Day 014 IQCODE

Record ID

_____

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

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

Day 014 primary outcome IQCODE v1.2

Informant Questionnaire on Cognitive Decline in the Elderly

▶ Please check consent form obtained.
▶ Please check Day 14, primary outcome form 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 (-))

Section B: Informant

B1. Assessment start time

_____
(Date DD-MM-YYYY HH:MM)

B2. Has an informant been consented? If "No" is selected, the form does not have to be filled in.
Enter the assessor's details and any comments before completing the CRF.

◯ Yes　◯ No

B3a. Relationship to Participant	⃝ Partner or spouse
	⃝ Daughter
	⃝ Son
	⃝ Sibling
	⃝ Other relative
	⃝ Friend or neighbour
	⃝ Other

B3b. If 'Other', please specify relationship

_____

B4. Informant ID

_____
(Auto calculated (2000 + trial ID))

Section C: Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE)

Now we want you to remember what your friend or relative was like 10 years ago and to compare it with what he/she is like now.

Below are situations where this person has to use his/her memory or intelligence and we want you to indicate whether this has improved, stayed the same, or got worse in that situation over the past 10 years.

Note the importance of comparing his/her present performance with 10 years ago. So if 10 years ago this person always forgot where he/she had left things, and he/she still does, then this would be considered "Hasn't changed much". Please indicate the changes you have observed by selecting the appropriate answer.

Average IQCODE score per question [iqcode_avg_014]

1= Much improved - 5= Much worse

Compared with 10 years ago how is this person at:

	1 - Much improved	2 - A bit improved	3 - Not much change	4 - A bit worse	5 - Much worse
C1. Remembering things about family and friends, e.g. occupations, birthdays, addresses	⃝	⃝	⃝	⃝	⃝
C2. Remembering things that have happened recently	⃝	⃝	⃝	⃝	⃝
C3. Recalling conversations a few days later	⃝	⃝	⃝	⃝	⃝
C4. Remembering his/her address and telephone number	⃝	⃝	⃝	⃝	⃝
C5. Remembering what day and month it is	⃝	⃝	⃝	⃝	⃝
C6. Remembering where things are usually kept	⃝	⃝	⃝	⃝	⃝

C7. Remembering where to find things which have been put in a different place from usual	◯	◯	◯	◯	◯
C8. Knowing how to work familiar machines around the house	◯	◯	◯	◯	◯
C9. Learning to use a new gadget or machine around the house	◯	◯	◯	◯	◯
C10. Learning new things in general	◯	◯	◯	◯	◯
C11. Following a story in a book or on TV	◯	◯	◯	◯	◯
C12. Making decisions on everyday matters	◯	◯	◯	◯	◯
C13. Handling money for shopping	◯	◯	◯	◯	◯
C14. Handling financial matters, e.g. the pension, dealing with the bank	◯	◯	◯	◯	◯
C15. Handling other everyday arithmetic problems, e.g. knowing how much food to buy, knowing how long between visits from family	◯	◯	◯	◯	◯
C16. Using his/her intelligence to understand what's going on and to reason things through	◯	◯	◯	◯	◯

Section D: The 4A Test - Collateral information (4AT)

Screening instrument for cognitive impairment and delirium

D. 4AT Acute change or fluctuating course

Has there been a change or fluctuation in the participant's alertness, cognition or other mental functions (e.g. paranoia, hallucinations) over the last 2 weeks that are still evident in the last 24 hours?

◯ 4: Yes   ◯ 0: No   ◯ Not done

Section E: Neuropsychiatric Inventory, Questionnaire Version (NPI-Q)

Ask the informant to answer the following question based on changes that have occurred since the participant first began to experience memory problems.
Tell the informant to answer 'yes' only if the symptom has been present in the last month. Otherwise answer 'no'.

For each item marked "Yes":

 a) Rate the SEVERITY of the symptom (how it affects the patient):

1 = Mild (noticeable, but not a significant change)
2 = Moderate (significant, but not a dramatic change)
3 = Severe (very marked or prominent, a dramatic change)

 b) Rate the DISTRESS you experience due to that symptom (how it affects you):

0 = Not distressing at all
1 = Minimal (slightly distressing, not a problem to cope with)
2 = Mild (not very distressing, generally easy to cope with)
3 = Moderate (fairly distressing, not always easy to cope with)
4 = Severe (very distressing, difficult to cope with)
5 = Extreme or Very Severe (extremely distressing, unable to cope with)

(NPI-Q) Apathy

E1. Apathy: ◯ Yes   ◯ No   ◯ Not done

Does the participant seem less interested in his/her
usual activities or in the activities and plans of
others?

E1a. Apathy: severity (patient)
- ◯ 1: Mild
- ◯ 2: Moderate
- ◯ 3: Severe
- ◯ Not done
 (Severity: 1-Mild, 2-Moderate, 3-Severe)

E1b. Apathy: distress (affects you)
- ◯ 0: Not distressing
- ◯ 1: Minimal
- ◯ 2: Mild
- ◯ 3: Moderate
- ◯ 4: Severe
- ◯ 5: Extreme or Very Severe
- ◯ Not done
 (Distress: 0-Not distressing, 1-Minimal, 2-Mild,
  3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Delusions

E2. Delusions: ◯ Yes   ◯ No   ◯ Not done

Does the participant have false beliefs, such as
thinking that others are stealing from him/her or
planning to harm him/her in some way?

E2a. Delusions: severity (patient)	○ 1: Mild ○ 2: Moderate ○ 3: Severe ○ Not done (Severity: 1-Mild, 2-Moderate, 3-Severe)
E2b. Delusions: distress (affects you)	○ 0: Not distressing ○ 1: Minimal ○ 2: Mild ○ 3: Moderate ○ 4: Severe ○ 5: Extreme or Very Severe ○ Not done (Distress: 0-Not distressing, 1-Minimal, 2-Mild, 3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Hallucinations

E3. Hallucinations: Does the participant have hallucinations such as false visions or voices? Does he/she seem to hear or see things that are not present?	○ Yes ○ No ○ Not done
E3a. Hallucinations: severity (patient)	○ 1: Mild ○ 2: Moderate ○ 3: Severe ○ Not done (Severity: 1-Mild, 2-Moderate, 3-Severe)
E3b. Hallucinations: distress (affects you)	○ 0: Not distressing ○ 1: Minimal ○ 2: Mild ○ 3: Moderate ○ 4: Severe ○ 5: Extreme or Very Severe ○ Not done (Distress: 0-Not distressing, 1-Minimal, 2-Mild, 3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Agitation/Aggression

E4. Agitation/Aggression: Is the participant resistive to help from others at times, or hard to handle?	○ Yes ○ No ○ Not done
E4a. Agitation/Aggression: severity (patient)	○ 1: Mild ○ 2: Moderate ○ 3: Severe ○ Not done (Severity: 1-Mild, 2-Moderate, 3-Severe)

E4b. Agitation/Aggression: distress (affects you)

○ 0: Not distressing
○ 1: Minimal
○ 2: Mild
○ 3: Moderate
○ 4: Severe
○ 5: Extreme or Very Severe
○ Not done
(Distress: 0-Not distressing, 1-Minimal, 2-Mild, 3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Depression/Dysphoria

E5. Depression/Dysphoria:

Does the participant seem sad or say that he/she is depressed?

○ Yes   ○ No   ○ Not done

E5a. Depression/Dysphoria: severity (patient)

○ 1: Mild
○ 2: Moderate
○ 3: Severe
○ Not done
(Severity: 1-Mild, 2-Moderate, 3-Severe)

E5b. Depression/Dysphoria: distress (affects you)

○ 0: Not distressing
○ 1: Minimal
○ 2: Mild
○ 3: Moderate
○ 4: Severe
○ 5: Extreme or Very Severe
○ Not done
(Distress: 0-Not distressing, 1-Minimal, 2-Mild, 3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Anxiety

E6. Anxiety:

Does the participant become upset when separated from you? Does he/she have any other signs of nervousness such as shortness of breath, sighing, being unable to relax, or feeling excessively tense?

○ Yes   ○ No   ○ Not done

E6a. Anxiety: severity (patient)

○ 1: Mild
○ 2: Moderate
○ 3: Severe
○ Not done
(Severity: 1-Mild, 2-Moderate, 3-Severe)

E6b. Anxiety: distress (affects you)

○ 0: Not distressing
○ 1: Minimal
○ 2: Mild
○ 3: Moderate
○ 4: Severe
○ 5: Extreme or Very Severe
○ Not done
(Distress: 0-Not distressing, 1-Minimal, 2-Mild, 3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Elation/Euphoria

E7. Elation/Euphoria:

Does the participant appear to feel too good or act excessively happy?

◯ Yes ◯ No ◯ Not done

E7a. Elation/Euphoria: severity (patient)

◯ 1: Mild
◯ 2: Moderate
◯ 3: Severe
◯ Not done
(Severity: 1-Mild, 2-Moderate, 3-Severe)

E7b. Elation/Euphoria: distress (affects you)

◯ 0: Not distressing
◯ 1: Minimal
◯ 2: Mild
◯ 3: Moderate
◯ 4: Severe
◯ 5: Extreme or Very Severe
◯ Not done
(Distress: 0-Not distressing, 1-Minimal, 2-Mild, 3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Disinhibition

E8. Disinhibition:

Does the patient seem to act impulsively, for example, talking to strangers as if he/she knows them, or saying things that may hurt people's feelings?

◯ Yes ◯ No ◯ Not done

E8a. Disinhibition: severity (patient)

◯ 1: Mild
◯ 2: Moderate
◯ 3: Severe
◯ Not done
(Severity: 1-Mild, 2-Moderate, 3-Severe)

E8b. Disinhibition: distress (affects you)

◯ 0: Not distressing
◯ 1: Minimal
◯ 2: Mild
◯ 3: Moderate
◯ 4: Severe
◯ 5: Extreme or Very Severe
◯ Not done
(Distress: 0-Not distressing, 1-Minimal, 2-Mild, 3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Irritability/Lability

E9. Irritability/Lability:

Is the participant impatient and cranky? Does he/she have difficulty coping with delays or waiting for planned activities?

◯ Yes ◯ No ◯ Not done

E9a. Irritability/Lability: severity (patient)

◯ 1: Mild
◯ 2: Moderate
◯ 3: Severe
◯ Not done
(Severity: 1-Mild, 2-Moderate, 3-Severe)

E9b. Irritability/Lability: distress (affects you)

○ 0: Not distressing
○ 1: Minimal
○ 2: Mild
○ 3: Moderate
○ 4: Severe
○ 5: Extreme or Very Severe
○ Not done
(Distress: 0-Not distressing, 1-Minimal, 2-Mild,
3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Motor disturbance

E10. Motor disturbance:

Does the participant engage in repetitive activities
such as pacing around the house, handling buttons,
wrapping string, or doing other things repeatedly?

○ Yes   ○ No   ○ Not done

E10a. Motor disturbance: severity (patient)

○ 1: Mild
○ 2: Moderate
○ 3: Severe
○ Not done
(Severity: 1-Mild, 2-Moderate, 3-Severe)

E10b. Motor disturbance: distress (affects you)

○ 0: Not distressing
○ 1: Minimal
○ 2: Mild
○ 3: Moderate
○ 4: Severe
○ 5: Extreme or Very Severe
○ Not done
(Distress: 0-Not distressing, 1-Minimal, 2-Mild,
3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Nighttime behaviour

E11. Nighttime behaviour:

Does the participant awaken you during the night, rise
too early in the morning, or take excessive naps
during the day?

○ Yes   ○ No   ○ Not done

E11a. Nighttime behaviour: severity (patient)

○ 1: Mild
○ 2: Moderate
○ 3: Severe
○ Not done
(Severity: 1-Mild, 2-Moderate, 3-Severe)

E11b. Nighttime behaviour: distress (affects you)

○ 0: Not distressing
○ 1: Minimal
○ 2: Mild
○ 3: Moderate
○ 4: Severe
○ 5: Extreme or Very Severe
○ Not done
(Distress: 0-Not distressing, 1-Minimal, 2-Mild,
3-Moderate, 4-Severe, 5-Extreme & Very severe)

(NPI-Q) Appetite/Eating

E12. Appetite/Eating: ⃝ Yes ⃝ No ⃝ Not done

Has the participant lost or gained weight, or had a
change in the type of food he/she likes?

E12a. Appetite/Eating: severity (patient)

⃝ 1: Mild
⃝ 2: Moderate
⃝ 3: Severe
⃝ Not done
 (Severity: 1-Mild, 2-Moderate, 3-Severe)

E12b. Appetite/Eating: distress (affects you)

⃝ 0: Not distressing
⃝ 1: Minimal
⃝ 2: Mild
⃝ 3: Moderate
⃝ 4: Severe
⃝ 5: Extreme or Very Severe
⃝ Not done
 (Distress: 0-Not distressing, 1-Minimal, 2-Mild,
 3-Moderate, 4-Severe, 5-Extreme & Very severe)

Section F: Lawton Activities of Daily Living (ADL)
LAWTON - BRODY
INSTRUMENTAL ACTIVITIES OF DAILY LIVING SCALE (I.A.D.L.)

* ♀♂ In the late 1960s, Lawton and Brody used the scale to assess all eight domains of function for women but only five for men (food preparation, housekeeping, and laundry were excluded).

A summary score ranges from 0 (low function, dependent) to 8 (high function, independent) for women and 0
through 5 for men to avoid potential gender bias.

F1a. Ability to use telephone

⃝ 1 - Operates telephone on own initiative; looks up and dials numbers, etc.
⃝ 1 - Dials a few well-known numbers
⃝ 1 - Answers telephone but does not dial
⃝ 0 - Does not use telephone at all

F1b. Shopping

⃝ 1 - Takes care of all shopping needs independently
⃝ 0 - Shops independently for small purchases
⃝ 0 - Needs to be accompanied on any shopping trip
⃝ 0 - Completely unable to shop

F1c. ♀ Food preparation *

⃝ 1 - Plans, prepares and serves adequate meals independently
⃝ 0 - Prepares adequate meals if supplied with ingredients
⃝ 0 - Heats, serves and prepares meals or prepares meals but does not maintain adequate diet
⃝ 0 - Needs to have meals prepared and served

F1d. ♀ Housekeeping *

◯ 1 - Maintains house alone or with occasional assistance
◯ 1 - Performs light daily tasks such as dishwashing bed making
◯ 1 - Performs light daily tasks but cannot maintain acceptable level of cleanliness
◯ 1 - Needs help with all home maintenance tasks
◯ 0 - Does not participate in any housekeeping tasks

F1e. ♀ Laundry *

◯ 1 - Does personal laundry completely
◯ 1 - Launders small items, rinses stockings, etc
◯ 0 - All laundry must be done by others

F1f. Mode of transportation

◯ 1 - Travels independently on public transport or drives own car
◯ 1 - Arranges own travel via taxi, but does not otherwise use public transport
◯ 1 - Travels on public transport when accompanied
◯ 0 - Travel limited to taxi or automobile with assistance of another
◯ 0 - Does not travel at all

F1g. Responsibility for own medications

◯ 1 - Is responsible for taking medication in correct dosages at correct time
◯ 0 - Takes responsibility if medication is prepared in advance in separate dosage
◯ 0 - Is not capable of dispensing own medication

F1h. Ability to handle finances

◯ 1 - Manages financial matters independently, collects and keeps track of income
◯ 1 - Manages day-to-day purchases, but needs help with banking, major purchases, etc
◯ 0 - Incapable of handling money

Section G: Assessor information

G1. Please enter the name of the person who collected the information

_____

G2a. What is his/her professional role?

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

G2b. If "Other", please specify role

_____

G3. Does his/her role involve working on stroke wards?   ◯ Yes   ◯ No

G4. Please enter your name if you did not collect the information

_____

G5. Please sign the form

_____

(✍ Signature)

Assessment completed

G6. Date & time assessment completed? Enter date and
time the assessment was completed. This will be used
to monitor the time required to complete the test.

_____

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