

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

HealthTech Programme

**GID-IPG10441 Unilateral and staged
bilateral MRI-guided focused ultrasound
thalamotomy for medication-refractory
essential tremor**

Final scope

1 Introduction

The procedure included in this NICE HealthTech evaluation is MRI-guided focused ultrasound thalamotomy for medication-refractory essential tremor. This includes both unilateral and staged bilateral procedures. Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy. NICE makes recommendations based on assessment of the efficacy and safety of new and significantly modified procedures, or established procedures if there is uncertainty about their efficacy or safety. In cases where an interventional procedure involves implanting or using a health technology, the recommendations will focus on the procedure itself rather than the specific technology used.

This is the first time that MRI-guided focused ultrasound thalamotomy as a staged bilateral procedure for medication-refractory essential tremor is being assessed by NICE interventional procedures. This is also a review of existing NICE interventional procedures on [unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor](#). This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the [Interventional procedures programme manual](#) and the [NICE HealthTech programme manual](#).

Lay description

Essential tremor causes involuntary rhythmic shaking of a body part, usually the hands and arms. Symptoms may be worse on 1 side of the body than the other. This procedure is used to treat essential tremor that does not improve with medicines (medication-refractory). MRI identifies the area of the thalamus, a part of the brain, that relates to the tremor. High-intensity focused ultrasound energy is then delivered to that area, and this heats and destroys the tissue (thalamotomy). Thalamotomy can be used to treat the side of the body with the worst symptoms (unilateral), with the less affected side treated later if needed (staged bilateral). The aim of this minimally invasive surgical procedure is to reduce symptoms and improve quality of life.

2 The condition

Essential tremor is a progressive neurological condition that causes involuntary movement of a body part, most typically the hands and forearms, that is usually absent at rest. Symptoms often present on both sides of the body, but functional impairment is usually worse on one side. However, it may gradually worsen and affect both sides. It may also involve the voice, the head, jaw, and legs. The cause is not known, although around 60% of all cases are inherited ([National Tremor Foundation](#)).

Essential tremor is one of the most common movement disorders worldwide, with an overall prevalence of 0.32% across all ages. Prevalence increases with age, ranging from 0.04% in people under 20 years to 2.87% in those aged 80 years and above ([Song, Peige et al. 2021](#)). In the UK, it is estimated that around a million people are living with essential tremor ([National Tremor Foundation](#)). Most people with essential tremor have mild symptoms and do not require treatment ([BMJ Best Practice](#)).

In some people, the symptoms of essential tremor are more severe and can be disabling, impacting activities of daily living, communication, employment, and quality of life. People with essential tremor may experience trembling of the hands, which may mean simple tasks such as drinking a cup of tea, holding

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objects securely, or producing legible handwriting are impossible ([National Tremor Foundation](#)). Social anxiety is also common among people with essential tremor ([How and Lei 2023](#)).

3 Current practice

Currently, essential tremor is managed with medication. First-line medications are propranolol or primidone. Second-line medications, including gabapentin, alprazolam, and topiramate can be used to treat essential tremor if first-line medications are either ineffective or not tolerated. Rarely, injections of botulinum toxin may be used.

Invasive surgical treatments may be considered for people with essential tremor that has not responded adequately to medications (medication-refractory). These include deep brain stimulation and radiofrequency thalamotomy. According to the [NHS England commissioning policy](#), unilateral MRI-guided focused ultrasound thalamotomy is currently an option when the person is not eligible for deep brain stimulation.

4 Unmet need

Essential tremor may not respond to medication. While the number of cases of severe tremor is unknown, it is estimated that about 50% of severe cases do not respond adequately or people have side effects to medication ([National Tremor Foundation](#)). Deep brain stimulation is an invasive procedure that requires general anaesthesia and implanted hardware with associated risks such as bleeding, infection, device-related complications, and ongoing need for battery replacements. Radiofrequency thalamotomy involves drilling in the skull, with risks of bleeding. Invasive surgical treatments may be unsuitable for some people with essential tremor, particularly in older people who comprise most of the essential tremor population.

MRI-guided focused ultrasound thalamotomy is an incisionless alternative to more invasive surgical treatments that could offer improved functional outcomes while maintaining the safety advantages of the focused ultrasound

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approach. This procedure uses focused ultrasound energy to ablate targeted tissues deep in the body without incisions. This is particularly relevant for people who decline invasive surgical treatment, or when invasive surgical treatment is not suitable. People with essential tremor who have bilateral functional impairment, and who have had one side treated by MRI-guided focused ultrasound thalamotomy may benefit from a second procedure on the other side.

5 The procedure

MRI-guided focused ultrasound thalamotomy is an outpatient procedure. It is done with the person lying on their back inside an MRI scanner. The person's head is shaved, and a stereotactic head frame is attached. The person is usually kept awake during the procedure so they can report any improvement of symptoms or adverse events and be regularly assessed by the treating healthcare professional to evaluate the clinical response. Some people may be offered light sedation.

Real-time MRI guidance and thermal mapping are used to identify the target area of the brain associated with the tremor (the ventral intermediate nucleus of the thalamus). The left ventral intermediate nucleus of the thalamus controls the right side of the body, and the right ventral intermediate nucleus of the thalamus control the left.

At first, low-power ultrasound is delivered to warm the target tissues to 40-45°C, and MRI is used to confirm the chosen location. The location of the ultrasound focus and temperature changes are monitored in real time using MRI thermometry. The target temperature is then increased to 46-50°C to test clinical effect and monitor for side effects. Finally, several high-power focused ultrasound pulses (sonications) are delivered to raise the focal temperature above 55°C, ablating the target tissues. An immediate post-treatment MRI is performed to confirm lesion creation and location. Throughout the procedure, chilled water is circulated around the head to prevent thermal damage to the

scalp caused by the increase in bone temperature. The procedure takes about 2 hours and symptom relief should be immediate.

Currently, unilateral MRI-guided focused ultrasound thalamotomy can be used in the NHS when there are special arrangements for clinical governance, consent, and audit or research. Most people receiving a unilateral procedure get improvement from the procedure on just one side. The treated side is the side of the body with functional impairment. Treatment of the second side is not always required, but it may be considered when the tremor on the opposite side also causes functional impairment. In staged bilateral MRI-guided focused ultrasound thalamotomy, the process is a repeat of the initial procedure, but performed on the other side of the thalamus. Procedures are usually separated by at least nine months.

5.1 Innovative aspects of the procedure

The proposed innovative aspect of the procedure is that it is minimally invasive because it does not require creating an opening in the skull. This avoids some of the risks associated with more invasive surgical treatments (that is, deep brain stimulation or radiofrequency thalamotomy) that require an incision. In addition, real-time feedback from the person having the procedure can be obtained.

5.2 Current known use of the procedure

There are currently four centres in the UK that offer the procedure, including two tertiary NHS trusts with Neurology and Neurosurgery services: St Mary's Hospital, Imperial College Healthcare NHS Trust London and The Walton Centre NHS Foundation Trust Liverpool. It is available on a case-by-case basis on the NHS in Scotland at the University of Dundee. It is also available privately at the Queen Square Imaging Centre in London.

6 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

- Essential tremor is more common in older people. In the UK, the incidence was highest among 60-79 years ([Antonazzo 2022](#)).
- In the UK, essential tremor is more common in males than in females ([Antonazzo 2022](#)).
- People with essential tremor may be covered by the Equality Act 2010 under the disability provision if their condition has had a substantial adverse impact on normal day to day activities for over 12 months.
- There is currently only one device available to do this procedure. For the treatment of essential tremor, the device is only intended for use in adults aged 22 and older.
- The available device used in the procedure is contraindicated for use in people who are pregnant.
- The procedure is currently available at four centres in the UK, but only two centres (St Mary's Hospital, Imperial College Healthcare NHS Trust London, and The Walton Centre NHS Foundation Trust in Liverpool) provide it as part of routine NHS practice. Due to limited availability geographically, some people may not be able to access it, particularly those find travelling more difficult, such as people who are older, more frail, and with limited mobility.

7 Decision problem

The key objective for this evaluation is to assess the efficacy and safety of unilateral and staged bilateral MRI-guided focused ultrasound thalamotomy

for medication-refractory essential tremor to determine whether it works well enough and is safe enough for use in the NHS.

Table 1: Decision problem

<p>Population</p>	<ul style="list-style-type: none"> • People with medication-refractory essential tremor <p>If the evidence allows the following subgroups may be considered:</p> <ul style="list-style-type: none"> • People with hand tremor • People with forearm tremor • People with voice tremor • People with head tremor • People with legs tremor
<p>Intervention</p>	<ul style="list-style-type: none"> • Unilateral MRI-guided focused ultrasound thalamotomy • Staged-bilateral MRI-guided focused ultrasound thalamotomy
<p>Key efficacy outcomes (may include but are not limited to)</p>	<ul style="list-style-type: none"> • Tremor scale • Quality of life • Tremor recurrence • Functional activities of daily living • Contralateral or ipsilateral outcomes • Non-motor symptoms
<p>Key safety outcomes (may include but are not limited to)</p>	<ul style="list-style-type: none"> • Effects of the procedure on surrounding structures of the ventral intermediate nucleus of the thalamus • Head discomfort or pain • Dizziness • Numbness/tingling • Headache • Dysarthria • Facial asymmetry

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	<ul style="list-style-type: none"> • Limb weakness • Paraesthesia • Dysmetria • Gait disturbance • Bleeding • Chorea • Stroke • Permanent side effects • Treatment failure • Need for subsequent procedures • Deep vein thrombosis • Nausea • Vomiting
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8 Other issues for information

There is currently only one device available to do this procedure. According to the [instructions for use](#), it is intended for thermal ablation of target tissues in the thalamus, subthalamus, and pallidum regions of the brain. For the treatment of essential tremor, the device is only intended for adults aged 22 and over.

9 NICE team

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Appendix A: Related evidence or guidance

Relevant registries or emerging key trials

- [NCT04501484: Bilateral Essential Tremor Treatment With FUS \(BEST-FUS\)](#). Estimated study completion: December 2025
- [NCT06676501: A Study to Evaluate the Safety and Efficacy of Staged Bilateral Magnetic Resonance-Guided Focused Ultrasound Thalamotomy for the Treatment of Essential Tremor \(ET-Bi-MRgFUS\)](#). Estimated study completion: November 2026
- [NCT03465761: Staged Bilateral Exablate Treatment of Medication Refractory Essential Tremor](#). Estimated study completion: December 2026

Related NICE guidance, standards or indicators

NICE interventional procedures guidance

- [Unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor](#) (2018) NICE interventional procedures guidance 617 – current guidance (Recommendation: special arrangements)
- [Deep brain stimulation for tremor and dystonia \(excluding Parkinson's disease\) \(2006\)](#) NICE interventional procedures guidance 188 (Recommendation: standard arrangements)
- [MRI-guided focused ultrasound thalamotomy for treating moderate to severe tremor in Parkinson's](#) (2024) NICE interventional procedures guidance 796 (Recommendation: research only)
- [MRI-guided focused ultrasound subthalamotomy for treating Parkinson's](#) (2024) NICE interventional procedures guidance 797 (Recommendation: research only)

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- [Transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain](#) (2018) NICE interventional procedures guidance 632 (Recommendation: should not be used)

NICE clinical guidelines

- [Suspected neurological conditions: recognition and referral](#) (2019) NICE guideline 127
- [Parkinson's disease in adults](#) (2017) NICE guideline 71

Other related documents

National policy documents

- [NHS England Clinical Commissioning Policy Transcranial magnetic resonance guided focused ultrasound thalamotomy for treatment of medication-refractory essential tremor \(adults\)](#) (2020). Reference: NHS England: 200803P (Recommendation: available as a treatment option through routine commissioning for patients with medication-refractory essential tremor that are not eligible for deep brain stimulation)
- [NHS England Clinical Commissioning Policy Deep brain stimulation in movement disorders](#) (2013). Reference: NHSBC/D03/P/b<https://pubmed.ncbi.nlm.nih.gov/31832649/>

International guidelines

- [American Society for Stereotactic and Functional Neurosurgery Position Statement on Magnetic Resonance-Guided Focused Ultrasound for the Management of Essential Tremor](#) (2020)