Using GU Liquid Energy Gel as a Fatigue Management Tool for Dysphagia Therapy

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Abstract

Dysphagia is a medical disorder characterized by difficulty swallowing. It is associated with a high rate of morbidity and mortality in the United States. The aim of this study is to investigate the efficacy and feasibility of incorporating GU Liquid Energy Gel into dysphagic therapy protocols to enhance swallowing function, reduce fatigue, and improve patient outcomes. The first stage of this line of inquiry focused on individuals with normal swallowing function. The participants were divided into three groups, with two receiving guaiac acid (GU) without caffeine and rest, one receiving GU with caffeine and rest, and one receiving only rest. The results of the study yielded interesting findings and aimed to determine if this particular gel could prove to be a valuable tool in managing fatigue during swallow therapy sessions. This suggests that GU may have the ability to provide sustained energy, potentially reducing fatigue and improving endurance during the therapy session. The use of GU as a supplement holds promise in improving patient outcomes and enhancing the overall effectiveness of treatment.

CHAPTER I

INTRODUCTION

In the realm of dysphagia therapy, managing fatigue is paramount to enhancing treatment efficacy, as it plays a critical role in maintaining focus and muscular endurance during swallowing exercises (Christmas & Rogus-Pulia, 2019). Energy gels, which have demonstrated utility among athletes due to their easily digestible source of carbohydrates, proteins, fats, electrolytes, amino acids, and sometimes caffeine (Savage, 2011), emerge as a promising intervention for dysphagic patients. Specifically, formulated energy gels containing maltodextrin and fructose provide both immediate and sustained energy release; maltodextrin rapidly converts to glucose for instant muscle fuel while fructose ensures prolonged energy availability through slower absorption (Gu & Lodge, 2011).

The inclusion of caffeine further bolsters muscular strength and endurance potentially improving performance during therapy sessions. Of particular note is the innovation involving nanoparticles within these gels that facilitate controlled energy release by interacting with metabolic processes to convert stored energy efficiently(Li et al., 2023). Given that nectar-thick consistencies are appropriate for dysphagic patients (Garcia et al., 2005), these advanced formulations not only address nutritional needs but also combat the detrimental effects of fatigue during dysphagia therapy. By providing an efficient source of readily available energy, these gels may support sustained focus and muscular endurance among patients undergoing therapy. Thus, this study aims to explore the efficacy of liquid energy gels in optimizing patient

performance throughout simulated therapy sessions by maintaining steady energy levels and mitigating fatigue's impact on therapeutic outcomes.

CHAPTER II

LITERATURE REVIEW

Swallowing

Swallowing is an essential and complex behavior that normally develops early in life. Swallowing is defined as the semiautomatic motor action of the muscles of respiratory, oropharyngeal, and pathophysiological mechanisms (Panebianco et al., 2020). A normal swallow normally occurs in four phases. These phases are the oral preparatory phase, the oral propulsive phase, the pharyngeal phase, and the esophageal phase. The oral preparatory phase is when food or a liquid is manipulated in the oral cavity until a bolus is formed. The bolus is sealed with the tongue to the hard palate. This leads to the oral propulsive phase. In this phase, the tongue moves the bolus toward the back of the mouth. To achieve this the tongue pushes the bolus against the hard palate and squeezes the bolus posteriorly. These two stages are voluntary, not reflexive, actions. The next stage is the pharyngeal phase. During this stage, the swallow reflex is triggered and the bolus is carried through the pharynx. The following actions coincide: (a) the velopharyngeal port is closed; (b) the bolus is propelled towards the upper esophageal sphincter; (UES) (c) the larynx elevates as the epiglottis, false vocal folds, and true vocal folds close to sealing the airway; and (d) the UES relaxes to allow the bolus to enter the esophagus. Finally, during the esophageal phase, the bolus is transported through the esophagus to the stomach (Shipley & McAfee, 2021).

The first three phases of swallowing have the most interest for a speech-language pathologist (SLP). If there are any problems with the final phase of swallowing, a gastroenterologist or other medical professional will need to treat the patient (Christmas &

Rogus-Pulia, 2019). Also, anatomical structures involved in swallowing change and mature as individuals age. Every individual's structure will mature and develop at different rates (Shipley & McAfee, 2021).

Dysphagia

Dysphagia is defined as difficulty swallowing. This condition can occur at any age, but it is most common in infants and older adults. A person with dysphagia may need to use more effort and time when swallowing. The primary complaint with dysphagia is that swallowing can be painful or extremely difficult (Auday, 2015). People with dysphagia often say that it feels like food is stuck in their throat or their chest. Dysphagia can lead to severe issues if it is left untreated. These can include malnutrition, dehydration, and respiratory infections such as pneumonia (Shipley & McAfee, 2021).

Etiology of Dysphagia. The causes of dysphagia can be broadly classified into two categories: mechanical/structural and neurological. Mechanical/structural causes encompass structural abnormalities or obstructions in the throat or esophagus, which may include the presence of tumors, strictures, or foreign objects (Rubenstein, 2007). Furthermore, it is noteworthy that certain medications or medical procedures, such as radiation therapy or surgery, can also contribute to swallowing difficulties experienced by certain individuals (Langmore & Krisciunas, 2010). On the other hand, neurological causes of dysphagia involve challenges associated with the nerves and muscles responsible for the intricate process of swallowing. Neurological dysphagia arises from various conditions such as stroke, Parkinson's disease, multiple sclerosis, and amyotrophic lateral sclerosis (ALS), all of which significantly impact the coordination and strength of the muscles involved in the act of swallowing. As a result, these conditions impede the seamless functioning of the swallowing mechanism, leading to the

manifestation of dysphagia (Panebianco et al., 2020). In addition to medical factors, certain lifestyle choices can also influence dysphagia development. Inadequate oral hygiene practices, smoking, or excessive alcohol consumption have the potential to contribute to the onset of dysphagia. These lifestyle factors, if not properly managed, can exacerbate the frequency and severity of dysphagia symptoms experienced by affected individuals (Christmas & Rogus-Pulia, 2019).

Types of Dysphagia. There are several different types of dysphagia. It can be classified into four categories, based on the location of the swallowing impairment: oropharyngeal, esophageal, esophagogastric, and paraesophageal. These four types occur separately, but they are part of a continuous anatomical system (Christmas & Rogus-Pulia, 2019).

Oropharyngeal dysphagia. This is characterized by difficulty in transferring the food bolus from the oral cavity to the cervical esophagus, a condition with significant implications for swallowing mechanics and patient safety. Symptoms manifest during the initial phase of swallowing when patients experience a sensation or actual occurrence of food sticking within the oral cavity or neck region. This dysfunction not only impedes efficient bolus propulsion but may also lead to complications. Critical to understanding this dysphagia type are deficits in pharyngeal residue clearance and laryngeal elevation, both of which exacerbate symptoms and compromise airway protection. Pharyngeal residue is the result of incomplete bolus transit through the pharynx. This often results from inadequate muscular contraction or coordination during swallowing. (Christmas and Rogus-Pulia, 2019). Insufficient laryngeal elevation can prevent effective epiglottic closure over the trachea. This heightens the likelihood of aspiration events (Wolf, 1990).

Esophageal dysphagia. This occurs when there is difficulty with the passage of a solid or

liquid bolus through the esophagus in the region between the upper and lower esophageal sphincter. It results from either abnormal motility of the segment of the esophagus or physical deficiency to the passage (Christmas & Rogus-Pulia, 2019). The mechanism requires a smooth, coordinated muscular contraction along with muscular relaxation in adjacent segments. Otherwise, the swallow may be disordered. Symptoms will depend on the etiology of the esophageal disturbance (Wolf, 1990).

Esophagogastric dysphagia. This occurs when there is an obstruction of the passage of a bolus from the lower esophageal sphincter into the gastric fundus due to motor or physical deficiency. This dysphagia type creates the sensation of food sticking at the lower end of the sternum (Christmas & Rogus-Pulia, 2019). Other symptoms of motility disorders may include odynophagia as well as chest pain resulting from forceful non propulsive esophageal contractions (Wolf, 1990).

Paraesophageal dysphagia. This occurs when there is either physical impingement on the esophageal wall or infiltration of the esophageal wall leading to a physical deficiency. If the person's dysphagia is severe, there may be a secondary motor effect on the esophagus (Christmas & Rogus-Pulia, 2019). This can lead to a painful sensation in the sternum and chest area and can cause a person to be extremely reluctant to swallow (Wolf, 1990).

Assessment for Dysphagia. Dysphagia requires a comprehensive examination in order to be diagnosed. The initial step in assessing dysphagia is the clinical bedside assessment, which serves as a primary means of evaluation. This method involves the evaluator closely observing the patient's swallowing functionality. It encompasses conducting an oral motor examination, evaluating the patient's cranial nerve function, and assessing their ability to tolerate different food consistencies (Raj & Martina, 2022). Patient-reported outcome measures, such as the

Dysphagia Handicap Index (DHI)(Silbergleit et al., 2012) and the EAT-10 (Belafsky et al., 2008) provide valuable insights into the subjective experiences of patients, empowering healthcare professionals to gauge the impact of dysphagia on the patient's overall quality of life. These measures consist of questionnaires and surveys that systematically assess the patient's perception of swallowing difficulties, dietary restrictions, and level of satisfaction with their ability to swallow (Shipley & McAfee, 2021).

Modified Barium Swallow Study. A modified barium swallow test is also known as a video-fluoroscopic swallow study (VFSS). This evaluation tool holds great importance in assessing individuals with dysphagia, a condition characterized by difficulties in the act of swallowing. During a VFSS, a person ingests substances of varied consistencies coated with barium sulfate, a radiopaque contrast agent. The ingestion occurs under real-time x-ray visualization, allowing for dynamic assessment of the swallowing mechanism from the mouth through the pharynx and into the esophagus. As these barium-coated materials move through the oral and pharyngeal phases of swallowing, clinicians observe their passage to identify any abnormalities or dysfunctions in coordination and timing that might indicate aspiration risks or other swallow-related pathologies. (Bastian, 1991) This analysis facilitates not only an understanding of structural abnormalities but also functional impairments that may impact feeding strategies or require therapeutic intervention. (Fynes et al., 2019)

While it is widely employed in clinical settings, it is crucial to thoroughly consider the advantages and disadvantages of this diagnostic method. One notable advantage of the barium swallow test is its capability to provide an instantaneous visualization of the swallowing process. This invaluable feature allows healthcare professionals to identify and analyze specific abnormalities or dysfunctions in the mechanism of swallowing. By utilizing dynamic imaging

techniques, structural anomalies such as strictures or tumors can be detected, along with functional impairments like aspiration or delayed swallowing reflex. Additionally, the modified barium swallow test assumes a pivotal role in assessing the severity of dysphagia and guiding the development of precise treatment plans (Bastian, 1991). However, it is important to recognize the limitations associated with the modified barium swallow test. It is crucial to acknowledge that this test may not present a completely accurate portrayal of the patient's capacity for swallowing. The controlled environment in which the test is conducted may not perfectly replicate the genuine eating conditions experienced by the individual. Additionally, the procedure may not be suitable for patients with a known barium allergy to determine why aspiration is occurring. Furthermore, the modified barium swallow test is unable to provide information about the microscopic changes occurring in the esophagus, such as inflammatory or neoplastic processes (Fynes et al., 2019).

Fiberoptic Endoscopic Evaluation of Swallowing (FEES). Fiberoptic endoscopic evaluation of swallowing (FEES) is a procedure commonly used to assess swallowing disorders in patients. It is a minimally invasive procedure and involves passing a flexible endoscope through the nasal passage to visualize the swallowing process. This allows for observation of swallowing function while the endoscope is placed in the pharynx. This non-invasive nature of FEES makes it a suitable option for patients who cannot tolerate the barium-based contrast materials used in VFSS (Jaafaripooyan, 2014). Additionally, FEES allows for real-time visualization of the pharyngeal phase of swallowing, providing valuable information about the presence of penetration or aspiration. This capability is particularly beneficial in identifying silent aspiration, where patients do not exhibit overt signs of swallowing difficulty. Furthermore,

FEES can be performed at the bedside, eliminating the need for patient transportation to radiology departments, resulting in potential cost savings (Jaafaripooyan, 2014).

However, FEES has its drawbacks as well. One notable limitation is that it does not provide a comprehensive assessment of the oral phase of swallowing, as the procedure focuses primarily on the pharyngeal phase. This limitation may hinder the ability to identify certain swallowing abnormalities that originate in the oral cavity. Additionally, FEES requires specialized training and expertise to perform and interpret accurately. As a result, it may not be readily available in all healthcare settings, limiting its accessibility (Jaafaripooyan, 2014).

General Treatment for Dysphagia. Acquiring a comprehensive understanding of the underlying factors, noticeable indications, and accurate diagnosis of dysphagia carries significant importance when it comes to formulating effective treatment strategies. In the management of dysphagia, non-invasive treatment methods such as exercises and therapies aim to improve swallowing function and thereby enhance overall swallowing safety (Christmas & Rogus-Pulia, 2019). Furthermore, the incorporation of advanced treatment approaches, including medications and surgical interventions, shows great potential in providing viable solutions for individuals suffering from severe dysphagia. By exploring these diverse treatment options, individuals with dysphagia can find relief and regain their ability to swallow comfortably and securely (McCabe et al., 2009).

Dietary Systems and Restrictions. Dysphagia has a specialized diet protocol to assist with treatment and lower patients' risk of aspiration. There are several stages in the dysphagia diet framework that patients move through while progressing in treatment. This diet involves altering the texture and consistency of food and liquids to facilitate swallowing. This system includes thickening liquids and only giving patients mechanical soft foods or pureed foods. The

International Dysphagia Diet Standardisation Initiative (IDDSI) is commonly used to determine the diet modification level a person needs. The IDDSI framework standardizes terminology and provides definitions and testing procedures to guide individuals with dysphagia and their health professionals, and anyone involved in meal preparation for those with dysphagia. The IDDSI has eight color-coded levels, which are numbered and labeled to describe the textures of drinks and food. These levels range from a regular diet with no thickener in a person's drink to a puree diet and thickened honey-thick liquid (Wu et al., 2022). This can help reduce a person's risk of aspiration and, with consistent, proper swallowing therapy, a person can progress through the levels (Christmas & Rogus-Pulia, 2019).

Exercises. The Mendelsohn maneuver has become well-known and widely recognized as an effective technique in addressing dysphagia. Its prominence stems from its ability to significantly improve swallowing function. This maneuver involves intentionally prolonging the elevation of the larynx during the swallowing process, which in turn extends the duration and scope of the opening of the UES. The commendable outcomes associated with performing the Mendelsohn maneuver include enhanced UES opening, reduced residue in the pharynx, and improved bolus clearance. The positive effects are attributed to the maneuver's capacity to amplify laryngeal excursion and enhance the coordination between the laryngeal and pharyngeal muscles. The Mendelsohn maneuver enhances swallowing efficiency and reduces the likelihood of aspiration pneumonia in patients with dysphagia. By prolonging laryngeal elevation, this technique enables a more controlled and efficient swallowing mechanism, thereby minimizing the risk of food or liquid entering the airway (Zhang et al., 2021).

Another exercise that proves effective in the treatment of dysphagia is the effortful swallow. The principle underlying this exercise revolves around exerting deliberate force and

effort during the act of swallowing. Its ultimate purpose is to bolster the strength and coordination of the swallowing muscles, leading to improved swallowing function. The effortful swallow exercise has demonstrated enhancements in swallowing function and a reduced risk of aspiration in individuals suffering from dysphagia. Additionally, it is reported that this exercise is generally well-tolerated and safe (Park et al., 2012). Both the Mendelsohn maneuver and the effortful swallow exercise specifically target the muscles and coordination patterns involved in the swallowing process. These exercises promote increased strength, coordination, and control, enabling individuals to overcome dysphagia and regain optimal swallowing function (McCabe et al., 2009).

Biofeedback

Biofeedback is used in swallowing therapy to provide patients with real-time information about their physiological responses in order to improve their swallowing function, thus allowing them to have greater control over these responses (Crary et al., 2004). In the context of swallowing function, biofeedback can be used to train patients to improve their swallowing technique and coordination. By providing visual or auditory feedback on specific muscle movements and timing, biofeedback enables patients to identify and correct any deficiencies in their swallowing function. This real-time feedback loop promotes a heightened sense of awareness and control over the swallowing process, leading to improved motor function and overall rehabilitation outcomes (Nelson, 2007). Biofeedback can also be used to enhance neuromuscular reeducation and strengthen the muscles involved in swallowing. The ability to visualize and monitor muscle activity during swallowing exercises allows patients to better understand the targeted muscle groups and optimize their rehabilitation efforts (Crary et al.,

2004). With this in mind, biofeedback would also allow patients and their healthcare providers to observe when a patient begins to fatigue in therapy.

Surface electromyography (sEMG)

Surface electromyography (sEMG) is a non-invasive technique that measures the electrical activity of muscles involved in swallowing. sEMG involves placing electrodes on the skin to measure muscle activity. sEMG can be used to monitor changes in swallowing function over time and assess the effectiveness of rehabilitation interventions. By providing objective measurements, sEMG can complement other clinical assessments and provide valuable biofeedback into the underlying neuromuscular mechanisms involved in swallowing (Poorjavad et al., 2019). The sEMG data can be visualized and displayed to the patient in real-time, allowing them to observe their muscle activity and make adjustments accordingly (Crary et al., 2004).

However, sEMG has some limitations. Firstly, the placement of the electrodes can affect the accuracy of the measurements, and incorrect electrode placement can lead to inaccurate results. Additionally, sEMG only provides information about muscle activity and does not capture other important aspects of swallowing such as bolus flow or pressure. Nonetheless, by detecting and analyzing the electrical activity of muscles, sEMG aids in the identification of swallowing disorders and helps guide the development of targeted interventions (Carnaby-Mann & Crary, 2010).

Fatigue

Given the demanding nature of repeated swallowing activities, which require the coordination of over 30 muscles and multiple cranial nerves, patients with dysphagia often experience fatigue when doing swallowing rehabilitation therapy (Brates et al., 2022). Fatigue can significantly disrupt productivity levels. When individuals experience fatigue, they often

struggle to concentrate and maintain a focus on tasks, leading to decreased efficiency and output. Fatigue can have detrimental effects on mood as well. Individuals experiencing fatigue are more likely to experience negative emotions such as irritability, frustration, and low motivation. These negative emotions can further contribute to decreased productivity (Huffman et al., 2021). The emotional burden of coping with swallowing difficulties often exacerbates feelings of fatigue and can lead to a diminished sense of well-being and motivation (Brates et al., 2022)

Fatigue can present a challenge during swallowing therapy sessions and impact the effectiveness and efficiency of treatment. This includes the physical demands of the therapy itself, such as repetitive exercises and muscle strengthening activities. This can lead to muscle fatigue and lower muscular outputs throughout a person's daily activities. Physical demands during swallowing rehabilitation therapy are not limited to the specific exercises targeting the swallowing mechanism but often include overall physical conditioning that aids in maintaining muscle strength and coordination (Brates et al., 2022). As previously noted, fatigue can result in decreased muscle endurance which can lead to decreased motivation and engagement in therapy sessions. This can further hinder progress and prolong the treatment duration (Christmas & Rogus-Pulia, 2019).

Caffeine and Fatigue

Caffeine ingestion has been shown to enhance performance by increasing endurance and muscle activation without necessarily leading to greater central or peripheral fatigue in athletes (Andrade et al., 2022). While these findings are promising, their applicability to individuals with dysphagia remains complex. Caffeine has also been shown to temporarily alleviate the sensation of fatigue, thus potentially improving compliance with therapy sessions (Andrade et al., 2022). Caffeine might offer a short-lived solution by temporarily boosting alertness and reducing

perceived exertion (Pakulaka et al., 2022) This burst of alertness and temporary relief of fatigue can lead to a person with dysphagia having more productive swallow therapy sessions. It can also help counter the negative emotions associated with fatigue (Huffman et al., 2021).

GU Liquid Energy Gel

The GU Liquid Energy Gel has gained significant popularity among athletes. The GU Liquid Energy Gel contains several key ingredients: maltodextrin, fructose, and electrolytes; some formulations also contain caffeine. Maltodextrin, a complex carbohydrate, rapidly breaks down into glucose, providing immediate access to energy for the muscles. Conversely, fructose, a simple sugar, is absorbed at a slower rate, sustaining energy levels over prolonged periods. The combination of maltodextrin and fructose in the GU Liquid Energy Gel ensures a continuous release of carbohydrates into the bloodstream, effectively fueling the body during extended physical exertion. Additionally, this gel incorporates essential electrolytes such as sodium and potassium, facilitating proper hydration maintenance and preventing muscle cramps (Gu & Lodge, 2011).

One aspect of the GU Liquid Energy Gel is its inclusion of nanoparticles, meticulously designed to release energy in a controlled manner. These nanoparticles consist of a unique blend of materials, including phene and transition metal dichalcogenides. Due to their nanoscale structure, these materials enable efficient energy transfer and storage. Upon consumption, the gel undergoes breakdown in the digestive system, releasing the nanoparticles. These nanoparticles then interact with the body's enzymes and metabolic processes, aiding in the conversion of stored energy into a form readily utilized by the muscles (Li et al., 2023). The GU Liquid Energy Gel could prove to be a valuable tool in managing fatigue during swallow therapy sessions. With its

exceptional formulation, it provides a rapid and efficient energy source, allowing individuals to sustain their energy levels and optimize their performance.

Purpose of the Study

This study aims to explore whether the incorporation of GU Liquid Energy Gel can be an effective strategy for managing fatigue during swallowing therapy sessions, hypothesizing that it will help individuals maintain their energy levels and enhance treatment efficacy. Swallowing therapy often demands high levels of sustained energy and concentration, leading to fatigue that can compromise the effectiveness of these sessions. By integrating GU Liquid Energy Gel into the therapy regimen, therapists could potentially optimize patient energy levels, allowing them to engage in longer and more productive sessions. The gel's composition, designed for rapid absorption and sustained release of carbohydrates and electrolytes, is expected to mitigate energy dips during therapy. Enhanced energy levels would not only improve patient performance but also foster greater compliance with prescribed exercises and consistency in attending scheduled sessions due to reduced feelings of exhaustion. This approach aligns with a holistic view of patient care which focuses on improving physical endurance while concurrently uplifting overall well-being. This is essential for long-term success in dysphagia rehabilitation programs. Therefore, this study holds promise not just in improving the immediate outcomes of swallowing therapies but also in promoting long-term adherence through better fatigue management. The results from this study will be used to answer the following questions:

(1) Will the use of Gu Liquid Energy Gel with caffeine improve peak muscle activity during the effortful swallow in healthy young participants?

(2) Will the use of Gu Liquid Energy Gel without caffeine improve peak muscle activity during the effortful swallow in healthy young participants?

(3) Will the use of Gu Liquid Energy Gel with caffeine improve duration of laryngeal elevation during the Mendelsohn maneuver in healthy young participants?

(4) Will the use of Gu Liquid Energy Gel without caffeine improve duration of laryngeal elevation during the Mendelsohn maneuver in healthy young participants?

Based on these questions, the following hypotheses were developed:

(1) The use of Gu Liquid Energy Gel with caffeine will improve peak muscle activity during the effortful swallow in healthy young participants.

(2) The use of Gu Liquid Energy Gel without caffeine will improve peak muscle activity during the effortful swallow in healthy young participants.

(3) The use of Gu Liquid Energy Gel with caffeine will improve duration of laryngeal elevation during the Mendelsohn maneuver in healthy young participants.

(4) The use of Gu Liquid Energy Gel without caffeine will improve duration of laryngeal elevation during the Mendelsohn maneuver in healthy young participants.

CHAPTER III

METHODS

Participants

The approval for this study from the Valdosta State University Institutional Review Board is provided in Appendix A. All of the participants completed the informed consent form and study questionnaire (see Appendices B and C). Six women between the ages of twenty to twenty-eight years volunteered to participate in the study. All participants were enrolled as graduate students in the Communication Sciences and Disorders program at Valdosta State University. Participants were in good general health with no history of respiratory or psychological disorders. All participants regularly drank caffeine, ranging from one to seven drinks per week. Additionally, all of the participants had similar activity levels, builds, and body mass. Any individual who reported a differing activity level or who had a noticeably different build or body mass from the majority of the participants were excluded from the study.

Two of the participants, one who received a caffeinated gel and one who served as a control, have a history of ADHD. The control participant was noted to manage her ADHD via medication and claimed to be medicated the day of her testing. She was also not noted to be overly distracted or active during her session. The experimental participant reported that she did not manage her ADHD with medication but seemed to maintain her attention for the majority of the session and was easily redirected back to the testing with minimal prompting.

Procedures

All participants were reminded, via text message, twenty-four hours prior to testing of the test time and location. Participants were asked to meet the researchers at the Valdosta State University Health Sciences and Business Administration building on testing dates at previously agreed upon times. All of the participants were tested between 1P.M. to 2 P.M. during a weekday. Participants were tested at approximately the same times during the day due to people's fatigue levels fluctuating throughout the day (Brates et al., 2022). Participants had to be tested on different days of the week (Monday-Thursday), due to all of the participants being graduate students at the time of the study and having widely varying availability.

Participants were randomly placed into one of three groups. These groups were GU with caffeine, GU without caffeine, and the control group which did not receive GU. Each participant participated in an hour-long dysphagia therapy session; the sessions consisted of two thirty-minute increments. Before the session began, the participants were educated on how to complete the exercises via a visual model and verbal explanation of the exercises. During each thirty-minute increment, the participants completed three sets of fifteen repetitions of an effortful swallow and of the Mendelsohn maneuver. Participants were given a 1-minute rest period between sets. The first ten effortful swallows and Mendelsohn maneuvers were completed without liquid. The participants were then given five milliliters (ml) of water to complete the last five effortful swallows and Mendelsohn maneuvers. The participants were given a five-minute break between the two thirty-minute increments to rest. The participants who received GU were given either GU with or without caffeine and five ml of water during this time. The control group received five ml of water but no other substances during the break. The five-minute break

between introduction of GU and continuation of the exercises was in agreement with the directions for using the gel during exercise.

Data were gathered during the therapy session using Synchrony Dysphagia Solutions (ACP®, Nevada) integrated sEMG biofeedback equipment sEMG electrodes were placed in the suprahyoid region on the participant's throat to record muscle activity. Measurements of peak muscle activity during the effortful swallow task and duration of duration of laryngeal elevation during the Mendelsohn task were recorded. The data were tracked via the Synchrony equipment before being directly transcribed into and stored in an Excel spreadsheet.

Variables

Independent variables for this study included the GU and caffeine. The dependent variables in this study were the biofeedback measures of the microvolt ranges for the effortful swallow and the sustained time for the Mendelsohn maneuver.

CHAPTER IV

RESULTS

The results of this study yielded mixed results indicating partial benefit of gel consumption during a therapy session. Participant attrition resulted in data collection being limited to four individuals: two receiving caffeinated gel, one with non-caffeinated gel, and one control participant. The results were as follows:

Effortful Swallow

As shown in Figure 1, the results of the study examining the impact of GU Liquid Energy Gel on peak muscle activity during effortful swallows revealed differential effects among the participants. The control participant maintained consistent micro-volt ranges across all trials. In contrast, participant 1 with the caffeinated GU exhibited a progressive increase in peak muscle outputs during the initial three trials before any GU gel was introduced. Upon introducing the caffeinated GU gel, her performance demonstrated a slight decline in the fourth trial, followed by a sharp decrease in subsequent trials. The second participant with caffeinated GU exhibited a slight but consistent decline in peak muscle output throughout the session, even after the introduction of caffeine. Meanwhile, the participant who received the non-caffeinated GU experienced a marked increase in peak muscle output during her sixth trial.

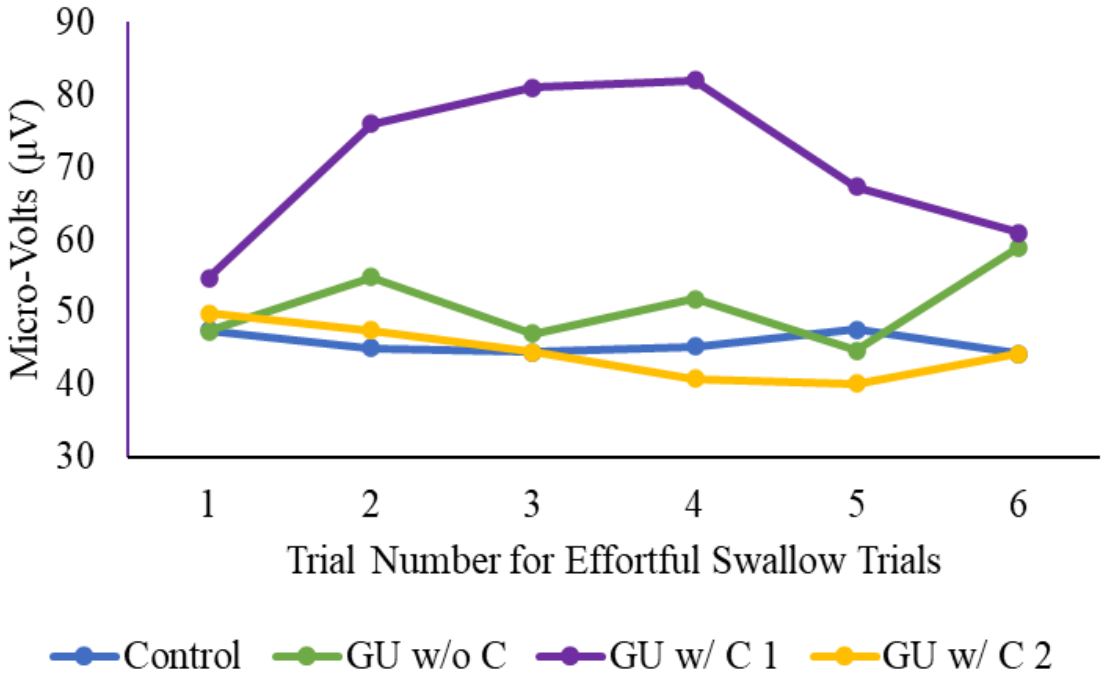


Figure 1. Peak muscle activity during effortful swallow exercise over 6 sets for the control participant, the participant with non-caffeinated GU (GU w/o C), and the two participants with caffeinated GU (GU w/ C 1 and GU w/ C 2).

Mendelsohn Maneuvers

The results of the study indicated noticeable differences during the Mendelsohn maneuver, particularly when comparing caffeinated and non-caffeinated gel interventions. As shown in Figure 2, the control participant managed to maintain laryngeal elevation between 5.19 and 5.95 seconds but displayed a decline in performance averages across repeated trials. Participant 1 with caffeinated GU was moderately consistent across sets until set 6, when she experienced a marked decline in duration; notably, this was after the introduction of the caffeinated GU. In contrast, participant 2 with caffeinated GU achieved the longest durations of all participants, ranging from 5.97 to 7.05 seconds. She exhibited a sharp decrease in duration during set 3 but demonstrated a mild increase for the remaining 3 sets after the introduction of

the caffeinated GU. In contrast, the participant with non-caffeinated GU demonstrated an upward trend for the last two sets following a mild decline observed in the middle 2 sets.

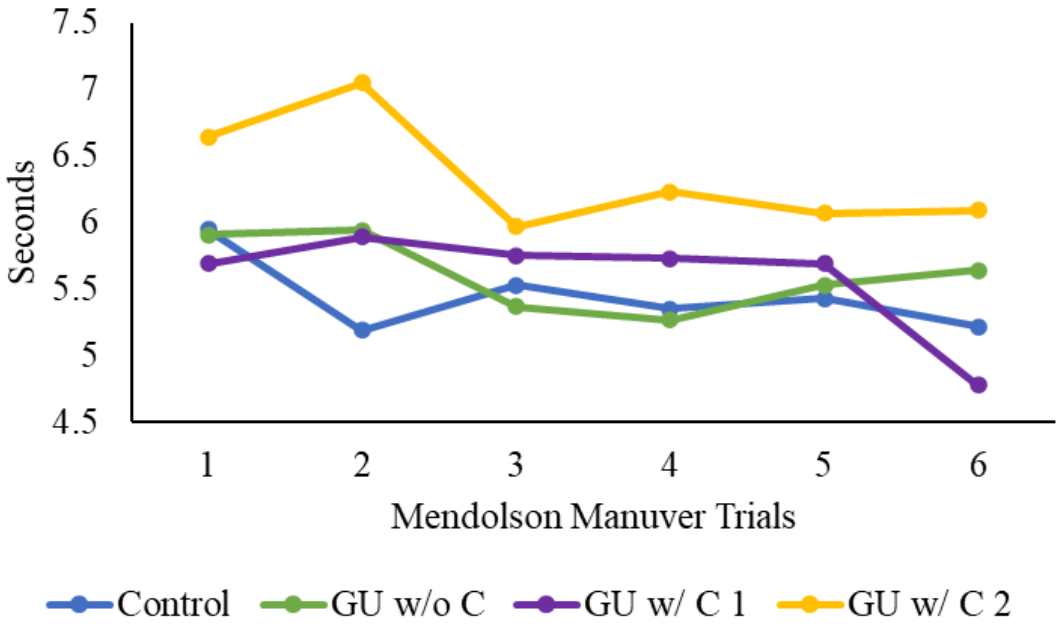


Figure 2. Peak muscle activity during effortful swallow exercise over 6 sets for the control participant, the participant with non-caffeinated GU (GU w/o C), and the two participants with caffeinated GU (GU w/ C 1 and GU w/ C 2).

CHAPTER V

DISCUSSION

This study investigated the effects of GU Liquid Energy Get on two parameters frequently measured during dysphagia therapy sessions. The results of this study provide partial support for the hypotheses previously generated, as discussed below.

Relationship to Data to Hypothesis

The first hypothesis stated that participants would exhibit increased peak muscle activity during the effortful swallow after consuming non-caffeinated gel. The results of the study support this hypothesis as the participant who was given non-caffeinated GU demonstrated an increase in peak muscle activity during the sixth trial, implying a delayed yet pronounced effect of energy supplementation without caffeine on muscular endurance at later stages of exertion.

The second hypothesis stated that participants would exhibit increased peak muscle activity during the effortful swallow after consuming caffeinated gel. The results of the study partially support this hypothesis. Participant 1 with the caffeinated GU exhibited a progressive increase in peak muscle output during the initial three trials before any GU gel was introduced. Upon introducing the caffeinated GU gel, her performance demonstrated a slight increase in the fourth trial, followed by a sharp decrease in subsequent trials. This suggests that caffeine may initially bolster muscle output but could lead to rapid fatigue or diminished returns over continued exertion. The second participant with caffeinated GU exhibited a slight but consistent decline in peak muscle output throughout the session, even after the introduction of caffeine.

These findings indicate that caffeine did not enhance muscle output but rather was associated with fatigue over continued exertion.

The third hypothesis stated that participants who received caffeinated GU would increase duration of laryngeal elevation during the Mendelsohn maneuver. The results of the study partially support this hypothesis. Participant 1 with caffeinated GU was moderately consistent across sets until set 6, when she experienced a marked decline in duration; notably, this was after the introduction of the caffeinated GU. In contrast, participant 2 with caffeinated GU achieved the longest longer durations of all participants, ranging from 5.97 to 7.05 seconds. She exhibited a sharp decrease in duration during set 3 but demonstrated a mild increase for the remaining 3 sets after the introduction of the caffeinated GU.

The fourth hypothesis stated that participants who received non-caffeinated GU would increase duration of laryngeal elevation during the Mendelsohn maneuver. The results of the study partially support this hypothesis. The participant with non-caffeinated GU demonstrated an upward trend for the last two sets following a mild decline observed in the middle 2 sets.

Interpretation

Using GU Liquid Energy Gel as a fatigue management tool in dysphagia therapy presents promising potential for enhancing patient outcomes and optimizing therapy sessions. Dysphagia often results in significant fatigue, which can impede therapeutic progress and generate frustration among both patients and therapists (McCabe et al., 2009). Designed initially for endurance athletes, GU Liquid Energy Gel integrates essential electrolytes such as sodium and potassium, which are crucial for maintaining proper hydration and preventing muscle cramps, thus facilitating sustained energy levels and optimized performance during strenuous activities (Gu & Lodge, 2011). The data from the current study suggest that GU may help reduce fatigue

and bolster endurance in healthy volunteers during dysphagia therapy sessions. Furthermore, non-caffeinated variants of the gel were associated with improved participant function by the end of therapy sessions, while the results were mixed for the caffeinated gels. The decline in performance for the one participant who consumed a caffeinated gel may be due to potential hypoglycemia triggers exacerbated by caffeine (Kuipers et al., 1990). Such findings underscore the importance of considering individual responses to caffeine and carbohydrate intake when utilizing energy gels as supplements (Watson & Kerr, 1999). Future research should incorporate comprehensive monitoring of nutritional status and blood glucose levels to refine the guidelines on timing for when to provide the supplements for maximum therapeutic benefit. The preliminary data from this study provide a valuable foundation for deeper exploration into how to optimize GU Liquid Energy Gel when managing fatigue within dysphagia therapy contexts.

Implications

Although no significant increases in percentages were observed when comparing its effects across participants, an interesting observation was made. The participants who received GU maintained their percentages at a more consistent rate compared to the control participant. This suggests that GU may have the ability to provide sustained energy, potentially reducing fatigue and improving endurance during dysphagia therapy sessions. GU is designed specifically for endurance athletes who require sustained energy during long periods of physical exertion. This makes it an ideal candidate for managing fatigue in dysphagia therapy, where patients often need to endure lengthy sessions to improve their swallowing abilities. In addition to its potential fatigue management benefits, GU Liquid Energy Gel offers convenience and ease of use. It can be easily consumed by patients with dysphagia due to its nectar-thick consistency. This makes it

a practical tool for therapists to incorporate into their therapy sessions, streamlining the process and reducing the burden on patients.

Limitations

One of the principal limitations of this study was the small number of participants, which was exacerbated by the unexpected loss of two participants, one from the control group and another who was supposed to receive the non-caffeinated energy gel. Their inability to participate was due to illness and scheduling conflicts. In addition, the researcher could only conduct one session per participant due to time limitations. This restriction potentially impacted the depth and comprehensiveness of the findings since multiple sessions would have allowed for a more thorough examination of effects over time. Furthermore, it is worth noting that some participants displayed competitive behaviors during their sessions. This competitiveness may have skewed performance metrics, thereby introducing variability that may have confounded the results.

Recommendations

This research's initial findings suggest that GU Liquid Energy Gel may hold promise as a fatigue management agent in dysphagia swallowing therapy, presenting a potential adjunctive tool for clinicians aiming to alleviate patient discomfort and improve functional outcomes. The results indicate some beneficial effects on fatigue levels; however, these investigations are limited by the small sample size and short durations of the therapy sessions. As for GU's role in dysphagia therapy to be conclusively validated, further research with larger sample participant pools and extended intervention periods are essential. These rigorous studies would not only ascertain the long-term efficacy of GU but also illuminate any possible adverse effects linked to prolonged use. Furthermore, when integrating GU into a therapeutic framework, multi-faceted

approaches warrant exploration through carefully designed clinical trials to optimize treatment protocols. By undertaking these comprehensive investigations, clinicians can make evidence-based decisions when incorporating GU into their practice, ultimately enhancing therapeutic outcomes for patients suffering from therapy-related fatigue.

Conclusions

The use of GU Liquid Energy Gel as a supplement for dysphagia therapy holds promise. Fatigue is a critical aspect of dysphagia therapy, as it can significantly impact a patient's ability to fully engage in the treatment regimen. Given the physical demands of swallowing exercises, patients often struggle with sustained participation due to exhaustion. GU, by providing a rapid and easily digestible source of energy, may mitigate these fatigue-related barriers. These data suggest that energy gels could potentially sustain or even enhance performance during dysphagia therapy sessions by maintaining or improving key metrics such as laryngeal elevation duration and overall muscle function; however, the addition of caffeine may enhance or negate this effect.

In sum, the enhanced energy supply from GU Energy Gels can empower individuals to perform swallowing exercises more effectively, thereby maximizing the therapeutic benefits. However, further research is warranted to ascertain the optimal dosage and timing for GU consumption that would best support dysphagia therapy without causing adverse effects. Additionally, investigating the long-term impacts of incorporating GU into treatment protocols will be crucial in understanding its overall efficacy in managing dysphagia. Should future studies substantiate these preliminary benefits, GU Liquid Energy Gel could emerge as a valuable adjunct in improving patient outcomes and enhancing the overall effectiveness of dysphagia therapy.

References

Andrade, V. F. dos S., Santos-Mariano, A. C., Coelho, D. B., Tomazini, F., Bertuzzi, R., Pereira, G., G., Silva-Cavalcante, M. D., & Lima-Silva, A. E. (2022). Caffeine ingestion increases endurance performance of trained male cyclists when riding against a virtual opponent without altering muscle fatigue. *European Journal of Applied Physiology, 122(8)*, 1915-1928. https://doi.org/10.1007/s00421-022-04969-5

Auday, B. (2015). Magill's literary annual 2014. *Reference Reviews*, *29*(7), 31–31. https://doi.org/10.1108/rr-05-2015-0135

Bastian R. W. (1991). Videoendoscopic evaluation of patients with dysphagia: An adjunct to the modified barium swallow. *Otolaryngology--Head and Neck Surgery: Official Journal of American Academy of Otolaryngology-Head and Neck Surgery*, *104*(3), 339–350. https://doi.org/10.1177/019459989110400309

Belafsky, P. C., Mouadeb, D. A., Rees, C .J., Pryor, J. C., Postma, G. N., Allen, J., & Leonard, R .J. (2008). Validity and reliability of the Eating Assessment Tool (EAT-10). *Annals of Otology, Rhinology, and Laryngology, 117,* 919-924.

Brates, D., Harel, D., & Molfenter, S. M. (2022). Perception of swallowing-related fatigue among older adults. *Journal of Speech, Language, and Hearing Research, 65(8)*, 2801-2814. https://doi.org/10.1044/2022_JSLHR-22-00151

Carnaby-Mann, G. D., & Crary, M. A. (2010). McNeill dysphagia therapy program: A case-control study. *Archives of Physical Medicine and Rehabilitation*, *91*(5), 743–749. https://doi.org/10.1016/j.apmr.2010.01.013

Christmas, C., & Rogus-Pulia, N. (2019). Swallowing disorders in the older population. *Journal of the American Geriatrics Society*, *67*(12), 2643–2649. https://doi.org/10.1111/jgs.16137

Crary, M. A., Carnaby Mann, G. D., Groher, M. E., & Helseth, E. (2004). Functional benefits of dysphagia therapy using adjunctive sEMG biofeedback. *Dysphagia*, *19*(3), 160–164. https://doi.org/10.1007/s00455-004-0003-8

Fynes, M. M., Smith, C., & Brodsky, M. B. (2019). The modified barium swallow study: When, how, and why? *Applied Radiology*, *48*(5), 2–7.

Garcia, J. M., Chambers, E., 4th, & Molander, M. (2005). Thickened liquids: practice patterns of speech-language pathologists. *American journal of speech-language pathology*, *14*(1), 4–13. https://doi.org/10.1044/1058-0360(2005/003)

Gu, Y., & Lodge, T. P. (2011). Synthesis and gas separation performance of triblock copolymer ion gels with a polymerized ionic liquid mid-block. *Macromolecules*, *44*(7), 1732–1736. https://doi.org/10.1021/ma2001838

Huffman, E. M., Athanasiadis, D. I., Anton, N. E., Haskett, L. A., Doster, D. L., Stefanidis, D., & Lee, N. K. (2021). How resilient is your team? Exploring healthcare providers' well-being during the COVID-19 pandemic. *American Journal of Surgery*, *221*(2), 277–284. https://doi.org/10.1016/j.amjsurg.2020.09.005

Jaafaripooyan E. (2014). Potential pros and cons of external healthcare performance evaluation systems: Real-life perspectives on Iranian hospital evaluation and accreditation program. *International Journal of Health Policy and Management*, *3*(4), 191–198. https://doi.org/10.15171/ijhpm.2014.84

Kuipers, H., Fransen, E. J., & Keizer, H.A. (1999). Pre-exercise ingestion of carbohydrate and transient hypoglycemia during exercise. International Journal of Sports Medicine, 20, 227-231. doi: 10.1055/s-2007-971122

Langmore, S. E., & Krisciunas, G. P. (2010). Dysphagia after radiotherapy for head and neck cancer: Etiology, clinical presentation, and efficacy of current treatments. *Perspectives on Swallowing and Swallowing Disorders (Dysphagia)*, *19*(2), 32–38. https://doi.org/10.1044/sasd19.2.32

Li, Z., Li, Y., Wang, Z., Wu, P., Liu, N., Liu, K., Gu, Z., Chen, Y., Nie, J., Shao, H., & He, Y. (2023). 3D-printable and multifunctional conductive nanocomposite with tunable mechanics inspired by Sesame Candy. *Nano Energy*, *108*, 108166. https://doi.org/10.1016/j.nanoen.2023.108166

McCabe, D., Ashford, J., Wheeler-Hegland, K., Frymark, T., Mullen, R., Musson, N., Smith Hammond, C., & Schooling, T. (2009). Evidence-based systematic review: Oropharyngeal dysphagia behavioral treatments. Part IV – Impact of dysphagia treatment on individuals' postcancer treatments. *The Journal of Rehabilitation Research and Development*, *46*(2), 205. https://doi.org/10.1682/jrrd.2008.08.0092

Nelson L. A. (2007). The role of biofeedback in stroke rehabilitation: Past and future directions. *Topics in Stroke Rehabilitation*, *14*(4), 59–66. https://doi.org/10.1310/tsr1404-59

Park, J. W., Kim, Y., Oh, J. C., & Lee, H. J. (2012). Effortful swallowing training combined with electrical stimulation in post-stroke dysphagia: A randomized controlled study. *Dysphagia*, *27*(4), 521–527. https://doi.org/10.1007/s00455-012-9403-3

Panebianco, M., Marchese-Ragona, R., Masiero, S., & Restivo, D. A. (2020). Dysphagia in neurological diseases: A literature review. *Neurological Sciences*, *41*(11), 3067–3073. https://doi.org/10.1007/s10072-020-04495-2

Poorjavad, M., Talebian Moghadam, S., & Ansari, N. N. (2019). Effects of the head lift exercise and neuromuscular electrical stimulation on swallowing muscles activity in healthy older adults: A randomized pilot study. *Clinical Interventions in Aging*, *14*, 1131–1140. https://doi.org/10.2147/CIA.S209055

Raj, T., & Martina, T. (2022). Informal and formal assessment of dysphagia following acute stroke. *Journal of Pharmaceutical Negative Results*, *13*, 1076–1078. https://doi.org/10.47750/pnr.2022.13.S05.169

Rubenstein, J. H. (2007). Esophageal etiologies of dysphagia: A guide for SLPS. *Perspectives on Swallowing and Swallowing Disorders (Dysphagia)*, *16*(4), 1–6. https://doi.org/10.1044/sasd16.4.1

Savage, J. (2011). Fellrnr: The science of energy gels. https://fellrnr.com/wiki/The_Science_of_Energy_Gels

Shipley, K. G., & McAfee, J. G. (2021). *Assessment in speech-language pathology: A resource manual.* Plural Publishing, Inc.

Silbergleit, A.K., Schultz, L., Jacobson, B.H., Beardsley, T., & Johnson, A.F. (2012). The Dysphagia Handicap Index: Development and validation. *Dysphagia, 27,* 46-52. doi: 10.1007/s00455-01-9336-2

Watson, J., & Kerr, D. (1999). The best defense against hypoglycemia is to recognize it: Is caffeine useful? *Journal of Diabetes Technol Ther, 1, 193-200*. doi: 10.1080/152091599317413

Wolf, D. (1990). Clinical methods: The history, physical, and laboratory examinations. *Annals of Internal Medicine*, *113*(7), 563. https://doi.org/10.7326/0003-4819-113-7-563_2

Wu, X. S., Miles, A., & Braakhuis, A. (2022). An evaluation of texture-modified diets compliant with the international dysphagia diet standardization initiative in aged-care facilities using the Consolidated Framework for Implementation Research. *Dysphagia*, *37*(5), 1314–1325. https://doi.org/10.1007/s00455-021-10393-2

Zhang, J., Wu, Y., Huang, Y., Zhang, S., Xu, L., Huang, X., Wang, X., & Huang, Q. (2021). Effect of the Mendelsohn maneuver and swallowing training in patients with senile vascular dementia complicated with dysphagia. *Journal of International Medical Research*, *49*(5), 030006052110131. https://doi.org/10.1177/03000605211013198

Appendix A

Institutional Review Board Approval

Institutional Review Board (IRB)
for the Protection of Human Research Participants

EXPEDITED PROTOCOL APPROVAL REPORT

Protocol Number: 04533-2024 **Responsible Researcher:** Dr. Mary Gorham-Rowan

Department: Communication Sciences & Disorders **Co-Investigator:** n/a

Project Title: *Inclusion of Liquid Energy Gels in Speech Therapy Sessions.*

Level of Risk: ☒ Minimal ☐ More than Minimal

Type of Review: ☒ Expedited ☐ Convened (Full Board)

Approval Categories: 4 & 6

Approval Date: 09.04.2024

Expiration Date: 09.04.2027

Consent Requirements:

- ☒ **Adult Participants – Written informed consent with documentation (signature)**
- ☐ Adult Participants – Written informed consent with waiver of documentation (signature)
- ☐ Adult Participants – Verbal informed consent (Research Statement)
- ☐ Adult Participants – Waiver of informed consent
- ☐ Minor Participants – Written parent/guardian permission with documentation (signature)
- ☐ Minor Participants – Written parent/guardian permission with waiver of documentation (signature)
- ☐ Minor Participants – Verbal parent/guardian permission
- ☐ Minor Participants – Waiver of parent/guardian permission
- ☐ Minor Participants – Written assent with documentation (signature)
- ☐ Minor Participants – Written assent with waiver of documentation (signature)
- ☐ Minor Participants – Verbal assent
- ☐ Minor Participants – Waiver of assent
- ☐ Waiver of some elements of consent/permission/assent

Comments: *Modifications must be submitted for review and approval prior to implementation.*

Approval:
This research protocol is ***approved*** *as presented. Your approved consent form, bearing the IRB approval stamp and protocol expiration date is attached. If you prefer the original stamped consent, please email tmwright@valdosta.edu and the form will be sent via inter-office mail, or you may come by the OSPRA office to obtain the original.*

Elizabeth Ann Olphie *09.04.2024*

Elizabeth Ann Olphie, IRB Administrator Date

ADDITIONAL INFORMATION FOR RESEARCHERS:

Form Revised: 07.09.2024 - tw

Appendix B

Informed Consent Form

VALDOSTA STATE UNIVERSITY
Consent to Participate in Research

You are being asked to participate in a research project entitled "**Inclusion of Liquid Energy Gels in Speech Therapy Sessions.**" This research project is being conducted by Mary Gorham-Rowan, a faculty member in the Dept. of Communication Sciences and Disorders at Valdosta State University. The purpose of this research is to determine if liquid energy gels will improve speech therapy outcomes for individuals with voice and/or swallowing problems. Your participation is entirely voluntary.

As described in more detail below, we will ask you to participate in a 1-hour therapy session of voice or swallowing exercises. After 30 minutes you will be given a rest break and may be given a liquid energy gel and water before starting the exercises again. These gels are often used by athletes to improve strength and performance. If you are unable to tolerate caffeine, sugar, or gluten, you will be given a rest break and only water before starting the exercises again. Someone in your position might be interested in participating because you know someone with voice or swallowing difficulties or you are interested in speech therapy, and the use of liquid energy gels may help individuals with voice or swallowing difficulties get better. Because there are some risks, such as not being able to tolerate the caffeine, sugar, or gluten in the gels, or fatigue from the exercises, you may not wish to participate. It is important for you to know that you can stop your participation at any time. More information about all aspects of this study is provided below.

This form includes detailed information to help you decide whether to participate in this study. Please read it carefully and ask any questions that you have before you agree to participate. Please be sure to retain a copy of this form for your records.

Procedures: You will be asked to fill out a brief questionnaire prior to participating in the study. After you have completed the questionnaire, you will be asked to participate in a voice or swallowing therapy session that will last about 1 hour. For the voice therapy session, you will be asked to hum, make different sounds, and change your pitch and/or loudness levels. For the swallowing therapy session, you will be asked to swallow numerous times during the session while your swallows are measured with a machine. The swallowing measurements are made with small chips that are placed on your neck; these chips are connected to a machine that measures muscular output. After 30 minutes of completing the exercises, you will be given a rest break and water. If you are able to and have agreed to receive a liquid energy gel, you will also be given the gel at this time. After 5 minutes, you will be asked to complete the exercises again. The total time needed for you to participate will be just over an hour.

The use of a liquid energy gel is experimental; you may choose to refuse the gel and still participate in the study.

Possible Risks or Discomfort: This is a minimal risk research study. That means that the risks of participating are no more likely or serious than those you encounter in everyday activities. You may experience mild bloating with the liquid energy gels; this bloating is temporary. You may also experience mild fatigue after the therapy sessions

If you are experiencing distress as a result of your participation in this study, please contact Mary Gorham-Rowan at 229-219-1321. Neither the researcher nor Valdosta State University has made special provision for services required to treat any distress that results from participation in this research study, beyond those normally

provided to VSU students. VSU students may request health care services from Student Health Services at 229-333-5886.

By agreeing to participate in this research project, you are not waiving any rights that you may have against Valdosta State University for injury resulting from negligence of the University or its researchers.

Potential Benefits: Although you may not benefit directly from this research, your participation will help the researcher gain additional understanding of the use of liquid energy gels as a therapeutic supplementation. Clients who participate may experience better outcomes in therapy.

Costs and Compensation: There are no costs to you and there is no compensation (no money, gifts, or services) for your participation in this research project. If you are a student, you may receive extra credit points. If you are a student and choose not to participate, you may receive extra credit points through an alternative assignment such as writing a review of a voice or swallowing therapy strategy.

Assurance of Confidentiality: Valdosta State University and the researcher will keep your information confidential to the extent allowed by law. Members of the Institutional Review Board (IRB), a university committee charged with reviewing research to ensure the rights and welfare of research participants, may be given access to your confidential information.

Any information obtained from you during the study, such as responses to the pre-enrollment questionnaire and data obtained from the therapy sessions, will be kept secured in a locked filing cabinet to which only the researcher has the key. If you are a client in the VSU Speech and Hearing Clinic, your medical information is maintained in your clinical file, which is kept in a locked filing cabinet and locked room within the clinic. For the purposes of information collected for the study, you will be identified by number only; no identifying information will be reported. Only the researcher will have access to the list of the participants. The list of participants will be kept in the secure filing cabinet with the other information from the study. The data obtained from this study may be reported as average data (your data combined with data from other participants) or by participant number; no identifying information will be included when reporting the data. After 3 years, all data will be destroyed, including any identifying information.

Voluntary Participation: Your decision to participate in this research project is entirely voluntary. If you agree now to participate and change your mind later, you are free to leave the study. Your decision not to participate at all or to stop participating at any time in the future will not have any effect on any rights you have or any services you are otherwise entitled to from Valdosta State University. If you are a student, your decision not to participate will have not affect your grades. If you are a client in the VSU Speech and Hearing Clinic, your decision not to participate will not affect your clinical care.

If you decide to withdraw from the study after data collection has been completed, your information will be deleted from the database and will not be included in the research results.

Information Contacts: Questions regarding the purpose or procedures of the research should be directed to Mary Gorham-Rowan at mmgorhamrowan@valdosta.edu. This study has been approved by the Valdosta State University Institutional Review Board (IRB) for the Protection of Human Research Participants. The IRB, a university committee established by Federal law, is responsible for protecting the rights and welfare of research participants. If you have concerns or questions about your rights as a research participant, you may contact the IRB Administrator at 229-253-2947 or irb@valdosta.edu.

Agreement to Participate: The research project and my role in it have been explained to me, and my questions have been answered to my satisfaction. I agree to participate in this study. By signing this form, I am indicating that I am 18 years of age or older. I have received a copy of this consent form.

I would like to receive a copy of the results of this study: ——Yes ——No

Mailing Address: _____

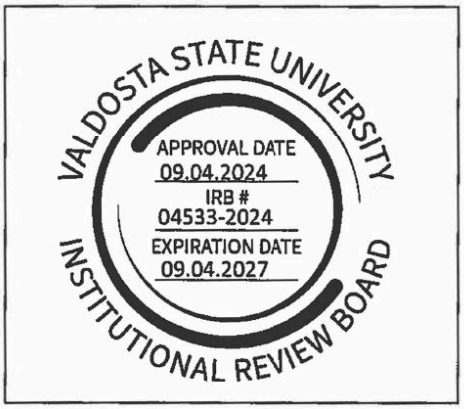
E-mail Address: _____

_____
Printed Name of Participant

_____
Signature of Participant Date

_____
Signature of Person Obtaining Consent Date

This research project has been approved by the Valdosta State University Institutional Review Board for the Protection of Human Research Participants through the date noted below:



Appendix C

Participant Questionnaire

Appendix A

Subject Questionnaire – GU-Voice/Swallowing Exercises

Subject ID #: _____ (number will be assigned by the experimenter)
Age: _____
Ht: _____ Wt: _____ BMI: _____

Rate your health compared to others your age:
(1=very good, 2=good, 3=fair, 4=poor, 5=very poor)

1 2 3 4 5

Date of last physical examination: _____

Do you have constant cold, flu, or allergies? If so, are you experiencing symptoms at the present time? Have you experience any symptoms recently?

Have you ever had surgery of the head, neck, or respiratory system? Any other major surgeries within the past 5 years?

Do you have a history of respiratory, cardiovascular, or neurologicaldisea se?

Do you presently smoke? If yes, for how long? Have you ever smoked? When did you last smoke?

Number of caffeinated drinks per week:

Are you a trained singer?

Do you use your voice professionally (i.e., as a teacher, presenter, sales, etc)?

Do you have any of the symptoms? (check all those that apply)

_____ Hoarseness (coarse or scratchy sound)
_____ Fatigue (voice tires or changes after speaking for a short period of time)
_____ Loudness disturbances (either too high or too low while speaking)
_____ Loss of range
_____ Breathiness
_____ Tickling or choking sensation
_____ Pain in the throat (inside or outside?)
_____ Voice shuts off briefly
_____ Voice changes pitch suddenly
_____ Other:_____

Are you an athlete or do you work out/exercise on a regular basis? If so, please explain:

Do you have any history of voice or swallowing difficulties?

Medical history:

****The liquid energy gel used in this study contains maltodextrin, an easily digestible carbohydrate; fructose, a form of sugar; and some varieties contain caffeine. If you have food allergies, a history of glucose sensitivity, diabetes, hypoglycemia, or caffeine intolerance, please indicate if any of the following apply:**

Do you have food allergies?	____ No	____ Yes
Do you have diabetes?	____ No	____ Yes
Do you have hypoglycemia or low blood sugar?	____ No	____ Yes
Do you have high blood pressure?	____ No	____ Yes
Do you have gluten sensitivity?	____ No	____ Yes
Do you have caffeine intolerance?	____ No	____ Yes

Do you have any other medical condition not listed on this form? If yes, please explain.