



National Institute for Health and Care Excellence

IP1033/2 Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults

IPAC date: 11th October 2018

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 NHS professional Coventry and Warwickshire Partnership Trust	General	<p>Hello</p> <p>We have carried out an audit for Transcutaneous Neuro Muscular Electrical Stimulation and here is the project report.</p> <p>I signed in and tried to find out where to attach it but couldn't see</p> <p>If this isn't correct can you tell me how to send it in another way</p> <p>Best wishes</p> <p>██████████</p> <p>SLT</p> <p></p> <p>SQ580 - NMES Clinical Audit Repor</p>	<p>Please respond to all comments</p> <p>Thank you for your comment and for sharing your clinical audit report.</p> <p>There were no safety outcomes reported in this clinical audit report.</p> <p>The consultee refers to a non peer-reviewed study. The NICE IP programme manual highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee, unless they contain important safety data.</p>
2	Consultee 2 Clinical Audit & Compliance Facilitator Safety and Quality Department	General	<p>Please find attached a clinical audit report on the use of Transcutaneous Neuromuscular Stimulation (NMES) for Oropharyngeal Dysphagia in Adult Community Speech & Language Therapy at Coventry & Warwickshire Partnership NHS Trust.</p>	<p>Thank you for your comment and for sharing your clinical audit report.</p> <p>There were no safety outcomes reported in this clinical audit report.</p>

	Coventry and Warwickshire Partnership NHS Trust		<p>We would like to submit this report for consideration as part of the NICE consultation for IPG490. Please could you confirm receipt?</p> <p>If you need any further information please let me know.</p> <p> SQ580 - NMES Clinical Audit Repor</p>	The consultee refers to a non peer-reviewed study. The NICE IP programme manual highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee, unless they contain important safety data.
3	Consultee 3 Specialist advisor NIHR Devices for Dignity HTC	Overview "Anecdotal and theoretical adverse events" section	<p>Under the Safety Summary Section (not numbered)</p> <p>It mentions "specialist advisers listed the following anecdotal adverse events: worsening of dysphagia" - my understanding is that Dr [REDACTED] reported this in relation to Head and neck cancer patients - I am not aware of any reports of worsening of dysphagia in Stroke patients. It would be helpful to clinicians to make this distinction as there have been a number of studies now on NMES in oropharyngeal dysphagia following Stroke and no adverse events reported.</p>	<p>Thank you for your comment.</p> <p>The committee decided to change this section of the overview to "worsening of dysphagia in head and neck cancer patients".</p>
4	Consultee 3 Specialist advisor NIHR Devices for Dignity HTC	General	There is currently an audit underway in several Trusts, collated and led by Professor [REDACTED] at Sheffield teaching Hospitals NHS Trust - they are using a	Thank you for your comment. This study is not yet published and IPAC only considers efficacy data when it is published in peer-reviewed publications. One audit report has been

			specific NICE audit tool and plan to publish findings towards the end of this year.	submitted to NICE during this consultation and the safety data have been considered by IPAC.
5	Consultee 4 Patient	General	<p>Sir, Madam</p> <p>Whilst travelling in the outside lane of the M62 at 70 MPH I suffered a stroke. A 3 week stay in hospital followed. The stroke caused complete failure of my swallow function. There was no oral intake at all, I couldn't even swallow my own saliva, this was spat out into endless kitchen rolls. Water and nutrients were now taken in through a peg feeder tube. The effect on social and family life was devastating, I became irritable, depressed, angry and miserable. After 7 months of this I had 'vital stim therapy' at [REDACTED] hospital with [REDACTED]. My swallow function began to work after only 2 sessions. The treatment was painless and none invasive, just a feeling of warm pins and needles. I now lead a normal life and eat and drink the same as everyone else, my peg tube was removed long ago. The effect of regaining swallow function has been life changing. You know better than I the costs of continuing treatment for dysphasia patients. If I had been offered this treatment soon after my stroke 7 months of, frankly, abject misery</p>	<p>Thank you for your comment.</p> <p>The committee very much welcomes hearing from patients who have had this procedure and considered your positive experience and views in their deliberations.</p> <p>Cost is not part of the remit of the IP Programme.</p> <p>The committee added the following comment in section 3.7: <i>"The committee was pleased to receive many comments from patients during consultation. The patients reported positive outcomes after the procedure."</i></p>

			<p>could have been avoided with possible large cost savings for the NHS.</p> <p>Thank you Mr [REDACTED]</p>	
6	<p>Consultee 5 Patient</p>	General	<p>I have undertaken a course of treatment by Vitalstim for swallowing difficulty due to diagnosed MND. The treatment eased swallowing difficulty where I can eat solid foods rather than soups and avoided the need for a peg which the consultant suggests. I fortunately was able to pay for this but can see my quality of life is vastly improved due to the treatment as against the high intervention normally expected. I also expect that the one off treatment will suffice for quite some time</p>	<p>Thank you for your comment.</p> <p>The committee very much welcomes hearing from patients who have had this procedure and considered your experience and views in their deliberations.</p> <p>The committee added the following comment in section 3.7: <i>“The committee was pleased to receive many comments from patients during consultation. The patients reported positive outcomes after the procedure.”</i></p>
7	<p>Consultee 6 Patient’s spouse</p>	General	<p>Dear Sir/Madam,</p> <p>I would like to take this opportunity to provide comment for the IPAM regarding transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults. I will do so by presenting the case history of my wife [REDACTED] who to the best of my knowledge was the first person to receive this treatment in the UK using VitalStim just over 11 years ago. Following a fall 12 years ago resulting in serious head injury my wife subsequently suffered from dysphagia and had a nasogastric feeding tube for about 11 months. During her time in hospital and</p>	<p>Thank you for your comment.</p> <p>The committee very much welcomes hearing from patients or carers of patients who have had this procedure and considered your experience and views in their deliberations.</p> <p>The committee added the following comment in section 3.7: <i>“The committee was pleased to receive many comments from patients during consultation. The patients reported positive outcomes after the procedure.”</i></p>

			<p>rehabilitation unit there was very little improvement in her swallowing and the therapists doubted that she would ever be able to eat or drink normally again. Subsequently she was discharged and continued nutritional support using the NG feeding tube. Shortly afterwards we became aware of Vitalstim through the internet and decided to pay for a course of this treatment. Almost immediately there was improvement with my wife's swallowing and within a few weeks she was eating and drinking normally and the NG tube was removed. The effect on her psychologically was dramatic and together with an improved dietary intake her recovery showed a marked improvement. There were no side effects from the treatment and she only felt slight tingling sensation during the procedure.</p> <p>So 11 years after the course of NMES using VitalStim my wife has been able to have a normal social life, eating out and at home with family and friends enjoying all the sorts of food that she likes. Without this treatment I think my wife would probably have endured a miserable existence and possibly not lived as long as she has.</p> <p>Yours faithfully, [REDACTED]</p>	
8	Consultee 7 Patient	General	<p><u>VitalStim Neuromuscular Electrical Stimulation Treatment for Dysphagia</u></p>	<p>Thank you for your comment. The committee very much welcomes hearing from patients who have had this procedure and</p>

		<p>Background</p> <p>I was a reasonably healthy 59 year old man in full time employment. Despite living alone I had family and friends living locally, across the Country and further afield.</p> <p>I suffered a stroke (Acute Infarct right brainstem – medulla) on 02/07/2018 and was admitted to ██████████ Hospital under the excellent care of Dr ██████████.</p> <p>Whilst at the hospital I was given, among other things, Physiotherapy, Occupational Therapy and Speech and Language Therapy. Within a week I had made significant progress with my Occupational therapy and after about four weeks my Physiotherapist was also happy that the progress I had made was good enough for me to be discharged if this was what I wanted.</p> <p>One of the main issues from day one, which remained, was my inability to swallow. I was unable to swallow anything, including the large quantity (in excess of 100ml a day) of white / translucent bubbly saliva that I was producing and so I regularly used yanker suction to clear it. I was given Hyoscine patches to try to reduce the quantity and it was also suggested that I had Botox, but this did not take place.</p> <p>I had initially been given a nasogastric (NG) feeding tube. It was later decided that a PEG should be fitted (this was done on 24/07/18) and I was being fed for up to 15 hours overnight, which was far from ideal as I had</p>	<p>considered your experience and views in their deliberations.</p> <p>The committee added the following comment in section 3.7:</p> <p><i>“The committee was pleased to receive many comments from patients during consultation. The patients reported positive outcomes after the procedure.”</i></p>
--	--	---	---

		<p>great difficulty sleeping in the upright position I needed to be in for feeding. I asked to try Bolus feeding and this started on 01/08/18 and consisted of five 'meals' of Ensure at regular times which gave me a better daily routine that I felt I could continue after my discharge.</p> <p>Unfortunately during the five weeks as an in-patient I had made no noticeable recovery with regards to my swallowing and the only treatment the SALT team were able to offer was thermotactile stimulation of my anterior facial arches (using a disposable foam lollipop-like object dipped into cold water and dabbed onto the area), as I was told this was the only procedure that was available.</p> <p>The Consultant could not provide a definitive prognosis, as my swallow function could return by itself in weeks, months or years, or never return.</p> <p>The SALT team had, however, done some research and discovered that VitalStim UK Ltd offered other options. The Consultant and the SALT team were fully aware that it was an expensive private treatment only available in one location in the UK, and couldn't recommend it as such as they had no personal knowledge of its use and success.</p> <p>A few days following a home visit with my Physiotherapist and Occupational Therapist I was discharged on 06/08/2018.</p> <p>At home I was able to start my new way of living, receiving the continued support from</p>	
--	--	--	--

		<p>family and friends. Despite this, my mood was quite often very low. Not being able to eat conventionally had totally changed my way of life, as socializing, which included travelling long haul, eating out, and drinking, (both alcohol and hot drinks) was now going to be impossible or extremely problematic.</p> <p>VitalStim Treatment</p> <p>I made contact with Ms [REDACTED] at VitalStim UK Ltd and following completion of their Patient Screening Form first met with her at her clinic in [REDACTED] on 06/09/2018. At that time I was still unable to swallow anything. An initial assessment, which included various tests, and a brief education of swallow anatomy, physiology and pathology took place. I also received relevant handouts mainly relating to facial and oral exercises that I should undertake.</p> <p>In total I had a series of 22 treatments of Neuromuscular electrical Stimulations for oral and pharyngeal dysphagia over 11 sessions. During the sessions Ms [REDACTED] explained exactly where she was placing the electrodes and why and she gave on-going education.</p> <p>Following the early treatments it was noticed by family and friends that my voice was getting stronger and my diction clearer, and I was aware that I was spitting out less secretions. At this stage it was suggested that I not replace the Hyoscine patch and note any</p>	
--	--	--	--

		<p>increased secretions. Luckily there weren't any.</p> <p>By close monitoring Ms [REDACTED] realised that the treatments were working and she suggested slowly trying to swallow small quantities of liquids – initially Ensure with a thickener added.</p> <p>I noticed that by about halfway through the course of treatments I was now able to be driven the 150mile round trip and attend the treatment sessions without spitting out any secretions.</p> <p>As treatments continued, and I progressed, foods tried included a smooth soup and a smooth yoghurt and fizzy orangeade. By the penultimate session I was able to drink small quantities of Ensure (without a thickener added) and finally water.</p> <p>Upon completion of the program yesterday (26/09/2018) I was given various additional documents mainly covering my on-going diet and reminded of the need to continue the facial and oral exercises she had given me, along with the conventional day to day exercise I normally undertook.</p> <p>Conclusion</p> <p>On hearing about VitalStim I did some research and decided that, despite the possibility of no or limited improvement, it was worth paying the not inconsiderable cost. My life as it was had changed dramatically as a result of the on-going effect of the stroke on my swallowing and there was no guarantee</p>	
--	--	---	--

			<p>that this would improve and so I considered it to be an investment, which may, or may not prove successful.</p> <p>I had been prudent throughout my life and saved. If I hadn't I would not have been able to afford to undergo the treatment, which I hope, based on my experience, will be recognised and available to others on the National Health Service in the future.</p> <p>At this moment I can still only consume small quantities of liquid / liquidised foods and will continue to rely on some nutrition and hydration being provided through my PEG for the time being, however I hope to return to a full diet eaten conventionally at some time in the not too distant future and the removal of the PEG and associated medicines needed for this feeding regime, all of which has left me in a much more positive frame of mind than when I was discharged from hospital and will also lift the huge mental burden that had been forced on family and friends and facilitate a return to full time employment, all at no additional cost to the NHS.</p> <p>I was lucky enough to have had a huge amount of support from family and friends throughout the entire time I was in hospital and my time with Ms [REDACTED], who was professional, yet personable, with myself and my family throughout the time I spent with her.</p>	
9	Consultee 8 Patient	General	Sir/Madam,	Thank you for your comment.

		<p>In 2014 I underwent surgery for head and neck cancer at The [REDACTED] Hospital. Much more tissue was removed during the operation than I had been previously lead to believe would be the case, in particular with an inactive flap put into my throat and part of the base of my tongue removed. This devastated my quality of life leaving me unable to eat normal food and unable to speak properly.</p> <p>Despite further surgical procedures and work by Speech & Language Therapists and Restorative Dentists, I was unable to improve my situation.</p> <p>In 2017 I embarked on VitalStim treatment, travelling from my home near [REDACTED] to the treatment centre in [REDACTED] on a daily basis. After a course lasting five weeks I felt able to manage more soft foods and my swallow seemed to improve. The improvement was not great, but an improvement all the same.</p> <p>Since that time there has been no further improvements to my condition and I have received no further VitalStim treatment, mainly due to financial cost which I cannot sustain. I applied, via my GP to get some reimbursement for the money I had spent, but have heard nothing since.</p>	<p>The committee very much welcomes hearing from patients who have had this procedure and considered your experience and views in their deliberations.</p> <p>The committee added the following comment in section 3.7: <i>“The committee was pleased to receive many comments from patients during consultation. The patients reported positive outcomes after the procedure.”</i></p>
--	--	--	--

			<p>I believe the VitalStim treatment is effective, though only quite limited in my particular circumstances.</p> <p>If I can be a any further help, do not hesitate to contact me.</p> <p>Regards</p> <p>████████████████████</p>	
10	Consultee 9 Patient	General	<p>My name ██████████, I have been asked to send my comments regarding the Neuromuscular Electrical Stimulation / VitalStim Therapy which I received in 2014, with particular reference to it's integral part in my recovery and return to a normal quality of life.</p> <p>I was diagnosed with squamous cell carcinoma in my right tonsil in december 2013 at the ████████ in ████████. Ten weeks of chemotherapy and radiotherapy treatment left me unable to swallow and being fed liquid food through a peg.</p> <p>Despite treatment by the NHS speech and language therapist to help encourage swallowing with exercises, I was still unable to drink or eat again and was confined to nil by mouth.</p>	<p>Thank you for your comment.</p> <p>The committee very much welcomes hearing from patients who have had this procedure and considered your experience and views in their deliberations.</p> <p>Cost is not part of the remit of the IP Programme.</p> <p>The committee added the following comment in section 3.7: <i>"The committee was pleased to receive many comments from patients during consultation. The patients reported positive outcomes after the procedure."</i></p>

		<p>Out of desperation, and following some research on the internet, my wife discovered a treatment called VitalStim Therapy – Neuromuscular Electrical Stimulation, being championed by consultant Speech and Language Therapist ██████████ in the UK. Fortunately for me, ██████████ was based 20 miles down the road.</p> <p>Before meeting ██████████ my future was bleak. I faced being unable to eat or drink ever again and began to realise how important this is to the quality of your life. Time spent with family and friends eating, drinking and socialising is a precious thing, and when it's taken away it is a massive hurdle to overcome. I was treated for depression at this time.</p> <p>When I met ██████████ for my first treatment I had no expectation of success, but by the end of that session, having eaten nothing for four months, I ate a yoghurt and drank half a litre of water.</p> <p>Each session consisted of the electrical pads being fitted to different areas of my throat and electrical pulses being generated while I swallowed different food and drinks. These ranged from ice cubes, to yoghurt and as the treatment progressed, to more solid food such as a banana.</p>	
--	--	---	--

		<p>After 10 sessions I was able to eat relatively normally (all bar a couple of things), and was able to remove my feeding tube.</p> <p>My life was been transformed and I was back to being able to appreciate the things that others take for granted.</p> <p>My treatment involved 10 sessions over a period of just 4 weeks. The total cost of the treatment (£2-3,000)was a small percentage of the cost of being fed through my stomach via a PEG for just one year.</p> <p>I was so fortunate to find this treatment so close to home, we would have been prepared to travel to the other side of the earth to get it (I understand it is available in Europe and North America) I was also fortunate to be able to afford the treatment.</p> <p>I feel very strongly that this treatment should be available to everyone, not just based on income or geography. It is non-invasive, has no side effects and IT WORKS! Dysphagia is a massive problem and people like [REDACTED] and Vital Stim should be allowed to treat people with this simple, cost effective and successful therapy.</p> <p>[REDACTED]</p>	
--	--	---	--

11	Consultee 10 Patient's spouse	General	<p>Dear Sir/Madam,</p> <p>I have been asked to record the treatment and benefits of the Vital-Stim neuromuscular electrical stimulation that my husband [REDACTED] received from Mrs [REDACTED].</p> <p>My husband [REDACTED] had a devastating stroke in May 2011 and was unable to swallow so was fitted with a PEG tube. After 10 months in hospital he came home in March 2012 to be looked after by myself. In July/ August 2012 I read various articles about the electrical stimulation that was helping people with their swallowing so I contacted 2 different people mentioned in the articles. They both explained what enormous benefit they were receiving from the Vital-Stim treatment and gave me full details of Mrs [REDACTED].</p> <p>I contacted Mrs [REDACTED] and arranged to take my husband to her clinic. We spent 3 weeks visiting [REDACTED] Hospital, [REDACTED] every day for treatment. At the end of 3 weeks my husband was able to swallow puréed foods & thickened liquids.</p> <p>We returned home to [REDACTED] and our lives changed dramatically as we were able to go out to restaurants (chefs did not mind liquidising the food for [REDACTED]) having</p>	<p>Thank you for your comment.</p> <p>The committee very much welcomes hearing from patients or carers of patients who have had this procedure and considered your experience and views in their deliberations.</p> <p>The committee added the following comment in section 3.7:</p> <p><i>“The committee was pleased to receive many comments from patients during consultation. The patients reported positive outcomes after the procedure.”</i></p>
----	----------------------------------	----------------	--	---

			<p>people round for meals and generally lead sociable lives again. Before the treatment my poor husband had to sit and watch everyone eat or we just did not go out and socialise.</p> <p>Sadly my husband's health has deteriorated and he now is receiving 24 hour care in an NHS facility and as NICE has not approved the treatment yet [REDACTED] has been put back on PEG feeding.</p> <p>I spoke to Dr [REDACTED], a neuro surgeon at the [REDACTED] Hospital about the benefits of the Vital-stim treatment and he said that even in the 1930s we had electrical stimulation and he couldn't understand the resistance to it by the NHS.</p> <p>I trust that you will be looking favourably on this marvellous treatment and that it will soon be available to all patients with a swallowing problem.</p> <p>Best wishes [REDACTED]</p>	
12	Consultee 11 NHS professional Association of British Neurologists (ABN)	General	NICE Consultation Start - [IP1033/2] Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults	Thank you for your comment about the mechanism of action of pharyngeal stimulation.

			<p>Thank you for asking the Association of British Neurologists (ABN) to comment on the technique of transcutaneous neuromuscular stimulation for oropharyngeal dysphagia in adults.</p> <p>The idea that stimulation of the pharynx triggers a swallow is derived from work done many years ago in which decerebrate cats had liquids of different viscosity dripped on to the region of the superior laryngeal nerve and the subsequent swallows were recorded electrically. This work demonstrated the way in which swallowing can be elicited as a reflex, but did not inform, directly, the way in which swallowing is something that in awake adults is initiated voluntarily.</p>	
13	<p>Consultee 11 NHS professional Association of British Neurologists (ABN)</p>	3	<p>The first randomised controlled trial to use pharyngeal stimulation using an electrical stimulus in stroke patients (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4878285/)</p> <p>did not show a beneficial effect,</p>	<p>Thank you for your comment.</p> <p>The pharyngeal electrical stimulation described in this study is a different procedure that involves the insertion of a catheter through the nose of the patient. Therefore this study was not included in the overview.</p>
14	<p>Consultee 11 NHS professional Association of British Neurologists (ABN)</p>	3	<p>although a more recent trial (https://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2818%2930255-2/fulltext)</p>	<p>Thank you for your comment.</p> <p>The pharyngeal electrical stimulation described in this study is a different procedure that involves the insertion of a catheter through the</p>

			has suggested that decannulation in stroke patients may be achieved earlier in patients receiving pharyngeal stimulation. This is an interesting finding but only stroke patients requiring a tracheostomy were included in the trial, and these patients form a small minority of the stroke population.	nose of the patient. Therefore this study was not included in the overview.
15	Consultee 11 NHS professional Association of British Neurologists (ABN)	General	The successful swallowing of a suitably prepared bolus depends on a number of movements including laryngeal closure, laryngeal elevation and pharyngo-oesophageal peristalsis. Mechanisms to protect the airway in the event of aspiration in to the larynx or trachea include coughing, retching, gagging and changes of posture. Breathing also has to be coordinated so that expiration follows swallowing, to promote the egress of bolus remnants away from the laryngeal inlet. If swallowing itself is relatively preserved, a number of other problems can unhinge oral feeding, including a depressed conscious level, poor posture control and food and drink of an inappropriate consistency. The complexity of the process of oral feeding and the number of discrete functions involved militates against stimulation of just one component part of the process producing a significant beneficial effect. Furthermore, stroke can impair swallowing and oral feeding in a number of different ways, ranging from a vocal cord palsy, nausea and vertigo in Lateral Medullary Syndrome to a depressed conscious level in occlusion of the middle cerebral artery; therapy directed at a single site is unlikely to produce comparable effects in patients with different types of swallowing disorder.	Thank you for your comment about the complicated coordination of the swallowing process and the multiple ways in which stroke can impede this. The committee considered your comment that therapy directed at a single site is unlikely to produce benefits for all patients with different types of swallowing disorder.

16	Consultee 11 NHS professional Association of British Neurologists (ABN)	1	<p>On the basis of the evidence available the ABN cannot support the widespread adoption of this technique in routine clinical practice but would be very interested in supporting the use of the technique in randomised controlled trials studying patients in whom the mechanism of the swallowing problem, and the mechanism of the related problem with oral feeding, has been clearly defined. Oral feeding problems are a very significant and harrowing problem for many patients with neurological disease.</p> <p>The views expressed here have been discussed with the stroke advisory group of the Association of British Neurologists, and has been informed by the information available about the consultation process from NICE.</p> <p>ABN Stroke Advisory Group</p>	<p>Thank you for your comment.</p> <p>IPAC considered your comment but decided not to change the guidance.</p> <p>The committee agrees that oral feeding problems are difficult and distressing for many patients with neurological disease.</p>
----	--	---	---	--

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."