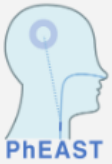
Day 014 Primary Outcome

Record ID

_____
(REDCap auto generated)



Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

UK ISRCTN 98886991
UK IRAS306761
UK CPMS 50913
WHO UTN U1111-1273-9942

Day 14, primary outcome form v1.9

▶ Please check consent form obtained.
▶ Please check Eligibility form completed.
▶ Please check Baseline & Baseline Clinical, EQ-5D, EQ-VAS forms completed.
▶ Please check PES 1-6 treatment forms are completed.

Section A: Participant details

A1. Centre name:

_____
(Centre)

A2. Participant ID :

_____
(Participant ID)

A3. Participant initials (e.g. ABC or A-C) :

_____
(3 uppercase letters, or 2 separated by a hyphen (-))

A4a. Follow-up status at day 14

◯ Randomised to control
◯ Agreed to follow-up
◯ Refused this follow-up
◯ Withdrawn from trial and all treatments and follow-ups
◯ Discharged
◯ Lost to follow-up
◯ Died
(Choose one answer)

A4b. If follow-up "Refused", please specify reason for refusal

_____

Section B: Dysphagia Severity Rating Scale (DSRS) - this is the primary outcome and is vital to collect

This is the professional SLT score, i.e. reflects the true level of dysphagia severity that is assessed by the SLT and would not include any recommendations for free water protocol or risk-feeding (this is scored later) but only what the patient would be considered safe to have or NBM if nothing is safe.

DSRS supervision score 3 is always chosen when a patient is on limited or consistent oral trials and still requires NG/ PEG/ RIG tube.

B1. DSRS, fluids

(Baseline: [dsrs_fluids_000])

◯ Thin fluids / IDDSI level 0
◯ Slightly or mildly thick / IDDSI level 1 or 2
◯ Moderately thick / IDDSI level 3
◯ Extremely thick / IDDSI level 4
◯ No oral fluids
(Choose one answer)

B2. DSRS, diet

(Baseline: [dsrs_diet_000])

◯ Regular diet / IDDSI level 7
◯ Easy to chew diet / IDDSI level 7
◯ Soft & bite sized diet / IDDSI level 6
◯ Pureed or minced/moist diet / IDDSI level 4 or 5
◯ No oral feeding
(Choose one answer)

B3. DSRS, supervision

(Baseline: [dsrs_supervision_000])

◯ Eating independently
◯ Eating with supervision
◯ Feeding by third party (untrained)
◯ Therapeutic feeding (SALT/trained staff)
◯ No oral feeding
(Choose one answer)

B4. DSRS, total

(Baseline: [dsrs_total_000])

NB: DSRS = 13 for Death

_____
(Calculated DSRS)

Section C: Feeding information (NGT/PEG/RIG, FOIS & FSS & IDD FDS & PRESS)

This is the professional SLT score, i.e. reflects the true level of dysphagia severity that is assessed by the SLT and would not include any recommendations for free water protocol or risk-feeding (this is scored later) but only what the patient would be considered safe to have or NBM if nothing is safe.

C1. Feeding tube type

(Baseline: tube_type_000])

◯ Nasogastric tube (NGT) feeding
◯ Percutaneous endoscopic gastrostomy (PEG/RIG) tube feeding
◯ None

C2. Functional oral intake scale (FOIS)

(Baseline: [fois_000])

FOIS calculated based on DSRS score: [fois_calc_014]

NB: FOIS = 0 for Death

◯ 1: Nothing by mouth (B4. DSRS=12)
◯ 2: Tube dependent with minimal attempts of food or liquid. (B4. DSRS=11 & B3. DSRS supervision: Therapeutic feeding)
◯ 3: Tube dependent with consistent oral intake of food or liquid
◯ 4: Total oral diet of a single consistency
◯ 5: Total oral diet with multiple consistencies, but requiring special preparation or compensations
◯ 6: Total oral diet with multiple consistencies without special preparation, but with specific food limitations
◯ 7: Total oral diet with no restrictions
◯ 0: Died
(FOIS Calculated based on DSRS score: [fois_calc_014])

C2b. FOIS total score

(Baseline: [fois_total_000])

NB: FOIS = 0 for Death

_____
(Calculated)

C3. Feeding status score (FSS)

(Baseline: [fss_000])

FSS calculated based on NGT & DSRS score: [fss_calc_014]

NB: FSS = 0 for Death

◯ 1: Oral diet/fluids, normal consistency
◯ 2: Oral diet/fluids, soft consistency
◯ 3: Non-oral diet/fluids, nasogastric tube (NGT) feeding
◯ 4: Non-oral diet/fluids, percutaneous endoscopic gastrostomy (PEG/RIG) tube feeding
◯ 5: Non-oral diet/fluids, intravenous/subcutaneous fluids only
◯ 6: No feeding/fluids
◯ 0: Died
(FSS calculated based on NGT & DSRS score: [fss_calc_014])

C3b. FSS total score

(Baseline: [fss_total_000])

NB: FSS = 0 for Death

_____
(Calculated)

⚠ FOIS/ FSS/ Feeding tube details C1-C3 should all be specified.

IDDSI Functional Diet Scale score

This is the professional SLT score, i.e. reflects the true level of dysphagia severity that is assessed by the SLT and would not include any recommendations for free water protocol or risk-feeding (this is scored later) but only what the patient would be considered safe to have or NBM if nothing is safe.

C4a. Food prescription
(7, 6, 5 are transitional foods)

◯ 7: REGULAR
◯ 6: SOFT & BITE-SIZED
◯ 5: MINCED & MOIST
◯ 4: PUREED
◯ 3: LIQUIDISED
◯ N/A: NO FOOD (N/A)

C4b. Drink prescription

◯ 4: EXTREMELY THICK
◯ 3: MODERATELY THICK
◯ 2: MILDLY THICK
◯ 1: SLIGHTLY THICK
◯ 0: THIN
◯ N/A: NO DRINKS (N/A)

IDDSI Functional Diet Scale score

How is IDDS Scored:

- If there is an NG Tube or PEG in, with no trials of food and drink (i.e. a FOIS score of 1) score 0
- If there is an NG Tube or PEG in, with trials of food and drink with minimal spoons < 15 (i.e. a FOIS score of 2) score 0.25
- If there is an NG Tube or PEG in, with trials of food and drink with some spoons >=15 (i.e. a FOIS score of 3) score 0.50

- Otherwise, score from the range of 0 to 8 according to the extended IDDSI framework.

_____
(Calculated)

Free water protocol and risk-feeding DSRS, FOIS, FSS and IDDSI: Based on what the patient is actually having (e.g. unlimited thin fluids, solid diet etc).

This is the pragmatic SLT score.

If the patient is on free water protocol i.e. if the patient is recommended to have thin water the DSRS score for fluids is therefore scored as 0 even if the patient is also having thickened fluids. (This latter information is captured in the professional SLT score.)

If the patient is risk feeding, choose appropriate DSRS score, if this is what the patient is recommended to have, even if this is considered to be at risk.
As these patients are not deemed to be appropriate for tube feeding, do not use tube feeding criteria or amounts patient is having to score. Only choose the consistency they have been recommended to have even if they are having less than that in reality.

Please only complete if the patient is on free water protocol or risk-feeding

C5a. Is the participant on a free water protocol?
If yes, please complete the DSRS, FOIS, FSS and IDDSS below based on what the patient is actually having (i.e. thin water).

◯ Yes - unlimited amount
◯ Yes - limited amount
◯ No

C5b. Is the participant risk-feeding?
If yes, please complete the DSRS, FOIS, FSS and IDDSS below according to what the patient is recommended to have even if this is considered at risk (e.g. unlimited thin fluids, solid diet etc).

◯ Yes
◯ No

Free water protocol or risk feeding DSRS: Based on what the patient is actually having

C5c(i). If Free water protocol DSRS, fluids based on what the patient is actually having (i.e. thin water)

OR

If risk feeding, choose appropriate DSRS score according to what the patient is recommended to have even if this is considered at risk

◯ 0: Thin fluids / IDDSI level 0
◯ 1: Slightly or mildly thick / IDDSI level 1 or 2
◯ 2: Moderately thick / IDDSI level 3
◯ 3: Extremely thick / IDDSI level 4
◯ 4: No oral fluids
(Choose one answer)

⚠ If the patient is on free water, the DSRS fluid should be 0

C5c(ii). Can you give more details why you chose this score

If this patient is on free water then a score of 0 was expected.

_____
(Reason why DSRS fluids score is not 0 and the patient is on free water)

C5d. DSRS, diet

If risk feeding, choose appropriate DSRS score according to what the patient has been recommended to have even if this is considered to be at risk.

◯ 0: Regular diet / IDDSI level 7
◯ 1: Easy to chew diet / IDDSI level 7
◯ 2: Soft & bite sized diet / IDDSI level 6
◯ 3: Pureed or minced/moist diet / IDDSI level 4 or 5
◯ 4: No oral feeding
(Choose one answer)

C5e(i). DSRS, supervision

If risk feeding, choose appropriate DSRS score

◯ 0: Eating independently
◯ 1: Eating with supervision
◯ 2: Feeding by third party (untrained)
◯ 3: Therapeutic feeding (SALT/trained staff)
◯ 4: No oral feeding
(Choose one answer)

⚠ If the patient is on risk-feeding, the DSRS supervision should not be 3

C5e(ii). Can you give more details why you chose this score

This patient is risk-feeding therefore not deemed appropriate for tube feeding and a score of 3 is not indicated.

_____
(Reason why DSRS supervision score is 3 and the patient is risk-feeding)

C5f. Free water protocol or risk feeding DSRS, total

_____
(Calculated)

Free water protocol or risk feeding FOIS, FSS: Based on what the patient is actually having

C5g(i). Functional oral intake scale (FOIS)

For risk feeding fill in according to what the patient is recommended to have even if this is considered at risk

◯ 1: Nothing by mouth (B4. DSRS=12)
◯ 2: Tube dependent with minimal attempts of food or liquid. (B4. DSRS=11 & B3. DSRS supervision: Therapeutic feeding)
◯ 3: Tube dependent with consistent oral intake of food or liquid
◯ 4: Total oral diet of a single consistency
◯ 5: Total oral diet with multiple consistencies, but requiring special preparation or compensations
◯ 6: Total oral diet with multiple consistencies without special preparation, but with specific food limitations
◯ 7: Total oral diet with no restrictions
◯ 0: Died

(Choose one answer - Based on what the patient is actually having (i.e. unlimited thin fluids, solid diet etc).)

⚠ If the patient is on risk-feeding, the FOIS should not be 1-2-3

C5g(ii). Can you give more details why you chose this score

This patient is risk-feeding therefore not deemed appropriate for tube feeding and a score of 1-2-3 is not indicated.

_____

(Reason why FOIS score is 1-2 or 3 and the patient is risk-feeding)

C5h(i). Feeding status score (FSS)

For risk feeding fill in according to what the patient is recommended to have even if this is considered at risk

◯ 1: Oral diet/fluids, normal consistency
◯ 2: Oral diet/fluids, soft consistency
◯ 3: Non-oral diet/fluids, nasogastric tube (NGT) feeding
◯ 4: Non-oral diet/fluids, percutaneous endoscopic gastrostomy (PEG or RIG) tube feeding
◯ 5: Non-oral diet/fluids, intravenous/subcutaneous fluids only
◯ 6: No feeding/fluids
◯ 0: Died

(Choose one answer - Based on what the patient is actually having (i.e. unlimited thin fluids, solid diet etc).)

⚠ If the patient is on risk-feeding, the FSS should not be 2-3-4-5

C5h(ii). Can you give more details why you chose this score

This patient is risk-feeding therefore not deemed appropriate for tube feeding and a score of 2-3-4-5 is not indicated.

_____

(Reason why FSS score is 2-3-4-or 5 and the patient is risk-feeding)

Free water protocol or risk feeding IDDSI

C5i. IDDSI, Food prescription

For risk feeding choose appropriate IDDSI score according to what the patient is recommended to have even if this is considered at risk

◯ 7: REGULAR
◯ 6: SOFT & BITE-SIZED
◯ 5: MINCED & MOIST
◯ 4: PUREED
◯ 3: LIQUIDISED
◯ N/A: NO FOOD (N/A)
(Choose one answer)

C5j(i). If Free water protocol IDDSI, fluids based on what the patient is actually having (i.e. thin water)

OR

For risk feeding choose appropriate IDDSI score according to what the patient is recommended to have even if this is considered at risk

◯ 4: EXTREMELY THICK
◯ 3: MODERATELY THICK
◯ 2: MILDLY THICK
◯ 1: SLIGHTLY THICK
◯ 0: THIN
◯ N/A: NO DRINKS (N/A)
(Choose one answer)

⚠ If the patient is on free water, the IDDSI fluid should be 0

C5j(ii). Can you give more details why you chose this score

This patient is on free water then a score of 0 was expected.

_____
(Reason why IDDSI drink score is not 0 and patient is on free water)

Free water or risk feeding protocol IDDSI Functional Diet Scale score

Based on what the patient is actually having (i.e. unlimited thin fluids, solid diet etc). How is IDDS Scored:

- If there is an NG Tube or PEG in, with no trials of food and drink (i.e. a FOIS score of 1) score 0
- If there is an NG Tube or PEG in, with trials of food and drink with minimal spoons < 15 (i.e. a FOIS score of 2) score 0.25
- If there is an NG Tube or PEG in, with trials of food and drink with some spoons >=15 (i.e. a FOIS score of 3) score 0.50

- Otherwise, score from the range of 0 to 8 according to the extended IDDSI framework.

_____
(Calculated - Based on what the patient is actually having (i.e. unlimited thin fluids, solid diet etc).)

Predictive Swallowing Score (PRESS)

C6a. Calculated PRESS score. Prognostic Model of Swallowing Recovery and Enteral Tube Feeding After Ischemic Stroke (Galovic et al. JAMA Neuro 2019; 11 Feb)

_____
(Calculated)

C6b. Risk estimate % of impaired oral intake after 7 days

Prediction estimates of Swallowing Recovery According to PRESS value [press_calc_014]

_____
(Risk of Impaired Oral Intake After 7 d. %)

C6c. Risk estimate % of impaired oral intake after 30 days

Prediction estimates of Swallowing Recovery According to PRESS value [press_calc_014]

_____ (Risk of Impaired Oral Intake After 30 d. %)

C6d. Risk estimate % of NO return to prestroke diet after 7 days

Prediction estimates of Swallowing Recovery According to PRESS value [press_calc_014]

_____ (Risk of No Return to Prestroke Diet After 7 d. %)

C6e. Risk estimate % of NO return to prestroke diet after 30 days

Prediction estimates of Swallowing Recovery According to PRESS value [press_calc_014]

_____ (Risk of No Return to Prestroke Diet After 30 d. %)

Section D: EAT-10 swallowing screening tool.

0= No problem - 5= Not eating

D1. My swallowing problem has caused me to lose weight?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D2. My swallowing problem interferes with my ability to go out for meals?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D3. Swallowing liquids takes extra effort?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D4. Swallowing solids takes extra effort?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D5. Swallowing pills takes extra effort?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D6. Swallowing is painful?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D7. The pleasure of eating is affected by my swallowing?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D8. When I swallow food sticks in my throat?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D9. I cough when I eat?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D10. Swallowing is stressful?

◯ No problem
◯ Mild
◯ Moderate
◯ Moderate-severe
◯ Severe problem
◯ Not eating, i.e. tube fed
(Choose one answer)

D11a. EAT-10 total score

_____
(Calculated EAT-10 (0-50))

D11b. Average EAT-10 total score

_____
(Calculated average EAT-10 (0-50))

Section E: Modified Rankin Scale (mRS) - Dependency, disability, cognition, mood scores

E1. Modified Rankin Scale (mRS), now

(Baseline: [mrs_total_000] / [mrs_000])

- ◯ No symptoms at all
- ◯ No significant disability despite symptoms; able to carry out all usual duties and activities
- ◯ Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
- ◯ Moderate disability; requiring some help, but able to walk without assistance
- ◯ Moderately severe disability; unable to walk and attend to bodily needs without assistance
- ◯ Severe disability; bedridden, incontinent and requiring constant nursing care and attention
- ◯ Deceased
- ◯ Withdrawn

(Choose one answer)

E2. mRS total score

(Baseline: [mrs_total_000])

NB: mRS = 6 for Death

_____

Section F: Barthel index

F1. Is the participant incontinent of urine?

- ◯ Yes, incontinent/has a catheter fitted
- ◯ Occasional accident (maximum once per 24 hours)
- ◯ No, continent

F2. How does the participant move from bed to the chair?

- ◯ Not at all
- ◯ With a lot of help from one or two people
- ◯ With a little help from one person
- ◯ On their own

F3. How does the participant get about?

- ◯ Not at all
- ◯ Propelling themself independently in a wheelchair
- ◯ Walking with the help and supervision of one person
- ◯ Walking with no help (even if they use a stick/frame)

F4. Is the participant incontinent of their bowels?

- ◯ Yes, incontinent
- ◯ Occasional accident (once per week)
- ◯ No, continent

F5. Does the participant wash their own face, brush their teeth and hair (for men, shave)?

- ◯ With help
- ◯ Without help

F6. How does the participant use the toilet (or commode)?

- ◯ With a lot of help
- ◯ With a little help
- ◯ On their own

F7. Does the participant feed themself?

- ◯ With major help
- ◯ With some help e.g. cutting
- ◯ Without any help

F8. Does the participant need any help with dressing?	◯ Yes, they need help with almost everything ◯ Yes, they are able to do about half unaided ◯ No, they can do everything
F9. How does the participant get up and down the stairs?	◯ Not at all ◯ With help (either supervision or assistance) ◯ Without any help
F10. Does the participant need help with bathing or showering?	◯ Yes ◯ No
F11. Barthel index	_____ (Calculated)

⚠ Barthel index details F1-F11 should be specified.

Section G: National Institutes of Health Stroke Scale (NIHSS)

G1. Can NIHSS scores be obtained? ◯ Yes ◯ No

If not, the NIHSS questions will all be blanked out.

NIHSS 1a. Level of Consciousness (LOC)

Score 0-1-2: Must be alert (score 0), arouse to minor stimulation (score 1) or require repeated stimulation (score 2) to be eligible.

Score 2-3: Patients with only movements to pain (also score 2) or postures/unresponsive (score 3) are ineligible.

Score 3: The investigator must choose a response if a full evaluation is prevented by such obstacles as an endotracheal tube, language barrier, orotracheal trauma/bandages. A 3 is scored only if the patient makes no movement (other than reflexive posturing) in response to noxious stimulation.

G1a. NIHSS 1a. Conscious or obtunded on NIHSS stroke scale question 1A. (Baseline: [nihss_1a_000])	◯ 0 = Alert, keenly responsive ◯ 1 = Arouses to minor stimulation ◯ 2 = Requires repeated stimulation to arouse ◯ 2 = Movements to pain ◯ 3 = Postures or unresponsive (Choose one answer)

NIHSS 1b. LOC Questions

What is the month and what is your age?

The answer must be correct - there is no partial credit for being close.

Score 2: Aphasic and stuporous patients who do not comprehend the questions will score 2.

Score 1: Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, language barrier, or any other problem not secondary to aphasia are given a 1.

It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues.

G1b. NIHSS 1b. What is the month and what is your age?

(Baseline: [nihss_1b_000])

◯ 0 = Answers both questions correctly
◯ 1 = Answers one question correctly
◯ 2 = Answers neither question correctly
(Choose one answer)

NIHSS 1c. LOC Commands

Open and close your eyes. Grip and release your hand.

The patient is asked to open and close the eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is given if an unequivocal attempt is made but not completed due to weakness.

If the patient does not respond to command, the task should be demonstrated to him or her (pantomime), and the result scored (i.e., follows none, one or two commands).

Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored.

G1c. NIHSS 1c. Open and close your eyes. Grip and release your hand.

(Baseline: [nihss_1c_000])

◯ 0 = Performs both tasks correctly
◯ 1 = Performs one task correctly
◯ 2 = Performs neither task correctly
(Choose one answer)

NIHSS 2. Best gaze.

Only horizontal eye movements will be tested. Voluntary or reflexive (oculocephalic) eye movements will be scored, but caloric testing is not done.

If the patient has a conjugate deviation of the eyes that can be overcome by voluntary or reflexive activity, the score will be 1.

If a patient has an isolated peripheral nerve paresis (CN III, IV or VI), score a 1.

Gaze is testable in all aphasic patients. Patients with ocular trauma, bandages, pre-existing blindness, or other disorder of visual acuity or fields should be tested with reflexive movements, and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of a partial gaze palsy.

G2. NIHSS 2. Best gaze.

(Baseline: [nihss_2_000])

◯ 0 = Normal
◯ 1 = Partial gaze palsy; gaze is abnormal in one or both eyes, but forced deviation or total gaze paresis is not present
◯ 2 = Forced deviation, or total gaze paresis not overcome by the oculocephalic maneuver
(Choose one answer)

NIHSS 3. Visual field loss (upper and lower quadrants).

Visual fields (upper and lower quadrants) are tested by confrontation, using finger counting or visual threat, as appropriate. Patients may be encouraged, but if they look at the side of the moving fingers appropriately, this can be scored as normal.

If there is unilateral blindness or enucleation, visual fields in the remaining eye are scored. Score 1 only if a clear-cut asymmetry, including quadrantanopia, is found.

If patient is blind from any cause, score 3. Double simultaneous stimulation is performed at this point. If there is extinction, patient receives a 1, and the results are used to respond to item 11.

G3. NIHSS 3. Visual field loss (upper and lower quadrants).

(Baseline: [nihss_3_000])

◯ 0 = No visual loss.
◯ 1 = Partial hemianopia.
◯ 2 = Complete hemianopia.
◯ 3 = Bilateral hemianopia (blind including cortical blindness).
(Choose one answer)

NIHSS 4. Facial palsy.

Ask - or use pantomime to encourage - the patient to show teeth or raise eyebrows and close eyes.

Score symmetry of grimace in response to noxious stimuli in the poorly responsive or non-comprehending patient.

If facial trauma/bandages, orotracheal tube, tape or other physical barriers obscure the face, these should be removed to the extent possible.

G4. NIHSS 4. Facial palsy.

(Baseline: [nihss_4_000])

◯ 0 = Normal symmetrical movements.
◯ 1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling).
◯ 2 = Partial paralysis (total or near-total paralysis of lower face).
◯ 3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face).
(Choose one answer)

NIHSS 5. Motor Arm.

The limb is placed in the appropriate position: extend the arms (palms down) 90 degrees (if sitting) or 45 degrees (if supine).

Drift is scored if the arm falls before 10 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime, but not noxious stimulation.

Each limb is tested in turn, beginning with the non-paretic arm. Only in the case of amputation or joint fusion at the shoulder, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice.

G5a. NIHSS 5a. Motor weakness, left arm

(Baseline: [nihss_5a_000])

◯ 0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.
◯ 1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support.
◯ 2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity.
◯ 3 = No effort against gravity; limb falls.
◯ 4 = No movement.
◯ UN = Amputation or joint fusion
(Choose one answer)

G5b. NIHSS 5b. Motor weakness, right arm

(Baseline: [nihss_5b_000])

◯ 0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.
◯ 1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support.
◯ 2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity.
◯ 3 = No effort against gravity; limb falls.
◯ 4 = No movement.
◯ UN = Amputation or joint fusion
(Choose one answer)

NIHSS 6. Motor Leg.

The limb is placed in the appropriate position: hold the leg at 30 degrees (always tested supine).

Drift is scored if the leg falls before 5 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime, but not noxious stimulation.

Each limb is tested in turn, beginning with the non-paretic leg. Only in the case of amputation or joint fusion at the hip, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice.

G6a. NIHSS 6a. Motor weakness, left leg

(Baseline: [nihss_6a_000])

◯ 0 = No drift; leg holds 30-degree position for full 5 seconds.
◯ 1 = Drift; leg falls by the end of the 5-second period but does not hit bed.
◯ 2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.
◯ 3 = No effort against gravity; leg falls to bed immediately.
◯ 4 = No movement.
◯ UN = Amputation or joint fusion.
(Choose one answer)

G6b. NIHSS 6b. Motor weakness, right leg

(Baseline: [nihss_6b_000])

◯ 0 = No drift; leg holds 30-degree position for full 5 seconds.
◯ 1 = Drift; leg falls by the end of the 5-second period but does not hit bed.
◯ 2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.
◯ 3 = No effort against gravity; leg falls to bed immediately.
◯ 4 = No movement.
◯ UN = Amputation or joint fusion.
(Choose one answer)

NIHSS 7. Limb Ataxia.

This item is aimed at finding evidence of a unilateral cerebellar lesion. Test with eyes open. In case of visual defect, ensure testing is done in intact visual field.

The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is paralyzed.

Only in the case of amputation or joint fusion, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice. In case of blindness, test by having the patient touch nose from extended arm position.

G7. NIHSS 7. Limb Ataxia

(Baseline: [nihss_7_000])

◯ 0 = Absent.
◯ 1 = Present in one limb.
◯ 2 = Present in two limbs.
◯ UN = Amputation or joint fusion.
(Choose one answer)

NIHSS 8. Sensory loss.

Sensation or grimace to pinprick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas (arms [not hands], legs, trunk, face) as needed to accurately check for hemisensory loss.

A score of 2, "severe or total sensory loss," should only be given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will, therefore, probably score 1 or 0. The patient with brainstem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic, score 2. Patients in a coma (item 1a=3) are automatically given a 2 on this item.

G8. NIHSS 8. Sensory loss

(Baseline: [nihss_8_000])

◯ 0 = Normal; no sensory loss.
◯ 1 = Mild-to-moderate sensory loss; patient feels pinprick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick, but patient is aware of being touched.
◯ 2 = Severe to total sensory loss; patient is not aware of being touched in the face, arm, and leg.
(Choose one answer)

NIHSS 9. Best language.

A great deal of information about comprehension will be obtained during the preceding sections of the examination. For this scale item, the patient is asked to describe what is happening in the attached picture, to name the items on the attached naming sheet and to read from the attached list of sentences. Comprehension is judged from responses here, as well as to all of the commands in the preceding general neurological exam.

If visual loss interferes with the tests, ask the patient to identify objects placed in the hand, repeat, and produce speech.

The intubated patient should be asked to write.

The patient in a coma (item 1a=3) will automatically score 3 on this item.

The examiner must choose a score for the patient with stupor or limited cooperation, but a score of 3 should be used only if the patient is mute and follows no one-step commands.

G9. NIHSS 9. Best language.

(Baseline: [nihss_9_000])

◯ 0 = No aphasia; normal.
◯ 1 = Mild-to-moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversation about provided materials difficult or impossible. For example, in conversation about provided materials, examiner can identify picture or naming card content from patient's response.
◯ 2 = Severe aphasia; all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided from patient response.
◯ 3 = Mute, global aphasia; no usable speech or auditory comprehension.
◯ 3 = Coma/unresponsive.
(Choose one answer)

NIHSS 10. Dysarthria.

If patient is thought to be normal, an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated.

Only if the patient is intubated or has other physical barriers to producing speech, the examiner should record the score as untestable (UN), and clearly write an explanation for this choice.

Do not tell the patient why he or she is being tested.

G10. NIHSS 10. Dysarthria.

(Baseline: [nihss_10_000])

◯ 0 = Normal.
◯ 1 = Mild-to-moderate dysarthria; patient slurs at least some words and, at worst, can be understood with some difficulty.
◯ 2 = Severe dysarthria; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/anarthric.
◯ UN = Intubated or other physical barrier.
(Choose one answer)

NIHSS 11. Extinction and Inattention (formerly Neglect).

Sufficient information to identify neglect may be obtained during the prior testing.

If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal.

If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of visual spatial neglect or anosagnosia may also be taken as evidence of abnormality. Since the abnormality is scored only if present, the item is never untestable.

G11. NIHSS 11. Extinction and Inattention (formerly Neglect).

(Baseline: [nihss_11_000])

◯ 0 = No abnormality.
◯ 1 = Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities.
◯ 2 = Profound hemi-inattention or extinction to more than one modality; does not recognize own hand or orients to only one side of space.
(Choose one answer)

NIHSS & NIHSS-Cog4 scores

G12. Stroke severity as National Institutes of Health stroke scale (NIHSS), NIHSS-Cog4 score: (0-9)

NIHSS-cog4 = orientation (1b) + executive (1c) + language (9) + inattention (11)

(Baseline: [nihss_cog4_000])

_____
(Calculated)

G12a. NIHSS score

Stroke severity as National Institutes of Health stroke scale (NIHSS), total 1-11

(Baseline: [nihss_total_000])

_____
(Calculated)

Section H: Penetration aspiration score (PAS) FEES: Fiberoptic endoscopic evaluation of swallowing
VFS: Videofluoroscopy
PAS: Penetration aspiration score

H1. Was FEES or VFS performed between days 6 and 14 (between last treatment and primary outcome) AND a PAS measured?

☐ No FEES or VFS, or no PAS
☐ Fiberoptic evaluation of swallowing (FEES)
☐ Videofluoroscopy (VFS)
(Choose one answer)

H2. Penetration aspiration score (PAS)

Specify PAS if performed since treatment on thin fluids (IDDSI level 0) finished using Fiberoptic Evaluation of Swallowing (FEES) or videofluoroscopy (VFS).

Please give lowest (best) and highest (worst) PAS if available.
Or give highest (worst) score only if known.

H2a. PAS highest (worst) score

(Baseline: [pas_high_000])

_____
(Integer 1-8)

H2b. PAS lowest (best) score

(Baseline: [pas_low_000])

_____
(Integer 1-8)

H2c. PAS score (mean)

(Baseline: [pas_000])

_____
(Integer 1-8)

H3. Date PAS score collected

_____
(Date DD-MM-YYYY)

Section I: Glasgow Coma Scale (GCS) - Level of consciousness

I1. Eye Opening Response

- ◯ 4: Spontaneous--open with blinking at baseline
- ◯ 3: To verbal stimuli, command, speech
- ◯ 3: To pain only (not applied to face)
- ◯ 1: No response

I2. Verbal Response

- ◯ 5: Oriented
- ◯ 4: Confused conversation, but able to answer questions
- ◯ 3: Inappropriate words
- ◯ 2: Incomprehensible speech
- ◯ 1:No response

I3. Motor Response

- ◯ 6 Obeys commands for movement
- ◯ 5: Purposeful movement to painful stimulus
- ◯ 4: Withdraws in response to pain
- ◯ 3: Flexion in response to pain (decorticate posturing)
- ◯ 2: Extension response in response to pain (decerebrate posturing)
- ◯ 1: No response

I4a. Glasgow Coma Scale (GCS) total

_____
(Calculated)

Section J: Other clinical information

Recommended diagnostic criteria for definite and probable pneumonia in patients not receiving mechanical ventilation based on CDC criteria:

At least 1 of the following:

Fever (>38°C) with no other recognised cause Leucopenia (< 4000 WBC/mm3) or leucocytosis (>12 000 WBC/mm3) For adults ≥70 y old, altered mental status with no other recognised cause AND
At least 2 of the following:

New onset of purulent sputum, or change in character of sputum over a 24 h period, or increased respiratory secretions, or increased suctioning requirements New onset or worsening cough, or dyspnea, or tachypnea (respiratory rate>25/min) Rales, crackles, or bronchial breath sounds Worsening gas exchange (eg, O2 desaturation [eg, PaO2/FiO2≤240], increased oxygen requirements) AND
≥2 serial chest radiographs† with at least 1 of the following:

New or progressive and persistent infiltrate, consolidation, or cavitation Note: In patients without underlying pulmonary or cardiac disease, 1 definitive chest radiograph is acceptable

J1. Pneumonia.

Has the participant had pneumonia or a chest infection since consent?

Note: In patients without underlying pulmonary or cardiac disease, 1 definitive chest radiograph is acceptable

◯ Yes ◯ No
(Choose one answer)

J2. Antibiotics.

Has the participant started a course of antibiotics since consent?

Note: Answer No if antibiotics were started before consent.

◯ Yes ◯ No
(Choose one answer)

J3. What is the participant's weight (or estimated weight) in kilos?

(Baseline: [weight_000])

_____
(Number (30-200) kg)

Section K: Recruitment recollection

K1a. Get Assessment recollection opinion from participant and Assessor

◯ Get Assessment and opinion
◯ Defer question for later (to day 90, 180 or 365)

Assessor's opinion

K1b. Which treatment group do you, the outcome assessor, think the participant was in?

◯ I know they were in the active / PES group
◯ I know they were in the control / no PES group
◯ I guess/suspect they were in the active / PES group
◯ I guess/suspect they were in the control / no PES group
◯ I do not know which group they were in
◯ Not answered
(Choose one answer)

K1c. Please explain your answer to the last question on what treatment group you think the participant was in?

_____
(Free text)

K2a. Did the participant receive open label, (i.e. not trial related), PES?

◯ Yes
◯ No

K2b. If yes: who supplied the information on open label PES?

◯ Patient
◯ Participant
◯ Carer
◯ Site
◯ Other

K2c. Please supply any relevant information

_____

Participant's or carer's opinion

K3. Can the participant remember being in the trial?
◯ Yes ◯ No

K4. Does the participant/carer remember which treatment group the participant was in?
◯ PES group
◯ Control / no PES group
◯ Don't know

K5a. Who answered question
◯ Participant ◯ Carer
◯ Other

K5b. If "Other", please specify who answered question
_____

Section L: Assessor information

L1. Please enter your name
_____
(Collected information)

L2a. What is your professional role?
◯ Doctor
◯ Research coordinator
◯ Nurse, clinical
◯ Research nurse
◯ Physiotherapist
◯ Occupation therapist
◯ Speech & Language therapist
◯ Other
(Choose one answer)

L2b. If "Other", please specify role
_____
(Professional role)

L3. Does your role involve working on stroke wards?
◯ Yes ◯ No
(Choose one answer)

L4. Please enter your name if you did not collect the information

Name of person entering the data, if it differs from the assessor.
* Blinded assessors often collect but do not enter the data as it could unblind them.

_____
(Filling the form)

L5. Please sign the form

_____
(✍ Signature)

Section M: 2nd Assessor information

If there are two members of staff completing the bedside assessment, please complete the second assessor's details below

M1a. Are there two members of staff completing the bedside assessment?

◯ Yes ◯ No

M1b. 2nd Assessor: Please enter your name?

_____
(Collected information)

M2a. 2nd Assessor: What is your professional role?

◯ Doctor
◯ Research coordinator
◯ Nurse, clinical
◯ Research nurse
◯ Physiotherapist
◯ Occupation therapist
◯ Speech & Language therapist
◯ Other
(Choose one answer)

M2b. If "Other", please specify role

_____
(Professional role)

M3. 2nd Assessor: Does your role involve working on stroke wards?

◯ Yes ◯ No
(Choose one answer)

M4. 2nd Assessor: Please sign the form

_____
(✍ Signature)

Comments and full explanation for missing data

Are any values missing due to tests not done (or measures not taken), or because data are unknown and every effort has been made to find the data - i.e. 'Not done' / 'Not known'?

◯ Yes
◯ No

If any values are missing, please provide a full explanation □□ Comments