Randomized Controlled Trial of the AMPCARE Effective Swallowing Programme for persistent dysphagia post stroke

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Background

Dysphagia post stroke is experienced by up to 78% of patients (Martino 2005) and is associated with increased mortality and morbidity, decreased quality of life and associated care needs.

It has been hypothesized that electrical stimulation of the supralaryngeal musculature can assist hyolaryngeal elevation and so improve swallow function (Freed 2001; Lim 2009; Permsirivanich 2009; Rofes 2013). However there have also been conflicting studies and lack of consistency and clarity regarding electrode design, placement and treatment programmes.

There is therefore an urgent need for further research to clarify the potential of this approach as a treatment for post stroke dysphagia.

Method

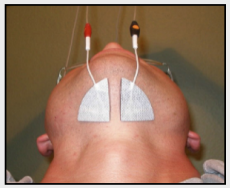
Previous research on neuromuscular electrical stimulation has yielded conflicting results.

The AMPCARE ESP programme uses a different approach, with a single pair of electrodes, placed submentally in order to stimulate the supralaryngeal muscles. Electrical stimulation is used in combination with simultaneous laryngeal exercises. This pilot trial builds on a successful feasibility study (Pownall & Enderby 2011) using the AMPCARE ESP programme which showed improvement in swallow function in a case series of 5 patients.

Funding was secured for a Randomized Controlled Pilot Study of 30 patients with post stroke dysphagia of >1-month duration.

The study will compare:

1. The control group, receiving usual Speech & Language Therapy (SLT) care.
2. The intervention group, receiving 4 weeks of treatment (5 days per week for 30 minutes) using the AMPCARE Effective Swallowing Programme (ESP) which involves electrical stimulation plus laryngeal exercises.



AMPCARE electrodes in situ

Patients wear a specially designed neck brace during treatment, to exercise against resistance during stimulation.

Outcome measurement

Assessment of swallow function is made at 3 points ; baseline, after treatment and one month later. The outcome measures used are:

- MASA (The Mann Assessment of Swallowing Ability)
- FOIS (Functional Oral Intake Scale)
- Rosenbek Penetration Aspiration Scale (during Videofluoroscopy)
- SWAL-QOL (Quality of Life in Swallowing disorders)

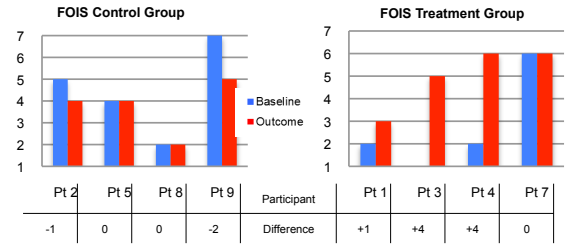
Participants in the intervention group also complete a treatment tolerability questionnaire about their experience of the intervention.

As this is a pilot study, data will be analysed using descriptive statistics.

Results

Efficacy

The study is still in progress, therefore we present initial findings from those participants who have completed the study to date.



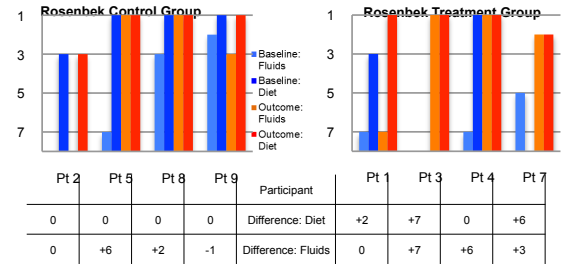
The FOIS data shows that 3 out of 4 participants in the treatment group improved, compared to 0 out of 4 participants in the control group.

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.*

Safety/Tolerability

So far there have been 160 treatment sessions and 0 adverse effects .



The Rosenbek data shows that 4 out of 4 participants in the treatment group improved, compared to 2 out of 4 participants in the control group.

Rosenbek Scale:

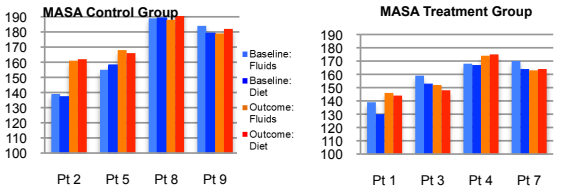
Score 8: *Contrast passes glottis; visible subglottic residue; absent patient response.*
Score 7: *Contrast passes glottis; visible subglottic residue despite patient response.*
Score 6: *Contrast passes glottis; no subglottic residue visible.*
Score 5: *Contrast contacts vocal folds; visible residue 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.*

Assessment of Patient Experience

Findings from the SWAL-QOL will be presented when more data is available. So far, participant quotes include:

"I feel I have no problems swallowing at all now".

"It's made such a difference not having to pull over to use my pot (to expectorate secretions) when I am driving – that's been a huge change in itself".



The MASA outcome scores represent an aggregate swallowing ability profile score, calculated from sub scores for 24 factors, (e.g. lip seal, dysphasia etc.). As the majority of these do not specifically relate to laryngeal elevation, we concluded that this measure may not have sufficient specificity for this study. Upgrades in recommended oral intake are also not reflected by the total scores.

MASA

The tables show the total MASA scores for each participant. It does not show improvement in terms of upgrades in recommendations for oral intake – for example, Pt 3 was recommended not safe for any oral diet on Baseline MASA and safe for fork mashable diet on Outcome MASA, however the MASA total scores do not reflect this.

Conclusions

As this is a pilot study, we are interested in evaluating the suitability of the outcome measures used as well as the initial findings on treatment efficacy. We also hope to gain information to calculate sample size for a full scale study.

Conclusions gathered from the findings of the pilot so far are that:

- There have been improvements in swallow function in the intervention group as assessed by range of oral intake (FOIS) and reduction in aspiration and/or penetration (Rosenbek) as measured during blinded Videofluoroscopy. This supports the findings of the feasibility study in 2011.
- There have been no adverse events during 160 treatment sessions.
- Piloting use of the MASA as one of the outcome measures demonstrated that it may not have sufficient specificity as an outcome measure for this particular study. It may therefore be necessary to consider alternative outcome measures for a full scale study.

References

Freed et al. Respir Care 46 (5): 466-474, 2001; Lim et al. J Rehabil Med. 41 (3): 174-8, 2009; Permsirivanich et al. J Med Assoc Thai 92 (2): 259-65, 2009; Rofes et al. Neurogastroenterol Motil 25 (11): 888-e701, 2013.

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