

Research Report

Combined electrical stimulation and exercise for swallow rehabilitation post-stroke: a pilot randomized control trial

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Abstract

Background: Dysphagia is common after stroke, affecting up to 50% of patients initially. It can lead to post-stroke pneumonia, which causes 30% of stroke-related deaths, a longer hospital stay and poorer health outcomes. Dysphagia care post-stroke generally focuses on the management of symptoms, via modified oral intake textures and adapted posture, rather than direct physical rehabilitation of the swallowing function. Transcutaneous neuromuscular electrical stimulation (NMES) is a promising rehabilitation technology that can be used to stimulate swallowing; however, findings regarding efficacy have been conflicting.

Aims: This pilot randomized controlled study involving three UK sites compared the efficacy of the Ampcare Effective Swallowing Protocol (ESP), combining NMES with swallow-strengthening exercises, with usual care in order to clarify evidence on NMES in the treatment of dysphagia post-stroke. A further objective was to pilot recruitment procedures and outcome measures in order to inform the design of a full-scale trial.

Methods & Procedures: Thirty patients were recruited and randomized into either (1) usual speech and language therapy dysphagia care; or (2) Ampcare ESP, receiving treatment 5 days/week for 4 weeks. Outcome measures included: the Functional Oral Intake Scale (FOIS), the Rosenbek Penetration-Aspiration Scale (PAS) and patient-reported outcomes (Swallow Related Quality of Life—SWAL-QOL).

Outcomes & Results: Thirty patients were recruited; 15 were randomized to the Ampcare ESP intervention arm and 15 to usual care. A greater proportion (75%, or 9/12) of patients receiving Ampcare ESP improved compared with 57% (or 8/14) of the usual-care group. Patients receiving Ampcare ESP also made clinically meaningful change (a comparative benefit of 1.5 on the FOIS, and on the PAS: 1.35 for diet and 0.3 for fluids) compared with usual care. The intervention group also reported much better outcome satisfaction.

Conclusions & Implications: The pilot demonstrated successful recruitment, treatment safety and tolerability and clinically meaningful outcome improvements, justifying progression to a fully powered study. It also showed clinically meaningful treatment trends for the Ampcare ESP intervention.

Keywords: dysphagia, stroke, electrical stimulation, randomized controlled trial, rehabilitation.

What this paper adds

What is already known on the subject

There is a growing movement to identify dysphagia interventions that can restore swallow function rather than simply manage symptoms. One method under evaluation is NMES; however, research to date on its efficacy has yielded conflicting results, although there is a growing consensus on its benefit as an adjunct to therapy. Therefore, we conducted a trial to work towards greater clarity to inform clinical practice.

What this paper adds to existing knowledge

This paper presents the results of a pilot randomized controlled trial (RCT) of a new treatment, Ampcare ESP, combining evidence-based dysphagia exercises (against resistance) in combination with simultaneous NMES against a control group receiving usual dysphagia care. Significantly more patients in the intervention group improved compared with usual dysphagia care; also, these patients made greater improvement in their swallow function and progress towards safe oral intake. They also reported significantly greater satisfaction with their progress.

What are the potential or actual clinical implications of this work?

This study presents promising data of measurable clinical swallow rehabilitation and justifies progression towards a full-scale trial. It also showed there were no adverse treatment effects and all patients found the treatment to be tolerable. We are now building funding applications for a full-scale trial and in the interim are carrying out a case series in seven NHS Trusts collecting data for National Institute for Health and Care Excellence (NICE) (using an approved NICE audit tool) on a series of cases using this intervention.

Introduction

Stroke is one of the top three causes of death and the largest cause of adult disability in England, and costs the National Health Service (NHS) over £3 billion a year (Department of Health/National Audit Office 2010). One of the common sequelae of stroke is dysphagia; Singh and Hamdy (2006: 389) reported that 'dysphagia affects up to half of acute stroke patients and carries a threefold to sevenfold increased risk of aspiration pneumonia'. This includes direct and informal healthcare costs and productivity losses due to mortality and morbidity. Stizmann and Mueller (1988) found that 60% of deaths due to pneumonia are secondary to aspiration; while Doggett *et al.* (2001) estimated that approximately 37% of dysphagic patients will develop pneumonia, and 3.8% of these will die if not included in a dysphagia programme.

Dysphagia also impacts on quality of life and psychological well-being. Social activities and daily routines are disrupted, resulting in isolation and social exclusion (Ekberg *et al.* 2002, Farri *et al.* 2007).

Usual speech and language therapy (SLT) management includes exercise regimes, modified oral intake and postural adaptations; however, most UK SLT services are not resourced to provide treatment on an intensive basis (Kilbride *et al.* 2014). There is also variation in SLT staff resources, resulting in different levels of provision (Rudd *et al.* 2009). Consequently, dysphagia care is often restricted to symptom management rather than direct rehabilitation of swallow function.

Variation in care provision increases along the care pathway, and treatment for persistent dysphagia is often limited, although there is evidence for the persistence of dysphagia longer term (Mann *et al.* 1999). Consequently, patients who do not improve in the acute stage are likely to experience long-term health complications and care needs (Kilbride *et al.* 2014).

Evidence is urgently required into techniques for rehabilitating swallow function. One method,

Table 1. Summary of the current literature on transcutaneous neuromuscular electrical stimulation (NMES) in dysphagia rehabilitation post-stroke

There is conflicting evidence that NMES *alone* is effective in treating dysphagia post-stroke

In favour:

Freed *et al.* (2001)
Permsirivanich *et al.* (2009)
Gallas *et al.* (2010)
Rofes *et al.* (2013)

Against:

Bulow *et al.* (2008)

There is evidence that NMES *as an adjunct* is more effective than traditional post-stroke dysphagia therapy alone

Lim *et al.* (2009)
Park *et al.* (2012)
Kushner *et al.* (2013)
Sun *et al.* (2013)
Lee *et al.* (2014)
Lim *et al.* (2014)
Terre and Mearin (2015)
Chen *et al.* (2016)
Zhang *et al.* (2016)
Guillen-Sola *et al.* (2017)

transcutaneous neuromuscular electrical stimulation (NMES), is based on improving the function of innervated but paretic/paralytic muscles by electrical stimulation of corresponding intact peripheral nerves. Low-level stimulation provides sensory feedback, whereas increased current intensity or pulse duration produces muscle contraction, provided the peripheral nervous system is intact (Doucet *et al.* 2012).

The role of NMES within dysphagia rehabilitation is controversial. Previous research using VitalStimTM (utilizing different electrodes and parameters) has yielded conflicting results. These are summarized in table 1.

Several systematic reviews and meta-analyses have attempted to clarify the evidence. However, some

authors felt unable to reach firm conclusions due to heterogeneity in methods used, the small number of studies and study design weaknesses (Clark *et al.* 2009, Geeganage 2012). As illustrated by the evidence summary table 1, the consensus to date is that there is insufficient robust evidence that electrical stimulation alone is more effective than traditional dysphagia therapy, but that where it is used as an adjunct, then there is a growing body of evidence that NMES plus traditional therapy is more effective than traditional exercises alone—although they also acknowledge limitations imposed by the quality of the available evidence (Langdon and Backer 2010, Tan *et al.* 2013, Kushner *et al.* 2013, Chen *et al.* 2016). Calls, therefore, remain for further robustly designed randomized controlled trials (RCTs) to clarify evidence for clinical guidelines and optimal patient outcomes (Geeganage 2012, National Institute for Health and Care Excellence (NICE) 2014).

This study is based upon the findings that NMES appears most effective when used in combination with traditional swallow-strengthening exercises. It also draws upon the growing literature supporting the use of resistance training in muscle strengthening in dysphagia (Smead 2008, Watts 2013). It is the first to report on the Ampcare Effective Swallowing Protocol (ESP), which specifically targets the suprahyoid musculature, simultaneously combining transcutaneous electrical stimulation with exercise against resistance.

Aims

The long-term aim of this research is to evaluate the effectiveness of the ESP in persistent dysphagia post-stroke. This study was a pilot RCT designed to evaluate recruitment feasibility, treatment tolerability and outcome measure suitability in order to inform a fully powered study.

Methods

This study was a parallel randomized controlled trial. Participants were randomized (detail below) either to group A: intervention with Ampcare ESP, or to group B: usual SLT care.

Selection criteria

Inclusion

Participants were selected if they:

- were medically stable;
- experienced dysphagia incorporating reduced laryngeal elevation (confirmed by videofluoroscopy) since the treatment protocol targets improved laryngeal elevation;

- were > 1 month post-stroke; and
- had no other neurological disease.

Exclusion

Participants were excluded if they:

- were under 18 years of age;
- had a pacemaker or other serious cardiac disease;
- had severe cognitive/communication difficulties (assessed by treating SLT on the American Speech–Hearing Association Functional Communication Measure); and
- had lesions/infections in the treatment site.

Thirty participants were recruited from three NHS Trusts across England including a large teaching hospital, an in-patient rehabilitation unit and a community service.

Randomization

Having given informed consent, participants underwent videofluoroscopy (by a specialist SLT and radiographer) to confirm reduced laryngeal elevation. They were then allocated using a randomized block design to achieve balanced group size. Randomization was achieved remotely by a medical statistician, using a computer algorithm selecting the cohort consecutively from date of referral. The sample size of 15 per group struck a balance between pragmatism and sufficient sample size to provide estimates of effect size and variability for the power calculation for a future fully powered RCT (Julious 2005).

Outcome measures

Three outcome measures were used in order to gather both quantitative and qualitative data:

- Functional Oral Intake Scale (FOIS; Crary *et al.* 2005): a well-used and validated scale quantifying the amount and variety of oral intake versus tube feeding.
- Rosenbek Penetration-Aspiration Scale (PAS; Rosenbek *et al.* 1996): used during videofluoroscopy to evaluate the presence and severity of any penetration/aspiration of contrast. The scores used for analysis represent the worst-rated swallow attempt for boluses given of each viscosity attempted during assessment.
- Swallow Related Quality of Life (SWAL-QoL; McHorney *et al.* 2002): captures patients' ratings of domains of dysphagia and its impact on their QoL.



Figure 1. Placement of electrodes. [Colour figure can be viewed at wileyonlinelibrary.com]

Assessments were conducted at three points:

- Baseline: on study entry; measures included FOIS, PAS and SWAL-QOL.
- Post-treatment: following a 4-week treatment period; FOIS and PAS were repeated, plus a questionnaire regarding treatment tolerability.
- Follow-up: 1 month post-end of treatment; FOIS and SWAL-QoL measures were conducted; videofluoroscopy was not repeated to minimize radiation exposure and patient burden.

Clinical assessments were completed by a team of three experienced SLTs, and a blinded SLT assessor and radiographer undertook the videofluoroscopy assessments.

Group A: Intervention

Treatment sessions lasted 30 min, 5 days/week for 4 weeks. Ampcare ESP involves NMES delivered via electrodes placed under the chin, targeting the suprahyoid muscles. This electrode placement differs from that used in earlier studies and is based on work by Burnett *et al.* (2003) to determine which muscle groups were most closely associated with laryngeal elevation. Figure 1 illustrates electrode placement.

A pulse rate of 30 Hz was used, providing muscle contraction without fatigue or muscle spasm. This setting follows the EMPI 1998 NMES Parameter Guidelines. During pulses of stimulation, participants were required to perform three sets of exercises (10 min for each exercise in each treatment session).

Each exercise (table 2) was selected based on evidence relating to efficacy in improving swallow function. During each 5-s pulse of stimulation, participants were instructed to undertake a repetition of the exercise for that 10-min section. Each exercise was completed whilst

pressing down lightly into a postural neck brace to produce a resistive force during the exercise programme (figure 2). Participants in this group received usual SLT input for their communication difficulties where relevant, but no other SLT intervention for their dysphagia other than monitoring.

After each 10-min period, participants were asked ‘can you tolerate more?’ to facilitate a gradual increase in pulse intensity, optimizing treatment effect and muscle strength. The rate and degree of the increase of the electrical stimulation was tailored according to each participant’s tolerance.

In week 1, stimulation pulses were separated by rest periods of 25 s; producing 60 swallow attempts per session. In week 2, the periods were reduced to 20 s, producing 72 swallow attempts. In weeks 3 and 4, the rest periods were reduced to 15 s, increasing the swallow attempts to 90. This represents a gradually increasing challenge on the swallowing musculature.

Group B: Usual care

We were keen to ensure that the study captured data from patients in different care contexts, e.g., acute hospital care, in-patient rehabilitation units and in domiciliary settings. Inclusion criteria included a minimum limit of 1 month post-stroke in order to control for initial spontaneous recovery, but we set no upper limit to length of time post-stroke. This resulted in a mixed group of patients for time from onset of dysphagia to intervention. Consequently, ‘usual care’ varied as determined by the local Trust Stroke Care Pathway protocols of each site and by the length of time post-onset of stroke. It was therefore not possible to prescribe what usual care should be across all sites. Usual care varied from periodic reviews primarily focusing on posture and diet modification to weekly visits with home-practise regimes. These regimes included exercises and postural adaptations based on videofluoroscopy findings.

Analysis

As this was a pilot RCT, no hypothesis tests were performed. Summary statistics were used to examine treatment tolerability, sensitivity to change of the outcome measures, and estimates of the size of the potential treatment effect and variability. These estimates were used to inform the sample size calculation for a full-scale trial.

Quantitative outcomes are summarized using means and standard deviations and the effect of treatment is presented as mean difference between groups (95% confidence interval) at final assessment adjusted for baseline. This was achieved using a linear regression model of the final values, with baseline fitted as a covariate.

All results are presented by intention to treat. For those participants who withdrew before completing the

Table 2. Exercise schedule with supporting evidence

Exercise programme (10 min per section)	Evidence
Chin to chest against resistance, followed by effortful swallow	Effortful swallow produces earlier onsets and peaks of pharyngeal pressures, greater driving force to move boluses through the pharynx and reduced pharyngeal residue (Burnett <i>et al.</i> 2003) Resistance training combined with effortful swallow improves strength, range of motion and timing of a swallow (Steele 2007) Chin to chest against resistance produced more muscle activity than shaker head lift (Smead 2008, Watts 2013)
Chin to chest, followed by Mendelsohn manoeuvre, followed by effortful swallow	Mendelsohn manoeuvre improves laryngeal and hyoid elevation (Lazarus <i>et al.</i> 2002, McCullough and Kim 2013)
Chin to chest, followed by jaw opening and closing, followed by effortful swallow	Jaw opening against resistance produced significant improvements in hyolaryngeal movement and wider upper oesophageal sphincter opening (Wada <i>et al.</i> 2012)



Figure 2. Ampcare Effective Swallowing Protocol (ESP) equipment showing the postural device used to provide resistance during exercise. [Colour figure can be viewed at wileyonlinelibrary.com]

full protocol, all data were included up to the point at which they withdrew (table 4). For some participants, data on some but not all the outcome measures were available at the end of study and/or 1 month follow-up, e.g., the FOIS measure, as this information can be obtained from medical notes, and was therefore accessible if participants did not want to attend additional hospital visits for videofluoroscopy.

Calculations of unit change were also made for the FOIS and PAS outcome measures in order to evaluate any clinically meaningful change between baseline and outcome scores. Qualitative data on patient reported outcomes and on treatment tolerability are reported. Figure 3 shows a flow chart of the RCT.

Ethical approval

Approval was obtained from the Yorkshire and Humber National Research Ethics Committee (13/YH/0100) and local ethical and governance approval from each recruitment site.

Results

Thirty participants were recruited and their characteristics at baseline are reported in table 3. Whilst some differences existed between groups, this is not unexpected given the small sample size. A total of 295 treatment sessions were completed. There were no adverse events and all participants in the intervention arm reported that the treatment was tolerable.

Recruitment to the trial and loss to follow-up is illustrated in figure 3. The overall attrition rate was 20%.

As can be seen from table 3, patients in the intervention group tended to be further post-stroke than the usual-care group; however, being a pilot study with only 30 participants, the research team felt it was not appropriate to carry out subgroup analysis.

Analysis of the results

Functional Oral Intake Scale (FOIS) outcomes

The comparative difference in outcomes between the intervention and control groups is illustrated in figure 4 and discussed further below.

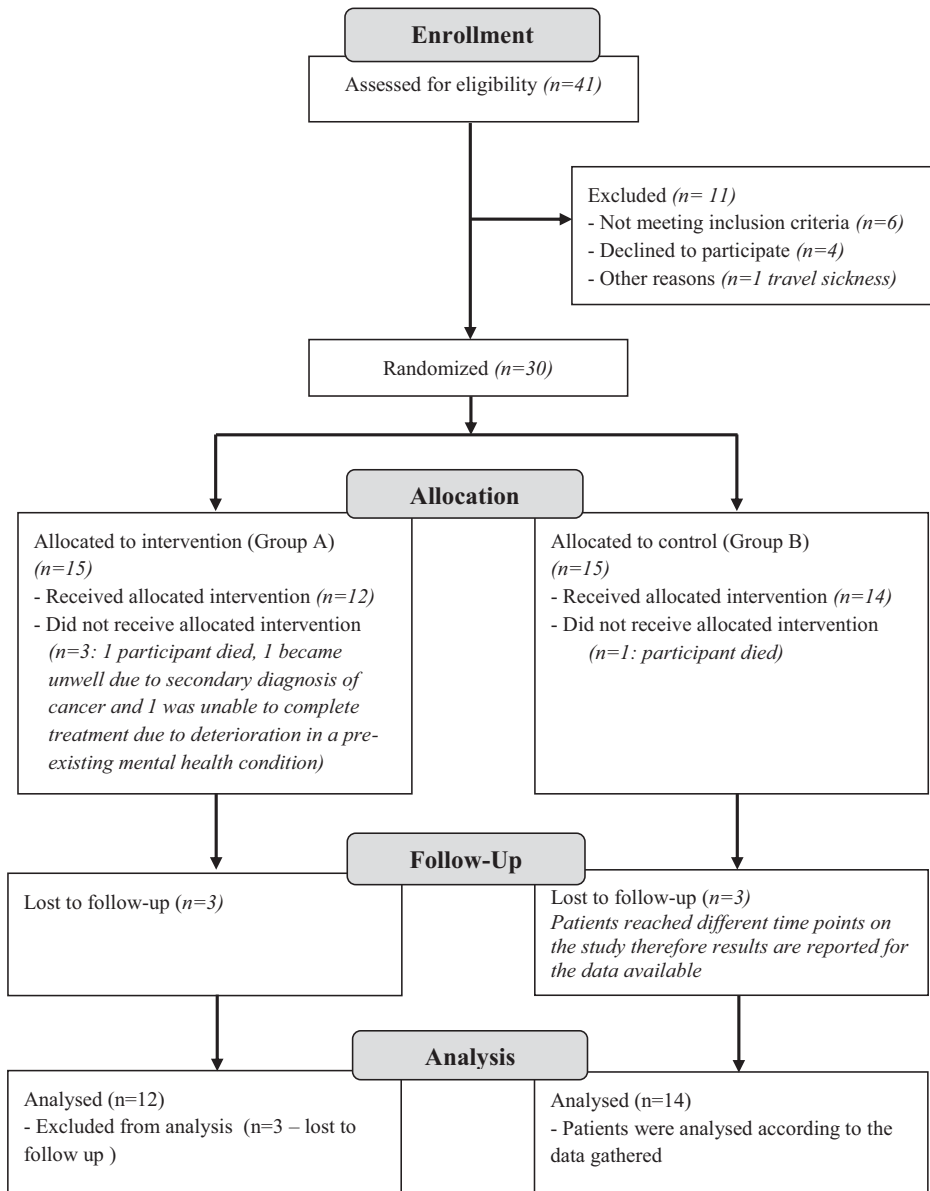


Figure 3. Flow chart of a randomized controlled trial (RCT).

Baseline to post-intervention

After treatment, the mean difference between the groups, adjusted for baseline values, was 0.50 (95% CI = -0.72 to 1.72) a positive difference in favour of the intervention. Clinical assessment of the participants showed that a greater proportion: 62% (8/13) of group A (intervention) had improved compared with 50% (7/14) of group B (usual care).

One-month follow-up

The difference in FOIS seen post-treatment persisted to 1 month post-end of treatment, 0.59 (95% CI: -0.98

to 2.15). Both groups had made further progress; however, the differential had increased, with 75% (9/12) of group A achieving better scores on the FOIS compared with 57% (8/14) of group B. None of the intervention group showed deterioration in FOIS scores either post-treatment or at 1 month follow-up compared with 14% (2/14) of the control group.

The research team determined that a change of 1 point on the FOIS scale would constitute clinically meaningful change. Unit changes were calculated for the FOIS and showed the usual-care group improved by a mean change of 0.5, while the intervention group improved by 2 units, i.e., an overall comparative benefit of 1.5 units.

Table 3. Patient characteristics at baseline

Patient characteristics at baseline	Control (n = 15)	Intervention (n = 15)
Age (years): mean (SD)	81 (11.0)	73 (15.3)
Median (IQR)	83 (74–88)	77 (63–83)
Sex male	9 (60%)	10 (67%)
Female	6 (40%)	5 (33%)
First stroke	10 (67%)	11 (73%)
> 1 stroke event	5 (33%)	4 (27%)
Time post-stroke (months): mean (SD)	9.8 (19.7)	14.0 (23.1)
Event to baseline median: (IQR)	1.0 (1–5)	3.0 (1–25)

Patient characteristics at baseline for those patients who completed the study (per protocol)	Control (n = 12)	Intervention (n = 12)
Age (years): mean (SD)	79 (11.4)	76 (11.4)
Median (IQR)	83 (73–86)	76 (64–83)
Sex male	8 (66.7%)	8 (66.7%)
Female	4 (33.3%)	4 (33.3%)
First stroke	8 (66.7%)	8 (66.7%)
> 1 stroke event	4 (33.3%)	4 (33.3%)
Time post-stroke (months): mean (SD)	9.1 (20.5)	17.3 (25.0)
Event to baseline median: (IQR)	1.5 (1–4.5)	3.0 (1–33)

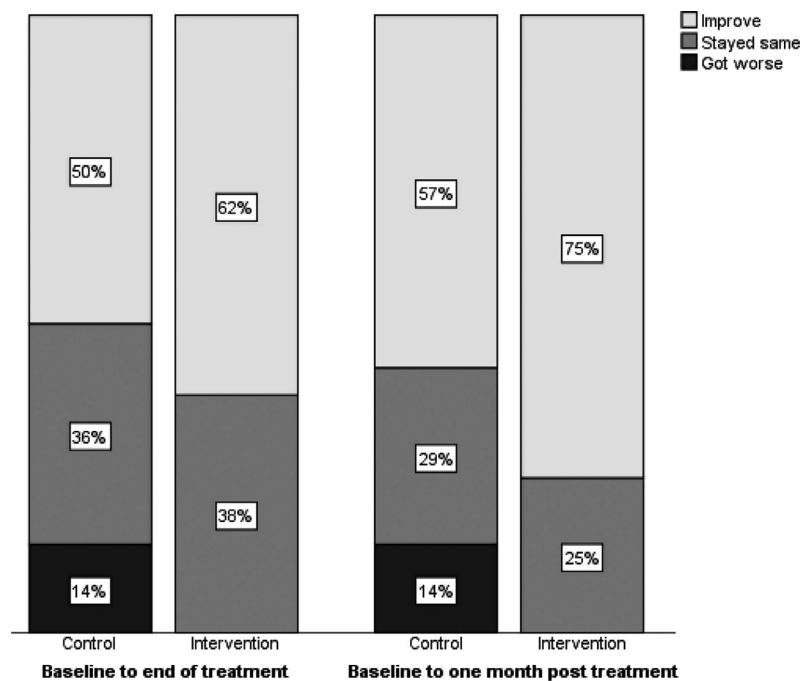


Figure 4. Functional Oral Intake Scale (FOIS) outcomes.

Rosenbek Penetration-Aspiration Scale (PAS) outcomes

The comparative difference between the intervention and control groups for diet and fluids is illustrated in figure 5 and discussed below. The analysis is based on the worst bolus swallow for each viscosity attempted during each assessment.

Assessment of videofluoroscopy data by a single (blinded) assessor showed a greater proportion of group

A (intervention)—58% (7/12) made progress on fluids compared with 50% (6/12) of group B, though looking at the mean change adjusted for baseline it was very close to zero, 0.40 (95% CI: -2.13 to 2.92) and the confidence interval included the null value. On diet, 58% (7/12) of group A made progress compared with 17% (2/12) of group B, and for this measure the difference was in favour of group A compared with group B, -0.62 (-2.77 to 1.54), as this was a negatively scaled measure,

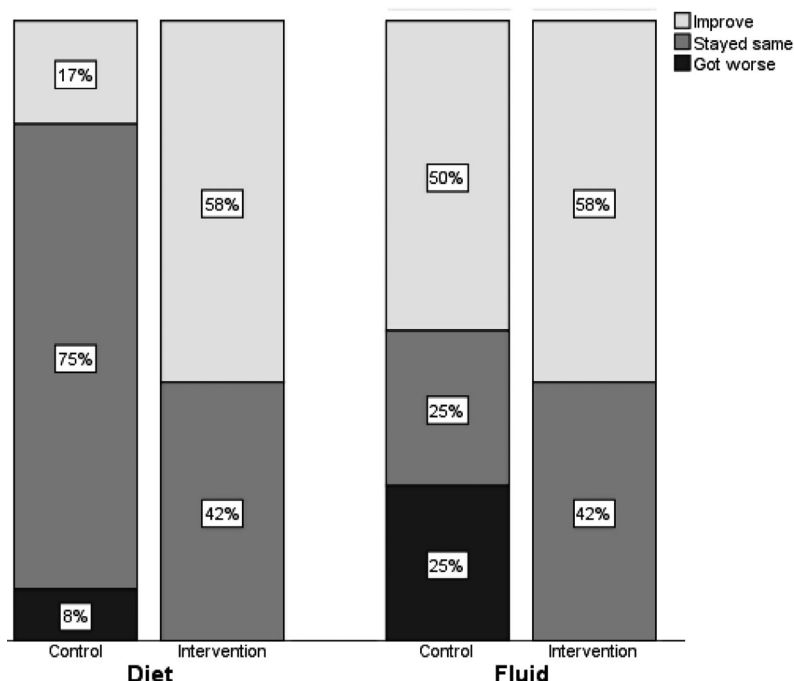


Figure 5. Rosenbek Penetration-Aspiration Scale (PAS) outcomes.

Table 4. Summary of the results for those who completed the study (per protocol)

	Control N	Control mean (SD)	Intervention N	Intervention mean (SD)	Difference between groups, adjusted for baseline (95% CI)
<i>FOIS</i>					
Baseline	15	4.3 (1.8)	15	3.5 (2.0)	
After treatment	14	5.1 (1.9)	13	5.1 (2.0)	0.50 (−0.72 to 1.72)
1 month post-treatment	14	5.1 (2.2)	12	5.3 (1.9)	0.59 (−0.98 to 2.15)
<i>Rosenbek PAS</i>					
Fluids Baseline	15	5.2 (2.7)	15	6.4 (2.3)	
After treatment	12	3.4 (2.7)	12	4.3 (3.0)	0.40 (−2.13 to 2.92)
Diet Baseline	15	2.5 (2.4)	15	4.6 (3.1)	
After treatment	12	1.8 (2.1)	12	2.5 (2.6)	−0.62 (−2.77 to 1.54)
<i>SWAL-QoL</i>					
Baseline	13	118 (22.8)	14	107 (17.8)	
After treatment	13	119 (23.6)	13	115 (15.1)	9.7 (−0.9 to 20.3)
1 month post-treatment	12	121 (24.9)	12	128 (14.3)	20.5 (4.2–36.7)

a negative difference indicates a change in favour of the intervention. There may be a ceiling effect to the data for diet as group averages for severity of penetration/aspiration scores showed the usual-care group were less severely dysphagic initially (table 4). (A total of 12/15 of the intervention group had scores of 6–8, indicating laryngeal penetration/aspiration compared with 7/15 of the usual-care group.)

As with the FOIS scale, the research team determined that a change of 1 point on the PAS would constitute clinically meaningful change. Unit changes for diet showed a mean reduction of reduction in severity of penetration-aspiration of 2.1 points for the

intervention group and 0.75 for the usual-care group. This constitutes a comparative benefit of 1.35 points for the intervention group. Unit changes for fluids showed a mean reduction of 2.1 points for the intervention group and 1.8 for the usual-care group. This is a comparative benefit of 0.3 for the intervention group.

Swallow-related Quality of Life (SWAL-QoL) outcomes

The comparative differences between the groups is illustrated in figure 6 and discussed below.

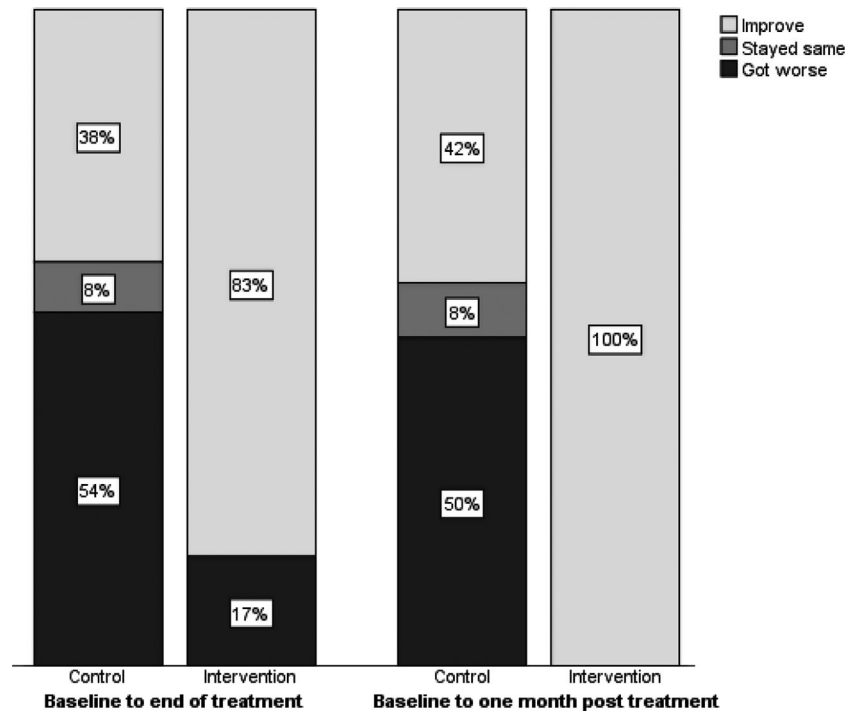


Figure 6. Swallow Related Quality of Life (SWAL-QoL) outcomes.

Post-treatment a greater proportion of group A, 83% (10/12), scored their quality of life as better compared with 38% (5/13) of group B, and the mean difference adjusted for baseline was 9.7 (95% CI: -0.90 to 20.3) in favour of group A (intervention).

At follow-up 1 month post-treatment end, both groups showed continued improvement, and again, the differential had increased, with 100% (12/12) of intervention group reporting improved SWAL-QoL scores compared with 42% (5/12) of group B. The mean difference in quality of life had increased such that the adjusted difference was 20.5 (4.2–36.7) in favour of the intervention.

There were significant differences in participants' ratings of swallow-related quality of life. This is particularly evident when looking at data from patients who reported a reduction in SWAL-QoL scores. In group A, 17% (2/12) reported lower SWAL-QoL scores compared with 54% (7/13) in group B.

This distinction was magnified by 1-month follow-up. In group A, 0% (0/12) reported a reduction in SWAL-QoL compared with 50% (6/12) of group B.

A further finding, across all outcome measures, was that there were notable differences between groups in the proportion of patients who showed any deterioration in swallow function. As can be seen in table 5, there was much less deterioration in swallow function in the intervention group. This was a supplemental finding of the study which the research team identified during data analysis. Consideration will be given to the study design

of a future full-scale trial in order to see whether this finding is replicated in a larger study and to explore the potential causes for the differences between the groups.

Qualitative data

All group A (intervention) participants reported that the treatment was tolerable. None found it disruptive to their lifestyle, however one patient would have preferred the treatment slightly less intensively, preferring three times per week rather than five. Other quotations from group A included:

Participants

- '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.'

Carers:

- 'He can drive short distances without having to pull over to use the pot (to expectorate secretions) and sleep through the night now without waking up coughing.'
- 'She's definitely not coughing anywhere near as much now'.

Table 5. Summary showing differences between groups in any deterioration in swallowing

Outcome measure	Control			Intervention		
	N	No. Patients	% of group	N	No. Patients	% of group
<i>FOIS</i>						
After treatment	14	2	14%	13	0	0%
1 month post-treatment	14	2	14%	12	0	0%
<i>Rosenbek PAS</i>						
Fluids	12	3	25%	12	0	0%
Diet	12	1	8%	12	0	0%
<i>SWAL-QoL</i>						
After treatment	13	7	54%	12	2	17%
1 month post-treatment	12	6	50%	12	0	0%

Discussion

The main findings of this study were that a greater proportion of the intervention group made progress in recovery of swallow function compared with the usual-care group. They also made comparatively greater progress as determined by clinically meaningful change on a range of accepted quantitative and qualitative outcome measures. Additionally, the intervention group tended to be longer post-stroke than the usual-care group (mean = 23.1 months compared with 19.7 months—also the longest period post-stroke in the usual-care group was 5 months, whereas for the intervention group it was 55 months).

The particular intervention protocol used in this study is novel in incorporating NMES with resistance exercises using a specifically developed resistance neck brace and novel electrodes, which have a larger surface area than those used with other NMES systems. They are also shaped specifically to fit in the submental area, as shown in figure 1. This permits distribution of the electrical stimulus more evenly than the smaller electrodes used in previous NMES studies, making the treatment more tolerable for patients.

Group A (intervention) showed greater improvement overall on most measures. This shows consensus with the previous research shown in table 1 which employed NMES as an adjunct to other therapeutic interventions (from traditional swallow strengthening exercises to respiratory muscle strength training).

We also found that at the 1-month end of treatment follow-up, improvement was not only sustained but continued. This was less evident in the results of the usual-care group (some of whom in fact deteriorated). We wonder whether the continued progress may indicate plasticity triggered by the intervention or greater improvement due to practise effects as this group were swallowing more frequently. This is an interesting finding and we compared this trend with results of the previous research into NMES as an adjunct. Of the studies shown in table 1, nine describe original research. Chen

et al. (2016) is a systematic review and meta-analysis. Of the nine original research studies, five did not investigate follow-up post-end of treatment (Lim *et al.* 2009, 2014, Park *et al.* 2012, Kushner *et al.* 2013, Zhang *et al.* 2016). Of the four studies that did look at long-term follow-up, two found no long-term effect at 12 weeks (Terre and Mearin 2015, Guillen-Sola *et al.* 2017) and two found a lasting effect: Sun *et al.* (2013) found sustained benefit at 24 months post-treatment (in a 'preliminary case series') and Lee *et al.* (2014) at 12 weeks post-treatment. We would therefore prioritize data collection on long-term effects in a full-scale study in order to clarify this issue in a larger group of patients.

We found that the FOIS, PAS and SWAL-QoL scales were well tolerated by patients as outcome measures and these pilot study data suggest that they offer acceptable sensitivity to change for this intervention. We also achieved successful recruitment to target.

Participants in the intervention group also judged that the Ampcare ESP treatment was tolerable and no immediate/long-term adverse effects of the intervention were found. Our attrition rate of 20% was deemed comparable with other studies of this kind.

These findings justify progression to a full-scale clinical trial and we have additionally calculated that we would require a sample size of 220 patients to power a full-scale study.

Limitations

Sample size

Thirty patients is a small sample, thus we cannot determine as yet with certainty whether the Ampcare ESP achieves better treatment outcomes when compared with usual care. The small sample size also meant we were unable to match for severity of stroke, severity of dysphagia, age and time post-onset of stroke; however, we would look to exclude baseline differences or to evaluate statistically any differences that could not be controlled for in a future, larger trial.

Complexity of intervention

This pilot trial involved a complex intervention and aimed to validate a new protocol that uses synergistic application of NMES plus exercise against resistance, and so it was not possible to determine which element—the NMES, exercises or treatment intensity—might comparatively have the greatest impact on outcomes. However, Bonell *et al.* (2012) suggested that RCTs of complex interventions, conducted within a critical realist framework, can produce pragmatic and useful evaluations. Furthermore, the majority of recent studies of NMES have concluded that NMES is of greater benefit when used as an **adjunct** to traditional swallowing rehabilitation exercises. Our findings therefore support this. A larger-scale trial should involve use of strengthening exercises alone as a control in order to compare effects with the use of combined NMES plus exercises in the intervention arm.

Heterogeneity of usual care

This is a genuine limitation but pragmatically a necessity of a multi-centre study focusing on persistent dysphagia, as local variation in care increases as time post-stroke increases. Acceptance of local procedures at each site was a requirement in order to recruit sufficient participants within the available time period.

Characteristics of stroke

We did not collect data in this pilot study on the stroke aetiology, severity or vascular territory. We would build collection of this data into a further full-scale study.

Follow-up measures

Videofluoroscopy was carried out at baseline and immediately post-treatment; however, it was omitted at 1 month follow-up post-end of treatment. Some may consider this a limitation in terms of omission of this measure at the final data point, but the research team determined that the burden to study participants outweighed the value of this measure as it would expose them to a further dose of radiation and necessitate a further hospital out-patient visit. It was therefore decided that we would repeat only the FOIS and SWAL-QoL measures at the final data point.

Conclusions

This pilot study demonstrated clinically meaningful improved swallow outcomes for a greater proportion of intervention group participants, together with significantly improved quality of life for participants receiving Ampcare ESP compared with those receiving usual care.

These findings support previous research into the use of NMES as an adjunct to therapy and support progression to a fully powered RCT.

A full-scale trial is required in order to help answer the calls that have been made for research (NICE 2014) and to clarify guidance for dysphagia practitioners. This trial should be sufficiently powered to address the question of treatment efficacy and also include evaluation of data on long-term benefit as prior research on this has been lacking in rigour.

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