

# **SWAT 168: Effects of enhanced monitoring and training of trial sites on the application of a treatment protocol in an international randomised trial**

## **Objective of this SWAT**

To investigate whether enhanced monitoring and training of site teams results in better adherence to a treatment application protocol.

Study area: Data Quality, Monitoring, Training

Sample type: Trial Team, Researchers, Healthcare Professionals

Estimated funding level needed: Low

## **Background**

This SWAT is part of the Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST; ISRCTN98886991), which is an international randomised open-label blinded-endpoint (PROBE) parallel group superiority trial of pharyngeal electrical stimulation (PES) vs no PES in hospitalised patients with subacute stroke and dysphagia.

Our previous trial of PES in the stroke population produced a neutral outcome.[1] Insufficient treatment stimulation levels and variability across sites have been suggested as a possible explanation for this neutral finding, because more recent positive studies in other patient groups involved higher treatment stimulation. We wish to establish whether increased monitoring of treatment stimulation levels and directed additional training has an impact on mean stimulation level.

## **Interventions and comparators**

Intervention 1: SWAT intervention in PES group - treatment current values recorded and values <20 mA will be flagged automatically to the Speech & Language Therapist (SLT) by the trial database. Flagged sites will receive targeted re-training and support from the SLT with the same information used in initial site training.

Intervention 2: SWAT control in PES group - treatment current values recorded and values <20 mA will be flagged automatically to the SLT by the trial database and simply recorded.

Index Type: Method of Monitoring, Visit, Site Training

## **Method for allocating to intervention or comparator**

Randomisation

## **Outcome measures**

Primary: Mean of day 1-3 treatment stimulation currents

Secondary: Proportion of mean day 1-3 current >20 mA

## **Analysis plans**

The host trial's statistical analysis plan (SAP) will detail the analysis plan for the SWAT. This will be developed when the trial starts. In brief, the effect of additional training/re-training by the SLT of sites who undertreat patients will be compared with that for those who do not receive training/re-training using a t-test of treatment currents (primary) and Chi-square test of patients who achieve a current >20 mA (secondary). If stimulation levels are higher in sites receiving additional training/re-training at an interim analysis, we will move to support all sites with this intervention.

## **Possible problems in implementing this SWAT**

Limitations in visiting sites due to COVID-19 restrictions will be mitigated by training via virtual meetings.

## **References**

Bath PM, Scutt P, Love J, Clavé P, et al. Pharyngeal Electrical Stimulation for Treatment of Dysphagia in Subacute Stroke: A Randomized Controlled Trial. Stroke 2016;47(6):1562-70.

## **Publications or presentations of this SWAT design**

## **Examples of the implementation of this SWAT**

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