

PhEAST Working Practice Document 012 **Title: Randomisation**

Patients who consent (individually, or by personal/professional legal representative) to participate in the trial will be randomised by a member of their local research team within **4 to 31 days** of stroke onset. Randomisation is done via bespoke, secure web-based system, maintained by the central Stroke Trials Unit in Nottingham.

Randomisation FAQs:

Q: What if we're unable to obtain certain data points?

A: Please click the 'M' symbol next to the question, and click not done or not known. If there is a not an 'M' symbol next to it, this information is required in order to proceed to randomisation

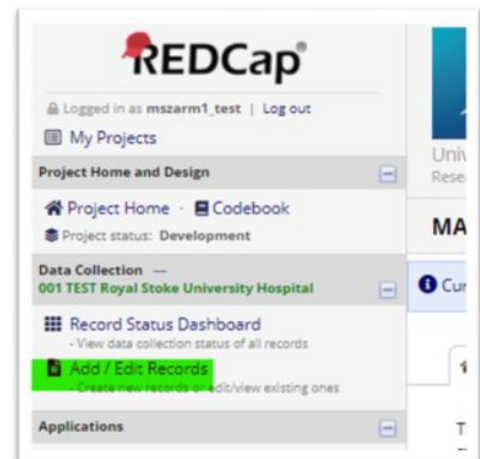
Q: Which forms need completing prior to randomisation?

A: Eligibility, Day 000, Day 000 Clinical and Day 000 EQ-5D-5L – please complete Day 000 cognition and Day 000 IQCODE as close as possible to randomisation (if incomplete this will not stop randomisation, but we like them to be done as close together as possible)

Q: Who can randomise?

A: Anyone who is delegated to do so on the log. Ensure it's not someone who will be completing blinded follow ups, as the randomisation result will blind them.

1. You will need to login into REDCap and then select the 'PhEAST' project. Once you're in PhEAST REDCap, head towards the column on the left-hand side of the page and select 'Add/Edit Records'



2. Then proceed to 'Add new record'.



The screenshot shows the 'Add/Edit Records' form. At the top, it says 'Total records: 36 / In group: 22'. Below that is a field 'Choose an existing Participant ID' with a dropdown menu showing '-- select record --'. The 'Add new record' button is highlighted in green.

3. In the new data entry, select 'Eligibility' and then complete this form.

NEW Record ID C001-0015

Data Collection Instrument	Status
Eligibility	<input type="radio"/>
Day 000	<input type="radio"/>
Day 000 Clinical	<input type="radio"/>
Day 000 EQ-5D-5L	<input type="radio"/>

Eligibility

Adding new Record ID C001-0015

Record ID: C001-0015

Eligibility form

Trial Identifiers:
 Name: Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)
 UK ISRCTN98886991
 UK IRAS306761
 UK CPMS 50913
 AT national data registry *
 WHO UTN U1111-1273-9942

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

Age >=18 years? (Must be Yes to be eligible) Yes No

Recent stroke between 4 and 31 days previously? (Must be Yes to be eligible) Yes No

Clinical dysphagia defined as a functional oral intake scale (FOIS) score of 1 (nothing by mouth, feeding by NGT/PEG) or 2 (tube dependent with minimal attempts of food or liquids)? (Must be Yes to be eligible) Yes No

Non-stroke dysphagia, e.g. due to traumatic brain haemorrhage, subarachnoid haemorrhage, brain tumour, Parkinson's disease, multiple sclerosis, severe dementia, head or neck cancer? (Must be No to be eligible) Yes No

Pre-stroke dysphagia? (Must be No to be eligible) Yes No

4. Once complete, click 'Save & Exit Form'

Assessor information

Please enter your name?

What is your professional role?
 Doctor
 Coordinator, research
 Nurse, clinical
 Nurse, research
 Physiotherapist
 Occupation therapist
 Speech & Language therapist
 Other

Does your role involve working on stroke wards? Yes No

Please sign the form [Add signature](#)

Form Status

Complete?

[Save & Exit Form](#) [Save & Go To Next Form](#) [Cancel](#)

5. Repeat steps 3-4 for 'Day 000', 'Day 000 Clinical' and 'Day 000 EQ-5D-5L' forms. Once all these 4 forms are complete on the picture you can move onto the next step.

Record ID C001-0015 LKI
 001 TEST Royal London Hospital

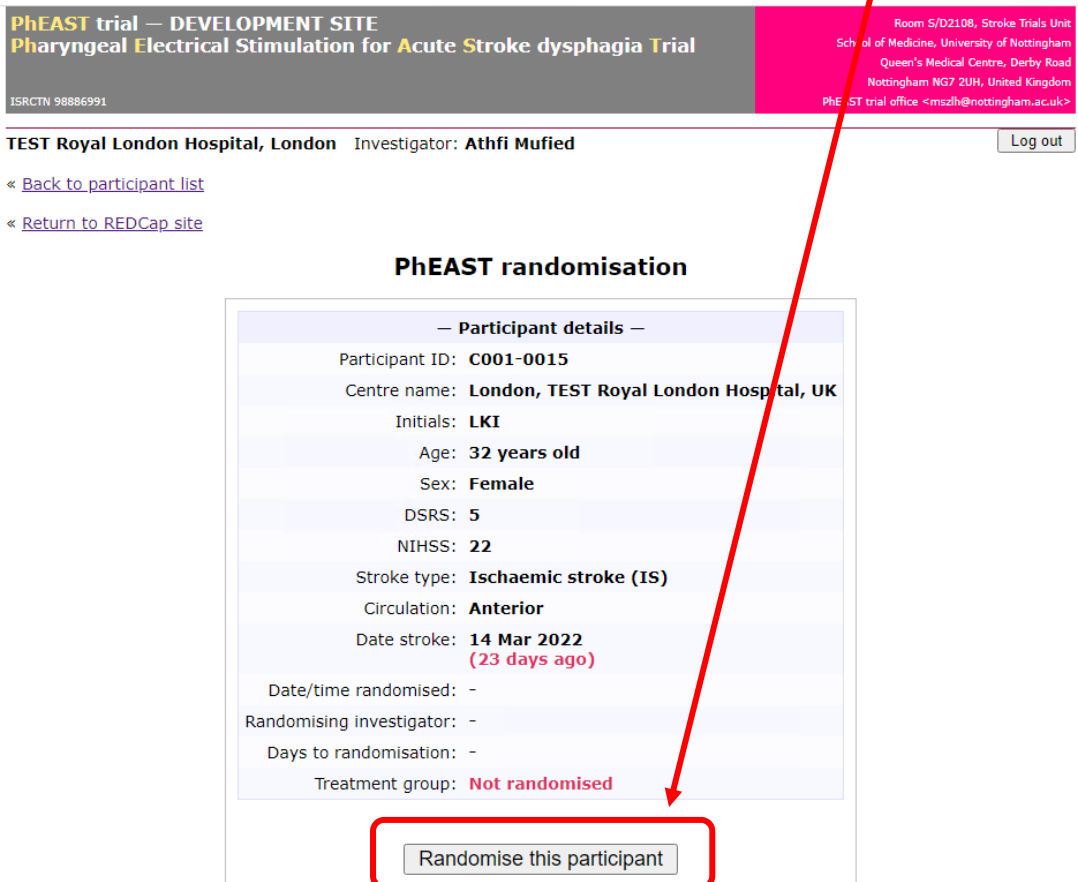
Data Collection Instrument	Status
Eligibility	<input checked="" type="radio"/>
Day 000	<input type="radio"/>
Day 000 Clinical	<input type="radio"/>
Day 000 EQ-5D-5L	<input type="radio"/>

- Head back towards the left-hand side of the page and click the 'Randomisation' link under 'Project Bookmarks'



The screenshot shows a 'Project Bookmarks' menu with four items: 'Randomisation', 'Supporting site', 'Delegation log', and 'Trial documents'. The 'Randomisation' item is highlighted with a red box.

- Check the information in the randomisation summary and then click 'Randomise this participant'.



The screenshot displays the PhEAST randomisation summary for a participant. The participant's details are as follows:

— Participant details —	
Participant ID:	C001-0015
Centre name:	London, TEST Royal London Hospital, UK
Initials:	LKI
Age:	32 years old
Sex:	Female
DSRS:	5
NIHSS:	22
Stroke type:	Ischaemic stroke (IS)
Circulation:	Anterior
Date stroke:	14 Mar 2022 (23 days ago)
Date/time randomised:	-
Randomising investigator:	-
Days to randomisation:	-
Treatment group:	Not randomised

Below the table, the 'Randomise this participant' button is highlighted with a red box. A red arrow points from the 'Randomise this participant' button in the previous step to this button.

8. Once complete, the following page should appear on your screen. Please click the link to get to the 'Success page'



PhEAST trial — DEVELOPMENT SITE
Pharyngeal Electrical Stimulation for Acute Stroke dysphagia Trial

ISRCTN 98886991

Room S/D2108, Stroke Trials Unit
 School of Medicine, University of Nottingham
 Queen's Medical Centre, Derby Road
 Nottingham NG7 2UH, United Kingdom
 PhEAST trial office <mszlh@nottingham.ac.uk>

Redirect page

TEST Royal London Hospital, London Investigator: Athfi Mufied Log out

« [Back to start page](#)

Please click the following link to continue.

- [Success page](#)

9. The next page should be displayed, which shows a summary of all the participant's randomisation information. This shows:

- Participant's trial ID number
- The name of the randomising investigator
- Participant's allocated treatment arm.



PhEAST trial — DEVELOPMENT SITE
Pharyngeal Electrical Stimulation for Acute Stroke dysphagia Trial

ISRCTN 98886991

Room S/D2108, Stroke Trials Unit
 School of Medicine, University of Nottingham
 Queen's Medical Centre, Derby Road
 Nottingham NG7 2UH, United Kingdom
 PhEAST trial office <mszlh@nottingham.ac.uk>

Participant submission

TEST Royal London Hospital, London Investigator: Athfi Mufied Participant ID: C001-0015 Initials: LKI Sex: Female Log out

Assigned treatment

« [Back to participant list](#)

« [Return to REDCap site](#)

10. Click into the secure vault site to enter the participant's contact details, which will be required for follow-up.

11. Identifiable data will be kept separately in the secure vault, whereas all other data will be kept in the REDCap database. For more information on the secure vault process please see WPD 010 Secure Vault Uploads.


Thank you for your submission – your randomisation record has been successfully submitted to the database.

This participant was randomised to the **Pharyngeal electrical stimulation** treatment group.

PES on top of guideline-based standard-of-care. PES will be administered on days 1-6 using a commercial catheter with integral feeding tube. PES involves six daily 10 minute treatments at 5 Hz; threshold and tolerability currents will be assessed and the treatment current set at threshold + 0.75 x (tolerability - threshold) with current generated by a base-station.

Please **do not** write down the treatment group.
 You may wish to print this page. Print

- To view the data you have entered, please [click here](#).
- Please enter the participant's contact details into the [secure vault](#). These will be encrypted and stored separately, **not** in the pseudonymised database that you are currently logged into for PhEAST.

 Switch to the secure vault site

Please don't forget to provide us with copies of the following.

- Consent form(s)
- Drug chart (showing treatment prescribed and time given)
- Chest X-ray report
- Daily log (once complete)

Participant details	
Participant ID:	C001-0015
Initials:	LKI
Sex:	Female
Date of birth:	24 Mar 1990
Age at randomisation:	32 years old
Centre name:	TEST Royal London Hospital
DSRS:	5
NIHSS:	22