Prophylactic-Dysphagia Intervention for Patients with Head and Neck Cancer Receiving Chemoradiation Therapy

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Prophylactic-Dysphagia Intervention for Patients with Head and Neck Cancer Receiving Chemoradiation Therapy

REPORTS

By

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Bachelor of Arts, University of Montana, Missoula, Montana, 2010

Thesis Paper

Presented in partial fulfillment of the requirements for the degree of

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The University of Montana, Missoula, MT

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Abstract

Many patients with head and neck cancer suffer from dysphagia caused by organ preserving regimens of chemoradiation therapy. However, intervention for this population varies in terms of timing, intensity, and types of treatments prescribed. This prospective study investigated swallowing-related quality of life, functional oral intake, and swallowing-related pain for patients who received two different types of preventative swallowing intervention before and during chemoradiation therapy. A total of eight participants who had undergone chemoradiation therapy participated in the study. Four participants completed direct swallowing exercises (exercises that require swallowing). The remaining four completed indirect swallowing exercises (exercises that do not require swallowing). There were no significant differences between groups for all outcome measures taken. These findings support the hypothesis that both programs were equally effective intervention methods. Due to these results and the high prevalence of odynophagia in this population, indirect swallowing exercises may cause the patient less pain than direct swallowing exercises while still sparing their swallowing function to the same degree as the direct regimen. However, due to the low census and lack of a control group, these findings should be interpreted with reasonable caution. Thus, further investigation with a larger sample size and comparator control data is warranted.

*Key words: dysphagia, prophylactic intervention, head and neck cancer, chemoradiation therapy, quality of life, pain, swallowing function*
Acknowledgements

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<tr>
<td>ASHA</td>
<td>American Speech and Hearing Association</td>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>CRT</td>
<td>Chemoradiation Therapy</td>
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<tr>
<td>EAT</td>
<td>Eating Assessment Tool</td>
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<tr>
<td>EORTC</td>
<td>European Organization of Research and Treatment of Cancer</td>
</tr>
<tr>
<td>FOIS</td>
<td>Functional Oral Intake Scale</td>
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<td>HADS</td>
<td>Hospital Anxiety and Depression Scale</td>
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<td>HNC</td>
<td>Head and Neck Cancer</td>
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<td>HPV</td>
<td>Human Papillomavirus</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<tr>
<td>MBS</td>
<td>Modified Barium Swallow Study</td>
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<tr>
<td>MDADI</td>
<td>M.D. Anderson Dysphagia Inventory</td>
</tr>
<tr>
<td>PDT</td>
<td>Preventative Dysphagia Therapy</td>
</tr>
<tr>
<td>PEG</td>
<td>Percutaneous Endoscopic Gastronomy</td>
</tr>
<tr>
<td>PSS-H&amp;N</td>
<td>Performance Status Scale for Head &amp; Neck Cancer</td>
</tr>
<tr>
<td>QOL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>RT</td>
<td>Radiation Therapy</td>
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<tr>
<td>SLP</td>
<td>Speech Language Pathologist</td>
</tr>
<tr>
<td>TNM</td>
<td>Tumor Node Metastasis</td>
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<tr>
<td>UAB</td>
<td>University of Alabama at Birmingham</td>
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Table of Terminology

For the purposes of this study, the terms listed below will be defined as follows:

**chemoradiation therapy** - combined regimen of chemotherapy and radiotherapy used to treat cancer.

**compensatory strategy** - behavioral approach used to offset loss of function.

**dysphagia** - an impairment in the ability to swallow.

**functional swallowing** - deglutition without the presence of aspiration with minimal pharyngeal residue and proper bolus propulsion and timing.

**odynophagia** - painful swallowing.

**preventative dysphagia therapy** - swallowing impairment treatment given to a client prior to the presence of dysphagia.

**prophylactic care** - treatment used to prevent the spread or occurrence of disease.

**head and neck cancer** - cancerous lesions found on the lips, tongue, salivary glands, floor of mouth, gum and other mouth, nasopharynx, tonsils, oropharynx and larynx.

**rehabilitative treatment** - intervention used to restore loss of function.

**study population** - patients who will be, are, or have had chemoradiation therapy to treat their current diagnosis of head and neck cancer.

**swallowing quality of life** - quality of life outcome measures related to physiological factors such as comfort while chewing and swallowing, the ability to chew food effectively, the amount of time needed to consume meals, the amount and types of food the patient is able to consume, coughing as a result of swallowing, food sticking in the throat and mouth, the presence of sticky saliva or dry mouth, social impacts such as amount of time spent eating with friends/family or out in public, and psychological impacts such as embarrassment related to swallowing function or amount of pleasure while eating.
Chapter 1: Introduction and Literature Review

Preamble

Despite four hundred years of documented systematic study, cancer is the second leading cause of death in the United States (American Cancer Society, 2011). The American Cancer Society (2011) reports that the number of incidences of cancer has remained unchanged over the past decade; however, the number of cancer survivors in the United States is increasing. Head and neck cancer (HNC) is the sixth most common cancer worldwide. The human papillomavirus (HPV) is now one of the leading causes of HNC, whereas 40-80% of cases effecting the oropharynx are caused by HPV (Marur, D’Souza, Westra, & Forastiere, 2010).

The five-year relative survival rate for head and neck cancer (HNC) specifically, was 54.7% in 1992-1996. Later, in 2002-2006, this rate improved to 65.9% (Pulte & Brenner, 2010). As a result of the growing survival rate, the number of patients requiring treatment and rehabilitation is rising in the U.S (Siegel, Naishadham, & Jemal, 2012). This makes treatment and rehabilitation for survivors a primary health concern for medical professionals and patients alike (Groher & Crary, 2010).

As demonstrated by the increased cancer survivorship, modern treatments have resulted in improved prognosis for patients with HNC. Chemoradiotherapy (CRT), which combines regimens of chemotherapy and radiotherapy (RT), is a conventional choice for HNC intervention in current practice. Forastiere et al. (2004) determined that CRT is the leading alternative to total laryngectomy for patients with stage III and IV laryngeal cancer. This is based on their findings that overall survival was excellent following CRT, as defined by 75% living two years post-treatment. The practice of CRT has become widespread due to the shift toward organ preservation, with the notion being that organ preservation leads to the preservation of function (Smith, Kotz, Beitler, & Wadler, 2000). However, Smith, et al. (2000) warn that although organ
preservation can be achieved using CRT, protecting against the loss of function may not be inevitable, especially when discussing swallowing-related functions.

Although CRT has improved organ preservation and survival rate, many patients who receive this treatment develop significant swallowing complications (Smith et al., 2000). Groher and Crary (2010) list the following sequelae of potential swallowing related side-effects associated with CRT: mucositis, xerostomia, sensory changes to taste and smell, fibrosis (including trismus), neuropathy, odynophagia (painful swallowing), loss of appetite, edema, infection and dentition changes, such as dental carries. In a retrospective investigation, Nguyen et al. (2002) reported that 45% of the 55 patients enrolled in their study developed severe dysphagia requiring up to three months of tube feeding during or shortly after CRT. Although this study lacked baseline swallowing studies needed to rule out pre-existing dysphagia, none of the patients required tube feeding prior to CRT. Thus, patients undergoing CRT are at high risk for developing swallowing impairments often severe enough to warrant tube feeding.

Potential dysphagia symptoms include delayed trigger of the pharyngeal swallow response, decreased laryngeal elevation, impaired tongue base retraction, impaired epiglottic inversion, and increased oropharyngeal transit times (Krammer & Robbins, 2011). Additionally, patients can experience reduced frequency of swallowing and misdirection of the bolus. All of which can result in increased risk for developing aspiration pneumonia, dehydration, and malnutrition (Groher & Crary, 2010).

In addition to the medical risks, CRT can also impact quality of life (QOL) related to swallowing (Murry, Madasu, Martin, & Robbins, 1998; Smith et al., 2000). Factors that influence QOL related to swallowing include the ability to chew food effectively, the amount of time needed to consume meals, the amount and types of food the patient is able to consume, and
pleasure while eating (Kotz et al., 2012; Kulbersh et al., 2012). Murry et al. (1998) found acute decreases in health-related QOL and swallowing function shortly after initiation and throughout the administration of CRT. Due to the physiological and psychological risks related to swallowing function subsequent to CRT, dysphagia intervention has become a necessity.

Speech Language Pathologists (SLPs) are largely responsible for intervening when patients are experiencing dysphagia, including iatrogenic dysphagia caused by CRT (American Speech Language and Hearing Association [ASHA], 2001; Ashford, Logemann, & McCullough, 2012). The American Speech-Language-Hearing Association (ASHA), which governs the policies and practices of SLPs, has outlined the best practices for assessing and treating dysphagia (ASHA, 2001). One such practice includes modification of the patient’s diet. Patients with swallowing impairment are often prescribed diet modifications such as thickening liquids or food texture modifications to improve the patient’s ability to swallow safely and efficiently. Another practice involves recommending compensatory swallowing strategies during mealtime to improve diet tolerance. With increased diet tolerance, patients are more likely to meet their nutrition and hydration needs, reduce safety concerns while swallowing, such as aspiration, and improve mealtime satisfaction. These strategies are often behavior modifications and postural changes which can include the following: varying bolus size, bolus temperature, amount of time between bites, tipping the patient’s chin forward when swallowing a bolus, or rotating the patient’s head when swallowing the bolus (Groher & Crary, 2010). Also, the practice of rehabilitative measures to restore lost or under-developed swallowing function, such as prescriptive exercises, are recommended. Exercises typically target strength and/or range of motion (ROM) of swallowing related anatomy. For example, the effortful swallow is a rehabilitative exercise intended to increase tongue base retraction and pharyngeal contraction.
pressure in patients with reduced function related to tongue base and pharyngeal wall strength (Kotz et al., 2012). Additionally, education related to oral hygiene, necessary for reducing the risk of aspiration pneumonia, is regularly provided (ASHA, 2001).

These intervention methods have been shown to improve functional swallowing outcomes resulting in reduced risks associated with dysphagia, which have been observed in patients adhering to the practices recommended by ASHA. Ashford et al. (2012) reported that compensatory strategies can improve swallowing safety and effectiveness, while rehabilitation can improve nutritional status, hydration, and reduce morbidity from pneumonia. Although, conventional professional practice supports intervening once dysphagia symptoms are present, recent empirical evidence supports the use of preventative intervention prior to developing dysphagia.

Preventative dysphagia therapy (PDT) for patients with HNC receiving CRT has been shown to improve patients’ functional swallowing outcomes (Carroll et al., 2008; Hutcheson & Lewin, 2012; Kulbersh et al., 2006; Roe & Ashforth, 2011). Hutcheson and Lewin (2012) performed a review of literature on PDT for this population. Based on their findings they recommended that patients with HNC be referred to an SLP prior to the onset of CRT as standard practice of HNC management. Although, according to Hutcheson and Lewin (2012), most of the literature to date supports the use of pre-treatment dysphagia intervention to improve functional swallowing outcomes, many unanswered questions about how best to provide this type of treatment remain.

**Background and Need**

There is a need for standardized PDT protocols. Given the rise in CRT related HNC survivorship (Krammer & Robbins, 2011), and the high risk for developing dysphagia due to
CRT (Eisbruch et al., 2007), care that focuses on prevention of dysphagia in these patients is necessary (Krammer & Robbins, 2011). Current best practices lack the research needed to produce evidence-based, standardized treatment protocols (Krisciunas, Sokoloff, Stepas, & Langmore, 2012; Roe et al., 2011). Establishing best treatment practices have been problematic due to variability in research design, inclusion criteria, and dysphagia assessment; which has produced inconsistent PDT protocols between agencies for these patients (Basu et al., 2012; Krisciunas, et al., 2012; Langmore & Krisciunas, 2010; Raber-Durlacher et al., 2012; Roe & Ashforth, 2011; Roe et al., 2011). Moreover, investigators have yet to systematically quantify patient baselines using instrumental studies, apply consistent methods for quantifying results (Hutcheson & Lewin, 2012; Raber-Durlacher et al., 2012), execute multiple comparisons of different treatment programs (Ahlberg et al., 2011; Roe et al., 2011), and effectively track patient compliance (Basu et al., 2012). Specifically, Roe et al. (2011) found treatment to be heterogeneous in timing (pre-, on-, post-CRT), types of strengthening and flexibility exercise interventions, and intensity (number of times per day) of the programs. CRT also commonly causes odynophagia, or painful swallowing (Raber-Durlacher et al., 2012), which often precludes patients from continuing with an exercise protocol (Van der Molen et al., 2011). Due to these factors, there is a great need for more research on this topic.

**Statement of the Problem**

Many patients with HNC treated with CRT experience iatrogenic dysphagia. Preliminary investigations into PDT have reported improved functional swallowing outcomes, and reduced QOL impacts for this population. However, current literature varies dramatically in terms of treatment protocols, and assessment measures; thus, heterogeneous intervention practices between agencies persist. While PDT is generally supported in the literature, determination of
the most effective exercises and treatment schedule (e.g., timing, intensity) has not been established. Additionally, there is a need for further investigation on how to maximize QOL, improve patient compliance rates, and maximize long-term swallowing outcomes.

**Purpose**

This study was designed to help to manage the care of patients with HNC who are at risk for developing CRT-related swallowing impairments. Through this investigation, researchers tried to determine if a mix of ROM and strengthening swallowing exercises that did not require the patient to swallow (indirect swallowing exercises) were as equally effective as exercises that did require the patient to swallow (direct swallowing exercises). This study was also designed to ascertain whether an indirect swallowing exercise program resulted in improved QOL outcomes as compared to a direct swallowing exercise program.

**Significance to the Field**

This investigation contributed to the current body of literature dedicated to the discipline of dysphagia intervention for individuals with head and neck cancer. Participants were provided with professional, ethical, and evidence-based intervention. Furthermore, this study helped to further develop best practices for this population. It did so by using instrumental swallowing evaluations (MBS) to determine patient baselines, comparing different treatment programs (direct swallowing exercises versus indirect swallowing exercises), and calculating outcomes using established PDT assessment measures published by Van der Molen, et al. (2011) and Kotz, et al. (2012), all while tracking levels of odynophagia which is known to impede patient compliance.
Literature Review

**Assessment Measures Overview.** Dysphagia is assessed and measured in a number of ways. Both instrumental and perceptual rating scales can be used to diagnose the extent and severity of swallowing dysfunction. The MBS, for example, is an instrumental diagnostic tool administered by an SLP and often times an attending radiologist. The MBS is performed under videofluoroscopy while the patient is asked to swallow various viscosities of liquid and textures of food mixed with barium. This assessment allows the clinician to see the oropharynx, larynx, and upper esophageal functions during swallowing to help diagnose dysphagia (Groher & Crary, 2010). Additionally, there are many perceptual rating scales employed to help diagnose dysphagia. Two specific rating scales used to compute swallowing function are the Functional Oral Intake Scale (FOIS), and Eating Assessment Tool-20 (EAT-20). The FOIS is a 7-point scale used to ascertain oral intake levels associated with diet modifications and feeding tube dependency (Appendix G). The EAT-20 is another assessment tool that can be used to measure patient outcomes (Appendix H). It is a patient-reporting 20-point likert scale questionnaire used to quantify symptom severity, QOL, and treatment efficacy.

**Dysphagia Treatment Overview.** Patients with HNC who receive CRT often develop dysphagia. Traditional dysphagia treatment can include compensatory strategies, rehabilitative exercises, or a combined regimen of both. Compensatory strategies such as positioning, bolus size, and consistency modification help patients maintain control of the bolus, and reduce the risk of aspiration (Pauloski, 2008). Rehabilitative exercises targeting range of motion and strength of the impaired anatomy can improve patients’ swallowing physiology (Pauloski, 2008). For the purpose of this study, this review will focus on rehabilitative strategies.
Range of motion exercises. Patients with HNC often experience reduced ROM of swallowing-related anatomy. This includes the tongue, jaw, and laryngeal musculature which results from the scarring effects associated with surgery and RT (Pauloski, 2008). To help mitigate these impacts, lingual ROM exercises can be used to reduce the formation of fibrotic tissue in the oral cavity, which may improve pharyngeal clearance in post-surgical irradiated patients (Pauloski, Rademaker, Logemann, & Colangelo, 1998). Moreover, by targeting ROM, tongue base retraction needed to maintain adequate pharyngeal driving pressure, which assists in propelling the bolus through the pharynx when swallowing (Pauloski, 2008), can be improved. The effortful swallow, which encourages the patient squeeze all of their swallowing muscles as hard as they can when swallowing (Murphy, & Gilbert, 2009), can increase tongue base retraction. The Mendelshon maneuver and tongue clamping (Masako maneuver) are also exercises used to effectively improve pharyngeal driving pressure by increasing tongue base retraction. The Mendelsohn maneuver requires the patient to swallow followed by holding the larynx up without letting it drop following the swallow for 5 seconds per set (Murphy, & Gilbert, 2009). The Masako maneuver exercise requires the patient to place their tongue lightly between their incisors while swallowing (Murphy, & Gilbert, 2009). In addition to targeting lingual ROM, targeting jaw and pharyngeal ROM also been shown to be helpful.

Many patients experience reduced ROM of the jaw and laryngeal anatomy due to the side-effects of CRT. Unassisted stretching exercises such as actively opening, and deviating the jaw were reported to improve jaw opening for patients that experience trismus related to HNC or its treatments (chemotherapy, radiation therapy, and/or surgery) (Dijkstra, Sterken, Pater, Spijkervet, & Roodenburg, 2007). Furthermore, it has been described in the literature that laryngeal ROM exercises such as the isometric Shaker, where patients are instructed to lie on
their back lifting only their head off of the ground for at least one minute per set (Shaker, Kern, Bardan, Taylor, Stewart, Hoffman, et al., 1997), falsetto voice which requires the patient to phonate a high pitched “ee” for as long as they can (Pauloski, 2008), and Mendelsohn maneuver (Lazarus, Logemann, & Gibbons, 1993; Kahrilas, Logemann, Krugler, & Flanagan, 1991) can increase the extent and duration of laryngeal elevation and upper esophageal sphincter opening. However, the effects of the isometric Shaker, falsetto voice were not studied in this population specifically. Even though improving ROM is crucial, and achievable, increasing strength should also be included as a key intervention target.

**Strengthening exercises.** Strengthening of the tongue and laryngeal musculature can improve swallowing function outcomes for a variety of patients. Robbins et al., (2005) showed that isometric tongue strengthening exercises increased oropharyngeal pressures needed for functional swallowing and reduced the rate of laryngeal penetration of liquids (liquids entering the laryngeal vestibule) in healthy older men and women. The Shaker exercise has been shown to strengthen laryngeal elevator musculature resulting in greater opening of the upper esophageal sphincter (Shaker, et al., 1997). The effortful swallow has been shown to result in increased pharyngeal pressure amplitudes and pressure durations in healthy young adults (Hiss & Huckabee, 2005). Lazarus, Logemann, Song, Rademaker, and Kahrilas (2002) studied three patients with HNC. They reported that the effortful swallow produced slightly less pharyngeal residue than the Mendelshon maneuver, Masako maneuver, and super-supraglottic exercise where the patient holds their breath while bearing down before and during the swallow and then coughs following the swallow. The tongue retraction exercise, where patients pull their tongue to the posterior aspect of the oral cavity, is also used to improve the strength of tongue base retraction (Murphy, & Gilbert, 2009). Additionally, the Masako maneuver has been shown to
improve contact between the base of the tongue and posterior pharyngeal wall (Fujiu, & Logemann, 1996), which helps maintain the driving pressure in the pharynx when swallowing (Pauloski, 2008). Strengthening impaired swallowing musculature is beneficial in this population, nevertheless, using appropriate assessment measures to determine outcomes should bear considerable weight.

**Treatment Models.** Standardized dysphagia intervention for this population does not exist (Krisciunas, Sokoloff, Stepas, & Langmore, 2012). However, treatment has historically followed one of three trajectories. The first, and most common model is to initiate treatment once dysphagic symptoms surface (Krisciunas, Sokoloff, Stepas, & Langmore, 2012). The second option is to monitor and educate patients about the side-effects of CRT as they relate to swallowing and make determinations regarding care as the patient progresses through his CRT regimen (Roe, et al., 2011). The third option is to provide prophylactic intervention prior to the development of swallowing impairment (Krisciunas, Sokoloff, Stepas, & Langmore, 2012). This intervention model is growing in popularity.

**Prophylactic treatment.** The majority of PDT studies have shown positive results related to the use of PDT (Kulbersh et al., 2006; Carroll et al., 2008; Van der Molen et al., 2011; Kotz et al., 2012). One study, however, failed to demonstrate improved outcome measures for patients who were provided PDT (Ahlberg et al., 2011). Kulbersh et al. (2006) completed a prospective cohort study and cross-sectional QOL analysis investigating the therapeutic outcomes of PDT using the University of Alabama at Birmingham (UAB) Dysphagia Protocol. Their population included 37 patients undergoing CRT to treat newly diagnosed hypopharyngeal, laryngeal, or oropharyngeal cancer at the UAB at Birmingham. Twenty-five patients were enlisted in the PDT group where they performed the UAB Dysphagia Protocol. The protocol utilized a number of
exercises, including the Mendelsohn maneuver, isometric Shaker, isotonic Shaker, tongue hold, and tongue resistance, which were initiated two weeks prior to the onset of radiation. Some, but not all PDT patients, also performed falsetto phonation. Each exercise was performed with 10 repetitions, five times per day except for the Shaker maneuvers. The isometric Shaker was performed three times per day, and the isotonic Shaker was prescribed at a rate of 30 repetitions, five times per day. The remaining 12 non-PDT patients were enrolled in the control group. Each control patient was provided with customary post-CRT swallowing intervention when warranted. The M.D. Anderson Dysphagia Inventory (MDADI) was administered an average of 14 months following treatment to assess swallowing QOL outcomes related to PDT. Results indicated significant improvement in the overall MDADI for the experimental group in comparison to the control group. Further analysis of individual MDADI domains revealed improved quality of life for patients in the experimental group in comparison to the control group.

Carroll et al. (2008) performed a retrospective case control study on 18 patients with HNC from the University of Alabama at Birmingham. All of the participants were being treated with CRT for advanced squamous cell carcinoma of the oropharynx, hypopharynx and larynx. Nine patients received PDT two weeks prior to CRT onset, and nine patients (control group) received customary post-treatment management. PDT exercises included the Masako maneuver, tongue resistance with tongue pressed firmly against a tongue depressor in four different directions holding for five seconds per position, effortful swallow, Mendelsohn maneuver, isometric Shaker and isotonic Shaker. All exercises were scheduled for 10 repetitions, five times per day except for the isometric Shaker and isotonic Shaker. The isometric Shaker consisted of three one-minute holds and was prescribed once per day. The isotonic Shaker was prescribed five times per day with 30 repetitions per set. Videofluoroscopy was completed before CRT and
approximately three months post-CRT to assess swallowing function outcomes. The swallowing functions evaluated included hyoid elevation, epiglottic inversion, tongue base movement, cricopharyngeal opening, and the Rosenbeck penetration-aspiration score. Carroll et al. (2008) found significantly better proper posterior tongue base retraction and epiglottic inversion in patients treated preventatively for dysphagia as compared to the control group. Percutaneous endoscopic gastronomy (PEG) tube use was compared across groups at 12 months post-CRT and did not reveal a difference; however, given that most patient’s PEG tubes are removed by 12 months post-CRT, comparisons at earlier time increments may have revealed group differences. Carroll et al. (2008) concluded that PDT produced measurable improvements in post-treatment swallowing function, which provided the groundwork needed to call for additional investigations.

Van der Molen et al. (2011) performed a randomized preventative rehabilitation trial that included 49 patients undergoing CRT for advanced oral cavity, oropharyngeal, hypopharyngeal, laryngeal, or nasopharyngeal cancer. The groups were randomized binarily into a standard arm and an experimental arm. Withholding rehabilitation was no longer considered ethical under the Dutch Head and Neck Cooperative Group, therefore a no-treatment control group could not be included (Van der Molen et al., 2011). The standard arm consisted of lingual and jaw range of motion exercises, as well as three strengthening exercises -- the effortful swallow, the Masako maneuver, and the super-supraglottic swallow. The experimental arm exercises included using the Therabite device to passively and slowly open the mouth and strengthening exercise, which included swallowing with the mouth open 50% while keeping the tongue pressed against the palate. Patients in both groups were told to practice the exercises three times per day, and to try to integrate the exercising into their daily routines. All exercises were performed with eight to
12 repetitions per session, and each ROM exercise was held for 10 to 30 seconds to a stretching point that elicited mild discomfort. Assessment measures included videofluoroscopy, mouth opening measurement, weight changes, body mass index (BMI), functional oral intake scale (FOIS), study-specific questionnaire related to QOL, and a visual analog scale to track patient-reported pain. These were administered at baseline and 10 weeks following completion of CRT. No significant differences at baseline were reports. Using videofluoroscopy, the experimental group had less pharyngeal residue than the standard group on cake consistency 10 wks post-CRT. Lastly, the standard group had better compliance than the experimental group.

Kotz et al. (2012) published a randomized controlled trial assessing the efficacy of PDT on 26 patients being treated with CRT. All patients were recently diagnosed with HNC from the Department of Otolaryngology-Head and Neck Surgery at the Mount Sinai Medical Center in New York, New York. Exclusion criteria included a history of surgery including tracheostomy, previous radiation therapy, and/or cognitive or intellectual impairment, which would prevent the patient from following multi-step commands, or impede their ability to answer study-specific questions. Patients were randomized into a PDT group and control group. PDT included five swallowing exercises initiated prior to the onset of CRT. The specific PDT onset time was not stated in the publication. These exercises included the effortful swallow, super-supraglottic swallow, tongue hold maneuver (Masako maneuver), tongue retraction, and Mendelsohn maneuver. All exercises were performed in sets of 10 three times daily. Control patients received standard care post-CRT swallowing intervention if dysphagic symptoms arose. Outcome measures included the FOIS and Performance Status Scale for Head and Neck Cancer (PSS-H&N), which were administered at baseline, immediately following last CRT session and three, six, nine, and 12 months post-CRT. Results revealed no significant difference in FOIS and PSS-
H&N scores between the PDT and control group immediately following CRT, and nine and 12 months post-CRT. However, the FOIS and PSS-H&N scores were significantly better in the PDT group compared to the control group at three and six months following CRT. Kotz et al. (2012) reported that small sample size may have limited their ability to detect statistically significant outcomes further than six months post-CRT.

Despite the seemingly overwhelming support for PDT in the literature to date, one study reported findings contradicting the theory that PDT improves patient outcomes. Ahlberg et al. (2011) performed a prospective, nonrandomized cohort study comparing parallel groups of patients diagnosed with HNC. Patients were treated in Stockholm at the Karolinska Hospital, Department of Otolaryngology and Head and Neck Surgery. At this site, there were two different units where patients received RT, a southern and northern unit. Patients who were treated in the southern unit received PDT. Patients treated in the northern unit comprised the control group, and did not receive prophylactic swallowing care. The southern unit study group performed a series of exercises including 10 repetitions of the Mendelshon maneuver and five repetitions of tongue mobility exercises (out, up, down, laterally) one to two times a day. PDT patients initiated the exercise program before CRT and were asked to continue with their regimen throughout CRT and for three months following CRT. In addition to the swallowing exercises, physiotherapists in the Ahlberg et al. (2011) investigation provided each study patient in the PDT group with exercises that strengthened, and stretched muscles of the head and neck including flexion/active rotation of the head in both directions, and lateral flexion/extension of the head with three sets of 10 repetitions, two times daily. These patients were also prescribed exercises using the ‘Acute Medic Jaw Trainer and Stretcher’ used to increase jaw ROM for 10 sets of 20,
two times per day. Neck ROM and mouth opening were measured at baseline before the start of CRT, and two, six, and 12 months following treatment.

Assessment measures used in the Ahlberg et al. (2011) study included clinical swallowing function, weight changes, two year survival, health-related quality of life (HRQOL), European Organization for Research and Treatment of Cancer (EORTC) questionnaires, Hospital Anxiety and Depression Scale (HADS), project specific questionnaire focused on self-reported functional losses, rehabilitation, and working ability (Ahlberg et al., 2011). Clinical swallowing function was measured using one swallow of two bolus sizes (5ml and 15 ml) for four consistencies including thin liquid, thick liquid (specific thickness was unreported), paste, and cookie. Clinical assessment measures were also used to determine oral motor, speech, and voice function. Results revealed no positive effects of PDT. Furthermore, compared to patients who received treatment following the development of dysphagia, patients enrolled in PDT reported significantly more swallowing difficulty and significantly fewer patients were able to return to work six months after treatment.

The review of literature generally supports the use of PDT (Kulbersh et al., 2006; Carroll et al., 2008; Van der Molen et al., 2011; Kotz et al., 2011), yet fails to demonstrate comprehensive benefits related to swallowing (Carroll et al., 2008; Ahlberg et al., 2011, Van der Molen et al., 2011; Kotz et al., 2011). Moreover, no significant differences were reported for reduced PEG tube use (Carroll et. al., 2008; Kotz et al., 2012). Both Carroll et. al. (2008) and Kotz et al., (2012) found no significant differences for reduced PEG tube use, yet they both theorized that PEG tube use outcomes may have been related to the small sample sizes. Finally, Ahlberg et al. (2011) and Van der Molen et al. (2011) reported no significant findings related to
weight or BMI maintenance. The variation in study outcomes could be attributed to a number of factors including differing intervention protocols.

**Current PDT Practices and Protocols.** PDT protocols for this population vary between agencies. While performing a web-based survey investigating the current trends in dysphagia assessment and intervention for patients with HNC receiving radiotherapy in the United Kingdom, Roe et al. (2011) found that of the 42 teams who completed the survey fully, 71.4% administered prophylactic treatment. Despite the relatively high rate of preventative care, the intensity, duration, and type of exercises prescribed varied between programs. In this survey, 36.1% of teams recommended patients perform their exercises five times per day, 19.4% prescribed their exercises three times per day, 5.5% recommended that patients do their exercises twice per day, 2.8% prescribed exercises once per day, and 25% of teams recommended that patients perform their exercises as much as possible. The most common exercises found to be prescribed in this survey targeted oral tongue ROM/resistance, hyolaryngeal movement, upper esophageal opening, tongue base ROM, and strength (e.g., effortful swallow and gargle). Less commonly prescribed exercises targeted neck stretching for strengthening, and stretching of the jaw, facial muscles, and lips. The least commonly prescribed exercises were the super-supraglottic swallow and supraglottic swallow.

Similar to the intervention programs revealed by the Roe et al.’s (2011) web-based survey, the seminal studies described above also demonstrate heterogeneous use of exercise programs. For example, both Kulbersh et al. (2006), and Carroll et al. (2008) prescribed their exercises five times per day. Kotz et al. (2012), and Van der Molen et al. (2011) recommended that their patients perform their exercises three times per day. Van der Molen, et al. (2011) also
added that patients should also incorporate their exercises into their daily routines. Finally, Ahlberg et al. (2011) asked their patients to do their exercises one to two times per day.

Ahlberg et al. (2011) reported findings that did not support the use of PDT. It could, however, be argued that this study had a less intense exercise program as compared to the other studies cited. Because Ahlberg et al. (2011) only required their participants to perform the exercises one to two times per day as compared to three to five times per day (Kulbersh et al., 2006; Carroll et al., 2008; Van der Molen et al., 2011; Kotz et al., 2012), it could be argued that a less intense exercise program may have contributed to the results reported in the Ahlberg et al. (2011) study.

Studies investigating the effectiveness of PDT also used varying exercises. Included in this list are the effortful swallow (Carroll et al., 2008; Roe et al., 2011; Van der Molen et al., 2011; Kotz et al., 2012), Masako (Carroll et al., 2008; Roe et al., 2011; Van der Molen et al., 2011; Kotz et al., 2012), super-supraglottic swallow (Roe et al., 2011; Van der Molen et al., 2011; Kotz et al., 2012), Mendelshon (Kulbersh et al., 2006; Carroll et al., 2008; Kotz et al., 2012), tongue resistance (Kulbersh et al., 2006; Carroll et al., 2008; Roe et al., 2011), tongue retraction (Kotz et al., 2012) falsetto /i/ (Kulbersh et al., 2006), passive jaw stretching, passive jaw stretching while swallowing (Van der Molen et al., 2011), and isometric Shaker and isotonic Shaker (Kulbersh et al., 2006; Carroll et al., 2008). Although many of the same exercises were used by two or more investigators (Figure 1), the variety of PDT treatment protocols makes it difficult to determine which method(s) were most effective.
Figure 1. Overlap of PDT exercises cited in the seminal studies.

All of the studies cited used a combination of direct (swallowing) and indirect (non-swallowing) exercises. Additionally, Roe et al. (2011) in a web-based survey found that many clinicians prescribe exercises that do not require the patient to swallow. These exercises consist of oral tongue ROM, and gargle, while some clinicians also prescribe neck stretching. Usually, these exercises are delivered in conjunction with standard strengthening protocols that often use exercises that require swallowing.

Table 1: Published use of PDT indirect and direct swallowing exercises

<table>
<thead>
<tr>
<th>Exercises</th>
<th>Citation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effortful Swallow</td>
<td>Carroll et al. (2008); Roe et al. (2011); Van der Molen et al. (2011); Kotz et al. (2012)</td>
</tr>
<tr>
<td>Masako Maneuver</td>
<td>Carroll et al. (2008); Roe et al. (2011); Van der Molen et al. (2011); Kotz et al. (2012)</td>
</tr>
<tr>
<td>Mendelshon Maneuver</td>
<td>Kulbersh et al. (2006); Carroll et al. (2008); Kotz et al. (2012)</td>
</tr>
<tr>
<td>Super-supraglottic Swallow</td>
<td>Carroll et al. (2008); Roe et al. (2011); Van der Molen et al. (2011); Kotz et al. (2012)</td>
</tr>
<tr>
<td>Passive Jaw Stretching while</td>
<td>Van der Molen et al. (2011)</td>
</tr>
<tr>
<td>Swallowing</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Indirect Exercises</th>
<th>Citation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tongue Resistance</td>
<td>Kulbersh et al. (2006); Carroll et al. (2008); Roe et al. (2011)</td>
</tr>
<tr>
<td>Lingual Retraction</td>
<td>Kotz et al. (2012)</td>
</tr>
</tbody>
</table>
The review of literature indicates support for the use of PDT in nearly all of the studies cited. However, an established intervention protocol with comprehensive, consistent patient outcomes has yet to be determined (Krisciunas, Sokoloff, Stepas, & Langmore, 2012). Thus, more research is required to verify which treatment protocol is most effective for this population; specifically, verification of which exercises improve patient outcomes the most. Although all of the investigations studied use a number and range of rehabilitative swallowing exercises, no one has compared a direct (swallowing) exercise program and an indirect (non-swallowing) exercise program. The direct exercise program would require the patient to perform exercises where they need to swallow. Whereas, the indirect exercise program would prescribe exercises that would not need them to swallow.

**Indirect Swallowing Exercise Program.** The programs prescribed to prevent CRT-related dysphagia in the literature to date incorporate a variety of exercises, some that require a patient to swallow and some that do not (Kulbersh et al., 2006; Carroll et al., 2008; Van der Molen et al. 2011; Kotz et al., 2012). In order for an exercise program to be effective, it must be feasible for the patient to comply with. Success of preventative and restorative intervention is dependent on patient compliance (Basu et al., 2012). CRT commonly causes odynophagia, or painful swallowing (Raber-Durlacher et al., 2012), which often precludes patients from continuing with an exercise protocol (Logemann et al., 2007; Van der Molen et al., 2011; Basu et al., 2012). Van der Molen et al. (2011) reported that 37% of patients stopped training because of pain. Given that swallowing becomes painful for most patients (Raber-Durlacher et al., 2012),
prescribing exercises that do not require the patient to swallow should result in less pain. Therefore, it could be argued that patients given an exercise program that does not require them to engage in swallowing may improve compliance rates and potentially patient outcomes.

There are a number of published PDT studies that include indirect swallowing exercises. These exercises include the isometric Shaker and isotonic Shaker (Kubersh et al., 2006; Carroll et al., 2008), falsetto /i/ (Kulbersh et al., 2006), passive jaw stretching (Van der Molen et al., 2011), and tongue retraction (Kotz et al., 2012). However, although patient benefits have been reported in studies that include indirect swallowing exercises, no one has compared a program consisting of direct and indirect swallowing exercises versus a program consisting of solely indirect swallowing exercises. Because of the high risk of CRT-related odynophagia in this population, and low compliance rates associated with it, investigating the use of exercises that do not require the patient to swallow (indirect) may unveil improved patient outcomes as compared to patients who are recommended exercise programs that incorporate both swallowing and non-swallowing exercises.

**Levels of Evidence and Need.** PDT is promoted in a number of studies, reviews, and textbooks (Kulbersh et al., 2006; Carroll et al., 2008; Focht, Simpson, & Martin-Harris, 2011; Krammer & Robbins, 2011; Roe, et al., 2011; Van der Molen, et al., 2011; Kotz et al., 2012; Basu et al., 2012; Hutcheson & Lewin, 2012; Raber-Durlacher et al., 2012). However, many of the studies endorsing PDT, as well as reviews of current literature on the topic, call for further investigation (Kulbersh et al., 2006; Carroll et al., 2008; Roe & Ashforth, 2011).

Studies on this topic vary significantly. Investigations differ in design, especially related to inclusion criteria, dysphagia assessment (Raber-Durlacher et al., 2012; Roe et al., 2012), treatment type, and outcome metrics (Roe et al., 2011; Ahlberg et al., 2011). Currently, level II,
level III, and level IV studies have been published; none of which use the same study design.

Two prospective randomized controlled clinical trials (Van der Molen et al., 2011; Kotz et al., 2012), a prospective non-randomized study comparing two parallel groups (Ahlberg et al., 2011), a prospective cohort study (Kulbersh et al., 2006), and a retrospective case control study (Carroll et al., 2008) have been published. Their inter-study differences make cross study analysis challenging.

The population, intervention, and assessment measures vary. Patients with HNC are naturally dissimilar. These dissimilarities surface in a number of ways: tumor site, size, stage and type, cause of dysphagia (CRT versus cancer), age and gender of the patient, existence of extraneous health impairments, amount of CRT used, and location of CRT targets (Raber-Durlacher et al., 2012). Additionally, ability to carry out treatment differs between subjects (Van der Molen et al., 2012). Largely due the heterogeneous nature of this population, evaluation of patients between organizations is divergent.

Assessment of dysphagia is inconsistent between agencies, as a range of evaluation measures are utilized. These tools include the use of the MDADI (Kulbersh et al., 2006), Rosenbeck Penetration-Aspiration Score, rate of PEG tube removal (Carroll et al., 2008), video fluoroscopy (Carroll et al., 2008; Van der Molen et al., 2011), FOIS (Van der Molen et al., 2011; Kotz et al., 2012), max incisor mouth opening, BMI, VAS for pain assessment, study specific questionnaire for QOL evaluation (Van der Molen et al., 2011), weight changes (Ahlberg et al., 2011; Van der Molen et al., 2011), clinical swallow evaluation, two year survival, HRQOL, and EORTC questionnaires, HADS, project specific questionnaire focused on self-reported functional losses, rehabilitation, and working ability (Ahlberg et al., 2011), PSS-H&N (Kotz et al., 2012). Additionally, PEG tube use, and dietary intake changes are also
reported in reviews of current practices/literature as being used to measure patient outcomes (Roe et al., 2012). Moreover, a similar degree of variability is also seen clinically.

Treatment type, timing, and intensity vary between investigations (Roe et al., 2011; Ahlberg et al., 2011). Many of the programs that studied PDT began intervention prior to the onset of CRT, with most beginning two weeks pre-CRT. However, the exercise intensity of the regimens and types of exercises prescribed were variable (Ahlberg et al., 2012; Carroll et al., 2008; Kotz et al., 2012; Kulbersh et al., 2006; Van der Molen et al., 2012). CRT related dysphagia therapeutic protocols now need to focus on specific exercise therapy programs (Logemann et al., 2007).

It is important to track patient progress using instrumental testing before, during, and after CRT in patients with HNC. This is needed to document swallowing function and diagnose aspiration (Hutcheson & Lewin, 2012; Raber-Durlacher et al., 2012). Raber-Durlacher et al., (2012) added that in addition to the outcome measures listed, patient-reported measures should also be used to determine level of function (Raber-Durlacher et al., 2012).

As a result of clinical and empirical variability of PDT, there is a call for higher levels of evidence for PDT. This includes prospective randomized studies (Kulbersh et al., 2006; Carroll et al., 2008; Ahlberg et al., 2012; Van der Molen, et al., 2011; Raber-Durlacher et al., 2012), larger sample sizes (Kulbersh et al., 2006; Carrol et al., 2008; Focht et al., 2011; Van der Molen et al., 2011), baseline functioning (Kulbersh et al., 2006; Hutcheson & Lewin, 2012; Raber-Durlacher et al., 2012), consistent diagnostics (Raber-Durlacher et al., 2012; Roe et al., 2012) investigation into specific exercise programs (Logemann et al., 2007) and harmonized outcome reporting methods (Van der Molen et al., 2011; Ahlberg et al., 2011; Roe et al., 2011; Hutcheson & Lewin, 2012). Although this list is not exhaustive, it highlights the research needs most cited.
Given that more evidence is needed, this study was designed to contribute to the current body of research in a number of ways. This study administered an instrumental measure to ensure accurate measurement of baseline swallowing function. It also incorporated the FOIS as a harmonized outcome measure used in previous studies (Kotz et al., 2011; Van der Molen et al., 2012), and investigated two different types of exercise programs, whereas the indirect program was a unique program that has not been studied independently from direct swallowing exercises. Thus, this study made needed and valuable contributions to the existing evidence base for PDT.

**Research Questions & Hypothesis.**

1. Is there a difference in functional swallowing outcomes between PDT emphasizing direct swallowing exercises, and PDT involving indirect swallowing exercises in patients undergoing CRT due to HNC of the tongue, palate, pharynx, or larynx?

   **Hypothesis 1:** There will be no significant difference in FOIS scores in patients undergoing CRT for HNC of the tongue, palate, pharynx, or larynx who complete PDT consisting of direct swallowing exercises and patients who complete PDT consisting of indirect swallowing exercises.

2. Is there a difference in QOL outcomes between PDT emphasizing direct swallowing exercises and PDT involving indirect swallowing exercises in patients undergoing CRT for HNC?

   **Hypothesis 2:** There will be a significant increase in QOL outcomes in the indirect swallowing exercise group compared to the direct swallowing exercise group, as measured by the three sub-sets of the EAT-20: 1) Physical, 2) Emotional, and 3) Functional.
3. Is there a difference in the level of patient-reported swallowing pain between PDT emphasizing direct swallowing exercises and PDT involving indirect swallowing exercises in patients undergoing CRT for HNC?

**Hypothesis 3:** Patients in the indirect swallowing exercise group will report less swallowing-related pain than patients in the direct swallowing exercise group as measured by a study-specific pain questionnaire.
Chapter 2: Methodology

Introduction

This was prospective study investigating the effects of PDT on patients with HNC who were being treated with CRT. This study had three goals: 1) determine if there was a difference in functional swallowing outcomes between PDT consisting primarily of direct (swallowing) swallowing exercises and PDT involving solely indirect (non-swallowing) exercises in patients undergoing CRT due to HNC of the tongue, palate, pharynx, or larynx; 2) determine if there was a difference in QOL outcomes between patients undergoing PDT consisting of direct swallowing exercises and patients undergoing PDT involving indirect swallowing exercises; 3) determine group differences in the level of patient-reported pain while swallowing for patients provided PDT involving direct swallowing exercises and patients provided PDT involving indirect swallowing exercises.

Setting

Participants were seen at Providence St. Patrick Hospital Missoula, MT and at the RiteCare Speech Language and Hearing Clinic at the University of Montana. Participants were evaluated, and treated by a licensed SLP board certified as a swallowing specialist in conjunction with supervised SLP graduate students from the University of Montana.

Participants and Recruitment

The total sample size included four males, and four females receiving chemoradiation therapy for lingual, palatal, pharyngeal, or laryngeal squamous cell carcinoma. Participant age ranged from 50 to 75 with an average age of 59.75 years. Inclusion criteria consisted of: 1) an existing diagnoses of stage III or IV squamous cell carcinoma of the tongue, palate, pharynx, or larynx, 2) with CRT as the expected primary mode of intervention, 3) the ability to be able to
begin PDT exercises prior to the onset of CRT, 4) at least 18 years of age, 5) and be cognitively, mentally, and legally capable of making independent decisions regarding personal medical care. Exclusion criteria consisted of: 1) an existing diagnosis of dysphagia unrelated to his/her current diagnosis of cancer, 2) surgical resection of the primary tumor, and 3) a diagnosis of neurogenic disease or disorder that may lead to dysphagia including traumatic brain injury, dementia, motor neuron disease, myasthenia gravis, cerebral palsy, Guillain-Barre’ syndrome, Poliomyelitis, Parkinsonism, Huntington’s disease, Progressive supranuclear palsy or Wilson’s disease (Groher & Crary, 2010).

Participants were recruited, enrolled, evaluated, treated, and followed-up with in a step-wise fashion. Patients were recruited and treated through a collaborative effort between Providence St. Patrick Hospital Missoula, MT and The University of Montana Communicative Sciences and Disorders Department. Dr. Kathryn Markette and Dr. Margaret Menendez at the Montana Cancer Center within Providence St. Patrick Hospital in Missoula, MT, informed patients of their inclusion or exclusion in this voluntary study according to the pre-established criteria listed above. If patients agreed to be contacted by the researchers, Dr. Kathryn Markette or Dr. Margaret Menendez provided the clients with the Consent to be Contacted form (Appendix A). Once the form was read and signed by the participant, Professor Laurie Slovarp SLP-CCC, BRS-S at The University of Montana Communicative Sciences and Disorders Department, or another researcher on the study, contacted the patient to schedule an initial appointment.

Procedures

Participants were assigned to one of two groups in alternating fashion according to enrollment date. Both groups began prophylactic swallowing exercises with demonstrated
treatment efficacy (Kulbersh et al., 2006; Carroll et al., 2008; Van der Molen et al., 2011; Kotz et al., 2012) an average of two weeks prior to onset of CRT (Kulbersh et al., 2006; Carroll et al., 2008; Van der Molen et al., 2011). One group was given PDT that focused on exercises that required the patient to swallow (direct swallowing exercise group). The other group was given exercises that did not require swallowing (indirect swallowing exercise group).

**Direct swallowing exercise program.** The direct swallowing exercises included the Mendelshon maneuver, effortful swallow, Masako maneuver, and isometric Shaker and isotonic Shaker (Appendix E). The frequency of the recommended exercise program was as follows: Mendelshon maneuver-15 repetitions per set, effortful swallow-20 repetitions per set, Masako-10 repetitions per set, isometric Shaker-held for 1 minute for three repetitions, and the isotonic Shaker was performed with one set of 20 repetitions. Each exercise was recommended three times per day, seven days per week.

**Indirect swallowing exercise program.** Indirect swallowing exercises included the falsetto /i/, tongue ROM, tongue-base retraction, jaw ROM, and isometric Shaker (non-swallowing group) (Appendix F). The frequency of each exercise were as follows: Falsetto /i/, 6-10 repetitions per set; tongue ROM, tongue-base retraction, and jaw stretching, 10 repetitions per set; the isometric Shaker was held for 1 minute for three repetitions per set; and the isotonic Shaker was performed with one set of 20 repetitions. Each exercise was recommended three times per day, seven days a week.

**Assessment and Outcome Measures**

An MBS was used to determine swallowing function prior to beginning therapy. Additionally, participants were asked to fill out three surveys. These surveys included 1) FOIS
(Appendix G), 2) EAT-20 (Appendix H), and 3) a study-specific nutritional and pain questionnaire (Appendix G).

**Data Collection and Phases**

Data collection spanned 12 consecutive months. The study began October, 2012 with recruitment and enrollment of the first participant, and concluded October, 2013 with the final data set documenting study-related outcomes with the last patient four weeks post-CRT.

**Enrollment phase.** During the initial visit with the researchers, participants meeting inclusion criteria were provided with the Subject Information and Informed Consent form (Appendix B), and Permission to Gather Personal Health Information document (Appendix C) to read and sign. After, the researcher(s) administered a case history (Appendix D). Due to the evidence in support of the use of PDT, all subjects were offered PDT. However, if clients chose not to participate in PDT, they had the opportunity to opt to have their progress tracked using the same measures as the PDT participants. This data would have been used in the study as a control group; however, no participants chose this route.

**Baseline phase.** Following enrollment, the baseline phase was initiated. Up to two weeks prior to beginning the exercise plan, a pre-treatment baseline swallowing measure using an MBS, and the questionnaires used for assessment were completed for each new participant.

**Training phase.** Subsequently, the training phase began. In this phase patients were seen by the investigator(s) up to two times to learn how to perform their exercise program. Once the patients achieved competence with their exercise program, as measured by the attending SLP or supervised SLP graduate student, the treatment phase was initiated.
Treatment phase. During the treatment phase, patients were seen once every two weeks throughout CRT (or more if necessary given the severity of their dysphagia) to treat, and document progress using FOIS, EAT-20, and the nutritional and pain questionnaire.

Follow-up phase. After CRT, the investigators followed-up with each participant at least every four weeks to administer the FOIS, EAT-20, and nutritional and pain questionnaire. All patients were monitored by an SLP until the client returned to full per oral (PO) intake with the least restrictive diet possible. When medically appropriate, the participants were seen for customized dysphagia therapy. Dysphagia therapy was guided by the nature of the participant’s dysphagia and current best practices as deemed appropriate by the treating SLP.

Ethical Considerations

All data collection procedures were appropriated in accordance with the joint St. Patrick Hospital, Missoula and University of Montana Investigational Review Board (IRB) for the Protection of Human Subjects in Research regulations. Data collection commenced following IRB approval on September 11, 2012.
Chapter Three: RESULTS

Statistical Analysis
All statistical analyses were performed using IBM SPSS v 22 (SPSS, Inc., Chicago, IL) software. Patients were randomized to their respective treatment groups in alternating fashion according to enrollment date. Descriptive and non-parametric statistics (Mann-Whitney U test, Fisher’s exact test) were applied to test baseline (pre-CRT), and post-CRT measures.

EAT-20 sub-sets were modeled after the MDADI, which measures swallowing QOL outcomes using three domains. These domains are 1) physical, 2) emotional, and 3) functional. Investigators from this study created a qualitative correlate between the questions used in the EAT-20 and the questions listed in the three MDADI domains. Following, a Chronbach’s alpha coefficient was applied to measure internal consistency within the EAT-20 sub-sets both pre-CRT, and post-CRT. Table 2 details the results of this analysis. Pre-CRT sub-sets for physical ($\alpha = 0.98$), and functional ($\alpha = 0.95$), and post-CRT domains for physical ($\alpha = 0.94$), emotional ($\alpha = 0.91$), and functional ($\alpha = 0.95$) were scored as having excellent internal consistency ($\alpha \geq 0.90$). The pre-CRT sub-set for emotional ($\alpha = 0.80$) was scored as having good internal consistency ($0.7 \leq \alpha < 0.9$).

Table 2: Chronbach’s alpha coefficient measuring internal consistency within the EAT-20 sub-sets (physical, emotional, functional) pre-crt, and post CRT

<table>
<thead>
<tr>
<th></th>
<th>Chronbach’s $\alpha$ coefficient</th>
<th>Internal Validity Category</th>
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</thead>
<tbody>
<tr>
<td>Pre-CRT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>0.98</td>
<td>Excellent</td>
</tr>
<tr>
<td>Emotional</td>
<td>0.91</td>
<td>Excellent</td>
</tr>
<tr>
<td>Functional</td>
<td>0.95</td>
<td>Excellent</td>
</tr>
<tr>
<td>Post-CRT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>0.94</td>
<td>Excellent</td>
</tr>
<tr>
<td>Emotional</td>
<td>0.80</td>
<td>Good</td>
</tr>
<tr>
<td>Functional</td>
<td>0.95</td>
<td>Excellent</td>
</tr>
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EAT-20: Eating Assessment Tool-20
All post-treatment variables including FOIS, EAT-20, and swallowing-related pain scores, were analyzed using the nonparametric Mann-Whitney U test. This test assessed between-group differences four weeks post-CRT. Hypothesis 1 was tested using the FOIS variable, Hypothesis 2 was tested using the EAT-20 variable, and Hypothesis 3 was tested using the swallowing-related pain variable.

Demographics

Due to the heterogeneous nature of the study population discussed in Chapter One of this thesis, statistical measures were used to identify possible confounding dissimilarities between treatment groups. Patient demographics at baseline included age, gender, tumor (T1, T2, T3, T4), node (N0, N1, N2, N3), metathesis (MX, M0, M1, M2, M3) rating, staging of the tumor (unknown, I, II, III, IV, ongoing), and site of the lesion. Descriptive statistics, the Mann-Whitney U test and Fisher’s exact test were applied to analyze demographic distributions between treatment groups.

Table 3 catalogs the mean age, age range, carcinoma type, TNM score, tumor stage, and site of lesion between groups and across all participants. The mean age in years for the swallowing group was 62.75, and the age range was 51-75. The mean age in years for the swallowing group was 56.75, and the age range was 50-62. The mean age in years for the total population was 59.75, and the age range was 50-75.

All participants were being treated with CRT for squamous cell carcinoma. The average T classification for the direct swallowing exercise group was 1.75 out of 4, whereas the average T classification for the indirect swallowing exercise group was 3.5 out of 4. Thus, on average, patients in the indirect swallowing exercise group had larger tumors. Two participants in the direct swallowing exercise group had an N1 classification, and two had an N2 classification.
Two participants in the non-swallowing group had an NX classification, meaning the lymph nodes could not be evaluated, and two had an N2 score. Because two participants in the indirect swallowing exercise group had a nodal score of NX, comparison between groups was not possible. The same was true for M classification, and tumor staging comparison as well. One participant in the direct swallowing exercise group, and two in the indirect swallowing exercise group had unknown M scores, two patients from each group had MX scores meaning presence of distant metathesis could not be assessed, leaving one remaining participant in the swallowing group with an M0 score, meaning there was no detection of metathesis. Three patients from each group were listed with unknown staging of their lesion(s), one participant in the direct swallowing exercise group had level III staging and one subject in the indirect swallowing exercise group had ongoing staging.

Finally, each participant’s tumor location was categorized by region, which included the oral cavity, oropharynx, larynx, or unknown (Table 3). The direct swallowing exercise group had one participant with lesion site(s) in the oral cavity, two subjects with lesion(s) in the oropharynx, and one patient with an unknown lesion site. The indirect swallowing exercise group had two subjects with lesion site(s) in the oral cavity, and two participants with lesion(s) in the larynx. In conclusion, all participants were diagnosed with squamous cell carcinoma, and the direct swallowing exercise group according to the mean T classifications, the indirect swallowing exercise group had larger tumors. Comparisons between groups for N scores, M scores, and staging of the lesion were not made due to the inability to classify the lesion.

**Table 3.** Demographics, tumor classification, presence of tracheostomy, history of surgery related to current diagnosis of cancer, tumor location at baseline

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Direct Swallowing Exercise Group</th>
<th>Indirect Swallowing Exercise Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Patients</td>
<td>4</td>
<td>4</td>
<td>8</td>
</tr>
</tbody>
</table>
Non-parametric tests were used to assess gender differences, and baseline age (years), cancer-related characteristics (tumor location, presence of tracheostomies, and cancer-related surgeries), functional measures (FOIS score), QOL (EAT-20), and patient-reported pain-related swallowing score (Table 4). Statistical analyses demonstrated no significant differences in
baseline measures between groups. Table 4 summarizes the outcomes of the Mann-Whitney U test, which compared groups at baseline based on age (p = 0.49), FOIS score (p = 0.34), patient reported swallowing-related pain score (p = 0.34), and EAT-20 sub-set (physical, emotional, functional) sores (p = 0.34). Fisher’s exact test was used to analyze gender distribution (p = 0.49), tumor location in the oral cavity (p = 1.00), in the oropharynx, and larynx (p = 0.43), tumor location unknown (p = 1.00), presence of tracheostomies (p = 0.43), and cancer-related surgeries (p = 1.00) at baseline between groups. Fisher’s exact test was chosen over the Pearson Chi-square because the expected value for each cell was below five.

**Table 4.** Baseline (Pre-CRT) Demographics, Tumor location, Cancer-related Characteristics, and Variable Outcomes including statistical test applied for analysis of variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Outcome</th>
<th>p-value</th>
<th>Test Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td>0.49</td>
<td>Mann-Whitney U</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td>0.49</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>Tumor location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral cavity</td>
<td></td>
<td>1.00</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>Oropharynx</td>
<td></td>
<td>0.43</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>Larynx</td>
<td></td>
<td>0.43</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td>1.00</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>Cancer-related Characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tracheostomies</td>
<td></td>
<td>0.43</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>Pre-treatment Surgeries</td>
<td></td>
<td>1.00</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>Variable Outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FOIS</td>
<td></td>
<td>0.34</td>
<td>Mann-Whitney U</td>
</tr>
<tr>
<td>Pain Rating</td>
<td></td>
<td>0.49</td>
<td>Mann-Whitney U</td>
</tr>
<tr>
<td>EAT-20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td></td>
<td>0.34</td>
<td>Mann-Whitney U</td>
</tr>
<tr>
<td>Emotional</td>
<td></td>
<td>0.34</td>
<td>Mann-Whitney U</td>
</tr>
<tr>
<td>Functional</td>
<td></td>
<td>0.34</td>
<td>Mann-Whitney U</td>
</tr>
</tbody>
</table>

*FOIS: Functional Oral Intake Scale, EAT-20: Eating Assessment Tool-20*

In addition to considering baseline demographics, MBS results were used to determine each patient’s functional swallowing level prior to the onset of CRT. Table 5 lists the outcomes
for all MBS results including a description of the symptoms of impairment if present. All participants in the swallowing exercise group, according to the results of the MBS, demonstrated an oral phase of swallow that was within functional limits. However, one (25%) participant in the indirect swallowing exercise group demonstrated oral dysphagia characterized by reduced bolus preparation and formation. As for the pharyngeal phase, one (25%) participant in the direct swallowing exercise group had difficulty swallowing during the pharyngeal phase. This was evidenced by trace residue in valleculae and pyriform sinuses following the swallow. The indirect swallowing exercise group had two (50%) participants who were experiencing mild pharyngeal dysphagia. Of those participants, one had premature spillage of thin liquid into the pharynx prior to initiation of the swallow, absence of epiglottic inversion, and one incidence of flash penetration during the swallow on a thin liquid trial using a chin tuck. The other participant demonstrated flash penetration of an applesauce consistency bolus, residue of banana consistency following the swallow at level of pyriforms, and reduced cricopharyngeal opening requiring multiple swallows with thin liquid to clear 1/3 tablet of barium.

Table 5. Description of patient’s MBS results categorized between treatment groups and level of swallowing impairment including oral, and pharyngeal phase

<table>
<thead>
<tr>
<th>Patient</th>
<th>Direct Swallowing Exercise Group</th>
<th>Indirect swallowing Exercise Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral phase</td>
<td>1 Within functional limits</td>
<td>Within functional limits</td>
</tr>
<tr>
<td>2 Within functional limits</td>
<td>missing data</td>
<td></td>
</tr>
<tr>
<td>3 Within functional limits</td>
<td>reduced bolus preparation and formation</td>
<td></td>
</tr>
<tr>
<td>4 Within functional limits</td>
<td>Within functional limits</td>
<td></td>
</tr>
<tr>
<td>No. of patients/group participants with impairment in oral phase</td>
<td>0/4</td>
<td>1/4</td>
</tr>
</tbody>
</table>
Pharyngeal phase

1  Within functional limits  Within functional limits
2  Within functional limits  missing data
3  Within functional limits  premature spillage of thin liquid into pharynx prior to initiation of the swallow, no epiglottic inversion observed, and one incidence of flash penetration during the swallow on thin liquid using a chin tuck
4  trace residue in valleculae and pyriform sinuses following the swallow  flash penetration of applesauce consistency, residue of banana consistency following the swallow at level of pyriforms, reduced cricopharyngeal opening requiring multiple swallows with thin liquid to clear 1/3 tablet of barium

No. of patients/group participants with impairment in pharyngeal phase

1/4  2/4

**Treatment Duration**

Table 6 lists the amount of time that patients in each group were provided PDT prior to the onset of CRT. The direct swallowing exercise group, and the indirect swallowing exercise group both averaged approximately two weeks of PDT (mean days=14, mean days=13) respectively. Although, the mean number of days of PDT prior to CRT onset in each group was relatively uniform, the range differed, whereas the swallowing exercise group had a range of 6 to 22 days, and the non-swallowing exercise group had a range of 0 to 24 days.

**Table 6:** Average number, and range of days that patients in each exercise group participated in PDT prior to the onset of CRT.

<table>
<thead>
<tr>
<th>Days</th>
<th>Direct Swallowing Exercise Group</th>
<th>Indirect Swallowing Exercise Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>14</td>
<td>13</td>
</tr>
</tbody>
</table>
Participant Outcomes Four Weeks Post-CRT

Statistical analyses demonstrated no significant differences between groups approximately four weeks following CRT for all outcome measures. Table 7 summarizes the outcome of the Mann-Whitney U test, which compared outcomes between groups four weeks post-CRT. These outcomes included FOIS scores (p = 0.69), EAT-20 physical, and functional sub-set scores (p = 0.34), and EAT-20 emotional sub-set scores (p = 0.11), and patient reported swallowing-related pain score (p = 0.11).

Table 7: Mean, and Mann-Whitney U p-value for functional problems, QOL changes, and swallowing-related pain within and between groups Pre-CRT, and four weeks post-CRT.

<table>
<thead>
<tr>
<th>Functional Outcomes</th>
<th>Direct Swallowing Exercise Group</th>
<th>Indirect Swallowing Exercise Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOIS</td>
<td>S1 S2 S3 S4 Mean Std Dev. S1 S2 S3 S4 Mean Std Dev. p value</td>
<td></td>
</tr>
<tr>
<td>Pre-CRT</td>
<td>7 7 7 7 0 7 7 5 6 1.15 0.34</td>
<td></td>
</tr>
<tr>
<td>Post-CRT</td>
<td>3 6 1 6 4 2.45 6 1 3 3 3.25 2.06 0.69</td>
<td></td>
</tr>
<tr>
<td>Swallowing-related Pain Rating</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-CRT</td>
<td>0 0 0 1 0.25 0.25 0 0 1 3 1 1.41 0.49</td>
<td></td>
</tr>
<tr>
<td>Post-CRT</td>
<td>0 1 1 0 0.5 0.58 1 1 3.5 2 1.88 1.18 0.11</td>
<td></td>
</tr>
<tr>
<td>EAT-20 Physical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-CRT</td>
<td>0 0 0.1 0.4 0.13 0.19 0 0.1 2.2 4.5 1.7 2.12 0.34</td>
<td></td>
</tr>
<tr>
<td>Post-CRT</td>
<td>0.1 0.5 5.1 0.4 1.53 2.39 0.8 2.3 2.1 2.3 1.88 0.72 0.34</td>
<td></td>
</tr>
<tr>
<td>EAT-20 Emotional</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-CRT</td>
<td>0 0 0 0 0 0 0 0 1.86 3.29 1.29 1.6 0.34</td>
<td></td>
</tr>
<tr>
<td>Post-CRT</td>
<td>0.0 0.29 0.54 0.89 0.14 2.57 2 2.57 1.82 1.15 0.11</td>
<td></td>
</tr>
<tr>
<td>EAT-20 Functional</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-CRT</td>
<td>0 0 0 0 0 0 0 0 3.67 5 2.17 2.56 0.34</td>
<td></td>
</tr>
<tr>
<td>Post-CRT</td>
<td>0 0 5 0.67 1.42 2.41 0.33 5 3 3.33 2.92 1.93 0.34</td>
<td></td>
</tr>
</tbody>
</table>

FOIS: Functional Oral Intake Scale, EAT-20: Eating Assessment Tool-20
Oral Intake

Table 8 details the mean FOIS scores four weeks post-CRT for the direct and indirect swallowing exercise groups were 2.45, and 2.06, respectively. A Mann-Whitney U test was performed to answer the question: *Is there a significant difference in functional swallowing outcomes between PDT emphasizing exercises that require swallowing (direct), and PDT involving non-swallowing (indirect) exercises in patients undergoing CRT due to HNC of the tongue, palatae, pharynx, or larynx?* Results did not indicate significant differences in FOIS scores between the groups approximately four weeks following CRT (p = 0.69). Additionally, the Wilcoxon signed rank test did not reveal significant differences in pre-CRT, and four weeks post-CRT FOIS scores within the direct swallowing exercise group (p = 0.07), and the indirect swallowing exercise group (p = 0.07) (Table 9). However, two (50%) of patients in the direct swallowing exercise group and three (75%) of patients in the indirect swallowing group were on PEG tube dependent diets four weeks post-CRT, whereas, all of the patients in the both exercise groups were on full oral diets at baseline (Table 9). However, pre-CRT, two (50%) patients in the indirect swallowing exercise group, and none of the participants in the direct swallowing exercise group were on modified diets.

**Table 8:** Distribution, and mean of patients in each group based on FOIS scores pre-CRT, and post-CRT, relative to each FOIS category (PEG tube dependent, Modified full oral diet, Unmodified full oral diet).

<table>
<thead>
<tr>
<th>FOIS scores</th>
<th>Direct Swallowing Exercise Group</th>
<th>Indirect Swallowing Exercise Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-CRT</td>
<td>Post-CRT</td>
</tr>
<tr>
<td>PEG tube dependent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Modified full oral diet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>
Table 9: Pre-CRT and four weeks post-CRT differences in variable outcomes within groups using the Wilcoxon signed rank test

<table>
<thead>
<tr>
<th>Variable Outcomes</th>
<th>Swallowing Exercise Group</th>
<th>Non-Swallowing Exercise Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOIS</td>
<td>0.07</td>
<td>0.07</td>
</tr>
<tr>
<td>Swallowing-related Pain</td>
<td>0.56</td>
<td>0.26</td>
</tr>
<tr>
<td>Rating</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EAT-20</td>
<td>0.11</td>
<td>0.85</td>
</tr>
<tr>
<td>Physical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional</td>
<td>0.18</td>
<td>0.46</td>
</tr>
<tr>
<td>Functional</td>
<td>0.18</td>
<td>1</td>
</tr>
</tbody>
</table>

FOIS: Functional Oral Intake Scale, EAT-20: Eating Assessment Tool-20

Quality of Life

The mean EAT-20 scores four weeks post-CRT for the direct swallowing exercise group for under each sub-set (physical, emotional, functional) was 2.39, 0.89, and 2.41, respectively (Table 9). The mean EAT-20 scores four weeks post-CRT for the indirect swallowing exercise group under each sub-set (physical, emotional, functional) was 1.88, 1.82, and 2.92, respectively (Table 9). A Mann-Whitney U test was performed to determine if: there is a difference in QOL outcomes between PDT emphasizing exercises that requires swallowing (direct) and PDT involving non-swallowing (indirect) exercises in patients undergoing CRT for HNC? Results indicated no significant differences in all three EAT-20 sub-sets (physical, emotional, functional) (p = 0.34, p = 0.11, p = 0.34) respectively, between groups four weeks following CRT (Table 9). Additionally, the Wilcoxon signed rank test did not reveal significant differences in pre-CRT, and four weeks post-CRT EAT-20 sub-set (physical, emotional, functional) within the direct unmodified full oral diet.
swallowing exercise group \( (p = 0.11, p = 0.18, p = 0.18) \) and the indirect swallowing exercise group \( (p = 0.85, p = 0.46, p = 1.00) \) respectively (Table 9).

**Pain**

The mean swallowing-related pain scores four weeks post-CRT for the direct swallowing exercise group was 0.5 on a likert scale ranging from 0-5, whereas 0 is no pain and 5 is severe pain (Table 7). The mean swallow-related pain scores four weeks post-CRT for the indirect swallowing exercise group was 1.88 (Table 7). A Mann-Whitney U test was performed to resolve the question: *Is there a difference in the level of patient reported pain while swallowing between PDT emphasizing exercises that requires swallowing (direct) and PDT involving non-swallowing (indirect) exercises in patients undergoing CRT for HNC?* Analysis revealed no significant differences in patient-reported swallowing-pain scores \( (p = 0.11) \) between groups four weeks following CRT. Additionally, the Wilcoxon signed rank test did not reveal significant differences in pre-CRT, and four weeks post-CRT on patient reported swallowing-related pain scores for the direct swallowing exercise group \( (p = 0.56) \) and the indirect swallowing exercise group \( (p = 0.26) \), respectively (Table 11).
Chapter Four: DISCUSSION

Many patients who undergo organ preserving CRT for HNC experience iatrogenic dysphagia. However, standardized intervention practices for this population have not been established. Thus, this investigation asked: Are there significant differences in functional swallowing, QOL outcomes, and levels of patient-reported pain while swallowing between PDT emphasizing exercises that require swallowing (direct swallowing exercise program) and PDT involving non-swallowing exercises (in-direct swallowing exercise program) in patients undergoing CRT due to HNC of the tongue, palatae, pharynx, or larynx?

Oral Intake

This analysis failed to disprove the hypothesis that there would be a statistically significant difference in FOIS scores between the groups of patients provided direct swallowing exercises and patients who were provided indirect swallowing exercises. These results can be interpreted in four ways. One, both treatment protocols were equally effective. Two, both treatment protocols were equally ineffective. Three, because baseline FOIS scores differed between groups (more participants in the indirect swallowing exercise group required modified diets compared to participants in the direct swallowing exercise group), but did not differ between groups at 1-month post CRT, it is possible that the indirect swallowing exercise group actually received a greater benefit from PDT relative to the direct swallowing exercise group. However, it is not possible to determine if explanation one, two, or three best describes the outcome because this study lacked a comparator control group. Additionally, the total sample size (n = 8) was too small to produce a measurable difference in outcomes.
Quality of Life & Pain

This study failed to disprove the null hypotheses that there would not be statistically significant higher QOL outcomes and reduced pain levels in patients who were provided PDT, which involved indirect swallowing exercises compared to those who were provided direct swallowing exercises. These results could indicate that both groups performed equally. The lack of control however, makes it impossible to determine whether both groups were equally effective or equally ineffective in improving or maintaining QOL, and reducing pain while swallowing. Also, measurable differences may not have been detected due to the small number of participants.

An additional consideration regarding the outcomes of the swallowing-related pain score should be made. The swallowing-related pain score was derived from a question that asked patients to rate the level of pain they experienced while swallowing throughout the day over a two-week interval of time. However, one of the goals of this study was to help determine strategies for improving the QOL of these patients during the intervention process. If patients experienced less pain while doing their exercises, but had statistically insignificant differences in all other measures including FOIS, and EAT-20 scores, then the argument could be made that choosing an exercise program the reduces the level of pain during execution of their exercises would be a worthy recommendation. This study, however, did not directly ask how much swallowing-related pain the patient experienced while exercising, thus, this specific determination cannot be made.

Limitations

There were limitations to this study which should be bear considerable weight when determining the strength of the conclusions discussed above. These limitations included the
heterogeneous nature of the population, small sample size (n=8), and the lack of a treatment control group. Additionally, the number of days of PDT the patient received prior to the onset of CRT, and inability to reliably measure patient compliance with the exercise programs all pose risks as possible confounding factors in this study.

The population varied in tumor size, stage, and location, the presence of pre-CRT surgery, tracheostomy, and gender distribution between groups (Table 5). Despite the apparent heterogeneity in this population, statistical analysis did not reveal a statistical difference between group demographics at baseline. The small sample size, however, could be an explanation for this outcome. Moreover, the lack of a control group made it impossible to measure the efficacy of PDT compared to no PDT for both groups. Rather, analysis of outcomes merely allowed comparison between the two different PDT programs.

Although baseline measures were taken prior to the administration of CRT, meaning that no patient had undergone CRT at baseline, there was a discrepancy in the range of time that patients in each group participated in PDT prior to the onset of CRT. The direct swallowing exercise group had a range of six to 22 days, while the indirect swallowing exercise group had a range of zero to 24 days (Table 8). Thus, the variability in the amount of PDT prior to the onset of CRT had the potential to reduce the validity of the results because most patients received varying amounts of PDT intervention prior to beginning their CRT regimen.

MBSs were administered by an SLP as standard practice for patients who were enrolling in CRT for HNC to determine baseline swallowing function at St. Patrick Hospital in Missoula, MT. Nevertheless, interpretation of these results of can vary between clinicians (Wilcox, Liss, & Siegel, 1996). There was no way to control for inter-rater reliability of assessment outcomes, thus baseline swallowing function as measured by the MBS could have been subject to variation.
in outcomes based on the likelihood that two separate judges would have interpreted each MBS differently.

Furthermore, the EAT-20 had test-retest reliability that was lower than the EAT-10 and did not have normative internal consistency data for sub-sets that measured the physical, emotional, and functional outcomes separately. Analysis of the sub-sets using the data gathered in this investigation using the Chronbach’s alpha rendered results favoring the convention that each sub-set correlated statistically based on how the participants answered the questions. However, due to the low sample size in this investigation, the results of the Chronbach’s $\alpha$ should be interpreted with caution.

Lastly, the investigators were unable to reliably measure compliance with the exercise programs for each participant. Originally, patients were given an iPod® with the iSwallow™ application, which was designed to track patient compliance and reinforce proper technique by providing each patient with a way to track when their exercises were completed and videos of their exercises. However, use of the iSwallow™ application by the participants occurred intermittently, thus the investigators enlisted the use of a paper form designed to track compliance. Again, however, use of this measure was sporadic, whereas several patients did not track their performance or did so retrospectively during their bi-weekly interview with the investigators. Thus, patient compliance was not reported in the results or discussed in the analysis of this study. Subsequently, there is no way to determine the level of participation each client upheld during their exercise program.

Consequently, this results in another consideration when interpreting the outcomes of this investigation. Compliance with the exercise program is an important factor when interpreting the results of this study. If some patients participated more than others in their exercise program,
they were effectively participating in varying degrees of intervention. Thus, outcomes for all measurements could be affected.

**Future Directions**

To improve the strength of the evidence required to make additional contributions to the trajectory of care for these patients, several considerations for future analysis are proposed. Although the nature of this population is inherently heterogeneous as described earlier, tumor size, stage, and location, the presence of pre-CRT surgery, and tracheostomy, and amount of radiation the patients receive should be controlled for. Additionally, although use of a control group would best suit future investigations, withholding PDT is deemed unethical due to the current evidence, but use of an existing control data set would improve the strength on analysis for future investigations. Moreover, larger sample sizes, compliance tracking, and use of a standardized measure when accounting for MBS outcomes such as the penetration/aspiration score are recommended. The MDADI is a more widely used and studied assessment tool compared to the EAT-20. Thus, it is suggested that future analysis employ the use of the MADI in conjunction with or as an alternative to the EAT-20. It is also recommended that the swallowing-related pain score be derived from a different question. Rather than asking how much swallowing-related pain a patient experiences on average over a two week period of time, it is suggested that the investigator ask the patient to define the amount of pain they experience while performing their exercises. Therefore, the outcome measure could be titled *exercise-related pain score* rather than *swallowing-related pain score*.

Finally, participant motivation, and locus of control should be included in future studies. Anecdotal patient reports indicated to some patients experienced a “sense of control” over their swallowing outcomes when provided PDT. This “sense of control” could pose as an important
indicator of the participants’ internal locus of control and subsequent motivation to comply with their program.

**Conclusion**

This study compared a unique PDT program, the indirect (non-swallowing) exercise program, to a more common primarily direct (swallowing) PDT exercise program and the results revealed no significant differences between groups for all assessment measures taken. This may indicate that both direct and indirect PDT swallowing exercise programs have the potential to make the same impacts on swallowing function for this population.

Due to the high prevalence of odynophagia in this population, choosing a program that may reduce the amount of swallowing-related pain while exercising should be a top priority for clinicians prescribing these programs. Indirect PDT does not require the patient to perform painful swallowing maneuvers, whereas patients who are prescribed a direct or mixed program are expected to swallow to perform their exercises despite the presence of odynophagia. Since both groups performed equally in this investigation, an indirect PDT program may be a better clinical recommendation as compared to a direct (swallowing exercises) or mixed (swallowing and non-swallowing exercises) regimen.

The results of the investigation, however, should be interpreted with reasonable caution. Due to the low sample size and lack of a control group, it is not possible to determine whether the patient outcomes were in the positive or negative direction. Yet, the likelihood of the results being in the negative direction, in light of the findings in previous PDT investigations, are most likely low. Thus, further investigation with a larger sample size and comparator control data is warranted. Nevertheless, given the results of this investigation and additional finding published
on PDT, providing prophylactic rehabilitative swallowing exercises should be standard practice for patients with HNC who are at risk of developing CRT-related dysphagia in the U.S.

In addition to improving management for this population, this investigation outlined the necessary steps needed to begin developing consistent, evidenced-based practices for these patients. These include controlling for the heterogeneity of the study population (e.g., tumor size, tumor location, site, and amount of RT, etc.), using larger sample sizes, standardizing assessment measures between agencies, using validated evaluation tools, and tracking compliance.

**Clinical Implications**

In the U.S., PDT for this population is not standard practice. Most agencies prescribe to the reactive or educational/monitoring service delivery model. Despite the need for additional research on this topic, a compelling argument supporting the use of PDT in the population can be made. Many patients experience iatrogenic dysphagia related to CRT and providing PDT may reduce both physical and psychological side-effects for this population.

Most of the research to date has demonstrated a reduction in the negative impacts of CRT on swallowing-related QOL, and/or swallowing function for these patients. The results of this investigation indicated that both a direct and indirect PDT program may reduce the swallowing-related side-effects of CRT on swallowing function, swallowing-related QOL, and pain while swallowing. Because this population often experiences odynophagia, choosing an indirect PDT program may reduce the amount of pain the patient experiences during their swallowing intervention.

In addition to reducing the side-effects of CRT, PDT may also provide a psychological buffer for these patients. Several of the participants in this investigation reported an improved sense of control over their health following prescription of their PDT program. This improved
internal locus of control may reduce the patients’ mental and emotional burden associated with a HNC diagnosis, while possibly increasing the patients’ compliance with their program.

Dysphagia and the trauma of being diagnosed with HNC may negatively impact the patients’ QOL and general psychological state. Patients in this investigation often appeared overwhelmed with their newly diagnosed HNC. In this study, the patients’ psychological state seemed to lower their ability to learn their exercise programs. Therefore, patients often required re-instruction on how to perform their exercises accurately. Because patients are often required to perform PDT independently, sufficient training time with their attending SLP should be provided to ensure proper execution of the exercises.

As a result of this investigation and previous studies on this topic, PDT is nearly unanimously supported for this population. Patients with HNC who are receiving CRT should be provided with a rehabilitative swallowing exercise program prior to and during their CRT regimen. Both the direct and indirect exercise programs performed equally well. Due to the high prevalence of odynophagia in this population, however, an indirect exercise program may cause less pain during the exercise regimen than a direct or mixed (direct and indirect exercises) exercise program. Therefore, an indirect PDT regimen is most likely a better clinical recommendation. Additionally, some patients who are provided PDT may demonstrate an improved internal locus of control. This may reduce the psychological burden associated with a HNC diagnosis, and increase the patients’ compliance with their program. Lastly, because many of the patients experience psychological trauma related to their newly diagnosed HNC, adequate training time should be provided to ensure proper execution of their exercises.
References


http://dx.doi.org/10.1016/j.oraloncology.2006.04.003


APPENDICES
Appendix A
Permission to be Contacted Form

Return this form to:
Attn: Laurie Slovarp/Shanna Stack
CSD Department
Fax: 406-243-2362

Study Title:
Preventative Dysphagia Intervention for Patients with Head and Neck Cancer receiving Chemoradiation Therapy (CRT)

Investigator(s):
Laurie Slovarp M. S., SLP-CCC, BRS-S, The University of Montana, Department of Communicative Sciences and Disorders (CSD 031), (406)243-2107
Ginger Collins Ph.d., SLP-CCC, The University of Montana, Department of Communicative Sciences and Disorders (CSD 021), (406)243-2626
Shanna L. Stack B.A., The University of Montana, Department of Communicative Sciences and Disorders (CSD), (406)243-2107

Purpose
You are being asked to be contacted by researchers at the University of Montana, to learn more about taking part in a research study comparing two different exercise programs used to help prevent or minimize dysphagia (an impairment in the ability to swallow). This study is designed to help develop an optimal treatment protocol that minimizes the prevalence and degree of dysphagia in patients treated with chemoradiation therapy (CRT) for oral, pharyngeal, and/or laryngeal cancer, while also minimizing discomfort.

Statement of consent to be contacted by the researchers:

I, ___________________________, agree to be contacted by the researchers at The University of Montana for additional information on the above mentioned study. I am in no way agreeing at this time to participate in the study.

You may contact me via:

☐ Phone: ___________________________

☐ Email: ___________________________

Patient Signature ___________________________ Date ___________________________

Patient’s projected start date of radiation therapy: ___________________________
Appendix B

Subject Information and Informed Consent

Study Title:
Preventative Dysphagia Intervention for Patients with Head and Neck Cancer receiving Chemoradiation Therapy (CRT)

Investigator(s):
Laurie Slovarp M.S., SLP-CCC, BRS-S, The University of Montana, Department of Communicative Sciences and Disorders (CSD 031), (406)243-2107
Ginger Collins Ph.d., SLP-CCC, The University of Montana, Department of Communicative Sciences and Disorders (CSD 021), (406)243-2626
Shanna L. Stack B.A., The University of Montana, Department of Communicative Sciences and Disorders (CSD), (406)243-2107
Kerrigan O’Connell, M.S., SLP, Speech-Language Pathologist, Saint Patrick Hospital
Kate McKay, M.S., SLP, Speech-Language Pathologist, Saint Patrick Hospital

Special instructions
This consent form may contain words that are new to you. If you read any words that are unclear to you, please ask the person who gave you this form to explain them to you.

Purpose
You are being asked to take part in a research study comparing two different exercise programs used to help prevent or minimize difficulty swallowing (called “dysphagia”). This study is designed to help develop a way to minimize the degree and discomfort of dysphagia in patients treated with chemoradiation therapy (CRT) for oral, pharyngeal, and/or laryngeal cancer.

Procedures
If you agree to take part in this research study you will be asked to

Preventative Dysphagia with H&N Cancer Patients Informed Consent (9/3/12) Page 1 of 7
1. undergo a baseline instrumental swallow study (modified barium swallow (MBS) or fiberoptic endoscopic evaluation of swallowing (FEES)),
2. complete daily swallowing exercises throughout your radiation therapy, and
3. periodically fill out a number of brief questionnaires to assess your swallowing function.

You will be assigned to one of two treatment groups. Both treatment groups will be given a series of swallowing exercises. Both types of exercise have been shown to be helpful for minimizing dysphagia during and after CRT.

Swallowing exercise group: The exercises for this group will primarily emphasize swallow strengthening with primarily exercises that require you to swallow (see “Swallowing Exercises Handout”).

Non-swallowing exercise group: The exercises for this group will not require swallowing during the exercises; rather the exercises will focus primarily on flexibility of the muscles used during swallowing (see "Non-Swallowing Exercises Handout").

The following is a description of the timeline/phases of the study.

- **Baseline Instrumental Swallow Study:** At least two weeks prior to beginning chemoradiation, you will undergo an instrumental swallow examination (either a Modified Barium Study (MBS) or a Fiberoptic Endoscopic Evaluation of Swallowing (FEES), either of which are routinely recommended prior to beginning chemoradiation to the mouth, pharynx, or larynx)

- **Training Phase:** Following the instrumental swallow study, you will be seen by the investigator(s) for 2-3 sessions for an initial interview and for training to learn how to perform your exercise program and how to track compliance to the program. Whenever possible the iSwallow™ application will be used for tracking compliance. iSwallow™ is an application that is used on Apple® devices that will remind you of your exercises, provide instructions when necessary, and track compliance with the exercise program. If you do not have access to an Apple® device (e.g., iTouch, iPhone, iPad), one will be provided to you for use during the treatment phase of this study by the researchers. If you are opposed to using iSwallow™, or the researchers do not have an extra Apple® device to provide you with, a paper tracking form will be provided and you will be asked to keep a daily record of your exercises.

- **Treatment Phase:** Following the training phase, you will be seen once every two weeks throughout CRT (or more if necessary given the severity of your dysphagia) to document progress using a number of tools. You will fill out three questionnaires. 1) Feeding tube use will be tracked using a questionnaire. 2) Behaviors, responses and quality of life related to dysphagia will be assessed using the SWAL-QOL (swallowing quality of life) survey. 3) The percentage of food you eat by mouth will be tracked using a survey developed by the researchers. 4) Body mass index (BMI) will be taken by measuring your height and weight using standard medical procedure.
After CRT, the investigators will see you as appropriate for dysphagia therapy until you return to full per oral (P.O., by mouth) intake with the least restrictive diet possible. Your dysphagia therapy at that point will be guided by the nature of your dysphagia and best practices.

• **Long-term Phase:** After you have been discharged from therapy, the principle investigator (Laurie Slovarp) will follow up with you every six months for one year and once per year for 10 years. During this phase you will fill out the SWAL-QOL and oral food intake surveys, and return them to the researcher. A self-addressed, stamped envelope will be included for you to return them at no cost to you. This should take you no more than 10 minutes.

**Risks/Discomforts**

You may experience pain, fatigue, frustration or aspiration (small amounts of food or liquid into your airway) during the therapy. The therapies chosen are considered safe and ethical practice and will not exceed the expected risks/discomforts from traditional dysphagia therapy. You will be able to take short breaks during treatment to help alleviate any pain, fatigue, or frustration that may occur as a result of therapy. You also may drop out of the study at any time without any penalty or effect on your medical treatment or care. The researchers will communicate with your medical team and will report any concerning effects that may warrant medical management, although it is highly unlikely that participation in this study will lead to any such effects.

**Benefits**

There is no guarantee that you will receive any direct benefit from taking part in this study, but participation may minimize your swallowing impairment severity while and after you complete CRT. Specifically, the exercises chosen for the study have been shown to improve swallowing function following CRT (Carrol, Locher, Canon, Bohannon, McCulloch, & Magnuson, 2008; Hutcheson & Lewin, 2012; Vander Molen, Van Rossum, Burkhead, Smeele, Coen, & Hilgers, 2011). You will also receive swallowing therapy from a certified Speech Language Pathologist. Additionally, you will be contributing to the knowledge base on how best to treat patients with head and neck cancer who suffer from dysphagia.

**Payment**

There will be no cost to you for participating in this study and you will not receive payment for participating. However, costs that are related to the standard treatment for your dysphagia and not related to this research will be billed to you or your insurance company (i.e., modified barium swallow studies and swallowing therapy following completion of CRT). If it is necessary for you to have additional swallowing therapy following completion of CRT, and you are unable to pay for such therapy (e.g., uninsured or underinsured), you will have the option to receive therapy at no charge through the RiteCare Speech, Language, and Hearing Clinic at The University of Montana.

**Confidentiality**
Your identity and the information that is obtained about you during this study will remain confidential to the extent provided by law. However, the study investigator, National Institute of Health, The US Food and Drug Administration (FDA), study staff, study sponsor, and the Joint Investigational Review Board may review your records to verify study related information. If the study results are published or presented, you will not be identified by your name.

Prior to the first screening, you will be given this research consent form, and HIPAA (Health Insurance Portability and Accountability Act) form. These will be the only forms containing your personal information (name, date of birth, address, phone number, email). The consent form has a place to write in a non-identifiable participant code. Your identification on all subsequent documents (other than the consent form and the HIPAA form) specifically pertaining to the research will be by the non-identifiable code rather than your name and will be kept in a locked file cabinet in room 031 in the Department of Communicative Sciences and Disorders. Consent and HIPAA forms, as well as medical records pertaining to standard dysphagia care that is outside the scope of the specific research protocol, will be kept in your therapy chart, which will be kept in a locked file cabinet. This will ensure that coded data is not easily associated with your name. Only the research team and necessary medical professionals outlined by the laws of HIPAA will have access to these files. All data files will be identified with the same anonymous code and will be password protected.

Compensation for Injury

Although we do not foresee any risk in taking part in this study, the following liability statement is required in all University of Montana consent forms: “In the event that you are injured as a result of this research you should individually seek appropriate medical treatment. If the injury is caused by the negligence of The University or any of its employees, you may be entitled to reimbursement or compensation pursuant to the Comprehensive State Insurance Plan established by the Department of Administration under the authority of M.C.A., Title 2, Ch 9. In the event of a claim for such injury, further information may be obtained from The University’s Claims representative or University Legal Counsel.” (Reviewed by University Legal Counsel, July 6, 1993)

It is not the regular policy of The University of Montana or Saint Patrick Hospital, the sponsor of this research study, to provide compensation for injury beyond what is stated in the above paragraph. You still have all of your legal rights to seek other compensation.

Pregnancy/Contraception

You should not undergo a modified barium swallow (MBS) study if you are pregnant. If you are pregnant, or become pregnant during the study, be sure to inform us. If this does happen, you will be given the option to have endoscopic swallow study (FEES) study instead. Your participation in this study poses no other risks pertaining to pregnancy or contraception.

Voluntary Participation/Withdrawal

Your decision to take part in this research study is voluntary. You may refuse to take part in or you may withdraw from the study at any time without penalty or loss of benefits to which you are
normally entitled. If you decide to withdraw, contact the lead investigator, Laurie Slovarp MS, SLP-CCC, BR-S at The University of Montana, Department of Communicative Sciences and Disorders (CSD 031), (406)243-2107.

Questions

This research study has been reviewed by the Joint Investigational Review Board (JIRB) for the purpose of protecting your safety and rights. The JIRB was instituted under Federal and State law to review studies such as this one in order to protect research participants from:

- unnecessary risks
- risks that outweigh the benefits
- procedures that are scientifically unnecessary

If you have any questions regarding your rights as a research study participant, you may call the Joint Investigational Review Board (JIRB) Coordinator at (406) 329-5669.

If you have any questions about the research procedures now or during the study contact: Laurie Slovarp, The University of Montana, Department of Communicative Sciences and Disorders (CSD 031), (406)243-2107.

Video Recordings

We would like to videotape the study procedures. Videotaping is completely voluntary. Participants are free to withdraw their recordings from this study at any time without penalty and without jeopardizing future services at The University of Montana or Providence Saint Patrick Hospital. We will provide an opportunity for you to review and edit the recordings if you request. We may also want to use the recordings for future related research or for educational purposes. Although the recordings will not be labeled with your name, someone who knows you may be able to identify you from the recordings.

We would like your consent to the following specific uses of the video recordings made of you. If you have any questions or concerns about the recordings or their use, you are free to restrict the uses described below. Restrictions will not affect your participation in any current or future research studies or clinical services at the RiteCare Speech, Language and Hearing Clinic or at Saint Patrick Hospital.

Do you consent to being video recorded for Research Purposes? (i.e., viewing/listening by The University of Montana faculty, students, and staff for research purposes)

☐ Yes  ☐ No  initials: ___

Do you consent to being video recorded for the following educational Purposes?

- Viewing/listening by The University of Montana faculty, students, and staff for education (e.g., course presentations, lectures, assignments, etc.)

☐ Yes  ☐ No  initials: ___

Preventative Dysphagia with H&N Cancer Patients Informed Consent (9/3/12)  Page 5 of 7
• Viewing/listening by participants in any educational activities at the discretion of Speech Pathology and Audiology faculty and staff. The educational activities include conferences and workshops attended by students, professionals, and caregivers. The recordings may be shared through any medium, provided it is not available to the general public.
  □ Yes □ No initials: ___
• Viewing/listening by the general public at activities or through media sponsored or licensed by The University of Montana, or its faculty or staff (e.g., Internet/World Wide Web, local television)? □ Yes □ No initials: ___
• Viewing/listening by the general public through licensed commercial enterprises for educational or research purposes, for example a CD-ROM enclosed in a textbook.
  □ Yes □ No initials: ___

Decline of Video/Audio Recording
• If you would not like to be video or audio recorded, place your initials here ___.

STATEMENT OF CONSENT
If you agree to be a participant of this study, sign one of the following two consent statements:

Statement of Consent to participate as a treatment participant

I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I voluntarily agree to take part in this study. I understand I will receive a copy of this consent form.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a participant in a research study.

I voluntarily agree to participate in this study and authorize the use and disclosure of my private health information as outlined in this form.

Participant Code: ________

Participant Name (printed): ______________________________ Date of birth: ____________

Age: ______________ Gender: □ male □ female

Address: _______________________________________

Primary phone number: ___________________ Alternative phone: ___________________

Email address: ________________________ Radiation Oncologist: ________________
We may need to contact you regarding scheduling. How may we contact you?

☐ Telephone ☐ Text messaging ☐ email

Participant signature: ____________________________ Date: ______________

Investigator Signature: ____________________________

Consent to participate only as a non-treatment control participant

I decline to participate in the baseline, training and treatment phases of this study, but agree to participate as a non-treatment control participant. I agree to answer the questionnaires at the same frequencies as the treatment participants.

Participant Code: __________

Participant Name (printed): ____________________________ Date of birth: ______________

Age: _______ Gender: ☐ male ☐ female

Address: ____________________________________________

Primary phone number: ______________ Alternative phone: ______________

email address: ____________________________ Radiation Oncologist: ____________________________

How may we contact you?

☐ Telephone ☐ Text messaging ☐ email

Participant signature: ____________________________ Date: ______________

Investigator Signature: ____________________________
Appendix C
Authorization for Access to Personal Health Information

The University of Montana
College of Education and Human Sciences
RicoCare Speech Language Hearing Clinic
32 Campus Drive
Missoula, MT 59812-6695
CSD Office: (406) 243-2363
Clinic Office: (406) 243-2405
Fax: (406) 243-2362

(Appendix B)

Preventative Dysphagia Intervention for Patients with Head and Neck Cancer Receiving Chemoradiation Therapy (CRT)

Authorization for Access to Personal Health Information

A federal government rule has been issued to protect the privacy rights of patients. The rule is designed to protect the confidentiality of your personal health information. We are required by these new regulations to obtain your authorization to share personal health information that may reveal your identity.

What Information will be Used or Disclosed
For this research study, the health information to be used or disclosed includes information contained in your existing medical records and new information created or collected during this study. Your records may include information about your physical examinations, medical procedures (e.g., surgeries, swallow studies, chemoradiation), medical history, and any other data collected or reviewed during the course of the study as described in the consent form.

Purpose for Use or Disclosure
The purpose for use or disclosure of information gathered will be to measure the effectiveness of the therapies being studied in this research and to develop a better understanding of how best to treat dysphagia in patients with head and neck cancer.

Who May Use or Disclose Information
The persons and organizations that may use or disclose your individually identifiable health information may include: your physicians, the study investigator (Laurie Slovarp) and investigator staff.

Who May Receive Information
The persons and entities that may receive your personal health information may include: National Institute of Health, The US Food and Drug Administration (FDA), and the Saint Patrick Hospital/Community Medical Center Joint Investigational Review Board.

Every effort will be made to maintain confidentiality of information accessed. However, absolute confidentiality cannot be guaranteed. Once your personal health information is released it may be re-disclosed, at which point your health information will no longer be protected by federal privacy regulations.

Duration of Authorization
This authorization does not have an expiration date. If you do not cancel this authorization, then it will remain in effect indefinitely.

Right to Refuse, Withdraw or Cancel Authorization
You may refuse to sign this authorization. If you refuse to sign this authorization, you will not be able to take part in this study. However, you will not be penalized or lose any benefits to which you are otherwise entitled. You will continue to receive treatment for your condition.

You have the right to cancel this authorization or withdraw from this study at any time with no penalty. If you choose to do so, you must notify the study investigator in writing at Laurie Slovarp, Department of Communicative

Patient Access to Records
You have the right to access your medical records at any time. However, you will not be able to access study specific information until the study is completed, at which time your right of access will be restored.

Privacy Authorization
I have read this Privacy Authorization and have had my questions answered to my satisfaction at this time. I understand that by signing this consent, I authorize the release of my medical records and health information related to this study. I authorize the use, disclosure, review, duplication, storage and data transfer of my medical records and study information. I understand this information may be obtained by the persons and organizations stated above. I will receive a copy of this signed authorization.

I authorize the following medical personnel/healthcare facilities to release my records.

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PROPHYLACTIC -DYSPHAGIA INTERVENTION

Or

____________________________________________________  ___________________  ______________________________
Signature of Legal Representative  Date  Name of Legal Representative
(Printed)

________________________________________________________________________________________
Relationship to Participant
Appendix D

Case History Questionnaire

Preventative Dysphagia Intervention for Patients with Head and Neck Cancer Receiving Chemoradiation

Case History Questionnaire

Participant code: ________________ Date __________

Date of initial diagnosis: __________ Site of Cancer: __________________________

TNM score: ______________ Tumor size: ____________________________

Physician Name: ____________________________

Physician Address: ____________________________

Surgery plan: □ NO □ YES: date: ____________________________

Description: ____________________________

Start date of radiation therapy: __________ Frequency: ____________________________

Projected weeks of radiation therapy: ____________________________

Start date of chemotherapy: __________ Frequency: ____________________________

Projected weeks of chemotherapy: ____________________________

Previous Diagnosis of Dysphagia (unrelated to current cancer dx) □ NO □ YES

Date: ____________________________________________

Description and cause of dysphagia: ____________________________

Preventative Dysphagia with H&N Cancer Case History From ____________________________
Was there full resolution of that dysphagia?  □ No  □ Yes

**Previous Diagnoses** (check all that apply below):

☐ brain injury  ☐ dementia  ☐ motor neuron disease

☐ myasthenia gravis  ☐ cerebral palsy  ☐ Guillain-Barre’ syndrome

☐ Poliomyelitis  ☐ Parkinson’s disease  ☐ Huntington’s disease

☐ Wilson’s disease  ☐ Progressive supranuclear palsy

☐ stroke  ☐ multiple systems atrophy

☐ previous cancer: ________________________________

☐ other: _______________________________________

**Description of any above medical diagnoses:**

---

**Current Nutritional Intake Status:**

**Oral diet:**  □ regular  □ soft solids  □ pureed  □ liquids only

**Liquids:**  □ regular/thin  □ nectar-thick  □ honey-thick  □ pudding-thick

**Tube feeding:**  □ NO  □ Yes  type:______________________________

Length of time on tube feeding? ________________________________
Appendix E

Direct (Swallowing) Exercises

Mendelsohn
When you swallow your throat elevates and then immediately drops back down. To do this, swallow and hold your throat up 2-3 seconds. To do this you will hold the contraction of the swallowing muscles. You have already swallowed so the food is gone, you are just not releasing the swallow. You will not be able to breathe while you are holding your throat up. Do this exercise 15 times in a row, 3 times per day, 7 days per week.

Effortful Swallow
When you swallow squeeze all you swallowing muscles as hard as you can. You can do this while swallowing anything. Do this exercise 20 times in a row, 3 times per day, 7 days per week.

Masako
Do this exercise when you only have saliva in your mouth. Place your tongue between your teeth and lightly bite down with enough force to hold your tongue in place. Be sure to keep your tongue between your teeth and swallow. Do this exercise 10 times in a row, 3 times per day, 7 days per week.

Shaker
This exercise has two parts. Both parts requires the same type of motion. Lie flat on your back without a pillow and lift your head so that your chin approaches your chest. Do not lift your shoulders off of the ground. Try to look at your toes. **Part 1**: hold your head up for one minute (or as long as you can). **Part 2**: lift and lower your head 20 times holding at the top each time for just 1-2 seconds. Do this exercise once per day, 7 days per week.
Appendix F

Indirect (Non-Swallowing) Exercises

Shaker

This exercise has two parts. Both parts require the same type of motion. Lie flat on your back without a pillow and lift your head so that your chin approaches your chest. Do not lift your shoulders off of the ground. Try to look at your toes. **Part 1:** hold your head up for one minute (or as long as you can). **Part 2:** lift and lower your head 20 times holding at the top each time for just 1-2 seconds. Do this exercise once per day, 7 days per week.

Fahetto “ee”

Take a deep breath and then say a soft, high pitched “ee” sound as long as you can. Do this exercise 6 times in a row, 3 times per day, 7 days per week. (IRB NOTE: the participant may be asked to do this exercise up to 10 times in a row if the length of time they can hold the note is shorter than normal. Normal is over 15 seconds.)

Tongue-Base Retraction

Stick your tongue out and grab it between your fingers with a washcloth. Then pull your tongue back into your mouth as far as you can, providing resistance by holding your tongue with the washcloth. You will likely have to stop to swallow intermittently. If you have trouble holding your tongue, you can just stick your tongue out and pull it in your mouth without resistance. If you do it this way, do it in front of a mirror and try to not curl your tongue tip. You should feel the back of your tongue touch the back of your throat. If it makes you gag, you likely did it correctly. Do this exercise 10 times, 3 times per day, 7 days per week.

Lingual Range of Motion Exercises

Stick out your tongue and move it up towards your nose and then down towards your chin. Stretch as far as you can in both directions. Repeat 10 times, 3 times per day, 7 days per week.

Move your tongue in a circle on the outside of all of your teeth (as if you are cleaning food off of the outer surface of your teeth). Repeat 10 times, 3 times per day, 7 days per week.

Press your tongue in to each of your cheeks (going back and forth). Stretch as far as you can. Do this exercise 10 times, 3 times per day, 7 days per week.

Jaw Range of Motion Exercises

Open your mouth as far as you can and hold for 2-3 seconds, close and repeat. Do this exercise 10 times, 3 times per day, 7 days per week.

Move your jaw from side to side as far as you can each way. Do this exercise 10 times, 3 times per day, 7 days per week.
Appendix G
Nutritional and Pain Questionnaire and Functional Oral Intake Scale

NUTRITIONAL AND PAIN QUESTIONNAIRE
APPENDIX G

Participant code: ___________________________ Date: ___________________________
Researcher Name: ____________________________

Body Mass Index (BMI):

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<th>Weight (kg)</th>
<th>Height (m)</th>
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*BMI = Weight (kg) / (Height (m) x Height (m))

Tube Feeding Use:
Do you currently have a tube inserted into your stomach for nutrition? Mark the correct answer.

Yes ☐ No ☐

If yes, please answer the following question. If no, please skip to pain rating section.

Approximately, what percentage of your daily food intake is consumed using your tube?
Check one option:

☐ 0-10%
☐ 10-25%
☐ 25-50%
☐ 50-75%
☐ 75-100%
☐ 90-100%

Pain Rating:
Please use the following scale to indicate the amount of pain you have with swallowing.

☐ 0 (no pain)
☐ 1-2 (mild discomfort)
☐ 3-4 (moderate discomfort)
☐ 5-6 (severe pain)
☐ 7-8 (very severe pain)
☐ 9-10 (excruciating pain)

Functional Oral Intake Scale

TUBE DEPENDENT (levels 1-3)

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

TOTAL ORAL INTAKE (levels 4-7)

4. Total oral intake of a single consistency
5. Total oral intake of multiple consistencies requiring special preparation
6. Total oral intake with no special preparation, but must avoid specific foods or liquid items
7. Total oral intake with no restrictions
### Eating Assessment Tool (EAT – 20)

**Participant code:** 

**Date:** 

<table>
<thead>
<tr>
<th>Circle the appropriate response:</th>
<th>0 = No problem</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>To what extent are the following scenarios problematic for you?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. My swallowing problem has caused me to lose weight.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. My swallowing problem interferes with my ability to go out for meals.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. My swallowing problem interferes with my work or other activities.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. Swallowing liquids takes extra effort.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. Swallowing solids takes extra effort.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. Swallowing pills takes extra effort</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7. I have altered my diet because of my swallowing problem.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. Swallowing is painful.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. The pleasure of eating is affected by my swallowing.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10. When I swallow food sticks in my throat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11. When I swallow food sticks in my chest.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. I cough when I eat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13. I am afraid to eat because of my swallowing problem.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>14. My swallowing problem is a burden to my family.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>15. I get tired when I eat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16. I avoid eating in front of people.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17. I am afraid of choking in my sleep.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>18. I become short of breath when I eat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>19. People perceive me as sick because of my swallowing problem.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>20. Swallowing is stressful.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**TOTAL:**

Joint SPH/CMC IRB

Expeditied approval [SEP 1 2012]