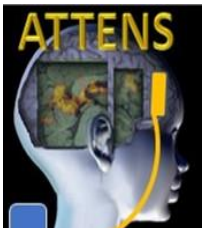
TEACHER INFORMATION SHEET

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

A multi-centre, double-blind, randomized, parallel-group, phase IIb study to compare the efficacy of real versus sham external Trigeminal Nerve Stimulation (eTNS) on symptoms in youth with Attention Deficit/Hyperactivity Disorder (ADHD)



We would like to invite you to take part in some research that is happening at the Department of Child & Adolescent Psychiatry/Social Genetic and Developmental Psychiatry Centre (SGDP) at the Institute of Psychiatry, Psychology & Neuroscience at King's College London or at the Centre for Innovation in Mental Health (CIMH), School of Psychology, University of Southampton. Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve and appreciate you taking the time to read the information carefully. Take your time in deciding whether you want to take part.

What is the purpose of the study?
The aim of this study is to test a new treatment for children with Attention-Deficit/Hyperactivity Disorder (ADHD). The best current treatment for children with ADHD is with stimulant medication. However, there are side effects and non-drug treatments are preferred by parents and patients.

This research is testing a new non-drug treatment, called external Trigeminal Nerve Stimulation (e TNS). eTNS has been shown to work well in children with ADHD in a study in the USA, and it has no serious side effects. Some have reported minor side effects such as headache, skin irritation, fatigue and increased appetite which go away on their own with time. eTNS is worn during sleep and has been shown to be safe and effective for ADHD; it is the first device based non-drug treatment that has been approved for children with ADHD by the US Food and Drug Administration (FDA) and the European Community. Approval was only obtained in 2019 so it is a very new treatment.

The purpose of the study is to test the eTNS treatment in a larger group of 150 children and adolescents with ADHD across two centres (London and Southampton). The study will establish whether eTNS is effective in reducing symptoms of ADHD and other problems such as mood, concentration, memory and sleep It will also establish whether it improves performance in attention and self-control which will be done by the completion of computer tests. The questionnaires and computer tests will be done before using the device, after four weeks of using the eTNS device while sleeping, and then again after 6 months to see whether the effects remain. We will also test whether eTNS improves brain activation in a magnetic resonance imaging (MRI) scanner. This part of the study is optional, and scanning will only be done at King's College London.

We want to ask you to fill in some questionnaires about the behaviour of the child with ADHD in your class that is participating in this research.

In order to find out if eTNS is effective, two different devices will be tested, one with real stimulation and one with hardly any stimulation (sham). The children will be randomly allocated by a computerised

system to one or the other treatment. Researchers, patients and parents are also blind to treatment allocation. We only expect the group who gets the real eTNS treatment to get improvements in their behaviour.

We expect that this research may lead to the establishment of a new non-drug treatment for ADHD which has minimal side effects. We expect that this treatment may improve the behavioural difficulties children with ADHD have and that it will also improve their attention and self-control skills. We also expect to see increases in brain activation in the brain regions like the frontal lobes, that are normally not working so well in children with ADHD. If this study is successful, it could establish eTNS as a non-drug treatment for ADHD.

What is external Trigeminal Nerve Stimulation (eTNS)?
The eTNS device used in this study is the NeuroSigma Monarch eTNS™ System. eTNS is an approved treatment for ADHD in the USA and was CE-marked in Europe until 2021. It is a non-invasive medical device that stimulates the trigeminal nerve using an external electric conductive patch, which resembles a large plaster directly on the forehead. The trigeminal nerve stimulates the brain and there is some indication that it increases the activity in the frontal lobes in people with ADHD. Below are images of the device.

Why have I been invited?
You have been invited to participate because you are a teacher of a child that is participating in this research.

Do I have to take part?
No, it is up to you to decide whether you wish to take part in the research. If you agree to take part, we will ask you to sign a consent form. You need to understand what the trial involves and what it will mean for your contribution before you can consent, and we will go through this with you.

What happens if I change my mind?
You can still change your mind at any time, and you do not have to say why.

What would I be asked to do if we took part?
If you decide to take part as a teacher, you would be asked to answer some questions about the child's ADHD behaviour, before they undergo the 4 weeks treatment, after the 4 weeks treatment and at 6 months follow-up. There will be 2 questionnaires and we will ask you to fill these in and send these to us digitally. We can also ask you the questions online (i.e., via Zoom or MS Teams) if you prefer.

How much time will this take?
Both questionnaires are very short and should take around 5-10 minutes each to complete.

What is good about taking part in the research?
We hope that the information we get will establish whether eTNS is a suitable treatment for ADHD and therefore help treat other young people with ADHD with eTNS in the future.

What happens when the research stops?
At the end of the study, we will send you a letter about the results of the study if you are interested.

Will the information that is collected about in this research be kept confidential?
The information we have collected from you about the child's behaviour will be saved in computer files but will be anonymised.

In extremely rare circumstances, information that is discussed during the assessment may raise concerns about the safety of either the child in your class or of others; in these cases, we are required by law to share such information with the appropriate authorities.

What will happen to the results of this research?
The results of this study will appear as scientific publications. If you would like to read the results you can have copies of these articles sent to you by asking Prof Katya Rubia.

Who is managing and paying for the research?
The Chief Investigator is Prof Katya Rubia, Department of Child and Adolescent Psychiatry, Institute of Psychiatry, King's College London. This study is being funded by National Institute of Health Research and the Medical Research Council, both UK government funding agencies that fund research.

Is there insurance in place for this research?
A professional indemnity policy is in place from King's College London for all studies conducted at King's College London. NHS indemnity insurance schemes apply to all patients in the NHS.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and granted a favourable opinion by the West Midlands – Solihull NHS Research Ethics Committee (REC) (Ref: 21/WN/0169).

Who can I contact for more information?
You can write to the ATTENS project team at the Department of Child and Adolescent Psychiatry, PO85, Institute of Psychiatry, Psychology & Neuroscience De Crespigny Park, London, SE5 8AF for any more information or you can telephone: 07468 708972 (email: attens@kcl.ac.uk).