Participant Information Sheet

A Randomized, Double Blind Sham Controlled Clinical Trial to Evaluate The Efficacy of Electrical Vestibular Stimulation (VeNS), Compared to a Sham Control for the Management Of Anxiety

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You are being invited to take part in research being conducted by Ulster University.

What you should know about this research study?

We give you this information so that you can read about the purpose, risks, and potential benefits of this study. The main goal of research studies is to gain knowledge that may help future patients. You have the right to refuse to take part, or to agree to take part now and to change your mind later. Please review this information carefully to make sure you fully understand what the research is for and what you will be asked to do and ask any questions before you make a decision. **Your participation is voluntary.**

Thank you for taking the time to consider this invitation.

PURPOSE

- Anxiety is known to be one of the most common health concerns and is known to have detrimental effects on an individual's mental and physical health.
- *Medications* are known to be effective, and are the most common management for anxiety, but their use is limited due to the risks involved.
- *Cognitive Behavioural Therapy (CBT) or bibliotherapy* (a creative art therapy involving storytelling or reading informative literature which may help) has also been shown to be effective and safer in the management of anxiety but it takes time and training and is expensive.
- The aim of this study is to investigate a new device called the **Modius Stress**, to test how effective it is at reducing anxiety. The **Modius Stress** device works by very gently stimulated a nerve in the brain. Previous work using similar stimulation technologies have shown it has could be really effective even on people who don't respond to CBT.
- If the new device is shown to be effective in the management of anxiety, it could provide a safe and effective management option that anyone can use.

This study aims to:

*Test how effective the new **Modius Stress device** is at reducing stress, improving sleep and your general quality of life.*

TAKING PART IS YOUR CHOICE

It is up to you to decide whether or not you take part. Your participation in the study is entirely voluntary, and you have the right to withdraw yourself, and your data, from the study at any time without giving a reason.

AM I ELIGIBLE TO TAKE PART?

You are eligible for the study if you:

- Are between 18-80 years old
- Suffer from anxiety but are not being treated for it
- Do not suffer from insomnia
- Are not using, nor have used, prescription, or over the counter, anxiety medications.
- Have no other relevant health conditions like skin conditions, HIV, epilepsy, migraine with aura, cognitive impairment, stroke or head injuries, pregnant, breastfeeding, current psychotic disorders, regular antihistamine use, implanted battery powered medical devices (e.g pacemaker), or vestibular dysfunction or other inner ear disease.
- Have access to Wi-Fi.
- Are willing to try to use the device daily and attend all study appointments and procedures

WHAT WILL I HAVE TO DO IF I TAKE PART?:

Each appointment will be virtual and take around 1 hour.

Compliance with using the headset will be measured via the study app and usage will be monitored. You will receive an email alert if your usage over the previous 7 days is lower than requested and you will also be contacted by a Clinical Trial Mentor (CTM) who will discuss with you any low usage and/or technical issues you may be experiencing.

What we ask you to do and not to do during the study!

Do:

- Attend a remote study at 0 and 4 weeks.
- Wear the device for 30 minutes every evening before going to bed
- Ensure the device is connected to your smartphone/iPod via Bluetooth connection.
- Ensure your smartphone/iPod is connected to Wi-Fi.
- Speak to the monitoring company (CTM) as required.
- Notify the UU team ASAP if your GP tells you to start taking beta-blockers or if your medication for anxiety or anti-depressants change during the 4-week study (these are part of the exclusion criteria).
- Do return your device at the end of the study (this will be arranged for you).

Don't:

- Do not use while moving around as it can affect your sense of balance.
- Do not use while consuming alcohol.
- Do not use when driving or operating machinery of any kind. If dizziness is still experienced after the device is removed, then avoid driving or operating machinery until dizziness has subsided.
- Do not use in wet environments or immerse the device in water.
- Do not use on your head if your hair or skin is wet.
- Do not reuse or reapply the electrode pads once removed. The electrode pads are single use only.
- Do not apply the electrode pads to broken or irritated skin.
- Do not try to remove the batteries as they are non-user replaceable.
- Do not apply electrode pads before using alcohol wipes to clean the skin around the mastoid area.

What do you do if you experience any technical issues with the device?

You will be provided with the contact details for a mentoring service (Clinical Trial Mentors) when you enrol onto the study should you experience any technical difficulties with the device during the study. They will help you fix any problems you are experiencing with the device, battery, charging or Bluetooth connection.

Which companies are involved in the study?
The sponsoring company **Neurovalens Ltd** will be involved with:

- telephone screening of potential participants
- posting of devices
- remote monitoring of device usage via the cloud

Ulster University will complete final screening, enrolment onto the study, completion of all study appointments and reporting of any side-effects

Clinical Trial Mentors:

- may assist with telephone screening
- will be your contact if you have any technical issues with the device
- follow-up with you if your device use is low

Randomisation
The computer will randomise you to receive either the active device (with stimulation) or a sham device (no stimulation), which will be used to compare to the test device. We will not know what group you are in until the end of the study**.**
You will be asked at the end of the study which device you think you had and why.

More information on the Modius Stress device

The Modius Stress device uses a technology called vestibular nerve stimulation (VeNS). The device is worn on the head (like earphones) as the photo below shows and sends a gentle electrical current (a maximum of 1.5mA at 100Hz) to the skin behind the ears. It works, and feels like, a TENS machine which is used to reduce pain. The device will be powered by a single 3.7V battery, rechargeable through a micro-USB cable. Usage of the product will be restricted to 30 minutes per day before bedtime.

You will be trained on how to use the device correctly. You should be sitting down when using the device and remain sitting for the duration of the session (a maximum of 30 minutes). You will begin by positioning the electrode pads on the skin behind your ears. When correctly positioned the headset should be switched on using the on/off button. When initially switched on the default level of stimulation is very low, you will then increase the stimulation slowly until the desired level is reached. You will determine the appropriate level of stimulation once you begin to experience a gentle sense of swaying indicating the device is working. The sham device will work in exactly the same way but has no stimulation.

FUTURE RESEARCH

You will be asked in the Consent Form if you give permission to be contacted by researchers from Ulster University at a later date to be invited to take part in similar related studies. You will only be agreeing to receive information and will not be under any obligation to take part in any future studies.

RISKS AND DISCOMFORT

A risk assessment for the device has been carried out in accordance with internal standards (ISO: 14971: 2012) which has indicated that the risk of the Modius Stress stimulator device is 'non-significant' due to the low current (1.5mA) and the device is 'safe' to use. However, the following specific risks do exist:

1. Skin irritation behind the ears

Discomfort during use such as:

2. an electrical tingling sensation
3. A moving sensation, like being on a boat or being pulled towards the device
4. Nausea.
5. Vomiting
6. Headache

If you experience any side effects from using the device you are asked to contact the UU study team when the side effects occur at the email address or telephone number provided to you when you enrol on to the study. The study team will collect information on your experience and protocols are in place to deal with these should they arise e.g. make suggestions as to how you can reduce the likelihood of any side-effects and/or seek medical opinion (if required).

We will also collect any information on side effects during your study appointments.

BENEFITS AND/ OR COMPENSATION

You will be helping us further understand the influence of vestibular stimulation on management of anxiety and you may benefit from this study through a reduction in your anxiety, however we don't know this yet. If the work is successful participation may allow the CE marking of a new device to help people with anxiety feel better and less stressed. You will also be given a **payment of £40** if you complete the study.

CONFIDENTIALITY
The researchers and study staff will keep all information about you confidential (private), to the extent allowed by law, and will not reveal the names of any participants who take part in the study. Consent forms will be stored on Ulster University's secure server, for a minimum of 10 years from the end date of the study, separate from the study data and linked only by your ID number.

You will not be identified by name in any information related to this study or in any published report of the study results. Information will be safely destroyed once it is no longer required or at your request should you decide that you no longer want to take part in the study.

To find out more about how we use your information visit the Ulster University website: https://www.ulster.ac.uk/about/governance/compliance/gdpr *OR the Health Research Authority* website (https://bit.ly/2Nv3byK) or by emailing the research team.

OFFER TO ANSWER QUESTIONS
Before you sign this form, please ask any question about any part of the study that is unclear to you. You may take as much time as you need to think it over before you decide whether or not to take part.

APPROVAL
Ethics approval for this study has been obtained from the Health Research Authority (*IRAS#305770*).

RESULTS
It is intended that the findings from this study will be published in scientific or medical journals and presented at conferences. You will not be identified in any report or publication.

WHO IS ORGANISING AND FUNDING THE RESEARCH?
This research has been organised by Ulster University researchers. Neurovalens Limited have designed the device, will support recruitment and will arrange delivery/collection of the devices but will not be involved in the trial.

Thank you for taking the time to read this information.

If you have any questions or would like more information, contact our research team at:
modiusanxiety@ulster.ac.uk

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