

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 answers the call (NICE 2014) for more robust research in this area, in order to help inform clinical practice.

Method

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

The Ampcare ESP™ protocol uses;

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



Ampcare electrodes in situ



AMPcare neck brace

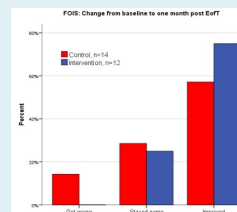
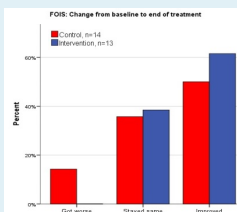
Outcome measurement

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

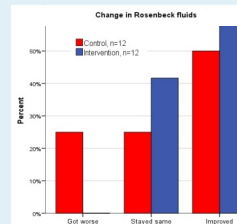
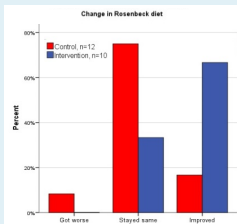
- FOIS (Functional Oral Intake Scale)
- Rosenbek Penetration Aspiration Scale (blinded assessment made during Videofluoroscopy)
- SWAL-QoL (Quality of Life in Swallowing Disorders)

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

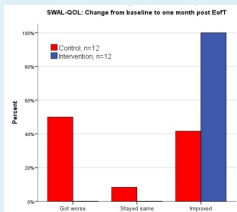
Results



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.



30 patients were recruited across 3 NHS hospital sites

FOIS End of treatment :

50% of usual care group improved, compared to 62% of intervention group.

P value for difference in amount of progress made = 0.29

FOIS 1 month follow up:

57% of usual care group improved, compared to 75% of the intervention group.

P value for progress made = 0.20

Rosenbek:

Usual care: 50% improved with fluids & 17% on diet.

Intervention: 58% improved with fluids & 67% on diet.

P values for difference in progress made = 0.01 for diet and 0.24 for fluids.

SWAL-QoL: End of treatment : 39% of

usual care group reported improved quality of life, compared to 83% of the intervention group.

SWAL-QoL: 1 month follow up: 42% of usual care group reported improvement, compared to 100% of the intervention group.

P value for progress made = 0.002

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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

- No adverse events occurred during 295 interventions
- The pilot study findings are positive and justify progression to a fully powered trial.

Acknowledgements

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