# Randomized controlled trial of the Ampcare Effective Swallowing Protocol for persistent dysphagia post stroke

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## Background

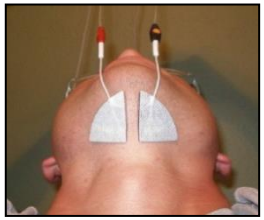
- Usual care for dysphagia post stroke has previously tended to focus on management of symptoms, rather than rehabilitation of swallow function
- More recently, a growing body of research is emerging to investigate potential new treatments. This has included electrical stimulation, however early research findings yielded conflicting results.
- This study therefore answers the call (NICE 2014 ) for more robust research in this area, in order to help inform clinical practice.

## Method

This Portfolio Randomized Controlled Pilot Study recruited 30 patients with post stroke dysphagia of >1 month duration.

It compared 2 groups:

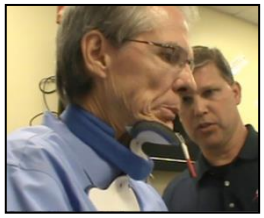
- the control group, who received usual dysphagia care and
- the intervention group, who received treatment using the Ampcare ESP™ (Effective Swallowing Protocol) for 30 minutes each weekday, for a total of 20 sessions.



**Ampcare electrodes in situ**

The Ampcare ESP™ protocol uses;

- a new electrode shape, placed submentally in order to target the suprahyoid muscles
- electrical stimulation is used in combination with simultaneous laryngeal exercises
- a new, specially designed neck brace, in order to provide resistance during exercising



**AMPCARE neck brace**

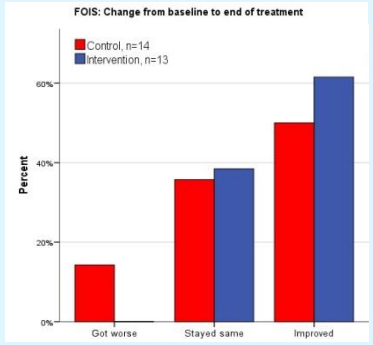
## Outcome measurement

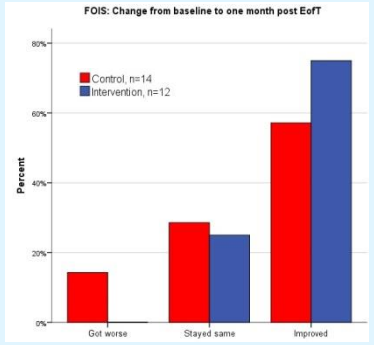
Data was collected at 3 points: baseline, after treatment and one month later. The outcome measures included:

- FOIS (Functional Oral Intake Scale)
- Rosenbek Penetration Aspiration Scale (blinded assessment made during Videofluoroscopy)
- SWAL-QOL (Quality of Life in swallowing disorders)

Participants in the intervention group also complete a treatment tolerability questionnaire about their experience of the intervention.

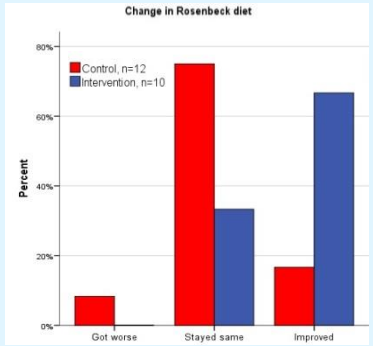
## Results

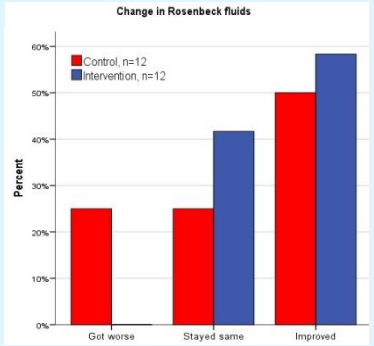



**FOIS Scale:**

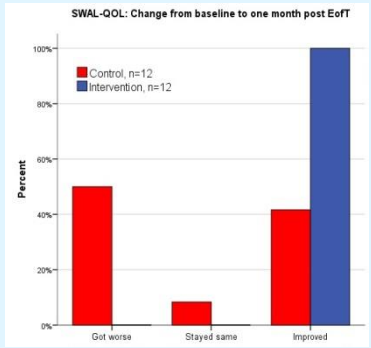
***Level 1:*** *Nothing by mouth.* ***Level 2:*** *Tube dependent with minimal attempts of food or liquid.* ***Level 3:*** *Tube dependent with consistent oral intake of food or liquid.* ***Level 4:*** *Total oral diet of a single consistency.* ***Level 5:*** *Total oral diet with multiple consistencies, 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.*




**Rosenbek Scale:**

***Score 8:*** *Contrast passes glottis; visible subglottic residue; absent patient response* ***Score 7:*** *Contrast passes glottis; visible subglottic residue despite patient response* ***Score 6:*** *Contrast passes glottis; no subglottic residue visible* ***Score 5:*** *Contrast contacts vocal folds; visible residue remains* ***Score 4:*** *Contrast contacts vocal folds; no residue* ***Score 3:*** *Contrast remains above the vocal folds; visible residue remains* ***Score 2:*** *Contrast enters the airway, remains above the vocal folds; no residue* ***Score 1:*** *Contrast does not enter the airway.*




**Patient feedback:**

**"I feel better at swallowing – no problems swallowing at all now."**

**"I thought the treatment was very good and I would recommend it to anybody."**

**"I've enjoyed taking part. It's given me a positive feeling about my swallow."**

**Carer feedback:**

**"He can drive short distances now without having to pull over to use the pot [to expectorate secretions] and he sleeps through the night now without waking up coughing."**

**"She's definitely not coughing anywhere near as much now."**

## Conclusions

The intervention group achieved greater improvements in swallow function (compared to the usual care group) as measured by:

- range of oral intake (FOIS)
- reduction in aspiration and/or penetration with diet (Rosenbek)
- Quality of Life (SWAL-QOL)

A greater proportion of the intervention group made improvement (compared to the usual care group), on FOIS, Rosenbek and SWAL-QOL measures.

There have been no adverse events during 294 treatment sessions.

This supports the findings of a previous feasibility study in 2011.

The pilot study findings are promising and justify progression to a fully powered trial.

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## Acknowledgement

We gratefully acknowledge funding for this study from: Sheffield Teaching Hospitals NHS Foundation Trust; Ampcare LLC; NIHR Devices for Dignity HTC; Collaboration for Leadership in Applied Health Research (South Yorkshire) and Royal College of Nursing (Lady Foley Award)

Sheffield Teaching Hospitals NHS Foundation Trust

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