The TRICEPS Trial protocol and updates:
TRranscutaneous lImb reCovEry Post-Stroke

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Does non-invasive transcutaneous vagus nerve stimulation (tVNS), paired with physiotherapy, improve arm motor function in post-stroke participants with arm weakness?

Background

- 15 million people per annum have a stroke worldwide; 1/3 left with arm weakness, affecting independence & quality of life
- Physiotherapy helps post-stroke, but the benefits are modest
- Invasive vagus nerve stimulation paired with physiotherapy has been shown to improve arm recovery in chronic stroke, where the stimulator was surgically implanted & stimulation triggered manually in a hospital setting

Methods

- **Design:** Adaptive, multi centre, double blinded, sham-controlled superiority trial
- **Participants:** Aged ≥18 years; moderate-severe arm weakness following anterior circulation ischaemic stroke (6 months -10 years previously); no longer undergoing active rehabilitation therapy
- **Sample:** 270 patients across 20 sites from Nov 2023 – July 2026
- **Randomisation:** minimisation stratified by centre, sex, age, & baseline ULFM to sham TVNS (very low stimulation) or active TVNS

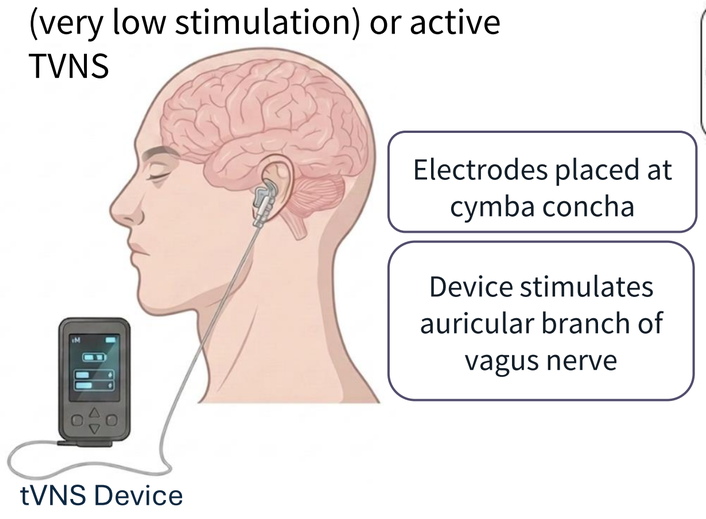


Fig 1: Trancutaneous Vagus nerve Stimulation

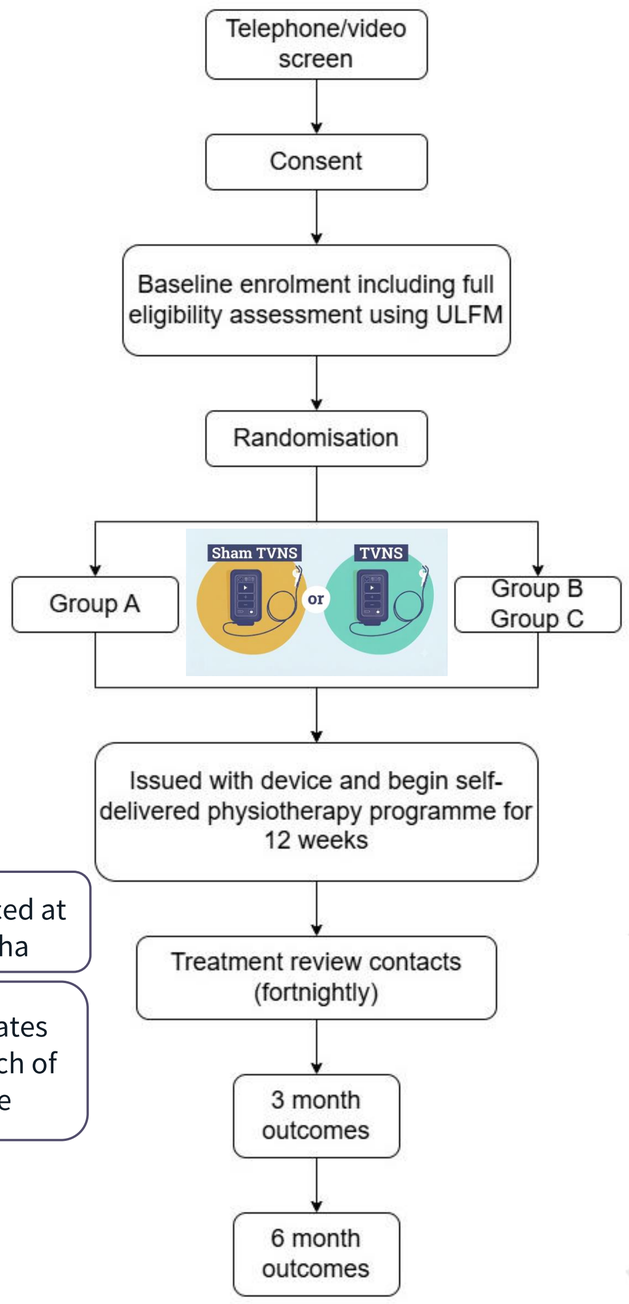


Fig 2: Patient pathway

- **12-week intervention:** TVNS device; home based self-delivered tailored rehabilitation therapy programme containing repetitive task training exercises (e.g., turning cards, moving objects); some participants also wear TVNS device whilst undertaking activities of daily living
- **Primary outcome:** Mean difference in Upper Limb Fugl-Meyer (ULFM) total score (compared to sham TVNS) at 3 months
- **Outcome measures:** Recorded 3 and 6 months after starting treatment

Fig 3: tVNS device; earpiece and stimulator

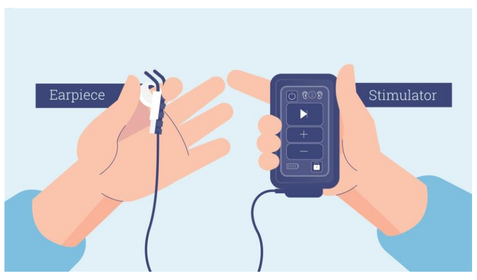
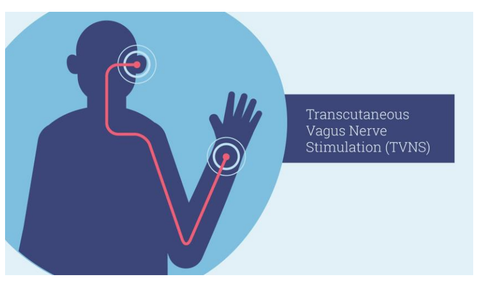


Fig 4:tVNS pathway



Participant identification

Participant identification initially planned via 3 methods:
(1) Community stroke rehabilitation team referrals
(2) The Stroke Association, local organisations & media
(3) Clinical database searches

Successful advertisement via national and local media such as BBC Breakfast, BBC Tech Now Show and regional TV news reports led to patients self referring to the trial.

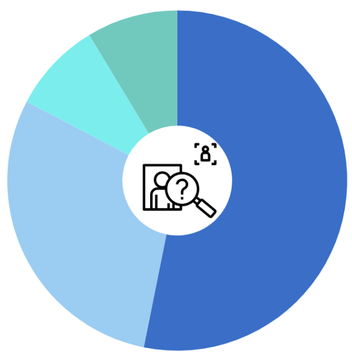


Fig 5: Participant identification routes
* Data as of June 2026 (N = 254)



Fig 6: ITV News Meridian, Dorset, January 2025



Fig 7:BBC Tech Now Show, February 2026

Sites

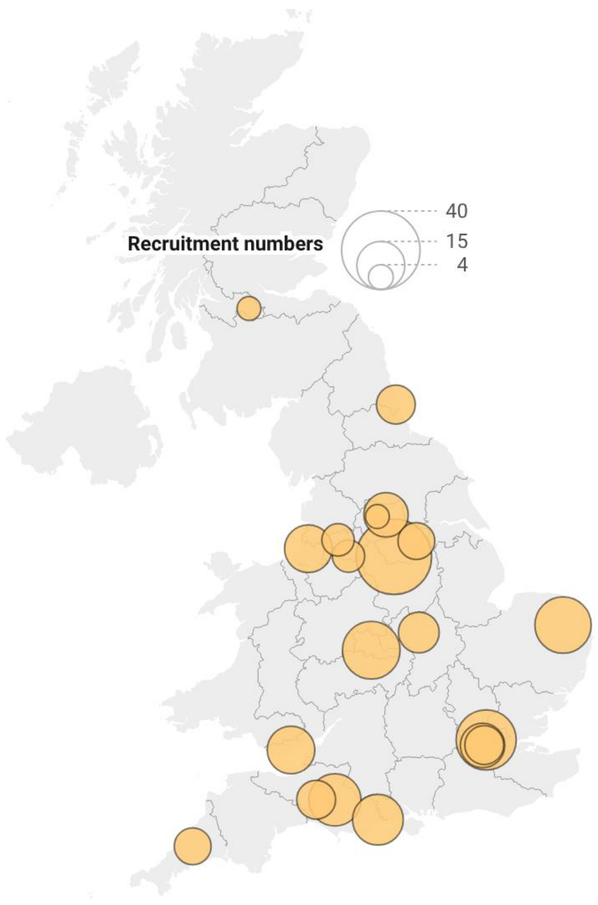


Fig 8: Recruiting site map

Trial site	n
Sheffield	37
Barts Health	23
Birmingham	21
Norfolk	20
Dorset Healthcare Trust	17
University Hospitals Dorset Trust	16
Cardiff	14
Liverpool	14
Leeds	12
Guy's and St Thomas	12
Leicester	10
King's College Hospital	9
Somerset	9
South Tyneside and Sunderland	9
Doncaster	8
Cornwall	8
Manchester	6
Bolton	6
Bradford	3
Lanarkshire	3

Conclusions / impact

- Recruitment to finish end of July 2026; results due summer 2027
- TRICEPS is the largest neuromodulation trial conducted in stroke
- Provides definitive data on effectiveness of TVNS as a treatment for arm weakness in stroke recovery
- Potential to improve patient outcomes & enhance stroke clinical guidelines

References

Baig SS, *et al* TRanscutaneous lImb reCovEry Post-Stroke (TRICEPS): study protocol for a randomised, controlled, multiarm, multistage adaptive design trial
BMJ Open 2025;**15:**e092520. doi: 10.1136/bmjopen-2024-092520

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