PARTICIPANT INFORMATION SHEET

Transcutaneous vagus nerve stimulation (tVNS) and behaviour study

We would like to invite you to take part in a research study to try a treatment called transcutaneous vagus nerve stimulation or tVNS for short.

This information sheet tells you what the research is about and what you would be asked to do if you choose to take part. It is important that you read this information before you decide whether or not you want to take part.

There is another information sheet called the CARE-GIVER OR FAMILY MEMBER INFORMATION SHEET. Please pass this on to someone who supports you or a member of your family who knows you well. You may want to talk about the study with them and you will need them to be able to be there with you when you are taking part in the study.

Who are we?

We are clinicians who are also researchers. We are based in the Universities of Cambridge and East Anglia and in local clinical services. Our work aims to improve the lives of people with acquired brain injury, learning disabilities or autism. We have been funded by the National Institute of Health Research’s Collaboration for Applied Research in Health and Care East of England to carry out some research.

What is this research about?

Many people have aggressive behaviour. This means shouting, or throwing things, or kicking or hitting out, or even threatening someone with a weapon. People with these kinds of behaviours often describe themselves or are described by others as ‘having a short fuse’ or ‘reacting to the slightest thing’. These kinds of behaviours are common among people with acquired brain injury or autism or learning disabilities.

We want to find out if a treatment called transcutaneous vagus nerve stimulation (tVNS) can help reduce aggressive behaviour. tVNS is already used to help people with epilepsy, but it has been
found that it could help other people who struggle to manage their behaviour and do not have epilepsy. We are doing this study to find out if tVNS can help people control their behaviour better.

**Why have I been asked to take part?**

We have asked you to take part because you have an acquired brain injury, or autism or a learning disability, and you are at least 18 years old. For this research we wish to include people who sometimes find it difficult to control their feelings and whose words or behaviour is seen by others as aggressive. That means people who often describe themselves or are described by others as ‘having a short fuse’ or ‘reacting to the slightest thing’. They may shout, or throw things, or kick or hit out, or even threaten others with a weapon. We want to find people who find it difficult to control their feelings at least once a week.

However, there are some circumstances in which you would not be able to take part in the research:

- You will not be able to take part in this research if you are pregnant, or think you could be pregnant, or plan to get pregnant during the time that you are taking part in the research.
- You will not be able to take part in this research if you currently have a diagnosis of epilepsy.
- You will not be able to take part in this research if you are currently dependent on alcohol or if you regularly use recreational drugs (for instance cannabis, amphetamine, cocaine, ecstasy).

**What will happen if I think I might want to take part?**

We will come to visit you and one of your care-givers or someone in your family. We will bring photographs of a vagus nerve stimulator and a heart-rate monitor which we will be asking you to wear so you can see what they look like.

We will also talk to you about what taking part will mean for you and your care-giver or family member. We will be asking them if they would support you in taking part.

If you would like to take part, it will mean you also keeping a diary about your feelings and behaviour. We will make this specially so it suits you. We will also be asking you to complete some assessments: these will be cognitive tests and some questionnaires.

If you choose to take part after this, we will ask you some questions to make sure that you understand what you will be asked to do.

**What will I be asked to do if I choose to take part?**

Once you are sure you would like to take part, we will ask you to sign a form to say that you agree to taking part in the study.

Here we describe what taking part in the research will involve for you:
1. We will ask you to complete an assessment. This will include cognitive tests to find out what you’re good at and we will also ask you about how you feel and what things you find difficult. We will set you up with a diary to let us know how you are feeling each day and any difficulties you have had in controlling your feelings. We will ask for this to be filled in every day through all the stages of the study.

We will also be asking your care-giver or a member of your family about your medical history and to complete some questionnaires about how they think you are managing. We will ask them to keep a diary every day too.

We will ask you for your permission to look at your medical records to collect information about your health and to make use of the results of any tests you might have had in the past 6 months of your problem-solving abilities.

2. Then we will ask you just to continue with your life as usual for 5 weeks. During the second week and again during the fourth week, we will ask you to wear a heart-rate monitor for 3 separate days and nights (24 hours), like the one in this picture. This device measures your heart rate, breathing and movement. It has 3 sticky pads joined by a short wire. You can walk about as you normally would while you are wearing it.

3. After this we will ask you to complete another assessment. We will not have to repeat everything so it will be shorter than the first one.

4. For the next phase we will ask you to continue keeping the daily diary about your feelings and behaviour. After another two weeks or so we will ask you to wear the heart-rate monitor for 3 separate days and nights (24 hours) and then to do this again another three weeks and then another two weeks later.

**Also in this stage of the research** we will also ask you to wear a transcutaneous vagus nerve stimulator for four hours each day. Altogether we will ask you to wear the stimulator for a total of up to eight weeks. We will explain to you and / or your caregiver how to use the stimulator and every week or so during this period one of the researchers will be in touch to check with you that the equipment is working as it should do.

What is a transcutaneous vagus nerve stimulator? The stimulator is called NEMOS® and is made by a company called Cerbomed. The stimulator is about the size of a mobile phone and sends small electrical pulses to a branch of the vagus nerve through the skin in one ear. It does this with an electrode (a kind of earpiece) that you wear in your left ear. It looks a bit like a mobile phone with just one earpiece. The picture below shows what the device looks like. The vagus nerve is a long nerve which is important in sending messages between the brain and the body.
Here is a picture of what the stimulator looks like when in your ear.

5. Then we will ask you to repeat the short form of the assessment.

6. After that you will stop using the stimulator but for the following 4 weeks we will ask you to keep on completing the daily diary and during the second week and again during the fourth week, we will again ask you to wear the heart-rate monitor for 3 separate days and nights (24 hours).

7. Finally, we will ask you to complete the short form of the assessments again.

All the stages of the research will be carried out where you live. We will be in touch with you, either by phone by visiting you at home, each week to find out how you are getting on and ask you and your care-giver or family member some questions about your behaviour and how you are getting on with the VNS. We will also ask about your medical history. We will ask you to do some tasks with us as well. These tasks are a bit like puzzles and will tell us about some of the things you find easy and the things you find harder.

If you or your care-giver would like to be in touch with the researcher by phone or email for support during the study then we can arrange this.

**Do I have to take part?**
No, you do not have to take part. You can say no if you do not want to take part. Choosing not to take part will not affect any of the care and support you normally receive. If you do choose to take part, you can still change your mind at any time and stop taking part. You do not have to tell us why. If you do stop taking part for any reason we would still use any information from you that we already have, but we wouldn’t ask you to do anything else.

**What else should I think about?**
This is a new treatment that we think might help people who have some problems with their behaviour. However, you do need to know that it might not work. This is a research study and we are doing it to find out whether tVNS does or does not help people improve their behaviour. We hope that it will help you, but we do not know for sure, and we can’t promise you that it will work.

tVNS is used in epilepsy and is not thought to be dangerous. However, you will feel a tingling sort of feeling in the skin close to the electrode when it is switched on. This should not hurt.

The study does ask you to commit to four months of taking part in the study and completing a diary about your behaviour and feelings every day during that time. We are also asking you to wear the tVNS device for four hours every day for 7 weeks and the heart rate monitor for 24 hours on 21 different days. If possible, we will also be asking someone who cares for you to keep a diary about you every day. There will also be visits by one of the researchers to where you live.

Why should I take part?
We hope that tVNS will help you control your feelings better and improve your life. It should also improve the lives of people who care for you or care about you. We also hope to find out more about what is happening in the brain and the body at times when people have trouble controlling their behaviour. This would mean that we could understand how we might be able to help you more.

What if you find that something is wrong?
We will ask you to sign a form to say that it is alright for us to contact your GP if you decide to take part. If we think that some of the other information you tell us will be helpful (for example, if we find you are feeling sad a lot of the time) or if we consider that any the results from the tests or assessments you will have (for example the ECG that measures heart activity) shows something important for your healthcare, we will ask you if it is OK for us to let your doctor know.

Will you keep my information private?
All the information about you that we collect when you take part in the study will be kept private. All the data will be anonymised. This means that nobody except the research team will know what you or your care-giver or family member have told us or any other information we collect about you while you are taking part. This information will be kept in a locked place for up to 10 years. No one else, except your doctor, will know you have taken part unless you choose to tell them.

If you think the information we gather might be helpful to share with the people who provide your care or rehabilitation, then we will ask your permission to share it with them. We will only share the information with the people you say.

The anonymised results of the study will be published in scientific journals. This means that we will write a report to tell other scientists what we have found out about whether VNS can help
improve behaviour. This report will not let people find out that you took part or any of your personal information. We will also send you a letter to tell you what we have found.

If you tell us something that makes us worried that you are not safe to yourself or to others, we will not be able to keep this private. We would have to tell someone who can support you and make sure you are safe.

**What if there is a problem?**
This study has been approved by …. [ETHICS COMMITTEE] and the University of Cambridge has insurance cover in case you are hurt. This means that you could get help if something went wrong. It would not matter if it was not anyone’s fault.

If you are worried about anything that has happened while you have been taking part in the study, you can telephone Dr Howard Ring on 01223 746121. He will do his best to help you. If you are still unhappy and want to complain formally, you can phone the Patient Advice and Liaison service on 0800 3760775.

**What if I have questions?**
Miss Sorcha Bolton is the Research Assistant for this study. Sorcha is very happy to talk to you about the study and answer any questions you may have. You can contact Sorcha by telephone on 01223 746035 or by email at sb931@medschl.cam.ac.uk

**What do I do if I want to take part?**
If you think that you want to take part please fill in the reply slip on the next page and post it to us in the stamped envelope. We will use the telephone number or address you give us to get in touch to arrange to visit you. You can give us your own address and telephone number. If you would rather we contacted your parent, another family member or carer, please give us their address and telephone number instead. When we visit you, we will talk about what will happen, give you a chance to try on the tVNS and heart rate devices, and to look at the questionnaires and forms that will need completing. You can then decide if you want to take part.

**What if I don't want to take part?**
If you don’t want to take part you don’t need to do anything.
REPLY SLIP

Vagus nerve stimulation (tVNS) and behaviour study.

If you think that you might want to take part in the study, please fill in the form below and post it to us using the stamped envelope. We will then contact you to arrange to visit you to talk about the study in more detail.

Name: ____________________________________________________________

Contact details are for (please tick):

☐ person with ABI or autism or LD
☐ care-giver / family: relationship to person: ________________________________

Address: __________________________________________________________
______________________________________________________________
______________________________________________________________

Telephone number: ________________________________________________
e-mail address: __________________________________________________

If you have lost the envelope, don’t worry. You can still post this slip to:

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