TRIAL MANUAL

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

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To assess whether Pharyngeal Electrical Stimulation (PES) is safe and effective at improving post-stroke dysphagia (PSD); does PES reduce pneumonia and hospital length of stay and therefore improve recovery?

Contents:

1. INTRODUCTION

The University of Nottingham are sponsoring a trial which is looking at the treatment of patients with swallowing problems (dysphagia) following acute stroke. Dysphagia in the early period after stroke is often managed through modifications to nutrition, be that changes to thickness and texture of food and drink, or through non-oral nutrition (nasogastric tube feeding, NGTF). The trial aims to examine whether electrical stimulation of nerves in the pharynx (throat) can speed up recovery to normal feeding reducing the need for compensatory modifications and NGTF, thus reducing length of stay in hospital. A common complication for patients with dysphagia, particularly those requiring NGTF, is the increased occurrence of pneumonia and the trial will also look at whether the incidence/severity of this is reduced.

Your site has agreed to take part in the trial.
Each participant will have 6 days of intervention at the site with data collection on days 1-6 and day 14. Follow up at 3 months will be carried out by the central co-ordinating centre.

2. WHAT IS THE PURPOSE OF THE TRIAL?

- To see if pharyngeal electrical stimulation (PES) improves functional swallowing as measured by the dysphagia severity rating scale (DSRS), functional oral intake scale (FOIS) and feeding status scale (FSS).
- To see if PES improves recovery by reducing pneumonia, the number of days needed to stay in hospital and longer-term quality of life outcome.

3. COGNITION SUB-STUDY

- The cognition sub-study will look at post-stroke cognitive impairment
- Adequate assessment of cognition and it's temporal trajectory in patients with severe ischemic stroke or intracerebral haemorrhage is often not performed
- The cognition sub-study will assess cognition at baseline, day 14, day 90, day 180 and day 365

4. HOW DO I SET THE TRIAL UP?

Having expressed interest in the trial, the research team will have:
- Had a follow up call with the trial coordinator to discuss the trial
- Confirmed that the site has capacity to participate in the trial
- Agreed a contract with University of Nottingham
- Identified lead staff who will be trained and take part
- Had a virtual SIV with the University of Nottingham Stroke Trials Team
- Had a training session led by the supplier of the devices, Phagenesis Ltd

5. WHO CAN ENTER THE TRIAL?

Inclusion criteria

1. 800 hospitalised adults:
2. Age >=18 years.
3. Recent (4-31 days) ischaemic or haemorrhagic, anterior or posterior circulation, stroke (as diagnosed clinico-radiologically) at a stroke centre.
4. 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).
5. NIHSS item 1a score of 0, 1 or 2 (where the patient requires repeated stimulation to arouse).

Women of childbearing age may be included since the treatment time is short (6 daily 10 minute sessions) with no residual effects.

Exclusion criteria

1. 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.
2. Pre-stroke dysphagia or dependency (modified Rankin scale, mRS 4/5).
3. NIHSS item 1a score of 2 (where the patient only responds to pain) or NIHSS item 1a score of 3
4. Patient expected to be repatriated to a separate organisation.
5. Patient expected to be rehabilitated at a separate organisation.
6. Patient not likely to be in the treating hospital for at least 14 days.
7. Ongoing or anticipated ventilation/intubation/tracheostomy.
8. Use or planned use of electrical or magnetic stimulation (e.g. NMES, rTMS).
9. Malignant middle cerebral artery syndrome (although this typically presents before 4 days).
10. Pacemaker.
11. Need for >35% of oxygen.
12. Two or more NGT tubes pulled out unless nasal loop in place.
13. Investigator feels patient will not tolerate PES catheter.
14. Expected to be discharged or transferred to a site not running the trial during the PES treatment period.
15. Pregnancy if known at time of enrolment
16. Participating in another randomised controlled treatment trial for post-stroke dysphagia.

Study participants will be participating in the study for 12 months.

6. INFORMED CONSENT

Informing patients/relatives

If a patient is deemed to have capacity and is interested, please give them the Participant Information Sheet to read; if appropriate, read them the sheet taking account of any sight or hearing problems. If a patient does not have

capacity, please call their nominated relative/next of kin, and email or post them the Consultee Information Sheet or the Legal Representative Information Sheet (Scotland).

After they have read the sheet, please answer any questions that the patient or their relative might have.

Then ask them if they are interested in participating in/believe their relative would like to join the study.

If the patient/relative says no, then clearly state that they will not be in the trial. Please record this decision in the patient's notes/records.

Consent Form

6.1 participants with capacity

- The Patient Information Sheet will need to be read by the patient, and then the Consent form signed accordingly. If the patient is unable to sign the Consent form, the consent process will need to be witnessed by an independent third party, with the consent form being signed by them.
- For patients with severe communication difficulties, an aphasia friendly version of the Patient Information Sheet has been developed. Please seek advice from your local speech and language therapy team as required.
- One copy of the consent form will be kept by the participant, one will be retained in the patient's hospital records and the master copy will be kept in your site file. The informed consent process will be conducted and documented in the patient's medical notes.
- We also have an aphasia friendly information sheet and consent form, for aphasic patients with capacity

6.2 participants without capacity

- If the patient is deemed by the Investigator or designate to lack capacity (e.g. due to confusion, cognitive impairment or severe dysphasia), an opinion will be obtained from their consultee or consent from a legal representative in Scotland.
- Provide the patient or consultee/legal representative a Consultee Information Sheet or the Legal Representative Information Sheet (Scotland) and explain the research study, and then answer any questions that may arise. If the consultee cannot attend the hospital, the consultee's opinion, may be obtained remotely by videoconference or telephone/teleconference means; the Consultee Information Sheet or Legal Representative Information Sheet (Scotland) may be sent via post or email.
- Consent will be witnessed by an independent third party where approval is provided by a consultee by phone.
- One copy of the consent form will be kept by the consultee, one will be retained in the patient's hospital records and the master copy will be kept

in your site file. The informed consent process will be conducted and documented in the patient's medical notes.

6.3 Informant Consent

- As part of the cognition sub-study, we want to collect some information on the participants' cognition from their relatives
- These relatives have their own information sheet (informant information sheet) and own consent form (informant consent form / informant tel consent form)
- Informant consents will not count as accruals for your sites
- Please consent as many informants as possible, it may be difficult to collect some of the cognition information from participants due to aphasia, so informant information is really important.

7. PHAGENESIS DEVICE: BASE STATION AND CATHETER

DETAILS OF DEVICE

Manufacture

- The Phagenyx® system is manufactured by Phagenesis Ltd (Manchester UK).
- It has an EU CE Mark and FDA breakthrough device designation.
- There is no control device.
- Phagenesis will provide devices (catheters, base stations) and training in their use without charge.
- If a site has an existing base station in use, this can be used.

Packaging and labelling

- The catheter is supplied by Phagenesis Ltd as a single-use sterile product.
- The catheter and accessories are supplied in a formed tray (Figure 1).
- The tray and contents are terminally sterilized using ethylene oxide.

There are two accessory parts supplied with the catheter:

1. A Garment Clip to secure the external parts of the catheter to alleviate weight
2. A Transition Adaptor to enable standard connections for feeding delivery

Fig. 1 Image of boxed pharyngeal catheter.

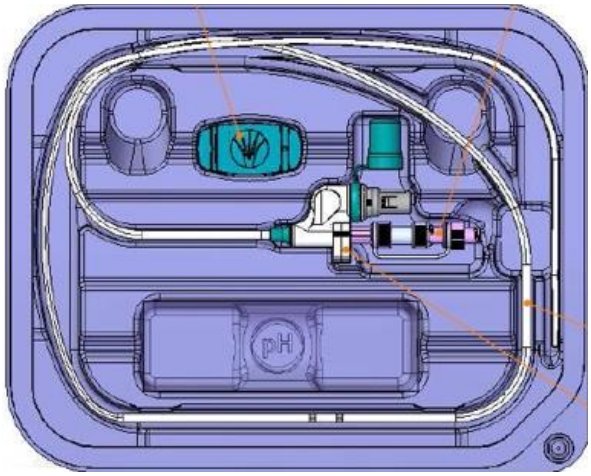
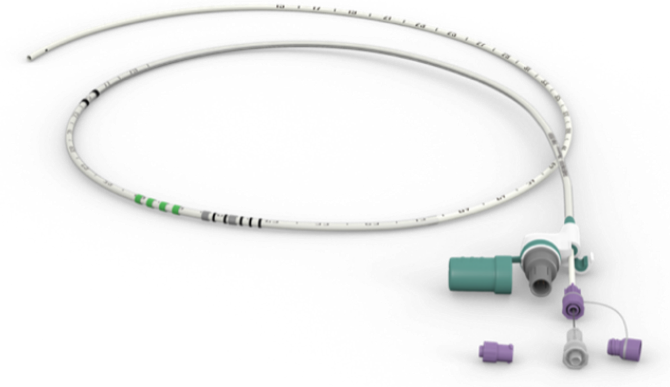


Fig 2. Image of unboxed pharyngeal catheter.



The catheter (Figure 2) design is based on that of a nasogastric feeding tube but incorporates electrodes with appropriate wiring and insulation for delivery of electrical stimulation to the lining of the pharynx.

The catheter can be used as an NGT alongside its use for stimulation, delivering enteral nutrition to the patient as needed.

Only one replacement catheter may be inserted, if pulled out before 3 treatments have been administered. If a second catheter is removed prior to completion of the treatment, no further catheters should be inserted and treatment will stop.

Please follow local policies and procedures with regards to confirmation of catheter / NG tube placement.

Phagenyx Base Station
The Base Station (Figure 3) is used to generate, optimize and monitor the delivery of electrical stimulation. It is mains operated only.

Fig. 3 Image of the Phagenyx Base Station

8. ESTABLISHING LEVELS

Screening
The Functional Oral Intake Scale (FOIS, Figure 4) is a measure of eating and drinking. It is a seven-level scale of descending severity, with 1 being the most severe score and 7 being normal eating and drinking. The FOIS has been validated in several languages and can be scored at bedside or from the medical notes.

Fig. 4 The Functional Oral Intake Scale (FOIS) (English version)

Level 1: Nothing by mouth.

Level 2: Tube dependent with minimal attempts of food or liquid.

Level 3: Tube dependent with consistent oral intake of food or liquid.

Level 4: Total oral diet of a single consistency.

Level 5: Total oral diet with multiple consistencies, but requiring special preparation or compensations.

Level 6: Total oral diet with multiple consistencies without special preparation, but with specific food limitations.

Level 7: Total oral diet with no restrictions.

To be included in the trial, participants must have a FOIS of 1 or 2 to be included i.e. requiring a NGT and not meeting their nutrition and hydration needs from oral intake.

We define a FOIS score of 2 (minimal attempts of food or liquid) as a person receiving no more than 15 teaspoons of any consistency within one day
e.g. up to 3 teaspoons of level 0 thin water only 3 times a day
OR up to 5 teaspoons of level 4 puree diet 3 times a day.

Treatment
Pharyngeal Electrical Stimulation (PES) has a 3-step process to set-up the participant's individualised treatment level. This process is completed before every treatment session. The base station will guide you through each step, in turn. Please refer to your practical training guide provided by Phagenesis.

Threshold
This is the lowest current (mA) at which the participant can feel the PES in their throat. Present them with the clear instruction:

"Tell me when you can feel stimulation in your throat".

Increase the stimulation level by one mA per second until the participant can feel the stimulation.
Do not prompt them as you increase each level - look for physical signs that they feel the stimulation as you increase the level.
The threshold level is the lowest current that the participant can feel.

Tolerance
This is the highest level of stimulation that the participant can tolerate. This will be above the treatment stimulation level. Present the participant with the clear instruction:

"Let me know when the stimulation gets too much, and you cannot continue".

Increase the mA whilst looking for physical signs of discomfort; if there is no physical reaction then increase the mA.
Remind the participant that the treatment stimulation level will be lower than their tolerance level.
Remind the patient that lower treatment stimulation levels may reduce the effectiveness of the treatment.
The tolerance level is the highest current that the participant can tolerate.

Stimulation
The base station will calculate the treatment stimulation level as:

Threshold + (0.75 x (Tolerance – Threshold))

Test the participant's optimised treatment stimulation Level for 8-seconds to ensure patient comfort. There is an option to reduce the Optimised Treatment Stimulation Level by 1mA and re-test. Only use this if the participant is unable to continue and there is a clear risk that they may not tolerate the full 10 minutes. Remind the patient that lower treatment stimulation levels may reduce the effectiveness of the treatment. But try to use the stimulation level determined by the base-station. Once the stimulation level is confirmed, continue to Treatment Delivery.

TRIAL / STUDY TREATMENT AND REGIMEN

Intervention arm: PES on top of guideline-based standard-of-care.

- PES will be administered on days 1-6 using a commercial catheter (Phagenyx®, Phagenesis Ltd, Manchester UK) with integral feeding tube
- PES involves once-daily, 10 minute treatments over 6 days with treatment at 5 Hz
- Threshold and Tolerance Levels will be assessed prior to each daily treatment
- PES current set at Threshold + 0.75 x (Tolerance - Threshold) with current generated by a base-station
- All sites will be randomised to a study within a trial (SWAT). Those sites randomised to the SWAT intervention will be re-trained on the importance of delivering adequate current if the stimulation current is too low, defined as:
  - Current <20 mA, or
  - Actual stimulation level is less than the stimulation level calculated by the base-station
- The catheter will be replaced once only, if pulled out before 3 treatments have been administered
- Treatment will be administered by PES-trained research coordinators, nurses or SLTs who are not involved in outcome assessment and data collection
- The Phagenyx Catheter can be removed following completion of 6 days of treatment or up to 30-days if used for enteral feeds

Comparator arm: Participants randomised to control will receive no PES catheter/stimulation.

A standard NGT will be used for feeding as necessary.

Table 1. Treatment schedule in order of priority:

No. of days of treatment (days of the week)	No. of days break	Resumed no. of days of treatment
6	**0**	**0**
5 (Mon-Fri)	2 (weekend)	1 (Mon)
4 (Tues-Fri)	2 (weekend)	2 (Mon-Tues)
3 (Weds-Fri)	2 (weekend)	3 (Mon-Weds)

The treatment cycle should, ideally, be 6 consecutive days.
If this is not possible, a treatment cycle should start with no less than 3 consecutive days.
If treatment can be given on one day at the week-end then use that day for treatment.

Outcome measures /assessments
Primary:
The Dysphagia Severity Rating Scale (DSRS, Figure 5) - Day 14, Day 90, Day 180 and Day 365

Fig. 5 The Dysphagia Severity Rating Scale (DSRS)

Score	Fluids	Score	Diet	Score	Supervision
4	No oral fluids	4	Non oral feeding	4	No oral feeding
3	IDDSI level 4	3	IDDSI level 4 and 5	3	Therapeutic feeding (SALT/trained staff)
2	IDDSI level 3	2	IDDSI level 6	2	Feeding by third party (untrained)
1	IDDSI level 1 and level 2	1	IDDSI level 7 easy to chew	1	Eating with supervision
0	IDDSI level 0	0	IDDSI level 7 regular	0	Eating independently

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

It is essential that assessing SLT's record detail around supervision so that the outcome assessor can calculate a DSRS score. Ensure that your SLT team is aware before recruitment starts.

DSRS scoring guidance:

Oral trials of fluid and/or food are commonly recommended for patients with post-stroke dysphagia. Scoring the DSRS can feel more difficult with patients on oral trials. We suggest the following criteria:

1. Minimal amount trials

This requires that there are no more than 15 teaspoons of any consistency given within one day. Fluid and food items should be scored as 4, and supervision scored as 3 to indicate trials are taking place.

Examples:
- 5 teaspoons of level 3 moderately thick fluids 3 times daily
- 3 teaspoons of level 4 puree yoghurt only 3 times daily

These are a DSRS = 11 (F=4+D=4+S=3) and FOIS = 2.

2. Consistent amount trials

More than 15 teaspoons of any consistency will be given each day.
Fluid and food should be scored as per the consistency advised with a supervision score of 3 to indicate trials are taking place.

Examples:
- ½ portions of level 4 puree diet + 100mls of level 2 mildly thick fluids 3 times daily = DSRS 7
- 10 tsps. of level 4 puree diet + up to 10 sips of level 1 slightly thick fluids 3 times daily = DSRS 6

Both are equivalent to a FOIS = 3.

Other outcomes:
Days 1-6 - PES Threshold, Tolerance and Treatment stimulation Levels; number of catheters used.

Day 14 – DSRS >3, FOIS, EAT-10 and feeding status score (FSS); NGT/PEG in situ; pneumonia; antibiotic use; weight; EQ5D-5L, EQ-VAS (source recorded - patient or proxy), cognition (MoCA, TICS, MMSE, semantic verbal fluency, phonemic verbal fluency, clinical diagnosis of dementia, cognition from informant, (IQCODE), dependency and disability (mRS, BI, NIHSS), frailty (CFI), mood / depression (Zung), global (Stroke Impact Scale)

Fig 6. Feeding Status Scale Scoring guide

Table 1. The Feeding Status Scale.

Intake route	Score	Level	Includes	Excludes
	1	Normal	• Regular oral diet (L7/L7 easy chew). • Normal oral fluids (L0). • Non-oral feeding route may be in situ but is not required to maintain nutrition.	• Tastes/oral trials of selected diet/fluids. • Managing some oral intake but requires non-oral supplementation to maintain nutrition.
	2	Soft	• Modified oral diet (L6 or below). • Oral fluids – normal or modified (L0-L4).	• Tastes/oral trials of selected diet/fluids. • Managing some oral intake but requires non-

Oral			• Non-oral feeding route may be in situ but is not required to maintain nutrition.	oral supplementation to maintain nutrition.
Non-oral	3	NGT	• Nasogastric tube feeding required to maintain nutrition. • May receive oral fluids – normal or modified (Lo-L4). • May receive tastes/oral trials of diet.	• Awaiting NGT placement/tube removed. • Meeting nutritional requirements through oral intake.
	4	PEG	• Percutaneous endoscopic gastrostomy feeding required to maintain nutrition. • May receive oral fluids – normal or modified (Lo-L4). • May receive tastes/oral trials of diet.	• Awaiting PEG placement. • Meeting nutritional requirements through oral intake.
	5	IV/Subcut fluids	• Non-oral supplemented fluid intake. • May receive oral fluids – normal or modified (Lo-L4). • May receive tastes/oral trials of diet.	• Meeting nutritional requirements through oral intake. • Other route of non-oral feeding in situ.
	6	Nothing	• May receive tastes/free water protocol for comfort. • May be awaiting placement of PEG/NGT.	• Meeting nutritional requirements through oral intake. • Non-oral feeding in situ.

Death/discharge - Length of stay; antibiotic use; swallowing therapy contact time; time to removal of NGT/PEG; EQ5D-5L, EQ-VAS (source recorded - patient or proxy); admitted to ICU; discharged with PEG; disposition (home, residential home, nursing home, hospital, death).

Day 90, Day 180 and Day 365 – DSRS, FOIS, EAT-10, FSS; home time; dependency (modified Rankin Scale 2), disability (Barthel Index), quality of life (EQ-5D5L/EQ-VAS.), cognition (TICS 3, MoCA, TICS, MMSE, semantic verbal fluency, phonemic verbal fluency, clinical diagnosis of dementia, IQCODE), mood (Zung 4);2,5-9 disposition, frailty (CFI), global (Stroke Impact Scale), Health Economic Resources

Safety - SAEs and SADEs over 9 days, fatal SAEs and SADEs for the remaining 81 days.

Follow up schedule.

	Screen	Baseline	Day 1-9	Day 14	Discharge or death	Day 90 †	Day 180 †	Day 365 †
Location	Hospital	Hospital	Hospital	Hosp. or outside	Hospital	Centrally	Centrally	Centrally
Eligibility	+							

Consent/proxy consent	+							
DSRS FOIS EAT-10 FSS		+		+		+	+	+
NIHSS, GCS		+		+				
Randomisation		+						
PES vs no PES			<>6 days					
Targeted outcomes: pneumonia			<	>				
All SAEs			<>					
Device-related (S)AEs			<	>				
Fatal SAEs			<	=	=	>		
All-cause mortality						+	+	+
Disposition					+	+	+	+
QoL: EQ-5D, EQ-VAS		+		+	+	+	+	+
mRS, BI, TICS, ZDS, home-time		+(mRS, BI)		+(mRS, BI)		+	+	+
Resource use					+	+		
Global (Stroke Impact Scale)		+		+		+	+	+
Cognition: MoCA, MMSE, semantic verbal fluency, phonemic verbal fluency, dementia diagnosis, IQCODE,		+		+		+	+	+
Frailty (CFI)		+		+		+	+	+

- Day 14-1 +3 (days 13-17) by hospital assessor blinded to treatment (please see PhEAST Blinding WPD 008 for best practice on blinding)
- Discharge/death by hospital assessor blinded to treatment
- Day 90±7, Day 180±7, Day 365±7 by central telephone assessor blinded to baseline, treatment and in-hospital data (or by post)

9. ENTERING DATA

Please see the follow up schedule for data collection time points. Sites can either enter data directly into the database or print off the CRFs and transcribe the data into the E-CRF as soon as possible after data collection.

The nominated senior nurse/ team leaders will be responsible for entering data for each participant into the online database – REDCap. The database is

accessed online via a standard internet browser (Chrome, Firefox, Safari), i.e. on a computer (PC or Mac), tablet (Android or iPad) or smart phone (Android or iPhone).

Data will be entered at a number of phases of the trial. The forms are listed below, with details of each one in section **10.**

Timing	**Form**
Screening	Eligibility
Baseline	Day 000, Day 000 Clinical, Day 000 EQ-5D-5L, IQCODE, Cognition
START PES	
Day 1 – 6 Treatment	PES 1 – PES 6
Day 14	Day 14 Primary Outcome, Day 14 EQ-5D-5L, IQCODE, Cognition
Discharge / Death	Discharge / Death, Discharge EQ-5D-5L
Day 90, Day 180 & Day 365	Done by central team
Safety	SAE /Device Deficiency

It is important that each form is completed as soon as the information is due. Ideally, data should be entered straight into the database. Alternatively, it could be collected onto paper forms and then entered onto the database.

Using the E-CRF.

Setting up and enrolling participants

Once your site has been enrolled in the trial and set up on the database, the trial office will set up individual log-ins to the REDCap database using the staff email address(es) provided by your Trust.

To log-in, enter the username and temporary password (which will be sent to you separately). The temporary password will need to be reset.

Once logged in, click 'My Projects' (Fig.1) to take you through to the Projects page. Then click on project 'PhEAST' to take you to the database (Fig 2).

Fig. 1

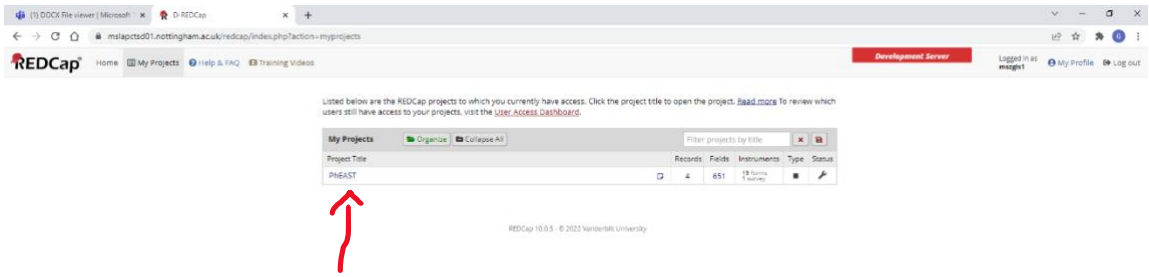
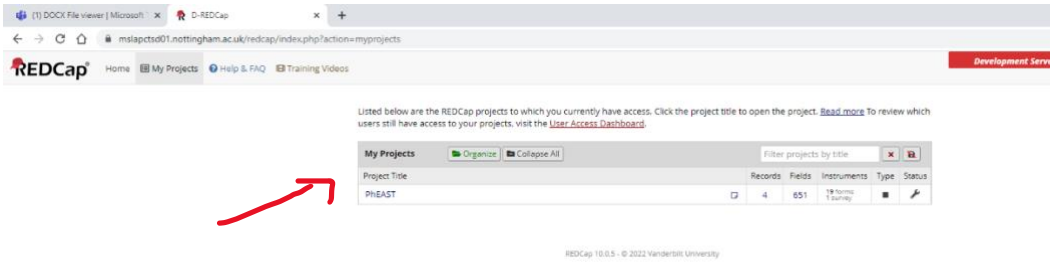


Fig.2



After clicking project 'PhEAST', you will be taken through to your site's page. On your site's page you will see a list of 'Current Users'. This is a list of all staff registered at the site, and those in the PhEAST trial team who have access to this site's data.

In order to enrol a patient, click 'Add / Edit Records' in the toolbar on the left of the page (Fig. 3). Once in the 'Add / Edit Records' page, click 'Add new record' (Fig 4.)

Fig. 3

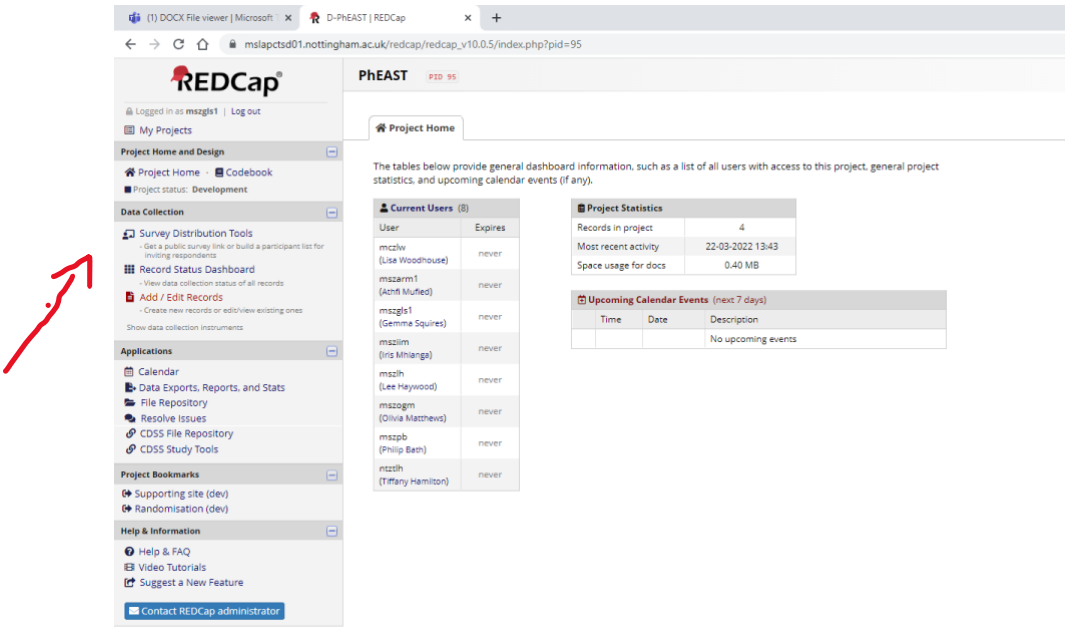
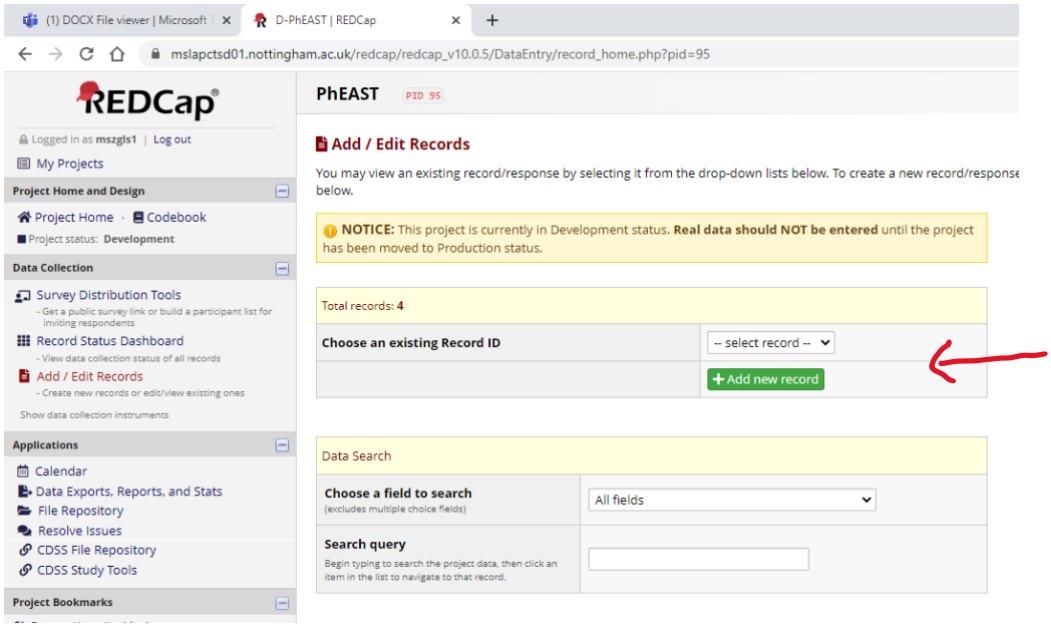

(1) DOCX File viewer | Microsoft
D-PhEAST | REDCap
mslapctsd01.nottingham.ac.uk/redcap/redcap_v10.0.5/index.php?pid=95
REDCap
Logged in as mszgls1 | Log out
My Projects
Project Home and Design
Project Home · Codebook
Project status: Development
Data Collection
Survey Distribution Tools
- Get a public survey link or build a participant list for inviting respondents
Record Status Dashboard
- View data collection status of all records
Add / Edit Records
- Create new records or edit/view existing ones
Show data collection instruments
Applications
Calendar
Data Exports, Reports, and Stats
File Repository
Resolve Issues
CDSS File Repository
CDSS Study Tools
Project Bookmarks
Supporting site (dev)
Randomisation (dev)
Help & Information
Help & FAQ
Video Tutorials
Suggest a New Feature
Contact REDCap administrator
PhEAST
PID 95
Project Home
The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).
Current Users (8)
User
Expires
mczlw (Lisa Woodhouse) never
mszarm1 (Athfi Mufied) never
mszgls1 (Gemma Squires) never
mszlim (Iris Mhlanga) never
mszlh (Lee Heywood) never
mszogm (Olivia Matthews) never
mszpb (Philip Bath) never
ntzzlh (Tiffany Hamilton) never
Project Statistics
Records in project 4
Most recent activity 22-03-2022 13:43
Space usage for docs 0.40 MB
Upcoming Calendar Events (next 7 days)
Time
Date
Description
No upcoming events

Fig. 4

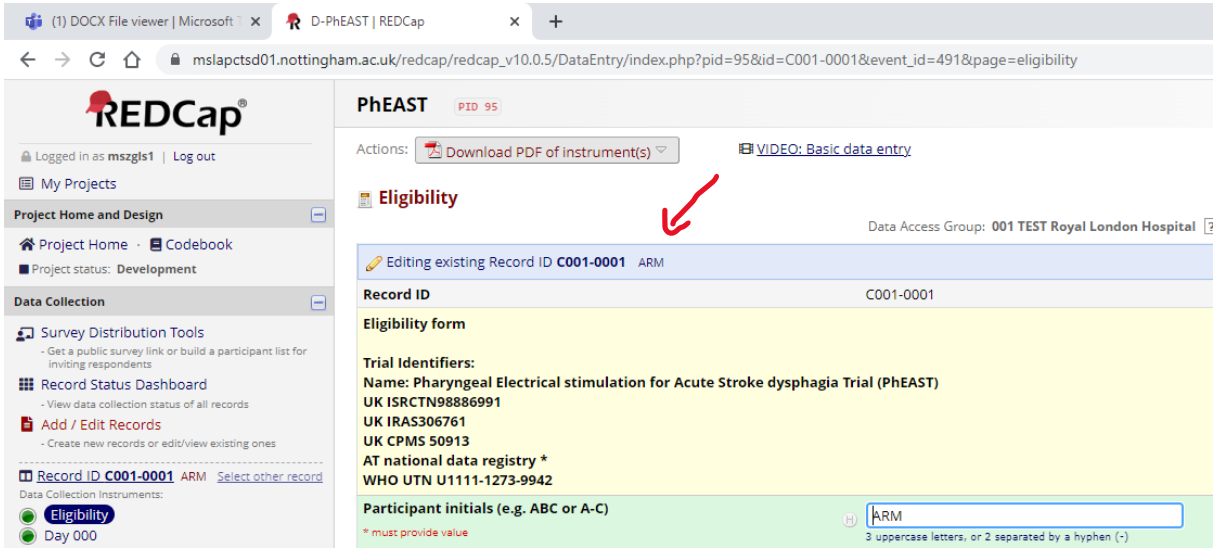

(1) DOCX File viewer | Microsoft
D-PhEAST | REDCap
mslapctsd01.nottingham.ac.uk/redcap/redcap_v10.0.5/DataEntry/record_home.php?pid=95
REDCap
Logged in as mszgls1 | Log out
My Projects
Project Home and Design
Project Home · Codebook
Project status: Development
Data Collection
Survey Distribution Tools
- Get a public survey link or build a participant list for inviting respondents
Record Status Dashboard
- View data collection status of all records
Add / Edit Records
- Create new records or edit/view existing ones
Show data collection instruments
Applications
Calendar
Data Exports, Reports, and Stats
File Repository
Resolve Issues
CDSS File Repository
CDSS Study Tools
Project Bookmarks
PhEAST
PID 95
Add / Edit Records
You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response below.
NOTICE: This project is currently in Development status. Real data should NOT be entered until the project has been moved to Production status.
Total records: 4
Choose an existing Record ID
-- select record --
Add new record
Data Search
Choose a field to search
(excludes multiple choice fields)
All fields
Search query
Begin typing to search the project data, then click an item in the list to navigate to that record.

This will generate a Participant ID (comprising the site ID and Individual participant Identifier) and bring up the participant's individual 'Record Home Page'.

The grid displays the form-by-form progress of the new participant's records. To fill in each form, click on the button in each section.

Once the eligibility form is complete, the initials of the patient will top each form (Fig 5.).

Fig 5.



10.2 Randomising a participant

In the new data entry, select 'Eligibility' and complete the eligibility form (fig 6 & 7)

Fig 6.

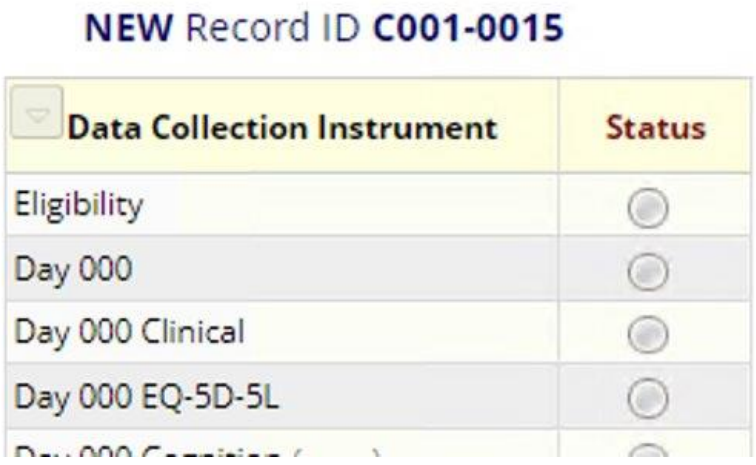
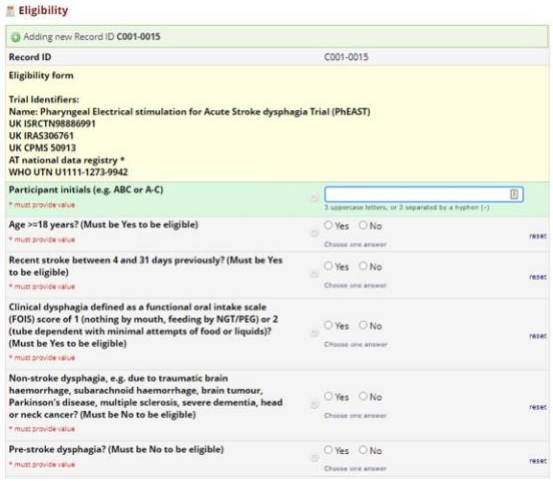
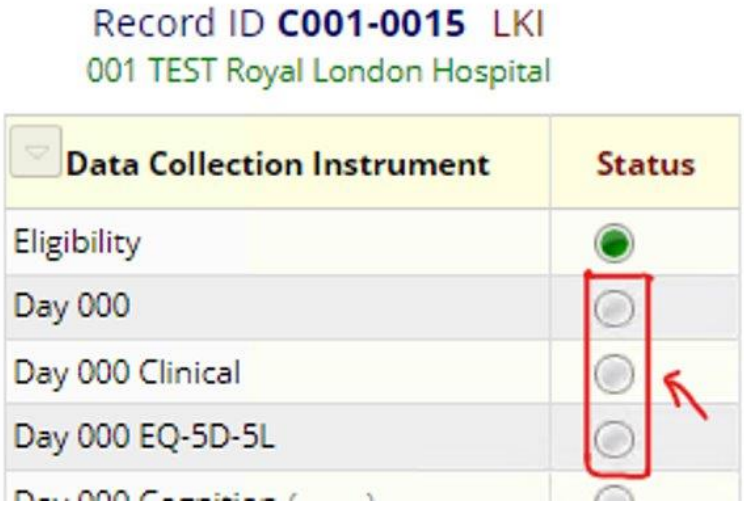


Fig 7.



Once complete, click 'save and exit form', then open and complete the 'Day 000', 'Day 000 Clinical', and 'Day 000 EQ-5D-5L' form (Fig 8)

Fig 8.



Once 'Eligibility', 'Day 000', 'Day 000 Clinical', and 'Day 000 EQ-5D-5L' forms are complete, Click the 'Randomisation' link under Project Bookmarks (Fig 9)

Fig 9.

Check the information in the randomisation summary and then click 'Randomise this participant' (Fig 10)

Fig 10.

Once complete, the following page should appear (Fig 11)

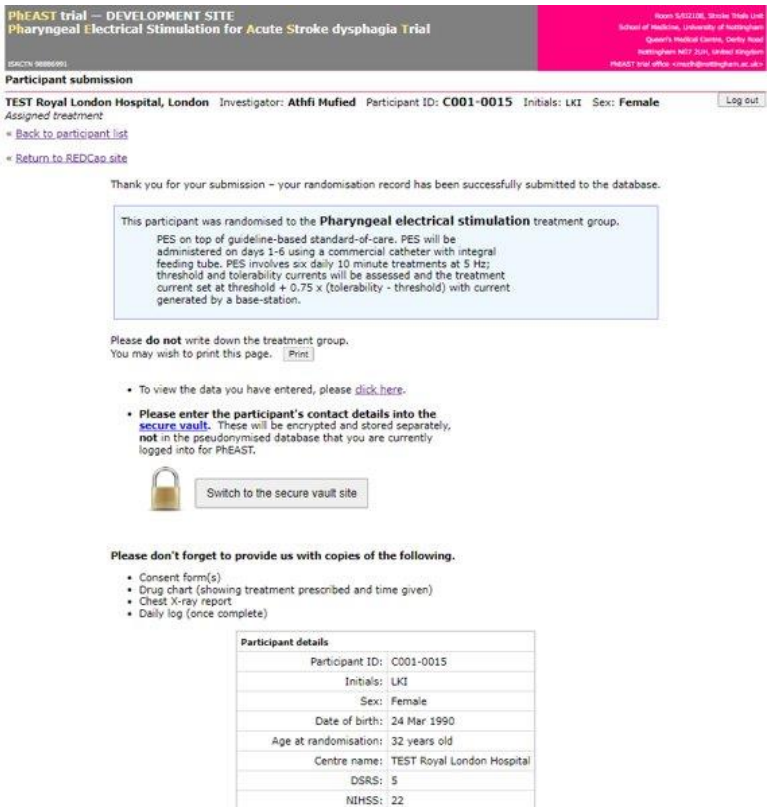
Fig 11.

The page below (Fig 12) should be displayed, which shows a summary of all of the participant's randomisation information.
This shows:

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

Click into the secure vault site to enter the participant's contact details, which will be required for follow-up.
Identifiable data will be kept separately in the secure vault, whereas all other data will be kept in the REDCap database.

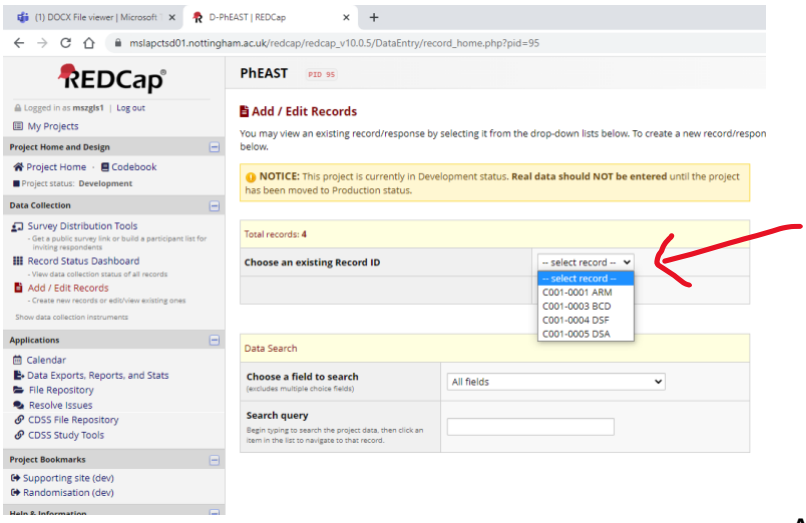
Fig 12.



10.2 Updating participant records

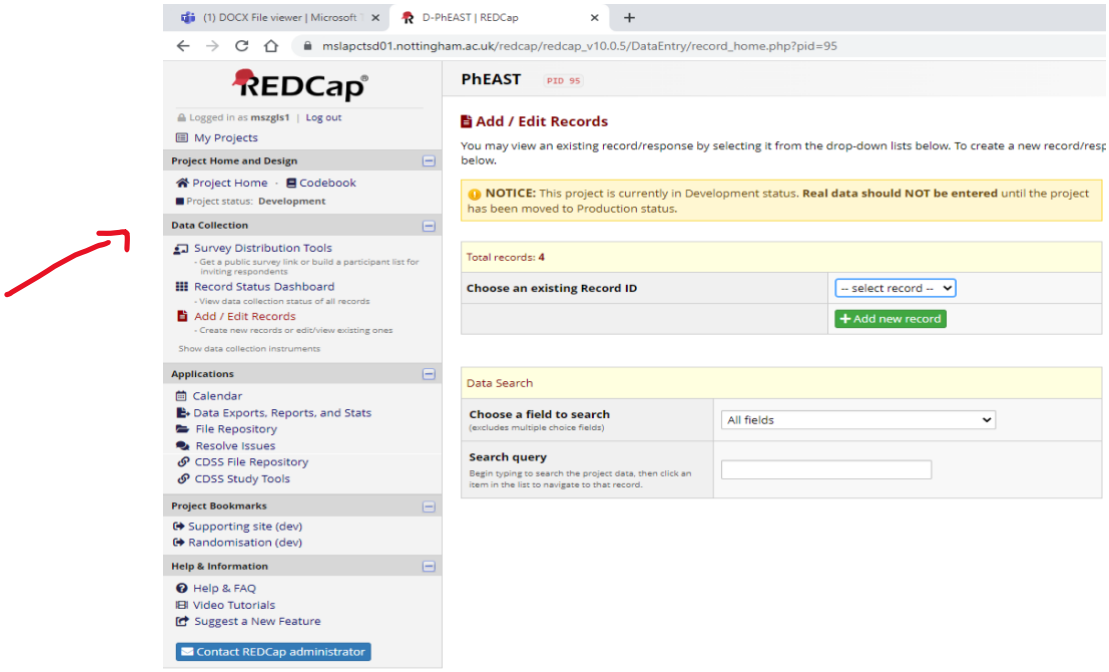
If you want to update a current Participant's records or check a status, you can select the record through the 'Add / Edit Records' tab (see Fig 13).

Fig 13.



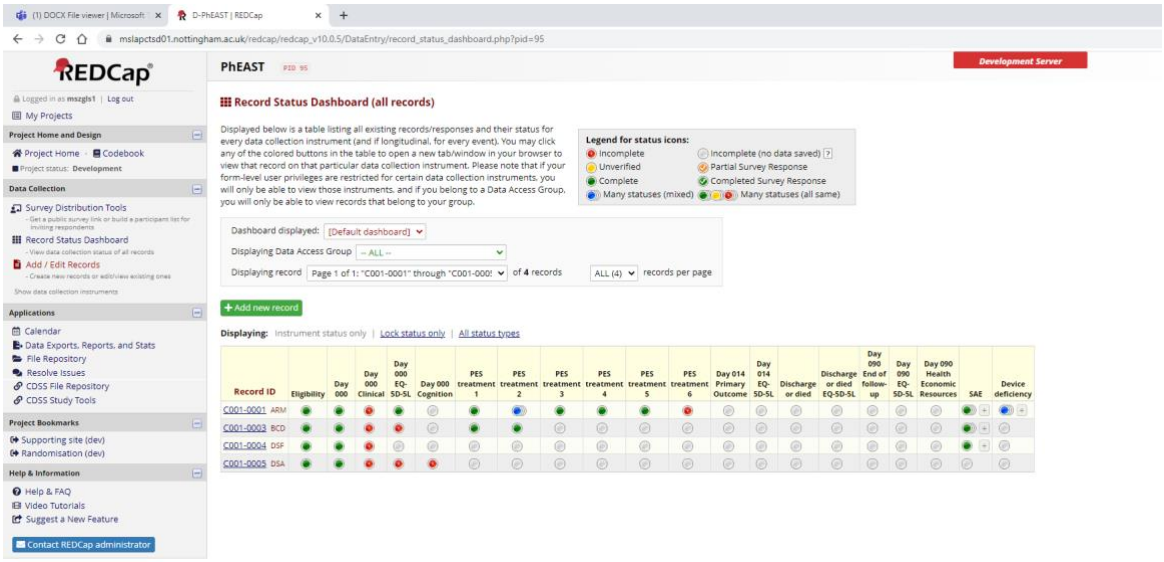
Alternatively, to see all participants at your site enrolled in the trial, click Record Status Dashboard (Fig 14).

Fig 14.



Once in the dashboard, any participant record can be selected which will take you through to the individual participant's record (Fig 15).

Fig 15.



Contact the Trial Manager or Trial Coordinator if you are having problems entering data.

Summary of Forms (in order)

Screening Forms

- **Eligibility Form**
  When to complete: Before baseline (if consent/consultee advice form has been completed.)
  Purpose: To confirm eligibility for trial.

- **Randomisation Form**
  When to complete: After consent, before baseline.
  Purpose: To collect detail and trigger randomisation.

- **Baseline Form**
  When to complete: After consent, before start of treatment.
  Purpose: To establish baseline measures prior to intervention start.

During Treatment

Stimulation levels should be entered to the online database after each session. This must be done immediately so that low treatment stimulation levels can be identified, and support given before treatment completion.

Day 14 Forms

Purpose: Primary and secondary outcome recording

Day 90, Day 180 and Day 365 follow up is done by central co-ordinating centre

Please upload all consent forms (within 24 hours), GP letters, file notes and signed SAE forms to the supporting site.

9. ADVERSE EVENT AND SERIOUS ADVERSE EVENT REPORTING

- All Serious Adverse Events to be reported via the E-CRF days 0-9
- All procedure / device related Serious Adverse Events to be reported via the E-CRF days 0-14
- All fatal Serious Adverse Events to be reported via the E-CRF days 10-90
- Abnormal laboratory results which are deemed clinically significant by the investigator and that lead to a change, or temporary or permanent discontinuation of the device should be reported as an Adverse Event in the E-CRF
- All AEs / SAEs should be followed until resolution or for at least 30 days after discontinuation of the use of the device, whichever comes first

10. WITHDRAWING FROM THE TRIAL, STOPPING TREATMENT OR MISSING A FOLLOW-UP

Withdrawing from the trial.

- If the participant does not want to continue in the trial in any way and does not want to participate in any more follow-up. Although the participant does not have to give a reason(s), please record any reason, if given, in the End of Study form. Please inform the Trial Coordinator via email if a participant withdraws from the trial.

Stopping treatment.

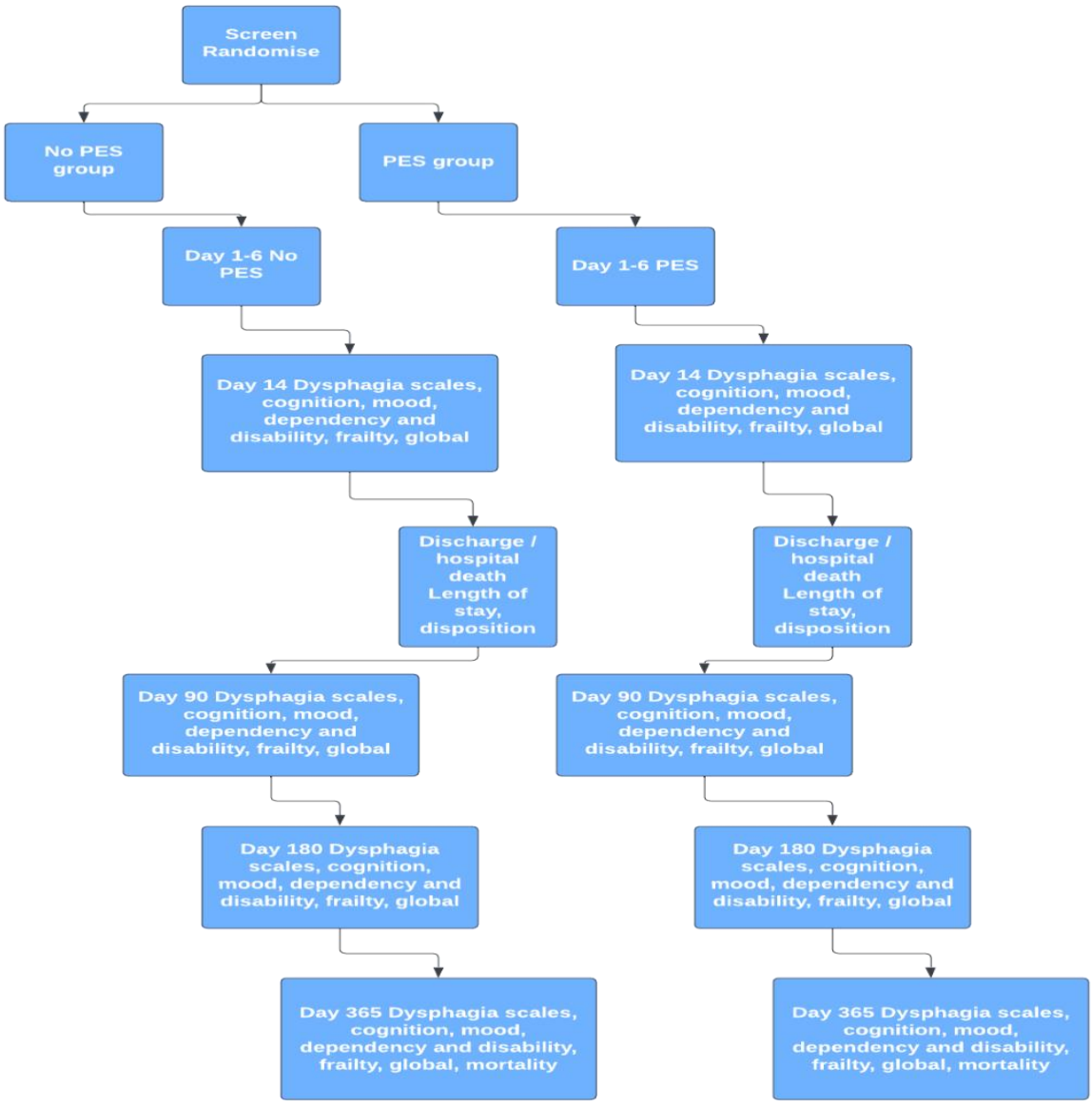
- Treatment will cease if participants regain normal feeding or are discharged early.
- If a participant has a catheter pulled out before 3 treatments are complete, the catheter will be replaced once only. If the second catheter is pulled out, treatment will cease.
- Participants may stop treatment if they, their family (if they lack capacity) or their clinical team wish for this.

Missing a follow up.

- Day 14 follow ups can be completed on days 13-17
- If a participant is busy with other staff members or does not want to complete a follow up at a particular time, please try again later on in the day, or the day after if the timeline allows this.

11. SUMMARY OF THE TRIAL

Trial Flowchart



TRIAL Primary endpoint

Dysphagia assessed using DSRS based on bedside clinical assessment/management conducted at days 14-1 +3 post randomisation.

Outcome assessment will be assessed by DSRS/FOIS-trained research coordinators, nurses or SLTs who are not involved in treatment, e.g. can use SLT from another care group in the hospital as long as listed on the delegation log.

Please see blinding WPD 008 for more advice on how to complete the blinded follow ups / trial primary endpoint.