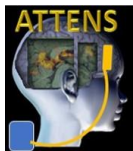




Information sheet for child (10-15)

The **ATTENS** project (*ADHD trial of external trigeminal nerve stimulation*)



What is the ATTENS project?

We are testing a new treatment for children with Attention Deficit/Hyperactivity Disorder (ADHD) because the typical treatment for children with ADHD is medication and this can have some side effects. We also do not know whether medication works in the longer run. This new device may help children to reduce symptoms of ADHD and other problems such as mood, concentration, memory, sleep and to be less hyperactive. The device is being used when you are asleep. It does not hurt, but some may get a slight headache. We will test two different devices, one with real stimulation and another one with fake stimulation (sham treatment). It is kept secret to everyone what device you are using until the very end of the project.

What is the device?

The device is called external Trigeminal Nerve Stimulation (eTNS) and you put a patch on your forehead which is connected to a battery by two cables. The device then stimulates a nerve called trigeminal nerve. As in the pictures below.



In a study in the USA, this device has been shown to be very good for children with ADHD and we want to test this further. Because this is a research study, 50% of the children will receive a device with hardly any stimulation which is called sham (with fake stimulation or placebo). You will be randomly allocated by a computerised system to one or the other treatment (like tossing a coin). The researcher who you will meet will not know either whether you will get the sham or real eTNS treatment. This means that both you and the researchers are “blinded” or masked. We only expect the group who gets the real eTNS treatment to get improvements in their behaviour.

Why have I been invited?

You are invited because you have been diagnosed with ADHD. Or you have been contacted through a support group or seen a flyer.

Do I have to take part?

No. You can decide whether you want to participate or not and you will always be able to change your mind or drop out at any time.

NO OBLIGATION!

What will I be asked to do if I take part in the ATTENS project?

To take part in this research you would be asked to:

- Be interviewed and asked to answer questions about your behaviour online
- Have your IQ tested
- Use the eTNS device while you are sleeping for 7-9 hours per night for four weeks
- For four weeks during the treatment answer questions online (like on zoom) every week
- Wear a device on your wrist for 3-4 hours during research visits like a “fitbit”
- Come to the research centre at least four times and do some computer tests and answer some questions about your behaviour
- At the centre you will have your height, weight, and pupils measured (we can measure how alert you are in the pupils) when doing computer tasks



If you are on ADHD medication, we would ask you to keep taking your normal dose. Also, on weekends and holidays during the 4 weeks of treatment. We would also like to record the interview but only if you are happy for us to do that.

We will ask your parents questions about you and would also like to ask your teacher what you are like in school. Also, we'll send a letter to your GP and the doctor that prescribes (if applicable) to make sure that they know that you are taking part in this study.

Can I still take my usual medication during the eTNS treatment or what happens if I want to start taking medication treatment for the first time?



Yes, you can still take your usual medication, but we ask you to not change the normal dose or type of medication and not to take it off during weekends or holidays during the 4 weeks of treatment. You can also stop taking your medication for 1 week before the treatment starts if you want to remain off medication while you use the eTNS treatment. We will discuss this with your parents, carers or guardians and find out what is best for you.

How will I know if I can take part?

We will meet you and your parents online (like on Zoom) to discuss if you can take part. This visit includes an interview with your parents (about 2-3 hours). Then an interview with you (1 hour), and a test of IQ (20 min) at the research centre.

There are some reasons why you would not be able to take part in this project such as if you have some other disorders such as for example Autism Spectrum Disorders (ASD) or if your ADHD is mild. Also, we need to make sure that you do not have epilepsy or diabetes and check what medication you use. Once the researcher has gathered all the information, they will confirm that you can take part, but they want to make sure that it is safe for you to do so first.

What does the optional brain scanning involve?

The brain scanner (MRI) is like a tunnel in which you must lie very still, you can see a picture of the MRI scanner below. The brain scan is perfectly safe, does not hurt and has no side effects but it is a bit noisy so you will have some headphones on. We will first show you on a test scanner what to do

before doing the proper brain scan. Each scan takes about 60 minutes, and you will be asked to lie still the whole time and do some computer tests while you are lying in the scanner. There is a microphone inside the scanner so that you can talk to us and let us know if at any time you want the scan to stop. Your parent can be in the room with you the whole time if they have no counterindications to the MRI scanner. Once the scan is done, we can give you a picture of your brain.



We can talk about this part of the project if you are interested, and you can then ask any questions. We aim to include mostly children who have never used stimulation medication or are currently off stimulant medication. If you know that you are afraid of enclosed spaces, then you should not be doing this part of the study. The brain scan can only be done at the London research centre. You would need to go into a mock scanner (a fake scanner). In the mock scanner we will show you how the scanner will feel like and also show you the tasks you will have to do. This is to ensure that you are happy to take part in this part of the trial. The fMRI scan would then be done on the following research visit to the research centre when you will also get the eTNS device and then again four weeks later.

To do this part of the project you cannot have any metal in your body (e.g., braces, metallic tattoos, pacemaker). If you take part, then we will ask you to not have any new metal tattoos or metal piercings made in the four weeks between the first and second visit at the research centres.

What are the advantages in taking part?

Taking part in a project like this can be interesting and exciting. It is very likely that it could help you with your ADHD if you are in the group that gets the real eTNS, but we cannot guarantee this as this is a research study. The study will help finding a new treatment for ADHD in the future.

What are the possible disadvantages and risk of taking part?

Possible discomfort: It is possible that it is a bit uncomfortable to sleep with the eTNS device at night. However, in the previous USA study, the sleep of the children who participated in the study became better and not worse.

Delay of medication treatment: If you are not taking medication, but are planning to start taking medication, you will have to wait until after the four weeks of the treatment.

Length of the assessment. You will have to come into the clinic three times. In addition, you and your parents will also have to fill in some questions every week during the treatment.

Personal information in assessments: Rarely some of the questions seem personal and can cause distress. These are similar to the questions asked when you were first diagnosed. We only ask questions that are important in gaining a full understanding of you, your family, and your school situation. The assessment can take 1-2 hours, but we will give you frequent breaks if you want to.

Side effects: There are no serious side effects with eTNS and we do not expect any major side effects. However, some people have complained about headache (that quickly goes away) or skin irritation (that goes away with cream). Other possible side effects could be tiredness and more appetite which goes away with time.

The National Institute for Health and Care Excellence (NICE) issued guidance regarding this treatment in January 2023 based on the USA trials. Their guidance mentions additional side effects such as

negative effects on cognitive function and worsening of symptoms. However, it should be pointed out that this was reported more often in the group with the sham device than the group with the real device. Given that the sham device is not doing anything, such side effects are then thought to be more likely to be related to ADHD itself rather than the device.

Worries about the scanner: MRI is a safe imaging method and there are no side effects. However, some people can sometimes be anxious about the scanner, which can be seen as noisy, unpleasant, and uncomfortable. We will stop all testing at the first sign that you feel uncomfortable or feel stressed. You are free to terminate the scanning session whenever you want to. There is a microphone in the scanner through which you can easily communicate with the radiographers. Also, the radiographers will constantly check that you are OK to remain in the scanner.

Unfortunately, this device is only available to you as part of this project and cannot be purchased in the UK currently. It will take some time until the study team can confirm if the device is beneficial, but they will let you know once they have analysed all the information gathered.

What happens when the research stops?

At the end of the study, we will send you a report about your response to the eTNS treatment. If you agree, we will also send it to your parents.

Who will access my medical records?

We will ask you for your permission that the research team can see your clinical records. This is important so that we can check if you can take part in the study.



Will the information that is collected about me in this research be kept secret?

- All information you give us will be kept secret
- Only the research team will know who you are
- Only if we are worried about your safety and wellbeing will we have to share any information
- The results of the project will be in special magazines, but your name will not be used

Will I get anything for taking part?

To thank you for your participation we will give you:

- £50 for the first assessment (this may be done on more than one occasion and may be at the research centre)
- £50 for each of the three research visits (total of £150)
- £150 for the four weeks of sleeping with the device
- If you do the fMRI scan you will also get £50 for each scan (up to £100)

You will get tokens and get all the money at the end of the research except the money from the first assessment which we will give you straight after. You can also get an additional £100 if you also do the fMRI scans

We will also give your parents, carers or guardians some money for travel expenses.

Important to know

If you feel worried about something to do with this study, you should let your parents know and get in contact with us and we will do our best to help you further. Our contact details are at the bottom of this sheet.

Who has reviewed the study?

This project has been checked by a group of people to ensure it is ok for children to be part of this project. It is the West Midlands – Solihull NHS Research Ethics Committee (REC) (Ref: 21/WM/0169) that have reviewed the study and approved it.

Who is managing and paying for this project?

The Chief Investigator for the project is Prof Katya Rubia, Department of Child and Adolescent Psychiatry, Institute of Psychiatry, King's College London and she has received funds from the National Institute of Health Research (NIHR).

Is there insurance in place for this research?

King's College London and NHS have insurances in place for this study, to cover bodily injury.

Further information and contact details

If you want more information on anything to do with this study, please get in touch with the research team email: attens@kcl.ac.uk or telephone: 07923-881937.

You can also write to Professor Katya Rubia at the Department of Child and Adolescent Psychiatry, PO85, Institute of Psychiatry, Psychology and Neuroscience, De Crespigny Park, London, SE5 8AF for any more information or you can telephone: 020-7848 0463 (email: katya.rubia@kcl.ac.uk).

We would like to thank you for reading all this information.