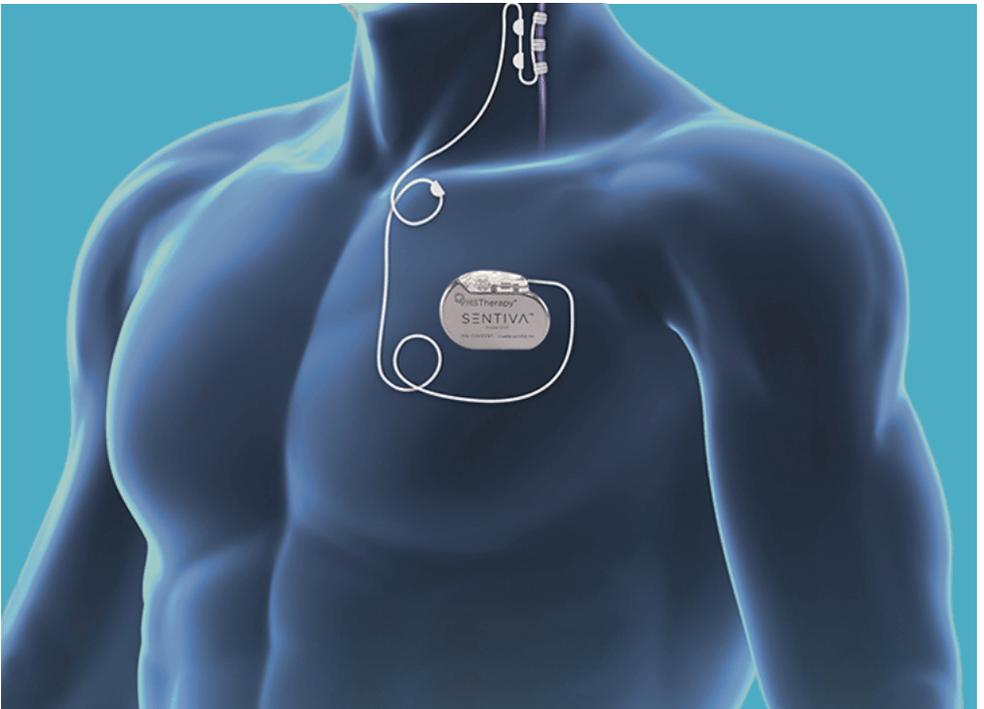


EPUT



Essex Partnership University
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VAGUS NERVE STIMULATION (VNS) THERAPY



PATIENT INFORMATION

EPUT

What is VNS Therapy and how does it work?

Vagus Nerve Stimulation (VNS) Therapy is a treatment for resistant depression that involves a stimulator or pulse generator which is connected inside the body to the left vagus nerves in the neck. The vagus nerve is the longest nerve in the body and connects your brain to the rest of your body.

VNS includes surgery to implant a device called a Neurostimulator. The Neurostimulator is placed under your skin on the left side of the chest. The battery transmits small electrical signals that are sent through a thin lead under the skin to your vagus nerves. These signals change brain wave patterns and help to reduce, or in some cases can stop symptoms of depression.

When can VNS not be used?

The VNS Therapy system cannot be used in patients if they have had their vagus nerve removed. There are certain procedures involving diathermy (a medical electrical procedure) which cannot be given to patients implanted with VNS Therapy system. Your anaesthetist or surgeon may also decide that there is a medical reason which may stop you from being put to sleep for your operation.

The implantation procedure

If believed that VNS Therapy will help you, your psychiatrist will refer you to a local surgeon who will then assess you to make sure the surgery is right for you. Your surgeon will tell you more about the anaesthetic, the procedure, and the hospital stay so that you will know what to expect.

You will normally be asleep during your procedure, which will take anywhere between one and two hours. In many cases, you can go home one the same day of the procedure, although some centres may want to keep you in overnight.

1. The surgeon makes a small cut on the left side of the neck and a second cut below the collarbone in the chest or armpit. Please see Figure A.

2. The lead (B) is passed under the skin between the two cuts. The surgeon wraps the lead around the left vagus nerve (A) in the neck and plugs the other end of the lead into the Neurostimulator (C). The Neurostimulator is placed in the "pocket" created at the site of the cut below the collarbone.

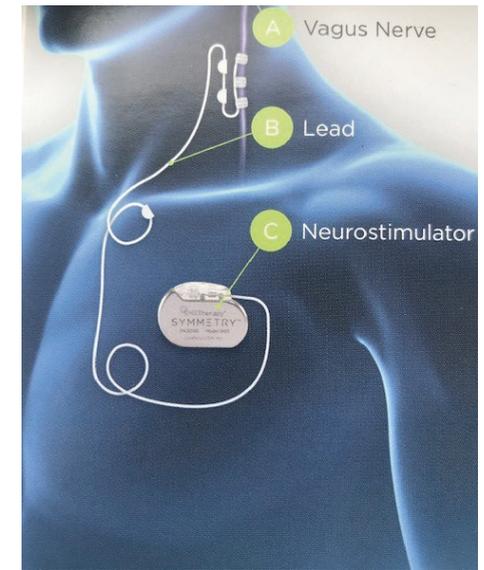


Figure A

3. Finally, the surgeon closes the cuts with stitches or clips.

Are there risks linked with the Procedure?

No surgery is without risk, though it is unlikely you will experience any major side effects. The most commonly reported side effect from the surgery is infection.

Other common implant issues include pain at the site of surgery, nausea, headaches and neck pain. You may also experience difficulty swallowing. Common sensations during stimulation include hoarseness or changes in the voice tone, a prickly feeling in the skin, shortness of breath, sore throat, and coughing.

These will become less noticeable over time.

Your surgeon or anaesthetist will run through the risks of the procedure with you and will make sure that any questions you have are answered. It is important that you discuss any worries or concerns you have with your surgeon or anaesthetist.

After the procedure

After your procedure (usually 2 weeks later), your psychiatrist will turn your device on with a special computer tablet and a 'wand' that talks to the Neurostimulator through the skin. From this point onwards, the VNS Therapy is active.

Please see Figure (B)

Your psychiatrist will then start the 'ramp up' process. The 'ramp up' process is where your psychiatrist will see you frequently over a couple of months and gradually turn up the settings to get you to the right treatment 'dose'. The speed of this process will be led by you and how quickly you are able to move through the settings.

If the stimulation feels uncomfortable, your psychiatrist can change it to make you more comfortable. Your progress will be monitored regularly and your treatment may change over time.



The effect of VNS Therapy on depression

The effect of VNS Therapy is not immediate and it may take some time to see results. Your psychiatrist has assessed you for VNS Therapy based on your treatment history.

However, over a few months, you may notice your symptoms significantly improve. Clinical trials have found that, when VNS Therapy is combined with traditional treatment (called adjunctive VNS Therapy), over two thirds of patients responded. (Clinical Trials, 2022)

Clinical Trials 2022, A Prospective, Multi-center, Randomized Controlled Blinded Trial Demonstrating the Safety and Effectiveness of VNS Therapy® System as Adjunctive Therapy Versus a No Stimulation Control in Subjects With Treatment-Resistant Depression (RECOVER), viewed October 2022 < clinicaltrials.gov/ct2/show/NCT03887715?term=RECOVER&recrs=ab&cond=Depression&draw=2 >

RECOVER Clinical trials found:

- 67.6% of the patients who had long term depression and whose standard treatments failed, depressive symptoms became significantly less severe when given adjunctive VNS Therapy
- Depressive symptoms decreased for most patients, while some patients had no change in depressive symptoms and some got worse while receiving VNS Therapy
- Amongst those patients whose symptoms did improve, some did not improve until they had been receiving VNS Therapy for six months or longer
- Over a 5-year period, patients were also more likely to experience periods of remission (when you have very few symptoms of depression), when VNS Therapy was added alongside standard treatment

Note: is impossible to predict response for individual patients.

Most patients do feel better by adding VNS Therapy to standard treatment, but if you find that you don't, you can talk to your psychiatrist about next steps. If you feel you are benefiting from VNS Therapy, you may wish to continue with the therapy, or your psychiatrist can turn the device off for a period of time. If you and your psychiatrist decide that you are not benefiting from the VNS Therapy, it can be removed or left in-place (but switched off) depending on your preference. You can also begin any other treatments at any time with VNS Therapy.

Frequently asked questions

Will I be able to tell when the Neurostimulator is on?

Many people notice a change in their voice (often described as hoarseness) or discomfort in the neck (typically mild pain or tingling sensation) during stimulation. In general, most side effects will become less noticeable over time.

Will I still need to take my medication?

VNS Therapy is known as an adjunctive treatment. This means that it is given along with your normal treatments. Patients treated with VNS Therapy in clinical trials also continued to take antidepressant medications. A significant number of patients had new medications added or doses of old medications increased during the reference.

Does VNS Therapy interfere with other devices?

The Neurostimulator can interfere with devices that operate in the 30 kHz to 100 kHz range.

Hearing aids and transistor radios operate in this range. The Neurostimulator could affect them, but no effects have yet been reported. The Neurostimulator may affect other implanted medical devices, such as cardiac pacemakers and implantable defibrillators. Please tell us about any other implants you may have and we will advise you on the best action to take.

Metal detectors should not affect the Neurostimulator or be affected by it. As a precaution, however, move through them at a steady pace; do not linger in the area and stay at least half a metre away from such equipment.

If you need an **MRI**, please let your psychiatrist know beforehand, so that your VNS Therapy system can be discussed with the MRI personnel. In many cases an MRI can be performed safely under certain conditions. However, surgery may be required to remove the VNS Therapy system prior to an MRI.

Will I see the implant device through the skin?

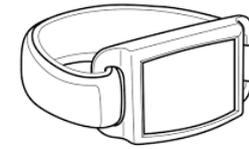
The lead that travels under the skin in your neck is not visible. The Neurostimulator is shaped like a disk and is up to approximately 5 centimetres (2 inches) in diameter, depending on the model. If you have a small frame or are very thin, the device may be visible below your left collarbone. This is the same as someone who may have a pacemaker for their heart. Talk to your psychiatrist if you have any worries.

The surgeon will try their best to make the scar on your neck in one of the natural skin folds, so once healed it will be difficult to see.

However, each person has different healing and scarring results, and some scars are easier to see than others. If this is a concern to you, please discuss it with the surgeon.

What does the magnet do?

Figure C



Watch-Style
(Wristband)



Paper-Style
(Belt Clip)

You will be given a magnet (wristband or belt clip) to stop stimulation.

The magnet is used to stop stimulation. You can use the magnet to stop stimulation temporarily or to turn **off** the Neurostimulator at any time. This could be if you plan to speak in public or sing (if stimulation bothers you when you do this), when you are eating (if you have swallowing problems), or if stimulation becomes uncomfortable or painful.

To stop stimulation, hold the magnet over the Neurostimulator and keep it there.

If you stopped the Neurostimulator due to unusual or painful stimulation, please call your doctor to let them know you have had issues with the treatment. You may need to visit the VNS Therapy clinic to adjust your stimulation settings.

Only the VNS Therapy magnet should be used with your VNS Therapy system, though in an emergency situation, you may use other strong magnets to stop the Neurostimulator. Please note, we cannot guarantee that other magnets will work, so please ask your psychiatrist if you need additional or replacement magnets.

For full safety information, how to use the Neurostimulator and any additional questions you may have around side effects or adverse effects, please visit the Symmetry website at: [symmetryvns.com](https://www.symmetryvns.com)

Contact Information

Essex Neuromodulation service
Brentwood Resource Centre
Greenwich Avenue
Brentwood
CM14 4SW
Tel: **0800 011 3024** Ext **4380**

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Patient Advice and Liaison Service (PALS)

If you have any concerns or need advice about accessing NHS services, you can speak in confidence to the Patient Advice and Liaison Service on **0800 085 7935** or you can email epunft.pals@nhs.net

This leaflet can be produced in large print, CD, Braille and other languages on request.



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