

Neuromuscular electrical stimulation (NMES) and oral sensorimotor stimulation in a young child with cerebral palsy and severe dysphagia

By

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LIST OF ABBREVIATIONS

CNS – Central Nervous System

FDA – Food and drug administration

FOIS – Functional Oral Intake Scale

HPCSA – Health Professions Council of South Africa

MASA – The Mann Assessment of Swallowing Ability

MBS – Modified Barium Swallow

NMES – Neuromuscular electrical stimulation

PEG – Percutaneous endoscopic gastrostomy

Plagiarism Pledge

Abstract

Background: A number of research studies implementing VitalStim® Therapy or neuromuscular electrical stimulation (NMES) found positive results in the swallowing abilities of adults with severe dysphagia. Percutaneous endoscopic gastrostomy (PEG) tube feeding is often recommended for children with severe dysphagia when oral feeding is deemed unsafe. Although PEG tube feeding has many benefits, there are associated disadvantages. NMES research, suggests it may limit the need for PEG tube feeding.

Objective: The aim of the study was to determine whether change took place in a young child's oral preparatory, oral and pharyngeal phase of swallowing after 20 sessions of NMES and oral sensorimotor stimulation. This participant has been long-term PEG tube fed.

Method: A pre-test-post-test single case design with a control was implemented. The participants were recruited at the same time and randomly assigned to act as the main and control participants. The participants were 62 and 40 months, with spastic cerebral palsy and were fed via PEG tubes. The main participant received NMES while both received oral sensorimotor stimulation. Data was collected by means of a case history, clinical evaluations and Modified Barium Swallow (MBS) examinations before and immediately after treatment. Both participants received 20 sessions of treatment over six weeks. Post-treatment follow-up MBS examinations were conducted at seven and 15 months on the main participant only.

Results: Both participants showed improvement of oral dysphagia after six weeks of treatment. Although both showed improvement in their oral preparatory and oral phase difficulties, the main participant showed better improvement of pharyngeal phase difficulties than the control. The main participant's improvement was not sustained at the seven and 15 month follow-up MBS examinations. Poor positioning could have attributed to this.

Conclusion: Similar oral preparatory and oral phase difficulties were identified before treatment in both participants. Initial positive post-treatment results in the oral preparatory and oral phase of both participants may have been associated with frequent oral sensorimotor stimulation only. Although only short-term differences were observed, it appeared that improvement in the pharyngeal phase of swallowing in the main participant could be associated with NMES. It appeared that oral sensorimotor stimulation only for the treatment of pharyngeal difficulties in the control participant did not yield positive results. Based on the

study results NMES may be used in conjunction with oral motor exercises to address oral and pharyngeal difficulties associated with feeding and swallowing difficulties in young children with severe dysphagia, especially after conventional dysphagia treatment has failed. Factors that could have contributed to the results are discussed.

Key words: Cerebral palsy, dysphagia, Modified Barium Swallow examinations, Neuromuscular electrical stimulation, oral sensorimotor stimulation, VitalStim® Therapy, young children

CHAPTER 1

1. Introduction

Research indicates that up to 40% of children with cerebral palsy present with dysphagia (Andrew, Parr & Sullivan, 2012). The underlying causes of cerebral palsy associated dysphagia vary from oromotor impairment, behavioural difficulties, food aversions and sensory integration difficulties (Andrew et al., 2012; Gerek & Ciyitepe, 2005), with oromotor and pharyngeal phase swallowing difficulties as the main causes of feeding challenges (Andrew et al., 2012; Rogers, Arvedson, Buck, Smart & Msall, 1994; Sjakti, Syarif, Wahyuni & Chair, 2008). The consequences of these feeding and swallowing difficulties may include malnutrition, dehydration, poor growth and possible negative effects on psychosocial wellbeing and quality of life for both the parent or caregiver and the child with cerebral palsy (Andrew et al., 2012). The most common characteristics of oromotor and pharyngeal phase swallowing difficulties experienced by children with cerebral palsy are the tonic bite reflex, jaw instability, jaw and tongue thrusting, poor lip control, reduced tongue movements for chewing and coughing during swallowing (Andrew et al., 2012; Gerek & Ciyitepe, 2005).

The ultimate goal of paediatric dysphagia management is ensuring that the child has adequate nutrition and hydration for long-term growth while minimizing the risk of aspiration (Arvedson, 1998). For some children with severe feeding and swallowing difficulties, oral feeding is not a safe option and a gastrostomy tube is recommended. Depending on the severity of these feeding difficulties Percutaneous Endoscopic Gastrostomy (PEG) tubes are alternative methods for feeding children when oral feeding is unsafe (Rogers, 2004). Although there are many advantages to the insertion of PEG tubes, for instance, improved weight gain, reduction in feeding difficulties, a better health condition for the children, reduced stress during feeding time for the caregivers and the ease of inserting medication via the tube when the children are sick (Gottrand & Sullivan, 2010; Rogers, 2004; Sleight, 2005), there are associated disadvantages too. Physical difficulties of tube insertion include anaesthetic complications, oesophageal laceration, perforations, stoma leakage, cellulitis, and the controversy as to whether the insertion of PEG tubes increases the presence of gastroesophageal reflux (Andrew & Sullivan, 2010; Andrew et al., 2012). An additional negative aspect regarding feeding via PEG tubes observed in clinical practice and in literature is tube displacement (Goldberg, Barton, Xanthopoulos, Stettler & Liacouras, 2010).

When young children who are exclusively tube fed are not granted the opportunity for oral exploration, hypersensitivity in the oral cavity is a consequence due to limited opportunity to experience different tastes and textures (Gottrand & Sullivan, 2010). Sucking and swallowing skills are lost when not used frequently while the oral input can be experienced as aversive (Morris, 1989). Hypersensitivity is common in children with cerebral palsy (Gangil, Patwari, Aneja, Ahuja & Anand, 2001). Therefore the implementation of oral stimulation or oral sensorimotor exercises is recommended to facilitate or maintain some form of feeding efficiency and to prevent the development of oral hypersensitivity and oral aversion (Gottrand & Sullivan, 2010; Morris, 1989). However, according to results obtained by Arvedson, Clark, Lazarus, Schooling and Frymark (2010) there is insufficient evidence available to claim positive effects of oral motor exercises on children with feeding and swallowing difficulties. Snider, Majnemer and Darsaklis (2011) confirmed the statement by indicating that there is conflicting evidence amongst authors regarding the successfulness of sensorimotor exercises for the improvement of oral motor skills and reduction of aspiration, especially in children with severe feeding impairments. There appears to be a long-standing uncertainty of the value of oral motor exercises as Ottenbacher, Scoggins and Wayland (1981) already stated that no significant change in oral motor abilities occurred in participants with severe and/or profound neuromotor disorders. Rogers (2004) also states that this treatment modality has not been found helpful in improving oral feeding efficiency and pharyngeal phase functioning. Although there have been identified benefits of this method of treatment such as improved lip closure, there is inadequate evidence according to the researcher's knowledge regarding the effect of oral sensorimotor exercises on the pharyngeal difficulties often identified in children with cerebral palsy, e.g. food residuals and reduced pharyngeal motility (Rogers, 2004).

A potential treatment modality that could possibly address both the oral motor and pharyngeal feeding and swallowing difficulties identified in children with cerebral palsy is NMES (NMES). This is a non-invasive treatment of dysphagia (Wijting, 2009). External stimulation is applied to specific muscles involved in swallowing together with traditional swallowing exercises. Various authors have suggested that electrical stimulation restores the motor function of weak muscles, initiates the re-learning of muscles and the area of the brain that controls the muscles responsible for swallowing (Barikroo & Lam, 2011). Shaw, Sechtem, Searl, Keller, Rawi & Dowdy, (2007) and Korfage, Schueler, Brugman & Van

Eijden (2001) hypothesized that NMES is aimed at rehabilitating type II muscle fibres which are responsible for speedy, strong contractions of some of the muscles involved in swallowing. Type II muscle fibres are said to be the first muscles to undergo disuse atrophy (Shaw et al., 2007). Traditional swallowing therapy only exercises type I muscle fibres and generally not type II (Wijting, 2009). It is therefore recommended that a combination of NMES in conjunction with swallowing therapy be implemented so as to stimulate both type I and type II muscle fibres (Shaw et al., 2007). The goal of NMES is said to strengthen and re-educate the muscular system while improving the motor control of the swallowing mechanism (Barnes, Miller & Latman, 2008; Permisirivanich et al., 2009; Wijting, 2009). Neuromuscular electrical stimulation has been used extensively in a wide variety of therapeutic and rehabilitative settings especially in the profession of physiotherapy (Wijting, 2009). The research has highlighted that NMES may be beneficial for adults with both long-term (>180 days) and short-term (<180 days) dysphagia (Freed, Freed, Chatburn & Christian, 2001). The treatment has also been effective for adult individuals who had dysphagia for 40 years, although an increase in the amount of treatment sessions is recommended (Freed et al., 2001). NMES has already been used for diverse causes of dysphagia, varied age groups and patients that differed in the time between the onset of dysphagia and treatment (Freed et al., 2001).

NMES was approved by the US Food and Drug Administration (FDA) in 2002 for the safe treatment of dysphagia; (Freed et al., 2001; Wijting, 2009). The approval of NMES for the treatment of dysphagia was based upon the accumulation of data from 892 adult and paediatric patients who received this treatment method (Freed et al., 2001). According to results, NMES was notably more effective than thermal application for restoring swallowing function after loss or impairment by stroke, neurodegenerative disease, cancer or respiratory problems (Freed et al., 2001; Lim, Lee, Lim & Choi, 2009). For those patients who had severe dysphagia, NMES had a success rate of 97.5%. The patients with severe dysphagia did not require the insertion of a PEG tube after NMES (Shaw et al., 2007). Blumenfeld, Hahn, LePage, Leonard and Belafsky, (2006) also studied the effect of electrical stimulation therapy on participants with severe dysphagia. The results indicated that patients with severe dysphagia who received NMES had improved swallowing function and required fewer treatments and shorter hospitalization (Blumenfeld et al., 2006). NMES is therefore showing promising results for patients with severe dysphagia.

NMES has also been used with patients with Multiple Sclerosis (Bogaardt, van Dam, Wever, Bruggeman, Koops & Fokkens, 2008). These patients experienced reduced pooling and less aspiration on thin liquids, improved swallowing ability and enhanced quality of life. The difference between the effect of NMES and the standardized swallowing exercise regimen as recommended by Logemann (1998) on swallowing function in chronic dysphagia patients was investigated by Carnaby-Mann and Crary (2008). Eighty percent of the patients involved in this study demonstrated significant improvement in their ability to swallow, efficient oral intake, weight gain, and greater insight of their swallowing ability. The researchers determined this improvement by clinical and instrumental swallowing evaluation (videofluoroscopic swallowing evaluation), participants' weight gain, and self-perception of their swallowing ability. The Mann Assessment of Swallowing Ability (MASA) (Mann, 2002) and the Functional oral intake scale (FOIS) (Crary, Carnaby-Mann & Groher, 2005) were used by the researchers to clinically assess the participants' swallowing ability. All participants increased the variety and amount of food they ate safely after NMES. Four of the five participants in this research study that was followed up for six months post treatment managed to maintain the gains made in their swallowing ability.

The use of NMES for individuals with head and neck cancer has also been investigated (Langmore et al., 2006). Aspiration in these participants was reduced from 50% to 14%. The ability of patients to return to some degree of oral diets was improved across the research group. PEG tube dependence was reduced from 58% to 42% (Langmore et al., 2006).

NMES has not only shown to be effective with the adult population, but also for patients with dysphagia between 1 and 4 years old. NMES also appears to be effective in infants less than 1 year old and those born with congenital dysphagia (Christiaanse, Glynn & Bradshaw, 2003). Based on the success rate of NMES in the adult population, Mitchell et al., (2010) designed a pilot study to determine if NMES would be effective in a neonatal sample. The results of this study indicated that NMES improved the amount of feeds and feeding safety in the participants. Mitchell et al. (2010) state that the application of NMES to infants with delayed oral feeding and unsafe swallowing skills may reduce the need for tube feeding and increased hospitalizations.

Christiaanse et al. (2003) also evaluated the use of NMES in the paediatric population and reported no adverse events in 30 participants. Participants ranging from two weeks to 16

years of age were chosen for this research study. Half of the participants were receiving either all or some of their feeds enterally. The diagnosis of these research participants' dysphagia was described as secondary to a congenital anomaly of the head/neck or CNS or due to an acquired CNS lesion or the cause was unknown. MBS examinations were conducted at the beginning and at the end of the study. The FOIS (Crary et al., 2005) was used to assign scores to each research participant. NMES sessions lasted an hour and oral-motor therapy was offered to research participants where necessary. NMES was terminated when the research participants' swallow improved or if no changes in their swallow were evident after three months of therapy. The researchers indicated that an average of 22 NMES sessions were required for improvement to be seen (Christiaanse et al., 2003). The results of this study indicated that there may be groups in the paediatric population with dysphagia e.g. those whose dysphagia is acquired or of unknown origin, who will benefit from NMES.

The position on NMES is tentative among therapists both locally and internationally. There have been possible benefits of this treatment modality identified, but there are also concerns for the safety of the clients and the long-term benefits of NMES (Doeltgen & Huckabee, 2007). There is a need for high quality controlled trials to determine the safety and efficacy of this treatment method (Langdon & Blacker, 2010).

Despite these uncertainties the majority of the studies on NMES have been conducted on adult populations of diverse dysphagia etiology (Baijens, Speyer, Roodenburg & Manni, 2008; Belafsky, Speirs, Hiss & Postma, 2004; Blumenfeld et al., 2006; Bogaardt et al. 2008; Bulow, Speyer, Baijens, Woisard & Ekberg, 2008; Carnaby-Mann & Crary, 2008; Freed et al., 2001; Shaw et al., 2007). There appears to be a shortage in the research regarding the effect of NMES on paediatric feeding and swallowing abilities of young children, specifically those who have been PEG tube dependent for a lengthy period of time (>6 months).

Therefore, this research study aimed to investigate the use of NMES on a young child's feeding and swallowing abilities who have been receiving feeds via PEG tube for a lengthy period of time.

The researcher's clinical observations and experience when working with paediatric dysphagia in a large tertiary hospital in a rural area are that conventional swallowing therapy often fails in those children who have severe dysphagia. The placement of PEG tubes is frequently the only option for these children to maintain nutritional support. Once

conventional swallowing therapy aimed at improving the feeding and swallowing of these children has been tried and failed, there appears to be no other treatment options. The caregivers are often left to feed the children via PEG tubes for the rest of their lives. This research study endeavoured to determine whether NMES may be an effective alternative or additional dysphagia treatment option for a young child who was feeding long-term via a PEG tube.

Clarification of concepts as used in the dissertation

- **Dysphagia** – Dysphagia refers to the difficulty in swallowing (Arvedson & Brodsky, 2002).
- **Feeding** – Feeding is the ingesting of food stuffs by sucking, chewing and/or swallowing (Arvedson & Brodsky, 2002).
- **Oral sensorimotor stimulation** – Arvedson and Brodsky (2002) refer to oral sensorimotor stimulation as all aspects of the motor and sensory function of the structures in the oral cavity and pharynx related to swallowing from the lips until the beginning of the pharyngeal phase of swallow is stimulated. All oral sensorimotor stimulation provided to the participants in this study was done passively. The researcher provided stimulation both outside and inside the oral cavity.
- **Neurodevelopmental basis of swallowing** – The embryo has six branchial arches which give rise to the muscles, cranial nerves and the skeleton that eventually develops into the anatomical structures of speech and swallowing (Hall, 2001). As the tongue moves food posteriorly, sensory receptors in the oropharynx and the tongue are stimulated. The sensory information is sent to the cortex and the brainstem, which control the swallowing response. This sensory information is recognized in the medulla and decoding of the information and identification of the swallow stimulus occurs. Information is sent to the nucleus ambiguus which initiates an involuntary pharyngeal swallow (Logemann, 1998).
- **PEG insertions and PEG feeding** – A PEG tube is preferred when tube feedings are anticipated for longer than two to three months. PEG tube feeding is used when oral feeding is unsafe or if the child does not receive enough nutrition due to neurological complications. A PEG tube is inserted into the stomach directly through the abdominal skin. A major disadvantage of feeding tubes is the negative effect on oral sensorimotor stimulation (Arvedson & Brodsky, 2002).
- **Severity of dysphagia** – In this dissertation, severity of dysphagia is referred to as dysphagia that requires non-oral feeding (feeding with a PEG tube).
- **Theoretical framework of the swallowing mechanism** – Morris and Klein (1987) associate the anatomy of the feeding system as a single tube which consists of the oral and nasal cavities superiorly and divides into the trachea inferiorly. The tube ends in the lungs and the oesophagus which leads to the stomach. Valves which are strategically placed along the tube guide food from the oral cavity to the stomach (Morris & Klein,

1987). The swallowing phase is divided into various phases. The oral preparatory phase of swallowing includes the intake of food into the mouth and the formation of a bolus. During this phase lip closure is important to keep the food or liquid in the oral cavity. Food and liquid is held between the tongue and the hard palate in the middle groove created by the tongue. The soft palate is lowered against the base of the tongue to prevent food from entering the pharynx. The airway is open during this phase. The oral phase begins when the bolus is moved posteriorly by the tongue and ends with the beginning of the pharyngeal swallow. The tongue touches the hard and soft palate as it moves the bolus posteriorly into the pharynx. The elevation of the soft palate against the posterior pharyngeal wall prevents nasoharyngeal reflux. With the voluntary production of a swallow and the elevation of the soft palate to close off the nasopharynx, the pharyngeal phase of the swallow begins. Pharyngeal constrictors contract to move the bolus down the pharynx. During this phase the larynx is closed. Peristaltic waves move the bolus from the pharynx into the stomach via the esophagus (Arvedson & Brodsky, 2002).

CHAPTER 2

2. Method

2.1. Aim

To determine whether change took place in the oral preparatory, oral and pharyngeal phase of swallowing in a young child who was receiving long-term PEG tube feeds, following twenty sessions of NMES and oral sensorimotor stimulation.

2.2. Research design

The study followed a true experimental design (Leedy & Ormrod, 2010) as depicted in Table 1. A randomised pre-test-post-test single case design with a control was used to determine whether any changes in the participant's feeding and swallowing abilities could be detected on MBS (Modified Barium Swallow) examinations before and after twenty sessions of NMES and oral sensorimotor stimulation. Researchers, such as Christiaanse et al., (2003) obtained improvement in participants when an average of 22 NMES sessions was conducted. However, the researcher obtained guidelines with regard to the implementation of 20 NMES sessions from training that was attended. The participants received therapy three times a week for an hour each session, over a period of six weeks. The treatment phase of the study was therefore long-term. A single control participant was included and observed by means of MBS studies before and after the same number of oral sensorimotor stimulation as the main participant. In order to control for potential threats to the internal validity of the study (Leedy & Ormrod, 2010), the participants were recruited at the same time and randomly assigned to act as main and control participants (Table 1). To ensure randomization, the participants' caregivers were each presented with an envelope. The contents of the letter, determined whether the child was the main or the control participant. Further threats of internal validity were controlled by using an objective measuring tool, the MBS, to collect data before and after treatment as displayed in Table 1. The MBS results were scored by a moderator who was blind to the phase of the study and the participants.

Both participants were subjected to oral sensorimotor stimulation, but only the main participant received neuromuscular electrical stimulation in the form of NMES. Since oral sensorimotor stimulation are part of the NMES protocol the hypothesis was that the inclusion of oral sensorimotor stimulation in the control participant may have clearly displayed the

effect, if any, of neuromuscular electrical stimulation according to the NMES protocol. The design also included a long-term component without treatment, since the main participant was followed-up with MBS examinations only over a period of 15 months.

The study was exploratory in nature as the research topic is relatively unknown. It appears that there has not been extensive research on the effect of NMES on children's feeding and swallowing skills who have been feeding via PEG tube for a lengthy period of time in South Africa or internationally.

Table 1: Randomised pre-test-post-test single case design with a control (n=2)

	Participant	Pre-test	Time	Post-test
Random assignment of participants	Main	<ul style="list-style-type: none"> • MBS examination • Case History interview • Clinical assessment of feeding and swallowing 	<ul style="list-style-type: none"> • 20 Sessions of NMES and oral sensorimotor stimulation 	<ul style="list-style-type: none"> • MBS examination • Clinical assessment of feeding and swallowing
	Control	<ul style="list-style-type: none"> • MBS examination • Case History interview • Clinical assessment of feeding and swallowing 	<ul style="list-style-type: none"> • No NMES • Only 20 sessions of oral sensorimotor stimulation 	<ul style="list-style-type: none"> • MBS examination • Clinical assessment of feeding and swallowing

2.3. Research Ethics

Permission to conduct this research was obtained from the University of Pretoria (Faculty of Humanities and Health Sciences) and the specific urban academic hospital at which the research was carried out (Appendix A, B and C). The primary caregivers of the two participants were a mother and a grandmother. Both received written information regarding the research study and granted written informed consent, made available in English and Setswana (Appendix D and E).

2.3.1. Protection from harm

Leedy and Ormrod (2010) state that the researcher has an ethical obligation to protect the research participants, within reasonable limits, from any form of physical discomfort or harm that may result from the research study. According to Freed et al. (2001) and Wijting (2009) no adverse effects were observed when using NMES on patients with dysphagia. The therapy procedure was therefore not viewed as potentially harmful to the main participant. The caregivers were informed about possible advantages, contraindications and precautions regarding NMES. The main participant's treating physician completed a consent form (Appendix F) indicating that the participant was medically stable to undergo NMES.

Each research participant's parents or caregivers participated in the research study out of their own will and could withdraw their child at anytime during the study. To ensure that no harm was incurred to the participants the caregivers were present at all times during the sessions. A new set of electrodes was used for each session to ensure an adequate electric current. The parents or caregivers were informed that the placement of the electrodes on the pilot and main participants and turning on the electrodes does not hurt their children but that it is a sensation that their children had to get use to. The caregivers were given toys to distract the participants from the increasing current of the electrodes.

Parents and caregivers were also informed that NMES may not have a positive impact on their child's feeding and swallowing abilities. This was done to prevent false expectations.

To overcome any ethical or practical issues regarding withholding of NMES from the control participant, the caregiver was informed that if it was found that the main participant's feeding and swallowing abilities improved, NMES will be given free of charge after the completion of the study.

2.3.2. Privacy and confidentiality

During the research study the privacy and confidentiality of the participants was not dishonoured (de Vos, 2009). The researcher kept the nature of the participants' medical history and therapy results confidential (Leedy & Ormrod, 2010). The names of the research participants or their caregivers were not reported in this study. The MBS examinations were anonymously viewed by the moderator. The moderator was blind to the phase of the research.

The hospital where the research was conducted was also not disclosed in the study or in the article.

2.3.3. Actions and competence of the researcher

The neuro muscular electrical machine (VitalStim®) was bought for the study by the researcher. The researcher attended a course in VitalStim® Therapy or NMES and is certified for the practice of this procedure (Appendix G). This research study is independent although the researcher corresponded with the VitalStim® Therapy trainers in South Africa and the USA. Electrodes were sponsored for this study by Yorick Wijting.

2.4. Participants

2.4.1. Participant selection criteria

The research participants needed to comply with the following criteria:

- *Inclusion criteria*

The participants had to be young children who could be matched for diagnosis of dysphagia, age, swallowing difficulty, medical diagnosis and length of time fed with a PEG tube. Obtaining participants who met the inclusion criteria proved to be challenging. After much consideration it was decided that participants would be included in the research study if they had been feeding with a PEG tube and had a similar diagnosis. Two participants were identified who met this inclusion criterion.

- *Exclusion criteria*

Possible research participants were excluded from participating in the study if they had significant unresolved reflux, if they had any oesophageal disorders that were preventing them from eating orally, or if they presented with repeated episodes of aspiration pneumonia. Repeated episodes of aspiration pneumonia are common in patients with significant reflux and therefore considered a precaution when using NMES (Wijting, 2009). NMES focuses on improving the strength of the swallowing muscles. If the participant's dysphagia is caused by any form of esophageal disorder, NMES will be ineffective. Active infection and neoplasms on the anterior neck also excluded possible participants from the research as stimulation may aggravate the condition by increasing local metabolic rate (Wijting, 2009). The researcher did not consider children who presented with dysphagia due to drug toxicity, have a demand

pacemaker, deep brain stimulator, implantable cardioverter defibrillators and seizures, as participants. Due to the many exclusion criteria, it was difficult to recruit participants.

- *Number of participants*

Initially, approximately ten children with feeding and swallowing difficulties who were receiving all their feeds via PEG tubes would have been the research sample for this study. Five of the children would have formed the control group and the other five the experimental group. However, it proved challenging to identify ten participants who fulfilled the selection criteria. After careful consideration and consultation, the researcher decided to conduct a single case experimental design with a control participant.

2.4.2. Participant characteristics

Two young children with feeding and swallowing difficulties who were fed via PEG tubes were purposively selected at the same time as research participants. The main participant had been feeding through a PEG tube for 11 months while the control participant for 25 months. MBS examinations were conducted on both participants by the staff at the hospital. From their interpretation of the results it was recommended by the therapists to have a PEG tube inserted. It is presumed that all therapeutic input was exhausted before the decision was made to have a PEG tube inserted. From the results of the MBS examinations (Table 1) it is presumed that the reason for PEG tube insertion would have been because of the poor oral phase that would presumably have lead to poor oral intake. The research participants both had spastic cerebral palsy and were randomly assigned to be the main and control participant.

The research participants for this study were 62 months (main participant) and 40 months (control participant) old. This age group was selected as there is limited research worldwide regarding the effect of NMES on the feeding and swallowing abilities in the paediatric population (Christiaanse et al., 2003). It was ideal that the research participants be matched according to their age, swallowing ability, diagnosis and length of time since the PEG tube was inserted. This however, was found to be challenging, so the participants were only matched according to similar diagnosis.

- *Geographical area*

Both participants were recruited from an urban academic hospital in the Gauteng region. The reason for this was due to logistical and financial constraints pertaining to the collection of data. The researcher resides in the Gauteng area, so collection of data was made easier this way. The hospital also had to be accessible to the participants to attend 20 data collection sessions each.

- *Medical status*

The main research participant in this study was declared medically stable by a paediatrician before participating in this study (Appendix F).

- *Diagnosis*

A specific congenital or acquired illness/diagnosis was not required for this study. Both research participants presented with spastic cerebral palsy, severe dysphagia and were fed via PEG tube for lengthy periods of time. At the time of the study the main participant had been feeding through a PEG tube for 11 months and the control participant for 25 months.

2.4.3. Criteria for selection of a moderator who reviewed the MBS examinations

The moderator recruited to review and evaluate the MBS examinations had to be a qualified speech-language therapist. The therapist had to have experience treating children with dysphagia and viewing paediatric MBS examinations. A therapist working at the hospital where this research was carried out was requested to be the moderator.

2.4.4. Participant selection procedure

Child participants

The researcher obtained a list of patients who received MBS examinations from the Speech Therapy Department at the hospital. The researcher identified children recommended for PEG tube feeding after MBS examinations were conducted. From the list, two participants who had a similar diagnosis were recruited for the study. As already discussed random assignment was conducted by presenting the caregivers with an envelope. The contents of the envelope indicated whether the child would be the control or the main participant.

Moderator

The moderator of the MBS examinations was a qualified speech-language therapist who worked at the hospital where the research was conducted. The moderator had extensive experience, since she was responsible for conducting MBS examinations twice a week. The moderator did not know the identity or the allocation of the participants and was blind to the pre-test and post-test MBS examinations. The researcher carried out the MBS procedures with assistance from one of the speech-language therapists from the hospital, while the moderator analyzed the MBS examinations. The information brochure to the moderator is included in Appendix H.

2.5. Materials and apparatus

The material and apparatus that was used in this study were as follows:

The research study was conducted in seven phases with specific material and/or apparatus used during each phase.

Phase 1: Case History interview with the research participants' parents or caregivers

Phase 2: Clinical Assessment of the participants' feeding and swallowing abilities

Phase 3: Pre-treatment MBS examinations were conducted on the main and the control participant

Phase 4: Twenty sessions of NMES and oral sensorimotor stimulation were provided to the main participant. The control participant received 20 sessions of oral sensorimotor stimulation only.

Phase 5: Post-Treatment MBS examinations were conducted on the main and the control participant

Phase 6: The main and the control participant's feeding and swallowing abilities were clinically assessed by the researcher

Phase 7: A seven and a 15 month MBS examination follow-up without treatment was conducted to determine the long-term effects of NMES

Phase 8: If NMES was found to be successful, the control participant was afforded the opportunity to receive NMES free of charge. This phase was not part of the research study

An explanation of the material and apparatus utilized during each phase of the study is described below:

Phase 1: Case history interview with the research participants' parents or caregivers

Material

- A structured case history interview (Appendix I) was conducted with a parent or a caregiver of each participant to obtain case history information. The rationale for including the case history was to obtain a clearer understanding of the development of the participants' oral-motor, feeding and swallowing skills. A description of the participants' current feeding abilities and feeding difficulties was obtained from the caregivers. The participants' medical records were consulted to obtain information regarding medical history and possible cause of dysphagia. The interview took place at the hospital where the research study was carried out.

Apparatus

- No apparatus was required for this phase of the research study.

Phase 2: Clinical Assessment of the participants' feeding and swallowing abilities

Material

- Each research participant's feeding and swallowing skills was clinically assessed by the researcher according to the 'Feeding and Swallowing Clinical Assessment' form (Appendix J). During this clinical assessment the researcher subjectively determined the participant's muscle tone, response to the environment, respiratory patterns, the participant's state before and after non-nutritive sucking evaluation, oral structure and function (lips, palate, jaw, gums and teeth, cheeks, tongue), swallowing and mother-child interaction during feeding. By conducting this clinical assessment the researcher was able to develop an understanding and insight into the participant's feeding and swallowing abilities at the start of the research study. Each participant was assigned a score according to the FOIS (Crary et al., 2005) (Appendix K). A

score was given to each participant so that any change in feeding function after the completion of the study could be documented. This assessment took place at the hospital.

Apparatus

- Gloves
- Shonaquip Madiba Buggy for the participant to be positioned in correctly.
- Massaging brush

Phase 3: Pre-treatment MBS examinations were conducted on the main and the control participant

Material

- The Rating of the Modified Barium Swallow Examination form (Appendix L) was adapted from The Evaluation of Swallow Function form (Wijting, Y, personal communication, March 18, 2010 and Appendix M) and was used to interpret the results of the MBS examinations. This form assisted in the identification of the signs and symptoms of the participants' swallowing difficulties (e.g. decreased lip closure, delayed swallowing trigger, coating and decreased laryngeal elevation, etc.) and the dysfunction (e.g. decreased airway protection, decreased cheek tone, decreased tongue base retraction, etc.). The dysfunction led to the identification of the impaired muscle groups which then specified which electrode placement to use.

Apparatus

- A screening machine from the department of Radiology at the urban academic hospital was used to conduct the MBS examinations (Appendix N).
- The Shonaquip Madiba Buggy was used to position the participants.
- The different consistencies used during the MBS examination were thin (water), puree (yoghurt) and paste (yoghurt mixed with a thickening agent) depending on how the participants managed the consistencies. These consistencies were given in 3, 5 and 10 ml volumes. Each consistency was mixed with barium sulphate. A solid consistency was not given as the participants were not able to chew adequately.

- Consistencies were given via syringes to compensate for the oral motor difficulties the participants presented with.

Phase 4 – Twenty sessions of NMES and oral sensorimotor stimulation were provided to the main participant. The control participant received 20 sessions of oral sensorimotor stimulation only.

Material

- A NMES Tracking form (Appendix O) was used to document any treatment data e.g. length of session, response to treatment, which oral sensorimotor stimulation were introduced and electrode placements. After each session of NMES and oral sensorimotor stimulation the participant was assigned a score according to the FOIS (Crary et al., 2005) to determine if any changes in functional feeding had taken place.
- The non-nutritive oral-motor treatment protocol (Appendix P) was used to direct the researcher in choosing appropriate oral sensorimotor stimulation for the control and main participant.
- The NMES treatment protocol (Appendix Q) was followed. This protocol guided the researcher in the correct electrode placement, when to use a specific placement and the rationale of using that placement. The protocol also guided the researcher in determining the correct stimulation level of the NMES.
- Control participant – The non-nutritive oral motor exercise tracking form (Appendix R) was used to document any treatment data for the control participant. On this form the researcher recorded the length of the session, where the session was conducted, the specific oral sensorimotor stimulation that were initiated in the session, how many of each exercise were conducted and in which order the exercises were completed. The researcher also documented the state of the participant during the oral sensorimotor stimulation, their response to the exercises and if the participant demonstrated any stress signals during the session. Finally the researcher was able to record the participant's FOIS (Crary et al., 2005) score.

Apparatus

- The VitalStim® Therapy machine from the Chattanooga group (manufacturer) was used during this phase of the research. The serial number of the unit is S/N 2007-2939 0119554.
- The current provided by the VitalStim® machine is a biphasic pulse waveform. Each phase in the waveform is 300 microseconds long. VitalStim® has a preset frequency of 80 Hz to target the fast twitch motor neurons. The VitalStim® machine has a maximum amplitude of 25 mA.
- The VitalStim® Therapy machine used 2 AA batteries.
- Adult electrodes were used for the main participant – Reference number: 59000 (large). Lot number: 109114. Manufactured in the USA for Empi, Chattanooga group. The size of the participant's neck allowed for the use of adult electrodes.
- Positioning equipment – Each participant was positioned in a Shonaquip Madiba Buggy. A Shonaquip Madiba Buggy is generally used to transport and position children with cerebral palsy in South Africa. The buggy provides full body and head support to children with cerebral palsy.
- The occupational therapist at the urban academic hospital where the research took place, demonstrated exercises to the researcher to normalize muscle tone in the neck and body to aid in feeding and swallowing and correct positioning in the Shonaquip Madiba Buggy.
- Clean-Cote (alcohol swab) skin wipes were used to clean the neck area before placement of the electrodes.
- A broad elastic tape was used to keep the electrodes in place after placement.
- Bubbles, balloons and age appropriate toys were used to distract the child initially from the increasing intensity of the NMES.
- Non-nutritive oral-motor exercise equipment: small spoon, teether, dummy, baby safe feeder/fruit feeder, small baby toothbrush set, vibrating tooth brush, ice, cup of water and a massaging brush.

Phase 5 – Post-treatment MBS examinations were conducted on the main and the control participant

Material

- The Rating of the MBS examination form (Appendix L) was used to interpret the results of the MBS examination. This form will aid in the identification of any improvement in the participants' swallowing ability and to determine whether NMES was successful.

Apparatus

- Same as in Phase 1

Phase 6: The main and control participants' feeding and swallowing abilities were clinically assessed by the researcher.

Material

- Same as in Phase 2.
- The aim of this phase of the research was to determine if a positive impact was evident on the functional feeding and swallowing skills of the participants after treatment.

Apparatus

- Same as in Phase 2.

Phase 7: A seven and a 15 month follow-up MBS examination without treatment was conducted to determine the long-term effects of NMES

Material

- Same as in Phase 3.
- The aim of this phase of the research was to determine the long-term or maintenance effects of NMES on the feeding and swallowing abilities of the main participant. No intervention was provided during this period.

Apparatus

- Same as in Phase 3.

2.6. Procedures

2.6.1. Pilot study

A pilot study served to strengthen the confidence of the researcher in conducting the clinical assessment, MBS examinations, NMES and specific oral sensorimotor stimulation and to determine the child's responses to the electrode placements and stimulation. An estimate of the time and cost of the study could be determined (de Vos, 2009). A single participant, three years of age, with spastic cerebral palsy and only fed via a PEG tube, was selected. After 22 sessions of NMES and specific oral sensorimotor stimulation the results of the MBS examination indicated that the participant was able to safely feed on small amounts of a puree (yoghurt) consistency orally, although the majority of the feeds would still be provided via the PEG tube. After some time and after ensuring that the participant would be able to manage all feeds orally, the PEG tube was removed. The pilot participant was still feeding orally on most consistencies at the time when the article was written. During the pilot study the researcher made changes to the NMES response form to include the presence of laryngeal elevation; and the Evaluation of Swallow Function (Wijting, 2009) form was changed to include the specific amounts of the different consistencies.

2.6.2. Main study

After obtaining ethical clearance, two suitable research participants were selected, case history interviews were conducted and a clinical assessment of feeding and swallowing abilities and a MBS examination was carried out on each participant. The participants were positioned in a Shonaquip Madiba Buggy to ensure optimal positioning and a clear image on the MBS screen during the examinations. The different consistencies, mixed with barium sulphate, was thin (liquid), puree (yoghurt) and a paste (mousse). The participants were given three, five and 10 ml of each consistency depending on how they were able to manage the bolus. Since the participants could not chew adequately, a solid consistency (biscuit) was not often included.

Both participants were positioned in the Shonaquip Madiba Buggy for each treatment session. An occupational therapist working at the hospital showed the researcher exercises to complete prior to the sessions to normalize the tone in the participants' muscles (neck and shoulders and legs), thereby ensuring appropriate positioning in the Shonaquip Madiba

Buggy and to eventually improve the muscle tone in the oral structures (Levitt, 2004). Each participant was seen three times a week for a total of 20 sessions. The main participant received NMES and oral sensorimotor stimulation while the control participant only received oral sensorimotor stimulation for the same number of days as the main participant. The exercises were administered in the same sequence each session and 10 repetitions of each exercise were conducted.

After the post-treatment MBS examination it was recommended that the main and control participant receive small amounts of a puree consistency orally, although most of the nutrition would continue to be supplied via the PEG tube. It was suggested to the caregivers that 3 to 5 ml of a puree consistency (yoghurt) be given orally to the participants via a syringe every time the participants were fed. The importance of correct positioning and observing any signs of aspiration, such as coughing and tearing of the eyes, were highlighted to the caregivers. The researcher and caregivers remained in telephone contact over the next few months and during this period feedback regarding the participants' feeding was positive. At seven and 15 months post-treatment the main participant received follow-up MBS examinations. Long-term follow-up data from the control participant could not be obtained as the participant sadly passed away. The main participant had not been receiving any oral sensorimotor stimulation during the post-treatment period.

NMES: The treatment protocol was followed according to Wijting (2009). The adult electrode placement 3b was identified as the most suitable position for the main participant (Wijting, 2009). Electrode placement 3b entailed that the electrodes of Channel 1 were horizontally aligned at or above the hyoid bone. Channel 2 electrodes were placed on either side of the thyroid notch. This specific electrode placement was used due to the reduced pharyngeal constriction identified during the pre-test MBS examination of the main participant. Before the electrodes were placed on the anterior region of the main participant's neck, excess cream or perspiration was removed with an alcohol swab. Once the adult electrodes were in place, a broad elastic tape was placed over the electrodes to keep them firmly attached to the skin. The participant's anatomy allowed for the use of adult size electrodes. Occasionally, the main participant pulled the electrodes off during treatment sessions. Firm attachment with tape prevented this.

The VitalStim® Therapy machine was switched on and both channels were increased alternately. To determine the effective level of stimulation the researcher observed any signs of reaching for the electrodes or any sudden movements or startle behaviour by the participant. When these behaviours were observed in the main participant the intensity was left at that level. At the beginning of each session the intensity level was increased to a higher level than in the previous session. The caregiver was given bubbles, balloons and age appropriate toys to distract the participant from the increasing intensity of NMES. Once the appropriate electrode intensity was identified, oral sensorimotor stimulation commenced. A new pair of electrodes was used for every session to ensure optimal strength of the current.

After each session with the main participant, the duration of the session, electrode placement, amount of electrodes used and stimulation levels were recorded. Oral sensorimotor stimulation were conducted, the participant's response to the NMES and to oral sensorimotor stimulation, the participant's state, any signs of stress signals and whether laryngeal elevation was felt or if it had to be elicited, were also recorded. Similar procedures were recorded for the control participant but neuro muscular electrical stimulation was excluded. Each participant was given a FOIS score (Crary et al., 2005) after every session. After the completion of the 20 sessions, each participant received a second MBS examination and a clinical assessment to determine any changes in their feeding and swallowing abilities after treatment. Pre-treatment FOIS scores were one for both participants, indicating no oral intake. After the post-treatment MBS examinations both participants' FOIS scores were two suggesting that although the participants were still tube dependent they had minimal or inconsistent oral intake. Upon completion of the seven and 15 month follow-up MBS examinations the main participants FOIS score was one, suggesting no oral intake.

Oral sensorimotor stimulation: These exercises served as a comparative intervention to NMES. The goal was to improve the oral motor movements and tone, reduce the occurrence of abnormal reflexes and improve normal oral sensation (Rogers, 2004; Snider, Majnemer & Darsaklis, 2011). Appendix P provides a description of these exercises.

2.6.3. Data analysis procedures

The data collected from the research was organised in MS Excel spread sheets according to the different data collection instruments. The data was read through a few times and categories and meaning in the data was obtained. The information was integrated and

summarized in the form of tables to provide possible conclusions. Descriptive statistics was used because case studies are detailed and rich in descriptions rather than numbers and statistics (Meline, 2010). No statistical tests could be used. The data was analysed based on the presence or absence of functions as observed in the MBS. The independent moderator evaluated the data obtained from the MBS examinations. The moderator was blind to the phase of the research and the participants when analysing the MBS data. No statistical analysis was possible as only two participants were utilized.

2.7. Reliability and Validity

The completion of a pilot study before the main study prepared the researcher for the main participant's possible response to the electrical stimulation, the electrode placement and operating the VitalStim® Therapy machine. The pilot study also improved the researcher's ability to conduct the oral sensorimotor stimulation. An independent moderator evaluated the data obtained from the MBS examinations. The moderator was blind to the phase of the research and the participant's when analysing the MBS examination data. Reliability and internal validity were further increased by randomly assigning the participants as either the control or the main participant. The randomised pre-test-post-test experimental design was the strongest factor to increase the internal validity of the study.

CHAPTER 3

Article: Neuromuscular electrical stimulation (NMES) and oral sensorimotor stimulation in a young child with cerebral palsy and severe dysphagia

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This manuscript was submitted to a journal for possible publication and edited according to the journal's specifications. The article is currently undergoing its second review.

3.1. Abstract

Background

Research on neuromuscular electrical stimulation (NMES), suggests it may limit PEG tube feeding in children with severe dysphagia.

Objective

The aim was to determine whether there were differences in the swallowing of a young child with PEG tube feeding after 20 sessions of NMES and oral sensorimotor stimulation, in comparison to a control. If differences were measured, a further aim was to determine whether improvement could be maintained at post-treatment observations.

Method

A pre-test-post-test design with a control was implemented for the first aim. The second aim involved a simple time series design where observations were carried out on the main participant over time. The participants were two pre-school children with spastic cerebral palsy fed via PEG tubes. One participant was randomly selected to receive NMES while both received oral sensorimotor stimulation. Data was collected by means of clinical evaluations of feeding and swallowing abilities and Modified Barium Swallow (MBS) examinations. Post-treatment follow-up MBS examinations were conducted at seven and 15 months on the main participant only.

Results

Both participants showed improvement of oral dysphagia after treatment. The main participant showed better improvement of pharyngeal phase difficulties than the control. The main participant's improvement was not sustained.

Conclusion

Initial positive post-treatment results in the oral phase of both participants may have been associated with oral motor stimulation. Short-term improvement in the pharyngeal phase of swallowing in the main participant could be associated with NMES. The study confirms previous research indicating that NMES is no more effective than conventional dysphagia treatment in children.

Key words: dysphagia, cerebral palsy, Modified Barium Swallow examinations

NMES, oral sensorimotor stimulation, VitalStim® Therapy, young children

3.2. Introduction

Management decisions in paediatric dysphagia include diet modifications, altering positioning, changing temperature, volume and consistency of foods, oral sensorimotor stimulation, adapting feeding equipment and possibly even surgical intervention (Arvedson & Brodsky, 2002; Prasse & Kikano, 2009). In instances where infants are malnourished, present with aspiration associated with respiratory difficulties or who present with stressful oral feedings, severe dysphagia is identified and recommendations for alternative non-oral means of nutrition are made (Prasse & Kikano, 2009; Rogers, 2004). If the dysphagia is seen to be long-term, a percutaneous endoscopic gastrostomy (PEG) tube will be inserted. Tube feeding in children has improved their quality of life by ensuring that the child receives sufficient nutrition to survive (Mason, Harris & Blissett, 2005). While the insertion of PEG tubes is beneficial to children with severe dysphagia, it requires specialized long-term care with a risk for serious complications (Arvedson & Brodsky, 2002; Vervloessem et al., 2009). Research has suggested that if the child no longer requires tube feeding, difficulties in resuming oral feeding may still be present (Mason et al., 2005).

A relatively new treatment for pharyngeal dysphagia that could possibly decrease the use of PEG tubes is neuromuscular electrical stimulation (NMES) (Lim et al., 2009). NMES has been used in a wide variety of therapeutic and rehabilitative settings especially in the profession of Physical Therapy (Wijting, 2009). The hand-held, battery operated electrical stimulation device was developed purposely for the stimulation of the anterior neck muscles via electrodes for the safe treatment of dysphagia and was approved by the United States Food and Drug Administration in 2001. The goal of NMES or VitalStim® Therapy is to strengthen weak muscles, to improve muscle contractions and to help clients with dysphagia regain motor control of their swallowing (Permsirivanich et al., 2009). NMES specifically stimulates type II muscle fibres which are used when swallowing, while conventional dysphagia therapy typically stimulates type I muscles fibres only (Wijting, 2009). The rationale behind neuro muscular electrical stimulation is that electrical stimulation together with conventional dysphagia exercises improves the client's swallowing, by activating both type I and type II muscle fibres, improving laryngeal elevation and pharyngeal transit time and thereby achieving better swallowing outcomes (Lim et al., 2009).

Numerous research studies using NMES showed positive results in the swallowing abilities of adults with chronic and severe dysphagia (Blumenfeld et al., 2006; Freed et al., 2001; Leelamanit, Limsakul & Geater, 2002; Li, Hoang, Yin, Shen & Shi, 2015; Lim et al., 2009; Park et al., 2014; Permsirivanich et al., 2009; Shaw et al., 2007). An improvement in swallowing, less time in hospital and fewer therapy sessions were found in comparison to patients who only received conventional dysphagia therapy (Blumenfeld et al., 2006) or thermal tactile stimulation (Freed et al., 2001; Lim et al., 2009) or a combination with conventional swallowing exercises and NMES (Permsirivanich et al., 2009). NMES in conjunction with conventional dysphagia therapy appears to be effective in adults. Limited research has determined the effect of NMES on the paediatric population.

One of the few research studies performed on the paediatric population aimed at contrasting the change in swallowing function between a group of children (two weeks to sixteen years) who received NMES and a group who did not (Christiaanse et al., 2003). Both groups showed improved swallowing function over the course of the treatment, but the degree of improvement was similar between the groups (Christiaanse et al., 2003).

Eight years later, Christiaanse et al., (2011) published new research stating that NMES is not more effective than conventional therapy for treating children with congenital dysphagia. Limitations of the previous study were addressed. The researchers resolved that children with acquired dysphagia and who received NMES had better swallowing function after treatment than participants with congenital dysphagia (Christiaanse et al., 2011). The improvement in children with acquired dysphagia could relate to previous swallow experience. It appears that the study may have limitations. The treatment group showed more severe dysphagia than the control group as indicated by the Functional Oral Intake Scale (FOIS) level and there were differences between the groups regarding the timing of post-treatment video-fluoroscopic studies. The study included a great diversity of children with dysphagia and the authors concluded that there may be subgroups of children with dysphagia who may benefit from NMES. The authors did not specifically report on the performance of the few participants with “central nervous system injury” or ‘CNS anomalies”, which may refer to cerebral palsy in their sample (Christiaanse et al., 2011).

An unpublished pilot study showed promising results for the effectiveness of NMES in the neonatal population (Mitchell et al., 2010). After two weeks of therapy infants in the experimental group showed an increased likelihood to return to oral feedings than those in the control group (Mitchell et al., 2010). A series of five paediatric case studies with no controls was carried out by Rice (2012) to determine the effect of neuromuscular electrical stimulation in treating dysphagia. Neuromuscular electrical stimulation was determined to be an effective intervention method in treating pharyngeal dysphagia in these cases.

Due to the increased positive effects of NMES indicated in investigations, the current study was conducted to contribute to the body of research investigating this method and its applicability in different contexts.

3.3. Method

3.3.1. Aim

The main aim was to determine whether there was a difference in the oral preparatory, oral and pharyngeal phases of swallowing in a young child who was receiving long-term PEG tube feeds, following twenty sessions of NMES and oral sensorimotor stimulation and a control who only received oral motor exercises. A further aim was to determine whether

sustained improvement could be observed during a post-treatment period if there was an initial difference in swallowing between the two participants.

3.3.2. Research design

A pre-test-post-test design with a control was used to determine whether any changes in the participant's feeding and swallowing abilities could be detected on the Modified Barium Swallow (MBS) studies before and after twenty sessions of NMES and oral sensorimotor stimulation. A single control participant was included and observed by means of MBS studies before and after the same number of oral sensorimotor stimulation as the main participant. In order to control for potential threats to the internal validity of the study (Leedy & Ormrod, 2010), the participants were recruited at the same time and randomly assigned to act as main and control participants. Both participants were subjected to oral sensorimotor stimulation, but only the main participant received neuromuscular electrical stimulation in the form of NMES. The hypothesis was that the inclusion of oral sensorimotor stimulation in the control participant may have displayed the effect, if any, of NMES. The design also included a long-term element of simple time series observations, since the main participant was followed-up over a period of 15 months.

3.3.3. Research Ethics

Permission to conduct this research was obtained from the University of Pretoria and the specific urban academic hospital at which the research was carried out. The primary caregivers of the two participants were a mother and a grandmother. Both received written information regarding the research study and granted informed consent. The caregivers were informed about possible advantages, contraindications and precautions regarding NMES. Delayed treatment was discussed as an option for the control participant if positive results were obtained from the main participant.

3.3.4. Participant selection criteria

Inclusion criteria were that participants had to be preschool children, present with severe feeding and swallowing difficulties, were fed via PEG tubes, failed to show sufficient progress following feeding and swallowing therapy to have the PEG tube removed, and present with cerebral palsy. It appears that NMES has not been extensively and exclusively investigated in children with cerebral palsy. The exclusion criteria were that the participants

should have had no history of seizures. The electric current used in NMES, if very strong and applied over bony prominences, might elicit a seizure (Wijting, 2009).

Both participants were purposively selected at the same time as research participants and then randomly assigned to be the main and control participant. Due to logistical and financial constraints research participants living close to the urban academic hospital in the Gauteng region, where the research was conducted, were selected for this study. The characteristics of the participants are described in Table 2.

TABLE 2: Participant characteristics (n=2)

Characteristics	Main participant	Control participant
1. Biographical Information		
<i>Age</i>	62 months	40 months
<i>Gender</i>	Female	Female
<i>Diagnosis</i>	Spastic, quadriplegic Cerebral Palsy	Spastic, quadriplegic Cerebral Palsy
<i>Associated Difficulties</i>	Hearing difficulties and wears hearing aids	Hearing and visual difficulties
2. Feeding history		
<i>Oral feeding after birth</i>	Breastfed after birth and was fed porridge but did not feed well	Bottle fed in hospital after birth, then breastfed at home
<i>Main feeding and swallowing difficulty according to mother/caregiver</i>	Cannot swallow	Difficult to feed the participant, coughing and vomiting.
<i>When did the caregiver realise there was a problem?</i>	Caregiver not sure	Caregiver realised after 12 months that there was something wrong
<i>When was the PEG tube inserted?</i>	51 months	15 months
<i>Frequency and volume of PEG feeds</i>	6 times a day, 180 ml at each feed	60 ml every hour, when a greater volume is given, the participant vomits
<i>Type of food taken through the PEG tube</i>	Potatoes, peas, soup, meat, porridge (mashed up)	Formula food and cooked vegetables
<i>Position of child during PEG feeding</i>	In the corner of the sofa	On the sofa or on the bed and Madiba Shonaquip Buggy
<i>MBS results in the hospital file</i>	Grinds teeth, anterior food spillage, bite reflex, uncoordinated tongue movements but no aspiration	Delayed oral transit phase, bite reflex, uncoordinated tongue movements but no aspiration.
<i>Early intervention</i>	Cerebral palsy clinic at the	Cerebral palsy clinic at the

local hospital, once a month local hospital, once a month

According to Table 2 the two participants were both pre-school girls with cerebral palsy, associated conditions and severe dysphagia. At the beginning of the study the main participant had been feeding through a PEG tube for 11 months and the control participant for 25 months. The caregiver of the main participant did not have any specialized equipment for positioning the child during feeding, while the control participant had a buggy to aid positioning during feeding. The caregivers were trained to feed the children via the PEG tubes by the paediatric department of the urban academic hospital. Both participants consumed liquids and food via PEG tube before the study began. The caregivers reported that both children occasionally drank small amounts of liquids orally.

3.3.5. Participant selection procedure

The researcher obtained a list of patients who received MBS examinations from the Speech Therapy Department at the urban academic hospital. Children recommended for PEG tube feeding after MBS examinations were conducted were identified. From the list, two participants who had a similar diagnosis were recruited for the study. Random assignment was conducted by presenting the caregivers with an envelope. The contents of the envelope indicated whether the child would be the control or the main participant.

3.3.6. Materials and apparatus

The data collection forms that were used included: A case history form, a clinical feeding and swallowing assessment form based on Arvedson and Brodsky (2002) and Swigert (2010), a FOIS form (Crary, Carnaby-Mann & Groher, 2005), the Assessment of Swallow Function form (Wijting, 2009) which contains different categories of dysfunction for each swallowing phase in order to describe the MBS results, and NMES and oral sensorimotor stimulation tracking forms based on Wijting (2009).

Apparatus used were as follows: The apparatus that delivered the NMES was the VitalStim® Therapy machine (serial number of the unit: S/N 2007-2939 0119554) from the Chattanooga manufacturing group was used during the research. The current provided by the VitalStim® machine is a biphasic pulse waveform with each phase in the waveform 300 microseconds long. VitalStim® has a pre-set frequency of 80Hz to target the fast twitch motor neurons. The VitalStim® machine has a maximum amplitude of 25mA (Wijting, 2009). Appropriate

equipment was used when carrying out the oral sensorimotor stimulation (small toothbrush set, teether, small spoon, massaging brush and a cup of ice to improve sensory stimulation). All equipment was disinfected after use.

3.3.7. Procedures

3.3.7.1. Pilot study

A pilot study served to strengthen the confidence of the researcher in conducting the clinical assessment, MBS examinations, NMES and specific oral sensorimotor stimulation and to test the child's responses to the electrode placements and stimulation. An estimate of the time and cost of the study could be determined (de Vos, 2009). A single participant, three years of age, with spastic cerebral palsy and only fed via a PEG tube, was selected. After 22 sessions of NMES and specific oral sensorimotor stimulation the results of the MBS examination indicated that the participant was able to safely feed on small amounts of a puree (yoghurt) consistency orally, although the majority of the feeds would still be provided via the PEG tube. After some time and after ensuring that the participant would be able to manage all feeds orally, the PEG tube was removed and the pilot participant was still feeding orally on most consistencies at the time when the article was written. During the pilot study the researcher made changes to the NMES response form to include the presence of laryngeal elevation; and the Assessment of Swallow Function (Wijting, 2009) response form was changed to include the specific amounts of the different consistencies.

3.3.7.2. Main study

After obtaining ethical clearance, two suitable research participants were selected, case history interviews were conducted and a clinical assessment of feeding and swallowing abilities, and a MBS examination was carried out on each participant. The participants were positioned in a Shonaquip Madiba Buggy to ensure optimal positioning and a clear image on the MBS screen during the examinations. The different consistencies, mixed with barium sulphate, was thin (liquid), puree (yoghurt) and a paste (mousse). The participants were given three, five and 10 ml of each consistency depending on how they were able to manage the bolus. Since the participants could not chew adequately, a solid consistency (biscuit) was not often included. The researcher carried out the MBS procedures with assistance from one of the speech-language therapists from the hospital, while the moderator analyzed the MBS

examinations according to the Assessment of Swallow Function (Wijting, 2009) at a later stage.

Both participants were positioned in the Shonaquip Madiba Buggy for each treatment session. An occupational therapist working at the hospital showed the researcher exercises to complete prior to the sessions to normalize the tone in the participants' muscles (neck and shoulders and legs), thereby ensuring appropriate positioning in the Shonaquip Madiba Buggy and to eventually improve the muscle tone in the oral structures (Levitt, 2004). Each participant was seen three times a week for a total of 20 sessions. The main participant received NMES and oral sensorimotor stimulation while the control participant only received oral sensorimotor stimulation for the same number of days as the main participant. The exercises were administered in the same sequence each session and 10 repetitions of each exercise were conducted.

The researcher and caregivers remained in telephone contact over the next few months and during this period feedback regarding the participants' feeding was positive. Seven and 15 months post-treatment the main participant received follow-up MBS examinations. Long-term follow-up data from the control participant could not be obtained as the participant passed away. The main participant had not been receiving any oral sensorimotor stimulation in the seven months post-treatment period.

NMES: The treatment protocol was followed according to Wijting (2009). The adult electrode placement 3b was identified as the most suitable position for the main participant (Wijting, 2009). Electrode placement 3b entailed that the electrodes of Channel 1 were horizontally aligned at or above the hyoid bone. Channel 2 electrodes were placed on either side of the thyroid notch. This specific electrode placement was used due to the reduced pharyngeal constriction identified during the pre-test MBS examination of the main participant. Before the electrodes were placed on the anterior region of the main participant's neck, excess cream or perspiration was removed with an alcohol swab. Once the electrodes were in place, a broad elastic tape was placed over the electrodes to keep them firmly attached to the skin. The participant's anatomy allowed for the use of adult size electrodes. Occasionally, the participant pulled the electrodes off during treatment sessions. Firm attachment with tape prevented this.

The VitalStim® Therapy machine was switched on and both channels were increased alternately. To determine the effective level of stimulation the researcher observed any signs of reaching for the electrodes or any sudden movements or startle behaviour by the participant. When these behaviours were observed in the main participant the intensity was left at that level. At the beginning of each session the intensity level was increased to a higher level than in the previous session. The caregiver was given bubbles, balloons and age appropriate toys to distract the participant from the increasing intensity of the VitalStim® Therapy machine. Once the appropriate electrode intensity was identified, oral sensorimotor stimulation commenced. A new pair of electrodes was used for every session to ensure optimal strength of the current.

After each session with the main participant, the duration of the session, electrode placement, amount of electrodes used and stimulation levels were recorded. Oral sensorimotor stimulation conducted, the participant's response to the NMES and to oral sensorimotor stimulation, the participant's state, any signs of stress signals and whether laryngeal elevation was felt or if it had to be elicited, were also recorded. Similar procedures were recorded for the control participant but NMES was excluded. Each participant was given a FOIS Score (Crary, Carnaby-Mann & Groher, 2005) after each session. After the completion of the 20 sessions, each participant received a second MBS examination and a clinical assessment to determine any changes in their feeding and swallowing abilities after treatment. **Oral sensorimotor stimulation:** These exercises served as a comparative intervention to NMES. The goal was to improve the oral motor movements and tone, reduce the occurrence of abnormal reflexes and improve normal oral sensation (Rogers, 2004; Snider, Majener & Darsaklis, 2011). Table 3 provides a description of the stimulation provided.

TABLE 3: Oral sensorimotor stimulation

Technique	Description
Reducing the tonic bite reflex (Morris & Klein 1987; Hall, 2001)	Firm pressure was applied to the face.
Facial moulding (Hall, 2001; Swigert, 2010)	Wipe from the outer cheek forward toward the lips. Wipe from the bottom of the chin up toward the lips. Both sides of the face were moulded at the same time to reduce lip retraction.

Massaging the temporo-mandibular joint (Swigert, 2010)	Massaging was only done when a tonic bite reflex was exhibited.
Massaging inside of cheeks (Hall, 2001; Swigert, 2010)	A gloved finger was used to massage the inside of the cheeks, sulci and gums. Massaging increased awareness in the oral cavity. The researchers' finger was dipped into ice before placed in the participants' mouth to improve sensory awareness.
Increasing tone in the lips (Hall, 2001)	A vibrating tooth brush was placed on the upper and lower lips to increase sensation.
Increasing sensory input to the tongue through vibration (to improve tone) (Swigert, 2010)	A massaging brush dipped in ice was used to rub the chewing surfaces of the gums, inside the cheeks, lateral borders of the tongue and the top of the tongue.
Vibrations on the face and cheek to reduce hyper tonicity or increase sensory input (Morris & Klein, 1987; Swigert, 2010)	The researchers' gloved finger was dipped into ice beforehand. The index finger was placed inside the participants' mouth in the buccal cavity and the middle finger on the exterior surface of the cheek. The researcher lightly held the cheek between the forefinger and the middle finger. A quick shaking or vibration of the fingers was executed while the cheek was pulled forward and the researchers' finger was pulled out of the participants' mouth. Each cheek was vibrated separately.
Increasing lip movement (Morris & Klein, 1987; Swigert, 2010)	The index and middle fingers were placed on either side of the bridge of the participants' nose and a quick vibration motion down all the way through the upper lip was used. The researcher continued until the corner of the upper lip was reached.
Improving lip movement and tone (Swigert, 2010)	The index and middle finger was placed on the upper lip immediately below the nose. Several quick stretches were executed toward the corner of the lips.
Improving lip closure (Hall, 2001)	The researcher's gloved thumb was used in a rolling motion around the participants' mouth on both the upper and lower lips.
Creating a tongue bowl (Swigert, 2010)	The bowl of an empty spoon/massaging brush was placed in the middle of the participant's tongue and pressed down. The spoon was dipped into ice before placed in the participant's mouth to improve sensory awareness.
Facilitating chewing (Swigert, 2010)	A teether was placed between the back teeth (one side at a time) and the participant was assisted with external jaw closure.
Improving the triggering of the pharyngeal swallow (Hall, 2001)	The massaging brush was dipped in ice and the faucial arches were stimulated on each side, 4-6 times.

Studies conducted on oral sensorimotor techniques have shown improvements in oral motor abilities such as chewing, tongue lateralization, lip closure and spoon feeding (Gisel, Appelgate-Ferrante, Benson & Bosma, 1996; Rogers, 2004). Intensive oral stimulation in children with severe spastic diplegia showed improved mouth opening with the presentation of food, reduced negative behaviours associated with swallowing, longer feeding times, consumption of larger quantities of food and tube fed children were able to depend less on their tube feeds (Clawson, Kuchinski & Back, 2007). The efficacy of this treatment is, however, limited (Andrew et al., 2012; Rogers, 2004).

3.3.8. Data analysis procedures

To increase the reliability of the results and limit bias, an independent speech-language therapist who worked at the urban academic hospital where the research was conducted, analyzed the MBS examinations. The moderator had extensive experience, since she was routinely conducting MBS examinations twice a week. As far as was possible, the moderator did not know the identity or the group allocation of the participants and was blind to the pre-test and post-test MBS examinations. The data collected from the research was organised in MS Excel spread sheets according to the different data collection instruments. The data was read through a few times and categories and meaning in the data was obtained. The information was integrated and summarized in the form of tables to provide possible conclusions. Descriptive statistics was used because case studies are detailed and rich in descriptions rather than numbers and statistics (Meline, 2010). No statistical analysis was possible as only two participants were utilized.

3.3.9. Reliability and validity

The completion of a pilot study before the main study prepared the researcher for the main participant's possible response to the electrical stimulation, the electrode placement and operating the VitalStim® Therapy machine. The pilot study also improved the researcher's ability to conduct the oral sensorimotor stimulation. To limit bias, an independent moderator evaluated the data obtained from the modified barium swallow examinations. The moderator was blind to the phase of the research and the participants when analysing the MBS data, as far as possible. Reliability was further increased by randomly assigning the participants as either the control or the main participant.

CHAPTER 4

Results

Differences between the main and control participants' MBS results of the pre- and post-treatment oral preparatory and oral swallowing phase functioning according to the Assessment of Swallow Function and FOIS

TABLE 4: MBS results of the oral preparatory and oral swallowing phase: Pre- and Post-treatment (n=2)

Oral preparatory and oral phase: Liquids				
Dysfunction	Main participant		Control participant	
	Pre	Post	Pre	Post
Decreased lip closure	√	√	√	√
Decreased cheek tone	√	Not id.	√	Not id.
Decreased chewing	Not id.	Not id.	√	Not id.
Decreased tongue movement	√	Not id.	√	Not id.
Decreased tongue base retraction	√	Not id.	√	Not id.
Oral preparatory and oral phase: Puree				
Dysfunction	Main participant		Control participant	
	Pre	Post	Pre	Post
Decreased lip closure	√	√	√	√
Decreased cheek tone	√	Not id.	√	Not id.
Decreased chewing	Not id.	Not id.	Not id.	Not id.
Decreased tongue movement	√	Not id.	√	Not id.
Decreased tongue base retraction	√	√	√	Not id.
Oral preparatory and oral phase: Paste				
Main participant		Control participant		

Dysfunction	Pre	Post	Pre	Post
Decreased lip closure	√	√	√	√
Decreased cheek tone	√	Not id.	√	Not id.
Decreased chewing	Not id.	Not id.	√	Not id.
Decreased tongue movement	√	Not id.	√	Not id.
Decreased tongue base retraction	√	√	√	Not id.

* √ - indicates that the dysfunction was identified during the MBS examination

*Not id. – indicates that the dysfunction was not identified during the MBS examination

From the pre-treatment results in Table 4 it is evident that there were almost similar oral preparatory and oral phase dysfunctions identified between the main and control participant during swallowing liquid, puree and paste consistencies. Decreased chewing abilities were identified in the control participant but not in the main participant during swallowing of the paste consistency. Upon further examination of the results, holding of the bolus in the oral cavity, premature spillage, coating of the posterior tongue, a delayed swallow and piecemeal deglutition was identified on all three consistencies in the control participant. Premature spillage and piecemeal deglutition was identified on all three consistencies in the main participant. Delayed swallows were identified on the liquid and puree swallows in the main participant. Holding of the bolus in the oral cavity was only identified on paste swallows in the main participant. During liquid and paste swallows, coating of the posterior tongue and pharyngeal wall was identified. Pre-treatment FOIS scores were One for both participants, indicating no oral intake.

As further indicated in Table 4, the main and the control participant's oral preparatory and oral phase swallowing dysfunctions appeared to have improved after the 20 therapy sessions on all three consistencies. Decreased lip closure and decreased tongue base retraction was the only dysfunction that was observed during swallowing of all three consistencies in the main participant. Decreased lip closure was the only dysfunction identified during the post-treatment MBS examination of liquid, puree and paste consistencies for the control participant. It is evident from the results that the implementation of oral sensorimotor stimulation (without NMES) in the control participant showed better tongue movement and

tongue retraction when swallowing all three consistencies. Cheek tone improved in both participants after treatment.

Differences in the main and control participants' MBS results of the pre- and post-treatment pharyngeal swallowing phase functioning according to the Assessment of Swallow Function and the FOIS

TABLE 5: MBS results of the pharyngeal phase: Pre- and Post-treatment (n=2)

Pharyngeal phase: Liquids				
	Main participant		Control participant	
Dysfunction	Pre	Post	Pre	Post
Decreased VP closure	Not id.	Not id.	Not id.	Not id.
Decreased hyolaryngeal excursion	√	Not id.	Not id.	√
Decreased airway protection	√	Not id.	Not id.	Not id.
Decreased pharyngeal contraction	√	Not id.	√	√
Pharyngeal phase: Puree				
	Main participant		Control participant	
Dysfunction	Pre	Post	Pre	Post
Decreased VP closure	Not id.	Not id.	Not id.	√
Decreased hyolaryngeal excursion	√	Not id.	√	Not id.
Decreased airway protection	√	Not id.	√	Not id.
Decreased pharyngeal contraction	√	Not id.	√	√
Pharyngeal phase: Paste				
	Main participant		Control participant	
Dysfunction	Pre	Post	Pre	Post
Decreased VP closure	Not id.	Not id.	Not id.	Not id.

Decreased hyolaryngeal excursion	Not id.	Not id.	√	Not id.
Decreased airway protection	Not id.	Not id.	√	Not id.
Decreased pharyngeal contraction	√	Not id.	√	√

* √ - indicates that the dysfunction was identified during the MBS examination

*Not id. – indicates that the dysfunction was not identified during the MBS examination

According to Table 5, decreased hyolaryngeal elevation and decreased airway protection was identified during swallowing liquids in the pre-treatment MBS examination in the main participant, but not in the control participant. These same pharyngeal dysfunctions were identified in the control participant but not in the main participant during swallowing of the paste consistency during the pre-treatment MBS examinations. The pre-treatment MBS examination results of the main and the control participant were comparable with regards to the identified pharyngeal dysfunctions during swallows of the puree consistency. Decreased pharyngeal contraction was evident during swallowing of all three consistencies for both participants at the pre-treatment MBS.

An improvement in the main participant's pharyngeal swallowing dysfunctions can be seen post-treatment on all three consistencies (See Table 4). After the post-treatment MBS examinations both participants' FOIS scores were Two, suggesting that although the participants were still tube dependent they had minimal or inconsistent oral intake.

After the post-treatment MBS examinations and the clear improvement in the oral preparatory and oral phases of swallow it was recommended that the main and control participant receive small amounts of a puree consistency orally. Most of their nutrition would continue to be supplied via the PEG tube. It was suggested to the caregivers that 3 to 5 ml of a puree consistency (yoghurt) be given orally to the participants via a syringe every time they were fed. The importance of correct positioning and observing any signs of aspiration, such as coughing and tearing of the eyes, were highlighted to the caregivers.

The results indicate the possible positive effect that NMES could have on the pharyngeal swallowing phase that oral sensorimotor stimulation do not target in children with feeding and swallowing difficulties. As can be seen from Table 4, the oral sensorimotor stimulation

provided to the control participant did not appear to significantly improve the pharyngeal dysfunctions identified during the pre-treatment MBS examination. Decreased airway protection was not identified during the post-treatment MBS examination for both participants on all three consistencies.

TABLE 6: MBS results of the long-term follow-up: Oral preparatory, oral and pharyngeal phase – Main participant only (n=1)

Main participant		
Oral preparatory and oral phase: Liquid		
Dysfunction	7 Months post-treatment	15 Months post-treatment
Decreased lip closure	√	√
Decreased cheek tone	Not id.	√
Decreased chewing	Not id.	Not id.
Decreased tongue movement	√	√
Decreased tongue base retraction	√	√
Oral preparatory and oral phase: Puree		
Dysfunction	7 Months post-treatment	15 Months post-treatment
Decreased lip closure	√	√
Decreased cheek tone	√	√
Decreased chewing	Not id.	Not id.
Decreased tongue movement	√	√
Decreased tongue base retraction	√	√
Oral preparatory and oral phase: Paste		
Dysfunction		15 Months post-treatment
Decreased lip closure	N/A	√
Decreased cheek tone	N/A	√
Decreased chewing	N/A	Not id.

Decreased tongue Movement	N/A	√
Decreased tongue base Retraction	N/A	√
Pharyngeal phase: Liquids		
Dysfunction	7 Months post-treatment	15 Months post-treatment
Decreased VP closure	Not id.	Not id.
Decreased hyolaryngeal excursion	Not id.	Not id.
Decreased airway protection	Not id.	√
Decreased pharyngeal contraction	Not id.	√
Pharyngeal phase: Puree		
Dysfunction	7 Months post-treatment	15 Months post-treatment
Decreased VP closure	√	Not id.
Decreased hyolaryngeal excursion	Not id.	Not id.
Decreased airway protection	√	√
Decreased pharyngeal contraction	√	√
Pharyngeal phase: Paste		
Dysfunction		15 Months post-treatment
Decreased VP closure	N/A	Not id.
Decreased hyolaryngeal excursion	N/A	Not id.
Decreased airway protection	N/A	√
Decreased pharyngeal contraction	N/A	Not id.

* √ - indicates that the dysfunction was identified during the MBS examination

*Not id. – indicates that the dysfunction was not identified during the MBS examination

*N/A – this consistency was not given to the participant

Table 6 indicates that similar results were obtained at the seven and 15 month follow-up as the pre-treatment MBS examination, indicating that sustained gains were not found in the main participant. The participant's FOIS score was One suggesting no oral intake. A possible contributing factor to the participant's poor results from the seven month follow-up MBS could be the poor positioning that the participant was placed in during the MBS. The participant was positioned in a Madiba Shonaquip Buggy which was too big for her. During the MBS examination, when food was presented, she hyper extended her head and neck. This influenced the participant's oral and pharyngeal swallowing abilities. Only liquid and puree consistencies were given during this MBS examination as decreased airway protection was identified and the participant was struggling to manage the consistencies already given. The participant was also referred to a paediatrician because upon closer examination, reflux was observed during the MBS examination. From these results it was recommended that the main participant only be fed with a PEG tube and that oral feeds be discontinued. Fifteen months post-treatment, using the correct size Madiba Shonaquip Buggy and after being on reflux medication for some time, the MBS examination was repeated. The results appeared to be much the same as in the seven month follow-up and pre-treatment MBS examination. The recommendations were to continue with exclusive PEG feeding.

CHAPTER 5

Discussion and conclusion

Feeding and swallowing difficulties of children with spastic cerebral palsy are incapacitating. These children present with poorly coordinated and unsafe swallowing behaviours which are potentially life threatening and make for stressful feeding times for both the parents and the child (Mirrett et al., 1994; Rogers, 2004). An evaluation of neuromuscular electrical stimulation in paediatric participants was carried out by Christiaanse et al. (2011). These researchers suggested that neuromuscular electrical stimulation is an effective treatment option for acquired (cerebral palsy) or unknown dysphagia.

Based on research evidence of NMES (Christiaanse et al., 2011) it appeared that the intervention applied in this study could have had positive effects on severe paediatric dysphagia associated with cerebral palsy in the main participant. The results of the study indicated initial positive effects which may be associated with NMES. The initial changes were considerable, since the main participant could eat small amounts of pureed food after treatment. Long-term gains, however, were not identified. This is contradictory to the long-term gains observed in the participant from the pilot study. This could be attributed to individual differences and the results can, therefore, not be generalised.

The findings of this research study validate the fact that NMES should be used in combination with oral sensorimotor stimulation. These exercises appeared to have benefitted the two participants' oral functioning, while NMES appeared to have improved the pharyngeal phase difficulties more than oral sensorimotor stimulation alone, although these gains were not maintained upon follow-up. The results regarding the long-term effects of NMES on the feeding and swallowing abilities of children are similar to those found by Christiaanse et al. (2011). These researchers commented on the use of additional tube feeding by the participants at a six month follow-up after treatment. The majority of the participants in the experimental group continued to feed the same way as they had been at the beginning of the treatment (Christiaanse et al., 2011).

NMES may not be a viable treatment option in under-resourced facilities in South Africa. Treatment has to be provided at least three times a week and factors interfering with compliance could be limited financial resources (transport) and cost of electrodes.

What was evident from this research study is the oral hypersensitivity that the participants presented with. Hyperextension of the neck and shoulder adduction is frequently found in neurologically impaired children who experience feeding difficulties (Redstone & West, 2004). It was challenging for the researcher to carry out the oral sensorimotor stimulation because the participants would go into hyperextension and present with bite reflexes. It may be beneficial to address the hypersensitivity first and improve the participants' ability to tolerate oral stimulation before providing NMES and oral sensorimotor stimulation.

For the purposes of this study, electrode placement 3b was used, which targeted pharyngeal contraction and not any oral motor ability. Making use of different electrode placements could have an effect on the remaining dysfunctions present after the post-MBS examination. Electrode placement 4a which targets the orbicularis oris muscle could be utilised to improve the reduced lip closure (Wijting, 2009). To improve bolus manipulation and tongue base retraction, electrode placements 4a, 2a and 3a could be used since these electrode placements target the intrinsic and extrinsic tongue muscles (Wijting, 2009).

The shortcoming of this study is the small number of participants and that the results can therefore not be generalised to the larger population. A well matched control participant in terms of age, period of time on the PEG tube feeding and swallowing difficulty should be included in future research studies. This improvement may assist to determine that it was in actual fact the NMES that made the difference in the feeding and swallowing of the participant and not any other factors such as maturation. Factors to be considered in future studies include the identification of diagnostic categories that could benefit from NMES and the effect of different electrode placements on the feeding and swallowing abilities of young children. The optimal intensity level of the VitalStim® Therapy machine should be determined in order to ensure that there will be a positive effect, especially in children who cannot communicate. The long-term effects or benefits of NMES require thorough research.

The results of this study must be interpreted with caution, even though the short-term gains cannot be disregarded. Clinicians are encouraged to keep an open mind about including NMES in their treatment regimen for children with feeding and swallowing difficulties and to continually re-investigate the available evidence on this topic.

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CHAPTER 6

Final Conclusion

The present study highlighted some of the challenges faced by South African speech-language therapists in dysphagia intervention and should be viewed within the broad context of health service provision in the country. There is an increased need for education regarding the management of dysphagia across professionals (Blackwell & Littlejohns, 2010). Educating nursing staff and medical practitioners regarding the identification of swallowing difficulties and the role of speech-language therapists in swallowing difficulties could have a positive impact on a patient's healthcare (Blackwell & Littlejohns, 2010). Due to limited diagnostic assessment material and equipment for the identification of aspiration, limited resources and limited staff funding in South Africa, dysphagia related deaths may be much higher than in first world countries (Blackwell & Littlejohns, 2010). Gastrostomy tube placement in children with severe feeding and swallowing difficulties is a treatment option to possibly reduce the deaths which may be associated with unsafe oral feeding. Norman et al., (2011) investigated gastrostomy placement in infants and children in a tertiary hospital in South Africa. The results suggest that gastrostomy tube feeding in children is highly prevalent in tertiary care settings in South Africa as 94% of the participants in this study required gastrostomy tubes for safe feeding and swallowing and were diagnosed with cerebral palsy (Norman, et al., 2011). According to Rogers, (2004) gastrostomy tube feeding continues to be an alternative means of feeding for children with cerebral palsy.

Children who are referred for gastrostomy tube placement should be managed within the context of a team. A pilot study conducted by Seedat, Mupawose and Choonara (2011) regarding the multidisciplinary management of paediatric dysphagia in government hospitals in Gauteng, suggested that although team members were aware of their role in the management of these patients, the professionals did not make the necessary referrals. Factors such as difficulty to achieve transdisciplinary assessments, high staff turnover, limited understanding of the roles of all team members and the lack of resources (such as equipment required to conduct modified barium swallow examinations) were identified by the participants as challenges hindering team work in the management of paediatric dysphagia.

The speech-language therapist in the team is involved in the assessment and intervention of feeding and swallowing difficulties before gastrostomy tube placement (Norman et al., 2011).

After the gastrostomy tube is inserted on-going management and reassessment of the need for continuous gastrostomy tube placement for feeding and swallowing difficulties needs to be implemented. However, Norman et al. (2011) state that this is not the case as 97% of participants received services from the speech-language therapist before gastrostomy placement, compared to 68% after placement. Although Norman et al. (2011) did not provide a specific reason for these findings, from the researcher's perspective various aspects could attribute to this such as, patients not returning for follow-up visits, patients getting "lost" in the system, patients financial difficulties, cultural differences, limited resources, large speech-language therapy case loads for the amount of staff available, limited or inaccurate referrals, death and the failure of conventional paediatric dysphagia treatment techniques to improve the children's feeding and swallowing difficulties hence requiring continuous gastrostomy tube feeding.

An additional factor that may hinder teamwork in the management of dysphagia is that there are only 824 speech-language therapists currently practicing in South Africa (HPCSA, 2015). Speech-language therapists are a small group of health care professionals in South Africa who are specialised to treat patients with dysphagia. With speech-language therapists being identified as the main multidisciplinary team member to assess and manage dysphagia (Seedat et al., 2011), it is advisable that speech-language therapists continue to educate themselves regarding the recent methods of identification and treatment of dysphagia despite the numerous challenges they experience (Blackwell & Littlejohns, 2010). It is the responsibility of speech-language therapists to provide their clients with the recent advances in the treatment of dysphagia and in doing so maintaining high-levels of service delivery and best practice. One of these recent advances in dysphagia treatment is NMES

Based on the present study results, NMES has the potential to be an effective method of improving the feeding and swallowing abilities of children who have been long-term PEG tube fed. Both oral motor and pharyngeal feeding and swallowing difficulties may be addressed if the NMES protocol is followed. The benefits of this method of treatment to the professional field are numerous. First of all, NMES may provide speech-language therapists with an alternative form of treating dysphagia after traditional swallowing exercises have been found to be unsuccessful with a specific client. As can be seen from the results of this research study, it is not intended that NMES replace traditional dysphagia techniques but that it is used in conjunction with the traditional oral motor exercises most often implemented in

the treatment of feeding and swallowing difficulties present in children with cerebral palsy. It is evident that oral motor exercises target the oral motor difficulties while NMES (depending on the electrode placement) targets the pharyngeal difficulties. Further research is required to determine the routine use of NMES in children. Secondly, improved feeding and swallowing abilities may improve the clients' and parents'/caregivers' quality of life. Thirdly, due to the positive effect of NMES on clients' swallowing abilities, there may be a reduced need for the insertion of PEG tubes and therefore reducing the number of PEG tube feeding related deaths. Fourthly, NMES may further lessen the financial burden that PEG feeding tubes place on the family and on the state. In addition, the positive results of NMES may shorten the hospital stay of patients who have swallowing difficulties.

Although NMES has many benefits to dysphagia intervention for children with severe developmental disabilities in South Africa, the researcher is unsure whether this modality of treatment will be effective in government hospitals where the majority of the disadvantaged South African community is served. The researchers' reasons for this are the high cost of electrodes, specialised training required by speech-language therapists and the equipment that must be bought and maintained. In a randomised experimental study such as the present research, protocols were strictly followed, which may not be possible in clinical practice (Kaura, 2013). The ideal conditions of the study which resulted in a positive outcome may not be always replicated when the NMES protocol is not carefully followed. For the treatment to be effective a new set of electrodes need to be used each session, due to the lengthy time period of the sessions, numerous pairs of electrodes will be used and this adds to the expense of this treatment modality. A limitation of this research study which could have influenced the results was the subjectivity of the moderators' interpretation of the MBS examinations.

An additional financial implication of NMES is that this method of treatment needs to be provided at least three times a week to be effective. The majority of the clients served at government hospitals in South Africa rely on public grants to sustain their families. These families also rely on public transport to get to and from the hospital. It may not be financially viable to come to the hospital three times a week for treatment. A possible solution may be when the specific client requiring NMES is admitted into the hospital for the entire length of the treatment. This however, would depend on the availability of beds in the hospital and the therapist's client caseload.

Lastly, it is hoped that the positive results of this study will further encourage other researchers to conduct additional research to strengthen the evidence for the effectiveness of the procedure on children's feeding and swallowing abilities.

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Please note: The title and the design of this research study has changed since the letters were used to obtain permission and informed consent. The researcher intended the study to be a group design, but had to change to a single case design with a control when it was evident that it would not be possible to recruit a sufficient amount of participants who would adhere to the inclusion criteria and to the 20 regular therapy sessions.

Appendices

Appendix A – Ethical clearance letter from the University of Pretoria: Faculty of Humanities

Appendix B – Ethical clearance letter from the University of Pretoria: Faculty of Health Sciences

Appendix C- Permission from the urban academic hospital to conduct the research

Appendix D: Research Participant information brochure: English

Appendix E: Research Participant information brochure: Setswana

Appendix F – Permission from main participants’ treating physician

Appendix G – VitalStim® Therapy certification as a therapy provider: Jemma Chadinha (née Dorkin)

Appendix H – Information brochure to the moderator

Appendix I: Case history form

Appendix J: Clinical feeding and swallowing assessment form

Appendix K: Function Oral Intake Scale

Appendix L: Rating of the modified barium swallow (MBS) examination form

Appendix M: 1. Evaluation of Swallow Function Form

2. Permission to use the Evaluation of Swallow Function Form

Appendix N – Permission to carry out MBS examinations at the urban academic hospital

Appendix O – NMES tracking form

Appendix P – Oral sensorimotor stimulation protocol

Appendix Q – NMES protocol

Appendix R – Oral sensorimotor stimulation tracking form



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Office of the Deputy Dean

29 November 2011

Dear Prof Kritzinger,

Project: The effect of VitalStim® Therapy on the feeding and swallowing of young children with long-term percutaneous endoscopic gastrostomy tubes
Researcher: JS Chadinha
Supervisor: Prof A Kritzinger
Department: Communication Pathology
Reference number: 22081144

I am pleased to be able to tell you that the above application was **approved** (with comment) by the **Postgraduate Committee** on 15 November 2011 and by the **Research Ethics Committee** on 24 November 2011. Data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

The Committee requests you to convey this approval to the researcher.

We wish you success with the project.

Sincerely

Prof John Sharp
Chair: Postgraduate Committee &
Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: john.sharp@up.ac.za



Faculty of Health Sciences Research Ethics Committee

23/01/2012

Number : S189/2011
Title : Effect of VitalStim® Therapy of the feeding and swallowing of young children with long-term percutaneous endoscopic gastrostomy tubes
Investigator : J S Chadinha, Department of Communication Pathology, University of Pretoria
(SUPERVISORS: Prof A Kritzinger / Mrs M Viviers)
Sponsor : None
Study Degree: M. Communication Pathology

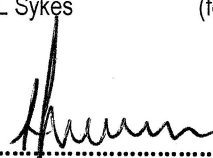
This Student Protocol was reviewed by the Faculty of Health Sciences, Student Research Ethics Committee, University of Pretoria on 23/01/2012 and found to be acceptable. The approval is valid for a period of 3 years.


Prof M J Bester BSc (Chemistry and Biochemistry); BSc (Hons)(Biochemistry); MSc (Biochemistry); PhD (Medical Biochemistry)
Prof R Delport (female)BA et Scien, B Curationis (Hons) (Intensive care Nursing), M Sc (Physiology), PhD (Medicine), M Ed
Computer Assisted Education
Prof J A Ker MBChB; MMed(Int); MD – Vice-Dean (ex officio)
Dr NK Likibi MBB HM – (Representing Gauteng Department of Health) MPH

Dr MP Mathebula Deputy CEO: Steve Biko Academic Hospital
Prof A Nienaber (Female) BA (Hons) (Wits); LLB (Pretoria); LLM (Pretoria); LLD (Pretoria); PhD; Diploma in Datametrics (UNISA)
Prof L M Ntlhe MBChB(Natal); FCS(SA)
Mrs M C Nzeku (Female) BSc(NUL); MSc Biochem(UCL,UK)
Snr Sr J. Phatoli (Female) BCur (Et.AI); BTech Oncology
Dr R Reynders MBChB (Pret), FCPaed (CMSA) MRCPCH (Lon) Cert Med. Onc (CMSA)
Dr T Rossouw (Female) MBChB.(cum laude); M.Phil (Applied Ethics) (cum laude), MPH (Biostatistics and Epidemiology (cum laude), D.Phil
Mr Y Sikweyiya MPH (Umea University Umea, Sweden); Master Level Fellowship (Research Ethics) (Pretoria and UKZN); Post Grad.
Diploma in Health Promotion (Unitra); BSc in Health Promotion (Unitra)
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Dr R Sommers **Vice-Chair** (Female) - MBChB; MMed (Int); MPharMed.
Prof T J P Swart BChD, MSc (Odont), MChD (Oral Path), PGCHE
Prof C W van Staden **Chairperson** - MBChB; MMed (Psych); MD; FCPsych; FTCL; UPLM; Dept of Psychiatry

Student Ethics Sub-Committee

Prof R S K Apatu MBChB (Legon,UG); PhD (Cantab); PGDip International Research Ethics (UCT)
Mrs N Briers (female) BSc (Stell); BSc Hons (Pretoria); MSc (Pretoria); DHETP (Pretoria)
Prof M M Ehlers (female) BSc (Agric) Microbiology (Pret); BSc (Agric) Hons Microbiology (Pret); MSc (Agric) Microbiology (Pret);
PhD Microbiology (Pret); Post Doctoral Fellow (Pret)
Dr R Leech (female) B.Art et Scien; BA Cur; BA (Hons); M (ECI); PhD Nursing Science
Dr S A S Olorunju BSc (Hons). Stats (Ahmadu Bello University –Nigeria); MSc (Applied Statistics (UKC United Kingdom); PhD
(Ahmadu Bello University – Nigeria)
Dr L Schoeman CHAIRPERSON: (female) BPharm (North West); BAHons (Psychology)(Pretoria); PhD (KwaZulu-Natal);
International Diploma in Research Ethics (UCT)
Dr R Sommers **Vice-Chair** (Female) MBChB; M.Med (Int); MPhar.Med
Prof L Sykes (female) BSc, BDS, MDent (Pros)


.....
DR L SCHOEMAN; BPharm, BA Hons (Psy), PhD;
Dip. International Research Ethics
CHAIRPERSON of the Faculty of Health Sciences
Student Research Ethics Committee, University of Pretoria


.....
DR R SOMMERS; MBChB; M.Med (Int); MPhar.Med.
VICE-CHAIR of the Faculty of Health Sciences Research
Ethics Committee, University of Pretoria

INITIAL CONSENT BY DEPARTMENTAL HEAD

I Prof B Vinck head of Communication Pathology
department of Pathology hospital in consultation
with the Chief Executive Officer / Superintendent of this Hospital grant permission to
submit an application to conduct a clinical trial/evaluation to the Chairperson (s) of the
relevant Ethics, Research and Therapeutic Committees of this Hospital.

The officer conducting the trial/evaluation will be Jemma Chadinha

Designation / Rank

A.R. Lloyd-Jones 14 04 11
THE HEAD OF THE DEPARTMENT MUST SIGN HERE

HEAD OF DEPARTMENT			DATE		
Signature	Initial(s)	Surname	Day	Month	Year
<u>[Signature]</u>	<u>BHM</u>	<u>VINCK</u>	<u>07</u>	<u>04</u>	<u>11</u>

THE APPLICANT MUST SIGN HERE

TRIALIST-INVESTIGATOR			DATE		
Signature	Initial(s)	Surname	Day	Month	Year
<u>[Signature]</u>	<u>J.S</u>	<u>Chadinha</u>	<u>31</u>	<u>03</u>	<u>2012</u>

THE APPLICANT THAT APPLY FOR THIS STUDY MUST SEE TO IT THAT THE SUPERINTENDENT / C.E.O. OF THE HOSPITAL WHERE THE STUDY WILL BE DONE - SIGN HERE BEFORE THE ETHICAL COMMITTEE RECEIVE THIS APPLICATION FORM.

APPROVAL BY HOSPITAL CHIEF EXECUTIVE OFFICER:

I Dr. B.J. Kibeiro Chief Executive Officer / superintendent of
Steve Biko Acad. Hospital, hereby agree that this trial / evaluation be
conducted in the Speech Therapy Department of this hospital.

The officer conducting the trial will be : Jemma Chadinha

The officer controlling supplies will be: Jemma Chadinha

HOSPITAL C.E.O. / Superintendent			DATE		
Signature	Initial(s)	Surname	Day	Month	Year
<u>[Signature]</u>	<u>B.J.</u>	<u>Kibeiro</u>	<u>14</u>	<u>04</u>	<u>2011</u>

STEVE BIKO
PRIVATE BAG X169
2011 -04- 14
PRETORIA 0001
ACADEMIC HOSPITAL



1 April 2011

Dr. B. Ribeiro
Medical Superintendent
Steve Biko Academic Hospital
Private Bag X 169
Pretoria
0001

Dear Dr. Ribeiro

Requesting permission to conduct a research study at Steve Biko Academic Hospital by a speech-language therapist.

Title of Research: The effect of VitalStim® Therapy on the feeding and swallowing of young children with long-term percutaneous endoscopic gastrostomy tubes

As part of a Masters degree in Communication Pathology at the University of Pretoria, I would like to perform a research project involving children from the age of 6 months – 5 years who have been feeding via long-term percutaneous endoscopic gastrostomy tubes. In this research study the use of VitalStim® Therapy on these children's feeding and swallowing abilities will be investigated. I therefore request to recruit participants from the hospital and have access to their medical records.

I have received formal training in this treatment modality and have experience with providing VitalStim® Therapy to children (Please see attached certificate).

I am in the process of obtaining ethical clearance from the Research Ethics Committee of the Faculty of Humanities, University of Pretoria.

VitalStim® Therapy is a non-invasive, electrical stimulation technique for the treatment of dysphagia. It is a specialized form of neuromuscular electrical stimulation (Wijting, 2009). Electrical stimulation is applied to specific muscles involved in the swallowing process together with traditional swallowing exercises. The goal of VitalStim® Therapy is to strengthen and re-educate the muscular system while improving the motor control of the swallowing mechanism (Barnes, Miller &, Latman, 2008; Permsirivanich, et al., 2009; Wijting, 2009). Neuromuscular electrical stimulation has been used extensively in a wide variety of therapeutic and rehabilitative settings especially in the profession of physiotherapy (Wijting, 2009). VitalStim® Therapy was approved by the US Food and Drug Administration (FDA) in 2002 for the safe treatment of dysphagia in adults and children (Christiaanse, Glynn & Bradshaw, 2003; Freed, Freed, Chatburn & Christian, 2001; Wijting, 2009).

If you would like more information about VitalStim® Therapy and its benefits you can visit www.vitalstim.com

The research method that will be used in this study is an ABA design with a control group, random selection to the two groups, and a period of treatment for the experimental group. Twenty four

children with PEG tubes will be selected. The speech therapy staff at your hospital have offered to help me identify these children.

Although VitalStim® Therapy has been proven to be safe in children and adults, certain precautions and contraindications do exist. (VitalStim® is not recommended for patients with dementia with non-stop verbalization, significant reflux, dysphagia due to drug toxicity, a demand pacemaker, deep brain stimulator, implantable cardioverter defibrillators, seizures, active neoplasm or infection on the anterior neck). Therefore, the children will need to be certified as medically stable by their attending physician before inclusion into the research study.

Participant information brochures will be handed out to the identified children's caregivers. The participant brochures will be available in English and Tswana to aid understanding of the research study. Only those who give informed consent will be considered for this study. Twelve children will be randomly selected for the control group and the other twelve children will then be part of the experimental group. Interviews to obtain case histories will be conducted with all the children's caregivers. Each child's feeding and swallowing abilities will be clinically assessed. All the children will then receive baseline modified barium swallow examinations before treatment is initiated. VitalStim® Therapy and non-nutritive oral-motor exercises will be provided to the children in the experimental group three times a week for an hour at a time, with a maximum of twenty sessions per participant. The research participants in the control group will only receive 20 sessions of non-nutritive oral-motor exercises, three times a week. Once the VitalStim® Therapy sessions have been completed, a repeat modified barium swallow will be conducted on all children (both in the experimental and control groups). A clinical assessment of the children's feeding and swallowing abilities will also be carried out at the end of the study.

If this specific modality of treating feeding and swallowing disorders is successful, it is hypothesized that there will be an improvement in the children's oral preparatory, oral and pharyngeal stage of swallowing. It is postulated that the experimental group will be able to begin to feed orally on certain or all consistencies of food. If VitalStim® Therapy is found to be effective in improving feeding and swallowing disorders in the experimental group of the research study, the children who were part of the control group will be afforded the opportunity to receive VitalStim® Therapy free of charge.

Personal identifying information of the research participants will be kept confidential.

I hope that this research study will provide caregivers hope for their children who are fed via PEG tubes to return to some degree of oral feeding.

I trust that my request will be considered favourably.

Yours Sincerely

Jemma Chadinha
Researcher
Department of Communication Pathology
University of Pretoria
082 628 9951
jdorkin10@gmail.com

Mrs. M. Viviers
Research Co-Supervisor
Department of Communication Pathology
University of Pretoria

Prof. A. Kritzinger
Research Supervisor

Prof. B. Vinck
Head: Department of Communication Pathology

Department of Communication Pathology
University of Pretoria

University of Pretoria

GAUTENG PROVINCIAL GOVERNMENT
DEPARTMENT OF HEALTH
STEVE BIKO ACADEMIC HOSPITAL
PRIVATE BAG X 169 PRETORIA 0001
2011-07-15
GAUTENG PROVINCIAL GOVERNMENT
DEPARTMENT OF HEALTH
STEVE BIKO ACADEMIC HOSPITAL

[Redacted]

Date: 15/07/2011

Signature: [Handwritten Signature]

Name of hospital / clinic: Steve Biko Academic Hospital

Title and name of Chief Executive Officer: Dr. B. Kubane

Permission to do the research study at this hospital / clinic and to access the information as requested, is hereby approved.

Signature of the Principal Investigator
[Handwritten Signature]
Yours sincerely

Ethics Committee, University of Pretoria.

We undertake not to proceed with the study until we have received approval from the Faculty of Health Sciences Research

We intend to protect the personal identity of the patients by assigning each individual a random code number.

We intend to publish the findings of the study in a professional journal and/or to present them at professional meetings like symposia, congresses, or other meetings of such a nature.

The researchers request access to the following information: clinical files, record books and data bases.

study involves access to patient records.
herewith request permission on behalf of all of us to conduct a study on the above topic on the hospital / clinic grounds. This

I am a researcher / student at the Department of Communication at the University of Pretoria.
Hospital, I am working with

This request is lodged with you in terms of the requirements of the Promotion of Access to Information Act, No. 2 of 2000.
gastroscopy tubes

TITLE OF STUDY: The effect of Valsalva Therapy on the feeding and swallow of young children with long-term percutaneous endoscopic

Re: Permission to do research at Steve Biko Academic Hospital / Clinic

Hospital / Clinic OR University of Pretoria

Chief Executive Officer/Information Officer
Steve Biko Academic Hospital
Investigator

TO: Dr. Kubane
FROM: Jemma Chodhwa

Permission to access Records / Files / Data base at Steve Biko Academic Hospital / Clinic



7 September 2011

PARTICIPANT INFORMATION LEAFLET

STUDY TITLE: The effect of VitalStim® Therapy on the feeding and swallowing of young children with long-term percutaneous endoscopic gastrostomy tubes

RESEARCHER: Jemma Chadinha

INTRODUCTION:

I am a speech-language therapist and I am currently conducting my masters degree study through the University of Pretoria.

You are invited to volunteer in my research project. This information brochure will help guide your decision making as to whether you would like to participate in this research project. Before you make any decisions please make sure that you fully understand the aims, nature and purpose of this research. If you have any questions that are not covered in this brochure please feel free to ask me.

1. ***The purpose of the study:*** The purpose of this research study is to describe the outcome of VitalStim® Therapy on the feeding and swallowing abilities of young children who have been fed via PEG tubes for a lengthy period of time. These children have been identified as the research participants due to the fact that traditional swallowing exercises have failed them and now their only means of feeding is non-orally. If this technique does in fact improve the swallowing and feeding abilities of the children, it will provide a new treatment option for children with feeding and swallowing difficulties who are fed with PEG tubes.
2. ***Procedures:*** You will be asked to bring your child to Steve Biko Academic Hospital for an examination of his/her swallowing abilities. Firstly, I will conduct an interview with you to obtain any background information on your child. I will then clinically assess your child's feeding and swallowing abilities. Then your child will receive a modified barium swallow examination. It is usually done at the radiography department of the hospital. Your child will be positioned in front of the screening machine and will then be given different types/consistencies of food to eat e.g. water, yoghurt, porridge and a cookie-consistency if your child is older. This food will be mixed with a substance that will make it easier for us to identify the food on the screen. Certain aspects of your child's swallowing will be written down and it will be recorded on a DVD. You are allowed to be with your child at all times during this study. The DVD will then be assessed by another qualified speech-language therapist. None of your identifying information will be provided to this specific therapist.
3. You will be given an envelope which will either indicate that your child is the experimental group or in the control group. By doing this the strength of the research is increased.
4. **If your child is in the experimental group,** after the modified barium swallow examination you will be asked to return to the hospital three times a week for an hour long VitalStim® Therapy and non-nutritive oral-motor exercise sessions. The researcher has received formal training in this treatment modality and has conducted VitalStim® Therapy on children. In this hour electrodes will be placed on your child's neck (please see photos at the end of this document). The electrodes will be used to stimulate the muscles involved in swallowing. The machine's intensity will gradually increase to a specific level. Your child might feel an uncomfortable sensation in the beginning but will soon get use to it. The sensations that your child will feel is not painful. I will be sensitive and not traumatize your child in any way. The electrodes will first be placed on your child's hand in order for him/her to get use to the sensation. These impulses are said to encourage the muscles involved in swallowing to contract and relax, ideally strengthening these

muscles and improving their functioning. At this specific intensity level non-nutritive oral-motor exercises will be provided to your child e.g. tongue and lip exercises. It is advisable to have approximately 20 of these one hour sessions. After the completion of all the sessions of VitalStim® Therapy and non-nutritive oral-motor exercises, a second modified barium swallow examination will be conducted on your child (same procedure as described above). The observations from the repeated modified barium swallow may show improvement in your child's swallowing. All of the appointments will be arranged at your earliest convenience and the therapy will be free of charge. Transport money will be provided for you and your child to attend the therapy sessions when scheduled.

5. **If your child is chosen to be in the control group, your child will not receive VitalStim® Therapy but will only receive non-nutritive oral-motor exercises 3 times a week for an hour each session and for a total of 20 sessions. At the end of the 20 sessions of non-nutritive oral-motor exercises another modified barium swallow examination will be conducted on your child. If VitalStim® Therapy shows positive effects, I will inform you and will provide this treatment to your child (free of charge) if you so wish.**
6. **Risks and discomforts:** Although VitalStim® Therapy has been proven to be safe for adults and children there are certain precautions and conditions for which VitalStim® Therapy should not be used. Your child's doctor will be required to indicate that your child is medically stable to undergo this treatment. The only negative effect that your child could experience is a rash due to the plasters that will hold the electrodes in place on his/her neck.
7. **Benefits:** It is strongly hoped that VitalStim® Therapy will help to improve your child's feeding and swallowing abilities so that he or she will be able to safely swallow certain consistencies of food orally. The therapy may decrease his/her dependence on the PEG tube for feeds.
8. **Your rights as a research participant:** Feel free to withdraw from the research study at any time without giving a reason.
9. **Confidentiality:** In order to determine if there is an improvement in your child's swallowing abilities after VitalStim® Therapy, your child's swallowing abilities will be recorded during the modified barium swallow examinations. These DVD's will only be reviewed by myself and qualified speech-language therapists who are specialists in the field of paediatric swallowing. None of your identifying information will be given out to anyone, unless it is discussed with you before-hand. The research data will be stored securely in the Department of Communication Pathology for 15 years.
10. **I ask for permission to consult your child's medical records.**
11. *If you have any further queries, please feel free to contact me, the researcher, Jemma Chadinha at 082 628 9951.*

Yours sincerely,

Jemma Chadinha

Researcher



Prof. B. Vinck

Head of Department of Communication Pathology

University of Pretoria



Prof. A. Kritzinger

Supervisor

PERMISSION TO PARTICIPATE IN RESEARCH

I UNDERSTAND MY RIGHTS AS A PARTICIPANT IN THIS RESEARCH STUDY. I VOLUNTARILY CONSENT THAT MY CHILD MAY PARTICIPATE IN THIS STUDY. I UNDERSTAND WHAT THIS STUDY ENTAILS AND HOW AND WHY THIS STUDY WILL BE DONE. I WILL RECEIVE A SIGNED COPY OF THIS CONSENT FORM.

DATE: _____

PARTICIPANTS' SIGNATURE

RESEARCHER

WITNESS

Electrodes that will be used and the VitalStim® Therapy unit



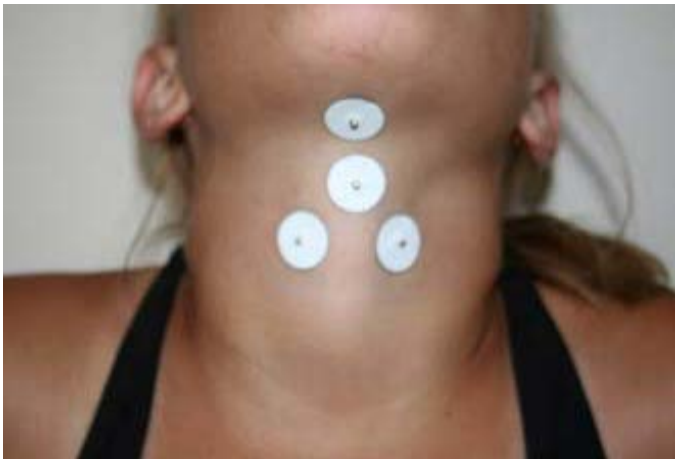
Placement A



Placement B



Placement C



Placement D

(Electrode placement will depend on the age of your child and his or her specific swallowing difficulty)

Permission was granted from Karin Mitchell to use the photographs showing the different placements of the electrodes - Personal communication, October 2010.



28 Lwetse 2011

LEKWALO-KITSISO LA MOTSAKAROLO

SETLHOGO SA THUTO: Tiro ya thuso ya VitalStim® mabapi le go ja le go metsa mo baneng ba banyenyane ba ba dirisang ditjhupu tsa Percutaneous Endoscopic Gastrostomy.

MODIRADIPATLISISO: Jemma Chadinha

MATSENO:

Mo nakong e ke dira jaaka mokatisi wa puo mme ke tsweletsa kitso ya me ka go dira Masters Degree le Unibesiti ya Tshwane.

Ke dira memo ya boithaopo mo go wena mabapi le projeke ya me ya dipatlisiso. Tlhaloso ee tlhagelelang mo lekwalong le e tla go thusa go dira tshwetso ya go dumela kgotsa go gana go tsaya karolo. Pele o tsaya tshwetso netefatsa gore o tlhalo-ganya maitlhommo, le mofuta wa dipatlisiso. Fa o na le dipotso tse di sa tlhagisiwang fa o na le tetla ya go mpotsisa.

1. **Maitlhommo a thuto e:** Maitlhommo a patlisiso e ke go tlhalosa mosola kgotsa go tlhoka mosola ga sediriswa sa VitalStim® mo baneng ba banyenyane ba ba nang le bothata ba go ja le go metsa mme ba dirisa ditjhupu tsa PEG sebaka se selelele. Bana ba, ba tsewa jaaka batsayakarolo mo patlisisong ka ntlha ya ge maleka a tlwaelo a go metsa a retela mme ba tshwanela go dirisa mokgwa o mong wa go ja kwantle le go dirisa legano. Fa tiriso e, eka nna le thuso ya go ja le go metsa mo baneng ba, e tla dirisiwa jaaka tsela ya go thusa bana ba ba nang le mathata a go ja le go metsa ba ba dirisang ditjhupa tsa PEG.
2. **Dikgato:** O tla kopiwa go tlisa ngwana wa gago kwa Steve Biko Academic Hospital go tla go tlhatlhabiwa mabapi le go metsa. Se sebidiwa tlhatlhoboya barium swallow. Ke tla simolola ka go go botsolotsa dipotso gore ke fitlhele kitso yotlhe e ke e tlhokang ka ngwana. Ke tla dira diteko mo ngwaneng wa gore gago ke e le tlhoko mokgwa oo a jaang le go metsa dijo ka gone. Morago ga moo ngwana wag ago o tla neiwa modified barium swallow examination. E direlwa ka tlwaelo kwa lefapheng la Radiography mo bookelong. Ngwana wa gago o tla beiwa fa pele ga motjhini mme a fiwa dijo tse di farologaneng go dija sekao; metsi, yoghurt, motogo le dikuku fa e le ngwana yo mogolwane. Diyo tse di tla tlhakantshiwa le sengwe se se tla thusang go bontsha dijo mo screening. Dintlha tse dingwe tsa go metsa tsa ngwana wa gago ditlakwalwa mo fatshe mme di tla gatisiwa mo go DVD. O letlellwa go nna le ngwana wa gago ka dinako tsotlhe mo patlisisong e. DVD e, etla sekasekwa ke mo katisi yo mogolwane wa puo. Leina la gago ga le kitla le tlhagisiwa mo go ope.
3. O tla fiwa envelopu e e tla kayang gore ngwana wa gago o mo setlhopheng se sefe, ka go dira jalo patlisiso e tla nna le matla le go tswelapele.
4. Fa ngwana wa gago a le mo setlhopheng sa go dira tshupetso fa morago ga tlhatlhubo ya barium swallow o tla kopiwa go tla sepetlele gararo mo bekeng gore ngwana a tle go fiwa kalafi ee tsayang ura ya VitalStim®, le katiso ya ditho tsa ka mo ganong. Motlhotlhomisi wa yone o bone ikatiso e e tseneletseng mo mokgweng wa kalafo o, e bile o dirile VitalStim® Therapy mo baneng. Mo ureng e, di-electrodes di tla bewa mo molaleng wa gagwe, lebelela mo ditswentshong ka fa

morago. Di electrodes di tšile go dirisiwa go matlafatsa mesifa ya gagwe ya go metsa. Motjhini oo dirisiwang o tla nna o tšhatloga go fitlhela kwa seelong se se rileng. Ngwana wa gago a ka nna a se rate se, kwa tšhimolong mme feela fa moragonyana o tla tlwaela. Tiro e, e tšhotlheletsa mesifa e e metsang go ngotlega le go bulega mme ka tsela e mesifa e a matlafala mme e simolle go dira botoka. Mo seeming se, katiso ya go ruta ngwana go dirisa leleme le molomo e tla dirwa. Ke tla leka ka thata ya me yotlhe gore ke se utlwise ngwana wa gago botlhoko le gore ke dire le ene ka kelo tlhoko. Ke tšile go simolola ka go baya di electrodes mo letsogong la ngwana gore a simolole go di tlwaela ka mokgwa oo di leng kateng. Mo seemong se jaanong ngwana o tla rutiwa go metsa sekao: go ja ka molomo. Go botlhokwa gore o tle makgetlo a le 20 a a tsayang ura go katisa ngwana. Fa katiso ya VitalStim® e fedile, katiso ya go dirisa molomo le leleme le poeletso ya barium swallow e tla dirwa (jaake pele). Maitemogelo go tswa go barium swallow ya bobedi a tla bontsha phetogo mabapi le go metsa ga ngwana wa gago. O tla itsisiwa nako e sa le teng gore ngwana o batlega neng mo bookelong. Tjhelete ya gago le ngwana e tla baakangwa gore o e fiwe go go tlamela ka transport.

5. Fa ngwana wag ago a le mo setlhopheng se se sa diriseng VitalStim®, go tla dirwa feela katiso ya molomo le leleme mo go ena. Gararo mo bekeng mo sebakeng s aura makgetlo a le 20. Marago ga moo tšhatlhobo ya barium swallow e tla dirwa mo ngwaneng wag ago. Fa VitalStim® e bontsha dipholo tse di siameng, ke tlogo itsise mme ngwana wag ago o tla fiwa kalafi e mahlala fa o batla.
6. ***Ditshoso le gosaitumedisise:*** Le ga diteko di supile gore Therapy ya Vitalstim® e bolokegile go dirisiwa ke bagolo le bana, re tšhawanetse go e dirisa ka kelotlhoko ka go na le maemo a a sa itumediseng ka tšweletso pele ya yone. Ga gona matshosetsi kgotsa go sa itumedisise gape go go itsegeng mabapi le patlisiso e. Tšhoso e e ka nnang teng ke diso tse di bakwang ke plastara e e tšhwarang di-electrodes mo molaleng wa ngwana wa gago. Ngwana o tla tšhwanela go tšhatlhoiwa ke ngaka pele a ka simolla ka tiriso ya patlisiso e.
7. ***Mosola:*** Go na le tshepo e e tiileng ya gore VitalStim® e tla nna le thuso ya go kgontsha bana ba banang le mathata a go metsa gore ba metse botoka le go kgona go ja dijo tse di farologaneng ka molomo. Thuso e, e tla fokotsa mokgwa wa go ja ka ditjhupu tsa PEG.
8. ***Tokelo ya gago jaaku motsayakarolo wa patlisiso:*** O na le tokelo ya go ikogela kwa morago fa o sa batle go tswella le patlisiso kwantle le go fana ka mabaka.
9. ***Sephiri:*** Go ka fitlhella kitso ya gore a thuso ya VitalStim® e nale le mosola mo ngwaneng wa gago, go tla dirwa kgatiso ya DVD mo nakong ya tšhatlhobo ya barium swallow. Nna le bakatise ba puo ba bagolwane re tla lekodisisa DVD ya ngwana wa gago. Ga gona gope moo leina la gago le tla phatla-latswa kante le tumello ya gago. Patlisiso e, e tšile go bolokwa sentle ke Lefapha la bothata bo puo, e tla nna e bolokilwe jalo mengwaga e le 15.
10. ***Ke kopa tumello ya go dirisa file ya ngwana wa gago.***
11. ***Fa o na le dipotso tse dingwe, etla re bue, modiradipatlisiso, Jemma Chadinha 082 628 99 51***

Yo o boikanyego,

Jemma Chadinha

Modira patlisiso

Prof. A. Krtizinger

Mokatsi-mogolo

Prof. B. Vinck

Tlhogo ya lefapha la katiso ya puo la

Unibesithi ya Pretoria

TUMELLO YA GO TSAYA KAROLO MO PATLISISONG

KE TLHALOGANYA TOKELO YA ME JAAKA MOTSAJA-KAROLO MO PATLISISONG. KE ITHAOPA GORE NGWANA WA KA A TSEYE KAROLO MO PATLISISONG E. KE TLHALOGANY TSOTLHE TSE DI LENG MO PATLISISONG E LE GORE GORENG PATLISISO E, E DIRWA. KE TLA FIWA FOROMO E SAENNENG YA TIRO E.

LETLHA: _____

TSHAENO YA MOTSAJAKAROLO

MODIRAPATLISISO

PAKI

Di-electrodes tse di tla dirisiwa

VitalStim® unit



Lefelo la Seditriswa A



Lefelo la Sediriswa B



Lefelo la sediriswa C



Lefelo la Sediriswa D

(Tiriso ya electrode e tla laolwa ke mengwaga ya ngwana wag ago le bothata ba gagwe ba go metsa.)

Tumello e filwe ke Karin Mitchell go dirisa ditshwantsho go bontsho mafelo a a farologaneng a tiriso ya di electrode – Personal communication, October 2010.



7 September 2011

To whom it may concern,

Title of Research: The effect of VitalStim® Therapy on the feeding and swallowing of young children with long-term percutaneous endoscopic gastrostomy tubes

As part of my Masters degree in Communication Pathology at the University of Pretoria, I would like to conduct a research project involving children from the age of 6 months – 5 years who have been long-term percutaneous endoscopic gastrostomy tube fed. In this research study the use of VitalStim® Therapy on these children’s feeding and swallowing abilities will be investigated.

VitalStim® Therapy is a non-invasive, electrical stimulation technique for the treatment of dysphagia. It is a specialized form of neuromuscular electrical stimulation (Wijting, 2009). Electrical stimulation is applied to specific muscles involved in the swallowing process together with traditional swallowing exercises. The goal of VitalStim® Therapy is to strengthen and re-educate the muscular system while improving the motor control of the swallowing mechanism (Barnes, Miller, Latman, 2008; Permsirivanich, et al. 2009; Wijting, 2009). Neuromuscular electrical stimulation has been used extensively in a wide variety of therapeutic and rehabilitative settings especially in the profession of physiotherapy (Wijting, 2009). VitalStim® Therapy was approved by the US Food and Drug Administration (FDA) in 2002 for the safe treatment of dysphagia in adults and children although several precautions and contraindications have been identified. (Christiaanse, Glynn & Bradshaw, 2003; Freed, Freed, Chatburn & Christian, 2001; Wijting, 2009).

If you would like more information about VitalStim® Therapy and its benefits you can log onto www.vitalstim.com

The specific precautions and contraindications are listed below:

It would be much appreciated if you could tick the precaution and/or contraindication that is/are applicable to the specific patient.

General Precautions	Yes	No
1. Dementia with non-stop verbalization		
2. Significant Reflux		
3. Dysphagia due to drug toxicity		
4. Presence of a Demand pacemaker		
5. Deep brain stimulator		
6. Implantable Cardioverter Defibrillators		

7. Seizures		
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General Contraindications	Yes	No
1. VitalStim therapy over an active neoplasm on the anterior neck		
2. VitalStim therapy over an active infection on the anterior neck		

If you have any further queries, please do not hesitate to contact me on 082 628 9951.

Yours sincerely,

Jemma Chadinha

Researcher

Prof. A. Kritzinger

Research Supervisor

Prof. B. Vinck

Head: Department of Communication Pathology

University of Pretoria

I, (Name and Surname) _____ confirm that _____ is medically stable to receive 20 sessions of VitalStim® Therapy.

Treating Physician

Date signed

VITALSTIM CERTIFICATION

This certifies that

Jemma Dorkin

STA 0028991

Has attended the VitalStim Certification Course in Johannesburg, South Africa on the 6,7 November 2009 and has completed all requirements for certification as a

VitalStim Therapy Provider

Provider Number: 27-VS-4057

15 CEU points – Level 2
PPB007/013/11/2009



Amanda McCulloch

RehabMatters, Johannesburg
Date: 6-7 November 2009



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UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Denkleiers • Leading Minds • Dikgopolo tša Dihlalefi

Faculty of Humanities
Department of Communication Pathology

Dear

RE: INDEPENDENT RATING OF MODIFIED BARIUM SWALLOW EXAMINATIONS

Title of Research: The effect of VitalStim® Therapy on the feeding and swallowing of young children with long-term percutaneous endoscopic gastrostomy tubes

As part of a Masters degree in Communication Pathology at the University of Pretoria, I would like to perform a research project involving children from the age of 6 months – 5 years who have been long-term PEG fed. In this research study the use of VitalStim® Therapy on these children's feeding and swallowing abilities will be investigated.

To improve the reliability and validity of this research study, it would be highly appreciated if you would evaluate the modified barium swallow examination/s on the DVD as an independent moderator. The form used to evaluate the patient's swallow is "Rating of Modified Barium Swallow Examination" (Wijting, 2009). A copy of the form is included for your use. You are encouraged to keep all case-specific information confidential and to be as objective as possible while rating the modified barium swallow examination/s.

If you wish, the results of the study will be made known to you

Your contribution to this research study is greatly valued.

If you have any further queries please don't hesitate to contact me on 082 628 9951.

Yours sincerely,

Jemma Chadinha

Researcher

Prof. B. Vink

Head of Department of

Communication Pathology

Prof. A. Kritzinger

Research Supervisor

CASE HISTORY FORM

PARTICIPANT NUMBER: _____

DATE: _____

Interview conducted with the parent/caregiver

CONTACT DETAILS

(Information to be kept confidential)

Name of the caregiver/s or parents: _____

Address: _____

Contact details: _____

SECTION A: BIOGRAPHICAL INFORMATION

1. What is your/the child's name? _____
(The name of your child will not be used in the research report)
2. When was he/she born? _____
3. What is the medical diagnosis of your/the child?

4. Does anyone in your family have any feeding or swallowing difficulties that you are aware of?

5. When was the diagnosis first made?

6. Does your child have any other problems?

7. Where does your/the child stay during the day? _____
8. Which languages do you speak at home?

SECTION B: PRENATAL AND BIRTH HISTORY

1. How was your/ the mother's general health during the pregnancy?

2. Length of pregnancy: _____

3. If the baby was born premature, for what reason?

4. Normal or caesarean birth? _____

5. Presentation of baby at birth: Vertex / Breech _____

6. Meconium aspiration _____

7. Did your/the baby receive any oxygen after birth and for how long?

Answers to Question 8 through to 20 will be obtained from the participants medical records.

8. Respiratory distress syndrome _____

9. Necrotizing enterocolitis _____

10. Hydrocephalus _____

11. Neonatal Convulsions _____

12. Hyperbilirubinemia _____

13. Bronchopulmonary dysplasia, bradycardia or apnoeic attacks _____

14. Patent ductus arteriosus _____

15. Intra-ventricular Haemorrhage _____

16. Any infections present after birth

17. What did your/ the baby weigh at birth? _____

18. What were your/the baby's Apgar scores? _____

19. Did your/the child spend any amount of time in the hospital after birth? If so, why and for how long?

20. Was your/the child fed orally after birth? How and for how long?

SECTION C: MEDICAL HISTORY

1. Has your/the child had any surgeries? If yes, what type and when?

2. Is your/the child on any medication? If yes, what type and why?

3. Has your/the child suffered from any illnesses e.g. measles, mumps etc.?

4. Does your/the child suffer from any upper respiratory diseases that would ultimately affect his/her feeding abilities?

5. Has your/the child ever suffered from gastro intestinal reflux? If yes, for how long? Is your/the child on any medication? And has the reflux improved?

SECTION D: DEVELOPMENTAL HISTORY

1. Provide the approximate age at which your/the child began to do the following:

Crawl_____

Sit_____

Walk_____

Stand_____

Dress self_____

Use toilet_____

2. Depending on the child's age can he/she do the following with regards to the development of speech and language skills?

0-6 Months

Coos, gurgles and makes pleasure sounds ____

Vocalizes and coos when alone or when talked to ____

Smiles when spoken to ____

Recognizes voices ____

Can laugh and make back-of-the-mouth sounds ____

Responds to changes in tone of voice ____

Listens to speech ____

Localizes to sound ____

Uses a different cry to express different needs ____

Uses the phonemes /b/, /p/ and /m/ in babbling ____

7-12 Months

Understand no ____

Responds to simple requests ____

Understands and responds to own name ____
Recognizes words for common items ____
Babbles using long and short groups of sounds (4 syllables or more) ____
Uses a large variety of sounds in babbling ____
Imitates some adult speech sounds and intonation patterns as well as coughs,
tongue clicks and kisses ____
Uses speech sounds rather than only crying to get attention ____
Listens when spoken to ____
Uses sound approximations ____
Uses speech intentionally for the first time ____
Uses nouns almost exclusively ____
Has an expressive vocabulary of one to three words ____
Uses characteristic gestures or vocalizations to express wants ____

13-18 Months

Imitates individual words ____
Uses adult-like intonation patterns ____
Uses echolalia and jargon ____
Omits some initial consonants and almost all final consonants ____
Produces mostly unintelligible speech ____
Follows simple commands ____
Receptively identifies one to three body parts ____
Has an expressive vocabulary of 3 to 20 or more words ____
Combines gestures and vocalization ____
Makes requests for more of desired item ____
Tries to sing ____

19-24 Months

Uses words more frequently than jargon ____
Has an expressive vocabulary of 50-100 or more words ____
Has a receptive vocabulary of 300 or more words ____
Is approximately 25% - 50% intelligible to strangers ____
Asks and answers "What's that?" questions ____
Enjoys listening to stories ____
Knows five body parts ____
Accurately names a few familiar objects ____
Understands basic categories ____
Points to pictures in a book when named ____
Combines two or more words into ideas e.g. Dada toilet ____
Begins to use possessives: My, Mine ____
Uses 3-word sentences ____

2-3 Years

Speech is 50% - 75% intelligible ____
Understand one and all ____
Verbalizes toilet needs ____
Requests items by name ____

- Identifies several body parts ____
- Follows two-part commands ____
- Asks one to two word questions ____
- Uses two to four word phrases ____
- Uses words that are general in context ____
- Continues use of echolalia when difficulties in speech are encountered ____
- Says a few nursery rhymes ____
- Gives the use of an object ____
- Uses What, Where, why, how, when ____
- Uses negation ____
- Answers: What's your name? ____
- Asks a spontaneous question: Where is daddy? ____
- Uses 200 or more recognizable words ____
- Uses connective words (So, and, cause) ____
- Uses pronouns ____
- Verbalizes sounds: w, m, p, b, n, t, d, k, g ____

3-4 Years

- Understands object functions ____
- Speaks in approximately 6 word sentences ____
- Understands opposites ____
- Follows two- and three-part commands ____
- Uses language to express emotion ____
- Can tell about a picture ____
- Engages in long conversations ____
- Tells two events in chronological order ____

4-5 Years

- Imitatively counts to five ____
- Understands the concept of numbers up to three ____
- Counts to ten by rote ____
- Listens to short, simple stories and can answer questions about the story ____
- Uses sentences of four to eight words ____
- Answers complex two-part questions ____
- Asks for word definitions ____
- Accurately tells about experiences at school, or at friends' houses ____
- Identifies and points to pictures described ____
- Communicates freely with friends, family and strangers ____

SECTION E: FEEDING DESCRIPTION

1. What is the main difficulty with your/the child's feeding according to you?

2. How is your/the child currently feeding? How often do you feed your/the child via the PEG tube and how much? What type of food does the child take via the tube?

3. Does your/the child sleep well? If not, please explain why?

4. In what position do you feed your/the child?

5. When feeding orally, what is your/the child currently eating? Which consistencies of food?

6. Does your/the child have difficulty with sucking, swallowing, drooling or chewing?

7. Did your/the child ever breastfeed? Any difficulties and for how long did he/she breastfeed?

8. Did your/the child ever eat solids before the PEG tube? What did he/she eat and for how long did he/she eat solid food?

9. Does your/the child have any food preferences?

10. Is your/the child allergic to any food? If so, which food/s?

11. Has your/the child received any feeding therapy before? If yes, for how long? Was there any improvement? Why was therapy terminated?

12. When was the PEG tube inserted?

13. Did your/the child ever receive a modified barium swallow? When? Where?

14. Do you know what the results were?

15. Does your/the child receive any special services e.g. speech-language therapy, physio, O.T.?

Based on:

Anderson, D., & Fowler, S., & Nelson, J. (1978). Developmental Assessment Schema (DAS). In Northcott, W.H. (Ed). *Curriculum Guide: Hearing Impaired Children 0-3 years*. Washington, D.C: The Alexander Bell Association for the Deaf.

Arvedson, J.C. & Brodsky, L. (2002). *Pediatric Swallowing and Feeding: Assessment and Management*. Early Childhood intervention Series. Canada: Thomson Delmar Learning.

Kritzinger, A. (1994). *Risk Assessment*. Vroeë kommunikasie-ontwikkeling van biologiese risikobabas. Unpublished Master's dissertation. Department of Communication Pathology, University of Pretoria.

Shipley, K. G., & McAfee, J. G. (2004). *Assessment in Speech-Language Pathology: A Resource Manual*. 3rd Edition. U.S.A: Thomson Delmar Learning.

Clinical Feeding and Swallowing Assessment

Participant number: _____

***FOIS Score at the beginning of the study:** _____

FOIS Score at the end of the study: _____

Control participant

Main participant

1. Muscle Tone	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral- motor exercises Date: _____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral- motor exercises Date: _____
Within normal limits		
Hypertonic		
Hypotonic		
Mixed		

Comments: _____

2. Response to the Environment	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral- motor exercises Date: _____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral- motor exercises Date: _____
Within normal limits		

Hyporeactive	Face: Oral Cavity:	Face: Oral Cavity:
Hyperreactive	Face: Oral Cavity	Face: Oral Cavity:
Defensive		

Comments:

3. Respiratory Patterns	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral- motor exercises Date:_____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral- motor exercises Date:_____
Within normal limits		
Stridor		
Wet vocal quality		
Abnormal breathing patterns	Shallow: Thoracic:	Shallow: Thoracic:

Comments:

4. State of the Baby	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____
Before non-nutritive sucking evaluation		
After non-nutritive sucking evaluation		

Comments:_____

5. Oral Structure and Function Lips	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____
Within normal limits		
At rest:	Symmetrical: Lips closed: Lips open:	Symmetrical: Lips closed: Lips open
Stretching (age appropriate)		
Puckering (age appropriate)		
Drooling present		

6. Oral Structure and Function Palate	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____
Within normal limits		
High arched		

7. Oral Structure and Function Jaw	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____
Within normal limits		
At rest:	Open: Closed: Symmetrical:	Open: Closed: Symmetrical:
Maintain closure		
Thrust		
Asymmetry on jaw opening		

8. Oral Structure and Function Gums and Teeth (age appropriate)	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date:_____
No teeth		
Teeth missing		

Overbite		
Underbite		
Ground down teeth		
Oral hygiene		
Swollen gums		

9. Oral Structure and Function Checks	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date: _____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date: _____
	Tone	

10. Oral Structure and Function Tongue	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date: _____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises Date: _____
	Tone	
Symmetrical		
Tongue thrust		
Protrusion		
Lateralization		
Elevation		

<p>11. Oral Structure and Function</p> <p>Head Control</p>	<p>Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises</p> <p>Date:_____</p>	<p>Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises</p> <p>Date:_____</p>
<p>Is able to hold head up for:</p>		

Comments:

<p>12. Non-Nutritive Sucking (Depending on the age)</p>	<p>Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises</p> <p>Date:_____</p>	<p>Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral-motor exercises</p> <p>Date:_____</p>
<p>Bursts per cycle</p>		
<p>Fatigue</p>		
<p>Lip closure</p>		
<p>Tongue cupping</p>		
<p>Strength of the suck</p>		
<p>Suck-Swallow-Breath Synchrony</p>		
<p>Bite Reflex present</p>		

Comments:

13. Swallowing	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral- motor exercises Date: _____	Before VitalStim® Therapy and non-nutritive oral-motor exercises/ non-nutritive oral- motor exercises Date: _____
Presence of a dry swallow		
Stimulated		
Delayed		
Laryngeal elevation present		

Comments:

14. Mother-child Interaction

References

Arvedson, J.C., & Brodsky, L. (2002). *Pediatric Swallowing and Feeding: Assessment and Management*. Early Childhood Intervention Series. Canada. Thomson Delmar Learning,

Swigert, N.B. (2010). *The Source for Pediatric Dysphagia*. 2nd Edition. USA. Linguistics.

***Functional Oral Intake Scale**

Tube Dependent (levels 1-3)

- 1- No oral intake
- 2- Tube dependent with minimal/inconsistent oral intake
- 3- Tube supplements with consistent oral intake

Total oral Intake (levels 4-7)

- 4- Total Oral intake of a single consistency
- 5- Total oral intake of multiple consistencies requiring special preparation
- 6- Total oral intake with no special preparation, but must avoid specific foods or liquid items
- 7- Total oral intake with no restrictions

Functional Oral Intake Scale¹

TUBE DEPENDENT (levels 1-3)

- 1 No oral intake
- 2 Tube dependent with minimal/inconsistent oral intake
- 3 Tube supplements with consistent oral intake

TOTAL ORAL INTAKE (levels 4-7)

- 4 Total oral intake of a single consistency
- 5 Total oral intake of multiple consistencies requiring special preparation
- 6 Total oral intake with no special preparation, but must avoid specific foods or liquid items
- 7 Total oral intake with no restrictions

¹ Crary MA, Carnaby-Mann GD, Groher ME. Initial psychometric assessment of a functional oral intake scale for dysphagia in stroke patients. *Arch Phys Med Rehabil* 2005;86:1516-1520.

Rating of the modified barium swallow examination

Patient number: _____

Date of modified barium swallow examination: _____

Please make a cross in the appropriate box where applicable

(* please indicate - min/minimal, mod/moderate, sev/severe)

Signs and Symptoms

- Decreased lip closure
- Decreased AP transit
- Abnormal chewing
- Pocketing/Holding
- Premature spillage*
- Decreased tongue base retraction
- Stasis/Coating
 - Posterior tongue*
 - Posterior pharyngeal wall*
- Delayed swallow trigger
- Piecemeal deglutition
- Oral/Nasal regurgitation*
- Decreased hyolaryngeal excursion
 - Decreased hyoid-thyroid approximation
 - Decreased hyoid protraction
 - Decreased laryngeal elevation
- Decreased airway protection
 - Penetration*
 - Aspiration*
- Decreased epiglottic inversion
- Decreased pharyngeal squeeze
- Vallecular pooling*
- Pyramidal pooling*
- Vallecular residuals*
- Pyramidal residuals*
- Decreased UES opening
- Cricopharyngeal bar
- Esophago-pharyngeal reflux*
- Decreased LES opening
- Esophageal stasis/dysmotility*
- Gastroesophageal reflux*
- Decreased coordination

Biscuit

Dysfunction

- Decreased lip closure
- Decreased cheek tone
- Decreased chewing
- Decreased tongue movement
- Decreased tongue base retraction
- Decreased VP closure
- Decreased hyolaryngeal excursion
- Decreased airway protection
- Decreased pharyngeal contraction
- Decreased UES opening/closure
- Decreased esophageal motility

Impaired muscle groups

- Oropharyngeal "sling"
- In- and Extrinsic tongue
- Velopharyngeal muscles
- Hyolaryngeal excursion muscles
- Laryngeal intrinsic
- Pharyngeal constrictors
- UES

Evaluation of Swallow Function

Therapist:		Date:	
Patient ID:		Diagnosis:	
Eval type:	<input type="checkbox"/> MBS; <input type="checkbox"/> FEES; <input type="checkbox"/> Bedside eval		

Signs and symptoms	Dysfunction	Impaired muscle groups	Weak	Stiff	Neuro	Electrode placement
<input type="checkbox"/> ↓ lip closure	<input type="checkbox"/> ↓ lip closure (lip seal)	<input type="checkbox"/> Oropharyngeal "sling"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 1
<input type="checkbox"/> Abnormal chewing	<input type="checkbox"/> ↓ cheek tone	<input type="checkbox"/> In- & Extrinsic tongue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 2a
<input type="checkbox"/> ↓ AP transit	<input type="checkbox"/> ↓ chewing	<input type="checkbox"/> Velopharyngeal muscles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 2b
<input type="checkbox"/> Pocketing/Holding	<input type="checkbox"/> ↓ tongue movement	<input type="checkbox"/> Hyolaryngeal excursion mm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 3a
<input type="checkbox"/> Premature spillage	<input type="checkbox"/> ↓ tongue base retraction	<input type="checkbox"/> Laryngeal intrinsics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 3b
<input type="checkbox"/> ↓ tongue base retraction	<input type="checkbox"/> ↓ VP closure	<input type="checkbox"/> Pharyngeal constrictors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 4a
<input type="checkbox"/> Stasis/Coating	<input type="checkbox"/> ↓ hyolaryngeal excursion	<input type="checkbox"/> UES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 4b
<input type="checkbox"/> posterior tongue	<input type="checkbox"/> ↓ airway protection					
<input type="checkbox"/> posterior pharyngeal wall	<input type="checkbox"/> ↓ pharyngeal contraction					
<input type="checkbox"/> Delayed swallow trigger	<input type="checkbox"/> ↓ UES opening/closure					
<input type="checkbox"/> Piecemeal deglutition	<input type="checkbox"/> ↓ esophageal motility					
<input type="checkbox"/> Oral/Nasal regurgitation	<input type="checkbox"/> other:					
<input type="checkbox"/> ↓ hyolaryngeal excursion						
<input type="checkbox"/> ↓ hyoid-thyroid approximation						
<input type="checkbox"/> ↓ hyoid protraction						
<input type="checkbox"/> ↓ laryngeal elevation						
<input type="checkbox"/> ↓ airway protection						
<input type="checkbox"/> Penetration						
<input type="checkbox"/> Aspiration						
<input type="checkbox"/> ↓ epiglottic inversion						
<input type="checkbox"/> ↓ pharyngeal squeeze						
<input type="checkbox"/> Vallecular pooling						
<input type="checkbox"/> Pyriform pooling						
<input type="checkbox"/> Vallecular residuals						
<input type="checkbox"/> Pyriform residuals						
<input type="checkbox"/> ↓ UES opening						
<input type="checkbox"/> Cricopharyngeal bar						
<input type="checkbox"/> Esophago-pharyngeal reflux						
<input type="checkbox"/> ↓ LES opening						
<input type="checkbox"/> Esophageal stasis/dysmotility						
<input type="checkbox"/> Gastroesophageal reflux						
<input type="checkbox"/> ↓ coordination						

Notes:

Clinical Indicators:

Permission to use “The Evaluation of Swallow Function” form to assess the participants’ modified barium swallows.

Hi Yorick

It's me again. I hope you are well.

I am hoping you can help me.

Remember the form you gave us during our course, The Evaluation of Swallow function. The one with the signs and symptoms, dysfunction, impaired muscle groups and electrode placement. I would love to use this form in my masters. Who do you suggest I ask for permission to do so?

I hope you can help.

Thanks

Jemma

Reply Reply to all Forward

Reply | Wijting, Yorick (EFL) to me

show details Mar 18

Hi Jemma,

Feel free to use the form as you wish.

Best, Yorick

From: Jemma Dorkin [mailto:jdorkin10@gmail.com]

Sent: Wednesday, March 17, 2010 11:17 AM

To: Wijting, Yorick (EFL); yorickw

Subject: Vital sitm

- Show quoted text -

Hi Yorick It's me again. I hope you are well.

I am hoping you can help me.

Remember the form you gave us during our course, The Evaluation of Swallow function. The one with the signs and symptoms, dysfunction, impaired muscle groups and electrode placement. I would love to use this form in my masters. Who do you suggest I ask for permission to do so?

I hope you can help.

ThanksJemma

Confidentiality Notice: This message, together with any attachments, is intended only for the use of the individual or entity to which it is addressed and may contain confidential or privileged information. If you think you have received this message in error, please advise the sender and then delete this message and any attachments immediately.

Reply Forward

Reply |Jemma Dorkin to Yorick

show details Mar 18

Thank you so much Yorick

Will let you know of my results.

Jemma

- Show quoted text -



DEPARTMENT
OF
HEALTH

DEPARTEMENT
VAN
GESONDHEID

Tel: (012) 354-2714

Fax/Faks: 0866900965

Enquiries/Navrae: Anneli Lloyd-Jones
Steve Biko Academic
Hospital
Private Bag x 169
Pretoria, 0001
2011-02-18

Ms. Jemma Chadinha
Dept. Of Speech Therapy & Audiology
UNIVERSITY OF LIMPOPO (MEDUNSA CAMPUS)

Dear Ms. Chadinha

RE: RESEARCH

Thank you for your letter regarding your research into paediatric dysphagia. I understand that you need to have Modified Barium swallow examinations done on all your patients. Our Department has been helping the therapists from Dr. George Mukhari for a long time now as the machine at their hospital is broken. Helping you would not be a problem and we will be happy to accommodate your research subjects. I trust that this arrangement will suit your needs. Please let me know if you require any further information.

Yours sincerely

Anneli Lloyd-Jones
ASD: Speech Therapy/
Audiology

Date of session: _____

Participant number: _____

NMES

TRACKING FORM

The effect of VitalStim® Therapy on the feeding and swallowing of young children with long-term percutaneous endoscopic gastrostomy tubes

Diagnosis: _____

Modified Barium Swallow Examination findings:

Session number: _____

Age: _____

Gender: _____

Behaviour	Notes
1. Duration of the session	
2. Electrode placement	
3. How many electrodes used?	
4. Stimulation level	

BASED ON "VITALSTIM THERAPY OUTCOME TRACKING" FORM, TRAINING MANUAL FOR THE USE OF NEUROMUSCULAR ELECTRICAL STIMULATION IN THE TREATMENT OF DYSPHAGIA, Y, WITJTING (2009)

Date of session: _____

Participant number: _____

5. Where was session conducted?	
6. Non-nutritive oral-motor exercises introduced (amount and sequence)	
7. Participant's response to VitalStim® Therapy	
8. Participant's response to non-nutritive oral-motor exercises	
9. Participant's state during VitalStim® Therapy and non-nutritive oral-motor exercises	
10. Any stress signals observed	
11. Is a swallow (laryngeal elevation) present before the session? Was stimulation necessary?	
12. Is a swallow (laryngeal elevation) present after the session? Was stimulation necessary?	
13. FOIS score*	

BASED ON "VITALSTIM THERAPY OUTCOME TRACKING" FORM, TRAINING MANUAL FOR THE USE OF NEUROMUSCULAR ELECTRICAL STIMULATION IN THE TREATMENT OF DYSPHAGIA, Y, WITJTING (2009)

Date of session: _____

Participant number: _____

Functional Oral Intake Scale

Tube Dependent (levels 1-3)

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- 4- Total Oral intake of a single consistency
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BASED ON "VITALSTIM THERAPY OUTCOME TRACKING" FORM, TRAINING MANUAL FOR THE USE OF NEUROMUSCULAR ELECTRICAL STIMULATION IN THE TREATMENT OF DYSPHAGIA, Y, WITJTING (2009)

Oral Sensorimotor Stimulation

Technique	Description
Reducing the tonic bite reflex (Morris & Klein 1987; Hall, 2001)	Firm pressure was applied to the face.
Facial moulding (Hall, 2001; Swigert, 2010)	Wipe from the outer cheek forward toward the lips. Wipe from the bottom of the chin up toward the lips. Both sides of the face were moulded at the same time to reduce lip retraction.
Massaging the temporo-mandibular joint (Swigert, 2010)	Massaging was only done when a tonic bite reflex was exhibited.
Massaging inside of cheeks (Hall, 2001; Swigert, 2010)	A gloved finger was used to massage the inside of the cheeks, sulci and gums. Massaging increased awareness in the oral cavity. The researchers' finger was dipped into ice before placed in the participants' mouth to improve sensory awareness.
Increasing tone in the lips (Hall, 2001)	A vibrating tooth brush was placed on the upper and lower lips to increase sensation.
Increasing sensory input to the tongue through vibration (to improve tone) (Swigert, 2010)	A massaging brush dipped in ice was used to rub the chewing surfaces of the gums, inside the cheeks, lateral borders of the tongue and the top of the tongue.
Vibrations on the face and cheek to reduce hyper tonicity or increase sensory input (Morris & Klein, 1987; Swigert, 2010)	The researchers' gloved finger was dipped into ice beforehand. The index finger was placed inside the participants' mouth in the buccal cavity and the middle finger on the exterior surface of the cheek. The researcher lightly held the cheek between the forefinger and the middle finger. A quick shaking or vibration of the fingers was executed while the cheek was pulled forward and the researchers' finger was pulled out of the participants' mouth. Each cheek was vibrated separately.
Increasing lip movement (Morris & Klein, 1987; Swigert, 2010)	The index and middle fingers were placed on either side of the bridge of the participants' nose and a quick vibration motion down all the way through the upper lip was used. The researcher continued until the corner of the upper lip was reached.
Improving lip movement and tone (Swigert, 2010)	The index and middle finger was placed on the upper lip immediately below the nose. Several quick stretches were executed toward the corner of the lips.
Improving lip	The researcher's gloved thumb was used in a rolling motion

closure (Hall, 2001)	around the participants' mouth on both the upper and lower lips.
Creating a tongue bowl (Swigert, 2010)	The bowl of an empty spoon/massaging brush was placed in the middle of the participant's tongue and pressed down. The spoon was dipped into ice before placed in the participant's mouth to improve sensory awareness.
Facilitating chewing (Swigert, 2010)	A teether was placed between the back teeth (one side at a time) and the participant was assisted with external jaw closure.
Improving the triggering of the pharyngeal swallow (Hall, 2001)	The massaging brush was dipped in ice and the faucial arches were stimulated on each side, 4-6 times.
Establishing a non- nutritive suck (Arvedson & Brodsky, 2002; Hall, 2001)	The tongue was stroked from the middle to the front with a massaging brush that was dipped into ice.

NMES (VitalStim® Therapy) Treatment Protocol

0-12 months – Paediatric electrode placement A, B, C or D will be chosen

Placement A



- Two electrodes placed horizontal above the thyroid notch (newborns) or just above the hyoid (12 months +)
- Care must be taken in taping the electrodes flush to the skin, especially on infants with “skin folds” or “chub”!! Skin is okay to lay on top of electrode, just not fold underneath the electrode.

When to use:

- Decreased tongue base retraction
- Dysfunctional laryngeal excursion
- Pooling in valleculae

Rationale:

- Stimulates extrinsic and some intrinsic tongue muscles as well as suprahyoid muscles promoting laryngeal elevation.
- Stimulates middle pharyngeal constrictor for infants as this muscle attaches to the hyoid cartilage. Hyoid is found mid-mandible for newborns and descends slowly.

Placement B



Two electrodes placed horizontal around the thyroid notch

When to use:

- Suitable for most laryngeal and pharyngeal motor deficits
- Great for silent aspirators to “wake up” the larynx and pharynx for airway protection.

Rationale:

- Current focuses through intrinsic laryngeal and pharyngeal muscles
- Increases sensory awareness in the pharynx and larynx.

Placement C



Two electrodes placed vertical, one above the thyroid notch (newborns), or hyoid (in 12 months +) and one below the thyroid notch

When to use:

- Decreased laryngeal excursion
- Upper esophageal sphincter (UES)/ cricopharyngeal difficulties
- Decreased tongue base retraction (not as direct as in placement A)
- Pooling in valleculae (not as direct as placement A)

Rationale:

- Stimulates extrinsic and some intrinsic tongue muscles as well as suprahyoid muscles promoting laryngeal elevation. Laryngeal elevation impacts opening of the UES.
- Babies born with hypotonia require higher laryngeal elevation during swallowing as their musculature rests lower due to tone.
- As the mouth and neck grow both in width and length, more laryngeal excursion is needed, this placement directly impacts hyolaryngeal excursion (anterior pull of the hyoid, laryngeal elevation as well as thyrohyoid approximation).

12 months – 5 years: Adult electrode placements will be used.

Placement D



Channel 1: First electrode above hyoid and second electrode between hyoid and thyroid notch

Channel 2: electrodes surround the thyroid cartilage

When to use:

- Decreased tongue base retraction
- Dysfunctional laryngeal excursion
- Pooling in valleculae (not as direct as placement A)

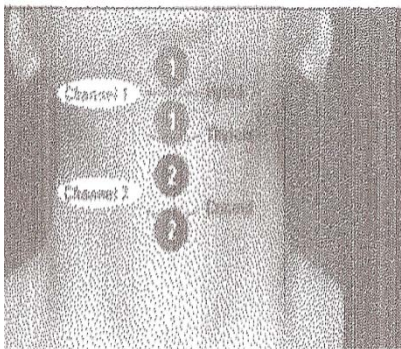
- Suitable for most laryngeal and pharyngeal motor deficits

Rationale:

- Stimulates extrinsic and some intrinsic tongue muscles as well as suprahyoid muscles promoting laryngeal elevation
- Current focuses on infrahyoid muscles and with sufficient intensity, also through intrinsic laryngeal and pharyngeal muscles

12 months – 5 years – adult electrode placements will be used

Placement 1



- All electrodes aligned vertically along midline.
- First electrode is placed well above the hyoid bone.
- Second electrode is placed just below first one, above the thyroid notch.
- 3rd and 4th electrode placed at equal distances below first two electrodes.

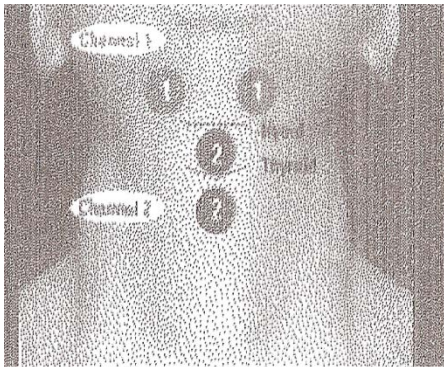
When to use:

- Decreased hyolaryngeal excursion
- Penetration, aspiration
- Voice abnormalities
- Decreased UES opening
- Pooling, residuals

Rationale:

Facilitation of supra and infrahyoid muscles

Placement 2a



- Channel 1: electrodes aligned horizontally at or above the hyoid bone
- Channel 2: electrodes aligned vertically along midline, top electrode at level of thyroid notch, bottom electrode below it

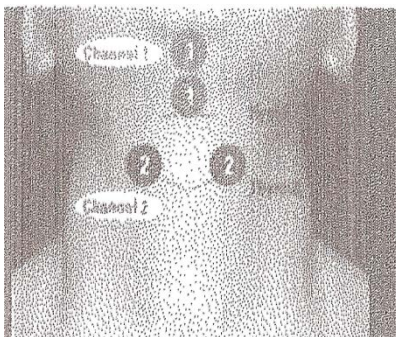
When to use it:

- Reduced anterior-posterior transit
- Premature spillage
- Coating tongue base or posterior pharynx
- Delayed swallow trigger
- Vallecular pooling

Rationale:

Facilitates tongue muscle recruitment

Placement 2b



- Channel 1: electrodes aligned along midline, over geniohyoid belly
- Channel 2: electrodes placed at either side of thyroid notch, over thyrohyoid muscle belly

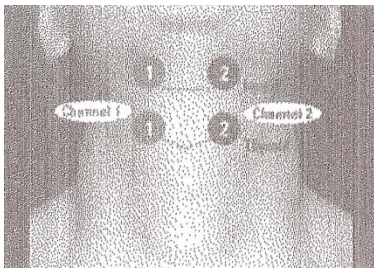
When to use it:

- Decreased hyolaryngeal excursion
- Penetration, aspiration
- Voice abnormalities
- Decreased UES opening
- Pooling, residuals
- Decreased opening UES, CP bar
- Premature closure UES

Rationale:

- Focuses on hyolaryngeal excursion
- Good facilitation of geniohyoid, mylohyoid and thyrohyoid muscles

Placement 3a



- Channels aligned vertically on either side of midline
- Top electrodes are placed just above hyoid bone
- Bottom electrodes are over the thyrohyoid muscle – at the level of the thyroid notch
- NB. Care must be taken not to put electrodes too far laterally so as not to send current through the carotid sinus.

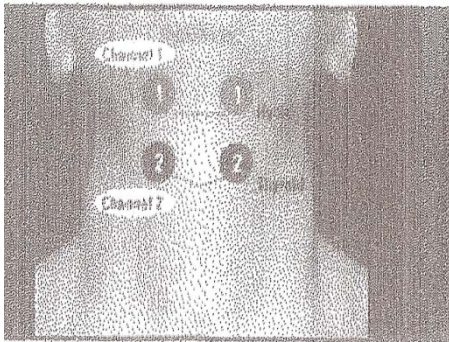
When to use it:

- Reduced anterior-posterior transit
- Premature spillage
- Coating tongue base or posterior pharynx
- Delayed swallow trigger
- Vallecular pooling
- Decrease hyolaryngeal excursion
- Penetration, aspiration
- Voice abnormalities
- Decreased UES opening
- Pooling and residual

Rationale:

- Good facilitation of digastrics and thyrohyoid muscles
- Focus on hyolaryngeal excursion

Placement 3b



- Electrodes Channel 1 aligned horizontally at or above the hyoid bone
- Top electrodes are placed just above hyoid bone
- Bottom electrodes are over the thyrohyoid muscle – at the level of the thyroid notch
- Care must be taken once again not to place electrodes too far laterally so as not to send current through carotid sinus

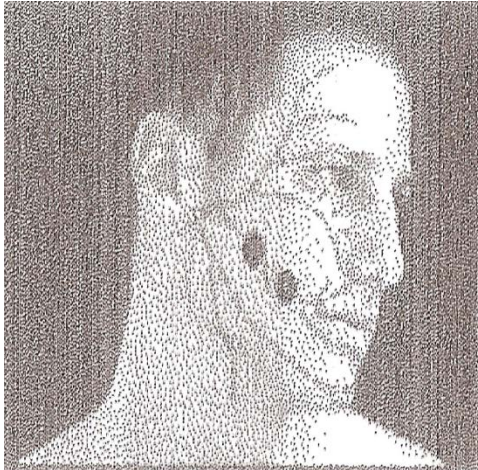
When to use:

- Decreased anterior posterior transit
- Premature spillage
- Coating tongue base or posterior pharynx
- Delayed swallow trigger
- Vallecular pooling
- Penetration, aspiration
- Piecemeal deglutition
- Residuals
- Decreased pharyngeal transit time
- Delayed opening UES
- Decrease opening of UES, CP bar
- Premature closure UES

Rationale:

Focuses on pharyngeal constriction

Placement 4a



- Electrodes are placed over buccal branch of facial nerve
- Channel may be placed bilaterally (maximum facilitation of synergists)
- Second channel may be placed superior to hyoid (as in top channel of placement 3b) to facilitate recruitment of CN XII
- Alternatively, 2nd channel may be placed on opposite side to increase facilitation of oropharyngeal sling

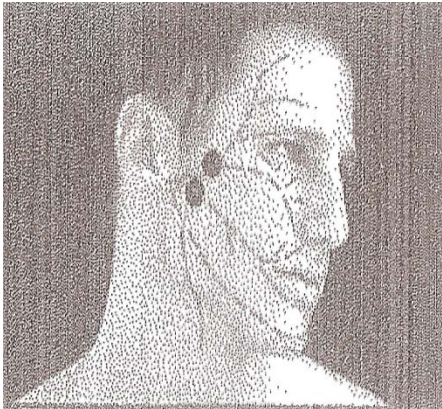
When to use:

- Anterior spillage or leakage
- Premature spillage, residuals
- Pocketing, holding, stasis
- Nasal regurgitation
- Decreased anterior posterior transit
- Coating tongue base or posterior pharynx
- Delayed swallow trigger

Rationale:

Increases sensory input – CN V and VII

Placement 4b



- Electrodes are placed over main trunk of facial nerve
- Second channel may be placed superior to hyoid (as in top channel of placement 3b) to facilitate recruitment of CN XII
- Alternatively, 2nd channel may be placed on opposite side to increase facilitation of oropharyngeal sling

When to use:

- Facial weakness

Rationale:

- Strengthens muscles of the face innervated by facial nerve

Treatment

1. Skin must be clean and dry. Remove any excess cream or perspiration with a warm cloth.
2. Clean skin with included cleaning swab or alcohol swab. This will improve adhesion and conductivity.
3. Maintain head position as neutral as possible.
4. Attach electrodes as per MBS
5. Electrodes must be firmly attached with additional taping or bandaging to ensure proper adhesion (crepe bandage)
6. Caregivers will be instructed in the progression of the treatment and the anticipated outcome.
7. Electrode placement is based on the impairment that has been identified
8. VitalStim therapy will last approximately 1 hour
9. During stimulation the patient will practice swallowing depending on patients specific age. Swallowing exercise will also be practiced.

Stimulation sequence

1. Each research participant is to be positioned correctly before the electrodes are placed on the anterior neck.
2. Apply electrodes
3. Turn on the unit
4. Increase both channels alternately
5. Look for some signs of “squeezing”, “holding”, “pulling” – level of stimulation (level 13 or 14)
6. Leave the stimulator at this level and initiate swallowing training
7. Progress with texture and quantity according to patient performance

Observable signs that a therapeutic level of intensity has been reached:

1. Audible quality of swallow – louder
2. Signs of squeezing or holding or pulling can be seen
3. Triggers the swallow (**more likely to be seen in paediatric patients**)
4. Better swallow with electrotherapy on than with it off
5. Body language: sitting up, reaching for the electrodes
6. Change of voice quality

References

Mitchell, K., Ramirez, K. & Robles, M. (2010). *The Effectiveness of NMES (VitalStim) Therapy in the Neonatal Population* Children's Hospital of Orange County.

Wijting, Y. (2009). *Training Manual for the Use of Neuromuscular Electrical Stimulation in the Treatment of Dysphagia*.

Date of session: _____

Participant number: _____

Oral Sensorimotor Stimulation
 TRACKING FORM
The effect of VitalStim® Therapy on the feeding and swallowing of young children with long-term percutaneous endoscopic gastrostomy tubes

Diagnosis: _____

Modified Barium Swallow Examination findings: _____

Session number: _____

Age: _____

Gender: _____

Behaviour	Notes
1. Duration of the session	
2. Where was session conducted?	
3. Non-nutritive Oral-motor exercises introduced (amount, sequence)	
4. Participant's response to non-nutritive oral-motor exercises	

BASED ON "VITALSTIM THERAPY OUTCOME TRACKING" FORM, TRAINING MANUAL FOR THE USE OF NEUROMUSCULAR ELECTRICAL STIMULATION IN THE TREATMENT OF DYSPHAGIA, Y, WITJTING (2009)

Date of session: _____

Participant number: _____

5. Participant's state during non-nutritive oral-motor exercises	
6. Any stress signals observed	
7. Is a swallow (laryngeal elevation) present before the session? Was stimulation necessary?	
8. Is a swallow (laryngeal elevation) present after the session? Was stimulation necessary?	
9. FOIS score*	

Functional Oral Intake Scale

Tube Dependent (levels 1-3)

- 1- No oral intake
- 2- Tube dependent with minimal/inconsistent oral intake
- 3- Tube supplements with consistent oral intake

BASED ON "VITALSTIM THERAPY OUTCOME TRACKING" FORM, TRAINING MANUAL FOR THE USE OF NEUROMUSCULAR ELECTRICAL STIMULATION IN THE TREATMENT OF DYSPHAGIA, Y, WITJTING (2009)

Date of session: _____

Participant number: _____

Total oral Intake (levels 4-7)

- 4- Total Oral intake of a single consistency
- 5- Total oral intake of multiple consistencies requiring special preparation
- 6- Total oral intake with no special preparation, but must avoid specific foods or liquid items
- 7- Total oral intake with no restrictions

BASED ON "VITALSTIM THERAPY OUTCOME TRACKING" FORM, TRAINING MANUAL FOR THE USE OF NEUROMUSCULAR ELECTRICAL STIMULATION IN THE TREATMENT OF DYSPHAGIA, Y, WITJTING (2009)