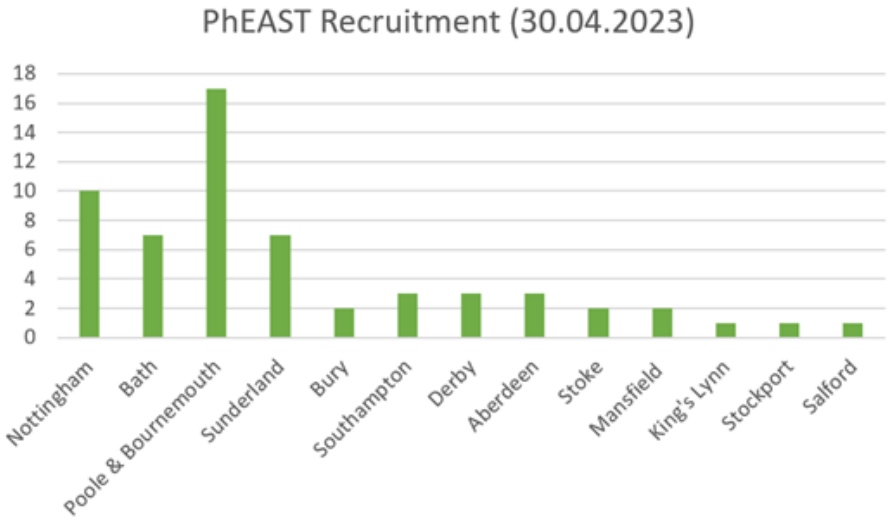
PHEAST NEWSLETTER | APRIL 2023
PHEAST@NOTTINGHAM.AC.UK

Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial

PhEAST

Milestone Update



Well done to all our recruiting sites in April! 59 participants and 15 open sites

Meet the team!

Swallowing problems are very common after stroke and yet have no proven treatment. We are delighted to have you all on board working on the PhEAST trial at your sites. We believe that it has an excellent chance of showing that pharyngeal electrical stimulation improves swallowing after stroke and so could benefit many people in the NHS. Please continue to screen daily and offer the trial to as many patients as possible. Recruitment into PhEAST needs to increase in order to help us with our stop-go decision in June. Thank you all for your hard work so far!

Professor Philip Bath,
Chief Investigator Of PhEAST

I'm really enjoying working with you all, and it's been great to meet some of you recently at monitoring visits, thank you for being so accommodating!
I'm a clinical research practitioner by background, having worked in stroke research for five years now. I'm really enjoying managing the PhEAST trial - dysphagia is a real problem for many patients, and it's exciting to be working on a trial investigating a potential treatment for this.
As always, I'm here to help, so please get in touch with any queries either by phone or email!

Gemma Squires
Clinical Trial Manager of PhEAST

Investigator Meetings

It was great to see so many of you at our latest investigator meeting, held on the 26th April 2023. An overview of randomisation was given by Gemma (Clinical Trial Manager) and then the open discussion involved talking about the latest dysphagia guidelines, and how blinded assessments can work with instrumental assessments. Special thanks to the PIs at Nottingham (Lisa Everton), Poole & Bournemouth (Deborah Broadbent) and Derby (Jacqueline Benfield) for their support and advice for more novice sites!
If you would like access to the recording please contact pheast@nottingham.ac.uk

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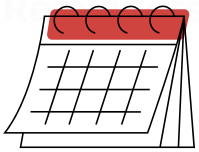
FAQs

Q: Can we include patients who are experiencing total sensory loss?
A: Yes, these patients are great candidates to potentially receive PES.
Q: Do we need to consent an informant even if the main trial participant has capacity?
A: Yes please, as the informants give us a different perspective on the participants' cognition. Please see the cognition sub-study WPD for more details on informant consent.
Q: If a participant passes away and we complete the discharge / death form, do we still need to report a Serious Adverse Event?
A: Yes, all fatal SAEs are recorded and must be reported up until day 90.
Q: If a participant has a VFS / FEES just before the day 14 follow up, can the blinded SLT know the outcome of them?
A: Yes, an unblinded SLT should give the blinded SLT a handover of the results. Please refer to the blinding WPD for more advice on blinding.

Best Practice Tips

- **When consenting a participant, please ensure you inform them that if they are randomised to receive PES, that they will need their standard NG tube replacing with a Phagenyx catheter, and that this will need replacing again with a standard NG tube at day 13 (if they are still requiring feeding).**
- **The SLT team and research team should work together to screen and identify any potential participants.**
- **Get ward nurses and doctors involved in the trial, they can be trained up to administer the treatment which can help with weekend cover, and even help to identify potential participants!**

Upcoming Events



PhEAST - Dysphagia Rehabilitation & Pharyngeal Electrical Stimulation - Thursday 18th May 2023 12.30pm -1.30pm BST

PhEAST - Investigator Meeting - Tuesday 20th June 2023 12.30pm -1.30pm BST

Amendments:

NSA/11/23 (Scotland only)
Approved 28/03/2023
Changes to all patient facing documentation

SA/07/23
Approved 25/04/2023
FOIS 3 to be included for entirety of enrolment window (days 4-31), use of independent physician consent allowed (if there is no NoK)
This amendment has been sent to all R&D departments - keep an eye out for local approval!

Please ensure you are using the latest paperwork which can be found:
https://stroke.nottingham.ac.uk/pheast/docs/

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