

Clinical Commissioning Policy:

Stereotactic radiosurgery for essential tremor refractory to medication (adults) [URN:2342]

Summary

Unilateral thalamic stereotactic radiosurgery for medication refractory essential tremor for adults will be routinely commissioned following a recommendation from the Clinical Priorities Advisory Group within the criteria set out in this document.

Committee discussion

Clinical Panel agreed with the policy and recommended that it progress as a routine commissioning policy. Please see Clinical Panel reports for full details of Clinical Panel's discussion.

The Clinical Priorities Advisory Group committee papers can be accessed here: [Clinical Commissioning Policy: Stereotactic radiosurgery for essential tremor refractory to medication \(adults\)](#)

What we have decided

NHS England has carefully reviewed the evidence to treat adult patients with medication refractory essential tremor with unilateral thalamic stereotactic radiosurgery. We have concluded that there is enough evidence to make the treatment available at this time.

Patients suitable for stereotactic radiosurgery must be referred to an all-tiers stereotactic radiosurgery service with an Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) designated radiosurgery practitioner who is part of an existing functional neurosurgery service. This must occur in accordance with the patient pathway for patients meeting all of the following inclusion criteria, and none of the exclusion criteria.

The evidence review which informs this commissioning position can be accessed here: [Clinical Commissioning Policy: Stereotactic radiosurgery for essential tremor refractory to medication \(adults\)](#)

Links and updates to other policies

- Clinical Commissioning Policy: Deep Brain Stimulation (DBS) In Movement Disorders: [d03-p-b.pdf \(england.nhs.uk\)](#)
- Clinical Commissioning Policy: Transcranial magnetic resonance guided focused ultrasound thalamotomy for treatment of medication-refractory essential tremor

(adults): [1904-transcranial-magnetic-resonance-guided-focused-ultrasound-thalamotomy-for-treatment-of-medication-refract.pdf \(england.nhs.uk\)](https://www.england.nhs.uk/1904-transcranial-magnetic-resonance-guided-focused-ultrasound-thalamotomy-for-treatment-of-medication-refract.pdf)

Plain language summary

About essential tremor

Essential tremor is the most common movement disorder. It causes parts of the body to move in an uncontrolled and repetitive manner, most commonly affecting the arms and hands. The cause is not known but many patients have a family history of the condition. At first, the tremor may not be present all the time. However, it gradually worsens. Purposeful movements, stress, tiredness, hunger, heightened emotions or extremes in temperature can make the tremor more pronounced.

The majority of patients are managed with medications. However, a small proportion may require neurosurgical intervention to treat their symptoms.

About current treatment

Medication is the first line treatment for essential tremor. Treatment for essential tremor includes medications such as beta blockers, anti-epileptics or sedatives. Drug treatments will stop working for between a quarter and a half of patients (Louis E.D., 2011) and essential tremor can then be considered refractory (or resistant) to medication once two or more trials of appropriate medical therapy have failed (Elias et al, 2016). Surgical intervention in essential tremor can then be considered if symptoms are severe and significant.

The following surgical treatments are commissioned by NHS England for the treatment of medication-refractory essential tremor with further details in Annex A:

- Deep brain stimulation (DBS), a surgical procedure.
- Surgical thalamotomy, a surgical procedure.
- Transcranial MRI guided ultrasound thalamotomy (TcMRgFUS), a non-invasive thermal ablation technique.

About unilateral thalamic stereotactic radiosurgery

Stereotactic radiosurgery is an alternative method of producing a focal lesion in the brain by delivering very highly focussed radiation to the ventralis intermedius (VIM) nucleus of the thalamus, typically targeting one side to alleviate the tremor on the most severely affected other (contralateral) side of the body. The patient is awake during the procedure in which a stereotactic frame is first fixed to the patient's head, and CT/MRI images are acquired before treatment is delivered. Stereotactic radiosurgery is a minimally invasive neurosurgical procedure, and is usually done as a day case, taking approximately 1 –1.5 hours.

Epidemiology and needs assessment

There are no estimates for the prevalence of essential tremor specific for England. Essential tremor has an estimated world pooled prevalence of 0.9% (all ages) that increases markedly with age (>65 years old prevalence increases to 4.6%, and >95 years old is 21.7%) (Louis & Ferreira 2010). The prevalence of essential tremor can

be hard to accurately estimate because it can often be mis- or under-diagnosed. The age of onset of essential tremor is bimodal with two peaks, one at age 15 years and a second peak at 50 to 70 years of age (Brin and Koller 1998). Some studies have also shown a higher prevalence of essential tremor in men (Louis and Ferreira 2010). There have been even fewer estimates of essential tremor incidence. One study in Spain estimated the annual incidence of essential tremor at 616 per 100,000 person-years, in people aged 65 years and above (Romero et al 2012).

In England, there are between 100 and 150 DBS surgeries for essential tremor commissioned each year. This number is not expected to change with the implementation of this policy. Surgical thalamotomy is a treatment that is used less frequently with the commissioning of alternative treatments, such as TcMRgFUS. It is estimated that specialist centres perform <1 operation/year.

Some patients are not suitable for or decline DBS and are then considered eligible for TcMRgFUS, which is currently commissioned. Of those referred for TcMRgFUS, approximately 50 patients per year are not eligible for TcMRgFUS and would be appropriate for consideration of the proposed treatment, stereotactic radiosurgery within the criteria set out in this document.

Implementation

NHS England will routinely commission stereotactic radiosurgery as an option for patients with medication-refractory tremor, after the currently commissioned procedures DBS and TcMRgFUS have been considered and following discussion at the joint TcMRgFUS and stereotactic radiosurgery MDT. Patients suitable for stereotactic radiosurgery must be referred to an all-tiers stereotactic radiosurgery service with an Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) designated radiosurgery practitioner who is part of an existing functional neurosurgery service. This must occur in accordance with the patient pathway for patients meeting all of the following inclusion criteria, and none of the exclusion criteria.

Inclusion criteria

Patients with a confirmed diagnosis of essential tremor who meet **ALL** of the following criteria:

- Medication-refractory essential tremor (as defined by failure of at least two classes of medication used to treat essential tremor).
- Either postural tremor or an intention tremor of grade 3 or 4 in the target upper limb (scored using the Clinical Rating Scale for Tremor (CRST) part A, (see Annex B) and a score of 2 or above in any one of its items in the CRST Part C (items 16-23).
- A discussion has taken place in a specialist movement disorder multi-disciplinary team (MDT) (with a movement disorder neurologist, neuroradiologist, functional neurosurgeon and appropriate specialist nursing, neuropsychological and in some cases, neuropsychiatric input) and the MDT agree the following:
 - The patient is not suitable for or has declined DBS or previous DBS treatment has failed.
- A discussion has taken place at an TcMRgFUS MDT and the following agreed:
 - The patient is not suitable for TcMRgFUS e.g. the patient has a skull density ratio that is not compatible with TcMRgFUS on a pre-procedure CT head scan.
- A discussion has taken place at a joint TcMRgFUS and stereotactic radiosurgery MDT and it is agreed that the patient is suitable for stereotactic radiosurgery

- Stereotactic radiosurgery has been discussed and agreed with the patient through shared decision making.
- Rockwood Frailty Scale <7¹.
- There are none of the exclusion criteria present.

Exclusion criteria

Patients who meet **any of** the following criteria are not eligible for stereotactic radiosurgery:

- Brain injury or anatomical abnormality at the targeted area, for example previous infarct.
- Individuals who:
 - Are unable to lie flat to tolerate the procedure safely²
 - Have received previous radiotherapy treatment to the brain and where the radiation dose from stereotactic radiosurgery is likely to exceed accepted dose limits
 - Are pregnant
 - Have a diagnosis of Parkinson's disease

Starting criteria

Patients that meet all of the inclusion criteria and do not meet any of the exclusion criteria can be considered for treatment. Patients need to have appropriate cross-sectional imaging before proceeding with stereotactic radiosurgery.

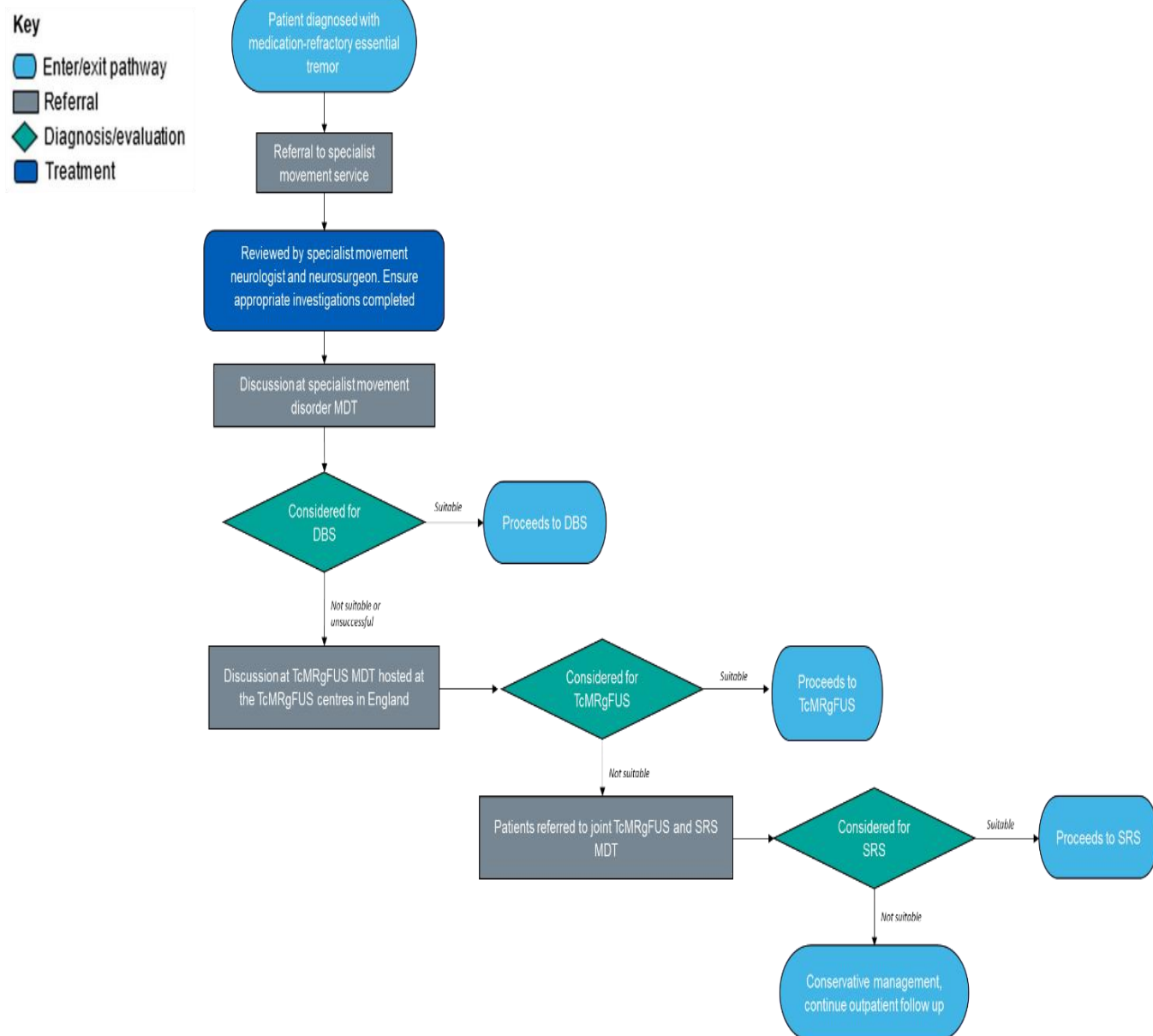
Monitoring criteria

Patients must have planned follow up with a movement disorder specialist at regular intervals post-procedure. It is suggested for repeat cross-sectional imaging and appropriate clinical tremor score at 6 months, and neuropsychological assessment and repeat clinical tremor score at 12 months.

¹ Patients with a Rockwood Frailty Scale of 7 may be considered, if their score is predominantly due to their essential tremor

² Patients may be considered for a general anaesthetic to facilitate the ability to tolerate the procedure

Patient pathway



DBS: Deep Brain Stimulation

SRS: Stereotactic Radiosurgery

TcMRgFUS: Transcranial magnetic resonance-guided focused ultrasound

Governance arrangements:

This policy should be used in conjunction with the following service specifications and must only be delivered by All Tier SRS providers:

- [Stereotactic radiosurgery and stereotactic radiotherapy \(intracranial\) \(all ages\) 2324](#)
- [Neurosurgery \(adults\) Service Specification 170109S](#)

Any provider organisation treating patients with this intervention will be required to assure itself that the internal governance arrangements have been completed before procedure takes place.

All providers must be compliant with Radiotherapy Quality Assurance (RTTQA) prior to offering this treatment. A national approach to regular peer review of patient eligibility and treatment plans will be required.

Mechanism for funding

Stereotactic radiosurgery within the criteria set out in this document will be commissioned and funded under existing arrangements for the provision of specialised services.

Audit requirements

Provider organisations must register all patients using prior approval software and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined. This information is collected to inform future policy revisions.

Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment, and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

Essential tremor	A common neurological disorder that causes involuntary, repetitive movements of body parts, often the arms and hands.
Medication refractory	Has not responded to two classes of medications.
Transcranial magnetic resonance guided ultrasound thalamotomy (TcMRgFUS)	Uses focused ultrasound waves generated externally to the body that are directed to and alter the function of a very specific area in the brain to improve tremor.
Thalamotomy	The precise destruction of a tiny area of the brain called the thalamus.

References

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Elias, W.J., Lipsman, N., Ondo, W.G., Ghanouni, P., Kim, Y.G., Lee, W., Schwartz, M., Hynynen, K., Lozano, A.M., Shah, B.B., Huss, D., Dallapiazza, R.F., Gwinn, R.

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NHS England. Deep Brain Stimulation (DBS) in Movement Disorders. Clinical Commissioning Policy. Reference: NHSCB/D03/P/b. NHS England 2013. Available from: <https://www.england.nhs.uk/wp-content/uploads/2018/07/DBS-for-MD.pdf>

Romero, J.P., Benito-Leon, J., Bermejo-Pareja, F. (2012) The NEDICES study: recent advances in the understanding of the epidemiology of essential tremor. *Tremor Other Hyperkinet Mov (NY)*. 2: tre-02-70-356-2. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3570054/>

Schuumann, P.R., Bosch, D.A., Merkus, M.P., Speelman, J.D. (2008) Long-term follow-up of thalamic stimulation versus thalamotomy for tremor suppression. *Mov. Disorder.* 23(8): 1146- 1153.

Annex A

NHS England Commissioned Surgical Treatments for Essential Tremor

The following surgical treatments are commissioned by NHS England for the treatment of medication refractory essential tremor:

- Deep brain stimulation (DBS) is a surgical procedure performed by neurosurgeons. A stereotactic frame is fixed to the patient's head (local and / or general anaesthesia may be used in the procedure) and thin electrodes are passed through burr holes in the skull and placed into the VIM nucleus of the thalamus. The VIM nucleus is a specific area of the brain responsible for modifying movements of the body. The electrodes are then connected to a wire running under the skin to a battery and implanted pulse generator (IPG) in the chest. The application of electrical current to the VIM nucleus alters its function and improves the tremor. Patients need to routinely attend out-patient visits for programming of the device post-operatively. The effects of DBS tend to diminish over time. Adverse events of DBS include pain, intracranial haemorrhage, infection, stroke, balance disturbances, hardware malfunction, speech and visual problems as well as a small operative mortality.
- Surgical thalamotomy is a surgical procedure. The patient is awake during the procedure in which a stereotactic frame is fixed to the patient's head and radiofrequency thermocoagulation is used to destroy the target cells (produce a lesion) in the VIM nucleus. Throughout the procedure, the patient is continuously monitored for changes in tremor. The success rate is similar to that of DBS; however, the incidence of some post-operative complications may be higher (Schuuman et al. 2008). It is generally used on one side only to improve tremor on the opposite side. It does not require the introduction of hardware into the brain, eliminating the risk of hardware malfunction and battery replacement. With the introduction of TcMRgFUS, this procedure is performed much less frequently.
- Transcranial MRI guided ultrasound thalamotomy (TcMRgFUS) is a non-invasive thermal ablation technique. A stereotactic head frame is fixed to the patient's head under local anaesthetic and then the patient lies down in an MRI scanner. Focused ultrasound waves are precisely delivered under image guidance to the VIM nucleus, to produce a lesion. TcMRgFUS is directed unilaterally at the VIM nucleus to improve tremor on the other (contralateral) side of the body. Throughout the procedure, the patient is continuously monitored for changes in tremor. This is performed as a day-case procedure taking approximately 4 hours. The technique does not require the introduction of hardware into the brain, eliminating the risk of hardware malfunction and battery replacement, while reducing the risk of infection. There is still an associated small risk of intracranial haemorrhage.

Annex B

Clinical Rating Scale for Tremor (CRST)

CRST is a tool that measures the severity and impact of tremor on daily activities. Scores range from 0 to 4 per component assessed and the higher scores indicate more severe tremor. The assessment criteria is outlined below:

Part A: Tremor location / severity rating (1-10)

1-10. Tremor: rate tremor

- At rest (in repose). For head and trunk, when lying down.
 - With posture** holding (upper extremity – arms outstretched, wrists mildly extended, fingers spread apart; lower extremity – legs flexed at hips and knees, foot dorsiflexed; tongue – when protruded; head and trunk – when sitting or standing).
 - With helium and intention** (upper extremity – finger to nose and other actions; lower extremity – toe to finger in a flexed posture)
- 0 – None
 1 – Slight; barely perceivable. May be intermittent.
 2 – Moderate; amplitude <2cm. May be intermittent.
 3 – Marked; amplitude 2-4cm.
 4 – Severe; amplitude >4cm.

		Rest	Posture	Action/Intention	Total
1.	Face tremor	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4			
2.	Tongue tremor	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4		
3.	Voice tremor			☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	
4.	Head tremor		☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4		
5.	RUE tremor	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	
6.	LUE tremor	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	
7.	Trunk tremor		☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4		
8.	RLE tremor	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	
9.	LLE tremor	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	
10.	Orthostatic (trunk/legs when standing)		☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4		

Table 1: CRST part A scoring. RUE – right upper extremity, LUE – left upper extremity, RLE – right lower extremity, LLE – left lower extremity.

Part B: Specific motor tasks / functional rating (11-15)

11. Handwriting: have patient write the standard sentence “This is a sample of my best handwriting,” sign their name, and write the date.

0 – Normal

1 – Mildly abnormal. Legible, but with considerable tremor.

2 – Moderately abnormal. Legible, but with considerable tremor.

3 – Markedly abnormal. Illegible.

4 – Severely abnormal. Unable to keep pencil or pen on paper without holding hand down with the other hand.

12-14. Drawings: (See parts A, B and C): ask the patient to join both points of the various drawings without crossing the lines. Test each hand, beginning with the lesser involved, without leaning the hand or arm on the table.

0 – Normal

1 – Slightly tremulous. May cross lines occasionally.

- 2 – Moderately tremulous or crosses lines frequently.
- 3 – Accomplishes the task with great difficulty. Many errors.
- 4 – Unable to complete drawing.

15. Pouring: Use firm plastic cups (8cm tall), filled with water to 1cm from top. Ask patient to pour water from one cup to another. Test each hand separately.

- 0 – Normal
- 1 – More careful than a person without tremor, but no water is spilled.
- 2 – Spills a small amount of water (up to 10% of total amount).
- 3 – Spills a considerable amount of water (10-50%).
- 4 – Unable to pour without spilling most of the water.

		Right					Left					Total
11.	Handwriting (Dominant only)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	
12.	Drawing A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	
13.	Drawing B	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	
14.	Drawing C	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	
15.	Pouring	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	

Table 2: CRST part B scoring.

Part C: Functional disabilities resulting from (16-23)

16. Speaking: This includes spastic dysphonia if present.

- 0 – Normal
- 1 – Mild voice tremulousness when nervous only.
- 2 – Mild voice tremor, constant.
- 3 – Moderate voice tremor.
- 4 – Severe voice tremor. Some words difficult to understand.

17. Feeding (other than liquids):

- 0 – Normal
- 1 – Mildly abnormal. Can bring all solids to mouth, spilling only rarely.
- 2 – Moderately abnormal. Frequent spills of peas and similar foods. May bring head at least halfway to meet food.
- 3 – Markedly abnormal. Unable to cut or uses two hands to feed.
- 4 – Severely abnormal. Needs help to feed.

18. Bringing liquids to mouth:

- 0 – Normal
- 1 – Mildly abnormal. Can still use a spoon, but not if it is completely full.
- 2 – Moderately abnormal. Unable to use a spoon. Uses cup or glass.
- 3 – Markedly abnormal. Can drink from cup or glass but needs two hands.
- 4 – Severely abnormal. Must use a straw.

19. Hygiene:

- 0 – Normal
- 1 – Mildly abnormal. Able to do everything but is more careful than the average person.
- 2 – Moderately abnormal. Able to do everything, but with errors; uses electric razor because of tremor.

- 3 – Markedly abnormal. Unable to do most fine tasks, such as putting on lipstick or shaving (even with electric shaver), unless using two hands.
- 4 – Severely abnormal. Unable to do any fine-movement tasks.

20. Dressing:

- 0 – Normal
- 1 – Mildly abnormal. Able to do everything but is more careful than the average person.
- 2 – Moderately abnormal. Able to do everything, but with errors.
- 3 – Markedly abnormal. Needs some assistance with buttoning or other activities, such as tying shoelaces.
- 4 – Severely abnormal. Requires assistance even for gross motor activities.

21. Writing:

- 0 – Normal
- 1 – Mildly abnormal. Legible. Continues to write letters.
- 2 – Moderately abnormal. Legible, but no longer writes letters.
- 3 – Markedly abnormal. Illegible.
- 4 – Severely abnormal. Unable to sign checks or other documents requiring signature.

22. Working:

- 0 – Tremor does not interfere with the job.
- 1 – Able to work but needs to be more careful than the average person.
- 2 – Able to do everything, but with errors. Poorer than usual performance because of tremor.
- 3 – Unable to do regular job. May have changed to a different job because of tremor. Tremor limits housework, such as ironing.
- 4 – Unable to do any outside job; housework very limited.

23. Social activities:

- 0 – No changes
- 1 – Minimal change in social activities, still socialises.
- 2 – Moderate change in social activities, avoids encounters with strangers.
- 3 – Marked change in social activities, avoids encounters with friends.
- 4 – Severe change in social activities, avoids any public encounters.

16. Speaking	☐ 0 ☐ 1 ☐ 2	☐ 3	☐ 4
17. Eating	☐ 0 ☐ 1 ☐ 2	☐ 3	☐ 4
18. Drinking	☐ 0 ☐ 1 ☐ 2	☐ 3	☐ 4
19. Hygiene	☐ 0 ☐ 1 ☐ 2	☐ 3	☐ 4
20. Dressing	☐ 0 ☐ 1 ☐ 2	☐ 3	☐ 4
21. Writing	☐ 0 ☐ 1 ☐ 2	☐ 3	☐ 4
22. Working	☐ 0 ☐ 1 ☐ 2	☐ 3	☐ 4
23. Social activities	☐ 0 ☐ 1 ☐ 2	☐ 3	☐ 4

Table 3: CRST part C scoring.