Tourettes action

NEUPULSE
PERIPHERAL NERVE STIMULATION FOR TOURETTE SYNDROME
AN UPDATE

ABOUT THIS INFORMATION SHEET

This information sheet is intended to provide an impartial summary of the current evidence relating to the Neupulse medical device, based on the research available at the time of writing. It has been prepared by the Tourettes Action Board of Directors' Research Subcommittee.

At Tourettes Action, our aim is to improve the lives of people affected by Tourette syndrome and tic disorders. We recognise that not everyone with tics require treatment and that no single treatment is right for everyone. We aim to provide our service users with the latest information, backed by research, which will enable them to make an informed decision about their care. Our hope is that, in the future, there will be a broad range of safe and effective evidence-based options available, allowing individuals and families to choose the approaches that best meet their needs and wishes.

Tourettes Action provided a charitable grant to fund the initial research that led to the development of the Neupulse device. For further details, see the Declaration of Interest and Transparency Statement below.

THE DEVICE

Neurotherapeutics Ltd. have developed a watch-style device called Neupulse, which uses a technique known as peripheral nerve stimulation (a method that sends mild electrical signals to nerves through the skin).

The device was originally designed to help reduce symptoms in people with Tourette syndrome.

There are currently two versions of the Neupulse device

- **Neupulse-C,** which is marketed as a consumer wellness device available for pre-order
- **Neupulse-M,** which is intended for medical use but is still pending regulatory approval.

Both versions are based on the same underlying technology. However, only the medical version is being formally evaluated for the treatment of Tourette syndrome and has not yet been approved for clinical use. This information sheet only focuses on the Neupulse medical device (Neupulse-M) and summarises the current available evidence regarding its use in the treatment of tics and Tourette syndrome. All references to the device in this document refer to the medical device pending regulatory approval, which may be given when further studies have been carried out to evaluate it.

BACKGROUND

The most common treatments for Tourette syndrome currently include behavioural therapies and medication. These approaches can be very helpful for many people, but not everyone responds to them. Some people find that the engagement and motivation needed to complete behavioural therapy is too much for them and some of the medicines used can cause unwanted side effects. Because of this, there has been ongoing interest in finding more accessible and better treatment options.

Researchers at the University of Nottingham developed this device, informed by neuroscientific research into the mechanisms involved in tic production in the brain. Researchers also spoke with people with lived experience of Tourette syndrome, who highlighted the need for treatment options that are more flexible, work quickly, can be used when symptoms are particularly problematic and are without some of the limitations of existing treatments. This feedback helped inform the design of a wearable device.

NEUPULSE AT A GLANCE – QUICK SUMMARY

WHAT IT IS	Neupulse is a wrist worn device, similar to a watch, that sends small signals to a nerve in the wrist, which may help reduce tics.
EVIDENCE SO FAR	One main clinical trial of 121 people of whom **39 were aged 12+ who tested the device**
HOW WELL IT WORKED	• **Around 60%** of people using the real device saw a **meaningful improvement** (more than 25% reduction in tics). • On average, tic severity improved by **about 35%** in the active group, which is similar to other treatments such as behavioural therapy and medication.
SAFETY	No serious side effects reported. The device did **not** appear to make tics worse.
LIMITATIONS	• The current evidence is mainly based on **a single small** clinical trial. Larger, independent trials are needed to confirm how well it works. • The trial lasted **4 weeks,** so long-term effects are unknown. • Not everyone improved; we cannot yet predict who will benefit.
REGULATORY STATUS	• The medical device is not yet approved for use, but a wellness device based on the same underlying technology is expected to be available from **June 2026.** • Not yet available on the NHS

WHAT IS PERIPHERAL NERVE STIMULATION (PNS)

Peripheral nerves are the nerves in our bodies, like in our arms and legs, that control movement and sensation. Peripheral nerve stimulation (PNS) works by sending small, controlled electrical signals through the skin to activate the nerves.

PNS is not new; it has been used for many years in different conditions. For example, it is similar in principle to other devices, such as a TENS machine, which stimulates nerves to help with pain. Other types of nerve stimulation have been used for the treatment of migraine, sleep problems and some other movement disorders.

The Neupulse medical tic device also uses gentle electrical signals, but it has been designed in a different way. Unlike general nerve stimulation devices, it does not aim to broadly stimulate nerves for symptom relief. Instead it targets a specific nerve in the wrist called the median nerve. The median nerve connects to brain networks involved in movement control. Research has shown that stimulating the median nerve at particular rhythms may temporarily reduce tics in some people. The Neupulse device uses this specific research informed stimulation pattern rather than a broad, non-specific stimulation used in devices such as TENS machines.

Importantly, this approach does not involve surgery and it does not permanently change the nerves. This is very different from treatments like deep brain stimulation, which require an operation to place electrodes inside the brain. It is a watch-style device that sits on the wrist and can be taken on or off whenever the person chooses.

HOW MIGHT PERIPHERAL NERVE STIMULATION HELP IN TOURETTE SYNDROME?

This is a picture of the Neupulse device currently and an example of how it is worn on the wrist.

The exact way PNS works is still being studied, however, research suggests that tics are linked to changes in the timing or rhythm of brain activity involved in movement control. The researchers think that stimulation of the median nerve may influence these rhythms, helping the brain settle into a more regular pattern.

WHAT IS THE EVIDENCE FROM CLINICAL TRIALS?

The main evidence for the Neupulse device comes from a clinical trial carried out in 2022. The study included 121 people aged 12 years and above with Tourette syndrome or persistent tic disorder (where someone has only motor tics or vocal tics). The average age of people in the trial was 24 years.

It was a special type of study called a randomised controlled trial (RCT), which is considered one of the best ways of testing whether a treatment works. People were randomly assigned to receive either:

- the active device (in which the device was active and working)
- a placebo (sometimes called a sham or dummy treatment)
- or to continue with their usual care without the device

The main analysis was based on the 39 participants who received the active device compared to those who did not. This helps researchers compare the true effects of the treatment against what might happen because of expectation, chance or other factors.

A placebo is designed to look and feel as similar as possible to the real treatment, but without the active effect being tested. People involved in the study would have no idea if they had the real device or a placebo.

In this study, the placebo was a 'sham' version of the device, meaning it was an inactive version of the real medical device. It gave a short burst of real stimulation at the start of the time that the watch was worn so it felt convincing but then reduced to a very low level that was not expected to affect brain activity.

Participants used the device at home for about 15 minutes, once a day on weekdays, for four weeks, so they did not wear the device all day.

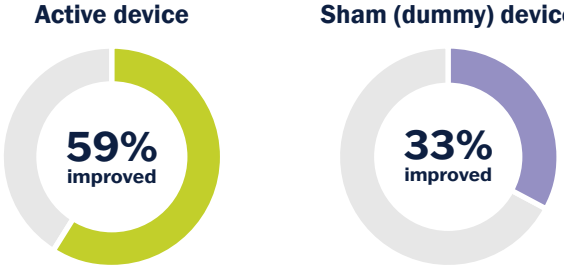
THE RESULTS

To measure improvement, the researchers compared tic severity during the week before using the device with tic severity in the final week of the trial. This means the results reflect overall changes in tic severity across everyday life, not just while the device was being worn.

Tic severity was measured using a standard clinical tic severity scale that assesses tics based on factors such as number, frequency and intensity. People were considered to have a meaningful improvement in their tics if their severity score improved by more than 25%.

About 60% of people using the active device experienced what the researchers defined as a meaningful improvement in their overall tic severity. In other words, their tic severity score reduced by more than 25%.

Meaningful improvement in overall tic severity

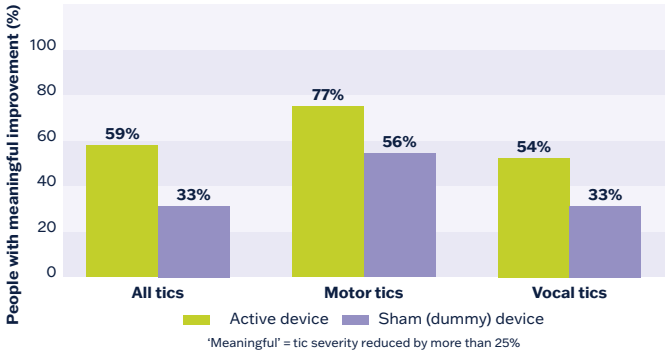


These graphs show the proportion of participants who achieved a clinically meaningful improvement in tic severity in the active device as compared to the sham (dummy) device group.

Improvements were also seen in the sham device group, where 33% of people improved. This is why studies compare treatments with placebo devices, as some improvement can happen for reasons other than the treatment itself. Even taking this into account, meaningful improvements were more common in those receiving the real stimulation.

The effect differed by tic type. Motor tics showed the greatest improvement, with 77% of people using the active device achieving meaningful improvement in tic severity. Vocal tics improved in 54% of people using the active device.

Who had a meaningful improvement? (active vs sham device)



These graphs shows how different tics responded to the the active device and the sham device.

In the trial, the device reduced tic severity for many people, but not for everyone. The device appeared to work at reducing tics both while the device was switched on and after it was switched off. It worked at reducing tics in people who have other commonly co-occurring conditions, such as OCD and ADHD. Although it may have improved tic severity, the study did not find meaningful improvements in daily-life impairment or premonitory urges, the sensation before tics happen. The results Neupulse found are similar to those found in behavioural therapy and medication.

ARE THERE ANY SIDE EFFECTS?

The trial reported that the device was generally safe and comfortable to use. The most commonly reported side affect was sensations that were mild tingling or a brief twitch of the thumb during stimulation. Some people had slight redness on the skin, which settled quickly. Importantly, the stimulation did not make tics worse and no serious side effects were reported.

WHO SHOULD *NOT* USE THE DEVICE (BASED ON CURRENT INFORMATION)

- ✕ People **under the age of 12**
- ✕ Anyone who is **pregnant** (not yet tested in pregnancy)
- ✕ People with **epilepsy or a history of seizures**
- ✕ Anyone who uses **electrical or implanted medical devices,** such as:
  - ✕ pacemakers
  - ✕ insulin pumps
  - ✕ neurostimulators
- ✕ People with **metal implants in the arm or wrist** (for example, from a previous broken bone)
- ✕ Anyone with **reduced sensation** in their hands or arms (e.g. numbness)
- ✕ Anyone with a **brain tumour** (not tested in this group)
- ✕ People with **broken skin, cuts or wounds on the wrist** where the device would sit

LIMITATIONS OF THE TRIAL

- In the trial, the device reduced tic severity for many people, but not for everyone. Some people had large improvements, some had smaller improvements and some had none. At present there is currently no way to predict who will respond and how well.
- The device was tested in people of different ages, but no participant under the age of 12 was included in the research trial. This means we do not yet know if it is effective in children under the age of 12 and therefore it is not yet recommended for this age group.
- The trial was on 121 people with 39 receiving the active device. This is usual for early research, but larger trials are needed to fully confirm how well the device works.
- The study lasted four weeks. As a result, we do not yet know how long the benefits last, whether improvements continue over time, what happens when people stop using the device or if there are other side effects associated with long-term use.
- This study provides evidence that the device may reduce tic severity in some people, but it does not provide evidence it improves impairment or quality of life, which for some people may be the most important measure of improvement.

IS IT AVAILABLE ON THE NHS YET?

The Neupulse medical device is still going through the approval process to make sure it is safe and meets medical-device standards for the UK and Europe. NICE, the organisation that evaluates new treatments for the NHS, has included the device in its Early Value Assessment programme, which means it is recognised as a promising technology. However, NICE has said it will wait for further information on long-term effects and benefits before making any recommendations or deciding whether it could be offered on the NHS.

DECLARATION OF INTEREST AND TRANSPARENCY STATEMENT

We believe in being open about our financial relationships. In 2017 and 2018, Tourettes Action provided funding for initial research undertaken by the University of Nottingham, which contributed to the development of the Neupulse device. The charitable grants were given as part of a broader 3-year funding program supporting a number of research projects or enabling studies to advance knowledge into and treatment of Tourette syndrome. More information about the grant program generally and the specific grants to the University of Nottingham can be found **here.**

Under AMRC (Association of Medical Research Charities) guidelines, when a charity funds research that leads to a new invention or technology, it can receive a share of any money made from it. Following these rules, Tourettes Action may receive a small share of any income generated by the Neupulse device. This means the charity may benefit financially from the sale or use of this product. However, any financial returns received are applied solely to furthering our charitable purpose.

In line with Charity Commission guidance, this interest is formally declared and actively managed to ensure that it does not influence decisions about services or recommendations provided by Tourettes Action.

This statement and the accompanying information provided about the device, has been developed through Tourettes Action's research governance processes, including review by the charity's Research Subcommittee, none of whom have any personal financial interest in the device, Neurotherapeutics Ltd. or any income generated from the product. It has also been independently reviewed by an external clinical advisor to support accuracy and balance. The information given is based on research studies conducted to date and does not give personal views or opinions.

You are under no obligation to use this device and alternative treatment approaches may be available. As with any treatment or medical device, we encourage individuals to consider their personal circumstances carefully and to discuss new treatment options with an appropriate healthcare professional. We have information on our website which covers treatment options available to those with Tourette syndrome, which will help individuals make a more informed decision.

REFERENCES AND FURTHER INFORMATION

MAIN CLINICAL TRIAL

Maiquez B.M., Smith C., Dyke K., et al. (2023). A double-blind, sham-controlled trial of home-administered rhythmic 10-Hz median nerve stimulation for the reduction of tics in Tourette syndrome. Journal of Neuropsychology.

NICE (UK NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE)

Early Value Assessment: Neuropulse Peripheral Nerve Stimulation Device: **www.nice.org.uk/guidance/hte25/chapter/2-The-technologies** (see NICE Digital Health Guidance, Draft Recommendations, 2023–2024)

NEUPULSE DEVICE INFORMATION

Neupulse (official website): **https://neupulse.co**

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