Stroke - Managing Risk Factors and Optimising Recovery

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Disclosures

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- Research grant funding from MicroTransponder Inc

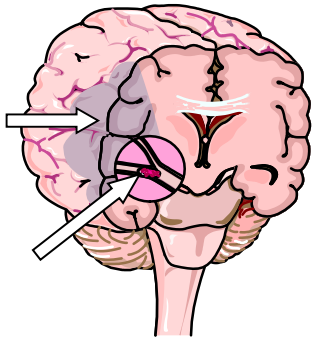
Outline

- What happens after stroke
  - Treatment
  - Recovery
  - Recurrence
- What's new?
  - In acute care
  - In rehabilitation

Three main stroke types

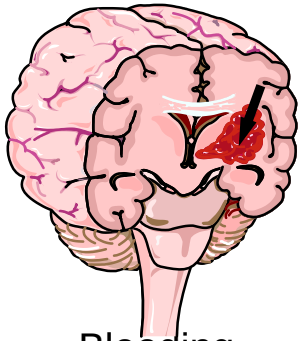
"rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin

Ischemic



Clot in artery 85%

Hemorrhage



Bleeding into brain 10%

SAH

Bleeding around brain 5%

www.acponline.org/about_acp/chapters/ok/gordon.ppt

Key facts

Key statistics

There are more than **100,000 strokes** in the UK each year. That is around one stroke every **five minutes**.

There are over **1.2 million stroke survivors** in the UK.

Every **two seconds**, someone in the world will have a **stroke**.

Stroke is the **fourth biggest killer in the** in the UK. Fourth in England and Wales, and the third biggest killer in Scotland and Northern Ireland.

More than **400** children have a **stroke** every year in the UK.

A **third** of stroke survivors experience depression after having a **stroke**.

More than **8 out of 10 people** in the **England, Wales and Northern Ireland** who are eligible for the emergency clot-busting treatment, thrombolysis, receive it. In **Scotland** only **1 in 10** of all **patients** will receive this treatment.

Almost **two thirds** of stroke survivors leave hospital with a disability.

People of working age are **two** to **three times** more likely to be **unemployed** eight years after their stroke.

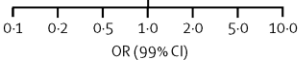
The cost of stroke to society is around **£26 billion** a year.

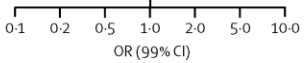
- Transient ischaemic attack, or TIA (also known as a mini-stroke) is the same as a stroke, except that the symptoms last for less than 24 hours.
- A TIA should be treated as seriously as a full stroke.
- Full strokes often happen after a mini-stroke. About half of all strokes that occur after a TIA, happen within 24 hours.[2]
- 1 in 12 people (8%) will have a full stroke within a week of having a TIA.[3]

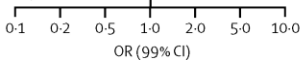
5%	8%	12%	17%
at 48 hours	at one week	at one month	at three months[3,4]

What causes stroke?

	Prevalence in controls (%)	All stroke	OR (99% CI)	PAR, % (99% CI)	Ischaemic stroke	OR (99% CI)	PAR, % (99% CI)	Intracerebral haemorrhage	OR (99% CI)	PAR, % (99% CI)
Self-reported history of hypertension	35·4		2·56 (2·33 to 2·80)	34·4 (32·0 to 36·9)		2·34 (2·10 to 2·60)	32·0 (29·1 to 35·1)		3·71 (3·19 to 4·31)	42·8 (38·9 to 46·8)
Self-reported history of hypertension or blood pressure ≥140/90 mm Hg	47·4		2·98 (2·72 to 3·28)	47·9 (45·1 to 50·6)		2·78 (2·50 to 3·10)	45·7 (42·4 to 49·0)		4·09 (3·51 to 4·77)	56·4 (52·0 to 60·6)
Current smoking	22·4		1·67 (1·49 to 1·87)	12·4 (10·2 to 14·9)		1·93 (1·69 to 2·21)	15·1 (12·8 to 17·8)		1·14 (0·95 to 1·36)	3·6 (0·9 to 13·0)
Waist-to-hip ratio										
T2 *vs* T1	34·1		1·24 (1·11 to 1·39)			1·31 (1·14 to 1·49)			1·16 (0·98 to 1·38)	
T3 *vs* T1	32·9		1·44 (1·27 to 1·64)	18·6 (13·3 to 25·3)		1·44 (1·25 to 1·67)	20·4 (14·3 to 28·2)		1·33 (1·09 to 1·62)	13·1 (6·4 to 25·1)
Diet (mAHEI score)										
T2 *vs* T1	34·0		0·77 (0·69 to 0·86)			0·75 (0·66 to 0·85)			0·80 (0·68 to 0·94)	
T3 *vs* T1	33·0		0·60 (0·53 to 0·67)	23·2 (18·2 to 28·9)		0·59 (0·52 to 0·68)	22·4 (17·0 to 29·0)		0·61 (0·50 to 0·74)	24·5 (16·5 to 34·8)
Regular physical activity	16·3		0·60 (0·52 to 0·70)	35·8 (27·7 to 44·7)		0·63 (0·53 to 0·74)	33·4 (24·2 to 44·0)		0·63 (0·48 to 0·81)	34·6 (21·3 to 50·7)
Self-reported history of diabetes or HbA_{1c} ≥6·5%	22·0		1·16 (1·05 to 1·30)	3·9 (1·9 to 7·6)		1·33 (1·18 to 1·50)	7·5 (5·0 to 11·1)		0·72 (0·60 to 0·87)	−7·0 (−11 to −3·0)
Alcohol										
Low or moderate	25·2		1·14 (1·01 to 1·28)			1·07 (0·93 to 1·23)			1·43 (1·17 to 1·74)	
High or heavy episodic	2·5		2·09 (1·64 to 2·67)	5·8 (3·4 to 9·7)		2·14 (1·62 to 2·82)	4·6 (2·0 to 10·0)		2·44 (1·64 to 3·63)	9·8 (6·4 to 14·8)
Psychosocial factors	..		2·20 (1·78 to 2·72)	17·4 (13·1 to 22·6)		1·98 (1·56 to 2·52)	15·1 (10·3 to 21·5)		2·84 (1·98 to 4·08)	24·7 (18·1 to 32·8)
Cardiac causes	5·0		3·17 (2·68 to 3·75)	9·1 (8·0 to 10·2)		3·49 (2·91 to 4·18)	11·4 (10·1 to 12·8)		1·58 (1·09 to 2·28)	1·4 (0·6 to 3·4)
ApoB/ApoA1 ratio										
T2 *vs* T1	34·0		1·28 (1·14 to 1·42)			1·41 (1·24 to 1·60)			0·94 (0·79 to 1·11)	
T3 *vs* T1	33·0		1·84 (1·65 to 2·06)	26·8 (22·2 to 31·9)		2·19 (1·92 to 2·49)	34·0 (29·0 to 39·3)		1·10 (0·92 to 1·31)	1·2 (0·0 to 98·3)
Composite PAR*				**90·7 (88·7 to 92·4)**			**91·5 (89·4 to 93·2)**			**87·1 (82·2 to 90·8)**

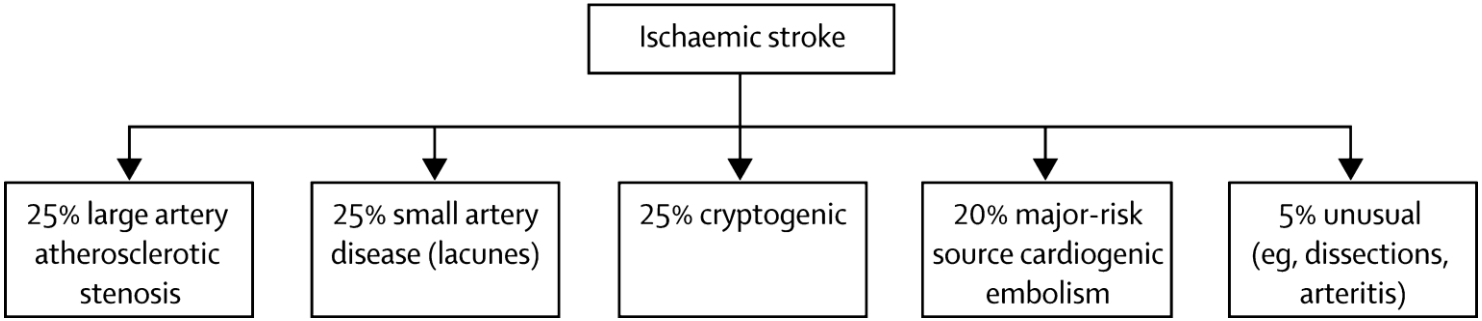






Lancet 2016;388, 761-775

What causes ischaemic stroke?



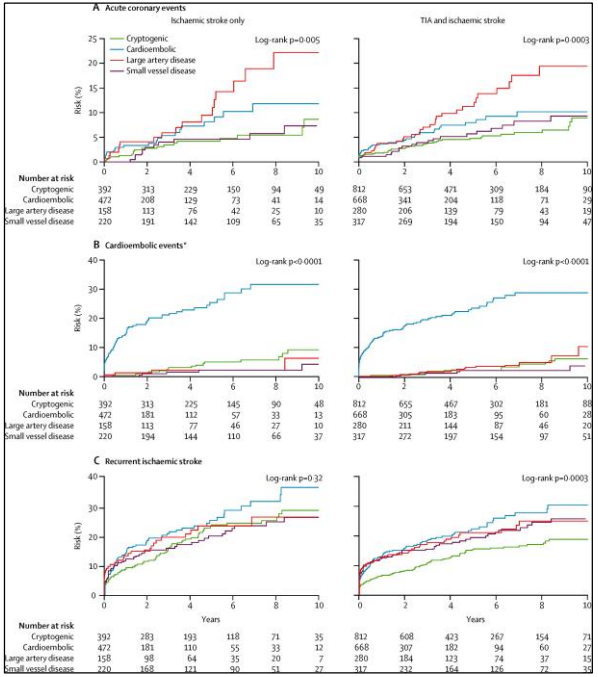
Adapted from Hart et al. Lancet Neurology. https://doi.org/10.1016/S1474-4422(13)70310-7

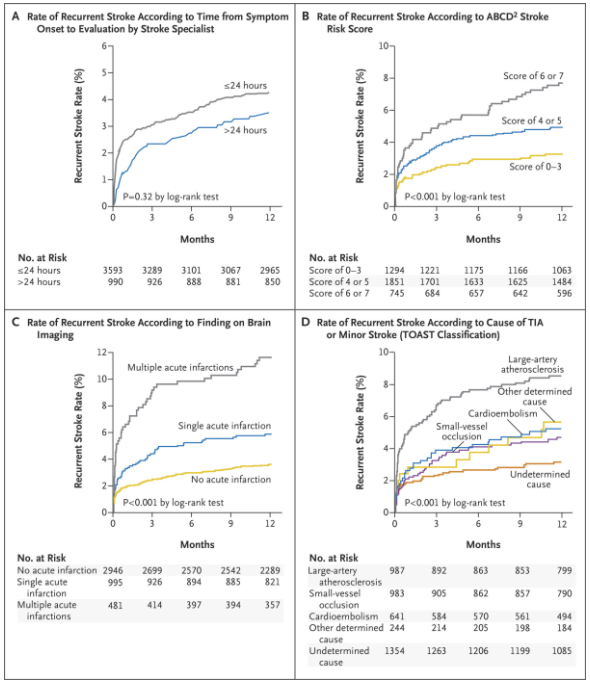
How do we treat strokes?

- Reperfusion therapy
- Neurosurgery
- Stroke unit care
- Prevent complications
- Prevent recurrence
- Rehabilitation

What happens to people after stroke?

Recurrence rates



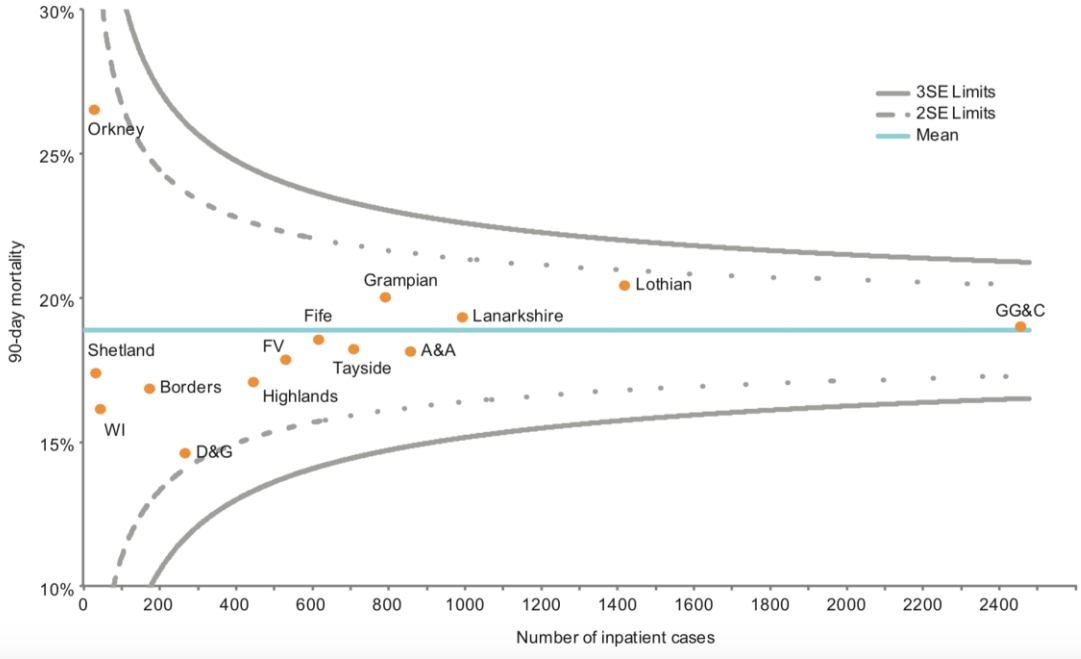


The Lancet Neurology 2015 14, 903-913

Amarenco et al, NEJM 2016;374:1533-42.

Mortality After Stroke in Scotland

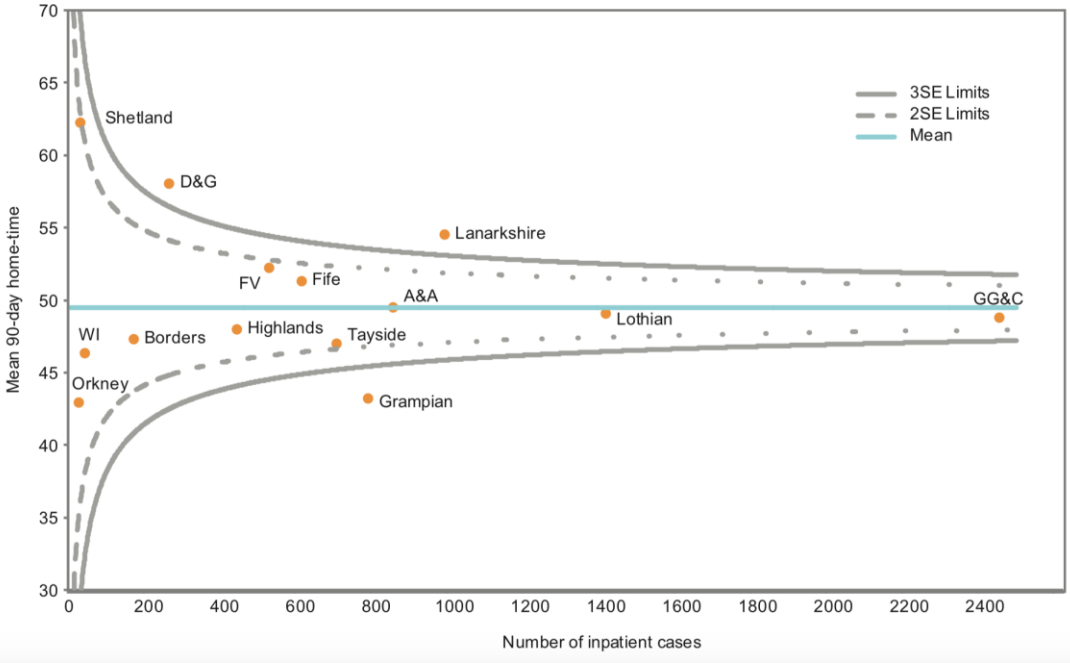
Chart 8.1: 90-day mortality for 2017 admissions by NHS board



Scottish Stroke Care Audit data 2019

Home Time After Stroke in Scotland

Chart 8.3: Mean 90-day home-time for 2017 admissions by NHS board



Scottish Stroke Care Audit data 2019

Outcome by stroke subtype

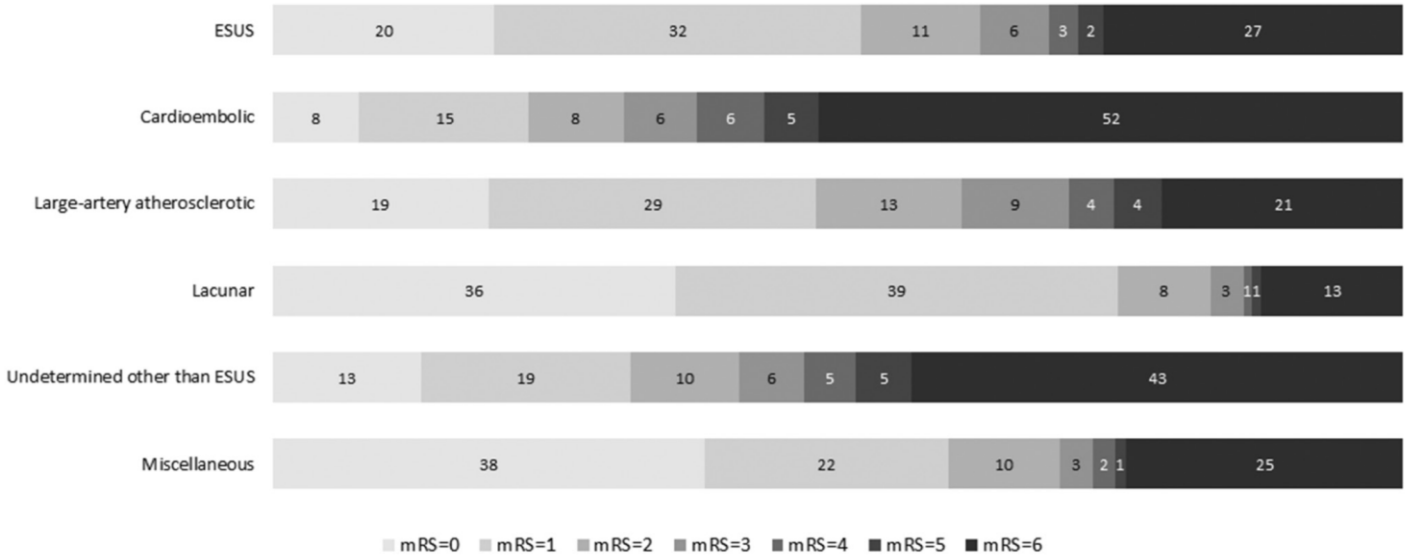
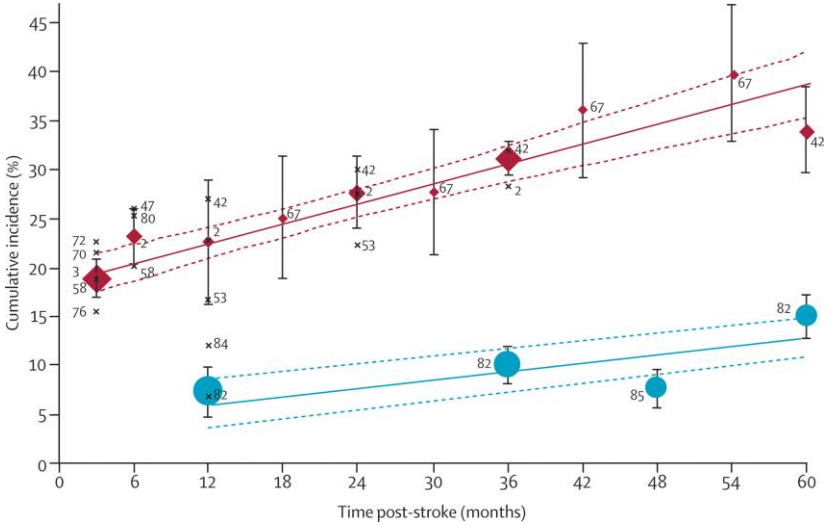
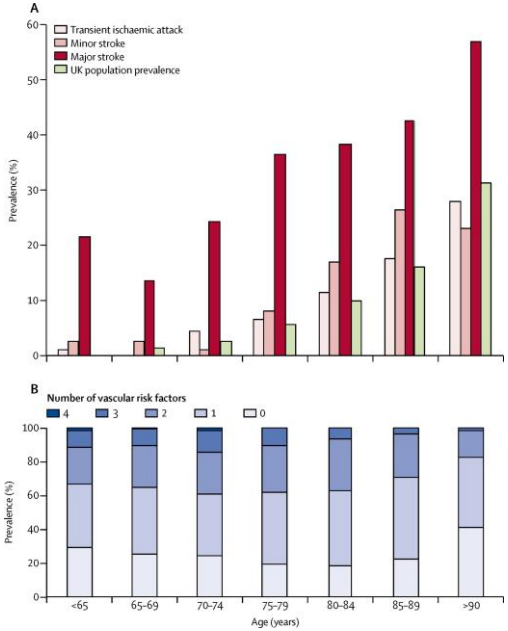


Figure 3. Functional outcome at the end of the follow-up. mRS indicates modified Rankin Scale score. Numbers in boxes represent percentages. ESUS indicates embolic stroke of undetermined source.

Ntaios et al. Stroke 2015

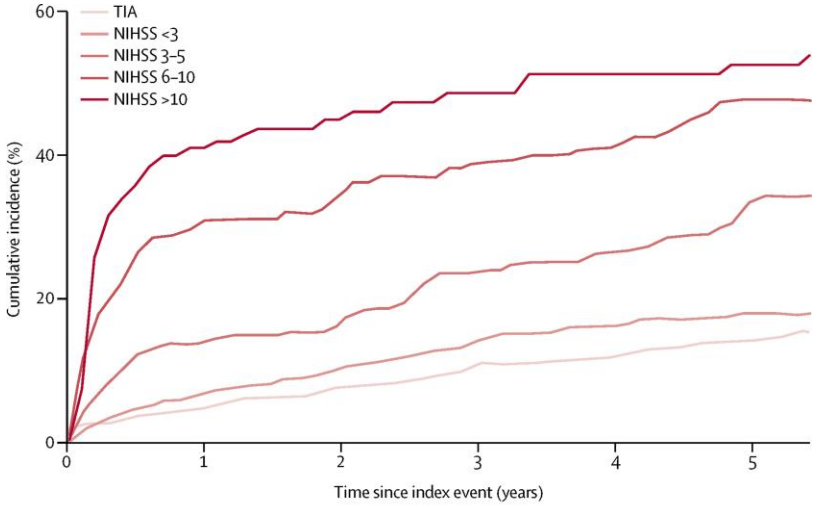
Cognitive problems after stroke





https://doi.org/10.1016/S1474-4422(18)30442-3

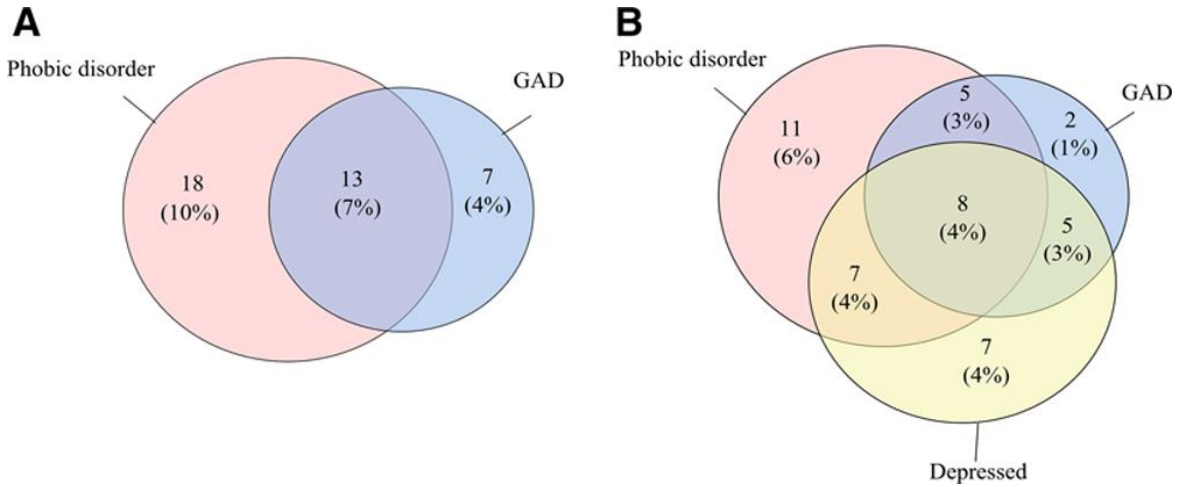
Cognitive problems after stroke



Number at risk					
TIA (n=655)	595	443	397	368	337
NIHSS <3 (n=714)	613	451	408	377	336
NIHSS 3–5 (n=295)	210	161	136	118	97
NIHSS 6–10 (n=181)	72	57	50	48	38
NIHSS >10 (n=235)	49	34	28	26	23

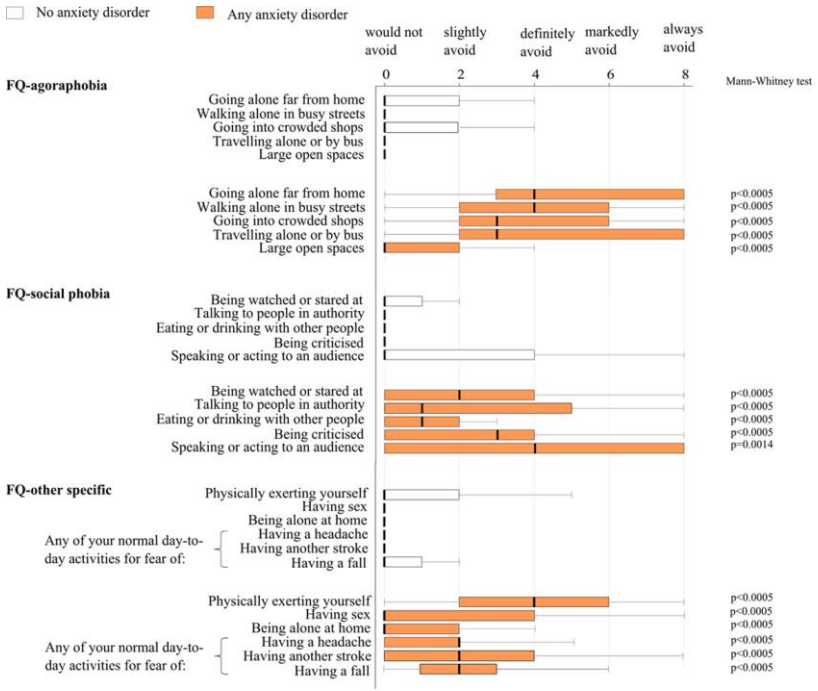
https://doi.org/10.1016/S1474-4422(18)30442-3

Anxiety after stroke



Chun et al. Stroke. 2018;49:556–564

Importance of post stroke anxiety



Chun et al. Stroke. 2018;49:556–564

Summary

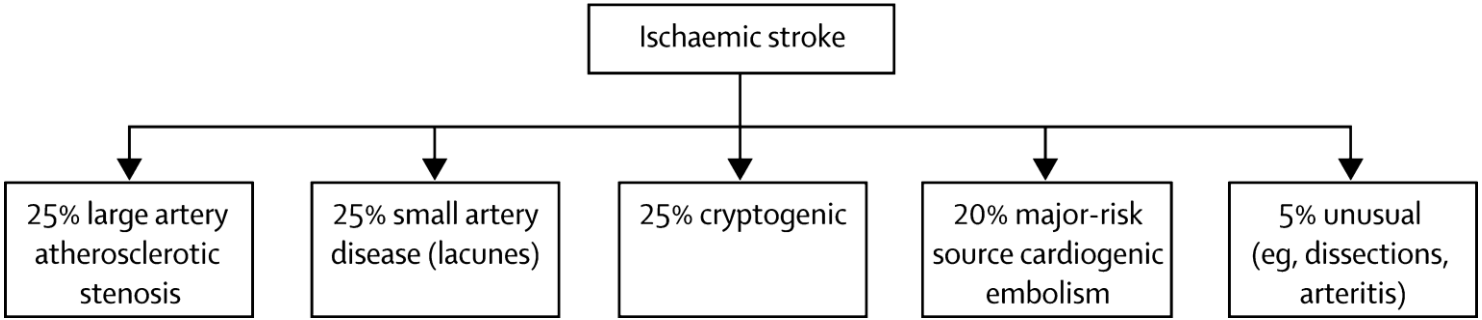
- Most people survive stroke
- Most people are independent but there are major other major issues
  - High rates of cognitive impairment
  - High rates of anxiety

- TIA is a high risk condition with high early recurrence rate
  - ½ of recurrent events are in first year

- Recurrence rate is aetiology specific
  - 10 year recurrence rate varies from 10 to 25%

So how do we stop second strokes??

Prevention of recurrent stroke



Anti-platelets / DAPT
Statins
BP reduction
CEA

Anti-platelets / No DAPT
Statins
BP reduction

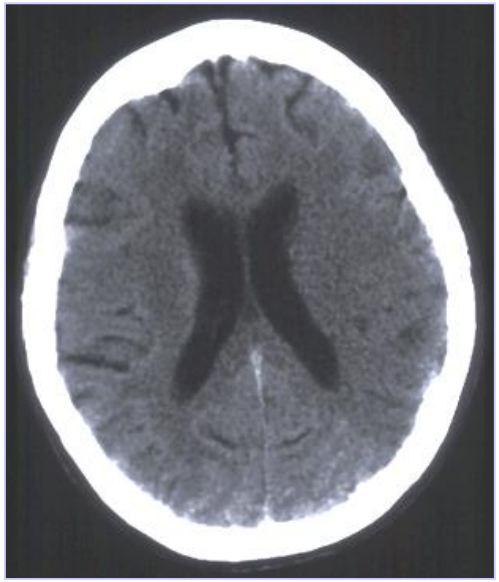
Anti-platelets
Statins
BP reduction
PFO closure

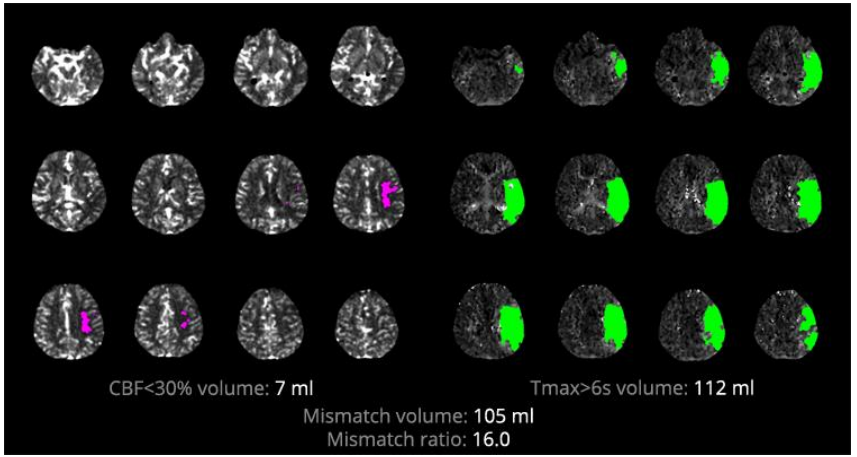
Anticoagulation
BP reduction
LAAO
? statins

Adapted from Hart et al. Lancet Neurology. https://doi.org/10.1016/S1474-4422(13)70310-7

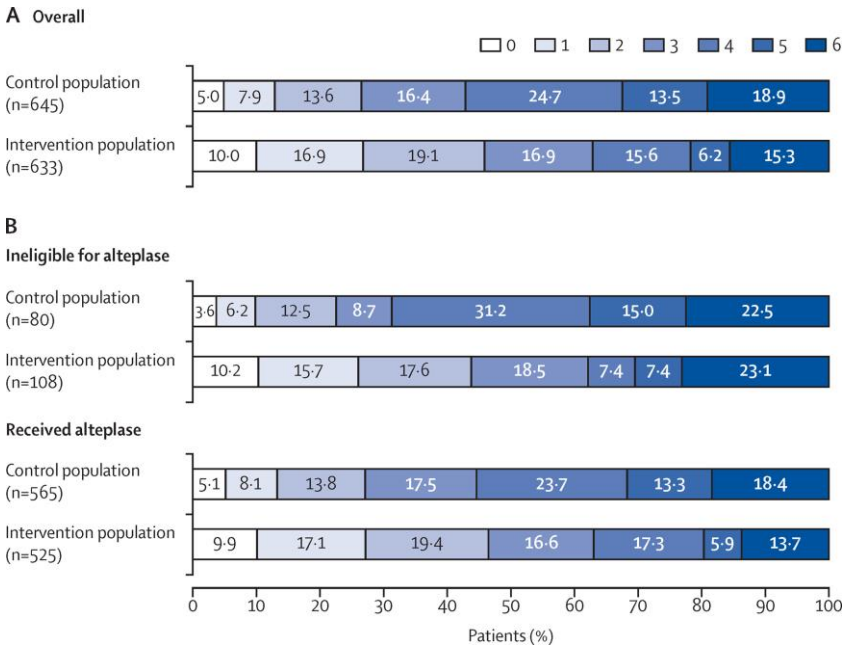
So what’s new???

Better patient selection





How good is thrombectomy?



Goyal et al. https://doi.org/10.1016/S0140-6736(16)00163-X

So where are we in the UK?

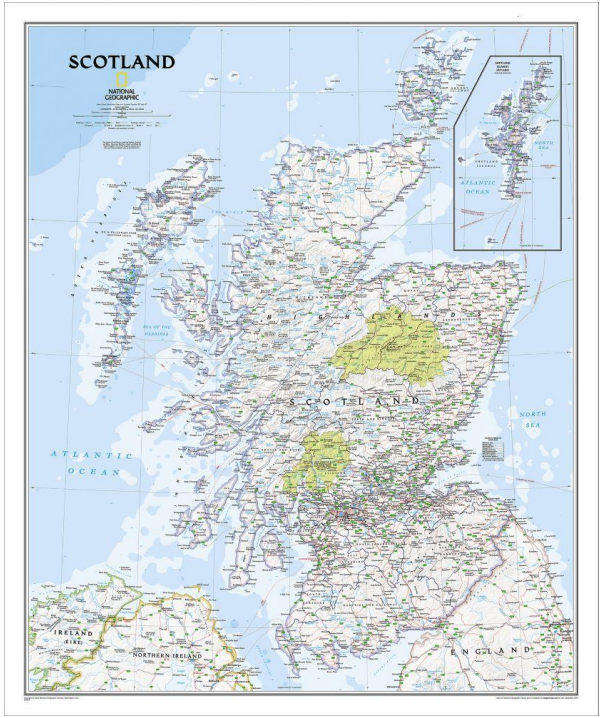
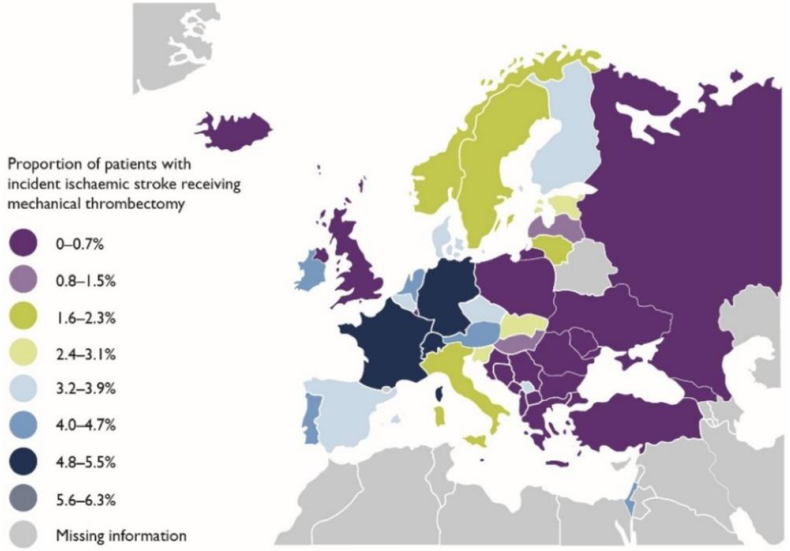


Figure 1. Map showing the proportion of patients with ischaemic stroke receiving mechanical thrombectomy across Europe.[3] Reprinted by permission of SAGE Publications, Ltd.

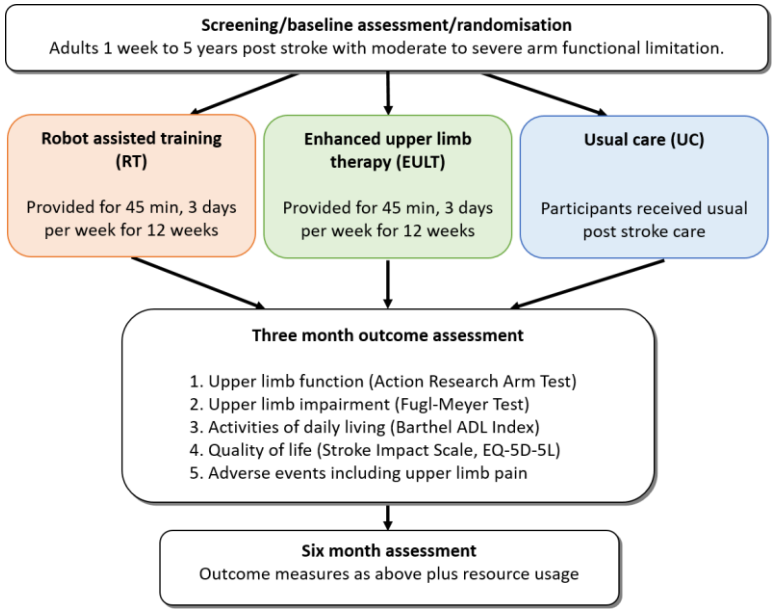


https://nationalgeographic.com/

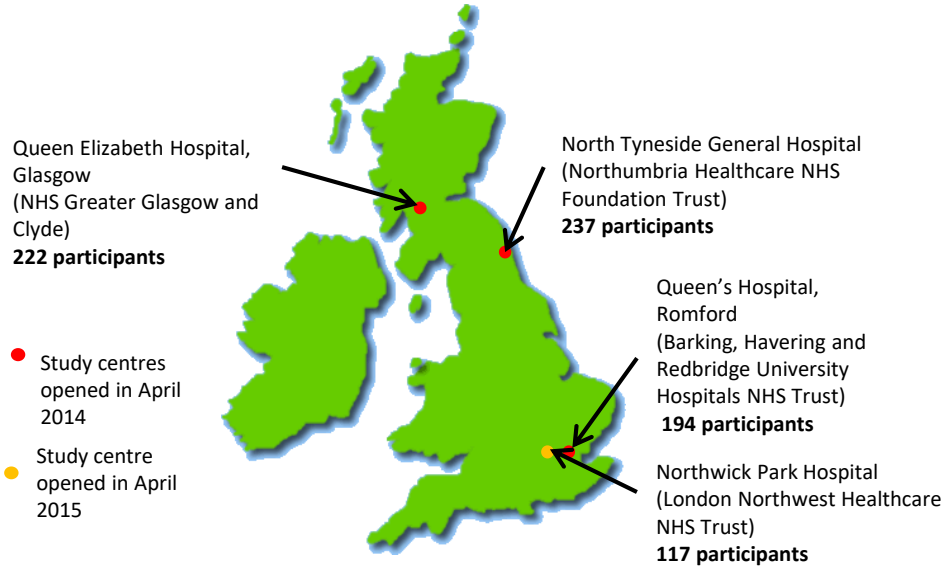
https://bsnr.org.uk/

Robot assisted training for the upper limb after stroke (RATULS): a multicentre randomised controlled trial

Helen Rodgers*, Helen Bosomworth*, Hermano I Krebs, Frederike van Wijck, Denise Howel, Nina Wilson, Lydia Aird, Natasha Alvarado, Sreeman Andole, David L Cohen, Jesse Dawson, Cristina Fernandez-Garcia, Tracy Finch, Gary A Ford, Richard Francis, Steven Hogg, Niall Hughes, Christopher I Price, Laura Ternent, Duncan L Turner, Luke Vale, Scott Wilkes, Lisa Shaw

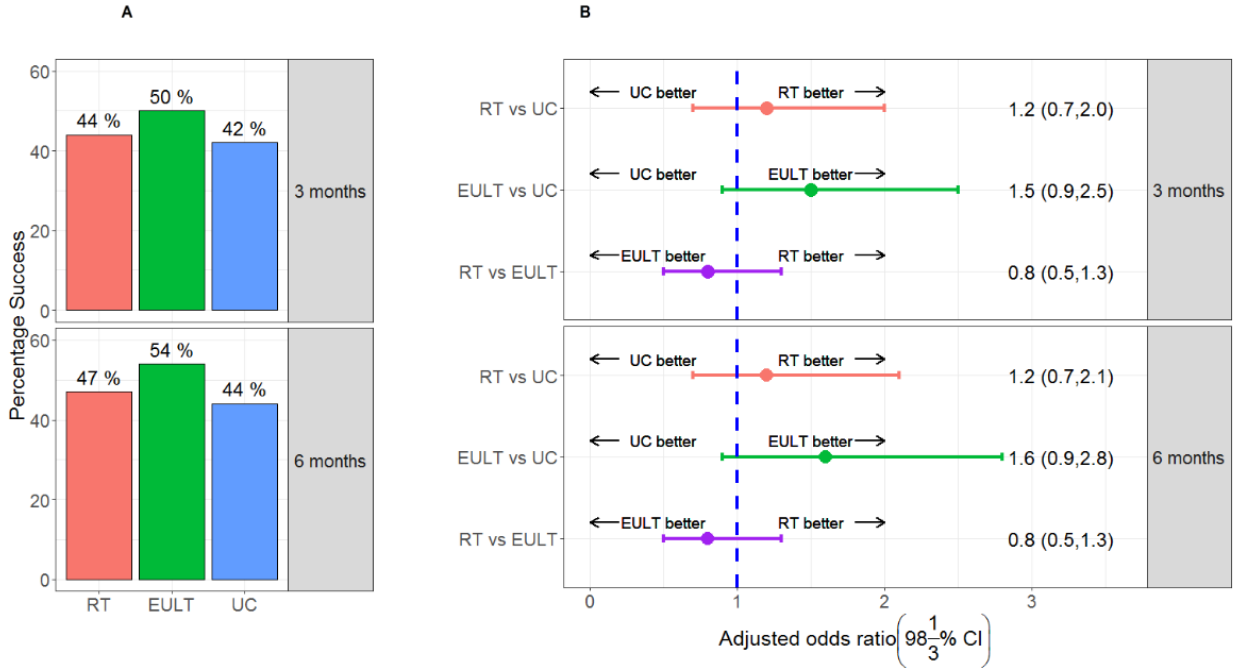


- 770 participants randomised between April 2014 to April 2018



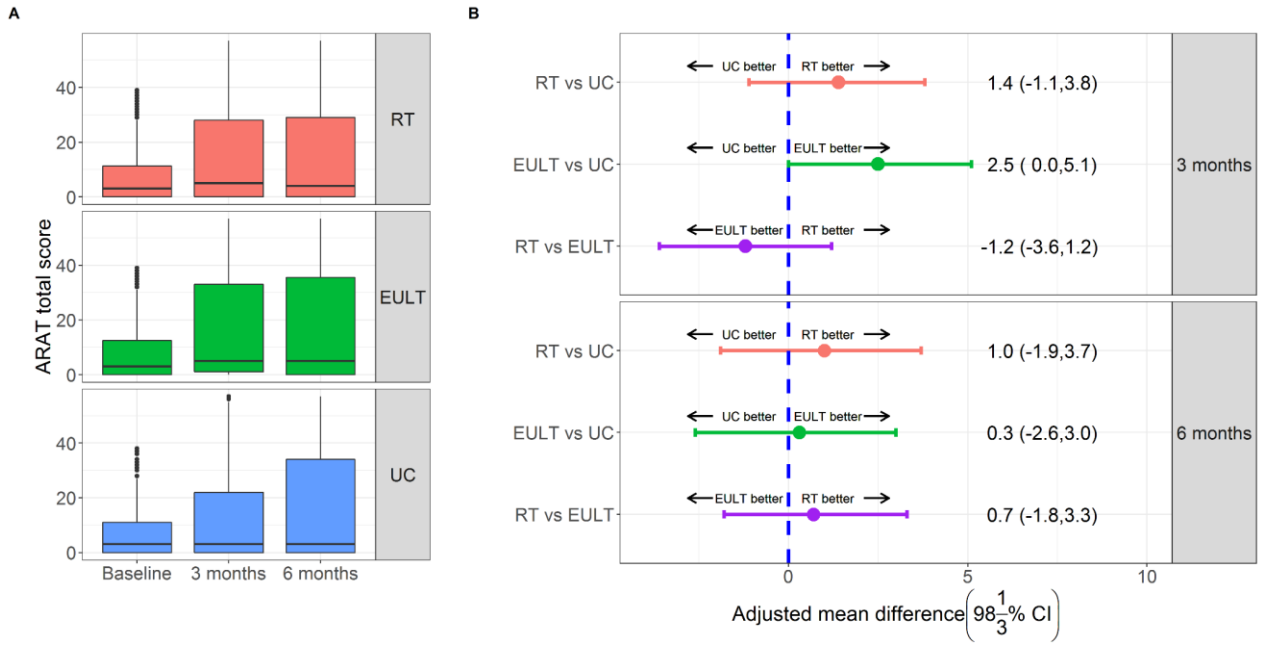
Lancet 2019, http://dx.doi.org/10.1016/ S0140-6736(19)31055-4

Primary outcome: ARAT “success”



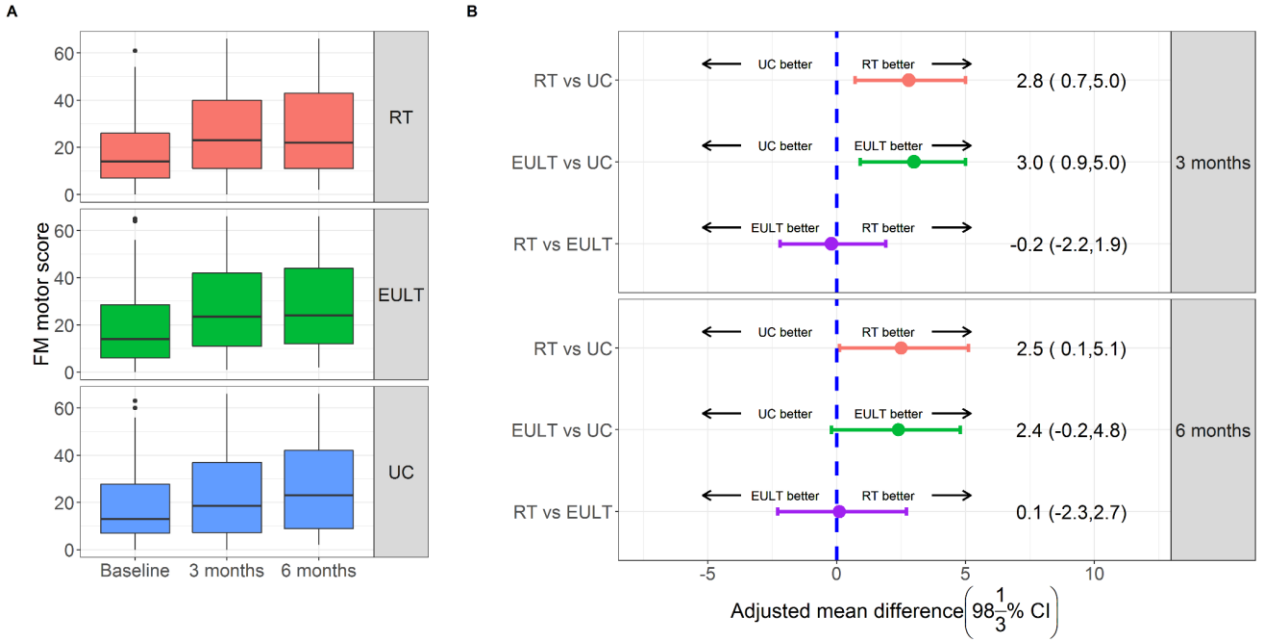
Lancet 2019, http://dx.doi.org/10.1016/ S0140-6736(19)31055-4

Upper limb function: ARAT



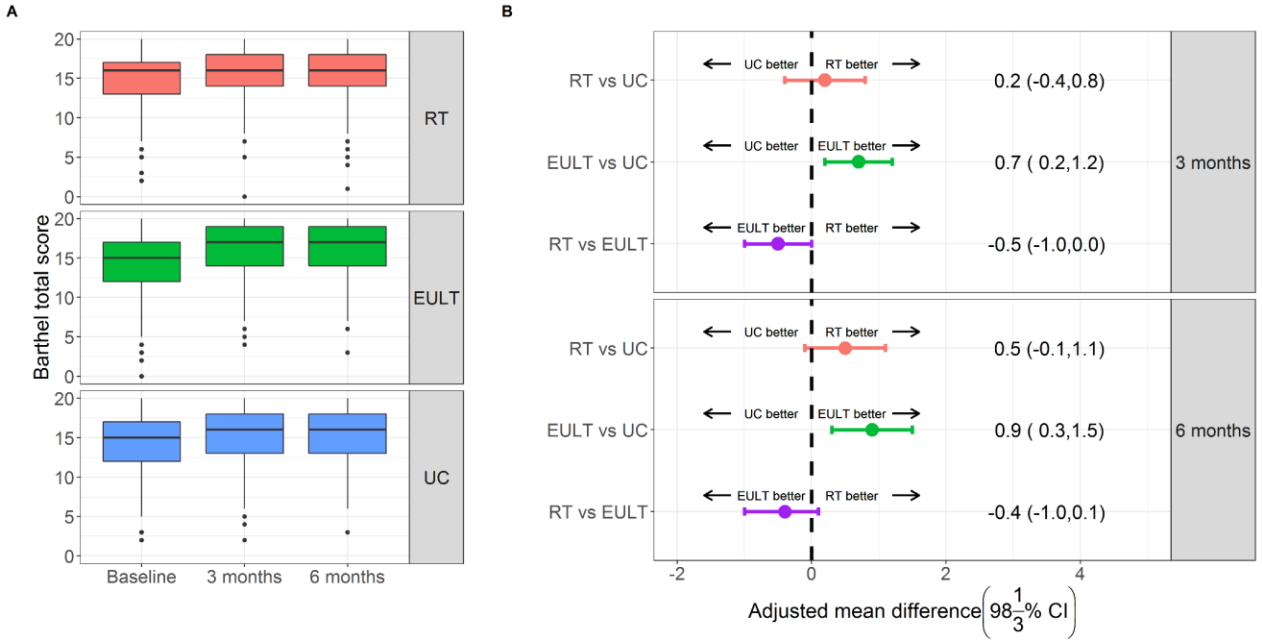
Lancet 2019, http://dx.doi.org/10.1016/ S0140-6736(19)31055-4

Upper limb impairment: FMA



Lancet 2019, http://dx.doi.org/10.1016/ S0140-6736(19)31055-4

Activities of daily living: Barthel ADL



Lancet 2019, http://dx.doi.org/10.1016/ S0140-6736(19)31055-4

Cost effectiveness

	Unadjusted mean cost (98·3% CI)	Unadjusted mean QALYs (98·3% CI)	Adjusted* incremental QALY (98·3% CI)	Adjusted* incremental costs (98·3% CI)	Adjusted incremental cost-effectiveness ratio	Probability that each therapy is cost effective at different willingness to pay thresholds†				
						£0	£10000	£20000	£30000	£50000
Robot-assisted training	£5387 (4777 to 5996)	0·212 (0·195 to 0·229)	..	..	More expensive and less effective than EULT in both adjusted and unadjusted analyses	0%	0%	0%	0%	0%
Enhanced upper limb therapy	£4451 (3548 to 5354)	0·229 (0·213 to 0·244)	0·010 (–0·005 to 0·025)	741 (–461 to 1943)	£74100	10%	15%	19%	26%	38%
Usual care	£3785 (2801 to 4770)	0·212 (0·194 to 0·230)	..	..	..	90%	85%	81%	74%	62%

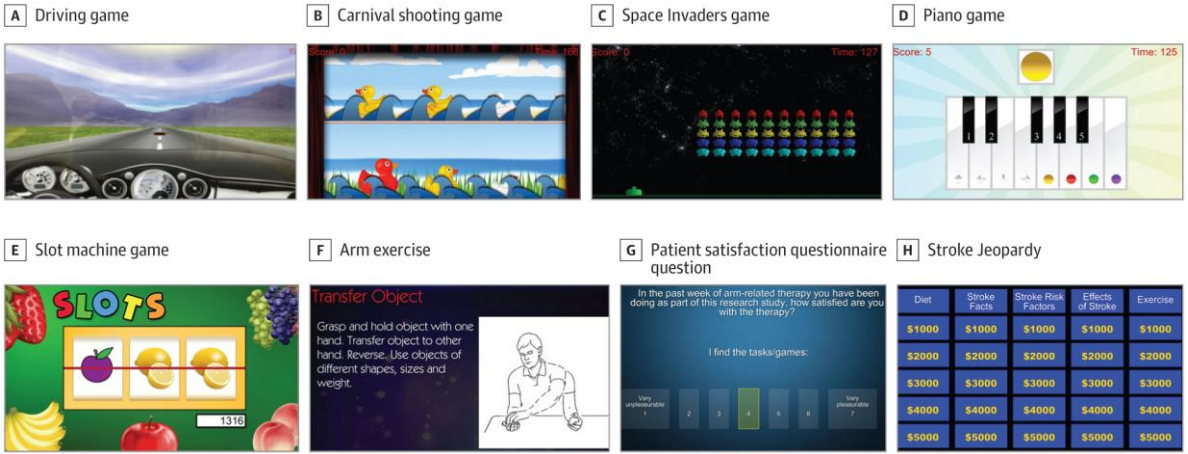
Numbers of patients included in analyses were 178 in the usual care group, 259 in the EULT group, and 257 in the robot-assisted training group for the unadjusted cost calculation; 254 in the usual care group, 259 in the EULT group, and 257 in the robot-assisted training group for the unadjusted QALY calculation; and 171 in the usual care group, 254 in the EULT group, and 247 in the robot-assisted training group for the adjusted analyses. EULT=enhanced upper limb therapy. QALY=quality-adjusted life-year. *Adjusted analysis done using the seemingly unrelated regression (sureg) function on STATA, version 15; adjusted for centre, baseline ARAT score, time since stroke, baseline costs, and baseline utility score; performed for the comparison between usual care and EULT as the next best alternative. †The probabilistic sensitivity analysis includes all three therapies and was done for different threshold values of society's willingness to pay per QALY (£0, £10000, £20000, £30000, and £50000).

Table 4: **Results from base-case and probabilistic cost-utility analysis for usual care, EULT, and robot-assisted training**

Lancet 2019, http://dx.doi.org/10.1016/ S0140-6736(19)31055-4

From: **Efficacy of Home-Based Telerehabilitation vs In-Clinic Therapy for Adults After Stroke: A Randomized Clinical Trial**

JAMA Neurol. Published online June 24, 2019. doi:10.1001/jamaneurol.2019.1604



From: **Efficacy of Home-Based Telerehabilitation vs In-Clinic Therapy for Adults After Stroke: A Randomized Clinical Trial**

JAMA Neurol. Published online June 24, 2019. doi:10.1001/jamaneurol.2019.1604

Table 1. Characteristics of Patients in Both Groups

Characteristic	TR Group (n = 62)[a]	IC Group (n = 62)[a]
Age, mean (SD), y	62 (14)	60 (13)
Baseline arm motor Fugl-Meyer score, mean (SD)	42.8 (7.8)	42.7 (8.7)
Box and Blocks score, mean (SD)	21.3 (13.3)	23.8 (12.7
Stroke Impact Scale hand domain score, mean (SD)	38.8 (26.3)	42.6 (24.1)
Handedness, No.		
Right	56	54
Ambidextrous	3	4
Left	3	4
Time after stroke		
No. of days, mean (SD)	132 (65)	129 (59)
Patients enrolled <90 d after stroke	16 (25.8)	22 (35.5)
Stroke subtype		
Ischemic	54 (87.1)	52 (83.9)
Intracerebral hemorrhage	8 (12.9)	10 (16.1)
Female sex	14 (22.6)	20 (32.3)
Race		
Asian	6 (9.7)	4 (6.5)
Black	15 (24.2)	18 (29.0)
White	41 (66.1)	39 (62.9)
Unknown	0	1 (1.6)
Ethnicity, Hispanic	3 (4.8)	0
Geriatric Depression Scale score, mean (SD)	3.4 (3.1)	3.6 (2.7)
Montreal Cognitive Assessment score, mean (SD)	24.9 (4.1)	24.4 (5.0)
Nottingham Sensory score, mean (SD)	9.5 (2.5)	9.9 (2.7)
Modified Ashworth Spasticity scale score, median (IQR)	0 (0-1)	1 (0-2)
Paretic side, right	27 (43.5)	36 (58.1)
Baseline NIHSS score, median (IQR)	3 (2-5)	3 (2-4)
Baseline Modified Rankin scale score, median (IQR)	2 (2-3)	2 (2-3)
Hypertension	50 (80.6)	53 (85.5)
Diabetes mellitus	14 (22.6)	17 (27.4)
Atrial fibrillation	10 (16.1)	4 (6.5)
Hypercholesterolemia	40 (64.5)	39 (62.9)

Abbreviations: IC, in-clinic; IQR, interquartile range; NIHSS, National Institutes of Health Stroke Scale; TR, telerehabilitation.

[a] Data are presented as number (percentage) of patients unless otherwise indicated.

Table 2. Treatment-Related Change in FM Motor Score[a]

Model	Patients, No.			FM Score for IC Group, Mean Change	FM Change (TR-IC), Difference Between Groups (95% CI)[b]
	TR	IC	Total		
Primary analysis					
ITT with multiple imputation of missing outcomes	62	62	124	8.23	0.06 (−2.14 to 2.26)
Secondary analyses					
ITT with substitution of “worst-best-case” missing outcomes	62	62	124	8.58	−0.19 (−2.29 to 1.92)
Complete case ITT	59	55	114	8.36	0.00 (−2.27 to 2.27)
Complete case PP	58	55	113	8.36	−0.15 (−2.41 to 2.10)

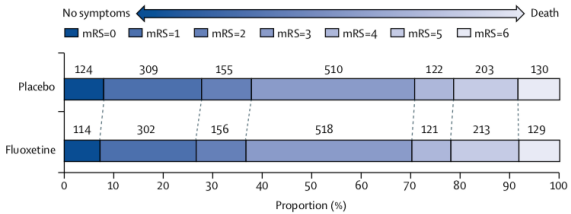
Effects of fluoxetine on functional outcomes after acute stroke (FOCUS): a pragmatic, double-blind, randomised, controlled trial

FOCUS Trial Collaboration*

Summary

Background Results of small trials indicate that fluoxetine might improve functional outcomes after stroke. The FOCUS trial aimed to provide a precise estimate of these effects.

Lancet 2019; 393: 265–74



		Fluoxetine (n=1553)	Placebo (n=1553)
mRS=0	No symptoms	114 (7%)	124 (8%)
mRS=1	No clinically significant disability despite symptoms	302 (19%)	309 (20%)
mRS=2	Slight disability-unable to do everything	156 (10%)	155 (10%)
mRS=3	Moderate disability-unable to live independently but can walk	518 (33%)	510 (33%)
mRS=4	Moderately severe disability and unable to walk without help from another person	121 (8%)	122 (8%)
mRS=5	Severe disability-unable to sit up	213 (14%)	203 (13%)
mRS=6	Dead	129 (8%)	130 (8%)

Figure 2: **Primary outcome of disability on the modified Rankin Scale at 6 months by treatment group**
Ordinal analysis of the modified Rankin Scale (mRS) adjusted with logistic regression for the variables included in our minimisation algorithm. 1553 patients had mRS data available in each group; 11 patients in the fluoxetine group and ten in the placebo group had missing mRS data. Common odds ratio 0·951 (95% CI 0·839–1·079), p=0·439; adjusted for baseline variables.

Safety and efficacy of co-careldopa as an add-on therapy to occupational and physical therapy in patients after stroke (DARS): a randomised, double-blind, placebo-controlled trial

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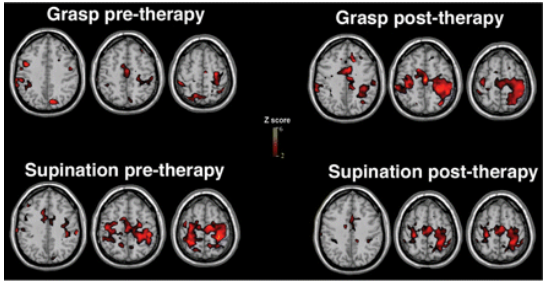
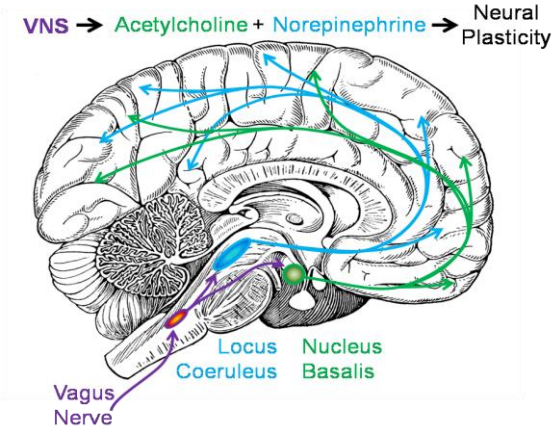
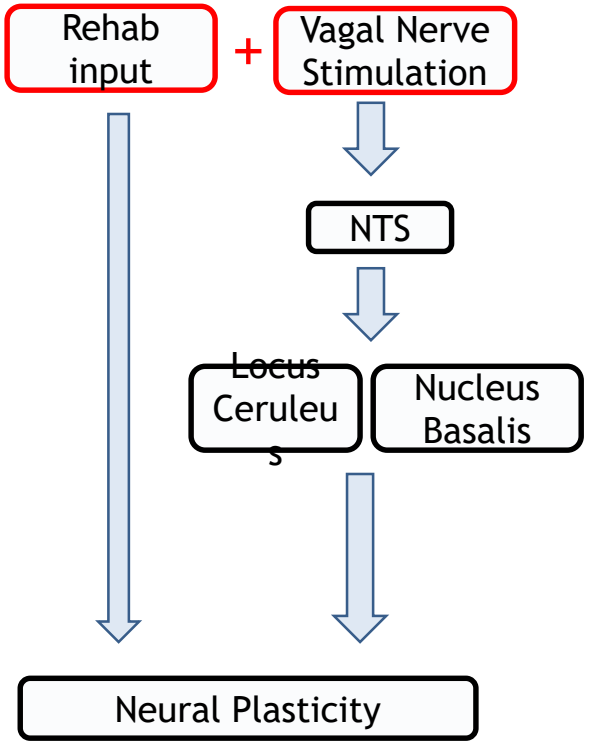
	Baseline		8 weeks		6 months		12 months	
	Co-careldopa (n=308)	Placebo (n=285)	Co-careldopa (n=271)	Placebo (n=261)	Co-careldopa (n=242)	Placebo (n=250)	Co-careldopa (n=222)	Placebo (n=221)
Able to walk independently	10 (3%)	7 (3%)	125/308 (41%)	127/285 (45%)	159/308 (52%)	152/285 (53%)	159/308 (52%)	162/285 (57%)
Odds ratio (95% CI); p value	..	..	..	0·78 (0·53–1·15); 0·212	..	..	..	..
Patient-reported RMI (as continuous)	2·4 (2·2)	2·5 (2·2)	6·8 (4·2)	7·0 (4·2)	8·3 (4·6)	8·1 (4·5)	8·7 (4·7)	8·5 (4·6)
Adjusted mean difference (95% CI); p value	..	..	..	−0·35 (−0·89 to 0·19); 0·198	..	0·14 (−0·50 to 0·79); 0·662	..	0·17 (−0·54 to 0·88); 0·637
NEADL*	59·0 (11·0)	58·6 (12·4)	21·0 (17·7)	20·0 (15·8)	27·2 (18·2)	27·3 (18·1)	30·4 (19·4)	29·8 (18·9)
Adjusted mean difference (95% CI); p value	..	..	..	1·02 (−1·27 to 3·30); 0·382	..	0·027 (−2·72 to 2·78); 0·985	..	1·04 (−1·56, 3·64); 0·434
Barthel Index	7·7 (3·8)	7·8 (3·7)	12·9 (5·1)	13·2 (4·9)	14·0 (5·1)	14·4 (5·1)	14·4 (5·4)	14·6 (5·1)
Adjusted mean difference (95% CI); p value	..	..	..	−0·22 (−0·87 to 0·43); 0·511	..	−0·33 (−1·08 to 0·41); 0·378	..	−0·22 (−1·04 to 0·59); 0·591
ABILHAND, logits	0·8 (3·9)	0·3 (1·8)	0·2 (2·3)	0·4 (2·2)	0·1 (2·4)	0·3 (2·5)	0·2 (2·6)	0·4 (2·6)
Adjusted mean difference (95% CI); p value	..	..	..	−0·10 (−0·46 to 0·26); 0·585	..	−0·15 (−0·57 to 0·27); 0·478	..	−0·16 (−0·59 to 0·28); 0·479
GHQ-12	19·4 (6·7)	19·3 (7·0)	16·9 (7·2)	16·4 (6·6)	15·1 (7·0)	16·3 (6·8)	14·0 (6·8)	14·4 (7·2)
Adjusted mean difference (95% CI); p value	..	..	..	0·24 (−0·88 to 1·36); 0·677	..	−1·33 (−2·57 to 0·10); 0·035	..	−0·77 (−2·01 to 0·52); 0·241
No sign of psychological distress	91 (30%)	94 (33%)	128 (42%)	121 (43%)	139 (45%)	125 (44%)	152 (49%)	133 (47%)

VNS – potential neuroplastic treatment

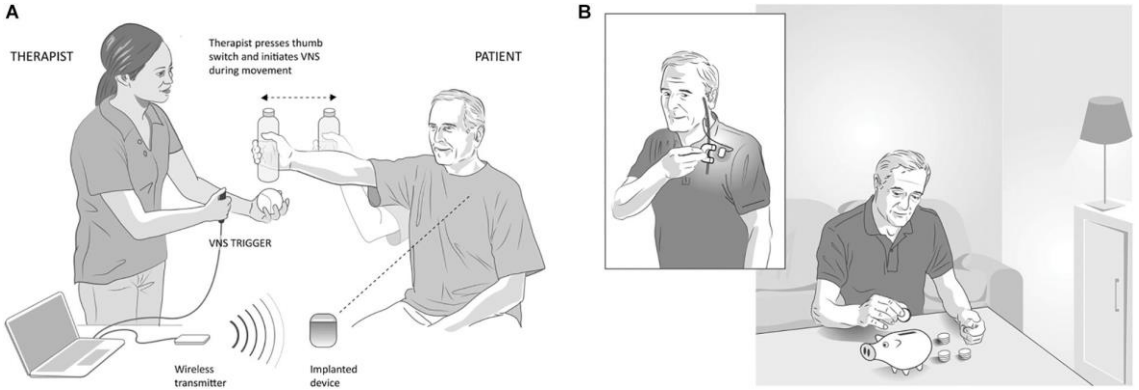


Takahashi CD et al. Brain. 2008;131:425-437





VNS treatment protocols



In Clinic Therapy

6-weeks paired VNS

0.5 second, 0.8mA stimulation given per movement (0.0 mA in controls)

Approx. 400 stimulations per session

At-Home Therapy

Once the patient has completed the In-Clinic Therapy

Patient initiate the Paired VNS

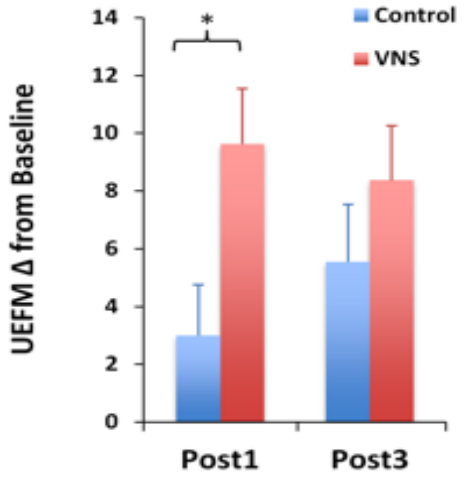
The physician or therapist will direct the patient to swipe the magnet over their IPG implant site to initiate a 30-minute session of stimulation

30-minute session of VNS + rehab tasks daily

After swiping the magnet, the patient should do the rehabilitation tasks that were assigned by the physician or therapist and should continue to do them for 30 minutes. (Automatic deliver of 0.5 sec of VNS every 7 seconds).

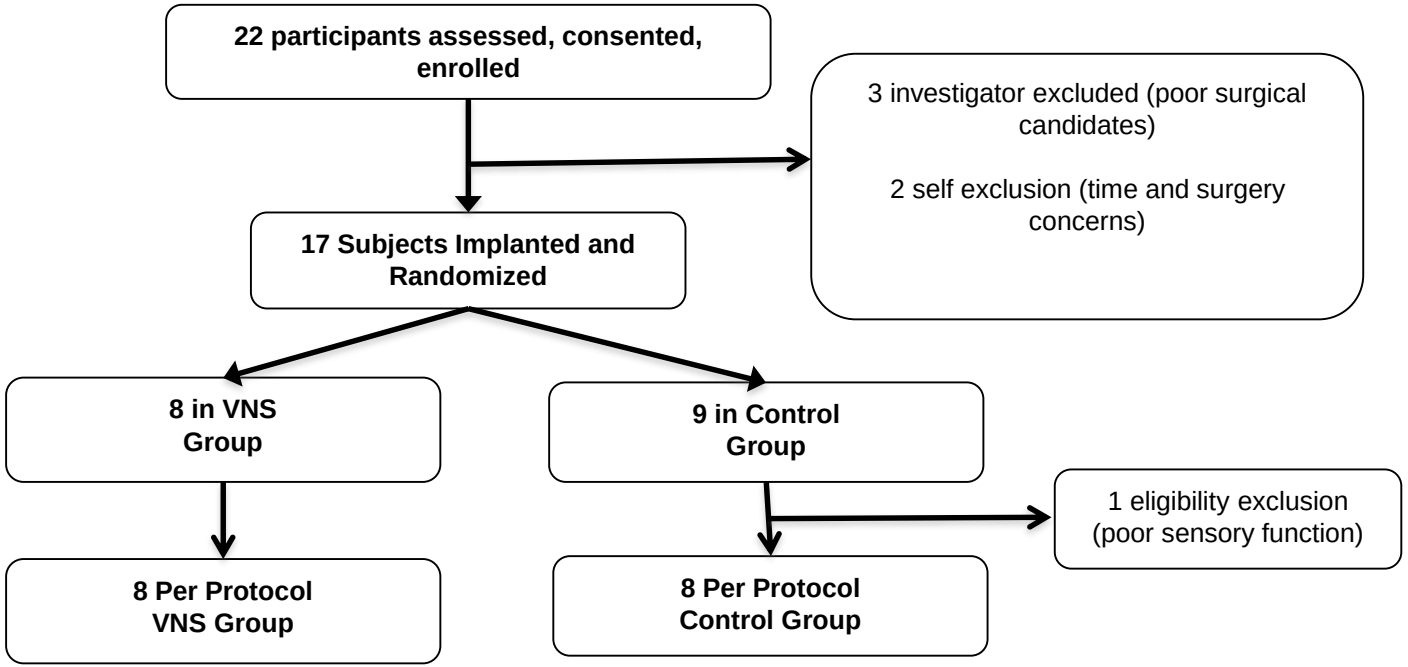
First clinical study

- 20 participant study
- PROBE design
  - 11 non-implant Controls
  - 9 Implanted Active Therapy
- ITT Analysis
  - 5.7 pt difference; 95% CI: -0.4, 11.8
- Per-Protocol Analysis
  - 6.5 pt difference; 95% CI; 0.4, 12.6
- Responder rate:
  - 75% VNS vs. 38% Controls
- Feasible, moving forward justified



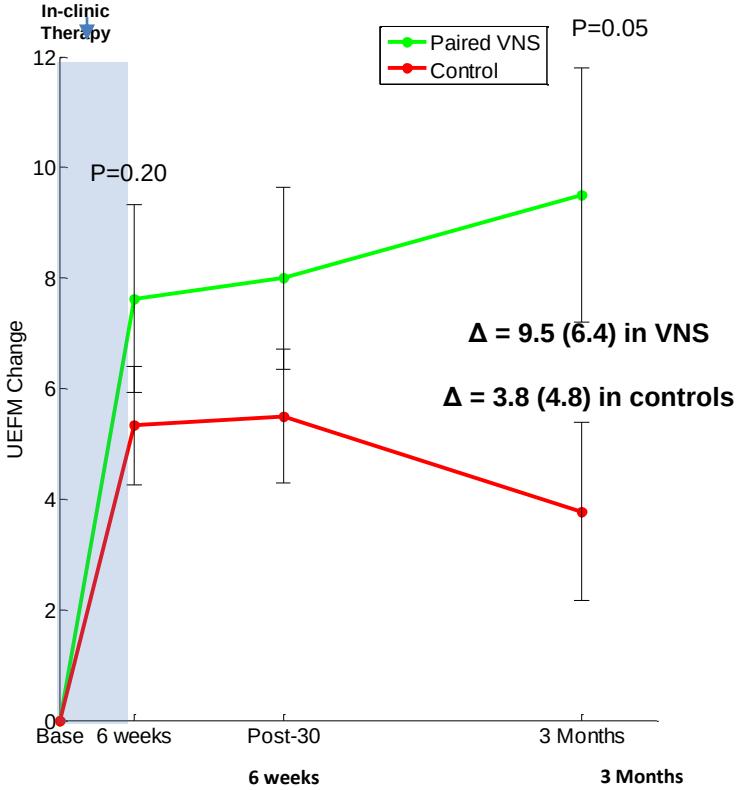
Stroke. 2016;47:143-50. doi: 10.1161/STROKEAHA.115.010477

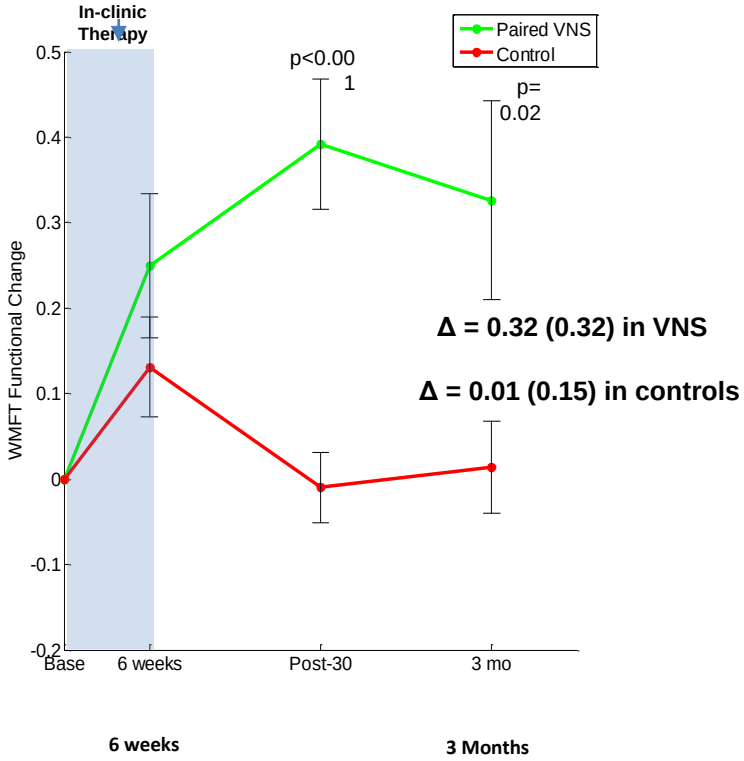
Second clinical study



Stroke. 2018;49:2789-92. https://doi.org/10.1161/STROKEAHA.118.022279

ITT Results





Stroke. 2018;49:2789-92. https://doi.org/10.1161/STROKEAHA.118.022279

Protocol

EUROPEAN STROKE JOURNAL

European Stroke Journal
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Study protocol for a pivotal randomised study assessing vagus nerve stimulation during rehabilitation for improved upper limb motor function after stroke

Teresa J Kimberley[1], Cecília N Prudente[2], Navzer D Engineer[2], David Pierce[2], Brent Tarver[2], Steven C Cramer[3], David Alexander Dickie[4] and Jesse Dawson[4]

Summary

- Mechanical thrombectomy is a sea change in stroke care
  - Scotland has a long way to go
- Robotic therapy was disappointing
- We can deliver effective rehab in people's homes
- So far drugs have failed to improve rehabilitation outcomes
- Other pro-neuroplastic therapies appear promising

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