligible to take part in SATURN, any identifiable information will be safely discarded at the end of study recruitment.

We will collect:

- Your contact details
- Your child/young person's name
- Your child/young person's date of birth
- Your answers to the DAWBA
- A list of your child/young person's current medications and treatments

We will not collect any data from required ADHD assessments except the final decision.

We may use your anonymised data in reports we write to explain reasons why patients did not take part in the study. The data used in any reports or academic articles will always be written in a way to maintain your anonymity.

For more information on how your data will be handled during the study please read the patient information sheet which can be found on the website or requested from your local research team.

Contact Us

If you have any questions ask your local research team:

<insert hub name and trust>

<insert hub contact name>

E-mail:<insert hub e-mail> | Tel: <insert hub tel.>

<hours information>

You can find out more about the study on our website: www.institutemh.org.uk/research/projects-and-studies/saturn

FAQ

How long would we be taking part for?

You and your child or young person will be involved in the study for a year, starting from when they are prescribed one of the medicines

Will I be reimbursed for taking part?

No but, you will receive a total of £30 in Amazon vouchers as a thank you for taking part. Vouchers of £10 will be provided to the parent or carer at three, six and twelve months.

Will I have to travel to take part?

Some visits will need to be in person, particularly during the early stages of the study. These are likely to take place at your local study centre. Several weekly check-ins may also need to be face-to-face to monitor your child or young person's wellbeing. Where possible visits will be conducted online or by phone. The research team can reimburse travel costs for baseline and follow-up appointments but unfortunately cannot pay travel costs to attend any ADHD diagnostic appointments. If you are unsure, you can always check with your local research team.

Do I have to take part?

No. Participation is entirely voluntary. You and your child or young person can choose to withdraw at any time without it affecting their ongoing care.

If I complete this form am I guaranteed to join the study?

No, completing this form allows the research team to contact you and begin the process of checking that you and your child or young person are eligible for the trial. They will explain the study in detail.

Who is conducting the study?

The study is led by Professor Chris Hollis at the Institute of Mental Health, University of Nottingham. It is a collaboration with experts from eight UK institutions and is managed by the Nottingham Clinical Trials Unit at the University of Nottingham.

How is the study funded?

The study is funded by the National Institute for Health and Care Research through the Health Technology Assessment programme