The Effects of a Jaw-Opening Exercise on Submental Muscles and Hyoid Movement During Swallowing in Healthy Adults

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List of abbreviations

1RM = 1-repetition maximum

2-D = two-dimensional

ANOVA = Analysis of Variance

ATP = adenosine triphosphate

GLM = General Linear Model

ICC = intra-class correlation

JOE = jaw-opening exercise

NPO = nothing per orem

NRBRI = New Zealand Brain Research Institute

RM = Repeated Measures

SE = sham exercise

sEMG = surface electromyography

SLT = speech-language therapist

UES = upper esophageal sphincter

VFSS = videofluoroscopic swallowing study

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Abstract

Objective: Traditionally, swallowing rehabilitation has involved the use of muscle strengthening exercises, such as the head-lift manoeuvre (Shaker et al., 1997), to strengthen the floor of mouth muscles. Clinical reasoning suggests that this particular exercise may be problematic for patients with cervical spine injuries or increased frailty. Recently, Bauer and Huckabee (2010) attempted to determine the efficacy of an alternative exercise for the floor of mouth muscles in healthy adults. The present study aims to expand on this work in a larger population of healthy adults.

Study design: Controlled trial; participants matched for age and sex.

Participants: 23 healthy adults with no history of neurological or muscular impairment.

Method: Participants were assigned into one of two groups: jaw opening exercise (JOE; n = 12) and sham exercise (SE; n = 11). Groups were matched for age and gender. Participants performed their respective exercises three times per day, five days per week, over a six week period. At three times during this period, measures of submental 2-D cross-sectional area and anterior hyoid movement were taken via ultrasound. Additionally, measures of submental muscle myoelectrical activity were taken via surface electromyography. Pre- and post-treatment comparisons, as well as inter-group comparisons, were undertaken.

Results: No significant differences were observed between groups on measures of muscle size, anterior hyoid movement, or myoelectrical activity over time. However, this study has contributed to the future development of an alternative exercise to target the submental muscle group.

Introduction

Introduction to healthy swallowing

Swallowing is the complex act of transporting food from the oral cavity safely through the esophagus and into the stomach in a smooth and timely manner. While in reality swallowing is a single dynamic event combining several interdependent processes, in order to conceptualise this, clinicians and researchers often describe swallowing as occurring in distinct functional phases.

Daniels and Huckabee (2008) describe deglutition as a four-stage process. The first phase, known as the pre-oral phase, prepares the system for the incoming bolus. This may include the initiation of airway protection mechanisms. External factors, such as eating behaviours, attention, and feeding method, may compromise swallowing safety at this stage (Daniels & Huckabee, 2008). The second phase, known as the oral phase, consists of bolus preparation, mastication, formation, and transport from the oral cavity to the pharynx by way of volitional tongue movement. The third phase, or pharyngeal phase, is characterised by hyolaryngeal excursion, velopharyngeal closure, base of tongue to posterior pharyngeal wall approximation, pharyngeal shortening, epiglottic deflection, laryngeal closure and upper esophageal sphincter (UES) opening. Cessation of breathing, airway protection, and resumption of breathing must also occur rapidly. Temporal coordination of all of these components is critical for the safe and efficient propulsion of the bolus through the pharynx (Daniels & Huckabee, 2008). Of particular interest to the scope of this research is hyolaryngeal excursion. Contraction of the suprahyoid muscles (anterior and posterior bellies of digastric, mylohyoid, stylohyoid, and geniohyoid) and thyrohyoid muscle results in superior and anterior movement of the hyoid bone and larynx. The superior movement is crucial in facilitating epiglottic deflection and subsequent airway protection, whilst movement in the anterior direction contributes to the opening of the UES. The final phase is known as the esophageal phase. During this phase, peristalsis propels the bolus through the UES and lower esophageal sphincter, and into the stomach.

This system of bolus transport is not without potential complications, due to the anatomy of the swallowing mechanism. As the esophageal and tracheal tubes lie in close proximity to one another, the risk for the bolus to bypass the esophagus and spill into the airway is significant. In healthy individuals, this risk is usually minimised by the body’s pulmonary protective systems. These include adduction of the true and false vocal folds, deflection of the epiglottis, and compression of the quadrangular membrane, effectively blocking the entrance to the larynx.

Dysphagia

Dysphagia, or disordered swallowing, is a potentially life-threatening condition arising from injury to the neural, sensory, and/or motor systems that underlie deglutition. Dysphagia may present in a number of ways, including, but not limited to, a delay in the initiation of swallowing, disruption to the temporal sequence of muscle contractions, or insufficient bolus clearance due to weak swallowing. Medical literature suggests that the incidence of dysphagia is particularly high in stroke patients – up to 78% (Martino et al., 2005). Similarly, chronic, unresolved dysphagia may be present in as many as 92% of survivors of head and neck cancer (Nguyen et al., 2006).

Changes in swallowing physiology have also been observed with increasing age in normal populations. Such changes are characterised by increased lingual gestures (Nicosia et al., 2000), prolonged bolus transport time through the oropharynx (Rademaker, Pauloski, Colangelo, & Logemann, 1998), increased duration of hyolaryngeal elevation (Rademaker et al.), decreases in UES resting tone and opening (McKee, Johnston, McBride, & Primrose, 1998), and increases in post-swallow residue (Rademaker et al.).

For people living with dysphagia, the consequences are often debilitating and can hinder recovery from illness, leading to longer hospital stays and long-term care requirements (Odderson, Keaton, & McKenna, 1995). The impact on quality of life is significant, as dietary restrictions, tube-feeding, and swallowing discomfort may contribute to feelings of social isolation and anxiety (Ekberg, Hamdy, Woisard, Wuttge-Hannig, & Ortega, 2002).

Swallowing rehabilitation

Over the years, a variety of approaches to dysphagia management have been trialled, some with more success than others. In the early 19th century, a physician named Stokes (1833) described a range of cures for dysphagia, including leeches "*boldly and repeatedly applied to the neck"* (p. 665), rigorous exercise in fresh air, and puncturing the epiglottis. Despite these well-meant interventions, it was believed that "*almost every patient afflicted with this disease must die a slow and painful death"* (Stokes, p. 664).

Until the 1980s, the use of alternative feeding modalities such as endogastric/nasogastric tubes (PEGs; NGTs) that bypass the impaired oro-pharynx were considered to be the ultimate remediation for dysphagia (Robbins et al., 2008). However, by 1990, treatment had shifted dramatically to focus on compensatory techniques, many of which remain to be heavily utilised in present clinical practice. Such techniques include changes to head position during swallowing, recruiting the mechanisms of airway protection, and changes in bolus viscosity, volume, and texture. These techniques were developed to modify bolus flow through the oropharynx, and can result in the immediate minimisation of symptoms, for example, aspiration (Kuhlemeier, Palmer, & Rosenberg, 2001). However, there are certain drawbacks: these strategies must be implemented for every swallow, no lasting physiological change is achieved, and their use likely reduces the pleasure in eating (Daniels & Huckabee, 2008; Robbins et al., 2008).

In response to these ongoing issues, patient care has continued to evolve from a purely compensatory approach to achieving a more permanent shift in underlying swallowing physiology. A team-based approach to treatment, combining the expertise of general practitioners, otolaryngologists, surgeons, speech-language therapists, occupational therapists, nurses, and dieticians is common. This has seen the development of exercises aimed at increasing strength, endurance, range of motion, or a combination thereof, in the muscles of deglutition. These exercises are now widely used in the context of dysphagia rehabilitation, with improvements in patients' functional swallowing attributed to their use (Carroll et al., 2008).

The effects of rehabilitative exercise on the muscles of deglutition have been somewhat neglected in the literature. However, evidence suggests that the muscles involved in mastication and swallowing do adapt in response to increases in load (Thompson, Throckmorton, & Buschang, 2008; Vincent et al., 2002). Of particular interest to the current project are findings relating to the effects of exercise on the group of muscles located anterior to the hyoid bone, known collectively as the submental muscles. These muscles assist in hyoid excursion and subsequent widening of the UES. Before exploring applications to this field of rehabilitative medicine, however, a general overview of the structure and function of the component muscles – digastric, mylohyoid, stylohyoid, and geniohyoid – and the hyoid bone is warranted.

Overview of submental muscle structure and function

Hyoid bone. As previously eluded, hyoid displacement is a critical component of swallowing by contributing to airway protection and facilitating UES opening. The hyoid bone is a small, horseshoe-shaped structure located above the thyroid cartilage. At rest, it lies level with the base of the mandible anteriorly, and corresponds to the third cervical vertebra posteriorly. The hyoid is the only bone in the body that is not directly attached to another bone. Rather, it is anchored in position by infrahyoid muscles. The hyoid bone also serves as an attachment point for the floor of mouth muscles anteriorly, the larynx inferiorly, and the epiglottis and pharynx posteriorly. Adequate anterior and superior hyoid excursion results in the epiglottis tilting to cover the vocal folds, preventing bolus entry to the larynx. Contraction of the suprahyoid muscles that facilitate hyoid displacement also serves to pull the cricopharyngeus muscle open (in the context of UES relaxation), allowing bolus acceptance into the esophagus.

As with all stages of swallowing, patterns of hyoid movement are dependent on the physical properties of the incoming bolus, especially with regards to bolus volume and viscosity (Chi-Fishman & Sonies, 2002). Furthermore, evidence suggests that factors such as age and gender may also influence hyoid kinematics. However, due to methodological differences, the available scientific evidence is somewhat ambiguous.

In a study by Chi-Fishman and Sonies (2002), the effect of bolus volume (5, 10, 20, 30 cc) and viscosity (thin, nectar-thick, honey-thick, pudding-thick) on hyoid kinematics was presented. For this study, ultrasound recordings from 31 healthy individuals (16 males, 15 females, age range = 20-79 years) taken during swallowing were analysed. Boluses were presented via a syringe, and participants were instructed to swallow following a verbal command. Results showed that hyoid movement was affected as a function of bolus properties. Specifically, larger bolus volumes resulted in significantly increased anterior hyoid movement and velocity. The only significant effect observed as a result of viscosity variations was during the volitional phase of swallowing, with an increase in pre-swallow hyoid gestures for thicker boluses. However, other factors also affected hyoid kinematics. Hyoid displacement was increased in the superior direction for older participants, and in both the superior and anterior direction for males. Later work by Daniels, Schroeder, DeGeorge, Corey and Rosenbeck (2007) would also suggest that swallowing was affected by the use of verbal cues, although in this study the use of verbal cueing was consistent across all individuals. The authors suggested that healthy elderly may be counteracting age-related reductions in neuromuscular reserve by increasing recruitment of the floor of mouth muscles as a compensatory strategy to increase vertical hyoid movement. This seems unlikely, given that this muscle group generally functions to pull the hyoid bone in the anterior direction. They also proposed that anatomical differences resulting in a greater muscle contractile force in males may explain the gender differences for hyoid excursion. However, the authors conceded that further evidence from a larger sample population was needed to confirm these theories.

It may be argued that the extent to which results reported by Chi-Fishman and Sonies (2002) can be described as representative of actual swallowing behaviour is limited by elements of the contrived. A different approach was described in a study that required young, healthy participants (*N* = 12; age range: 20-28 years) to chew and swallow a range of solids and liquids whilst undergoing videofluoroscopy (Ishida, Palmer, & Hiiemae, 2002). Contrary to findings reported by Chi-Fishman and Sonies (2002), results suggested that degree of anterior hyoid displacement was not influenced by bolus size of consistency, while these same variables did appear to influence superior hyoid movement. Specifically, superior hyoid displacement was significantly reduced during liquid and small solid bolus swallowing. These findings are perhaps not directly comparable to the Chi-Fishman and Sonies study, as Ishida and colleagues did not strictly control bolus volume. The authors concluded that superior and anterior hyoid displacement relate to the oral and pharyngeal phases of swallowing, respectively. They suggest that for liquid swallowing, the hyoid bone is already in a high position due to the effects of glossopalatal approximation, and thus further superior hyoid movement is limited. Additionally, small boluses (considered in this study as "second swallows") require less overall movement from the tongue and jaw, resulting in less superior hyoid movement than for bigger boluses. Regarding anterior movement, the authors postulate that hyoid displacement occurs in this direction in response to the rapid contraction of the submental muscles that facilitate UES opening. As this is the primary mechanism for facilitating bolus acceptance to the esophagus, consistency in the degree of muscle contraction that displaces the hyoid bone is required.

A later study by Kim and McCollough (2008) would attempt to quantify the degree of hyoid displacement that occurs during swallowing. In a retrospective review of 40 videofluoroscopic swallowing studies of healthy individuals (age range 21-87 years), hyoid movement for 5ml and 10ml thin liquid boluses was examined. Results were analysed according to the age and sex of the individuals. Findings appeared to contradict earlier reports from the Chi-Fishman and Sonies (2002) study. In fact, Kim and McCollough found that anterior hyoid displacement was significantly decreased in older individuals compared to younger individuals. No such difference for superior hyoid excursion was found, and, contrary to reports from Chi-Fishman and Sonies and

Ishida et al. (2002), degree of hyoid excursion did not differentiate males from females. The authors supported Chi-Fishman and Sonies' suggestion that increased muscle weakness and fatigue in old age reduces the extent of hyoid excursion, but proposed that this effect is offset in the vertical direction because relatively more suprahyoid muscles are involved in this process than for the anterior direction. However, the extent to which generalisations about hyoid excursion can be made from these results was tempered by a small sample size and limited range of bolus volumes and consistencies.

The comparison of findings reported by Chi-Fishman and Sonies (2002), Ishida et al. (2002) and Kim and McCollough (2008) is made difficult due to differing methodologies, including the method of outcome measurement, sample size, and bolus characteristics. They all, however, tend to support a link between age and hyoid kinematics. More specifically, elderly people may compensate for age-related muscle weakness by increasing recruitment of the submental muscles. Whether this affects anterior or superior excursion, or both, is yet to be confirmed.

Anterior belly of the digastric. Lying inferior to the mylohyoid muscle and arising from the digastric fossa of the mandible are the left and right anterior bellies of the digastric. This muscle is continuous with the posterior belly of the digastric muscle – the two are separated by the intermediate tendon, which anchors to the hyoid bone by a loop of connective tissue. The anterior belly is innervated by the mandibular branch of the trigeminal nerve. Contraction of this muscle acts to move the hyoid bone anteriorly, or, if the hyoid is held stabile by the infrahyoid muscles, to open the mouth.

This muscle, along with the geniohyoid and mylohyoid, contains fatigue-resistant (Type I) and rapid-contacting (Type IIa) fibres in almost equal parts, with hybrid fibres making up just 10% of the total muscle (Korfage, Koolstra, Lagenbach, & vanEijden, 2005). Muscle contractions are undertaken in quick succession with minimal fatigue. This property allows these muscles to function with the balance of force and precision necessary for swallowing.

Mylohyoid. The mylohyoid muscle is a small, flat muscle located directly above the anterior belly of the digastric muscle. It extends the entire length of the mylohyoid line of the mandible to insert into the hyoid bone, forming the muscular floor of the oral cavity. Like most skeletal muscles it is paired. Innervation of the mylohyoid by the mandibular branch of the trigeminal nerve facilitates depression of the mandible and elevation of the hyoid bone, floor of mouth, and tongue.

Stylohyoid. The stylohyoid originates from the styloid process of the temporal bone, and inserts at the hyoid bone. Near its point of insertion this muscle separates into two strands, between which the posterior belly of the digastric passes. It is innervated by the facial nerve, and contributes to hyoid elevation and jaw opening.

Geniohyoid. The left and right geniohyoid muscles rest against the superior surface of the mylohyoid. Arising from the mental spine of the mandible and inserting at the hyoid bone, the geniohyoid assists in anterior hyoid excursion/depression of the mandible. Innervation is through fibres from the first and second cervical nerves, carried by the hypoglossal nerve.

Considering the vital role the submental muscles play in swallowing biomechanics, it becomes clear why this muscle group is often the target of swallowing rehabilitation exercise. Evidence from the fields of sports medicine, physiotherapy, and exercise science provide a framework of training principles suitable for application in swallowing rehabilitation to ensure that exercise is prescribed at it’s most efficient and effective levels.

Principles of training

Training can be conceptualised as some form of skill learning plus resistance exercise with the goal of achieving peak performance. Skill training is the act of practising a particular sequence of movements resulting in a smooth action and achievement of a specific task. Examples include learning to walk, putting a golf ball, or playing an instrument. At the cortical level, skill training is associated with increases in corticospinal excitability and expansion of cortical areas corresponding to the muscles recruited for the skilled task over time (Jensen, Marstrand, & Nielsen, 2005). Skill training is one component of motor execution, however, without a corresponding muscle-strength component, gains in training cannot be made (Burkhead, Sapienza, & Rosenbek, 2007).

Strength training utilises resistance to muscle contraction to increase force output, size, and endurance in skeletal muscles. Resistance may be in the form of gravity, elastic tension, or incremental increases in weight. In the early stages of strength training, increases in strength, coordination and precision are attributed to a shift in the way the central nervous system activates previously neglected skeletal muscles, as opposed to increased muscle mass (Burkhead et al., 2007; Jones & Rutherford, 1987). In contrast to skill training, these changes in neural plasticity are associated with decreased corticospinal activity (Jensen et al., 2005), and may also involve larger numbers of motor units recruited (Abernethy, Hanrahan, Kippers, Mackinnon, & Pandy, 2005; Honeybourne, Hill, & Moors, 2004), increases in motor unit activation and coordination (Honeybourne et al., 2004; Sale, 2003), decreased activation of antagonist muscles and increased activation of agonist muscles (Abernethy et al., 2005). Over time, the contribution of morphologic changes to the muscle tissue increases (Burkhead et al., 2007). These morphologic changes include fibre type transformations towards slow-twitch, fatigue-resistant Type I fibres, and enlargements in fibre size (hypertrophy). Training type and intensity will determine whether these changes do, in fact, occur (Burkhead et al., 2007; Magyari, 2010) and eventually the rate of hypertrophy will reach a plateau (Blazevich, 2006). Table 1 summarises the American College of Sports Medicine's recommendations for exercise intensity, depending on the exercise goals of the individual (Magyari, 2010). Literature suggests that shifts in fibre type may happen during the earlier phases of training, with hypertrophy likely commencing after five weeks or more of training (Burkhead et al., 2007).

In order to facilitate neuromuscular adaptation and muscle fibre changes, exercise movements that increase demand on the muscle, outside of the usual activity of the muscle, must occur (Salmons & Henriksson, 1981). This is known as the overload principle (Kraemer et al., 2002; McArdle, Katch, & Katch, 2010). Exercise movements that increase muscular strength are commonly classified as one of three kinds: isotonic, isometric, and isokinetic exercise.

Types of exercise. Exercise is isotonic if the body is moving, and the muscle fibres are contracting, against resistance. Lifting weights at the gym is an example of isotonic exercise. The advantage of this type of exercise over others is that it works the muscles throughout the entire range of motion. However, it should be noted that resistance is not consistent across the entire contraction – there is always a "weak spot" contributed by weaker muscles or joint angles. For best results, isotonic exercise should be performed slowly.

In contrast, isometric exercise refers to sustained muscle contraction in the absence of body movement. Instead of the muscle fibres lengthening, intra-muscular tension increases. Pushing against an immovable object, such as a wall, is an example

Table 1

Exercise parameters in relation to training goals

		% of 1RM	Repetitions	Sets
Goal:	Strength	60-80	8-12	1-3
	Hypertrophy	70-100	1-12	1-6
	Endurance	varying load	10-25	multiple

of isometric exercise. This type of exercise has the advantage of facilitating maximum muscle contraction and strength; however it does not enhance endurance or flexibility. Ideally, this type of exercise should be held until fatigue is felt, then stopped, then repeated.

Isokinetic exercise combines elements of both isotonic and isometric exercise. Utilising specialist equipment, the muscle maximally contracts (isometric component) throughout the entire range of motion (isotonic component) at a constant, set velocity. This type of exercise is often used to improve strength and endurance following injury.

A fourth kind of exercise also exists: elastic. Elastic training combines dynamic movement with variations in force and velocity due to stretching. This excludes it from any of the above exercise categories. Despite this, clinical data suggests that the effects of elastic resistance exercise are similar to isotonic exercise. Both result in similar increases in strength and muscle mass (Colado & Triplett, 2008), with no significant differences in muscle activation (Andersen et al., 2010). A major advantage of elastic resistance training is the ability to perform almost any exercise in a variety of situations. This makes it ideal for use in rehabilitation settings.

Effective muscle training Any type of training should be cost-effective, time-efficient, and not require unnecessary effort. Effective muscle strength training can be enhanced using four main principles: intensity, specificity, transference, and maintenance.

Intensity of training Intensity is a function of the demand, or resistive load, placed on the muscle. As previously mentioned, for neuromuscular adaptation to occur, the load must exceed usual activity levels (Salmons & Henriksson, 1981). In addition, as strength improves, progressive increases to resistive load are necessary in order to continue these improvements (Burkhead et al., 2007). This is calculated as a percentage of the maximum load a person can shift in a single repetition, or one-repetition maximum (1RM). There are inconsistencies in the literature surrounding the ideal initial load for strength training, but sources tend to agree that a figure between 30-40% of 1RM represents light training, 50-60% of 1RM is moderate, and 70-90% of 1RM constitutes heavy training.

Burkhead et al. (2007) identified difficulty with applying previous research largely based on corticospinal training to corticobulbar training, as the upper and lower limits for the latter have not yet been clearly defined. They hypothesised that, because other skeletal muscles tend to respond to loads of 60% of 1RM, this would be a reasonable place to begin training in swallowing muscles. However, a recent investigation into the effects of resistance training on the submental muscles completed by Bauer and Huckabee (2010) found that 40% is the maximum initial load perceived by participants to be tolerated for the corticobulbar muscles.

Additional factors that contribute to exercise intensity are the number of repetitions of the activity, and overall training duration. It is generally recommended that 8-12 repetitions of an exercise activity, 2-3 times per week, is an appropriate, efficient starting point for exposing muscles to an increased load during a new exercise regime (Burkhead et al., 2007; Kraemer et al., 2002). In terms of exercise “dosage”, it is yet to be determined how long a swallowing exercise regime should be to maximise its effectiveness (Burkhead et al., 2007). Nevertheless, a trend towards an intensive approach to treatment has emerged in dysphagia rehabilitation, ranging from five days to eight weeks in duration (Carnaby, Hankey, & Pizzi, 2006; Huckabee & Cannito, 1999; Robbins et al., 2007; Shaker et al., 1997), with reports of positive functional outcomes for patients, such as increased diet level tolerance.

Specificity of training task Exercise specificity incorporates elements of endurance and strength training, with the addition of a component specific to the actual task or exercise objective being trained for. In other words, specificity refers to how closely an exercise resembles the desired outcome. For example, if becoming a better swimmer was the aim, then swimming would be considered an exercise with high specificity.

Evidence from the field of exercise science illustrates the importance of specificity. Although seemingly counter-intuitive, this literature suggests that training a particular muscle group or system does not necessarily transfer into benefits in related activities for that muscle group. For example, the heart rate and pulmonary ventilation of long distance runners is elevated in cycling tasks as compared to running tasks, suggesting a lack carry-over of cardiovascular training effects (Pannier, Vrijens, & Van Cauter, 1980).

In terms of swallowing rehabilitation, swallowing itself would be considered a highly specific training task. Indeed, the effects of exercise on muscle strength may be even greater when paired with the specific act of functional swallowing (Burkhead et al., 2007). Burkhead et al. (2007) further suggest that exercises should incorporate an appropriate number of swallowing repetitions with progressively increasing physiologic resistance. The reality of working with patients with brain injury means that this may not always be possible, as the resulting loss of ability to control a bolus and/or initiate pharyngeal swallowing presents a barrier to incorporating the principles of intensity and specificity into rehabilitative treatment plans (Burkhead et al., 2007).

Instead, general strength training is considered an appropriate precursor to performing functional activities (Buchner, Larson, Wagner, Koepsell, & De Lateur, 1996; Burkhead et al., 2007; Tanaka & Swensen, 1998). Strength training used as a precursor to, or in conjunction with task-specific exercise may significantly improve performance in functional tasks by preparing the neuromuscular system, increasing muscle strength, and building functional reserve (Burkhead et al., 2007). The carry-over of these effects to functional swallowing tasks is the basis of dysphagia rehabilitation.

Transference of training task to functional task Transference refers to focussed practice of an isolated component of the target action. Repeated drills serve to "fine tune" a specific action, and improve overall performance. Some studies have found increased somatosensory processing and increased neuromuscular firing patterns as a result of implementing specific rote practice (El Sharkawi et al., 2002).

Complex neural and biochemical systems are activated during exercise, the effects of which are widespread throughout the body (Burkhead et al., 2007). In regards to swallowing rehabilitation exercises (e.g. head-lift, tongue-strengthening), the principle of transference may in part account for the gains in therapy made in the absence of specific swallowing practice (Burkhead et al., 2007).

Maintenance While all age groups can benefit from resistance training-type exercise, it seems that when it comes to maintenance, the elderly population may be particularly susceptible to decline in function. Trappe, Williamson, and Godard (2002) found that elderly men (N = 10, average age = 70 ± 4 years) who continued resistance training exercises for just one day per week maintained gains made in muscle size and strength following a 12-week resistance training program. When no attempt was made to maintain treatment gains, a loss in muscle strength and size resulted (Trappe et al., 2002).

Detraining effects tend to appear more rapidly than training effects, and are observable as soon as four weeks following training cessation (Mujika & Padilla, 2001). Muscle fibre responses to detraining involve reduction in size (atrophy), reduced strength, and a shift towards the fatigue-prone, fast twitch Type IIb fibres (Lieber, 2002).

Muscle detraining may result from chronic bed-rest. In this situation, muscle disuse leads to reductions in muscle mass and force generation (Stuempfle & Drury, 2007), particularly in the elderly (Urso, Clarkson, & Price, 2006). This may have consequences for the dysphagic patient prescribed prolonged bed-rest. In their study on swallowing frequency, Murray, Langmore, Ginsberg, and Dostie, (1996) compared the frequency of swallowing of elderly in-patients with and without dysphagia, and compared this to non-hospitalised peers, as well as young, healthy adults. They found that elderly in-patients with dysphagia spontaneously swallowed their secretions significantly less often than all other groups, suggesting that this group recruited the muscles of swallowing less frequently.

Similarly, Burkhead et al. (2007) suggested that patients on non-oral diets may also show muscle detraining effects, as the need for recruitment of the swallowing muscles is decreased. These findings suggest that, for any patient with dysphagia, the risk of muscle detraining should be taken into consideration when devising a management plan and course of rehabilitation action.

Further informing these decisions are results from instrumental assessments. Such tools are used for outcome measurements because they provide objective, repeatable information regarding changes to a patient's swallowing. Determinants of diagnosis and rehabilitation in swallowing therapy therefore depend on the validity, reliability and repeatability of such measures.

Measuring outcomes in swallowing rehabilitation Current technology allows clinicians and researchers to undertake instrumental measurement of various aspects of swallowing. Selection of an appropriate measurement tool often depends on the measure of interest, for example, muscle size or intrabolus pressure. However, other factors, such as degree of invasiveness, portability, and visualisation may also influence this decision. The means for measuring outcomes in swallowing rehabilitation may differ from those used for differential diagnosis, as rehabilitation usually requires multiple measurements (i.e. pre-treatment baseline, post-treatment maintenance, etc). The most commonly reported means of measurement in the swallowing rehabilitation literature include pharyngeal manometry, surface electromyography, videofluoroscopy, videoendoscopy, and ultrasonography.

Pharyngeal manometry Pharyngeal manometry is a means of providing information about the timing and amplitude of pharyngeal pressure patterns generated during swallowing. A special catheter that contains 3-4 solid-state transducers is inserted into the pharynx, usually via the nares. The catheter is positioned in such a way that the transducers, each containing one sensor, are in line with the cricopharyngeus, hypopharynx, base of tongue, and esophagus (optional). When dry or bolus swallows are performed, information about pharyngeal pressure and co-ordination is generated by the transducers, and displayed as waveforms through a computer.

The primary application of pharyngeal manometry is for the differential diagnosis of disorders of pharyngeal motility. Researchers may also find manometry a useful tool for measuring outcomes, as it is a means of providing objective data without time constraints, and requires little training to perform. However, as manometry cannot be used to visualise structures or dynamic movements within the swallowing system, applications to dysphagia research are limited to measures of pharyngeal pressure.

Surface electromyography Surface electromyography (sEMG) is a means of recording and measuring the electrical activity, or the action potential, of a muscle fibre. The procedure is non-invasive, but like pharyngeal manometry, cannot provide a picture of the swallowing muscles or their biomechanics. sEMG involves the placement of surface electrodes on the skin overlying the muscles of deglutition. During muscle contraction, myoelectric impulses are released that are detected by the surface electrodes and displayed as a time by amplitude waveform on a computer screen. Recordings reflect a combination of the number of motor neurons recruited and their rates of firing, commonly referred to as “motor unit activity”. The activity of individual motor units, however, cannot be monitored, and recordings may also be contaminated with “noise” from the firings of nearby muscles (e.g. intrinsic tongue muscles). For these reasons, sEMG is primarily considered a biofeedback tool in dysphagia rehabilitation, with applications to research when a summative measure of muscle activity is desired. For example, an increase in the size of the EMG waveform following training is considered to represent an increase in motor unit activation, and subsequent neural adaptation (Sale, 2003).

Videofluoroscopy To obtain a view of the entire swallowing sequence, videofluoroscopy may be used. In a videofluoroscopic swallowing study (VFSS), x-ray techniques are used to track the flow of a barium-coated bolus (or barium mixed with liquid) through the oral, pharyngeal, and esophageal stages of swallowing. The result is a quantifiable, dynamic, two-dimensional (2D) image of the hard and soft tissue structures of swallowing as well as the moving bolus. This method is generally considered the “gold standard” in dysphagia diagnosis (Martino et al., 2000), as it integrates the entire swallowing sequence and can be used qualitatively to evaluate the effects of different compensatory strategies. However, the radiation exposure involved in VFSS significantly limits the length of the studies and the extent to which they can be repeated. This has implications for research, as it is unethical to require healthy participants to undergo videofluoroscopy. Furthermore, limitations such as restricted availability, certain hospital policy requirements for radiology presence, and patient transport issues all contribute to high associated costs.

Videoendoscopy Like videofluoroscopy, videoendoscopy provides real-time, 2D images of swallowing. This method involves the use of a flexible laryngoscope placed above the uvula in order to visualise the nasopharynx and larynx. It is particularly useful for the direct evaluation of airway protective mechanisms, and when teaching compensatory manoeuvres during swallowing.

There are certain advantages of this tool over videofluoroscopy. The foremost is that videoendoscopy does not involve radiation. As such, studies are able to be repeated and are not constrained by time. Another advantage is that videoendoscopy is portable, allowing examination at bedside or while a patient is sitting in a wheelchair. The use of real food in a more familiar environment may facilitate more natural swallowing behaviours in some patients, particularly where cognition is reduced. It may also be considered the best means of evaluating patients suspected of specific deficits of airway protection (e.g. vocal fold paresis).

However, several limitations of videoendoscopy also exist. For instance, due to the location of the endoscope, neither the oral stage of swallowing nor esophageal functioning can be assessed. Furthermore, during velar elevation and base of tongue to posterior pharyngeal wall approximation, light from the endoscope is reflected back into the lens causing “whiteout”, or a loss of view, during critical moments of swallowing. There is minimal to no ability to observe bolus flow during swallowing, which instead must be deduced from the presence/absence of patterns of pre-swallow pooling/post-swallow residual. For these reasons, videoendoscopy is best suited for use where videofluoroscopy is not indicated – for example, when physical or cognitive functioning is compromised, radiation exposure is limited, or the patient is ventilated or in intensive-care.

Ultrasound Ultrasound is another means of objectively measuring aspects of swallowing. Like videofluoroscopy and videoendoscopy, ultrasound also provides quantifiable, 2D images of swallowing in real-time. Stone (2007) provided a useful review of the principles and practices of ultrasound as they relate to swallowing research. To summarize, ultrasound is a cyclic sound pressure wave with a frequency higher than audible sound. Sound waves are produced via the vibrations of piezoelectric crystals, or pressure crystals, when voltage is applied. Ultra-high frequency sound waves are usually above 1 MHz, depending on the resonant frequency of the crystals. The reflective nature of these sound waves are utilised to produce an on-screen image.

In ultrasonography, the transducer both produces and detects ultrasound waves. Placing the transducer on the surface of the skin allows the sound waves to travel until they encounter impedance mismatch from internal body structures, causing reflection. If the sound wave is perpendicular to the object, the reflected waveform returns to the source (i.e. the transducer) and the information is used to create an image. If the object is at an angle, the sound wave refracts, and may not be detected by the transducer.

Ultrasound images are created by converting the time it takes for the sound waves to return to the transducer into a measure of distance, based on the speed of sound through water. Object density is measured by the strength of the reflected sound wave, or echo. The clearest images result where high density differences exist, such as tissue-to-air or tissue-to-bone reflections. Objects of similar density, such as tissue-to-water or tissue-to-tissue, issue weak echos and unclear images.

Different scanning modes may be utilised in medical ultrasonography to achieve different results. In A-mode (amplitude-mode), ultrasound waves travel along a single line, are reflected back, and displayed as a function of depth. The high level of image accuracy in A-mode makes it ideal for use in tumour treatment. The linear arrangement of transducers in B-mode (brightness-mode) ultrasound allows waveforms to travel simultaneously along a plane, producing a two-dimensional image useful in diagnosis. Multiple scans per second in B-mode (real-time B-scan) can be used to visualise dynamic body movements, such as swallowing. M-mode (motion-mode) uses a rapid sequence of A-mode pulses to create time-motion images. It is worth noting that the display is not the object in motion, rather it is the surface of the object moving towards and away from the transducer. M-mode, in conjunction with B-scanning, may also be used to capture swallowing images. Doppler mode concerns the visualisation of blood flow, and is generally used in midwifery.

Image quality may be affected by the ultrasound machine settings. If the depth setting, or the speed at which the transducer omits waveforms, is too great, the transducer will wait longer between firing as it waits to detect distant echos, and image resolution deteriorates. Additionally, setting the focal zone will provide superior spatial resolution of images.

One disadvantage of ultrasound is that stages of swallowing cannot be evaluated directly. Another is that aspiration events cannot be confirmed (Langmore, 2001). Finally, measuring swallowing outcomes requires exact replication of transducer position under the chin, which is unlikely to be achieved without the use of additional mechanisms.

Recent research has utilised ultrasonography as an outcome measure, with degrees of success. Kuhl, Eicke, Dieterich, and Urban (2003) compared swallowing in patients with dysphagia (n = 18) and their healthy peers (n = 42) on measures of laryngeal shortening. Ultrasound was used to measure the shortest average hyo-thyroid distance during swallowing of water boluses. Participants had six swallows recorded on an ultrasound device, each of which was analysed off-line for hyo-thyroid distance at rest and during swallowing. The average of these six trials was calculated and used for analysis. Results showed that measures taken using ultrasound were sensitive enough to detect highly significant amounts of laryngeal shortening during swallowing across all participants. The authors concluded that ultrasound was an effective option for measuring laryngeal movement during swallowing, due to it being non-invasive and able to produce clear, dynamic images of laryngeal mechanics. However, no information was provided about the reliability of the initial measurements or the interpretation of these ultrasound images.

Ultrasonography presents as an inexpensive means of measuring muscle change in swallowing rehabilitation specifically and non-invasively. In particular, target structures and muscles can be identified and examined on measures of distance and cross-sectional area. In terms of muscle rehabilitation research, it is important to be aware of the ways in which different exercises may facilitate structural changes within specific muscles.

Swallowing rehabilitation exercises It has been established that muscle weakness may be counteracted by regular exercise (Fiatarone et al., 1994). Furthermore, according to the overload principle, exercise that increases demand on the muscle over and above usual activity will induce muscle changes (Salmons & Henriksson, 1981). The application of these principles in swallowing rehabilitation has seen the devising of exercises that focus primarily on muscle strengthening during the swallowing task. The Effortful Swallow (Kahrilas, Lin, Logemann, Ergun, & Facchini, 1993) exercise targets the suprahyoid and pharyngeal constrictor muscles by requiring the individual to swallow with increased force. The Mendelsohn manoeuvre (J. A. Logemann & Kahrilas, 1990) is performed by initiating a pharyngeal swallow and prolonging muscle contraction at the peak of hyolaryngeal excursion, thus sustaining activation of the suprahyoid muscles. The Masako manoeuvre (Fujiu & Logemann, 1996) is another example of muscle strengthening in the context of swallowing. For this exercise, the individual is required to protrude the tongue and gently hold it between the teeth while swallowing, stimulating the pharyngeal constrictor muscles to shift the posterior pharyngeal wall anteriorly. The common limitation in all of these approaches is the difficulty encountered in quantifying and progressively increasing the load applied to the swallowing muscles over the course of treatment. The implication is that increases in muscle strength that would otherwise be possible may be restricted by the inability to increase physiologic load over the course of rehabilitation (Burkhead et al., 2007).

Other rehabilitation exercises may target the muscles of swallowing indirectly. An example of a swallow-nonspecific task (i.e. execution of the task does not involve swallowing) is Expiratory muscle strength training (EMST; Kim & Sapienza, 2005). For this exercise, an individual is required to exhale forcefully into an external device with a one-way release pressure valve. Valve release is adjustable to provide varying degrees of resistance. The reported benefits of EMST include increased and prolonged submental muscle activity during expiratory pressure tasks compared to normal swallowing (Wheeler, Chiara, & Sapienza, 2007). However, as EMST is not designed to specifically target the submental muscle group, the extent to which this positive side-effect can be applied to swallowing rehabilitation may be limited. It is yet to be proven that increasing the resistance provided by the EMST device increases the resistive load provided to the submental muscles.

The head-lift manoeuvre Another rehabilitation exercise that integrates some degree of resistance training is the head-lift manoeuvre (Shaker et al., 1997). Shaker et al. first described this exercise as a viable treatment for dysphagia involving upper esophageal sphincter (UES) impairment. The exercise involves the patient lying supine and performing three repetitions of raising the head for one minute, with a rest period of one minute in between repetitions. This is followed by 30 successive repetitions. From a physiological point of view, strengthening the muscles responsible for hyoid excursion (i.e. anterior belly of digastrics, geniohyoids, mylohyoids) may facilitate opening of the cricopharyngeus muscle (in the context of UES relaxation), allowing bolus acceptance into the oesophagus.

Shaker et al. (1997) aimed to test the hypothesis that the head-lift manoeuvre would increase UES deglutitive opening, and consequently improve bolus flow through the hypopharynx. The exercise was studied in a group of healthy, elderly participants (*N* = 19, age range 62-91 years). A group of 12 participants (age range 67-77 years) performing a “sham” treatment of successive fist-clenches were also included as a control. Both treatments were carried out three times per day over a six week period. Outcome measures included UES diameter and duration of UES opening, degree of anterior and superior hyolaryngeal excursion, and degree of hypopharyngeal intra-bolus pressure as measured via pharyngeal manometry and videofluoroscopy. Intra-group comparisons of the exercise group showed mixed results. Results within the treatment group showed significant increases in anterior laryngeal excursion (18-32% increase from pre-treatment values) and subsequent degree of UES opening. In addition, a significant decrease in intrabolus pressure within the hypopharynx was observed (p <0.05). No significant differences from pre- to post-treatment could be found for superior laryngeal excursion or anterior or superior hyoid movement. However, it should be noted that, as participants were healthy, capacity for increases in hyoid movement may have been somewhat limited. Predictably, no significant changes in anterior laryngeal excursion, degree of UES opening, or intrabolus pressure were observed in the placebo group. The authors interpreted these findings as indication that, in normal elders, UES opening can be increased via implementation of exercises aimed at strengthening the muscles responsible for hyolaryngeal excursion. In particular, they suggest that the head-lift targets the mylohyoid, anterior belly of the digastric, and geniohyoid muscles. They went on to suggest that similar results may be achieved for patients with dysphagia secondary to inadequate UES opening. However, generalisation to the dysphagic population was restricted by results gathered from a small number of asymptomatic participants. By solely recruiting healthy participants, functional swallowing outcomes, such as efficiency of bolus clearance, or amount of post-swallow residual, could not be measured. The authors also conceded that, although the participants were provided with detailed instructions pertaining to the exercise protocol, no attempt was made to record actual compliance during the 6-week study. As such, variability in daily exercise performance and effort may have presented a confounding variable.

However promising the results of Shaker et al. (1997) were in terms of facilitating biomechanical change in the swallowing mechanism, it remained to be seen whether this exercise would result in improved functional outcomes for people with dysphagia. The next stage was to examine the effects of the head-lift manoeuvre (Shaker et al., 1997) on patients with dysphagia. In order to do this, Shaker et al.

(2002) recruited tube-fed patients with severe pharyngeal dysphagia secondary to inadequate UES opening. There was a range of etiologies within the participants, including pharyngeal radiation, stroke, and endarterectomy. Participants with cervical spinal injury, tracheostomy, or who were unable to perform the exercise independently, were excluded from the study. After the 6-week exercise regime, all participants in the head-lift manoeuvre (Shaker et al., 1997) group (*n* = 11) had significantly improved on measures of UES opening, anterior laryngeal excursion, and aspiration of post-swallow residual to the extent that they no longer required tube-feeding. Among the sham exercise group (*n* = 7), there were no significant changes in maximum UES diameter or anterior laryngeal excursion, nor was there any improvement in functional swallowing. However, when this group was crossed over to the head-lift manoeuvre (Shaker et al., 1997) group, significant increases in degree of UES opening and anterior laryngeal excursion, and improvements in functional swallowing were observed. The authors concluded that the head-lift manoeuvre (Shaker et al., 1997) may be effective in restoring suprahyoid muscle strength to the extent that oral feeding can be resumed in some patients with dysphagia.

The 2002 study aimed to add credibility to the results reported in earlier work by Shaker et al. (1997) by recruiting participants with dysphagia. These new results however were tempered by the characteristics of the participants, specifically the duration of their dysphagia, and a relatively small sample size. Shaker et al. (2002) acknowledge that time-related recovery in swallowing was not controlled for, and thus may be responsible for the observed improvements in swallowing. Most swallowing problems following cortical stroke spontaneously resolve within two weeks (Gordon, Hewer, & Wade, 1987), and recovery of swallowing has been documented after one year or more in 32% of patients following chemoradiation

(Nguyen et al., 2006). By these benchmarks, 22% of participants in Shaker et al.'s (2002) study potentially may have spontaneously recovered swallowing function. Despite this, the authors maintain that spontaneous recovery alone was unlikely to be the source of improvement in swallowing. These improvements, however, may not be a true reflection of the effects of the head-lift manoeuvre (Shaker et al., 1997), as neither participant compliance nor effort in completing the 6-week exercise regime was monitored.

Shaker et al.'s (2002) reported success in restoring oral feeding in a small number of participants of a range of etiologies and dysphagia durations raised questions surrounding the effectiveness of this exercise in more naturalistic settings. Easterling, Grande, Kern, Sears, and Shaker (2005) attempted to answer these questions by providing functional information regarding the practicality of the head-lift manoeuvre (Shaker et al., 1997) in rehabilitation for elders. They aimed to discover compliance rates, length of time taken to achieve isometric (i.e. 3x sustained head-lifts) and isotonic (i.e. 30x consecutive head lifts) goals, reasons for non-compliance, and complaints related to performing the head-lift exercise in a sample of healthy, elderly participants (*N* = 26, age range 66-93 years). Participants performed three sets of head-lifts per day for a period of six weeks. During this time they recorded their compliance and any associated problems on a questionnaire. Four participants were selected at random to undergo a VFSS to compare pre- and post-exercise biomechanical outcomes including degree of hyolaryngeal excursion and UES opening. Results showed that participants were most likely to discontinue the regime during the first two weeks. Of those who completed the programme, 100% were able to achieve their isotonic goals, and 74% attained their isometric goals. The authors deduced that isotonic goals are easier to obtain. Feedback from participants included mild muscle pain, which quickly resolved, and inconvenience to their busy schedules. Functional physiologic changes pre- and post-exercise were also observed in those participants who underwent VFSS. Anterior hyoid movement, anterior laryngeal excursion and UES opening increased by up to 18%, 35% and 30% respectively. From the participants who completed the six-week programme, 12 were selected to continue the head-lift manoeuvre (Shaker et al., 1997) at a reduced rate of once per day, for a period of six months. Participants in this group did not undergo VFSS, thus the effect of this extended programme on hyo-laryngeal excursion and UES opening was not measured.

Easterling et al.'s (2005) findings were limited by several methodological constraints. Compliance with the 6-week head-lift protocol (Shaker et al., 1997) was assumed on the basis of log sheets completed by the participants, as opposed to direct supervision. This introduced the possibility that consistency in exercise duration and/or effort may have varied across participants. Interestingly, while the effect of the head-lift manoeuvre (Shaker et al., 1997) on swallowing biomechanics was not reported by the authors as a primary aim of the study, pre/post-exercise measurements of hyo-laryngeal excursion and UES opening during swallowing were still reported and discussed. These measurements, taken during VFSS, were based on a sample of four participants only – an arguably inadequate number from which to draw cause-and-effect type conclusions. Investigators were blinded to participant identity and pre/post-exercise status during VFSS interpretation, increasing the internal validity of the study, however, in the absence of a control group, the VFSS results in isolation carry little weight. Furthermore, the ethical implication of exposing healthy participants to radiation during VFSS discourages direct replication of this study.

In applying these results to the dysphagic population, the authors suggested that, where independent rehabilitation is prescribed, a controlled, progressive approach to swallowing exercise is vital for positive outcomes. It may be that with increased support for patients through the initial two weeks of the exercise regime the rate of patient "drop out" would be alleviated. Further investigation into the minimum number of repetitions, and minimum duration of head-lifts required to augment UES opening may have also proved valuable towards this goal.

Despite promising results reported by Easterling et al. (2005), the effectiveness of the head-lift manoeuvre had yet to be validated against existing, traditional swallowing therapy. Logemann, Rademaker, Pauloski, Kelly, Stangl-McBreen, and Antinoja (2009) completed a randomised control trial to determine whether the head-lift exercise was more effective at decreasing aspiration and improving swallowing than traditional swallowing therapy (defined as a series of exercises targeting the tongue-base, suprahyoid muscles, and pharyngeal constrictor muscles) in dysphagic patients who aspirate. All participants were nil-by-mouth (NPO), and experiencing oro-pharyngeal dysphagia (defined videofluoroscopically by inadequate UES opening, aspiration, and residual) of at least 3 months' duration at the start of treatment. Participants were randomised into one of two different treatment conditions: traditional dysphagia therapy (n = 11), or the head-lift exercise (n = 8). The traditional therapy regime was completed ten times per day, for five minutes each time. In addition to rehabilitation exercises, participants in this group were taught a compensatory technique, the super-supraglottic swallow (inspiring deeply, "bearing down" to close the laryngeal vestibule, swallowing, then performing a volitional cough post-swallow). Participants in the head-lift group completed 3 sustained and 30 consecutive head-lifts from supine position, with intermittent rest periods. After 6 weeks of treatment, both groups showed significant improvements in UES opening. Participants in the head-lift group experienced significantly less (60% less) aspiration of post-swallow residual than the traditional group (0%; $p = 0.028$). Anterior hyoid movement improved to a greater degree for participants in the traditional group than participants in the head-lift group, specifically for paste boluses ($p = 0.056$).

Logemann et al. (2009) interpreted these findings as indicative that, for patients with post-swallow aspiration, head-lifting exercises are more effective than traditional swallowing therapy. However, traditional therapy may also have facilitated greater muscle effort, as evidenced by improvements in this group with denser consistencies, which are thought to require more pharyngeal pressure to swallow than less dense consistencies (Dantas, Dodds, Massey, & Kern, 1989). Given this, for patients with reduced range of movement traditional therapy is indicated.

While providing some evidence for the effective use of the head-lift manoeuvre in dysphagia rehabilitation, the results of this study are limited by somewhat stringent exclusion criteria and a small, rather select, participant pool i.e. 14 participants, with etiologies of either stroke or head and neck cancer, who were able to lift their head from supine position. Participants had to have had dysphagia of at least 3 months duration; however no data were provided of individual participants' length of dysphagia. As previously mentioned, swallowing problems following cortical stroke or chemoradiation have the capacity to spontaneously resolve after two weeks or over one year, respectively (Gordon et al., 1987; Nguyen et al., 2006). In a larger participant pool, randomisation could be used to account for participant spontaneous recovery, however in a group of 14 this is less likely. Given this, it is possible that the improvements in participants' functional swallowing observed by

Logemann (2009) et al. were not due to either treatment, rather spontaneous recovery alone. Further research in this area is clearly warranted.

The jaw-opening exercise During the head-lift manoeuvre (Shaker et al., 1997), the act of lifting the head against resistance (gravity) provides a load for the submental muscles that is above their usual functioning, thus incorporating the overload principle. However, if this principle is to be maintained over time, as muscle strength increases, so too should the resistive load. The head-lift manoeuvre is limited in this respect, as the work performed by the submental muscles lessens as gains are made in force-generating capacity with treatment progression. Another limitation is the ability of this exercise to be performed by certain patient groups. It has been suggested that, for patients with cervical spinal injuries, large osteophytes, or those unable to manipulate the head and neck, the head-lift manoeuvre may be unsuitable as a rehabilitation exercise (Mepani et al., 2009).

Bauer and Huckabee (2010) attempted to address these issues by investigating the effects of a jaw-opening exercise (JOE) in a non-impaired population. Healthy adults undertaking a jaw-opening exercise (n = 14) were compared to an age and sex-matched placebo group undertaking a sham exercise regime (n = 13) on three biomechanical features of swallowing: submental muscle bulk, anterior hyoid movement, and submental muscle activity. The JOE involved the use of a Theraband® (elastic exercise band) secured around the head of a seated participant to provide resistance to contraction from the submental muscles during jaw opening. As with the act of head-lifting, jaw-opening requires contraction of the same submental muscles, i.e. anterior belly of digastrics, geniohyoids, mylohyoids. Similar to the head-lift exercise protocol, participants completed 3 isometric and 30 isotonic repetitions of jaw-opening three times per day. In addition, resistance to jaw-opening provided by the Theraband® was progressively increased over the six-week period. The sham exercise consisted of participants squeezing a rubber ball in one hand. Resistance provided by the rubber ball was also progressively increased. Results confirmed that, in healthy adults undertaking a JOE, geniohyoid muscle size and anterior belly of digastric muscle size increased to a greater degree than in healthy adults undertaking a sham exercise ($p = 0.007$). This did not translate to significant differences in submental muscle activation, as measured via sEMG ($p = 0.582$). Adults in the JOE group also tended to show increased hyoid excursion – more so than adults in the sham exercise group – however, this difference was not statistically significant ($p = 0.202$). The author interpreted these findings as suggestive that the JOE could present as a clinically useful alternative to the traditional head-lift manoeuvre (Shaker et al., 1997) in the rehabilitation of patients for whom the head lift manoeuvre may be difficult. However, it is yet undocumented whether increases in hyoid excursion and submental muscle bulk result in improvements in functional swallowing, and further investigations involving other contributing factors – such as degree of UES opening – are required.

Despite promising results, the robustness of Bauer and Huckabee's (2010) findings was tempered by low observed statistical power and difficulties related to inter-rater reliability in ultrasonography. Furthermore, the lack of blinding on the researcher's behalf during the randomisation of participants and interpretation of the ultrasonographs introduced subjective bias and a threat to the internal validity of the study. The authors also suggested that a task which required the submental muscles to increase force generation, such as an "effortful" swallowing task, may have been more revealing of gains made in submental muscle strength. Considering these issues, it remains unclear whether a treatment effect stronger than that reported by Bauer and Huckabee (2010) would be observed in a larger population.

Statement of the Problem

Previous research has found that exercise aimed at targeting the submental muscle group, such as the head-lift manoeuvre, may augment UES opening and result in functional improvements in swallowing (Shaker et al., 1997). Clinical experience suggests that, for patients with cervical spine problems, or increased frailty, this exercise may be problematic, as pain or weakness may restrict the ability to perform the exercise correctly. Previous studies have failed to identify a minimum dosage of the exercise required for treatment effects to be observed. Furthermore, objective measurements and progressive increases of the load placed on the suprahyoid muscles are not easily performed. The results of Bauer and Huckabee (2010) suggest that an alternative jaw-opening exercise leads to increases in submental muscle size in healthy participants, and tend to support a link between increased hyoid excursion and jaw-opening exercise, however the robustness of these findings was tempered by methodological constraints. It remains unknown whether a jaw-opening exercise will significantly increase submental muscle size and hyoid excursion in healthy participants.

Aims

The present study aims to examine specific biomechanical outcomes in healthy participants who have undergone a JOE regime and compare them to controls matched for age and sex. In particular, the biomechanical features of submental muscle bulk, anterior hyoid movement, and submental muscle activity will be examined at rest and under normal and effortful swallowing conditions. On this basis, the following hypotheses are proposed:

1) Adults who perform a JOE regime for 6 weeks will demonstrate significant increases in the two-dimensional area of the geniohyoid and anterior belly of digastric muscles compared to pre-treatment measures.

2) Adults who perform a JOE exercise regime for 6 weeks will demonstrate significant increases in anterior hyoid movement, compared to pre-treatment measures.

3) Adults who perform a JOE regime for 6 weeks will demonstrate significant increases in submental muscle activity compared to pre-treatment measures.

4) Adults who undertake a SE regime for 6 weeks will demonstrate no increases in the two-dimensional area of the geniohyoid and anterior belly of digastric muscles compared to pre-treatment measures.

5) Adults who undertake a SE regime for 6 weeks will demonstrate no increases in anterior hyoid movement, compared to pre-treatment measures.

6) Adults who perform a SE regime for 6 weeks will demonstrate no significant increases in submental muscle activity compared to pre-treatment measures.

7) Two-dimensional area of the geniohyoid and anterior belly of the digastric muscles will differentiate adults who perform a JOE regime for 4 weeks from adults who undertake a SE for 4 weeks.

8) Degree of anterior hyoid movement will differentiate adults who perform a JOE regime for 4 weeks from adults who undertake a SE for 4 weeks.

9) Submental muscle activity will differentiate adults who perform a JOE regime for 4 weeks from adults who undertake a SE for 4 weeks.

The data from the present study will be analysed independently. Subsequently, as identical methods are employed, it will be combined with the data from Bauer and Huckabee (2010) to increase statistical power. This information will contribute to the body of literature in swallowing rehabilitation, specifically in the development of an effective, functional alternative to the traditional head-lift manoeuvre (Shaker et al., 1997).

Method

Participants

For this study, healthy participants aged 18 years or more were sought. After approval from the Regional Health and Disability Ethics Committee Upper South A in Christchurch, New Zealand was obtained, individuals were invited to participate in the present study for a 6-week period and provided with verbal and written information regarding the nature and extent of the study. Participants who agreed to take part in the study were asked to provide their written consent and complete a questionnaire to ensure compliance with inclusion criteria. The inclusion criteria were as follows and were all required:

1. Aged 18 years or more.
2. Able to perform the jaw-opening or sham exercises and willing to comply with the exercise protocols
3. Able to attend baseline and outcome measurement sessions.

Exclusion criteria included:

1. Surgical procedures of the suprahyoid muscles (mylohyoid, geniohyoid, anterior belly of digastric, stylohyoid)
2. Head/neck/jaw injury
3. Gastroesophageal reflux disease
4. Teeth grinding
5. Disease of the jaw, spinal cord, and/or pharynx
6. Neurological and/or musculoskeletal disorder
7. Dysphagia

On the basis of an a priori significance level of $\alpha = .05$ and an effect size of $d = .80$, a sample size of 25 participants was sought for the study. Two participants did not meet inclusion criteria and were not enrolled in the study. One participant dropped out of the study after 5 weeks, and was replaced with another participant. In total, 23 participants were included in the data analysis. Participants were assigned in a sequential, counterbalanced manner to one of two treatment groups: JOE (n = 12) and SE (n = 11). Groups were matched for sex and age (within five years). Table 2 gives details of participant demographics.

Developing the jaw-opening device

The resistance device developed by Bauer and Huckabee (2010) was replicated for the present study using a commercially available Thera-Band®, Orfit® Drape 3.2mm splinting material, a nylon strap, a metal ring, and Velcro®.

Thera-Band® is a latex material available in a variety of resistance levels and commonly used in the fields of occupational therapy and physiotherapy for resistance training. Thera-Band® Gold provides the highest level of resistance.

Orfit® Drape NS is a type of splinting material that is commonly used in the fields of occupational therapy and physiotherapy to support or immobilise damaged limbs. When heated, it is able to be fitted to a patient; when cold, it becomes rigid. To determine the precise length of Thera-Band® required to make the jaw-opening device, the relationship between Thera-Band® elongation and resistance was calculated (Table 3). This calculation was made on the basis of normative values for jaw-opening force (Koyama, Izumi, Sakaizumi, Toyokura, & Ishida, 2005) and %RM recommended in the muscle-training literature. According to the norms describing jaw-opening force, 24.3kg is the reported average maximum for adult males and 16.4kg for adult females (Koyama et al.). The Bauer and Huckabee (2010) study used an initial load of 40% of 1RM, based on the normative data described by Koyama et al. In line with this method, the present study also used an initial training load of 40%

Table 2.

Participant demographics

Participant	Age (years)	Sex	Treatment group
1	20	F	JOE
2	22	F	SE
3	20	F	JOE
4	22	F	SE
5	25	F	SE
6	22	F	JOE
7	82	F	SE
8	81	F	JOE
9	70	F	JOE
10	73	F	JOE
11	74	F	SE
12	74	F	SE
13	71	F	SE
14	23	M	SE
15	22	M	SE
16	25	M	JOE
17	23	M	JOE
18	23	M	SE
19	23	M	JOE
20	71	M	JOE
21	65	M	JOE

Table 2 *(Continued)*

22	70	M	JOE
23	71	M	SE
M	47		
SD	25.98		

Note: F = female; M = male; JOE = jaw-opening exercise; SE = sham exercise

Table 3.

Thera-Band® Gold resistance based on % elongation

% Elongation	Resistance (kg)
25%	3.6
50%	6.3
75%	8.2
100%	9.8
125%	11.2
150%	12.5
175%	13.8
200%	15.2
225%	16.6
250%	18.2

of 1RM.

A formula was used to determine the appropriate resistance provided by the JOE. This formula was described by Bauer and Huckabee (2010) and is based on the resistance provided by a 20cm length of Thera-Band® Gold. By inserting the desired resistance level of the JOE into the formula, the appropriate length of Thera-Band® Gold was determined. The relationship between length of Thera-Band® Gold and resistance provided by the JOE based on resistance to maximum jaw-opening force is described in Table 4.

With regards to the width of the Thera-Band®, Bauer and Huckabee (2010) reasoned that halving the width of a Thera-Band® and using double layers provides the same resistance as a single layer Thera-Band® of the original width. To allow for comfortable placement of the Thera-Band® underneath the chin, a double layer Thera-Band® halved in width was used in the present study.

To create the jaw-opening device:

1. A 10cm x 14cm x .32cm piece of ORFIT® DRAPE NS splinting material was used. Two 8cm x 0.3cm slots were cut out of the sides.
2. The splinting material was heated for one minute in a hot water bath until it was pliable (Figure 1).
3. To protect from the heat of the splinting material, a towel was placed over the participant's head. The splinting material was draped over the towel, and shaped to the contour of the head (Figure 2).
4. Nylon webbing (i.e. seatbelt material) was threaded through the slots of the head piece (Figure 3). Two Velcro® strips were attached to one end of the webbing.
5. A metal ring served as the attachment point of the Thera-Band® to the webbing. Two Velcro® strips were attached to one end of the Thera-Band®, which was

Table 4

The relationship between Thera-Band® Gold length (cm) and resistance provided by the JOE (kg) based on resistance to maximum jaw-opening force (%) for males and females

	Females			Males		
Resistance to max. jaw-opening force (%)	40%	50%	60%	40%	50%	60%
Length of Thera-Band® Gold (cm)	13.5	11.3	9.8	9.9	8.2	7
Resistance provided by the JOE (kg)	6.6	8.2	9.8	9.7	12.2	14.6

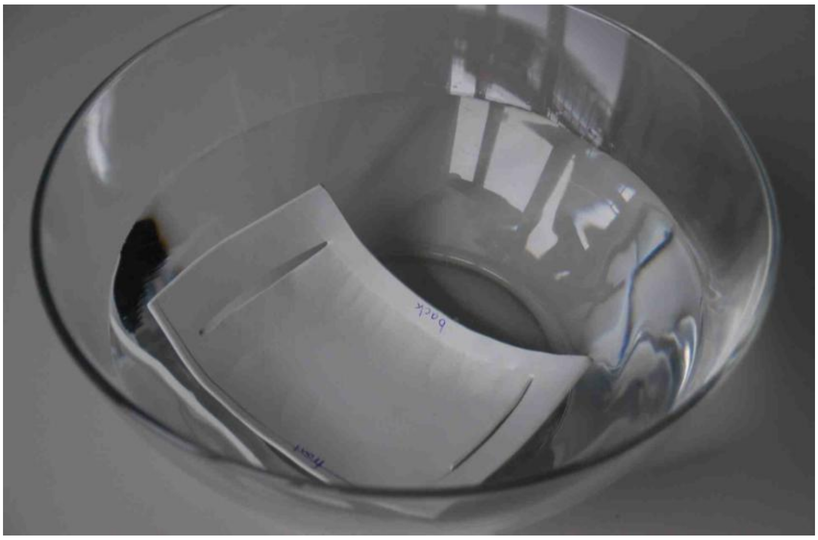

Figure 1. Heating the head piece

Figure 2. Moulding the head piece

Figure 3. Preparing the jaw-opening device

6. threaded through the metal ring, doubled over and affixed to the webbing by the Velcro® (Figures 4, 5).
7. The jaw-opening device was positioned on the participant's head so as the Thera-Band® lay directly underneath the chin. The jaw-opening device was fitted to the participant by threading it through the metal clip, doubling it back over the participant's head, and affixing it to the device with two further Velcro® strips (Figures 6, 7).

Treatment groups

Participants were assigned to one of two treatment groups: JOE or SE. Anonymity was preserved by assigning participants a 5-figure identification code obtained through a random-number generator.

Jaw-opening exercise group. Participants in the JOE group were instructed to sit comfortably in an upright position. A jaw-opening device was placed around the head and adjusted to provide an initial training load of 40% maximum jaw-opening force. Participants were instructed to complete three repetitions of sustained (one minute) jaw-opening movements against the resistance of the exercise device (isometric component), with each repetition separated by one minute of rest. Following this, participants completed 30 brief, consecutive jaw-opening movements (isotonic component) against resistance (Figures 8, 9.) Verbal feedback regarding task performance was provided as required. This pattern of exercise follows the training paradigm of the traditional head-lift manoeuvre (Shaker et al., 1997). In addition, resistance provided by the Thera-Band® was increased in 10% increments every two weeks, by adjusting the length of the band.

Sham exercise group. As with most controlled research in the field of dysphagia, providing a placebo that will have no confounding effect on the variable of interest is

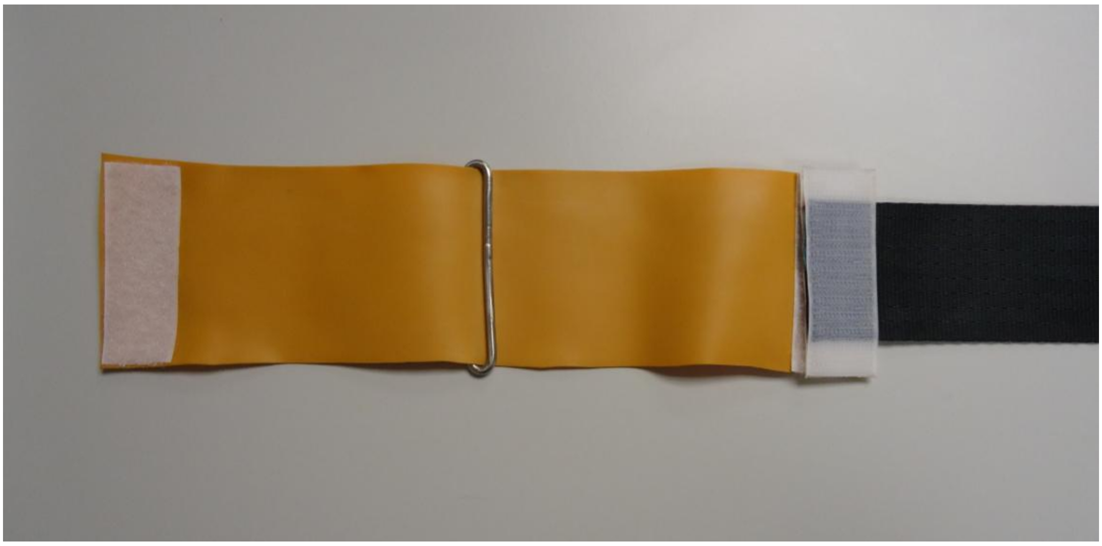

Figure 4. Preparing the Thera-Band®

Figure 5. Preparing the jaw-opening device

Figure 6. Fitting the jaw-opening device

Figure 7. A jaw-opening device.

Figure 8. Jaw-opening exercise against resistance: at rest.

Figure 9. Jaw-opening exercise against resistance: at maximum contraction.

difficult. In the present study, the option of providing a sham JOE device with no resistive load to participants in the control group was considered inappropriate, as repetitive mouth-opening with no load is not a true placebo. Instead, in line with the methods described in Bauer and Huckabee (2010), participants undertook an exercise involving squeezing a Thera-Band® Hand Exerciser Rubber Ball (Figures 10, 11). Resistance provided by the rubber ball was pre-determined by the kilograms of force required to reach 50% compression; different colour balls represented different levels of resistance (Table 5).

Before participants were assigned a coloured exercise ball, an initial measure of maximal hand-grip force was undertaken. Using a Dynatest® hand dynamometer, the hand-grip force of the participants' non-dominant hands was measured during the initial session. This determined the initial resistance level to be provided by the exercise ball. Participants with a maximal hand-grip force of less than 0.5 mmHg began their exercise regime with an extra soft (yellow) exercise ball. Participants with a maximal hand-grip force of greater than 0.5mmHg started with a soft (red) exercise ball. Similarly to the JOE, exercise ball resistance was increased by one level every two weeks.

Participants were instructed to complete three repetitions of sustained (one minute) ball-squeezes (isometric component), with a one-minute rest in between each movement. Following this, participants completed 30 brief consecutive ball-squeezes (isotonic component). Verbal feedback regarding task performance was provided as required.

Participants in both groups were provided with an exercise record sheet, on which they logged their daily exercise performance. Participants were instructed to carry out their respective exercise regimes three times per day for a period of six

Figure 10. Sham exercise: at rest.

Figure 11. Sham exercise: at maximum contraction.

Table 5.

Kgs of force required to reach 50% compression for different coloured Thera-Band® Hand Exerciser Rubber Balls

Thera-Band® Hand Exerciser Rubber Ball colour	Description	Kgs of force to reach 50% compression
Yellow	Extra soft	0.68
Red	Soft	1.36
Green	Medium	2.27
Blue	Firm	3.63

weeks. This equated to 33 repetitions (3 sustained plus 30 rapid movements) of either jaw-opening exercise (JOE group) or ball-squeezes (SE group) per session, or 99 daily repetitions. The researcher contacted all participants bi-weekly to address any concerns that arose, and to ensure compliance with the exercise protocol.

Instrumentation and outcome measures

Surface electromyography. Consistent with Bauer and Huckabee's (2010) methods, sEMG using submental surface electrodes was chosen to measure myoelectrical activity of the collective submental muscles during swallowing. sEMG was performed using Ag-AgCl T 3404 surface electrodes (Thought Technology Ltd.) in conjunction with the Swallowing Signals Lab of the Kay Elemetrics Digital Swallowing Workstation. A standard computer monitor displayed the myoelectrical activity of the submental muscle group during swallowing as a time by amplitude waveform. One investigator performed all examinations.

Ultrasound. Ultrasonography was performed using a Siemens Acuson Antares™ ultrasound system (Figure 12). A CH6-2 curved array transducer was used to measure anterior hyoid movement (defined as the change in distance between the hyoid bone and mentalis of the mandible at rest and at maximal contraction during swallowing), and a VF13-5 linear array transducer was used to measure the 2-D cross-sectional area of the geniohyoid and anterior belly of digastric muscles (Figure 13). One investigator performed all examinations.

Procedures

Before formally enrolling in the study, potential participants were provided with written and verbal information pertaining to the nature and extent of the study (Appendix A). If participants wished to proceed, arrangements were made for commencing participation in the project.

Figure 12. Siemens Acuson Antares™ ultrasound system

Figure 13. Ultrasound transducers VF13-5 and CH6-2

Each participant underwent one pre-treatment baseline assessment session and one post-treatment assessment session. Furthermore, to investigate the minimum exercise dosage required to produce treatment effects, a mid-treatment data collection session was completed after four weeks. The chronology of participants' visits is shown in Figure 14. Assessment sessions took place at the Swallowing Rehabilitation Research Laboratory at the New Zealand Brain Research Institute (NZBRI) on the first day of study participation, and within three days of the four- and six-week milestones of the exercise regimes. The following measurements were obtained: 2-D cross-sectional area of the submental muscles, anterior hyoid movement during swallowing, and myoelectrical activity during swallowing. Throughout the study, the primary researcher contacted every participant biweekly by phone, text-message, or email to confirm compliance with exercise protocols and to address questions or concerns raised by participants.

Baseline assessment session. On the first day of study participation, participants were asked to complete a questionnaire to ensure that inclusion criteria were met. All participants then underwent a baseline assessment including sEMG and ultrasound procedures, and were either fitted with a jaw-opening device or provided with a Thera-Band® Hand Exerciser Rubber Ball

sEMG assessment. Participants were seated in a comfortable chair and the skin overlying the submental muscles was cleaned with an alcohol wipe. Two surface electrodes were placed on the skin underneath the chin at midline. A third electrode, as a ground, was placed laterally, on the skin overlying the inferior face of the mandible (Figures 15, 16). Participants were instructed to remain as relaxed as possible and to limit extraneous movements of the tongue and head. They were told to gather saliva in their mouth and to perform a single swallow when they heard the

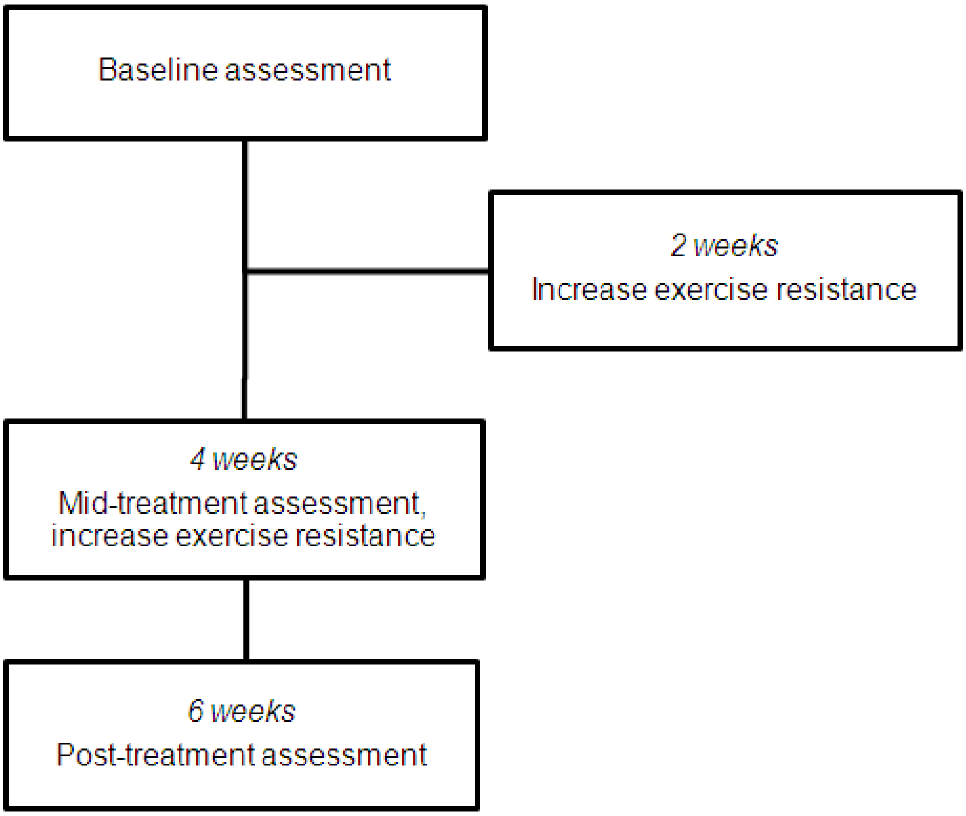

Figure 14. Chronology of participants' visits.

Figure 15. Electrode placement of sEMG measurement

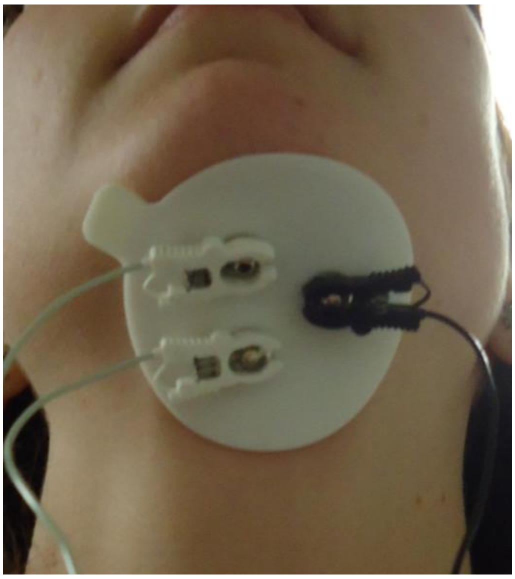

Figure 16. Electrode placement of sEMG measurement

investigator give the verbal cue: “swallow when you are ready”. This was repeated for ten saliva swallows, with time provided between swallowing for participants to gather saliva. Each saliva swallow was electronically tagged to assist with later identification and measurement. Participants were then instructed to perform a single “effortful” swallow when they heard the investigator give the verbal cue: “swallow hard, when you are ready”. “Effortful” swallowing was described to participants as “like swallowing a whole egg”. This was repeated for ten swallows, with time provided between swallowing for participants to gather saliva. Each “effortful” swallow was electronically tagged to assist with later identification and measurement.

At times throughout the assessment, participants were offered sips of water to moisten the mouth – the data from these swallows were ignored. At the conclusion of the assessment, the data file was saved under the participants’ identification code.

Ultrasonographic assessment. Unpublished data from the Swallowing Rehabilitation Research Laboratory at the NZBRI would suggest that the accuracy of ultrasonographic assessment in measuring hyoid excursion and 2-D submental cross-sectional area is not affected by the method of transducer placement, i.e. free-hand versus stabilised. Furthermore, experience suggests that participants find the free-hand method to be more comfortable than the stabilised method. For these reasons, the present study used the free-hand method. This is in contrast to the Bauer and Huckabee (2010) study, which utilised a dental bite-block and floor stand to stabilise transducer placement.

Participants were seated in a comfortable chair for ultrasonographic assessment of the pharyngeal phase of swallowing. Generous amounts of Aquasonic 100 ultrasound conductive gel were applied to the CH6-2 curved array transducer, which was then positioned submentally in the midsaggital plane. Adjustments to gain and depth were made to achieve maximum image clarity and compensate for variations in participant size. The adjustments made during this first assessment session were recorded, and kept constant within participants across all further ultrasound sessions. Correct transducer placement was determined by the presence of both the shadow of the hyoid and the shadow of the mandible on the ultrasound system screen. Participants were instructed to remain as relaxed as possible and to limit extraneous movements of the head and neck. They were told to gather saliva in their mouth and to perform a single swallow when they heard the investigator give the verbal cue: “swallow when you are ready”. This was repeated five times, with time provided between swallowing for participants to gather saliva. Participants were also instructed to perform a single “effortful” swallow when they heard the investigator give the verbal cue: “swallow hard, when you are ready”. This was repeated five times, with time provided between swallowing for participants to gather saliva. A five-second video of each swallowing sequence was recorded to the ultrasound system for later measurement. At times throughout the assessment, participants were offered sips of water to moisten the mouth – the data from these swallows were ignored.

The transducers were then changed, and measurement of the submental muscles was undertaken using the VF13-5 linear array transducer. Liberal amounts of conductive gel were applied to the transducer, which was then positioned submentally with passive contact in the coronal plane. Adjustments to gain and depth were made to achieve maximum image clarity and compensate for variations in participant size. These adjustments were also recorded, and kept constant within participants across all further ultrasound sessions. Correct transducer placement was determined by the presence of both left and right anterior belly of digastrics, mylohyoids, and geniohyoids on the ultrasound system screen. Participants were instructed to remain as relaxed as possible and to limit extraneous movements of the head and neck while five still images of the submental muscles were captured. At the conclusion of the assessment, the data file was saved under the participants' identification code and a back-up file was saved to CD-ROM.

At the conclusion of the baseline assessment session, participants were equipped with either a jaw-opening device or exercise ball. The investigator explained the exercise protocol, and asked the participants to demonstrate the exercise in order to ensure correct performance. Participants were also provided with a log sheet (Appendix B, Appendix C) to record their daily exercise performance. Participants were given the opportunity to ask questions, and a follow-up appointment was made for two weeks' time.

Follow-up assessment sessions. Within three days of the two-week milestone following exercise initiation, the researcher met briefly with every participant to increase the resistance offered by their respective exercises, using the method outlined above. Within three days of the four-week milestone, every participant was required to return to the NZBRI for a 30-minute mid-treatment assessment session, to investigate the minimum exercise dosage required to produce treatment effects. This involved the same sEMG and ultrasound methods described above, and also served as an opportunity to increase the resistance offered by the respective exercises. Finally, within three days of the six-week milestone following exercise initiation, every participant returned to the NZBRI for a 30-minute follow up assessment session, involving sEMG and ultrasound methods identical to those described above.

Data analysis

Blinding. All data was analysed by a single investigator trained in both speech-language therapy and in ultrasonographic evaluation of swallowing. In order to achieve blinding of the investigator during analysis of outcome measurements, data from every assessment session was represented by a 5-digit code provided by a random-number generator. Under this system, every participant was represented by a total of three different codes.

Analysis of raw data. Analysis of hyoid excursion as a function of distance from the mentalis of the mandible involved reviewing the video recordings of participants' volitional swallowing using ultrasound software (OsiriX v.4.0, © Antoine Rosset). Each clip was visually inspected to identify 1) the position of the hyoid at rest, and 2) the position of the hyoid at maximal contraction during swallowing (defined as the shortest distance between the hyoid and the mentalis of the mandible). Electronic callipers were then used to measure hyo-mandibular distance at these two points (Figures 17, 18). Data analysis was based on the calculated percentage change between hyo-mandibular distance at rest (H_{rest}) and at maximum approximation (H_{max}). Percentage change was defined as H_{max} divided by H_{rest} and multiplied by 100. The average percentage change of hyoid displacement for five normal swallowing sequences and five "effortful" swallowing sequences was calculated for each participant.

The 2-D cross-sectional area of the geniohyoid and anterior belly of digastric muscles was calculated using the same ultrasound software. A continuous trace calliper was used to outline the area of the anterior belly of the digastric and geniohyoid muscles in centimetres squared (Figure 19). The muscle perimeter of the left and right anterior bellies of the digastrics were traced separately, while the paired

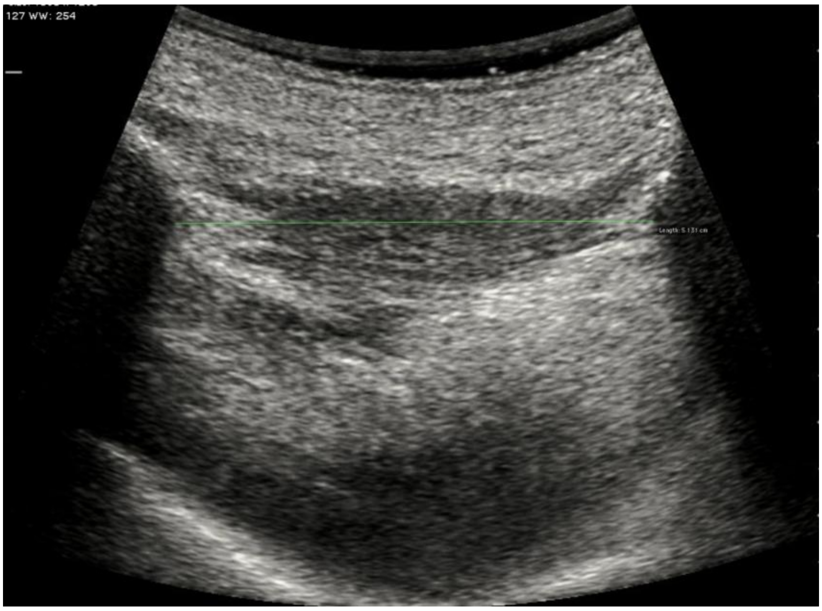

Figure 17. Ultrasonographic image of distance measurement between the reference point (mandible – left) and the hyoid bone (right) at rest

Figure 18. Ultrasonographic image of distance measurement between the reference point (mandible – left) and the hyoid bone (right) at maximal hyoid excursion during swallowing

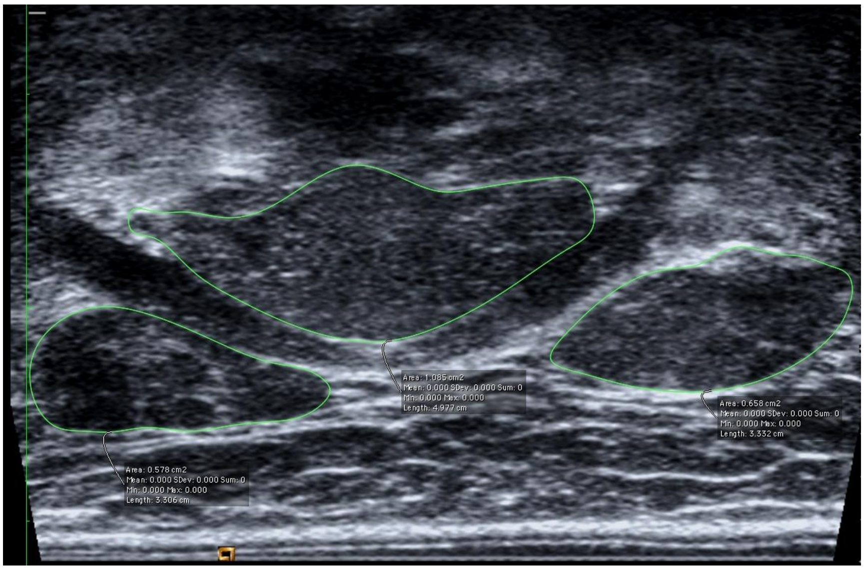

Figure 19. Ultrasonographic coronal image of submental muscles with anterior belly of digastric muscles and paired geniohyoid muscles outlined

geniohyoid muscles were traced collectively due to difficulty detecting the midline border between the muscles. Once the traced muscle boundaries were delineated, the cross-sectional area was displayed on the screen in centimetres squared. The average surface area of both the anterior belly of digastric and geniohyoid muscles was calculated for each participant.

The myoelectrical activity of the collective submental muscles during normal and effortful swallowing was obtained using the Swallowing Signals Lab of the Kay Elemetrics Digital Swallowing Workstation, which provided a peak amplitude value in mmHg. Average values based on ten normal and ten “effortful” swallows were calculated for each participant.

In addition to quantitative measures, qualitative data regarding participants’ exercise tolerance was also recorded. This was achieved by encouraging all participants to make daily comments in their log books. These comments were then analysed by the primary investigator and organised into the following categories: time (weeks), age (young versus old), gender, and treatment group.

Statistical methods

Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS Release 17.0). An initial analysis was completed comparing the raw data from the present study with the raw data from the Bauer and Huckabee (2010) study. This was done in order to determine whether the group means differed significantly between the two studies, with the intention of pooling statistically similar data to increase statistical power. For ultrasound measures, a general linear model (GLM) mixed effects analysis of variance (ANOVA) was used to was used to compare outcomes by study. Three variables (anterior hyoid excursion, 2-D cross-sectional area of geniohyoids, 2-D cross-sectional area of anterior belly of digastrics) were compared at three time points (baseline, four weeks, six weeks). A further two variables (change in 2-D cross-sectional area of geniohyoids, change in 2-D cross sectional area of anterior belly of digastrics) were compared at three points of time (baseline versus four weeks, four weeks versus six weeks, baseline versus six weeks), giving a grand total 15 outcome variables against which the studies were compared. For sEMG measures, an independent samples *t*-test was completed to compare outcomes (i.e. change in sEMG amplitude over time) by study. Additional analyses were also completed using the dataset from the present study alone.

Statistical analysis. A repeated measures design using a GLM mixed effects ANOVA was used to detect the presence of significant differences in 1) percentage change in hyoid displacement during swallowing 2) 2-D cross-sectional area of anterior belly of digastric and geniohyoid muscles 3) myoelectrical activity of the submental muscles between the two exercise conditions (JOE, SE) over time (baseline, post-4 weeks of treatment, and post-6 weeks of treatment).

Hyoid displacement. Data collected during ultrasound measures of hyoid displacement during swallowing were analysed using a RM ANOVA. The within-subject variables were time, (baseline, four and six weeks), condition (normal versus "effortful swallowing) and trial (five swallowing sequences per condition), and age was a covariate. The across-subjects variable was treatment (JOE versus SE).

2-D cross-sectional area of the submental muscles. All measurements subjected to statistical analysis were averaged across the five images collected during ultrasonographic examination. An initial bivariate correlation was completed in order to compare raw data from measurements of the left and right anterior belly of digastrics. Subsequent analysis of data collected during ultrasound measures of the anterior belly of digastric and geniohyoid muscles were analysed using a RM

ANOVA with time (3) as a within-subject variable, age as a covariate, and treatment as an across-subjects variable.

sEMG activity of the submental muscles. A RM ANOVA was completed using the within-subject variables of time (3), condition (2), and trial (10), the across-subjects variable of treatment (JOE, SE), and age as a covariate.

Participant compliance with exercise protocols. All data subjected to statistical analysis were first converted into a measure of exercise units. One exercise unit represented a complete set of three isometric plus 30 isotonic repetitions. Three exercise units per day was considered optimum. This equated to 15 units per week or 90 units over six weeks.

Initially, an independent samples *t*-test was performed on data from the present study to determine whether JOE differed from SE in terms of exercise performance (i.e. number of total exercise units recorded over six weeks). Secondly, a RM ANOVA was used to test for the possible effect of time on exercise performance. The within-subject variable was time (weeks 1-6), the across-subjects variable was treatment (JOE, SE), and the covariate was age. Finally, an independent samples *t*-test was carried out including data from the Bauer and Huckabee (2010) study to determine whether the respective JOE groups differed in terms of their overall exercise performance.

The relationship between submental muscle size and exercise performance. A bivariate correlation was completed using data from the present study alone to determine whether there was a significant relationship between the total amount of exercise performed by participants and change in size of the submental muscles (expressed as a percent-change from baseline to six weeks). Data from the SE group were excluded from this analysis, as they acted as a control for submental muscle size.

Reliability

Intra-rater reliability was estimated by the primary researcher re-analysing 20% (n = 207) of the combined ultrasound dataset (N = 1035), and 20% (n = 138) of the sEMG dataset (N = 690) chosen at random. The same 20% samples were also used to estimate inter-rater reliability by an independent rater. Single measure interclass correlation coefficient (ICC) was used.

Delays in re-assessment

Over the course of the study, confounding variables such as adverse weather conditions and participant ill-health prevented participants from attending follow-up sessions within the three-day timeframe following two, four, or six weeks of exercise. This was a factor for six participants – one in the JOE group and five in the SE group – and resulted in a delay in re-assessment and/or increases to exercise resistance of between one and six days.

Results

Reliability Measurement

Reliability measurement was interpreted as follows (Altman, 1991): intra-rater reliability analysis of hyo-mandibular distance at rest was very high, with a single measure intra-class correlation (ICC) of .83. Reliability was moderate for measures of hyo-mandibular distance at maximum contraction during swallowing, and degree of anterior hyoid excursion (i.e. percent change from rest to maximum contraction) with ICCs of .52 and .50, respectively. Reliability of measurements for combined anterior belly of digastric muscles size was very high, with an ICC of .88, and was outstanding for geniohyoid measurements at .96. The ICC for submental myoelectric activity was .80, indicating very high intra-rater agreement.

Similarly, inter-rater reliability for hyo-mandibular distance at rest was very high, with a single measure ICC of .84. Reliability was moderate for measures of hyo-mandibular distance at maximum contraction during swallowing, and degree of anterior hyoid excursion with ICCs of .52 and .49, respectively. Reliability of measurements for combined anterior belly of digastric muscle size was very high, with an ICC of .86, and was outstanding for geniohyoid measurements at .96. The ICC for submental myoelectric activity was .80, suggesting very high inter-rater agreement.

A Comparison of Data Sets

Initial statistical tests using a combined dataset produced mixed results. For ultrasound measures, results from the ANOVA suggested that the two studies differed significantly on 14 out of 15 outcome variables (Table 6). However, closer inspection of participant characteristics revealed a significant difference in age range between the two studies (Table 7). Specifically, the average age of participants in the present

Table 6.

A comparison of ultrasound outcome variables between the two studies

Outcome measure	Time	*F*	*p*
Anterior hyoid excursion	Baseline	725.50	.00*
	Post 4 weeks	826.18	.00*
	Post 6 weeks	4413.95	.00*
2-D cross-sectional area of geniohyoids	Baseline	19.38	.00*
	Post 4 weeks	18.20	.00*
	Post 6 weeks	19.50	.00*
Change in 2-D cross-sectional area of geniohyoids	Baseline – 4 weeks	117.44	.00*
	4 weeks – 6 weeks	370.02	.00*
	Baseline – 6 weeks	138.00	.00*
2-D cross-sectional area of anterior belly of digastrics	Baseline	.63	.43
	Post 4 weeks	8.18	.01*
	Post 6 weeks	4.83	.03*
Change in 2-D cross-sectional area of anterior belly of digastrics	Baseline – 4 weeks	270.49	.00*
	4 weeks – 6 weeks	952.57	.00*
	Baseline – 6 weeks	248.77	.00*

*significant at $p < .05$

Table 7.

A comparison of participant ages between the two studies

Study	Mean age (years)	*SD*	Range	*n* “young”	*n* “old”
Present study	47	25.98	62	12	11
Bauer and Huckabee (2010)	33	12.67	43	24	3

study was 47 years (*SD* = 25.98), with 11 participants aged 60+ years, while the average age of participants from the Bauer and Huckabee (2010) study was 33 years (*SD* = 12.67), with just three participants aged 60+ years. It was postulated that the observed difference between datasets may in fact have been due to age-related differences in the effect and/or performance of exercise. To further explore this possibility, a second ANOVA was completed with the exclusion of participants aged 60+ years. Results of this test revealed a persisting significant difference on 12/15 ultrasound measures, $F(1,34) = 5.90$, $p = .02$ (Table 8).

For sEMG measures, results showed that, on average, degree of change in participants' sEMG amplitudes from baseline to six weeks (expressed as a percentage change) was slightly higher in the Bauer and Huckabee (2010) study ($M = 17.61$, $SE = 7.37$) than in the present study ($M = 10.21$, $SE = 7.34$). However, this difference was non-significant $t(47) = -.704$, $p > .05$, and represented a small-sized effect $r = .10$. Raw data pertaining to sEMG amplitudes after four weeks of exercise from the Bauer and Huckabee (2010) study were not available, and thus no comparison could be made to the four-week outcome data from the present study.

Finally, an independent samples *t*-test was carried out to determine whether the respective JOE groups differed in terms of their overall exercise performance. Findings revealed that, overall, participants in the Bauer and Huckabee study performed more exercise units across six weeks ($M = 81.08$, $SE = 2.56$) than participants in the present study ($M = 69.42$, $SE = 7.88$). This difference was not significant $t(23) = -1.454$, $p = .16$; however, it did represent a medium-sized effect $r = .31$.

On the basis of these comparisons overall, the plan to pool data from the two studies was abandoned and further statistical analyses were completed on data from

Table 8.

A comparison of ultrasound outcome variables amongst young participants between the two studies

Outcome measure	Time	*F*	*p*
Anterior hyoid excursion	Baseline	407.34	.00*
	Post 4 weeks	482.43	.00*
	Post 6 weeks	2263.90	.00*
2-D cross-sectional area of geniohyoids	Baseline	8.61	.01*
	Post 4 weeks	5.83	.02*
	Post 6 weeks	6.86	.01*
Change in 2-D cross-sectional area of geniohyoids	Baseline – 4 weeks	54.53	.00*
	4 weeks – 6 weeks	233.11	.00*
	Baseline – 6 weeks	80.09	.00*
2-D cross-sectional area of anterior belly of digastrics	Baseline	.16	.69
	Post 4 weeks	3.15	.09
	Post 6 weeks	1.47	.23
Change in 2-D cross-sectional area of anterior belly of digastrics	Baseline – 4 weeks	147.00	.00*
	4 weeks – 6 weeks	485.02	.00*
	Baseline – 6 weeks	146.30	.00*

*significant at $p < .05$

the present study alone, consisting of 23 participants (10 males, 13 females) with an age range of 20-82 years (*M* = 46.61 years, *SD* = 25.98).

Ultrasound Data.

Anterior hyoid excursion. Groups did not differ significantly on measures of percentage change in anterior hyoid excursion at baseline during normal swallowing, $t(21) = .677$, $p = .51$, or "effortful" swallowing, $t(21) = .683$, $p = .50$, thus were considered appropriately comparable.

Results of the ANOVA revealed no main effect of time on degree of anterior hyoid excursion, $F(2, 38) = 1.02$, $p = .37$, with low observed power, $1\text{-}\beta = .21$, indicating that the extent of anterior hyoid excursion amongst participants remained similar throughout the study. Mean, standard deviation, and 95% confidence interval values are described in Table 9. There was also no significant interaction between time and treatment, $F(2, 38) = .496$, $p = .61$, with low observed power, $1\text{-}\beta = .13$. This suggests that degree of anterior hyoid excursion across JOE and SE groups over time was generally the same.

There was a significant main effect of trial, $F(4, 76) = 2.71$, $p = .04$. To break down this interaction, pairwise comparisons were performed on each swallowing trial. Results revealed that participants behaved differently on the first swallowing trial compared to the fifth trial, $p = .01$. The RM ANOVA was repeated, excluding all data from trial one and averaging the raw data from trials two to five. As Mauchly's test of sphericity was significant ($p < .001$), the Greenhouse-Geisser correction was applied for analysis of results. There was no main effect of time, $F(2, 30) = 2.14$, $p = .15$, with low observed power, $1\text{-}\beta = .35$. Similarly, there was no significant interaction effect between time and treatment, $F(2, 30) = 1.02$, $p = .35$, with low observed power, $1\text{-}\beta = .19$. Furthermore, there was no main effect of condition, $F(1, 20) = .083$, $p = .78$, with

Table 9.

Mean, standard deviation, and confidence interval values for percentage-change in anterior hyoid movement during normal swallowing and effortful swallowing tasks over time in JOE and SE groups.

Time	Condition	Treatment group	*M*	*SD*	*95% CI*
Baseline	Normal swallowing	JOE	29.90	5.57	27.62 – 32.18
		SE	27.3	5.13	26.94 – 32.88
	Effortful swallowing	JOE	29.91	7.26	25.20 – 29.40
		SE	28.82	5.58	26.54 – 31.10
4 weeks	Normal swallowing	JOE	31.18	7.38	28.16 – 34.20
		SE	31.52	7.26	28.55 – 34.49
	Effortful swallowing	JOE	29.47	4.95	27.45 – 31.49
		SE	26.83	4.81	24.86 – 28.80
6 weeks	Normal swallowing	JOE	29.81	4.87	27.82 – 31.80
		SE	31.19	9.60	27.27 – 35.11
	Effortful swallowing	JOE	26.90	4.68	24.99 – 28.81
		SE	26.15	6.32	23.57 – 28.73

Note: Data from trials 2-5

low observed power, *1-ß* = .06, and no significant interaction effect between condition and time, *F*(2, 40) = 1.26, *p* = .30, with low observed power, *1-ß* = .26. This indicates that the two groups did not behave differently on measures of anterior hyoid excursion whether the task was normal or effortful swallowing.

2-D cross-sectional area of anterior belly of digastrics. Groups did not differ significantly on individual measures of 2-D cross-sectional area of the combined anterior belly of digastrics at baseline, *t*(21) = .212, *p* = .83.

Measurements of the left and right anterior bellies of digastrics were highly correlated at baseline (*r* = .891, *p* < .01), four weeks post-exercise initiation (*r* = .944, *p* < .01), and six weeks post exercise initiation (*r* = .948, *p* < .01). For this reason, the sum total of the right and left anterior bellies were used for all further analyses.

A RM ANOVA was completed. As Mauchly's test of sphericity was significant (*p* < .001), the Greenhouse-Geisser correction was applied for analysis of results. There was no main effect of time, *F*(1, 28) = .107, *p* = .83, with low observed power, *1-ß* = .06, indicating that the size of the combined anterior belly of digastrics could not differentiate the JOE and SE groups over time. Mean, standard deviation, and 95% confidence interval values are described in Table 10.

2-D cross-sectional area of geniohyoids. Groups did not differ significantly on measures of 2-D cross-sectional area of the geniohyoids at baseline, *t*(21) = -.328, *p* = .75. There was no significant main effect of time, *F*(2, 40) = .889, *p* = .42, with low observed power, *1-ß* = .192. Mean, standard deviation, and 95% confidence interval values are described in Table 11. In addition, there was no main interaction effect between time and treatment, *F*(2, 40) = .138, *p* = .87, with low observed power, *1-ß* = .070. These findings indicate that JOE and SE did not significantly differ on measures of 2-D geniohyoid muscle cross-sectional area over time.

Table 10.

Mean, standard deviation, and confidence interval values for 2-D cross-sectional area of anterior belly of digastrics over time in JOE and SE groups

Time	Treatment group	*M*	*SD*	*95% CI*
Baseline	JOE	1.61	0.51	1.40 – 1.82
	SE	1.57	0.50	1.37 – 1.77
4 weeks	JOE	1.69	0.50	1.49 – 1.89
	SE	1.55	0.40	1.39 – 1.71
6 weeks	JOE	1.69	0.51	1.48 – 1.90
	SE	1.53	0.51	1.32 – 1.74

Table 11.

Mean, standard deviation, and confidence interval values for 2-D cross-sectional area of geniohyoids over time in JOE and SE groups

Time	Treatment group	*M*	*SD*	*95% CI*
Baseline	JOE	1.06	0.35	0.92 – 1.2
	SE	1.10	0.29	0.98 – 1.22
4 weeks	JOE	1.06	0.41	0.89 – 1.23
	SE	1.15	0.39	0.99 – 1.31
6 weeks	JOE	1.00	0.40	0.84 – 1.16
	SE	1.10	0.31	0.97 – 1.23

sEMG Data.

One participant (young, male, SE) was excluded from analysis of sEMG data due to technical difficulties during data collection. As Mauchly's test of sphericity was significant ($p < .001$), the Greenhouse-Geisser correction was applied for analysis of results. As expected, there was a significant main effect of condition, indicating that myoelectrical activity was different during normal and "effortful" swallowing, $F(1, 19) = 25.38$, $p < .001$, with high observed power, $1\text{-}\beta = .998$. However, there was no main effect of time, $F(2, 28) = .829$, $p = .412$, with low observed power, $1\text{-}\beta = .159$. Mean, standard deviation, and 95% confidence interval values are described in Table 12. In addition, there was no main interaction effect between time and treatment, $F(2, 28) = .217$, $p = .74$ with low observed power, $1\text{-}\beta = .07$. These results suggest that sEMG swallowing amplitudes could not differentiate JOE from SE over time, regardless of whether the task was normal swallowing or "effortful" swallowing.

Participant Compliance with Exercise Protocols.

One participant (young, male, JOE) from the present study was excluded from analyses of compliance as their log book could not be recovered. Results from the *t*-test showed that, overall, participants in the JOE group performed slightly more exercise units in total ($M = 82$, $SE = 11.23$) than participants in the SE group ($M = 79$, $SE = 7.27$). This difference was not significant $t(20) = .217$, $p = .83$ and represented a negligible effect $r = .05$.

Secondly, a RM ANOVA was used to test for the possible effect of time on exercise performance. As Mauchly's test of sphericity was significant ($p < .001$), the Greenhouse-Geisser correction was applied for analysis of results. Results are shown in Figure 20. There was no main effect of time, $F(3, 48) = .537$, $p = .64$ with low

Table 12.

Mean, standard deviation, and confidence interval values for sEMG amplitudes during normal swallowing and effortful swallowing tasks over time in JOE and SE groups

Time	Condition	Treatment group	*M*	*SD*	*95% CI*
Baseline	Normal swallowing	JOE	74.51	69.18	46.24 – 102.78
		SE	97.33	54.75	74.95 – 119.71
	Effortful swallowing	JOE	50.03	28.47	38.39 – 61.67
		SE	74.12	43.62	56.29 – 91.95
4 weeks	Normal swallowing	JOE	73.74	54.22	51.58 – 95.90
		SE	103.02	65.00	76.46 – 129.58
	Effortful swallowing	JOE	77.34	132.18	46.13 – 161.51
		SE			
6 weeks	Normal swallowing	JOE	65.76	26.78	54.82 – 76.70
		SE	103.49	46.35	84.55 – 122.43
	Effortful swallowing	JOE	51.61	32.88	38.17 – 65.05
		SE	75.71	44.27	57.62 – 93.80

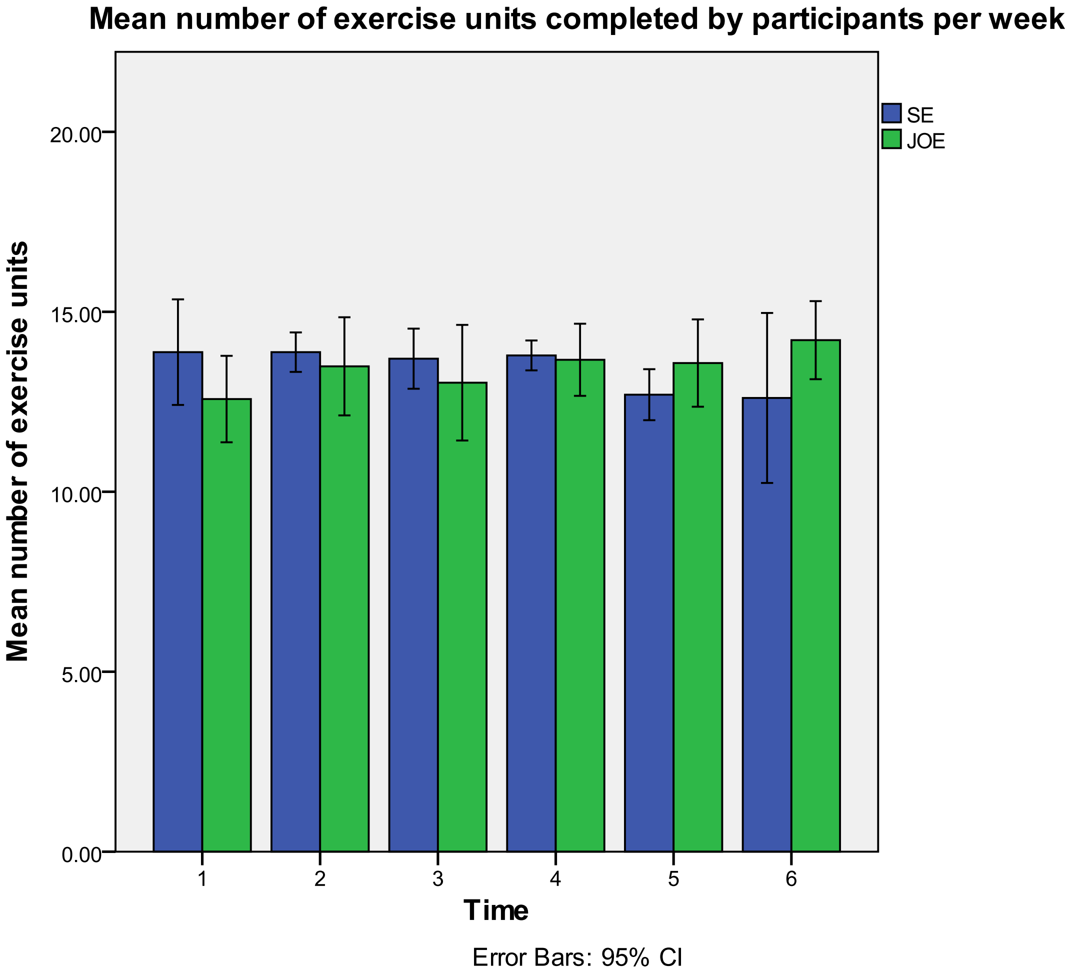

Figure 20. The relationship between time and exercise performance within the JOE and SE groups.

observed power, $1\text{-}\beta = .146$, indicating that JOE and SE did not behave differently in terms of exercise performance over the six-week protocol.

The relationship between submental muscle size and exercise performance. Results revealed that the total number of exercise units completed was not significantly correlated with change in size of the anterior belly of digastrics, $r = .08$, p (one-tailed) = .40. Similarly, total exercise units was not significantly correlated with change in size of the geniohyoids, $r = .34$, p (one-tailed) = .16.

Participant tolerance of the JOE and SE.

Few comments were made by participants in the SE group, and all were related to exercise performance (e.g. “forgot today, will do extra tomorrow”) as opposed to exercise tolerance. For this reason, the SE group was excluded from further analysis.

Overall, older participants appeared to find the JOE initially uncomfortable and tiring (“I don’t like it, it’s bloody painful”; “I was quite tired for the first few days”) with some muscle pain in the neck and cheeks reported in week one. However, this discomfort appeared to have subsided by the second week (“it’s not sore anymore”). This was consistent across both males and females. Young participants showed an opposite pattern, with no reports of discomfort in the first two weeks (“it’s not uncomfortable”), followed by increasing discomfort in the third and sixth weeks (“I can only just do the three minutes and that’s in pain”). Comments were consistent across both genders. A number of participants reported experiencing a “clicky” jaw that was not associated with pain – this was reported across both age groups and genders.

Only one participant (young, female) had to withdraw from the study due to experiencing adverse effects while performing the JOE. This participant reported “sharp” headaches associated with performing the JOE, which did not immediately subside. By the fifth week the participant was no longer able to tolerate the JOE, and withdrew from the study.

Discussion

Previous research in the field of dysphagia rehabilitation has found that exercise targeting the submental muscle group, such as the head-lift manoeuvre, may augment UES opening and result in functional improvements in swallowing (Shaker et al., 1997). Indeed, such exercises are widely used in clinical practice to treat patients with pharyngeal phase dysphagia resulting from stroke, head and neck cancer, etc. However, clinical experience suggests that, for patients with cervical spine injuries or increased frailty, such exercise may be problematic, as pain or weakness may restrict the ability to perform the exercise correctly. Furthermore, progressive increases to the load placed on the submental muscles are not easily provided, and previous studies have failed to identify an optimum or minimum exercise dosage required for treatment effects to be observed. Bauer and Huckabee (2010) first explored the idea of an alternative exercise when they investigated the effects of a novel jaw-opening exercise in healthy participants. Their findings suggested a significant increase in submental muscle size, and a non-significant trend towards increased hyoid excursion as a result of the exercise. However, results were limited by low observed power.

This research was designed as a partial-replication of the Bauer and Huckabee study, with the aim of independently examining specific biomechanical outcomes in healthy participants who have undergone a JOE regime and comparing them to controls matched for age and gender. In particular, the biomechanical features of submental muscle activity and 2-D cross-sectional area, and anterior hyoid movement were examined. A further aim was to combine data from the present study with the data from the 2010 study to increase statistical power.

Anterior Hyoid Excursion

Analysis of hyoid excursion for JOE and SE revealed no significant difference across groups over time. There was, however, a significant main effect of trial. Specifically, participants behaved differently on the first swallowing trial compared to the fifth trial. One explanation for this finding is that all initial swallowing trials may have been subject to a ‘first trial’ effect. In other words, participants behaved differently on the first swallowing trial as they became accustomed to swallowing under unusual conditions (i.e. during ultrasonographic evaluation). This would affect the validity of data from the first trials. This hypothesis was tested by repeating the RM ANOVA and excluding all data from trial one. However, results continued to show no significant difference between groups over time.

This is a somewhat surprising outcome, given that the JOE was designed to target the anterior belly of digastrics, geniohyoids and mylohyoids, which are responsible for anterior hyoid excursion. However, this result is in line with the findings reported by Bauer and Huckabee (2010), although the same study also reported a non-significant trend in the JOE group towards increased anterior hyoid excursion compared to the SE group after six weeks of exercise. Similarly, Shaker et al. (1997) failed to observe any significant increases in healthy participants’ anterior hyoid excursion after six weeks of head-lifting exercise, as measured by videofluoroscopy. A common factor between these three studies is the relatively small sample size – Bauer and Huckabee recruited 28 participants, Shaker et al. recruited 19 participants, and 23 participants were examined in the present study. It is conceivable that an effect may be revealed in a larger sample size with increased statistical power. Similarly, the three studies all recruited healthy participants, whose capacity for functional change may be somewhat limited.

However, a lack of increased functional change in hyoid excursion does not necessarily equate to a lack of increased physiologic change. Burkhead et al. (2007) describe swallowing as a “submaximal muscular activity” (p. 255) – in other words, the force that is generated by the swallowing muscles is far below the maximum force generating capacity of the muscles. Put in the context of the results of the present study, it is conceivable that differences did exist between groups in terms of the maximum force generating capacity of the collective submental muscles, but these differences were unable to be detected during normal, and even “effortful”, swallowing tasks.

2-D Submental Muscle Cross-sectional Area

No significant differences could be detected between groups using 2-D cross-sectional measures of either the anterior belly of digastrics or the geniohyoids. This is in direct contrast to findings reported by Bauer and Huckabee (2010), who found a significant increase in combined submental muscle size in their JOE group following six weeks of exercise. Indeed, it has been established in the exercise science literature that any regime involving progressive increases to resistive load placed on the muscles over time will result in changes to the muscle structure (Burkhead et al., 2007; Kraemer et al., 2002; McArdle, Katch, & Katch, 2010; Salmons & Henriksson, 1981). On the other hand, it is recognised that gross muscular hypertrophy may only occur after 5-12 weeks of training (Burkhead et al., Jones & Rutherford, 1987). In light of this, the present findings may be entirely appropriate.

There are several possible explanations for this discrepancy. One possibility relates to difficulties in obtaining accurate ultrasonograms. At times, the length of the transducer used in the present study restricted the ability to view the submental muscles at their widest point. Although every effort was made to be consistent in transducer placement, this inherent flaw in transducer size may have masked a possible treatment effect in the JOE group.

Another possible explanation relates to the age of the participants. Eleven participants in the present study were aged 60 years or more, compared to just 3 participants in the Bauer and Huckabee (2010) study. It is conceivable that participants in the latter study were able to perform their JOE with increased vigour, compared to participants in the present study, and this may account for some of the variation in findings between the two studies. This is supported by previous studies of normal elders, which have found changes in swallowing physiology and biomechanics with increasing age (Chi-Fishman & Sonies, 2002; Kim & McCollough, 2008; McKee et al., 1998; Nicosia et al., 2000; Rademaker et al., 1998).

Submental Muscle Myoelectric Activity

Analysis of peak myoelectrical activity of the submental muscles during swallowing for JOE and SE revealed no significant difference across groups during a normal dry swallowing task. This is consistent with findings from Bauer and Huckabee (2010), who postulated that submental muscle strength may have improved in their JOE group, but the normal swallowing task was not sufficient to demonstrate this change. They suggested that a task which required the submental muscles to increase force generation, such as an “effortful” swallowing task, may have revealed changes in the JOE group.

The present study attempted to answer this question by including an “effortful” swallowing task as an outcome measure. However, results revealed no significant differences between JOE and SE. The reason for this is unclear. The most likely explanation relates to the large variability inherent in measures of swallowing using sEMG signals. A recent publication by Steele, Bennett, Chapman-Jay, Cliffe

Polacco, Molfenter and Oshalla (2012) outlined the fact that sEMG amplitudes may vary as a function of electrode placement, and the amount of fatty tissue between the electrode and the submental muscles. In fact, the authors recommended that sEMG amplitudes should not be used to make between-subject comparisons due to variations in signal attributable to fatty tissue differences across participants. Where within-subject, repeated-measures comparisons are concerned, they recommended using a data normalisation procedure in order to adjust amplitudes relative to a reference level. It is possible that using this method may have revealed greater within-subject differences in the present study.

Participant Compliance with Exercise Protocols

One possible confounding variable was the amount of exercise completed by participants. The effect of this was explored by comparing exercise compliance in participants from the Bauer and Huckabee (2010) study to participants from the present study. It was revealed that the JOE group from the former study completed on average 11.66 more exercise units than the JOE group from the present study over the course of six weeks. Although this finding was not statistically significant, it equates to almost one week of extra treatment for participants in the Bauer and Huckabee study, and represented a medium-sized effect. This perhaps explains some of the discrepancies in findings between the two studies.

Further comparisons were made between groups in the present study. Results revealed no significant differences between the number of exercise units performed by the JOE group compared to the SE group, and the two groups did not appear to behave differently over time.

On examination of individual data it was revealed that every participant in the JOE group completed at least 70% of their total exercise requirements, with the exception of one participant who only completed 21%, and exercise performance remained stable across the entire study. Yet despite this high reported compliance, the amount of JOE performed was not significantly related to changes in the size of the submental muscles. The reason for this remains unclear, but may suggest a discrepancy between participants' self-reported exercise performance and their actual exercise performance, or support the argument for increasing exercise intensity in the JOE protocol.

In terms of participant drop-out rates, the present study presents promising results. There was one drop-out from the JOE group, and there were no drop-outs in the SE group. A similar study by Easterling et al. (2005) reported a 50% drop-out rate amongst healthy elderly assigned to a head-lifting protocol. The reason for this discrepancy in drop-out rates between studies is not clear. Although the JOE has a certain novelty factor, it is unlikely that this would continue to remain an important factor in motivation after six weeks of constant exercise. Maintaining contact with participants, on the other hand, may be. In the present study participants were contacted bi-weekly by the main investigator, whereas in the Easterling et al. study contact was made weekly. Yet even with increased participant contact, it is difficult to determine the exact amount of exercise that participants received. Closer monitoring of participant compliance may have allowed firmer conclusions to be drawn.

Whatever the source of motivation for healthy participants may be, it remains unclear whether a patient population would behave similarly. Dysphagic patients may show increased motivation to complete a JOE if they believe it will improve their swallowing, or if they feel a sense of empowerment through this independent model of therapy. Conversely, they may have deceased motivation as a result of other factors such as fatigue. It will be crucial for future studies to identify whether a patient population are able to perform a JOE as faithfully as this group of healthy participants, or whether modifications to the protocol are required.

Participant Tolerance of the JOE

Overall, participants were able to tolerate six weeks of JOE with no adverse effects, with the exception of one participant (young, female) who experienced muscle-tension headaches associated with the exercise. Younger participants tended to report discomfort immediately following increases to exercise resistance, and also when performing the exercise at maximum resistance (60% 1RM), as might be expected. Older participants tended to report muscle soreness and fatigue at the initial stages of the treatment, however, this had subsided by the second week. This confirms reports from Easterling et al. (2005), who examined compliance with the head-lift manoeuvre (Shaker et al., 1997) amongst healthy elderly subjects and found that most drop-outs occurred in the first two weeks of exercise. Furthermore, the authors reported that mild discomfort associated with the exercise spontaneously resolved within two weeks.

It is important, however, to acknowledge that the JOE was exceedingly difficult for some participants to perform. This was reflected in comments such as: "*I don't like it, it's bloody painful*", and "*I can only just do the three minutes and that's in pain*". Comments like these lend support to the suggestion that participant compliance may not have been as high as indicated in self-reports.

Again, it remains to be seen whether the same result would be observed in a patient population. Burkhead et al. (2007) suggested the muscles of swallowing are susceptible to atrophy secondary to disuse in dysphagic patients who are tube-fed. This population would most likely show an increase in reported discomfort as the effects of atrophy are reversed using JOE, and a modified protocol may need to be developed to balance patient discomfort with physiologic change.

Intensity of the JOE

The JOE was designed in accordance with the principles of exercise intensity, specifically, to a) provide a load that would exceed the usual activity levels of the submental muscles, b) progressively increase this load over time. Yet whether adequate exercise intensity was experienced by participants in the present study remains uncertain. The starting point of 40% 1RM used in the present study is in accordance with previous reports of maximum patient tolerance for submental muscle strength training (Bauer & Huckabee, 2010), however, other sources have recommended an initial training load of 60% 1RM (Burkhead et al., 2007). Additionally, more frequent increases in resistive load provided by the JOE may have been more appropriate. Until the upper and lower limits for corticobulbar training are more clearly defined, the ideal initial training load for the JOE remains unclear.

Additional factors that contribute to exercise intensity are the number of repetitions of the activity, and overall training duration. Participants in the present study performed three repetitions of their exercise, five times per week. Previous studies have detected significant treatment effects following the same amount of repetitions (Bauer & Huckabee, 2010; Shaker et al., 1997), thus it is unlikely that the number of repetitions is to blame for the lack of significant results in the present study.

In terms of exercise “dosage”, it is yet to be determined how long a swallowing exercise regime should be to maximise its effectiveness (Burkhead et al., 2007). The current trend in dysphagia rehabilitation is towards an intensive approach to treatment, ranging from five days to eight weeks in duration (Carnaby et al., 2006;

Huckabee & Cannito, 1999; Robbins et al., 2007; Shaker et al., 1997). Findings from the present study suggest that neither four nor six weeks of JOE were sufficient to observe physiologic change in swallowing. On the other hand, only 3/11 participants in the JOE group completed 100% of their exercise requirements. Of those 8/11 who under-performed their respective JOEs, self-reports still may not accurately reflect the exact amount of exercise dosage performed. Participants may have continued to log exercise performance when in fact they had ceased performing the JOE. In this case, they may have behaved very differently on outcome measures depending on whether they had performed high amounts of JOE over a short period of time, or small amounts of JOE over a longer time period.

Specificity of the JOE

In terms of exercise specificity, the JOE is comparable with the traditional head-lift manoeuvre (Shaker et al., 1997), as both exercises are reasonably unrelated to functional swallowing. Evidence from the field of exercise science suggests that training a particular muscle group does not necessarily transfer into benefits in related activities for that muscle group. This is consistent with findings from the present study, and may explain the lack of observed treatment effects.

It has been proposed that the effects of exercise on muscle strength may be even greater when paired with the specific act of functional swallowing (Burkhead et al., 2007). Indeed, Burkhead et al. (2007) suggest that exercises should incorporate swallowing repetitions with progressively increasing physiologic resistance training. The reality of incorporating swallowing repetitions into a JOE protocol for patients with dysphagia may not be possible, as their loss of ability to control a bolus and/or initiate pharyngeal swallowing presents a barrier to safe swallowing. Instead, the JOE may be considered as a precursor exercise with the aim of exciting the neuromuscular system, increasing muscle strength, and building functional reserve. The carry-over of these effects to functional swallowing tasks may form the basis of future dysphagia rehabilitation.

Transference of the JOE to Functional Swallowing

As previously established, repeated exercise can serve to activate complex neural and biochemical systems, which has widespread effects throughout the body. It has been suggested that the principle of transference may in part account for gains in swallowing following rehabilitation exercises in the absence of specific swallowing practice (Burkhead et al., 2007). However, such gains were not observed in the present study.

Limitations

Several methodological issues should be taken into consideration when evaluating and interpreting the results presented in this study. Firstly, although the initial aim was to pool the data with that from the Bauer and Huckabee (2010) study – thereby increasing statistical power – due to significant differences between the two datasets on ultrasound measures this was not possible, and the majority of statistical analyses were completed on a relatively small dataset (N = 23) with resulting low power. This small number of participants increases the chances of a Type II error, and limits the extent to which results can be generalised to the wider population.

Another limitation of the present study relates to the methods of outcome measurement, specifically, the use of ultrasonograms. Several aspects of this technique need to be addressed. Firstly, by using ultrasonograms, evaluation of functional swallowing behaviour is limited to analysis of hyoid excursion. Other aspects of swallowing where one might expect to see biomechanical change – for example, UES opening – are unable to be evaluated. A possible solution would be to include videofluoroscopy in the assessment battery, however, this would be ethically challenging in a study of healthy participants. Secondly, two different techniques for conducting ultrasound evaluation were used between the present study and the Bauer and Huckabee (2010) study, namely free-hand transducer placement compared to stabilised transducer placement. While unpublished data from the Swallowing Rehabilitation Research Laboratory at the NZBRI suggest there is no difference in the reliability of data obtained via these two methods, the difference in technique introduces a confounding variable. Sources tend to agree that ultrasonography is highly sensitive to technique-related variables such as transducer pressure and orientation (Emshoff et al., 2002; Satiroglu, Arun, & Isik, 2005). However, when a strict imaging protocol is used and excessive transducer placement is avoided, it is also a highly reproducible method of accurately measuring muscle size (Emshoff et al., Satiroglu et al.). Despite careful attempts to control for technique-related variables in the present study, the lack of significant findings may testify to variability in the ultrasonograms. This was also reported as a limitation in the Bauer and Huckabee study.

As previously mentioned, a third consideration when interpreting the findings of this study is the reliability of participant self-reports regarding exercise performance. The self-report bias refers to an effect in experimental research where participants tend to report their behaviour in a way that will appear favourable to others (i.e. the investigator). In relation to the present study, it is possible that participants exaggerated reports of their exercise performance in order to satisfy the requirements of the exercise protocol, and thus these results should be interpreted with caution.

Related to exercise performance is the issue of participant expectation and blinding. While technically a single-blinded research design was employed, it may be argued that participants in the control group knew that they were performing a placebo exercise, and thus expectation bias was introduced. On the other hand, participants in the experimental group may also have considered themselves to be performing a placebo exercise, as the relationship between mouth-opening and swallowing is not apparent to non-experts. Regardless, this issue could have been better managed by including specific hand-grip outcome measures for all participants.

Finally, the lack of randomisation of swallowing tasks during outcome measurement may also be problematic. For both sEMG and ultrasound measurements, participants performed normal swallowing followed by "effortful" swallowing. This introduced fatigue as a possible confounding variable, and thus caution should be applied when interpreting results, especially with regards to "effortful" swallowing data.

Future Directions

Future work into the development of the JOE as a clinically viable rehabilitation tool should focus on the level of resistance provided to the submental muscles. The JOE group in the present study received 40%, 50% and 60% resistance training across six weeks, however, these values were calculated on the basis of normative data as opposed to individual data. It is proposed that in order for participants to receive optimal resistance training, individualisation of the JOE is required. This could be performed relatively easily using the indirect cervical traction device described by Koyama et al. (2005) to quantify jaw-opening force.

Furthermore, more research into the optimal training load needs to be undertaken before the association between resistance and corticobulbar muscle adaptation is understood. Findings from the corticospinal literature suggest training effects can be observed using as little as 20% 1RM resistance (de Vos et al., 2005), but higher resistances of 60% to 85% 1RM result in greater effects (Burkhead et al., 2007; de Vos et al., 2005). However, the upper and lower limits for resistance training in corticobulbar muscles have not yet been defined. It is clear that a JOE must be performed using an initial load of 40% 1RM or less in order to avoid participant discomfort (Bauer & Huckabee, 2010), and future work may focus on establishing an optimal protocol for increasing the resistance offered by the JOE so as to balance participant comfort with optimal training load.

Future studies may also investigate the effects of the JOE using different tools of outcome measurement, and/or different outcome measures. Magnetic resonance imaging (MRI) may be one possible alternative for measuring outcomes in submental muscle size. Robbins' (2005) study used MRI to effectively demonstrate increased lingual volume in participants who had undergone a lingual exercise regime. This method of outcome measurement is not influenced by the same technique-related variables as ultrasonography and therefore can be said to have greater reliability. Another direction to explore is the effect of the JOE on pharyngeal pressures during swallowing, as measured by pharyngeal manometry. Also, as previously mentioned, degree of UES opening as measured by videofluoroscopy is another potential direction for research, as it is assumed that the JOE targets UES opening.

Finally, although no significant effect of the JOE could be detected in a healthy population, it remains to be seen whether the same is true for a patient population. In fact, it is likely that these populations would behave quite differently, due to inherent differences in muscle-fibre composition in a dysphagic population, as well as a lack of inherent drive for neuromuscular change in a healthy population, a phenomenon known as the ceiling effect.

This raises several more research questions relating to longevity of treatment effects and ultimate functional outcomes for patients. A similar study by Trappe et al.(2002) found that continued resistance training exercise for just one day per week following strength training was sufficient to maintain gains made in muscle size and strength following a 12-week resistance training program. Although beyond the scope of the present study, further investigation is warranted.

Conclusion

Although no convincing physiologic effect of the JOE could be detected, the present study lends additional information to the development of an alternative rehabilitative exercise for patients who are unable to perform the traditional head-lift manoeuvre (Shaker et al., 1997). The potential for the JOE to be used not only in the treatment of dysphagia, but as a prophylactic in healthy elderly, warrants pursuit. Based on the present findings, it may be possible for future studies of the JOE to be developed. Such studies might utilise more sensitive tools of outcome measurement, explore alternative physiologic outcomes, promote increased exercise intensity, and/or explore possible effects on a patient population.

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Appendix A

Consent Form

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

VAN DER VEER INSTITUTE FOR PARKINSON'S & BRAIN RESEARCH

CONSENT FORM

The effects of a jaw-opening exercise on suprahyoid muscles and hyoid movement during swallowing in healthy adults

English	I wish to have an interpreter.	Yes	No
Maori	E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.	Ae	Kao
Samoan	Oute mana'o ia iai se fa'amatala upu.	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea.	Io	Ikai
Cook Islands	Ka inangaro au i tetai tangata uri reo.	Ae	Kare
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu.	E	Nakai

I have read and I understand the Information Sheet for volunteers taking part in the study designed to evaluate the effect of two exercises on swallowing. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time. I understand that if I choose to withdraw from the study, I may also withdraw all information that I have provided.

I understand that the information obtained from this research may be published. However, I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study.

I understand that the investigation will be stopped if it should appear harmful to me and I know whom to contact if I have any side effects to the study or have any questions about the study.

I understand there are potential risks of participation in the study as explained to me by the researcher. I have filled out the questionnaire, and I feel confident that none of the risk factors outlined in the questionnaire apply to me.

I consent to the use of my data for future related studies, which have been given ethical approval from a Health and Disability Ethics Committee.

I have had this project explained to me by ________________________________.

I understand the compensation provisions for this study.

I have had time to consider whether to take part.

I wish to receive a copy of the results.

YES / NO

* Please note that a significant delay may occur between data collection and publication of the results

I would like the researcher to discuss the outcomes of the study with me

YES / NO

I, ___________________________ hereby consent to take part in this study.

Signature____________________________________Date___________________

Signature of researcher: ________________________

Name of researcher____________________________

Name of primary researcher and contact phone numbers:

Sarah Davies, BSLT (Hons)

(03) 378 6068

Secondary Researcher:

Maggie-Lee Huckabee, PhD

(03) 378 6070

(Note: A copy of the consent form to be retained by participant)

Appendix B

Log Sheet for Jaw Opening Exercise

Contact information:

If you have any concerns or questions, please contact one of the researchers.

Sarah	03 378 6068
Maggie-Lee	03 378 6070

Van der Veer Institute

66 Stewart St, Christchurch
At the corner of Stewart and St Asaph Sts.
Behind Hagley Community College

UC UNIVERSITY OF CANTERBURY Te Whare Wānanga o Waitaha CHRISTCHURCH NEW ZEALAND

VAN DER VEER INSTITUTE FOR PARKINSON'S & BRAIN RESEARCH

Swallowing Rehabilitation Research Laboratory

Exercise log for ______________________

Exercise Log and Summary

The University of Canterbury
Department of Communication Disorders

Swallowing Rehabilitation Research Laboratory at the
Van der Veer Institute

UC UNIVERSITY OF CANTERBURY Te Whare Wānanga o Waitaha CHRISTCHURCH NEW ZEALAND

VAN DER VEER INSTITUTE FOR PARKINSON'S & BRAIN RESEARCH

Weekly Treatment Log: Week 1

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

JAW-OPENING EXERCISE

Using your jaw-opening device, open your mouth as wide as you can and hold this position for **one minute**. Repeat 3 **times.**

Now open and close your mouth 30 **times.**

Comments: Week 1

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 2

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

JAW-OPENING EXERCISE

Using your jaw–opening device, open your mouth as wide as you can and hold this position for **one minute**. Repeat 3 **times.**

Now open and close your mouth 30 **times.**

Comments: Week 6

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 6

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

JAW-OPENING EXERCISE

Using your jaw-opening device, open your mouth as wide as you can and hold this position for **one minute**. Repeat 3 **times.**

Now open and close your mouth **30 times.**

Comments: Week 2

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 3

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

JAW-OPENING EXERCISE

Using your jaw-opening device, open your mouth as wide as you can and hold this position for **one minute**. Repeat 3 **times.**

Now open and close your mouth **30 times.**

Comments: Week 5

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 5

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

JAW-OPENING EXERCISE

Using your jaw-opening device, open your mouth as wide as you can and hold this position for **one minute**. Repeat 3 **times.**

Now open and close your mouth 30 **times.**

Comments: Week 3

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 4

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

JAW-OPENING EXERCISE
Using your jaw-opening device, open your mouth as wide as you can and hold this position for **one minute**. Repeat 3 **times.**

Now open and close your mouth 30 **times.**

Comments: Week 4

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Appendix C

Log Sheet for Sham Exercise

Contact information:

If you have any concerns or questions, please contact one of the researchers.

Sarah	03 378 6068
Maggie-Lee	03 378 6070

Van der Veer Institute

66 Stewart St, Christchurch
At the corner of Stewart and St Asaph Sts.
Behind Hagley Community College

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

VAN DER VEER INSTITUTE
FOR PARKINSON'S & BRAIN RESEARCH

Swallowing Rehabilitation Research Laboratory

Exercise log for ____________________

Exercise Log and Summary

The University of Canterbury
Department of Communication Disorders

Swallowing Rehabilitation Research Laboratory at the
Van der Veer Institute

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

VAN DER VEER INSTITUTE
FOR PARKINSON'S & BRAIN RESEARCH

Weekly Treatment Log: Week 1

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

BALL-SQUEEZING EXERCISE

Hold the rubber ball in your hand and squeeze hard for **one minute**. Repeat 3 **times.**

Now squeeze the ball quickly 30 **times.**

Comments: Week 1

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 2

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

BALL-SQUEEZING EXERCISE

Hold the rubber ball in your hand and squeeze hard for **one minute**. Repeat **3 times.**

Now squeeze the ball quickly **30 times.**

Comments: Week 6

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 6

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

BALL-SQUEEZING EXERCISE

Hold the rubber ball in your hand and squeeze hard for **one minute**. Repeat 3 **times.**

Now squeeze the ball quickly 30 **times.**

Comments: Week 2

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 3

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

BALL-SQUEEZING EXERCISE

Hold the rubber ball in your hand and squeeze hard for **one minute**. Repeat 3 **times.**

Now squeeze the ball quickly 30 **times.**

Comments: Week 5

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 5

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

BALL-SQUEEZING EXERCISE

Hold the rubber ball in your hand and squeeze hard for **one minute**. Repeat 3 **times.**

Now squeeze the ball quickly 30 **times.**

Comments: Week 3

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Weekly Treatment Log: Week 4

	Morning	Noon	Night
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

BALL-SQUEEZING EXERCISE

Hold the rubber ball in your hand and squeeze hard for **one minute**. Repeat **3 times.**

Now squeeze the ball quickly **30 times.**

Comments: Week 4

	Comments/questions/concerns
Mon	
Tues	
Wed	
Thurs	
Fri	

Appendix D

Advertisement for Participants

UC UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

VAN DER VEER INSTITUTE
FOR PARKINSON'S & BRAIN RESEARCH

RESEARCH PARTICIPANTS WANTED

We are looking for participants to investigate the effects of exercise on swallowing.

This research project will take approximately 15 hours of your time, carried out over 6 weeks. It involves three assessment sessions (of 1 hour duration) each which involves 2 painless procedures to test your muscles including:

- Ultrasound of the muscles under your chin to measure how big the muscles used in swallowing are.
- Surface Electromyography: three electrodes are placed under your chin to measure muscle tension during swallowing.

You will be required to carry out 10 minutes of swallowing exercises 3 times a day for a 6 week period before you are re-evaluated. A questionnaire will be carried out prior to your involvement to ensure your suitability for the study and to ensure there is no risk associated with your participation in this study. If you do agree to take part in this study, you are free to withdraw at any time, without having to give a reason.

If you are interested in participating, please contact:

Sarah Davies

Ph: 03 378 6068 **Email: sarah.davies@pg.canterbury.ac.nz**

Van der Veer Institute for Parkinson's and Brain Research, 66 Stewart St., Christchurch

Appendix E

Information Sheet for Participants

INFORMATION SHEET

Research Title:

The effects of a jaw-opening exercise on suprahyoid muscles and hyoid movement during swallowing in healthy adults

Primary Researcher:

Maggie-Lee Huckabee, PhD

Senior lecturer, Department of Communication Disorders

University of Canterbury

Van der Veer Institute for Parkinson’s and Brain Research

66 Stewart St., Christchurch NZ

(03) 378 6070

Secondary Researcher:

Sarah Davies, BSLT (Hons)

MSc candidate, Department of Communication Disorders

University of Canterbury

Van der Veer Institute for Parkinson’s and Brain Research

66 Stewart St., Christchurch NZ

(03) 378 6068

Introduction and aims of the project:

You are invited to participate in a research project that will explore the effect of two exercises on swallowing function. Participants will be assigned to one of two exercise groups. One group will perform a mouth-opening exercise against resistance; the other group will squeeze a soft rubber ball in their hand. Effects of exercise will be evaluated using ultrasound, and surface electromyography, techniques which non-invasively measure muscle size and function. Interest in participating should be expressed within 2 weeks of the information being provided. You have the right not to participate in the study or subsequently withdraw from this study at any time.

Participant selection:

Your participation in this study is due to your reply to advertisements or information seminars requesting research participants. Upon your consent, you will complete a questionnaire that will determine your suitability for the study. The study will include 28 participants who have no swallowing problems. In total this study will require approximately 30 hours of your time over 6 weeks.

Exclusion criteria for healthy participants:

You may not be eligible to participate in this study if you have or ever have had any of the following conditions:

- stroke
- any brain-related condition or any illness that caused brain injury
- any swallowing difficulties
- any problems with your jaw or mandible (i.e. gnashing teeth)

Completing a questionnaire will ensure that inclusion criteria are met and possible risk factors for participating are identified.

The research procedure:

The study involves three assessment sessions at the Van der Veer Institute for Parkinson’s and Brain Research. In addition to these assessment sessions, you will be required to carry out exercises for 10 minutes, 3 times per day, for 6 weeks. Below is a table showing how the time is broken up over the 6 weeks.

Baseline 1 assessment	**Exercise period**	**Mid-treatment assessment**	**Exercise period**	**Outcome assessment**
1 hour	4 weeks Includes 3 sessions of approximately 10 minutes per day	1 hour	2 weeks Includes 3 sessions of approximately 10 minutes per day	1 hour

The assessment sessions and the exercise period are described below. If you agree to participate in the study, the following will occur:

1. You will be given an appointment and asked to come to the Swallowing Rehabilitation Research Laboratory at the Van der Veer Institute, 66 Stewart St, Christchurch, New Zealand.

2. A researcher will meet with you at the Van der Veer Institute and you will have an opportunity to have any questions answered. After signing the consent form, you will be asked to complete a standard safety questionnaire to screen for risk of adverse events during the procedures. You will also complete a generic questionnaire to ensure inclusion criteria are met and risks are minimised. You will then be seated in a comfortable chair and be ready to begin.

Assessment sessions:

I.***Electromyography measurements***

3. In each assessment session, the researcher will attach 2 small electrodes to the skin underneath your chin, and 1 to your cheek bone. These will be used to measure muscle activity when you swallow. These electrodes are used only for recording and do not put any electricity into the muscles.

4. Once the electrodes are in place, you will be asked to swallow 10 times, and contract the muscles under your chin as hard as you can 10 times. This is so the strength of your swallows can be determined and will enable the

researchers to adjust the equipment to your individual muscle activity during swallowing.

II.***Ultrasound measurements***

5. You will be seated in a comfortable chair at the Van der Veer Institute. A clear conductive jelly will be put on the skin under your chin to allow imaging of the muscles. The ultrasound transducer (the imaging tool) will be lightly placed under your chin.

6. You will be asked to remain very still and relaxed during the first part of the ultrasound imaging procedure. For the second part you will be asked to swallow 10 times, at a rate that is comfortable for you. During these procedures, you will not feel anything unusual or experience any discomfort. Ultrasound procedures should take no more than 20 minutes.

III.Exercise demonstration

7. Once your assessment session is completed, you will be given instructions on how to complete one of two exercises. You will carry out your first exercise session in the swallowing rehabilitation research laboratory. The instructions will vary depending on which exercise group you are assigned to:

a. *Jaw-opening:* You will sit comfortably in a chair, and will have a Thera-Band® device positioned around your head. A Thera-Band® is similar to a large rubber band and is commercially available for use in other exercise programmes. You will then open your mouth against the resistance of the Thera-Band®. You will hold this opening for one minute, followed by one minute of rest. This sustained mouth-opening action will be repeated 3 times. Then you will open and close your mouth briefly for thirty times.

b. *Ball-squeezing:* You will sit comfortably in a chair, with a small rubber ball in your hand. You will then squeeze the ball for one minute, followed by one minute of rest. This sustained ball-squeezing will be repeated 3 times. Then you will squeeze the ball briefly for thirty times.

8. Following the exercise practice, you will be given the chance to ask any questions or clarify any aspect of the exercise you don't understand. You will be given a weekly log sheet and the researcher will show you how to fill it in. You will use this log sheet at home to record when you carry out the exercises and can also make comments regarding any difficulties you experience each time you carry them out.

IV.***Exercise programme***

9. For 6 weeks following the assessment session, you will be required to complete the exercise you practised after the assessment session (either jaw opening exercise or ball squeezing exercise) 3 times per day. Each daily session should take no more than 10 minutes and involve 30 repetitions of brief exercise and 3 repetitions of sustained exercise. You will be required to record each session on your weekly log sheet.

10. The researcher will contact you once per week to answer any questions that you may have about the exercise.

Outcome measurements

11. After four and six weeks of the exercise programme, you will be required to attend an assessment session at the Van der Veer Institute at a time that suits you. The procedure for these sessions will be the same as that described in steps 3-6.

12. The whole research project should take approximately 30 hours of your time, over 6 weeks.

Risks and Benefits:

For healthy participants enrolled in the study, there are no direct benefits to you as an individual although you will receive $20 as reimbursement for travel expenses. You will be part of a study that contributes important information on how exercise influences the nerves and muscles that control swallowing. This information will, in turn, assist with the development of improved treatment techniques for swallowing disorders.

There are no risks associated with participation in the study. Though not expected, you will be monitored very carefully by the researchers for any negative outcomes arising from your participation in this study. The Van der Veer Institute has equipment for dealing with medical emergencies.

Participation:

If you agree to take part in this study, you are free to withdraw at any time, without having to give a reason.

Confidentiality:

Research findings will be presented at international research meetings and submitted for publication in peer reviewed journals. Additionally, research findings will be made available to the local Canterbury medical community through research presentations and regional forums. However, no material which could personally identify you will be used in any reports on this study. Consent forms will be kept in a locked filing cabinet in the locked Swallowing Research Laboratory or will be stored on password-protected laboratory computers. Research data will be stored for a period of ten years after data collection is complete, at which time they will be destroyed. With your permission, data from this study may be used in future related studies, which have been given ethical approval from a Health & Disability Ethics Committee

Results:

If requested, you will be offered copies of the publications that arise from this research. However, you should be aware that a significant delay may occur between completion of data collection and completion of the final report. Alternatively, or in addition, you can choose to have the results of the study discussed with you personally by the lead investigator.

Compensation:

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention

Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

Questions:

You may have a friend, family, or whanau support to help you understand the risks and/or benefits of this study and any other explanation you may require.

Please contact the primary researcher, Maggie-Lee Huckabee, if you require any further information about the study.

If you need an interpreter, this can be provided.

If you have any queries or concerns about your rights as a participant in this study, you may wish to contact a Health and Disability Advocate, telephone:

South Island 0800 377 766 or (03) 377 7501 in Christchurch. Free Fax (NZ wide): 0800 2787 7678 (08002SUPPORT) Email (NZ wide): advocacy@hdc.org.nz

This study has received ethical approval from the Upper South A Regional Ethics Committee.

Appendix F

Questionnaire for Participants

UC UNIVERSITY OF CANTERBURY Te Whare Wānanga o Waitaha CHRISTCHURCH NEW ZEALAND

VAN DER VEER INSTITUTE for Parkinson's & Brain Research

QUESTIONNAIRE

The effects of a jaw-opening exercise on suprahyoid muscles and hyoid movement during swallowing in healthy adults

Identification number:_____________________ Age:

Which ethnic group do you belong to?

☐ New Zealand European
☐ New Zealand Maori
☐ Samoan
☐ Tongan
☐ Chinese
☐ Indian
☐ Niuean
☐ Cook Islands Maori
☐ Other ______________________________

Please complete the following questionnaire by ticking the box that is most applicable to you.

Do you suffer from the effects of any of the following medical problems?

☐ Stroke
☐ Swallowing difficulties
☐ Head and/or neck injury
☐ Head/ and/or neck surgery
☐ Gnashing teeth
☐ Gastroesophageal Reflux Disease
☐ Problems with jaw or mandible
☐ Neurological disorders (e.g. Multiple Sclerosis etc.)

Are you currently taking any medications that may affect your swallowing?

Yes / No (Please circle one)

If yes, please describe

____

____

☐ Do you have any other medical problems which you feel may impact on your ability to participate (e.g., inability to understand instructions)?

Yes / No (Please circle one)

If yes, please describe

____

____
____

Throughout the project, the primary investigator will contact you twice per week, to answer any questions that you may have about the exercise you have been given. Would you prefer that the investigator contact you: (please tick one)

☐ By phone
Ph:_________________________________

☐ By email
Email address: _______________________

☐ By text message
Mobile no.___________________________

☐ Other (e.g. facebook)
Please state__________________________