NO PAIN, A LOT TO GAIN
EXPLORING THE USE OF VIRTUAL REALITY TO INCREASE ADHERENCE TO DYSPHAGIA THERAPY IN HEAD AND NECK CANCER PATIENTS

By

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ABSTRACT

Background: Radiation therapy (XRT) for head and neck cancer (HNC) can significantly impact a person's ability to swallow. Dysphagia exercises completed during XRT are known to benefit long term swallowing outcomes. However, adherence to therapy during XRT is low often because of pain from the oncological treatment. Complementary and integrative pain management techniques have been investigated with various cancer populations, including some focus on patients with head and neck cancer. Virtual reality (VR) is one such method, but it has not yet been studied with HNC patients as a pain mitigation approach to increase dysphagia therapy adherence. The goals of this dissertation are to: (1) determine the perceptions and experiences of speech-language pathologists (SLPs) on pain and pain management because they would principally be the ones doing such work, (2) assess the user experience (UX) in VR of adults without HNC, and (3) assess the feasibility and user experience of VR with HNC patients who are completing XRT. This foundational information is needed to inform future work assessing the efficacy of using VR for pain mitigation to optimize dysphagia therapy adherence. The feasibility and UX studies are vital because HNC patients in XRT often already experience negative side effects from their cancer treatment that might be exacerbated by effects from VR.

Methods: The first study surveyed clinically practicing SLPs (N=207) regarding pain and pain management education, training, and implementation. Study two assessed adults without HNC (N=30) to establish a UX data set for adults without HNC. Following a single session VR, participants completed UX survey tools regarding usability, acceptability, and negative side effects. Study three assessed the UX of HNC patients (N=10) who participated

in three sessions of VR (Pre-, Mid-, and Post-XRT). As part of this protocol, within session changes from pre- to post-VR in self-rated swallowing and general pain was tracked. In Studies 2 and 3, groups were block randomized into one of two VR conditions (active or passive VR) to allow exploration of the type of VR on UX.

Results: SLPs reported limited education and training in pain and pain management despite caseloads frequently having individuals with pain that impacted evaluation and treatment, including therapeutic progress. There was strong support for the use of novel techniques for pain management. In study two, there were no differences in UX between active and passive VR experiences for adults without HNC. Patients with HNC in study three also showed no differences between active and passive virtual reality experiences. Negative side effects were minimal and remained consistent throughout the course of XRT. There were no differences in UX between individuals with and those without HNC in terms of usability and acceptability of VR, or presence of negative side effects. There were clinically meaningful reductions in both general and swallowing-related pain with use of virtual reality in the HNC patients.

Conclusions: SLPs would benefit from increased opportunities in education and training on pain and pain management. They expressed willingness to use novel techniques, like VR, for this purpose. The user experience of VR in active and passive environments was positive for adults with and without HNC and both groups expressed a high level of willingness to adopt VR use. There were minimal negative side effects in both groups. Of importance was that clinically meaningful decreases in perceived pain (swallowing and general) occurred following VR sessions in the HNC patients. These

results are promising and justify further studies beginning to look at the efficacy of VR as a pain mitigation tool for patients with HNC undergoing XRT.

This dissertation is dedicated to Matt Boersma and his family. Your strength, perseverance, and positive outlook are truly inspiring. Thank you for placing your trust in a young SLP with an idea (and a bag of Sweet Tarts) – I couldn't have imagined a better way to begin this journey.

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LIST OF ABBREVIATIONS

aVR	active virtual reality
BTP	break through pain
CAM	complementary and alternative medicine
CIM	complementary and integrative medicine
CT	chemotherapy
DHT	Dobhoff tube
ESAS-r	Edmonton Symptom Assessment System-Revised
HFH	Henry Ford Health
HNC	head and neck cancer
MAIA-2	Multidimensional Assessment of Interoceptive Awareness, Version 2
NPR	numeric pain rating
NRS	numeric rating scale
OM	oral mucositis
PEG	percutaneous endoscopic gastrostomy
PM	pain management
pVR	passive virtual reality
QOL	quality of life
SCC	squamous cell carcinoma
sEMG	surface electromyography
SLP	speech-language pathologist
UX	user experience
VEQ	Virtual Experience Questionnaire

VR	virtual reality
XRT	radiation treatment/therapy

CHAPTER 1. INTRODUCTION

Cancer. A word that holds significant weight as it can incite a multitude of feelings in individuals. Whether patient or caregiver, family, friend, or medical professional, nearly everyone has been impacted by this diagnosis in some way. Head and neck cancer (HNC) is the 6th most common cancer globally (Sung et al., 2021) and is known to have profound impact on individuals' communication and swallowing because structures affected involve the face, oral cavity, pharynx, and larynx. Oncologic interventions required for HNC include chemotherapy (CT), immunotherapy, radiation, surgery, or a combination of these options. Radiation therapy (XRT), with or without concurrent CT, is often utilized as a means of organ preservation, rather than surgical excision, to avoid permanent anatomical change to structures involved in communication and swallowing.

The comorbidity of dysphagia, or difficulty swallowing, and HNC is significant with up to 66% of individuals reporting its occurrence at some point during their cancer journey (Russi et al., 2012). Dysphagia in HNC can be symptomatic of either the cancer itself or the oncologic interventions required for treatment. Exacerbation of dysphagia from oncologic intervention is often due to side effects such as odynophagia (painful swallowing), xerostomia (dry mouth), mucositis (inflammation of tissue), lymphedema (fluid build-up), dysgeusia (altered taste), and muscle weakness (National Cancer Institute [NCI], 2021; Sroussi et al., 2017). An unfortunate reality of HNC is that despite an individual having concluded treatment successfully with their cancer irradicated or controlled, many communication and swallowing related side effects persist well into survivorship, if not

permanently (Hutcheson et al., 2012). Dysphagia prevalence in HNC survivors has been reported at about 45% (Hutcheson et al., 2019).

Speech-language pathologists (SLP) are the primary healthcare professionals responsible for diagnosis and management of dysphagia. Participation in dysphagia therapy throughout the course of cancer-related treatments has proven successful in reducing long-term swallowing deficits which ultimately improves overall quality of life (QOL) (Cristofaro et al., 2021). Despite established benefits to dysphagia therapy, adherence levels in HNC patients are extremely low at ~13% (Shinn et al., 2013). Barriers include factors such as fatigue, depression, reduced motivation, presence of prophylactic feeding tubes (i.e., PEG tubes), and pain (Rowe et al., 2023; Shinn et al., 2013). With individuals living longer following completion of cancer treatment, determining novel methods for increasing dysphagia therapy adherence is imperative to improving long-term swallowing outcomes.

Pain is a key limiting factor in adherence to dysphagia therapy for individuals with HNC (Zebralla et al., 2021). Given the subjective nature of pain, management can be challenging as some interventions might benefit one individual, but not another (Janssen, 2002). Cancer-related pain is typically managed pharmacologically, but there is an increased desire for nonpharmacologic options by patients and physicians alike as many have become opiophobic, or fearful of using opioids (McMenamin & Grant, 2015). This fear is not unfounded as many individuals with HNC are reliant on opioids long after completion of their cancer treatment (Zhao et al., 2022). SLPs are not responsible for primary pain management (PM), however they do become integrated within the process; and often are the interdisciplinary team member with whom the patient might reveal true levels of pain,

for example during swallowing therapy activities, and whether they feel their pain is being managed appropriately and effectively.

Use of virtual reality (VR) has entered the forefront of society not only for entertainment, but also as a tool in health and healthcare. Virtual reality has been applied successfully across several patient populations as a means of nonpharmacological pain management by way of distraction (Gupta et al., 2018). For example, VR has been shown to decrease reported pain by up to 50% in burn patients undergoing skin debridement (Hoffman et al., 2011) and has had positive impact in managing symptoms in both chronic (Austin et al., 2022) and cancer-related pain (Chirico et al., 2016). Although the benefit of VR has emerged in recent years, use of this technology within the HNC population for PM is understudied. Specifically, the use of VR to support rehabilitative processes for dysphagia in HNC has not yet been investigated.

The long-term goal of this line of research is to determine the impact of VR as a means of improving adherence to dysphagia therapy in the HNC population. The proposed research focuses on foundational understanding of VR application to this population, including SLPs perceptions of the impact of pain on clinical activities and an early phase interventional study of the HNC patients placed in VR. Specifically, data will be gathered to determine HNC user experiences with VR, presence of toxicities, and feasibility for implementation of VR within dysphagia therapy for HNC patients undergoing XRT. These data will be critical for subsequent studies assessing the efficacy and effectiveness of using VR as a nonpharmacologic pain mitigation technique to optimize dysphagia exercise completion. Secondary information gathered will detail individual characteristics that might be related to aspects of user experience (UX). Given that individuals are living longer

following cancer treatment, increasing adherence to dysphagia therapy is imperative to improving long-term swallowing outcomes and QOL.

CHAPTER 2. LITERATURE REVIEW

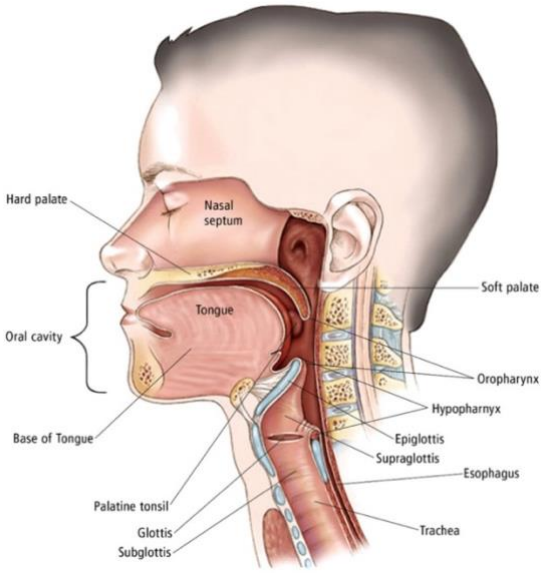
2.1 Dysphagia

2.1.1 Head and Neck Cancer and Dysphagia

Head and neck cancer accounts for more than 660,000 new cases, and 325,000 deaths annually (Johnson et al., 2020; Sung et al., 2021). This number has been steadily increasing with the rising incidence of human papillomavirus (HPV)-related oropharyngeal cancers (Gormley et al., 2022). Head and neck cancer typically begins in the squamous cells lining the mucosa on the surfaces of the head and neck regions; when originating in the squamous cells this cancer type is categorized as a squamous cell carcinoma (SCC) (Johnson et al., 2020). Approximately 90% of HNCs are SCC (HNSCC). Internationally, the incidence of HNSCC as of 2020 is about 7.9% of all new cases and HNC cases in general are anticipated to increase by 30% by 2030 (Bray et al., 2018; Sung et al., 2021).

Head and neck cancers may arise from the face, ear, nasal and oral cavities, pharynx, and larynx. The oral cavity is bound by the lips, cheeks, floor of mouth, and the oropharynx. The oropharynx begins at the junction of the hard and soft palates and base of tongue and extends inferiorly to the epiglottis. Laterally it is defined by the pharyngeal walls. The hypopharynx is the next region inferiorly and is the lowest part of the pharynx. It ends at the upper esophageal sphincter, or level of the cricopharyngeus muscle. The larynx includes the supraglottis, glottis, and subglottis; the space then continuing as the cervical trachea. These regions are further depicted in Figure 1.

Figure 1. *Lateral schematic of the head and neck*



Oncologic interventions for HNC such as XRT, CT, immunotherapy, surgery, or a combination of treatment modalities, can lead to exacerbation of existing swallowing deficits from the presence of the cancer itself, and/or development of new dysphagia due to involvement of oropharyngeal structures and musculature impacted by the cancer treatments. Dysphagia can have profound affect not only on nutritional and hydrational health, but on psychosocial well-being given the significance of food culture on QOL (Christofaro et al., 2021; Dornan et al., 2021; Farri et al., 2007; Fitchett et al., 2018; Ihara et al., 2022; Kenny, 2015; Nguyen et al., 2005). In fact, the HNC population has the second highest suicide rate among cancer subgroups, following pancreatic cancer, due to the psychological distress and significant detriments the cancer journey has on individuals (Osazuwa-Peters et al., 2018).

Although XRT (+/- CT) is used as a means of organ preservation, and as the common treatment for those with HPV positive (HPV+) cancers (Yang et al., 2022), it can result in structural, mechanical, and/or neurologic damage to the swallowing system. Modern external-beam XRT techniques, such as intensity modulated radiation therapy (IMRT), aim to reduce radiation induced toxicities with precision-based administration of radiation. This allows for lower radiation dosages to be given to healthy tissues adjacent to the tumor. Specifically, the goal is to deliver higher, more effective doses of radiation to the tumor with decreasing amounts given to surrounding areas and to critical structures that may be nearby (e.g., major vessels). Rathod et al. (2013) compared QOL outcomes in individuals treated with IMRT versus 3D conformal radiation therapy (external-beam radiation given without varying intensities) and found clinically meaningful results. Patients receiving IMRT reported significantly less occurrence of xerostomia, trismus, pain, and dysphagia, as well as overall improved QOL. However, even with use of advanced techniques, XRT for curative intent includes aggressive treatment regimens that have impacts on functions such as swallowing. Most patients with HNC receive daily radiation fractions of 1.8-2.0 Gray (Gy) for approximately 5-7 weeks (~35 sessions), resulting in totals of up to 66-70 Gy (Alfouzan, 2021). Rancati et al. (2010) reviewed radiation dosage impact on swallowing with use of various endpoints. They found increased aspiration, weight loss, stricture, PEG tube usage, and edema as well as reduced QOL with mean doses as low as 45 Gy. The standard of care XRT protocols result in 66-70 Gy for individuals with HNC, which means these patients are well above the threshold associated with dysphagia deficits.

With the cumulative nature of XRT, the pathophysiology behind damage to the tissues of the oropharynx is complex. Continuous injury to the system impedes the body's healing

process as normal molecular and cellular regulatory processes are inhibited (King et al., 2016). Specifically, radiation damages the DNA of rapidly proliferating cells (e.g., epithelial (squamous)) hindering cell survival and increasing apoptosis, or cell death (Barecellos-Hoff et al., 2005); subsequently eliminating tumors. However, radiation does not discriminate among cell types such that healthy as well as cancerous cells within the field of radiation are at risk for damage. Muscle cells, despite their slow regeneration, are also sensitive to radiation with impacts often manifesting after radiation has been completed. Additionally, acinar cells, which make up the salivary glands, are highly susceptible to radiation, leading to atrophy and loss of saliva production and secretion (Wu & Leung, 2019) which creates additional difficulties with swallowing.

Radiation injury is classified based on the time between exposure to radiation and the appearance of clinical or histological damage (Stone et al. 2003). Injury from XRT is further defined as acute, consequential (or late), or delayed. Acute effects are observed during XRT or within a few weeks following treatment completion. Consequential injury is defined as persistent acute damage that arose during XRT that continues beyond the last session of XRT for weeks or months. Lastly, delayed effects are symptoms that emerge months to years following radiation exposure. In the dysphagia literature however, deficits are often categorized into early versus delayed (or long-term or late), which typically corresponds to injury manifesting before (early) and those after 1 year (delayed) since ending XRT (King et al., 2016). For this dissertation, the temporal classifications outlined by the radiation literature will be used – acute, consequential, and delayed.

Within the acute phase of injury, the impact of radiation on swallowing may include mucositis, xerostomia, dysgeusia, odynophagia, and edema (King et al., 2016). These

deficits are often reversible and occur during or immediately following treatment. The consequential phase of injury includes these same deficits in a prolonged manner – persisting for months after therapy completion. Delayed injury often manifests as fibrotic tissues, trismus, neuropathy, lymphedema, stricture, and generalized musculature atrophy (Chiu et al., 2022). The latter phase deficits are often irreversible and can cause significantly reduced QOL. Radiation injury impact on swallowing ordered by time is detailed in Table 1.

Table 1. *Radiation Injury Differences in Swallowing Dysfunction*

Injury Classification		Timing	Clinical Features
Dysphagia Literature	**Radiation Literature**		
Early	Acute	During or weeks after XRT	Mucositis, xerostomia, dysgeusia, odynophagia, tissue edema
Delayed, Long-Term, or Late	Consequential or Late	Weeks to months after XRT	Symptoms similar to acute injury
	Delayed	Years post XRT	Muscle atrophy and fibrosis, trismus, neuropathy, lymphedema, stricture formation

Table content based on Chiu et al. (2022) and King et al. (2016).

2.1.2 Dysphagia Management

Management of dysphagia over the years has transitioned from heavy reliance on compensatory strategies and diet modification to rehabilitative protocols focused on building physiological capabilities of the swallowing musculature (Kraaijenga et al., 2014). Fortunately, many of the strategies have demonstrated success. In addition to strength-building approaches in isolation, there has been investigation of skill-based programs training improvement in force, timing, or coordination of swallowing (Huckabee et al., 2022; Malandraki & Hutcheson, 2018). Both types of rehabilitation rely on principles grounded in motor learning, neural plasticity, system loading, and exercise dosing (Krekeler et al., 2021; Zimmerman et al., 2020). Examples of exercise or strength-based

approaches with known success include the Shaker exercise and expiratory muscle strength training (Langmore & Pisenga, 2015; Steele, 2012). More comprehensive therapy programs which target skill in addition to strength include but are not limited to the Intensive Dysphagia Rehabilitation approach and the MD Anderson Swallowing Boot Camp protocol (Hutcheson et al., 2015; Malandraki et al., 2016; Malandraki & Hutcheson, 2018,).

Within the HNC literature, common dysphagia management practice is to combine exercise with continuation of oral diet (Barbon et al., 2022). With XRT in particular, the concept of "use it or lose it" is often applied as research has demonstrated the benefit of prophylactic swallowing exercises, initiated either prior to the start of XRT or concurrent with it, to prevent disuse atrophy of musculature (Hutcheson et al., 2013, Loewen et al., 2021). Typical dysphagia treatment plans for HNC patients undergoing XRT include a discussion of current oral intake, range of motion stretches, and swallow related exercises. Dysphagia treatment protocols with the most success emphasize use of swallowing exercises and continuation of oral diet consumption before, during, and after radiation treatment (Barbon et al., 2022; Hutcheson et al., 2013; Malandraki et al., 2016). According to a literature review by Loewen et al., (2021) detailing prehabilitative dysphagia therapy in HNC patients, the exercises utilized most are the Mendelsohn maneuver, effortful swallow, Shaker, and Masako. The most common reported dosage across studies was 10 repetitions of each exercise, three times daily throughout XRT with measurements of success including patient reported outcome measures, PEG tube dependence, extent of mouth opening, and swallowing physiology features determined from videofluoroscopic swallow studies (Loewen et al., 2021).

2.1.3 Adherence to Dysphagia Treatment

In general, rehabilitation approaches rely on patient follow-through with recommendations to complete specific actions, exercises, or activities. The extent to which patients follow through on these recommendations is broadly described as the patient's level of adherence to the intervention. Compliance is a term that has been used interchangeably with adherence; however, such use has fallen out of favor in recent years. Compliance has been defined as the "act of conforming to professional recommendations... whether or not an intervention is performed as directed but does not consider the context in which that intervention takes place" (Wells & King, 2017). Whereas adherence can be defined more formally as "a process influenced by the environment, recognizing that behavior is shaped by social contexts as well as personal knowledge, motivation, skills, and resources" (Wells & King, 2017). The World Health Organization (WHO) categorizes barriers in one's ability to follow treatment, or recommendations, as disease, socio-economic, or patient related (Sabate, 2003) further indicating the impact of not just the individual, but the context around them. Thus, for the purpose of this research, adherence is the term adopted for use.

Adherence is dynamic, influenced by a multitude of internal and external factors that may impact an individual at any given time. A factor of significance, especially within cancer populations, is coping style as one out of four cancer patients use maladaptive coping mechanisms (Meggiolaro et al., 2016). Coping, or the thoughts and behaviors individuals use to navigate stressful situations (Folkman & Moskowitz, 2004), is generally categorized into different styles and their use varies situationally from person to person. The four coping categories most described in the literature include problem-focused

(addressing the cause behind the distress), emotion-focused (targeting the negative emotions associated with the stressor; an example being distraction), meaning-focused (utilizing cognitive strategies to manage the implication of the situation; i.e., reframing), and social coping (gathering support from one's community), and each of these can be useful in different scenarios (Algorani & Gupta, 2023). The importance of understanding coping styles and mechanisms is that the use of maladaptive coping, or when coping strategies are harmful instead of helpful, has a higher association with an individual being increasingly non-adherent to medical advice and less likely to follow recommended lifestyle changes (Algoarni & Gupta, 2023). Maladaptive coping includes behaviors such as avoidance, disengagement, rumination, denial, substance abuse, and social withdrawal (Aloka et al., 2024). Avoidance related behaviors are further associated with anxiety and depression (Santarnecchi et al., 2018), both of which are highly prevalent affecting 25-33% of the HNC population (Shunmugasundaram et al., 2020). Understanding which coping style and mechanisms individuals use, as well as which might best suit the current situation, provides the opportunity for healthcare professionals to personalize rehabilitative programs and bolster the relationship with the patient.

2.2 Pain

2.2.1 Perception of Pain

Pain is a multidimensional experience that arises from a combination of biological, psychological, and social factors and thus requires a biopsychosocial approach to its management (Gatchel et al., 2007; Lugg, 2022). Historically, pain was thought to be exclusive to the body, i.e., having only biological causation related solely to genetics, tissue

damage, system dysfunction, inflammation, hormones, or pathology in the pain transmission system (Zoffness, 2022). Biomedical, or physical pain has been defined as an unpleasant sensation ranging from mild to agonizing that is associated with real or potential tissue damage (Trotter et al., 2013). The concept of pain being purely physical is challenged by the phenomenon of phantom limb pain, which is the sensation that pain is coming from a limb that is no longer present (Schone et al., 2022). Neuroscientists, psychologists, and researchers have not been able to determine the specific reason this sensation occurs, but its presence indicates that pain stems not only from physical dysfunction or damage but potentially also from psychological factors.

Perception of pain is highly subjective and varies amongst individuals, making management of pain challenging. Cognition, emotion, and behavior are components of the psychological domain of pain implying that a person's thoughts, beliefs, prior experiences, coping styles, feelings, and expectations can all reduce, moderate, or amplify the perception of pain (Zoffness, 2022). Given that emotions affect sensations in our body (e.g., pain) the concept of interoception, or the process by which an individual senses, interprets, integrates, and regulates the physiological condition of the body (i.e., one's inner state) is of specific interest as it can provide insight into individual differences in perceived pain and better guide management (Khalsa et al., 2018). Interoception however is a complex meta-cognitive process, and researchers have expressed differing opinions about how it should be defined (Murphy et al., 2017). Historically, interoception was thought to reference only the visceral sensations provided from key internal organs such as the heart, lungs, and stomach (Dworkin, 2007), but current definitions include other places in the body (i.e., the skin) and incorporate sensations such as hunger, thirst, temperature, and pain (Craig,

2002). More recent definitions of interoception also include the term regulation (Chen et al., 2021) and consider interoception to be an iterative process in which there is interchange between our perceptions of body states and the cognitive responses we initiate to address these states (Craig, 2009; Farb et al., 2015).

Interoceptive ability can be measured in terms of accuracy, sensibility, and awareness (Critchley & Garfinkel, 2017). Interoceptive accuracy is the objective ability to consciously detect and perceive internal sensations grounded in physiological activity such as heart rate and respiratory rate (Maister et al., 2017) and is measured by tasks such as heartbeat counting. Interoceptive sensibility is the subjective perception and beliefs about the accuracy that one perceives (Bort et al., 2021). Sensibility is assessed via self-reported measures in which individuals make explicit statements about how accurate they are in perceiving their body sensations and changes, or how attentive they are to body sensations. Lastly, interoceptive awareness is the meta-cognitive awareness of accuracy; essentially converging accuracy with sensibility (Critchley & Garfinkel, 2017). Definitions and examples of measurements related to interoceptive accuracy, sensibility, and awareness are further detailed in Figure 2.

Figure 2. *Dimensions of Interoception*

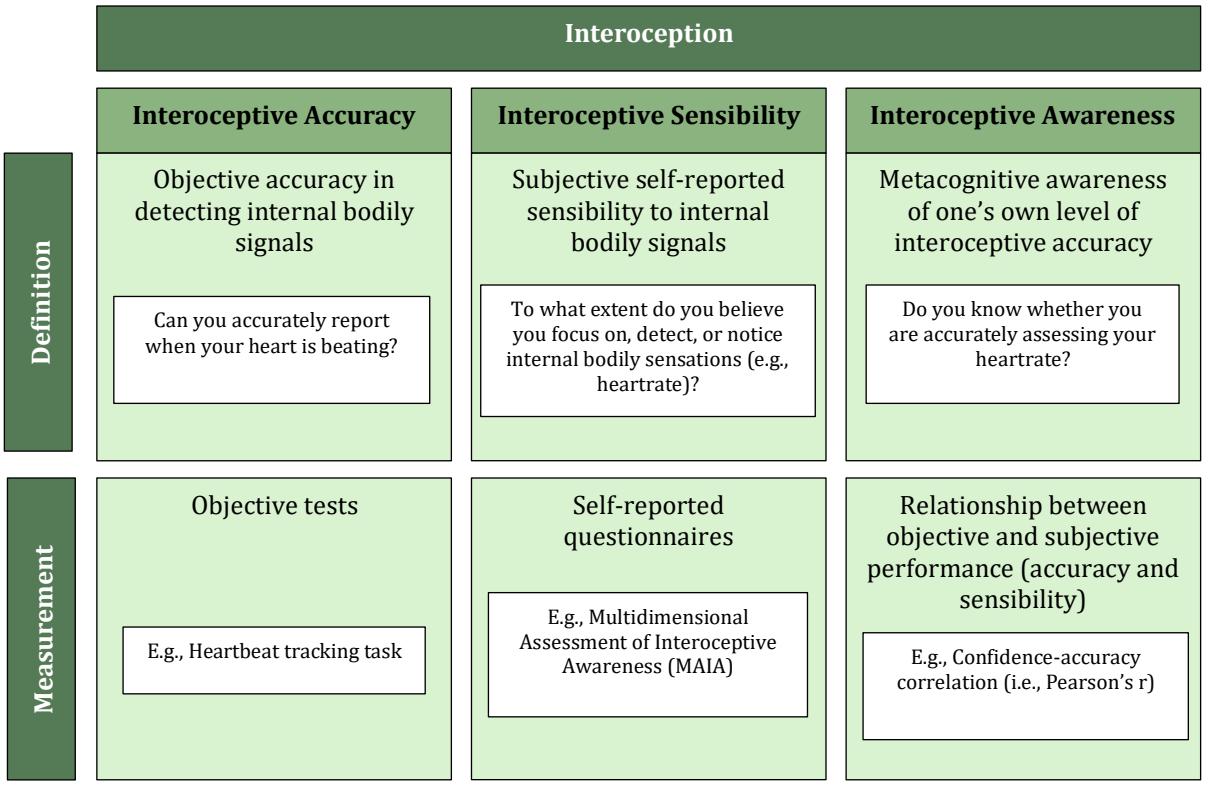


Figure based on Garfinkel et al. (2015) and Locatelli et al. (2023).

To determine how interoceptive ability can be influenced, Schuette et al. (2021) assessed undergraduate participants during a heartbeat perception task (interoceptive accuracy). The participants also completed the Multidimensional Assessment of Interoceptive Awareness (MAIA; Mehling et al., 2012), a measure of interoceptive sensibility, and reported use of coping strategies via the Brief Coping Orientation to Problems Experienced (Brief-COPE; Carver, 1997). Interoceptive sensibility, or what they called noticing, was found to be predictive of use of adaptive coping behaviors thus determining that one's ability to perceive internal sensations predicts the use of adaptive coping strategies. Tan et al. (2023) took this concept one step further by analyzing the relationship between interoceptive accuracy and coping strategy use during negative life

events. Over 200 undergraduate students were provided with prompts randomly throughout the day to report on various life events and which coping strategies had been used, if any. Individuals with higher interoceptive accuracy tended to use distraction techniques during negative life events. With the apparent link between interoceptive abilities and coping strategies, it implies that training interoception could improve one's ability to employ beneficial coping strategies, such as distraction, during negative life events (i.e., when in pain) (Ardi et al., 2021; Sugawara et al., 2020).

The relationship between pain perception and interoception has received attention over the years. A systematic review by Horsburgh et al. (2024) looked at whether interoception is altered in individuals experiencing pain. They found that those with chronic pain tend to have increased interoceptive sensibility, but decreased interoceptive accuracy (Horsburgh et al., 2024), meaning they are aware of sensations occurring in the body but are not necessarily detecting them accurately. For example, an individual might report pain but not accurately describe the level of pain, potentially leading to inadequate PM. The current literature demonstrates improvement in interoceptive awareness in individuals with chronic pain with the use of nonpharmacologic pain interventions such as mind-body therapies (i.e., Tai Chi, mindfulness-based interventions, massage therapy, etc.) (Gnall et al., 2024).

2.2.2 Pain in Head and Neck Cancer

Cancer-related pain is categorized in three ways: tumor-induced pain, iatrogenic pain that is directly related to the cancer treatment, and incidental pain caused by coexisting conditions (Trotter et al., 2013). Iatrogenic pain in HNC patients, especially those undergoing XRT, can result from side effects like oral mucositis (OM), xerostomia, oral

candidiasis (infection), trismus (reduced mouth opening), dermatitis (skin reaction), and neuropathic pain (Salvo et al., 2010; Sroussi et al., 2017); any of which can exacerbate or lead to dysphagia. In a questionnaire-based study, Havard et al., (2021) found that HNC patients reported significantly more pain than patients with other types of cancer. While attempting to validate a Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) item set for surveillance of radiation toxicities in patients, Sandler et al. (2018) also determined that pain is a commonly reported symptom of patients with HNC. Specifically, 66% of individuals endorsed its occurrence on symptom checklists and in open-ended questions.

Presence of pain within the HNC population is well documented (Macfarlane et al., 2012) with reports of occurrence in 50% of individuals prior to beginning treatment, 81% during, and remaining in 70% of individuals upon completion of oncological intervention (Mirabile et al., 2016). Further, at least 36% of individuals have pain persisting up to 6 months or more after treatment completion (Mirabile et al., 2016). Side effects causing acute pain include mucosal inflammation, such as OM, and xerostomia or dermatitis which can lead to a burning sensation (Blanchard et al., 2014). Late onset deficits like fibrosis and trismus can lead to neuropathic or joint related pain (Blanchard et al., 2014).

Pain in HNC patients can lead to social isolation, general functional impairments, and both emotional and spiritual distress (Mirabile et al., 2016; van den Beuken-van Everdingen et al., 2018). In addition, pain from XRT can contribute to fatigue, sleep disturbances, and increased difficulty with concentration (Bossi et al., 2019). Oral pain is the most frequently reported reason for reduced QOL by individuals with HNC (Epstein et al., 2007) and research supports a strong link between pain and QOL in general (Wong et

al., 2006). Expert consensus statements regarding pain management in HNC patients detail the importance of appropriate PM for oncologic intervention success because poorly controlled pain can lead to a cycle of deficits (Mirabile et al., 2016). For example, poorly controlled pain can negatively impact swallowing, which may cause impaired nutrition and hydration intake. This may then lead to reduced tolerance of oncologic intervention with breaks in treatment or hospitalizations (Russo et al., 2008; Sutherland & Browman, 2001), which further exacerbates pain, and so the cycle continues. Individuals have described pain during swallowing as "razor blades cutting up your insides" (Wong et al., 2006, p. 34) or that the pain was so intense they "avoided swallowing at all cost[s]" (Wong et al., 2006, p. 34). For many of these individuals there is also a persistent fear of pain and fear of its permanence. The importance of improving swallow related pain is significant as dysphagia is reported as one of the highest priorities for rehabilitation (Govender et al., 2013).

2.2.3 Pain as a Barrier to Dysphagia Management

In the dysphagia literature, pain in HNC populations is frequently described when referencing adherence to therapy before, during, and after completion of XRT treatments. A challenge in determination of overall adherence is defining how to measure it. Adherence is considered continuous or dichotomous. Continuous means there is a range of adherence levels, or a percentage of completion across the recommended dosage, time period, or number of sessions (Wells & King, 2017; Zhu et al., 2022). An example of continuous adherence would be a description of how many therapy sessions a patient completed in a prescribed number of weeks of treatment. Dichotomous adherence is defined as the extent to which a pre-defined threshold (e.g., high vs. low, or a specific percentage goal assigned by the researcher) is achieved (Pinto et al., 2009). That is, dichotomous distinguishes

adherence from non-adherence, and continuous allows for a measure of partial adherence (Lam & Fresco, 2015).

HNC patients have reportedly low levels of adherence to dysphagia therapy. Results from a survey study completed by Shinn et al. (2013) reported that only 13% of patients were fully adherent to their recommended treatment regimen. This study focused on individuals with oropharyngeal cancer, a population known to have increased levels of non-adherence in dysphagia therapy compared to patients with other tumor sites (Starmer et al., 2014; Zhu et al., 2022). Individuals in Shinn et al. (2013) were considered fully adherent if they demonstrated competency of 11 assigned swallowing exercises. However, this method of measuring adherence is not necessarily an accurate reflection of the extent to which participants completed the recommended exercises. A more appropriate, and repeatable, measure of adherence was utilized in a randomized controlled trial by Wall et al. (2017) looking at the impact of service delivery model and patient factors on adherence to prophylactic swallowing therapy during XRT. They defined adherence based on the percentage of repetitions completed per week which they categorized as negligible (<25 % reps), low (25-50% reps), moderate (50-75% reps), and high (>75% reps) practice adherence. This measurement of adherence has been used in other randomized controlled trials such as the PRESTO trial (Baudelet et al., 2024).

In addition to considering adherence to dysphagia exercises during XRT (Baudelet et al., 2023; Shinn et al. 2013), others have focused on adherence to additional aspects of the intervention approach. Rowe et al. (2023) completed a systematic review on the “eat” aspect of therapy. Measures of adherence in this instance included maintenance of oral intake, PEG use and duration, participation in treatment sessions with the SLP, use of

swallowing compensations, patient reported outcome measures (PROMS), and diet levels at completion of radiation treatment (Badr et al., 2015; Britton et al., 2019; Langmore et al., 2012; Starmer et al., 2011; van den Berg et al., 2016). Their systematic review findings identified previously described barriers to adherence (i.e., pain) and also identified facilitators to treatment adherence. These included behavioral intervention, attendance at a multidisciplinary clinic, individualized swallowing therapy, absence of PEG, positive influence from spouse, and pain relief (Rowe et al., 2023). Another issue with pain-related adherence in this population is the common clinical practice of encouraging exercise completion until pain increases or becomes unbearable, then "only do what they can until the pain subsides" (Shinn et al., 2013, p.2). Patients could interpret this statement to mean that pain is an obstacle not worth overcoming. It has been determined by multiple studies that patients have improved adherence to dysphagia therapy when the service delivery model includes an SLP (Baudelet et al., 2023; Starmer et al., 2023; Wall et al., 2017). This support from the SLP could very well include assistance with pain mitigation, although that has not specifically been described or identified in the literature.

Radiation induced pain has a trajectory which aligns with dysphagia therapy adherence level (Shinn et al., 2024). Some individuals will not have pain at the start of treatment making it challenging to justify prophylactic intervention to insurance companies, and to motivate patients at this point in their treatment regimen. Typically, patients have often just learned of their cancer diagnosis which can have profound emotional, psychological, and physical effects as they prepare to fight a potentially life-threatening disease. Pain-causing side effects tend to peak around week five which typically aligns with administration of a second dose of cisplatin-based CT for those undergoing multimodal

intervention. This pain continues through the rest of XRT and typically persists at least a few weeks after completion. Unfortunately, there is not a standard of care protocol for dysphagia therapy in this population, let alone one that targets pain mitigation. The PROACTIVE trial (Martino et al., 2021), a randomized controlled trial comparing the effectiveness of prophylactic swallowing exercises with reactive swallowing exercises, is currently underway. This study should provide insight into which exercises should be used and when. Once a standard intervention is established regarding dysphagia treatment, measurement of adherence to that protocol can be measured.

2.2.4 Pain Mitigation Approaches

Mechanisms for managing radiation induced pain have varied over the decades. With rapid medical advances in this area, this review focuses primarily on the last 25 years. Pain mitigation techniques fall into categories of pharmacologic versus nonpharmacologic and local versus systemic. Cancer-related pain is typically managed pharmacologically, with 40% of patients requiring some type of analgesic prescription (i.e., opioids, anti-inflammatory, etc.) (Adhikari et al., 2024). However, this approach can have significant unwanted side effects such as nausea, fatigue, constipation, and skin irritation (Hartl et al., 2022; Trotter et al., 2013). Given the variance in pain amongst patients with HNC, general pain management is currently guided by the WHO 3-tiered ladder for pain (Anekar et al., 2016; Hank et al., 2001). These guidelines state that pain occurrence should be managed promptly based on level of pain. If the pain is mild (1-3 out of 10 on a numeric rating scale [NRS]), nonopioids such as acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended. For moderate pain (4-6 out of 10 on NRS), mild opioids such as tramadol or oxycodone are to be prescribed in conjunction with those medications

implemented for mild pain. Finally, if pain is severe (7-10 out of 10 on the NRS) strong opioids (i.e., fentanyl, morphine, etc.) are recommended until the patient is free of pain. The WHO further specifies that medications should be given "by the clock" (rather than "on demand") to ensure the individual remains pain free. Breakthrough pain (BTP), or transitory exacerbation of pain on top of otherwise stable pain that is controlled with continuous opioids, is subsequently managed with adjuvant or on demand medications as needed (Bhatnagar et al., 2010). Odynophagia is typically categorized as an incidental, predictable BTP because it occurs in response to a stimulus, namely swallowing, despite otherwise pharmacologically controlled pain (Bossi et al., 2019).

The literature on PM in HNC patients undergoing XRT focuses on both the etiology of the pain as well as the type of management (e.g., pharmacologic vs. nonpharmacologic). For example, there are several studies analyzing pain mitigation strategies for OM as this is the most common side effect experienced by those undergoing XRT for HNC (Tolentino et al., 2011), and many patients report that it is the most debilitating side effect of the entire treatment (Rose-Ped et al., 2002). The original study of OM related pain due to XRT dates to 1989 at which point 100% of patients developed mucositis related pain (Weissman et al., 1989).

2.2.4.1 Pharmacologic Approaches

Systemic, pharmacologic analgesics used in XRT include anti-inflammatory drugs such as NSAIDs (i.e., ibuprofen), antiepileptics (i.e., gabapentin, pregabalin), and opioids (i.e., oxycodone, morphine, fentanyl, etc.) (Lefebvre et al., 2021; Ma et al., 2022). Fentanyl and oxycodone are the most commonly prescribed opioids for individuals with HNC undergoing XRT with 85% of patients being prescribed opioids at some point in their cancer journey;

specifically, 40% within 30 days of starting treatment and 37% in days 30-60 after starting treatment (Lasonde et al., 2023). Strong opioid use (i.e., fentanyl) was documented in 78% of patients suffering from OM with the highest dosages occurring during the 6th week of XRT (Schaller et al., 2020). Other studies noting successful pharmacologic pain mitigation for OM include use of doxepin (tricyclic antidepressant) (Lefebvre et al., 2021) and fentanyl pectin spray (Mazzola et al., 2017). Gabapentin however is a medication with mixed findings. Starmer et al. (2014) found that 13% of patients using gabapentin didn't require additional pain medication and had shortened duration of pain. However, a more recent study determined that prophylactic use of gabapentin to reduce OM had no benefit in relation to patient reported outcomes or opioid use, and the incidence of feeding tubes actually increased (Cook et al., 2022). Still, gabapentin is prescribed concurrently with opioids in up to 91% of patients during XRT (Lasonde et al., 2023).

Local, pharmacologic PM methods include topicals, lozenges, and rinses such as antimicrobials (Dodd et al., 2022) and antifungals (i.e., nystatin) (Rai et al., 2022). One such local, pharmacologic method used for many years with HNC patients is "Magic Mouthwash", a combination of diphenhydramine (an antihistamine), lidocaine (anesthetic), and antacid. This has been a pillar in pain management for OM for years despite mixed evidentiary support (Rai et al., 2022; Sio et al., 2019).

Effectiveness of pharmacologic approaches varies across individuals but generally these drugs have demonstrated statistically significant pain reduction for HNC patients, thus reinforcing their continued use during and after treatment (Kouri et al., 2022; Schaller et al., 2020). However, they remain a concern for patients due to the high likelihood of adverse drug reactions (ADRs). A prospective observational study recorded prevalence of

ADRs in relation to opioid prescriptions in HNC patients (Vacchani et al., 2024). Of the ADRs reported, 38% of patients reported having constipation, 24% reported drowsiness, and 14% reported dizziness. Other ADRs mentioned were dry mouth (10%), nausea (10%), headache (2%) and lightheadedness (2%). In addition to the known potential for pharmacologic pain relievers, especially opioids, to cause ADRs, many patients are averse to their use due to the fear of BTP, or the opioid itself. Break through pain is a common occurrence in HNC patients with up to 63% of individuals requiring additional support despite pharmacologic management per the WHO's 3-tiered ladder for pain (Vacchani et al., 2024). Opiophobia, or the fear of using opioids, is not baseless in this population as many patients require continued pain mitigation long after their cancer treatment has concluded (McMenamin & Grant, 2015; Zhao et al., 2022). These concerns give rise to the desire for nonpharmacologic methods of pain management and have been the driving factor behind specialties like complementary and integrative medicine.

2.2.4.2 Nonpharmacologic Approaches

Complementary and integrative medicine (CIM) as defined by the National Center for Complementary and Integrative Health (NCCIH) are health approaches that have origins outside of usual Western practice and are not typically included in conventional medicine (NCCIH, n.d.). This needs to be differentiated from complementary and alternative medicine (CAM) as the terms complementary, alternative, integrative, and functional are often used interchangeably; thus, further descriptions are required. Per the NCCIH, complementary refers to a "non-mainstream approach used together with conventional medicine" whereas alternative is an "non-mainstream approach used in place of conventional medicine" (NCCIH, n.d.). Functional refers to approaches more aligned with

naturopathy whereas integrative health blends conventional and complementary approaches with an emphasis on treating the whole person (NCCIH, n.d.; Witt et al., 2017; Yun et al., 2017). Complementary health approaches are classified based on the primary therapeutic input, or how the therapy is taken or delivered, and include categories such as nutritional (e.g., diet-based), psychological (e.g., meditation), and physical (e.g., yoga) (Barnes et al., 2008; NCCIH, n.d.). Integrative oncology is a field that blends the use of CIM in conjunction with cancer treatments and focuses on clinical outcomes and QOL throughout the cancer journey (Deng & Cassileth, 2014). An estimated 50% of cancer patients use integrative medicine (Horneber et al., 2012).

Within the HNC literature, CIM has been investigated as an adjunct to standard oncologic treatments to prevent or reduce treatment induced side effects such as OM, xerostomia, lymphedema, fibrosis, fatigue, nausea, pain and anxiety (Hendershot et al., 2014; Lettner et al., 2017). Nonpharmacologic techniques for PM, many considered to be CIM therapies, in HNC patients include acupuncture, behavioral therapy, and use of natural-based products. One study found that up to 22% of HNC patients utilized some form of CIM including nutritional methods such as herbal teas, vitamins, or minerals (Molassiotis et al., 2006). Supplements or rinses with salt, Manuka honey, aloe vera, zataria multiflora, or turmeric however have inconsistent success (Aghamohammadi et al., 2018; Bonomo et al., 2022; Marucci et al., 2017; Pranadwista & Nur'aeny, 2023). Unique methods targeting mucosal related toxicity, in relation to OM specifically, include use of low-level laser therapy (Legouté et al., 2019), human placenta via placentrex (Kondaveeti et al., 2018) and hyperbaric oxygen therapy (Teguh et al., 2009); again, with inconsistent results across the methods. One study found benefit from cognitive behavioral therapy (CBT) use

in that both OM occurrence and grade level were reduced in nasopharyngeal carcinoma (He et al., 2023); while others found CBT successful for improving nutrition or overall mental health and QOL (Britton et al., 2019; Thilges et al., 2023). Garland et al. (2019) found CBT to also demonstrate clinically meaningful reductions in pain severity in cancer survivors. Acupuncture has been used primarily in HNC patients for pain induced by xerostomia; however, results were mixed (Bonomo et al., 2022).

2.2.4.3 Implementing Nonpharmacologic Approaches

The idea of CIM use within the HNC population is complicated as it is not discouraged, yet it is not widely discussed during medical visits (Hendershot et al., 2014). This may be due to the misconception that CIM includes alternative medicine (e.g., CAM). Up to 67% of HNC patients have reported use of CAM (Lim et al., 2010) which can be alarming to oncologists treating HNC as individuals who seek out and utilize alternative medicine options often delay conventional cancer treatment up to 22 days (when compared to those not using CAM) resulting in poorer outcomes in potentially curable HNC (Balogh et al., 2021; Davis et al., 2006). A cross-sectional survey of HNC patients who used CAM found those individuals to more often be female, younger, and more highly educated (Lim & Loh, 2010). Additionally, 82% of those individuals perceived CAM to be effective despite having the knowledge that there is lack of evidentiary support for these methods, and without endorsement by their physician. Maniyar et al. (2024) discuss the common physician concerns for use of CAM to include lack of evidentiary support on their efficacy and safety, as well as the potential for negative interactions with conventional cancer treatments, which could ultimately comprise outcomes for patients. This demonstrates the importance of physician knowledge of both CAM and CIM, as well as the need for open discussions of

these treatment methods with patients. Through a series of structured interviews, Hendershot et al. (2014) discovered that the majority of patients with HNC are either positive about use of CIM or are "open minded: needing more input", with 93% of patients reporting that they would be comfortable having a discussion with their provider to explore the options and potential uses of CIM.

Medical providers should be discussing patient beliefs and preferences at the onset of oncologic treatment to encourage collaborative care and appropriate use of CIM (Goodman & Wang, 2022). However, it can be challenging for practitioners to navigate providing CIM recommendations to patients as there is a paucity of resources to guide its use with HNC patients (Matovina et al., 2017). This again may be due to the potential stigma behind CIM being considered an "alternative" to conventional treatment because of reduced training in integrative medicine practices, and the societal push for patients to use these methods in lieu of conventional medicine instead of in conjunction with it (Maniyar et al., 2024; Matovina et al., 2016). Alternatively, it could be related to the fact that most studies completed on CIM focus on statistical significance alone (which many do not achieve) and fail to include clinically meaningful changes (defined by a two point reduction on a 0-10 scale), such as in pain severity (Mao et al., 2022). Despite limited evidence for CIM efficacy in HNC patients, there is a plethora of research supporting its use in other cancer populations. For example, the breast cancer literature alone has over 200 randomized controlled trials related to integrative therapies for symptom management (Greenlee et al., 2014). To further guide healthcare professionals in implementing CIM for pain management specifically, the American Society of Clinical Oncology (ASCO) created a set of guidelines based on a panel of experts' consensus statements from a comprehensive

literature review (Mao et al., 2022). The review spanned 30 years and 224 studies looking at pain intensity, symptom relief, and adverse events with use of mind-body therapies and natural products. Resulting statements were that specific CIM were to be recommended pending the type of pain. Acupuncture was recommended for general cancer pain or musculoskeletal-related pain, hypnosis for procedural pain, massage during palliative care or hospice, and other mind-body interventions were deemed low quality or inconclusive (Mao et al., 2022). Given that pain varies by person based on etiology, presentation, and duration, it was also recommended that PM recommendations should thus use an interdisciplinary approach with both pharmacologic and nonpharmacologic methods.

It is known that HNC patients have a higher percentage of pain compared to other cancers (61% and 44% respectively), require pain management more often (86% vs. 72% in other cancers) and have a generally lower satisfaction rate with PM (74% vs. 80% in other cancers) (Cho et al., 2019). It has also been established that concurrent use of CIM with XRT may reduce treatment induced toxicities generally across cancer populations (Lapen et al., 2021). However, the majority of current literature regarding PM during XRT for HNC focuses on pharmacologic treatment with relatively few investigations of complementary or integrative methods of pain management. This is likely due to the aforementioned success rates with pharmacologic methods (Kouri et al., 2022) and limited statistical evidence within the current studies investigating CIM (Mao et al., 2022). Nonpharmacologic PM focused on HNC patients undergoing XRT is an area of research to be further explored.

Conceptually, the idea of using distraction as a potential means of pain reduction was introduced in 1979 (Leventhal & Everhart, 1979). One part of the proposed mechanism of

action is that diverting attention, or cognitive resources, to something besides the pain will reduce the emotional component of perceived pain (Quartana et al., 2007). The gate control theory of pain further supports this model of distraction (Mendell, 2014). This theory is based on the knowledge that humans have limited amounts of attentional resources. When distracted, or dividing attention amongst tasks, the body reduces the amount of pain signals sent to the brain to account for attentional resources allocated to alternative tasks, essentially gating pain signals (Rischer et al., 2020). When fewer pain signals are sent to the brain, an individual perceives less pain. Distraction can be passive, such as viewing calming scenery or listening to music (Fauerbach et al., 2002; Reese et al., 2022), or active such as engaging in a cognitive or physical task (Dumoulin et al., 2020). Additionally, distraction techniques range from using a simple item such as a toy (Aydin et al., 2017) or having a conversation, to more complex with use of technology like iPads and virtual reality (Hundert et al., 2021; Shahid et al., 2015). Distraction techniques are often used for procedural related pain such lumbar punctures or port access, wound care, and dental procedures (Ibitoye et al., 2019; Wiederhold et al., 2014a; Wint et al., 2002). For those with chronic pain, however, the research is ambiguous with results dependent on the specific type of distraction (e.g., VR demonstrated positive results but a task such as divergent naming did not) (Austin et al., 2022; Van Ryckeghem et al., 2018).

The cancer literature is robust with studies indicating the positive influence of distraction techniques for pain reduction. Both active and passive distraction have been employed successfully with cancer patients. With regard to passive distraction, Chirico et al. (2016) found music therapy to be successful at alleviating anxiety and improving mood states of patients with breast cancer during CT. Additionally, De Paolis et al. (2019)

demonstrated that guided imagery was able to produce statistically significant reductions in pain in individuals in hospice with terminal cancer. Active distraction has proven successful in children with leukemia during port access, specifically the children playing a ball shooting game in VR reported less pain and distress (Hundert et al., 2021). In patients with nasopharyngeal cancer, CBT was found to aid in distracting patients from OM related pain (He et al., 2023). Despite successful pain reduction across cancer populations, even within HNC, to date there are no studies employing distraction approaches with HNC patients undergoing XRT.

2.3 Virtual Reality

2.3.1 Foundational Concepts

Virtual reality (VR) has been in existence since Ivan Sutherland, a computer scientist, developed the first head-mounted system in 1968 (Saldana et al., 2020), with Sega debuting the first commercially available headset for entertainment purposes in the early 1990s. In the past few decades, with technological advances that have decreased the equipment size and cost, application of VR in other areas beyond entertainment have grown, including its use within education, healthcare, and business (Iqbal et al., 2024; Kshetri & Dwivedi, 2024; Perez-Munoz et al., 2024;). Virtual reality is a technology that immerses users into a three-dimensional world that gives the illusion of participating in a synthetic environment (Mazuryk et al., 1999). As an immersive, multisensory experience, VR has many potential applications such as improving procedural skills for a work task (Samadbeik et al., 2018), reducing daily life stress (Ladakis et al., 2024), and enhancing travel and tourism (de Lurdes Calisto & Sarkar, 2024; Sarkady et al., 2020). Extended

reality (XR) refers to the overarching concept of technological generation or modification of reality (Rauschnabel et al., 2022). It includes augmented reality (AR), virtual reality (VR), and mixed reality (MR). The three realities lie on a spectrum from a virtual environment with elements of the real world (VR), to the real world superimposed with virtual objects or items (AR), to the fusion of both virtual and real spaces with artificial interaction within both spaces (MR) (Zhang et al., 2022b). This dissertation focuses solely on VR.

The theory behind VR success centers around two factors: immersion and presence (Gupta et al., 2018). Immersion is an "objective property of the system, to the extent to which a VR system can support natural sensorimotor contingencies for perception including the response to a perceptual action" (Slater, 2018, p.431). Essentially, immersion relates to the amount of sensory input the VR system creates – such as visual, auditory, and/or tactile stimuli; it is the technical component. Presence is defined as the "subjective feeling of being present in the virtual environment, rather than the real space" (Cooper et al., 2018, p.4). In this regard, presence is the psychological component, focused on the user (Nilsson et al., 2016). Enhanced immersion is achieved when multiple sensory stimuli are employed and this increase in immersion subsequently improves presence. In order to be fully immersed in VR so that one might have adequate presence to disassociate from their real environment, the user interface (UI), the point of human-computer interaction (i.e., keyboard, display screen, controllers), must be designed in such a way that the user feels competent in use of the technology.

User experience (UX) is another set of parameters that developers and researchers consider very important when developing VR. For UX, usability of a VR environment or experience goes beyond measures of the application's effectiveness, efficiency, and

satisfaction by also considering the emotions evoked in the user and their impact on the experience as a whole (Marques et al., 2021). The concept of UX has become so salient in recent years that UX research is now its own area of study which focuses on the user, their needs, and how their insight can guide design processes, development of products and services, and forecasting whether or not a product will be well received by the intended audience. The aim of UX, however, is not just to report user experiences, but to also determine what problems or unintended negative consequences, if any, may rise within the VR user (Marques et al., 2021). One such example is cybersickness which is largely akin to motion sickness. Symptoms associated with cybersickness are generally grouped into three categories: nausea, disorientation, and oculomotor; with disorientation encompassing symptoms such as dizziness and vertigo, and oculomotor including eyestrain, headache, and fatigue (Stanney and Kennedy, 1997; Yildrim, 2020).

Two key elements of UX design are usability and acceptability. Usability is a quality attribute that evaluates the ease with which one interacts with a UI (Nielsen, 2012). Usability has several components which are learnability, efficiency, memorability, error in use within the experience, and satisfaction. Acceptability assesses the degree to which a new intervention, or technology, is received and to what extent it aligns with the needs of a target population (Alexandre et al., 2018). An example of how acceptability is measured are user ratings of their willingness to use VR (Shahid, 2024).

2.3.2 Virtual Reality Use for Pain in Cancer Populations

Virtual reality use has demonstrated significant benefit in reducing pain in several patient populations including but not limited to burn (Lan et al., 2023), chronic pain (Austin et al., 2022), palliative care (Mo et al., 2022), mental health (Riches et al., 2023),

and cancer patients (Hartshorn et al., 2022). In these groups VR has been used as an alternative for guided imagery and other relaxation techniques (Mehesz et al., 2021; Riches et al., 2021), as a supplement to CBT (Wu et al., 2021) and as a distraction technique (Krisciunas et al., 2012). In a randomized controlled trial focusing on pain in 128 hospitalized patients with cancer (including HNC), Groninger et al., (2022, 2024) found statistically significant improvements in those participants who utilized VR for distraction instead of 2-D guided imagery to mitigate moderate-severe cancer disease and treatment-related pain. Time spent in VR was only 10 minutes, yet the impact was significant with sustained reductions in pain for 24 hours. A literature review completed by Li et al. (2011) hypothesized that VR acts as a nonpharmacologic method of PM by applying emotion-based cognitive and attentional processes to the body's pain modulation system. They concluded that the literature supports the use of VR for distraction from pain due to its immersive properties (Li et al., 2011).

Virtual reality use for pain mitigation in cancer patients has been most studied within the breast and pediatric populations. Research related to breast cancer has demonstrated that VR can help reduce pain during various procedures with subsequent positive impacts on mental health, overall symptom management, and QOL (Zhang et al., 2022a). The pediatric cancer literature has found VR use to be successful for both procedural pain reduction and improvement of depression and anxiety (Cheng et al., 2022). Studies have also demonstrated positive pain mitigation using VR for patients with bladder (Łuczak et al., 2021), brain (King et al., 2023; Leggiero et al., 2020), cervical (Varnier et al., 2021), and colorectal cancer (Kelleher et al., 2022); and even benefit from the survivorship lens (Melillo et al., 2022).

Despite several positive findings regarding the use of VR to reduce pain in some cancer populations, there are few such studies in patients with HNC. A case presentation by Chitlange & Yadav (2023) detailed the experience of using VR to train controlled breathing techniques for an individual post mandibulectomy for buccal mucosa carcinoma. The patient participated in a two-week program that consisted of daily, 20-minute VR sessions. The patient was guided through various breathing techniques (e.g., diaphragmatic breathing) while viewing natural settings of lakes and woodlands. Measures of stress, anxiety and depression on the Depression, Anxiety, and Stress Scale-21 were all reduced following the VR treatment protocol. However, the researchers only reported pain ratings prior to initiating the VR protocol and not post-VR training, so it is not possible to know if pain was also reduced. Pandrangi et al. (2022) reported a prospective, pilot randomized clinical trial investigating the impact of VR use on post-operative pain in patients with HNC. After coming out of their HNC surgery, participants provided pain scores prior to entering VR, immediately after participating in an interactive game in VR for 15 minutes, and hourly for four hours. The researchers also gathered data regarding opioid use in this post-operative period as well as the patient's experience in VR. Fourteen patients were randomized to the treatment arm and 15 to the control arm. There were statistically significant reductions in pain scores immediately after use of VR, as well as clinically meaningful reductions in pain scores at one, two, and three hours post VR. Additionally, the researchers reported a reduction in opioid use at both four and eight hours post VR. Overall, this study indicated that VR did reduce pain scores in the post-operative period for patients with HNC. However, the use of VR to reduce pain in HNC patients undergoing XRT and completing dysphagia therapy has not yet been investigated.

2.4 Summary

The literature is clear that radiation-related pain negatively impacts dysphagia therapy, swallowing outcomes, and QOL. This pain often results in poor adherence to therapeutic interventions that have been shown to optimize swallowing outcomes in the HNC population. Unfortunately, pharmacologic approaches to mitigating this pain are not without risks and, therefore, there has been growing interest in identifying or developing complementary approaches. Virtual reality has been used for this purpose in non-HNC patients. Other means of bolstering adherence to dysphagia therapy exercises in patients with HNC who are receiving, or have received, XRT have been attempted. These have included attempts at targeting adherence barriers such as forgetfulness with support for home therapy (Wall et al., 2017) by way of mobile applications (Constantinescu et al., 2021), virtual coaches (Starmer et al., 2023), and websites (Shinn et al., 2019), but nothing thus far has directly targeted pain as a barrier to dysphagia therapy adherence. This is a significant shortcoming in the literature because pain is identified as a primary barrier to treatment adherence.

Virtual reality in the HNC literature is scarce with only one article highlighting its use for direct PM, and it focused on post-surgical pain, not pain from XRT (Pandrangi et al., 2022). VR has the potential to be used as a method of adjuvant pain control for BTP caused by swallowing and swallowing exercises. This research begins to address the possibility of using VR to help reduce pain in HNC patients with an ultimate goal of improving adherence to dysphagia exercises.

2.5 Significance and Specific Aims

2.5.1 Significance

The current research consisted of three studies that provide foundational knowledge to better understand how VR might be implemented to improve adherence in dysphagia therapy with HNC patients by reducing pain from XRT. The first study surveyed SLPs for their perceptions about their education and training on pain and pain management, the impact of pain on treatment sessions and patient progress, and their opinions on use of additional techniques for PM. The goal was to determine the current state of the field of speech-language pathology in terms of knowledge and understanding of pain and pain management. Results inform about the views on pain and the likelihood that SLPs will accept implementation of VR for PM to improve adherence within their sessions. The second study was a cross-sectional comparative design that gathered data on UX of adults in VR. The goal of this study was to determine usability, acceptability, and potential negative side effects of VR use in adults matching the expected age range of most people diagnosed with HNC. Such data do not currently exist in the literature. The resulting data begins building a normative data set, a portion of which was also used for an age and gender match comparison to the HNC patients in the final study. The third study focused on UX in a group of HNC patients through an interventional, early clinical phase trial. Specifically, the purpose was to determine the usability, acceptability, and potential toxicities (i.e., cybersickness) of VR use in patients with HNC. The resulting data helps to determine if, and why, VR is a feasible technology to use within the HNC population.

2.5.2 Specific Aims

Specific Aim 1: Determine SLPs' knowledge, experience, attitudes, and perceptions on pain and pain management relative to clinical practice. This information is necessary to determine overall willingness and confidence of SLPs to implement complementary pain mitigation techniques in SLP service delivery.

RQ 1.1: What education and/or training have SLPs had related to pain and its management?

Hypothesis (H1.1): SLPs will report having limited education and training on pain and pain management.

RQ 1.2: What do SLPs report in terms of their patients' experiences of pain during SLP therapy sessions? Of interest is characterizing the pain in terms of specific populations reporting more/less pain, and the impact on therapy progression.

H1.2: SLPs will report that pain is most frequently reported in patients with voice and swallowing problems, and that pain interferes with therapeutic progression.

RQ 1.3: What do SLPs report about: (1) their confidence in helping to manage pain that their patients are experiencing; and (2) their willingness to utilize complementary pain management techniques with patients in their therapy sessions?

H1.3: SLPs will report limited confidence in managing pain but will be interested and open to implementing complementary pain mitigation techniques in their therapeutic practice.

Specific Aim 2: Elucidate the user experience of adults without HNC who are placed in active and passive VR environments. Currently, such UX data for healthy adults does not exist. Results can be used for comparison to future population-specific data, including the HNC sample included in Aim 3.

RQ 2.1: Does the usability of VR in adults without HNC differ between active and passive experiences?

H2.1: Individuals will have higher satisfaction levels in the active experience (H2.1.1). Adults without HNC will report the same level of learnability between active and passive experiences (H2.1.2).

RQ 2.2: Does the level of acceptability of VR use expressed by adults without HNC vary depending on which VR application is used, active versus passive?

H2.2: There will be increased engagement levels in the active experience (H2.2.1). The level of adoption of VR will be the same in both groups (H2.2.2).

RQ 2.3: What are the negative side effects of VR use among adults without HNC? Does this differ between active and passive experiences?

H2.3: Adults without HNC are expected to report some cybersickness and other VR side effects (H2.3.1). There will be an increase in reported side effects in those in the active VR (H2.3.2).

Exploratory Aim: Explore factors and relationships that might have impact on UX outcomes, including interoception.

Specific Aim 3: Determine the feasibility of VR use in HNC patients. These patients may have elevated risk of negative side effects (e.g., nausea, vertigo, etc.) because of their cancer treatment. An interventional, early phase trial assessing HNC patient UX is needed to

inform about overall UX, and potential toxicities of VR use. Preliminary data on the impact of VR on perceived pain when swallowing (odynophagia) will also be evaluated.

RQ 3.1: Does the usability of VR in HNC patients differ between active and passive VR experiences? Of interest is whether this changes over the course of XRT?

H3.1: Patients with HNC in the active experience will report increased satisfaction (H3.1.1) There will be similar learnability between the passive and active groups (H3.1.2). Usability of VR in patients with HNC will increase over time across both active and passive VR experiences (H3.1.3).

RQ 3.2: Does the level of VR acceptability expressed by HNC patients differ between active and passive VR experiences? Does this change over time?

H3.2: Patients with HNC will have increased engagement levels in the active experience (H3.2.1). There will be no differences in level of VR adoption between groups (H3.2.2). Furthermore, the level of reported acceptability will increase over time (H3.2.3).

RQ 3.3: What are the negative side effects of VR use in HNC patients? Does it change over the course of XRT?

H3.3: Negative side effects reported will be consistent with cybersickness (H3.3.1). Reported side effects will worsen over time in concordance with XRT (H3.3.2).

RQ 3.4: Is there a difference between patients with HNC and adults without HNC in terms of experience in VR?

H3.4: Individuals will report similar usability levels compared to an age and gender control group (H3.4.1). Levels of acceptability will be the same between HNC and control groups (H.3.4.2). Adults with HNC are expected to report cybersickness and

other negative side effects of VR at rates higher than what is found in age and gender matched adults without HNC (H.3.4.3).

RQ 3.5: Does use of VR have carryover effect that impacts swallowing-related pain (odynophagia)?

H3.4: VR use will result in lower perceived pain during swallowing.

Exploratory Aim: Investigate the potential impact of VR on general pain levels in patients with HNC.

CHAPTER 3. METHODOLOGY

3.1 SLP Pain Survey Study

3.1.1 Participants

Speech language pathologists (SLPs) were recruited to complete an online survey regarding their knowledge, experience, attitudes, and perceptions of pain and pain management as it relates to clinical practice. Inclusion criteria were > 18 years old and currently licensed and practicing in any clinical area of the field. Those who completed schooling/training outside of the United States were excluded.

The study was reviewed by the Michigan State University Human Research Protection Office of Regulatory Affairs and was deemed exempt (STUDY00010876). The Office of Regulatory Affairs letter of exemption determination is provided in Appendix A.

3.1.2 Survey Construction and Distribution

A study-specific survey was developed to address the research questions. Besides basic demographic, educational, and employment related information, survey questions addressed their experiences and perceptions of pain and PM within the clinical setting. Topics covered included which categories of patients tended to experience pain, whether pain interfered with therapy, management of the pain, and openness to utilizing nonpharmacological alternative pain mitigation strategies. The survey was developed in an iterative process with the intent to establish its face and content validity. Survey questions were initially constructed by the researcher. The survey draft was first evaluated by one speech-language pathologist who has practiced clinically for 20+ years and currently works in academia. The SLP was asked to review the survey for clarity, readability, and relevance.

Minor modifications were made to improve item wording and comprehension, and alignment with the study objectives. The survey was then distributed to two speech-language pathologists, one who has practiced clinically for approximately 10 years and the other who was two years post-graduation from a Master's in Speech-Language Pathology program but has not practiced clinically in the United States. The SLPs were instructed to look for any discrepancies with intended content or survey construction. The survey was then revised again and re-distributed to two of the reviewers for final review. This feedback was used to finalize the survey. A total of 39 questions were included in the survey with 14 reliant on display logic (i.e., displayed only if a prior question is answered with a specific response). Survey questions were a mix of Likert-type ratings, yes/no, multiple choice, and open-ended questions with an estimated completion time of 5-10 minutes. See Appendix B for survey questions.

The survey was completed anonymously and online via Qualtrics (Provo, UT, 2024). Distribution channels for recruitment included SLP Facebook groups, the American Speech Language Hearing Association (ASHA) Special Interest Group (SIG) forums, the Michigan Speech Language Hearing Association (MSHA) list serve, and the professional contacts and networks of the researcher. The recruitment message encouraged SLPs to also pass the message and survey link to colleagues (i.e., snowball sampling). The number of surveys submitted was monitored by the researcher daily and the recruitment message was sent a second time to all distribution channels approximately two weeks after the initial message. The survey remained open until no complete responses were submitted for a period of two weeks. Overall, the survey was open from 06/18/2024 to 08/22/2024.

3.1.3 Analysis

The primary analysis utilized descriptive statistics. For items with nominal data, frequency counts and percentages were calculated. Ordinal data were reported in terms of frequency count, percentages, mode and/or median, range, and interquartile range. For interval and ratio data, mean, standard deviation, and range were reported. Grounded theory content analysis was used to categorize items from the open-ended questions about medical populations and SLP diagnoses into broader groups or themes. A single stage of coding was used to define the data by the primary researcher given that the main interest was quantitative (frequency count of categories), not qualitative (specifics on meanings, themes or patterns of responses). A total of 337 surveys were recorded. Ten were from individuals who completed SLP training outside of the United States and 120 surveys were incomplete resulting in a total of n=207 for analysis. Secondary analysis used the Chi-Square test of Independence to look at potential differences in SLP's willingness to adopt novel therapeutic techniques as a function of their age and years of clinical experience.

3.2 Comparative Cross-Sectional Study: Adults without HNC

This study was deemed exempt from full institutional review. It was approved as expedited (categories 6 and 7) via Non-Committee Review procedures by the Institutional Review Board at Michigan State University Human Research Protection Office of Regulatory Affairs (STUDY00010999). The approval letter is provided in Appendix C.

3.2.1 Participants

Adults meeting the following criteria were recruited from the community at large.

1. Inclusion Criteria: >18 years old.

2. Exclusion Criteria: Current HNC diagnosis, recreational VR use, or medical contraindications for VR use (per Meta Oculus 2 user manual, individuals should consult with a doctor prior to use if they are pregnant, elderly, have pre-existing vision abnormalities or psychiatric disorders, suffer from heart conditions or seizure, or have medical devices such as pacemakers, hearing aids, and defibrillators (Meta, 2020)). Individuals with a pacemaker or defibrillator, and those with seizure disorders were excluded.

Recruitment was primarily via professional and personal communications. Snowball sampling was encouraged. This recruitment was occurring in parallel with HNC patient recruitment for study 3 described below. One intent of study 2 with non-HNC adults was to build a large enough dataset from which a subset could be extracted as an age- and gender-matched subgroup for the HNC patients being enrolled. Therefore, the researcher did use some targeted recruitment via personal and professional contacts to help assure strong age and gender matching. Ultimately, 30 adults were enrolled and all completed the study.

3.2.2 Instrumentation and Survey Tools

3.2.2.1 Virtual Reality Headset

The VR headset utilized was the Meta (Oculus) Quest 2 (see Figure 3). The headset has a fast-switch LCD display with 1832x1920 resolution and a refresh rate of 120Hz (Meta, 2024). The headset has six degrees of freedom position tracking allowing accurate detection of the body and head movements of the participant without the need for external cameras or motion trackers. The headset is integrated with two hand controllers that can be attached via wrist straps. The hand controllers have a joystick and several buttons and triggers that allow navigation within and interaction with the VR environment. A soft,

adjustable head strap holds the headset in place; it weighs approximately 17.7 ounces. A spacer is inserted in the headset for those wearing eyeglasses. The headset has 3D positional audio built in allowing the user to experience sound. A volume knob controlled the sound level and participants were allowed to set this for comfortable listening. Participants were given the choice to sit or stand during the VR experience. See Figure 4 for demonstration of participant set up.

Figure 3. *Meta (Oculus) Quest 2 Headset (Fig. 3a) and Controllers (Fig. 3b)*

Fig. 3a

Fig. 3b

Figure 4. *Participants partaking in VR experience seated (Fig. 4a) or standing (Fig. 4b)*

Fig. 4a Fig. 4b

3.2.2.2 Survey Tools

There were four surveys completed by all participants. The first was the UX for VR Pre-Survey which was a study-specific tool with five items completed prior to entering VR (Appendix D). This survey gathered information about patient demographics, education, and medical history. This information was used to help describe the participant group

The second survey completed prior to starting the VR experience, was the Multidimensional Assessment of Interoceptive Awareness, Version 2 (MAIA-2; Mehling et al., 2018; Appendix E). The MAIA-2 is a survey assessing multiple aspects of interoception. It consists of 37 items that can be used to calculate eight subscales of interoceptive awareness that are noticing, not-distracting, not-worrying, attention regulation, emotional awareness, self-regulation, body listening, and trust. Participants answer each question using a rating scale from 0-5 (0 = never, 5=always). The subscale, Not-distracting, specifically addresses the tendency of a person to not ignore or distract from

uncomfortable body sensations such as pain. Given the direct relevance to the focus of the research, this subscale served as the primary MAIA-2 measure that was used in the analysis.

The third survey, completed after the participant's VR experience, was a second study-specific tool, UX for VR Post-Survey created by the researcher. This survey gathered information about the participants' prior experience with VR, comfort level with technology, history with gaming, and willingness to use VR again. These survey questions are detailed in Appendix F.

The Virtual Experience Questionnaire (VEQ, v2), formerly named the User eXperience in Immersive Virtual Environment Questionnaire (QUXiVE) (Tcha-Tokey et al., 2016), was completed after the VR experience (Appendix G). This questionnaire solicits detailed information from individuals about their UX in immersive virtual environments. It contains 68 items in which 10-point Likert-type scales are used and three open-ended questions (total of 71 questions). The 68 items are categorized into 9 subscales corresponding to various domains of UX, specifically presence, engagement, immersion, flow, skill, emotion, experience consequence, judgement and technology adoption.

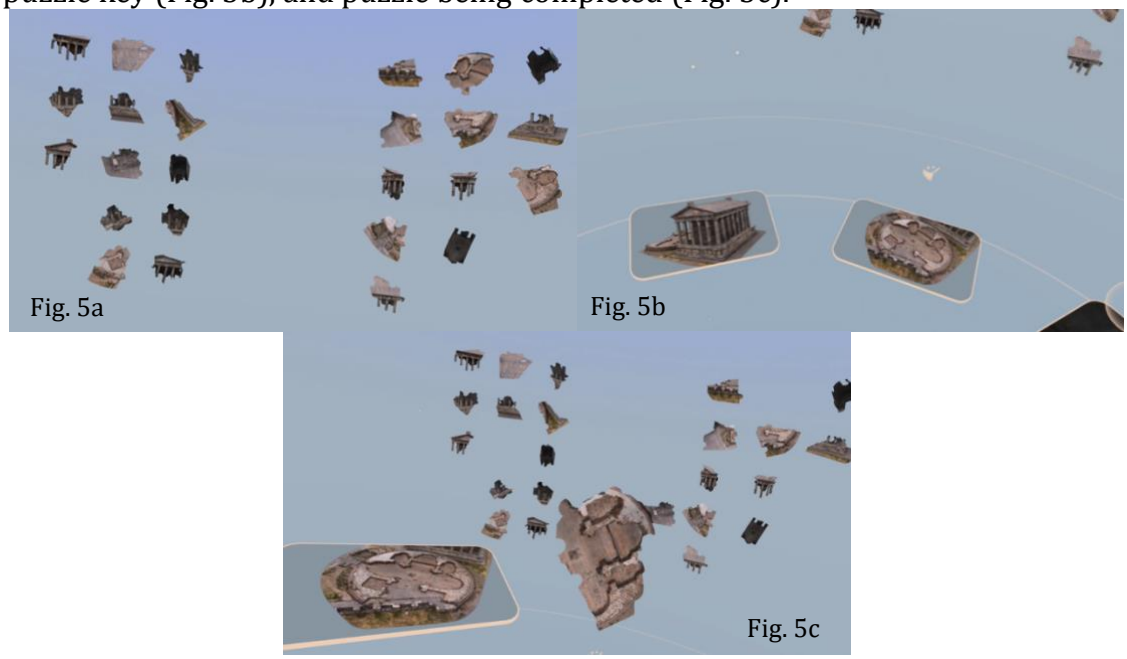
All surveys were available for completion in paper-pencil format, or they could be completed via a Qualtrics (Provo, UT, 2024) on an iPad depending on the participant's preference. Research personnel were available during survey completion to answer questions and provide clarifications for participants.

3.2.3 Procedures

Block randomization was used to divide the participants into two groups: active VR (aVR) and passive VR (pVR). Through this process, there were 15 participants in each

group. Participants in the aVR group used the Puzzling Places application (realities.io inc., 2021, version 1.55). This application involves building a 3-dimensional puzzle of a room, structure, or outdoor space with options including real settings such as temples or stadiums. The puzzle used was the Garni Temple with the 25-piece option selected (Figure 5). The participant was provided general instruction on how to grab, organize, and manipulate the puzzle pieces and puzzle keys, where to build the puzzle, and what occurs when the pieces are a fit/match. This is considered an active application as the user is required to interact or engage with the environment by performing actions or manipulating objects.

Figure 5. *Puzzling Places Application, the Garni Temple.* Screen shot of puzzle pieces (Fig. 5a), puzzle key (Fig. 5b), and puzzle being completed (Fig. 5c).



The Nature Treks VR (John Carline, 2019, version 1.27) application was used for the pVR condition. This application consists of various nature scenes which the user can explore. The application allows for both passive viewing of the scenery without interaction or limited interaction within the setting. Interactions include movement within the scene,

growing trees or flowers, changing the weather or time of day, or feeding animals. The Green Meadows scene was used (Figure 6). Participants were provided instruction on how to move within the nature scene and how to interact with the setting if desired. This is considered a passive application as the user can observe or navigate the virtual environment with minimal to no interaction. Additionally, there is likely to be less cognitive load compared to the aVR in which visuospatial skills are highly engaged to complete the 3-dimensional puzzles.

Figure 6. *Nature Treks VR Application, Green Meadows.* Screen shot of nature scene (Fig. 6a) and orbs for interacting with environment (Fig. 6b).

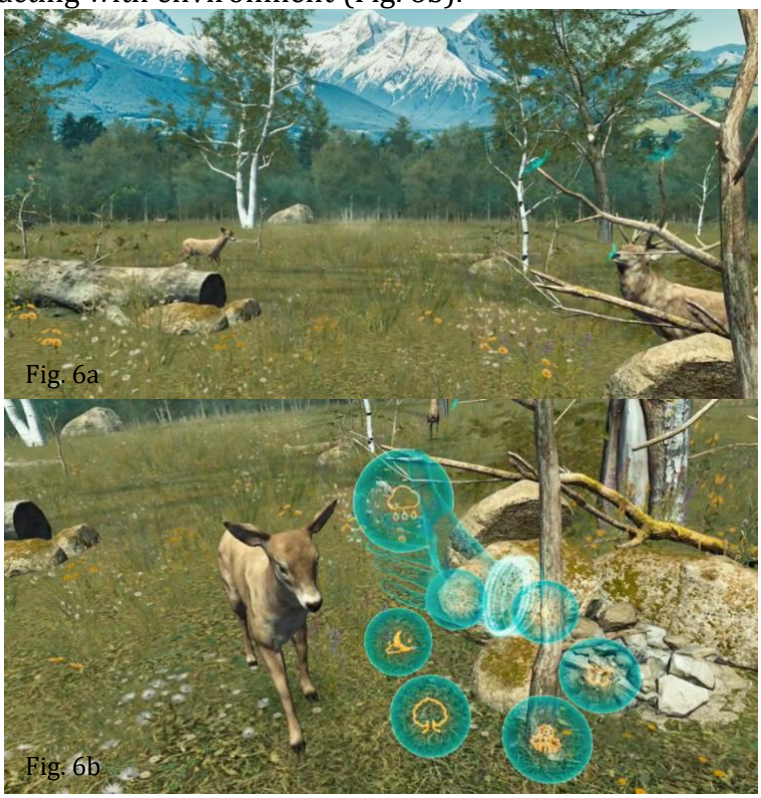


Fig. 6a

Fig. 6b

Prior to entering their assigned application (aVR or pVR), participants completed the Meta First Steps for Quest 2 (Oculus, 2020, version 1) application to introduce them to VR. This application teaches players how to use the controllers and provides an initial opportunity for them to interact with a virtual environment. This included learning actions

such as picking up and manipulating items and engaging with either a dancing robot or a target shooting game (Figure 7).

Figure 7. *Meta First Steps for Quest.* Screen shot of VR orientation instructions (Fig. 7a), initial interactive game play (Fig. 7b), and dancing robot activity (Fig. 7c).

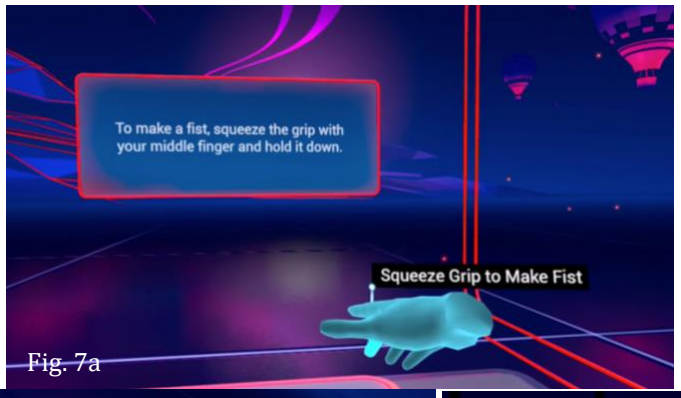


Fig. 7a

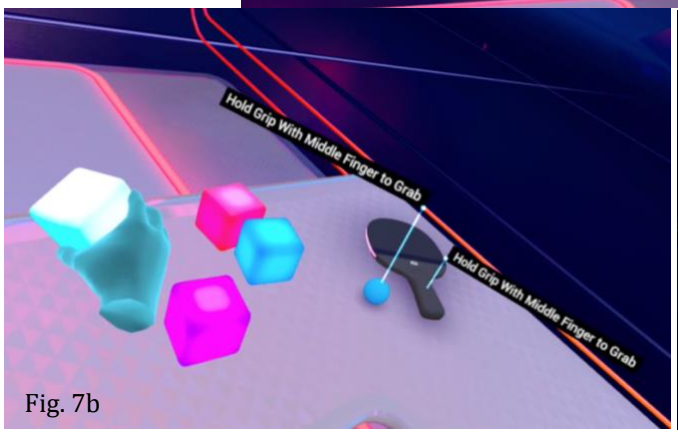


Fig. 7b

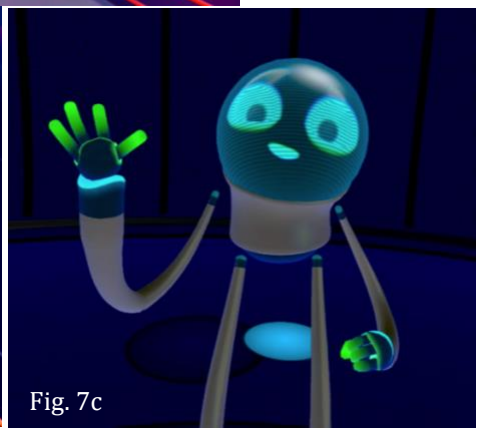


Fig. 7c

In order to facilitate play within the VR applications, the researcher screencast the headset to a laptop computer so the participants' real-time actions within the VR environment could be observed. This allowed the researcher to provide guidance about how to maneuver within the game, how to manipulate objects, and other aspects of game play if the participant requested help or expressed frustration in the game interaction. During the time in VR the researcher kept field notes including spontaneous comments and exclamations from participants, challenges that were observed in playing the game, and assistance provided.

The study procedures were the same for both VR groups. Data was collected in a single session lasting approximately 30-45 minutes and scheduled at a time and location of the participants choosing. The researcher ensured that the data collection location was private and quiet without environmental distractions. After completing the informed consent process (including written consent), the procedures were as follows.

1. **Complete pre-VR surveys**.
    a. Study-specific pre-VR questionnaire (secondary measure)
    b. MAIA-2 (secondary measure)
2. **VR interaction.**

    With the participant seated comfortably in a chair with their feet on the floor and their back supported, or standing in a clear space measuring approximately 6x6 feet, the researcher provided a general overview of the headset and the controllers. The headset was given to the participant to place on their head with the fit adjusted as needed. The headset was already turned on with the Meta First Steps application open and ready for the participant to begin. The controllers were placed in the participant's hands. The time the participant entered the virtual environment was noted by the researcher; participants were not in VR for longer than 15 minutes total. Verbal instructions or hand-over-hand guidance to learn manipulation of hand controller actions was used if the participant requested help verbally or was notably stuck without being able to progress in the experience for a period of greater than one minute. The participants first spent approximately 5-10 minutes in the Meta First Steps application; time was dependent on how long it took for the participant to express confidence with the UI. With the headset still on the participant and

continued screen casting, the researcher used one of the controllers to place the participant in their assigned application (e.g., Puzzling Places or Nature Treks VR). The controller was returned to the participant, and they engaged with the application for approximately 5-10 minutes pending their time spent in the First Steps application. After 15 minutes the participant was instructed to hand the controllers to the researcher and remove the headset.

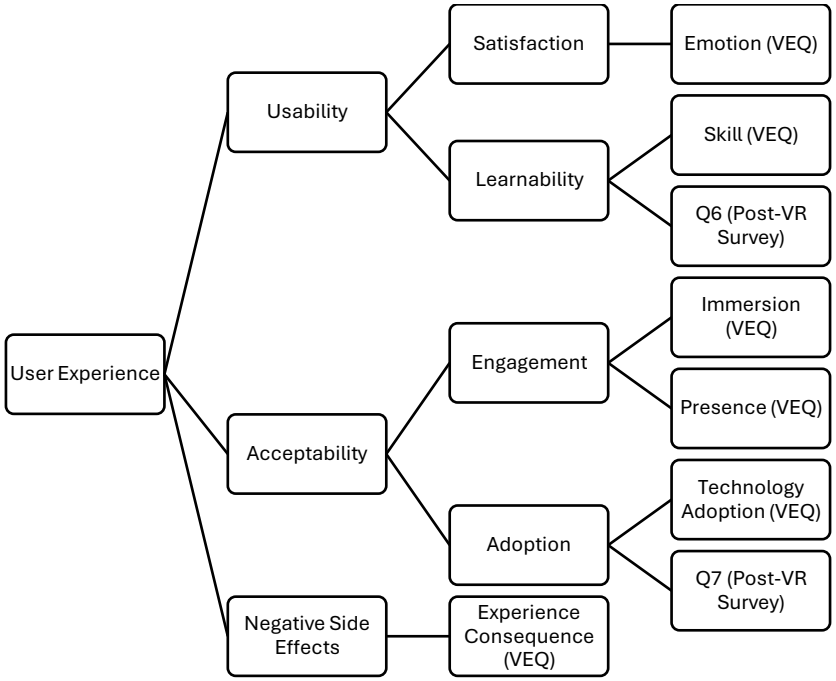
3. **Complete post-VR surveys**.
    a. Study-specific post-VR questionnaire (primary and secondary measure)
    b. VEQ, v2 (primary measure)

3.2.4 Analysis

Primary interests were the overall VR usability and acceptability in adults, and occurrence of negative side effects. The components of user experience and the associated VEQ and study-specific survey questions that provided data for each UX component are depicted in Figure 8. Usability was measured with one question from the study-specific post-VR survey as well as the *Emotion* and *Skill* subscale scores from the VEQ (RQ 2.1). The *Emotion* subscale provided data on user *Satisfaction*. The *Skill* subscale, and a single question from the study-specific post-VR survey, provided information on overall *Learnability* of VR for users. Acceptability was measured with a single question from the post-VR survey as well as the *Immersion*, *Presence*, and *Technology Adoption* subscales from the VEQ (RQ 2.2). *Immersion* and *Presence* reflect the user *Engagement* whereas the survey question and *Technology Adoption* subscale were used to determine *Adoption*. The presence of negative side effects was determined from the *Experience Consequence* subscale from the

VEQ (RQ 2.3). Additionally, each question in the experience consequence subscale was analyzed individually to determine which specific side effects occurred most often.

Figure 8. *Study two measures used for analysis of UX.* VR = virtual reality.



Non-parametric statistics were used for the analysis given the small sample size and the expectation that assumptions about normality of the VEQ score distributions would not be met. An a priori power analysis was conducted using G*Power (version 3.1) to determine the required sample size for detecting a medium effect size of .50, assuming an alpha level of .05 and a power of .80. Results indicated a total sample size of n=102 (51 per group) was required to detect a statistically significant difference between groups. While underpowered, the recruitment of 30 participants begins the process of building a normative data base of UX in VR in adults and also allowed generating a control group for comparison to HN patients in study 3. For research questions RQ 2.1, 2.2, and 2.3, a series of Mann-Whitney U Tests were applied to evaluate differences between the aVR and pVR

groups for each of the VEQ subscales and the study-specific survey questions linked to each research question (Figure 8). Statistical tests were completed using IBM SPSS Statistics (Version 30). An alpha level of .05 was considered statistically significant. To help control type I error, the Holm-Bonferroni correction was applied. To assess the relationship between interoception and aspects of UX, Spearman's Rank Correlations were computed between the MAIA-2 *Not-distracting* subscale score and the VEQ *Experience Consequence* subscale score. To assess the relationship amongst UX components, Spearman's Rank Correlations were computed between the VEQ subscales (i.e., *Presence* and *Experience Consequence*). Additionally, differences in VEQ subscale scores as a function of participant gender were assessed with the Mann-Whitney U test. A Kruskal-Wallis Test was utilized to assess the difference in each VEQ subscale score based on participant age. For this analysis, participants were binned by age decade.

3.3 Early Phase Interventional Study: HNC Population

This study was deemed to be exempt from full institutional review through Henry Ford Health. It was approved as expedited categories 4, 5, and 6 via the Expedited IRB Committee at Henry Ford Health System (ID: 17573). The approval letter is provided in Appendix H.

3.3.1 Participants

Target enrollment for HNC patients was set at 10 given the study was designed as an early phase (Phase 0) clinical trial, or a feasibility study, focusing on safety and user experience. Power and sample size analysis are not typically implemented at this early stage where the focus is most often on determining potential negative impacts from a new

treatment that is being trialed on patients (American Cancer Society, n.d.; Cancer Research UK, n.d.). Participants were recruited through the Head and Neck Cancer Team in the Department of Otolaryngology – Head & Neck Surgery at Henry Ford Health (HFH). Rolling recruitment was conducted of patients matching the criteria below until the targeted number of participants was attained.

1. Inclusion Criteria: >18 years old, diagnosed with HNC in the oral cavity, pharynx, or larynx, standard XRT +/- CT as their treatment plan. Inclusion criteria were confirmed by review of the medical chart and consultation with the treating radiation oncologist.
2. Exclusion Criteria: HNC in nasal cavity or ear, recreational VR use, or medical contraindications for VR use (per Meta Oculus 2 user manual, individuals should consult with a doctor prior to use if they are pregnant, elderly, have pre-existing vision abnormalities or psychiatric disorders, suffer from heart conditions or seizure, or have medical devices such as pacemakers, hearing aids, and defibrillators (Meta, 2020)). Individuals with history of seizure or those with implantable cardiac device (pacemaker or defibrillator) were excluded. The treating radiation oncologist provided medical clearance for all participants.

Past medical history and demographic information were gathered from HFH's electronic medical records system (Epic).

3.3.2 Instrumentation and Survey Tools

3.3.2.1 *Virtual Reality Headset*

The VR equipment utilized in this study is the same as in study 2 (see 3.2.2.1) The participants were required to sit during the VR experience.

3.3.2.2 Surface Electromyography

The Mobili-T surface electromyography (sEMG) device (True Angle, 2024) was used to track the amplitude and number of swallows a participant completed during data collection. It is a small, portable sEMG sensor adhered under the chin with a single-use, double-sided tape (Figure 9). The device syncs via Bluetooth to a mobile application loaded on a tablet controlled by the researcher (Figure 10). When the individual swallows, the muscle activity is detected and transmitted for display in the application. Swallowing counts and amplitude were tracked via the Mobili-T clinician portal and used for exploratory purposes only, data was not formally analyzed.

Figure 9. *Mobili-T sEMG device.* Photo of device front (Fig. 9a), surface electrodes (Fig. 9b.), and device adhered to patient's neck (Fig. 9c).

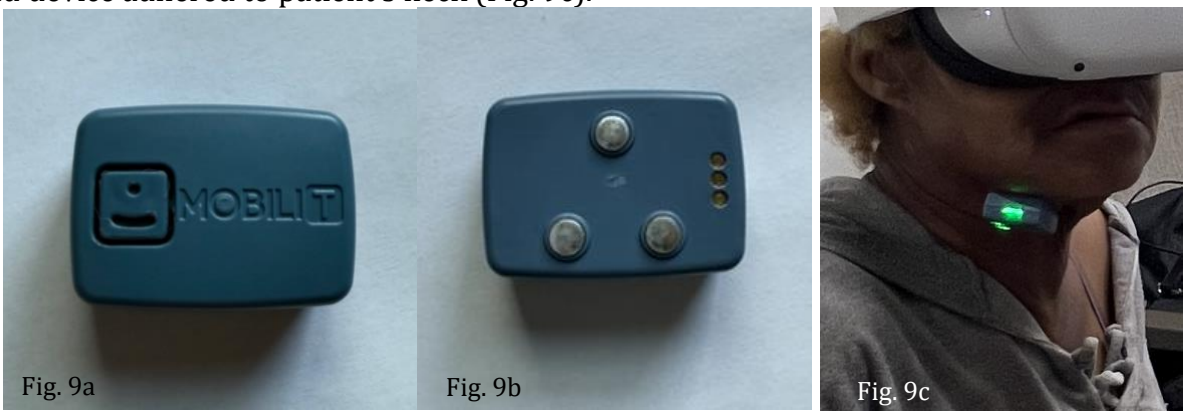


Figure 10. *Mobili-T Mobile Application Interface.* Screenshot of calibration process (Figs. 10a & 10b) and exercise session (Fig. 10c).

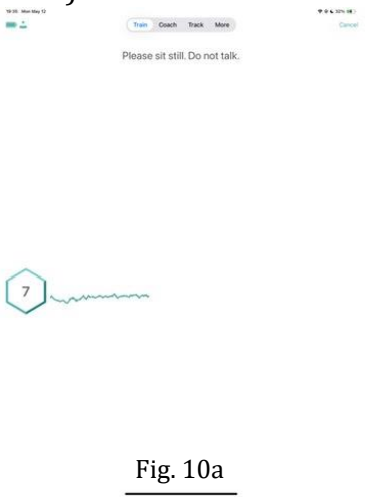


Fig. 10a

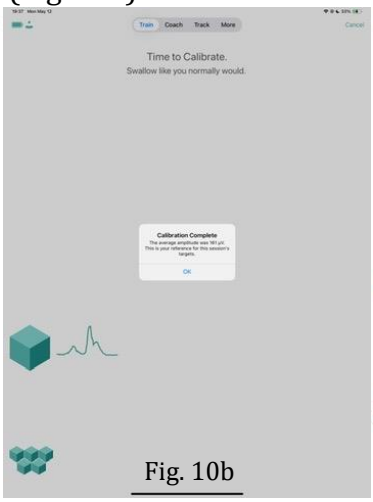


Fig. 10b

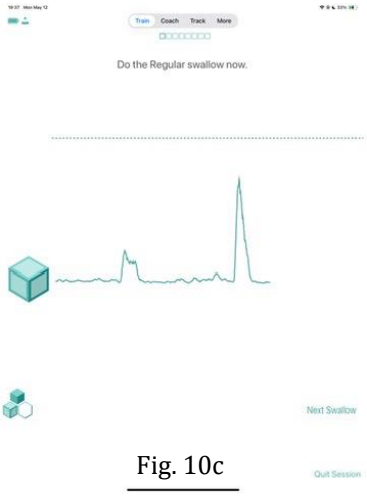


Fig. 10c

3.3.2.3 Survey Tools

One scale and one survey were completed by the HNC participants. These are detailed below. The set of surveys used in studies 2 and 3 are not fully the same given the different objectives for each study. This, and heightened concern about survey-burden when studying the HNC population required some differences in the tools utilized in order to reduce completion time for the cancer patients.

The scale used for study 3 was the Edmonton Symptom Assessment System-Revised (ESAS-r; Watanabe et al., 2011). Originally developed for advanced cancer patients, the ESAS was designed to be used repetitively to measure symptom intensity without significant patient burden (Wantanabe et al., 2011). The revised ESAS, or ESAS-r, is a psychometrically validated and widely used tool to assess and track several symptoms of patients with various health conditions, including patients with HNC, as well as those undergoing XRT (Johnstone et al., 2017; Noel et al., 2021). The survey consists of 10 symptoms; each rated on an 11-point scale where lower scores indicate no/none/absent symptoms and higher ratings indicate the "worst possible" perception for the symptom

being rated. The ESAS-r is in Appendix J. Given that each symptom is individually rated, it allows for use of single-item measures from the scale (Pantilat et al., 2012). From the ESAS-r, two primary and one secondary measures of interest were derived. The Numeric Rating Scale score for nausea (NRS-N), a primary measure, was extracted from the ESAS-r for analysis because of the focus of the early intervention pilot study, namely, to assess user experience in VR and potential negative side effects. The second primary measure extracted from the ESAS-r was the Numeric Pain Rating for swallowing pain (NPR-S). For this, patients rated perceived pain associated with swallowing specifically. Participants also rated their general pain on one item of the ESAS-r; this is indicated as a Numeric Pain Rating for general pain (NPR-G) and was a secondary measure in the analysis. The three measures derived from the ESAS-r (NRS-N, NPR-S, and NPR-G) were gathered twice at each data collection session, immediately before and after being in VR (Table 2).

The VEQ, v2, described above in study 2 was also given to the HNC participants. As noted previously, the VEQ, v2 provides detailed information about UX related to the VR experience. The VEQ provided primary measures of interest for study 3 which were subscale scores for *Immersion, Presence, Skill, Emotion, Technology Adoption,* and *Experience Consequence*. Usability was assessed by looking at scores for *Skill* and *Emotion*. The *Immersion*, *Presence*, and *Technology Adoption* subscales provided insight into acceptability. Lastly, the subscale for *Experience Consequence* was analyzed to determine potential negative side effects.

All surveys were completed in paper-pencil format. Research personnel were available during survey completion to answer questions and provided clarifications for participants.

3.3.3 Procedures

The participants were followed by their HFH cancer team and received standard of care appointments and treatments throughout their participation in this study. All patients were scheduled for standard radiation treatment regimens of either 63 Gy in 28 fractions or 70 Gy in 35 fractions. Patients typically complete XRT sessions 5 days a week for 7 weeks. Radiation schedules, however, can vary from one patient to the next, and also may be altered for a specific patient during the course of their treatment, based on the recommendations from the HNC team or radiation oncologist. Details about such alterations to the planned XRT were noted by the researcher and reported in the results.

Data collection occurred at three time points across the course of radiation: 1) Pre-XRT which was operationally defined as data collection prior to or during the first week of XRT (during which time a participant may have received up to 10 Gy), 2) Mid-XRT which was defined as collection during the fourth or fifth week (participant received up to 45 Gy), and 3) Post-XRT which was data collection during the last week of treatment. This timeline is demonstrated in Table 2. The emphasis was on ensuring that the primary outcome measures were gathered first at each session, followed by the secondary measures.

Table 2. *Study 3 Measures and Data Collection Time Points.* Highlighting indicates time points for primary data analysis. Lower case "x" is used for secondary analysis. XRT = radiation therapy.

Measure Category	Measure	Pre-XRT	XRT Week						Post XRT
			1	2	3	4	5	6	7	
Primary	ESAS-r [b] – Nausea (NRS-N)									
	Pre-VR	X				X				X
	Post-VR	X				X				X
Primary	Numeric Pain Rating – Swallowing adapted from ESASr [b] (NPR-S)									
	Pre-VR	X				X				X
	Post-VR	X				X				X
Primary	VEQ, v2 [a]	X				X				X
Secondary	Numeric Pain Rating – General from ESASr [b] (NPR-G)									
	Pre-VR	x				x				x
	Post-VR	x				x				x
Exploratory	sEMG Amplitudes & Swallow Counts									
	Pre-VR	x				x				x
	Post-VR	x				x				x

[a] Virtual Experience Questionnaire (Tcha-Tokey et al., 2016)
[b] Edmonton Symptom Assessment System-Revised (Watanabe et al., 2011)

Standard of care at HF for HNC patients undergoing XRT includes evaluations and routine check-ins from a multidisciplinary team of specialists including a nurse practitioner, dietitian, psychologist, medical and radiation oncologists, head and neck surgeons, social worker, SLP, and others depending on the patient's needs and plan of care. The SLP on the team conducts a clinical swallow evaluation and videofluoroscopic swallow study prior to the start of XRT and follows the patient throughout XRT for dysphagia monitoring and therapy. This monitoring and therapy are completed during the multidisciplinary check-ins. Dysphagia treatment typically occurs every other week at the start of XRT for approximately 30 minutes, with increasing frequency to weekly sessions as radiation accumulates and symptoms begin to cause or exacerbate existing swallowing impairments. The SLP determines what type(s) of dysphagia therapy is appropriate as part

of the patient's standard care and there were no modifications to this care dictated by the researcher or research protocol. Dysphagia treatment sessions with the treating SLP usually consist of discussion of current oral intake (consistency, quantity, ability), review of compensatory strategies, other advice to aid in the oral intake process, presentation of bolus trials, and completion of exercises and stretches (e.g., effortful swallow, Masako maneuver, falsetto, etc.).

The Pre-, Mid- and Post-XRT data collection sessions for study 3 were scheduled in conjunction with a participant's radiation visits, occurring either immediately prior to or after XRT simulation or treatment that day to eliminate an additional hospital visit for the participant. These data collection visits were intentionally not scheduled during a patient's dysphagia therapy session with their SLP to eliminate potential for the dysphagia therapy to impact experimental measures and vice versa (i.e., fatigue from dysphagia therapy completion affecting swallow abilities in the study).

The participants were block randomized into two groups as was done in study 2 so that half were in an aVR (n=5) and the other half in a pVR group (n=5). Block randomization was used given the small sample size and to ensure balance between the groups resulting in 5 participants in each of the groups. The active and passive applications used in study 2 were used here in study 3 (i.e., Puzzling Places for aVR and Nature Treks for pVR). Because this study involved multiple data collection sessions, different puzzles and nature scenes were used at the Pre-, Mid-, and Post-XRT time points. During the Pre-XRT session, the Garni Temple (set to 25 pieces) was used for those in aVR and the Green Meadows scene for those in pVR. The puzzles used for Mid- and Post-XRT were the Billiards Room and Acrisure Stadium, respectively, with both set to 25 pieces (Figure 11). The nature scenes

used were Red Savanna for Mid-XRT, and Green Bamboo for session Post-XRT (Figure 12). Similar to study 2, the Meta First Steps for Quest 2 application was used prior to entering the aVR or pVR games to introduce the participants to VR. Also, screen casting was used by the researcher to help facilitate participant interactions with the VR applications and field notes were recorded.

Figure 11. *Puzzling Places application additional puzzles.* Screenshots of the Billiards Room (Fig. 11a) and Acrisure Stadium (Fig. 11b).

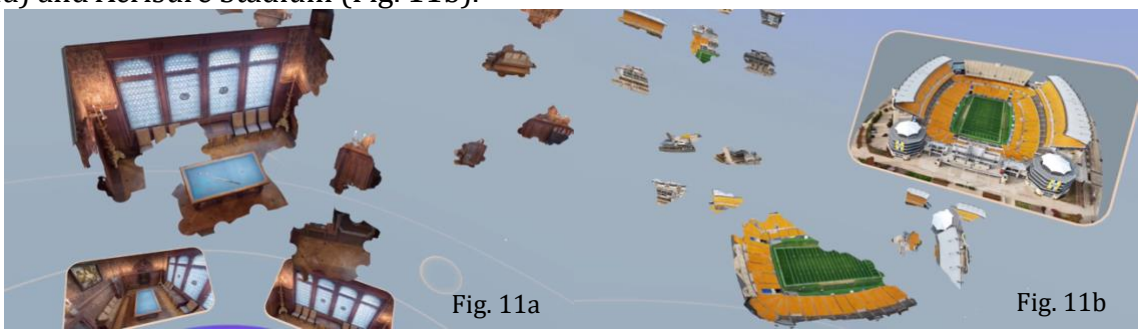
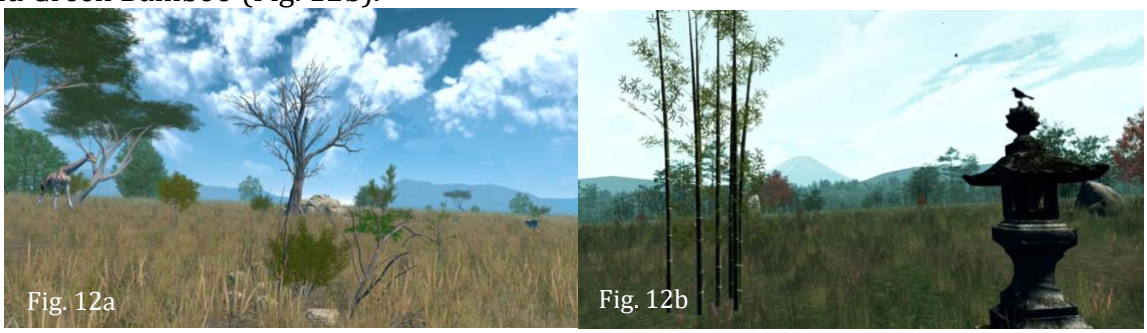


Figure 12. *Nature Treks VR application additional scenes.* Screenshots of Red Savanna (Fig. 12a) and Green Bamboo (Fig. 12b).



The study procedures were the same at all data collection sessions and for both VR groups. The Pre-XRT session that included the consent process lasted about 60 minutes. The Mid- and Post-XRT sessions lasted about 30-45 minutes. All sessions were completed in a patient room in the Department of Radiation Oncology in the Henry Ford Cancer Pavillion in Detroit, Michigan. The sequence below was completed at each session (with consent added to the Pre-XRT visit).

1. **Complete pre-VR measures.**
    a. NRS-N (primary measure)
    b. NPR-G (secondary measure)
    c. sEMG amplitude (exploratory measure). For the sEMG data collection, the participant's neck was assessed for breakdown. The submental region was cleaned with an alcohol wipe. The Mobili-T device was placed on the patient with use of double sided bio-adhesive tape. Device calibration requires 5 dry swallows, completed as instructed by the application. Water was used for sips in-between calibration swallows as necessary if a swallow was not recognized by the app. Resulting sEMG amplitude was recorded by the researcher.
    d. NPR-S (primary measure). Participants then rated their swallowing-related pain immediately after the 5 swallows. If the sEMG sensor could not be secured to the neck (e.g., skin breakdown or sensitivity, facial hair, etc.), the participant still completed 5 swallows then rated pain (NPR-S).
2. **VR interaction**.

    All HNC participants completed the VR experience seated comfortably in a patient chair with their feet on the floor and their back supported. The VR interaction procedures for the patients at the Pre-XRT time point were the same as those described in study 2. Briefly, they entered the Meta First Steps application to provide orientation to operating within VR. The participant was then placed into their assigned VR application (e.g., Puzzling Places or Nature Treks VR). In total, they spent 15 minutes in VR. The VR experience sequence was similar for the Mid-

and Post-XRT sessions except no time was spent in the Meta First Steps application. In these two sessions when the headset was placed on the participant, they immediately were in their assigned active or passive application.

3. **Complete post-VR measures.**
    a. NRS-N (primary measure)
    b. NPR-G (secondary measure)
    c. sEMG amplitude and swallow adherence (exploratory measure). The Mobili-T device was again calibrated with 5 dry regular swallows (water in-between as necessary) as instructed by the Mobili-T app. Resulting sEMG amplitude was recorded. An additional 5 regular swallows were completed as the assigned "Clinic Workout" per the app. These were completed dry, with water in-between swallows if requested by participant. In total, the participant completed 10 swallows.
    d. NPR-S (primary measure). Immediately after completing their 10^{th} swallow for the sEMG data collection, the participant gave their swallowing-related pain rating. If sEMG measurement was not possible for a participant, they completed 5-10 swallows as able. Participants then rated swallowing-related pain (NPR-S).
    e. VEQ, v2 (primary measure)

3.3.4 Analysis

There were two approaches to analyzing the data for study 3. The first was utilization of non-parametric statistics to analyze the primary and secondary measures with a focus on assessing differences between the aVR and pVR groups and also assessing changes in the

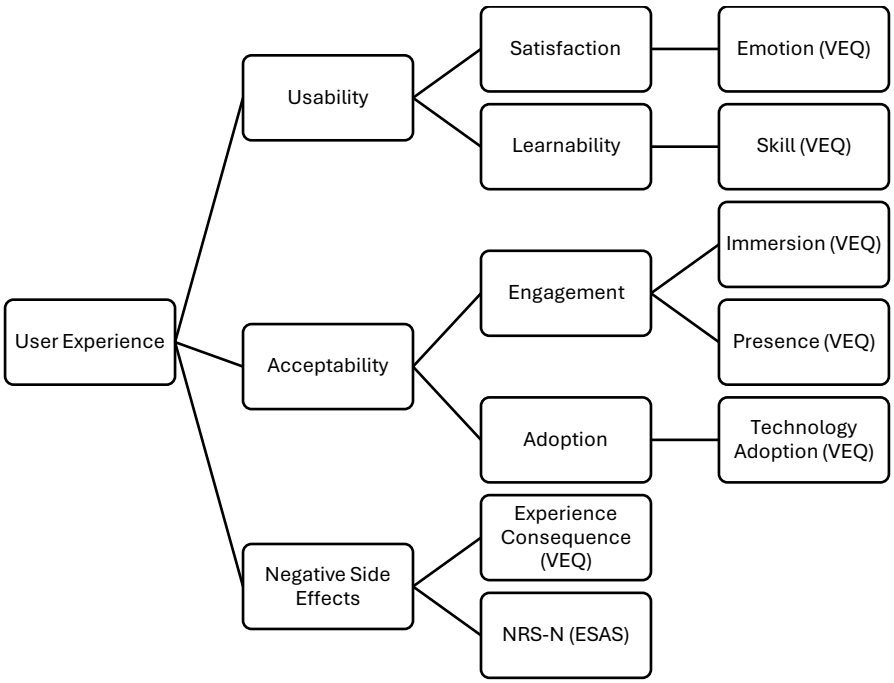
measures over time (Pre-, Mid-, and Post-XRT). The non-parametric approach also included comparison on the UX subscales between the study 3 patients and a group of age and gender matched participants from study 2. The second approach to assessing study 3 data was descriptive in nature. Early phase interventional studies often focus on describing patterns within the small data set and depending on the measures involved, looking for early clinical indicators of effects. Each approach is described below.

The non-parametric analysis was applied to the VEQ subscale scores for *Immersion, Presence, Emotion, Skill, Technology Adoption,* and *Experience Consequence*, and the NRS-N, and NPR-S from the ESAS-r. Figure 13 shows the alignment between measures and each element of UX assessed for study 3. As in study 2, a series of Mann-Whitney U tests were used to evaluate differences between the aVR and pVR groups for each of the measures. Friedman tests were applied to evaluate changes in the subscales over the three data collection points (Pre-, Mid- and Post-XRT). In all cases, families of Mann-Whitney U tests (VEQ subscales, NPR-S) and Friedman's tests (VEQ subscales, NPR-S) each shared an alpha level of .05 using the Holm-Bonferroni correction. Additionally, the VEQ subscale scores from the HNC patients were compared to an age- and gender-matched control group (drawn from study 2) with a series of Mann-Whitney U tests. This comparison with controls was made using a single time point, specifically Pre-XRT. Lastly, differences between the aVR and pVR groups on the secondary outcome measure NPR-G was analyzed with the Mann-Whitney U test.

For the descriptive analysis, medians, ranges, and interquartile ranges were calculated for the primary and secondary measures and plotted for visual display in various ways. Additionally, plotting of subscale scores and ratings by individual patients grouped as aVR

and pVR was also completed. For the pain scales (NPR-S and NPR-G), the individual participant data was tabled. For pain rated on these scales, a +/- 2 point change is considered a clinically meaningful change (Mao et al., 2022). Frequency counts and percentages of clinically meaningful changes in pain were obtained.

Figure 13. *Study two measures used for analysis of UX.* VR = virtual reality.



CHAPTER 4. RESULTS

4.1. Study 1 – SLP Pain Survey Study

As a reference, Table 3 provides the associated research questions and hypotheses for specific aim 1. Additionally, the survey measure utilized and specific questions that were analyzed are detailed.

Table 3. *Study one research questions, hypotheses, and specific survey questions utilized for analysis*

Research Questions & Hypotheses	**Survey Question #**	**Question**
RQ 1.1: What education and/or training have SLPs had related to pain and its management? H1.1: SLPs will report having limited education and training on pain and pain management.	2	Have you had any education/training on **pain**? Select all that apply.
		In what formal setting(s)? Select all that apply
		In what informal setting(s)? Select all that apply
	3	Have you had any education/training on **pain management**? Select all that apply.
		In what formal setting(s)? Select all that apply.
		In what informal setting(s)? Select all that apply.
	15	I feel SLPs are provided enough education/training on **pain**.
		I feel SLPs are provided enough education/training on **pain management**.
RQ 1.2: What do SLPs report in terms of their patients' experience of pain during SLP therapy sessions? Of interest is characterizing the pain in terms of specific populations reporting more/less pain, and the impact on therapy progression. H1.2: SLPs will report that pain is most frequently reported in patients with voice and swallowing problems, and that pain interferes with therapeutic progression.	6	Which **medical populations** that you see, if any, have pain?
	7	Do any of the patients/clients you see with **SLP diagnoses** have pain? (e.g., articulation, dysphagia, aphasia, dysphonia, etc.) If yes, please list which diagnoses
	12	Does patient-reported pain ever **impact** your ability to complete evaluations or treatment? Select all that apply
	13	Does patient-reported pain ever **impact** their therapeutic progress?
		What percentage of your caseload has pain that impacts their therapeutic progress?
RQ 1.3: What do SLPs report about: (1) their confidence in helping to manage pain that their patients are experiencing; and (2) their willingness to utilize complementary pain management techniques with patients in their therapy sessions?	14	Do you implement pain management techniques with patients?
		Rate how **confident** you are in using pain management techniques.
	15	If provided appropriate education/training, I would be willing to **implement novel** pain management techniques into my practice with clients/patients.

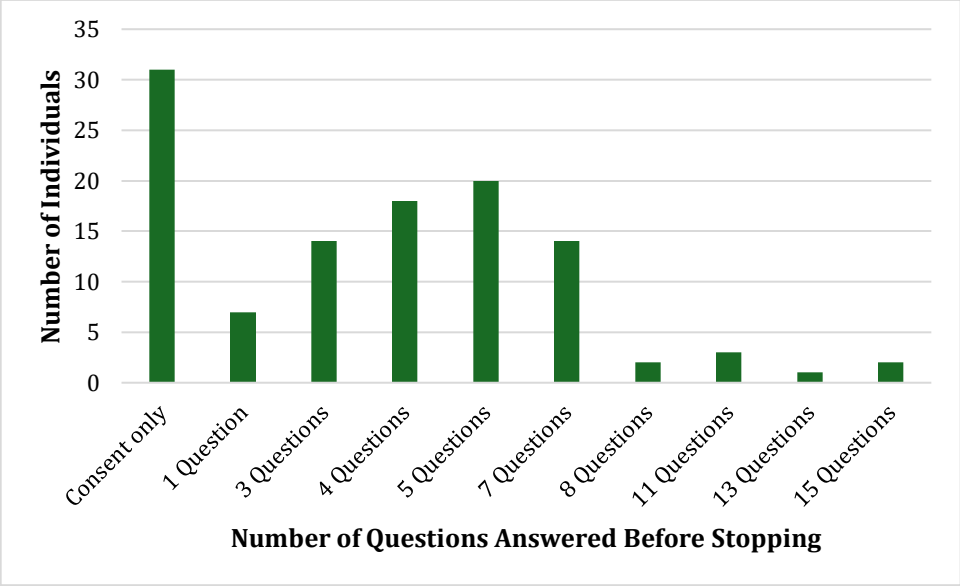
Table 3. (Cont'd)

H1.3: SLPs will report limited confidence in managing pain but will be interested and open to implementing complementary pain mitigation techniques in their therapeutic practice.		

4.1.1 Respondent Demographics

A total of 337 survey responses were received. Ten from individuals outside of the United States were removed leaving 327. Of these, there were 120 incomplete surveys that were not included in the analysis leaving a final set of 207 fully complete surveys. Overall, among the responses from the United States, the survey completion rate was 63%. For the incomplete surveys, a distribution showing how many questions were completed before stopping is in Figure 14 which indicated that 93% had done only the consent or responded to less than 30% of the questions before stopping.

Figure 14. *Distribution of incomplete surveys based on how many questions were completed before stopping*



In the respondents completing the full survey, the majority identified as female (92.3%), White/Caucasian (82.1%), and 31-40 years old (26.1%). A funnel plot with the full age range distribution is in Figure 15. Respondents represented a variety of practice settings with General medical/hospital (20.8%) and Outpatient clinic/office (21.5%) selected most often with 46.4% of individuals reporting that they worked in a single practice setting. There were approximately 49% of respondents who worked exclusively with adults, about 15% working with only pediatric populations, and the remaining having a caseload split between adults and pediatrics (34%). Years of practice as an SLP ranged from currently in clinical fellowship through 31+ years; 6-10 years was the most frequent selection (19.3% of respondents). Demographics are displayed in Figures 16 and 17, as well as detailed in Appendix J.

Figure 15. *Funnel plot of the age distribution of survey respondents*

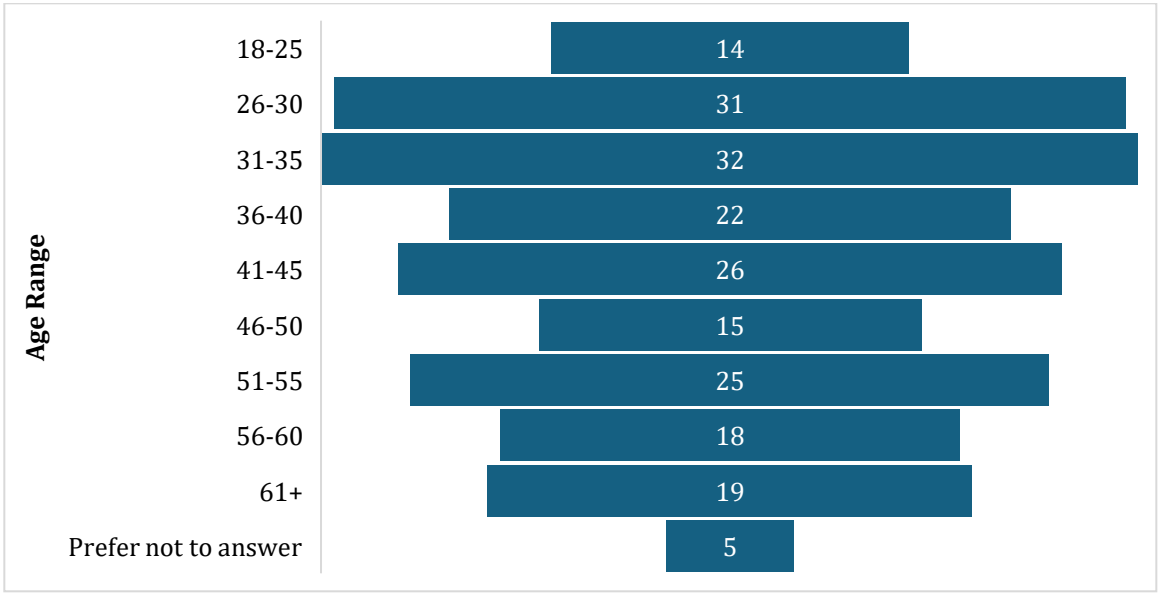


Figure 16. *Pie chart of gender distribution of survey respondents*

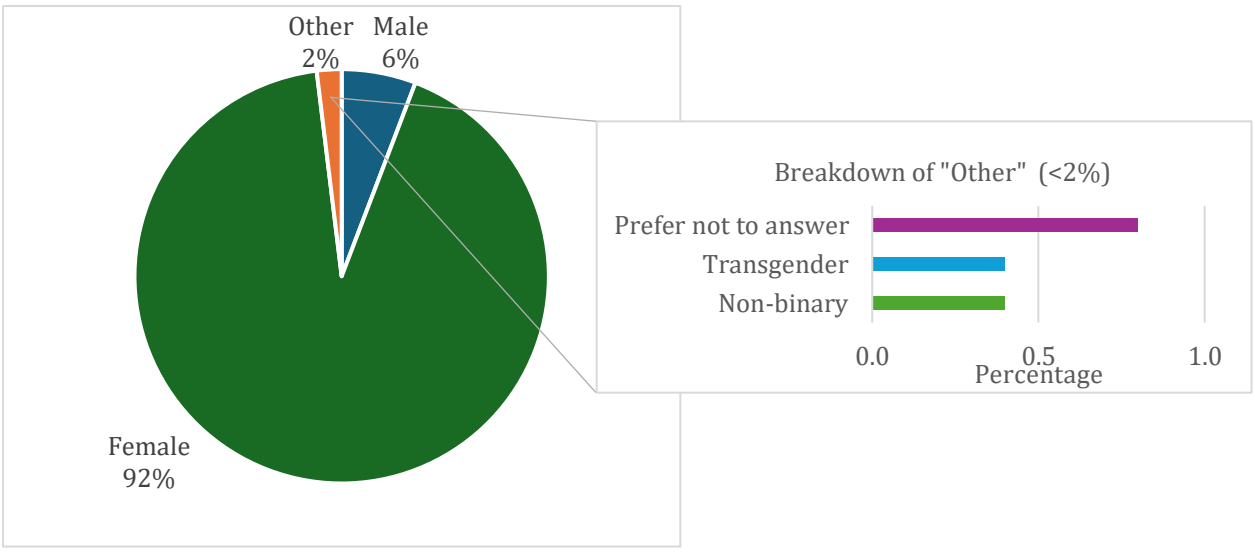
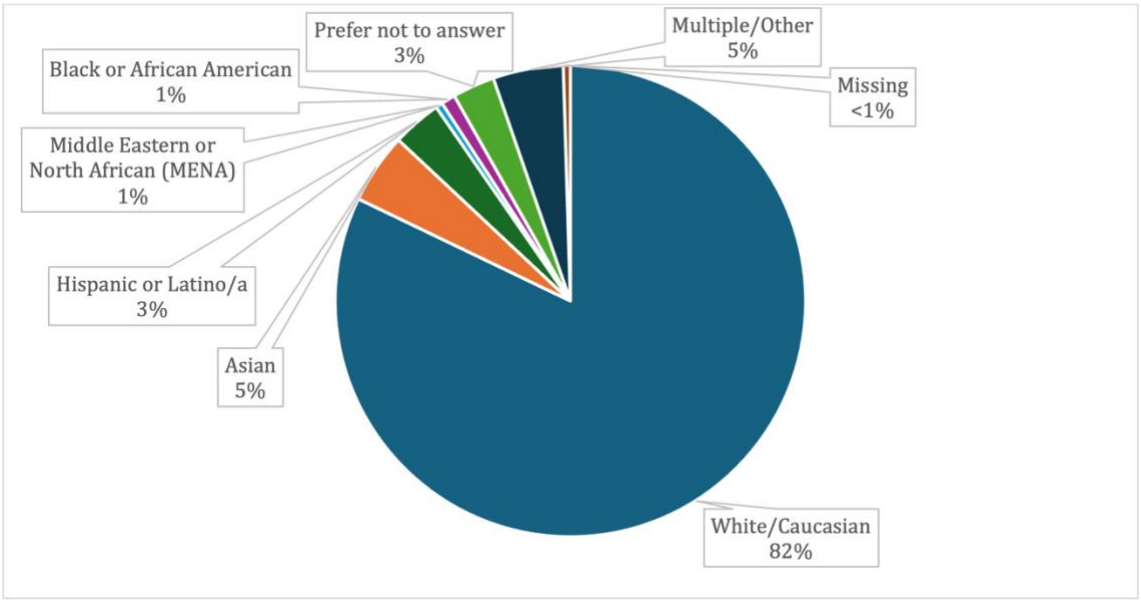


Figure 17. *Pie chart of race and ethnicity distribution of survey respondents*



4.1.2 Education on Pain and Pain Management (RQ 1.1)

To address RQ1.1, descriptive statistics were utilized to learn what education/training on pain and pain management the respondents had completed. Three survey questions were analyzed to address this issue (2, 3, and 15). The majority (77.3%) reported some training about pain, and most frequently this was acquired in "informal" rather than "formal" settings (Table 4). A similar pattern was reported about pain management with 68.6% reporting receiving some training, also occurring more frequently in informal settings. Informal training about pain and pain management was obtained primarily through a combination of activities (i.e., on the job, journal club, etc.) rather than any one particular activity (Figure 18). Continuing education was the most frequent means of formal training about pain (79.7%) and pain management (88.2%) as shown in Figure 18. The majority of respondents disagreed that SLPs were provided enough education/training on pain and pain management (Figure 19). This is reflected in 72.5% disagreeing or strongly disagreeing that SLPs receive enough training about pain, and 76.8% saying the same about pain management training.

Table 4. *Reported Settings for Pain and Pain Management Education/Training*

n (%)

	Yes - Formal	Yes - Informal	No	Yes - Both	I'm not sure	Missing
Pain	57 (27.5)	91 (44)	46 (22.2)	12 (5.8)	1 (0.5)	0
Pain Management	41 (19.8)	90 (43.5)	60 (29)	11 (5.3)	3 (1.4)	2 (1.0)

Figure 18. *Types of education and training on pain and pain management*

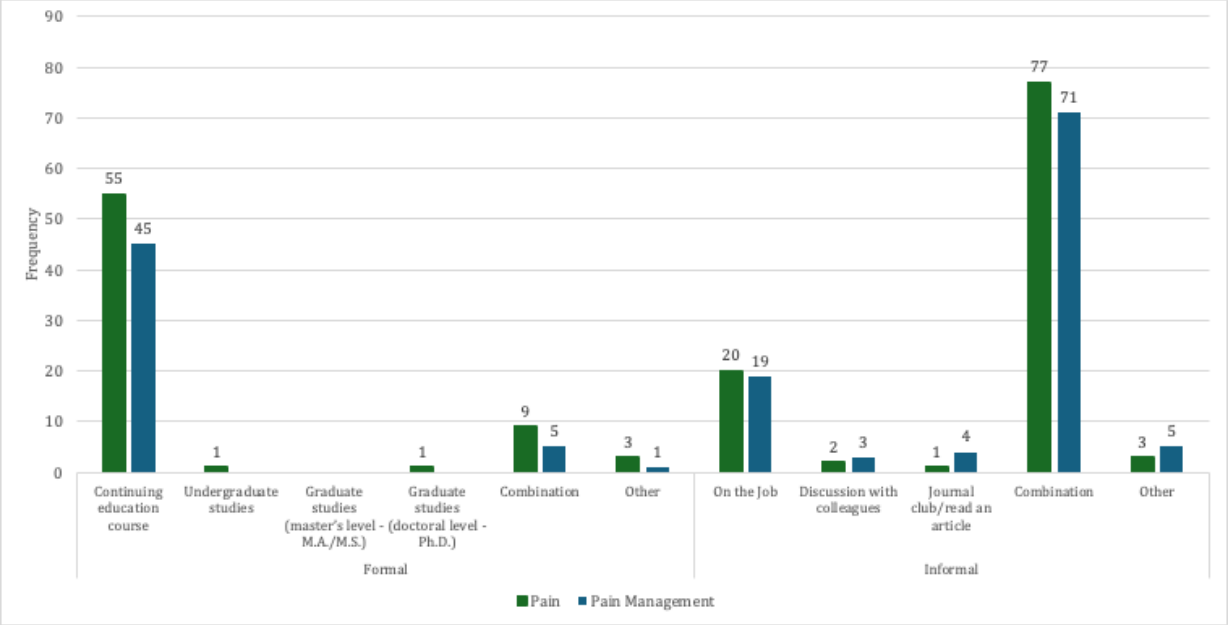
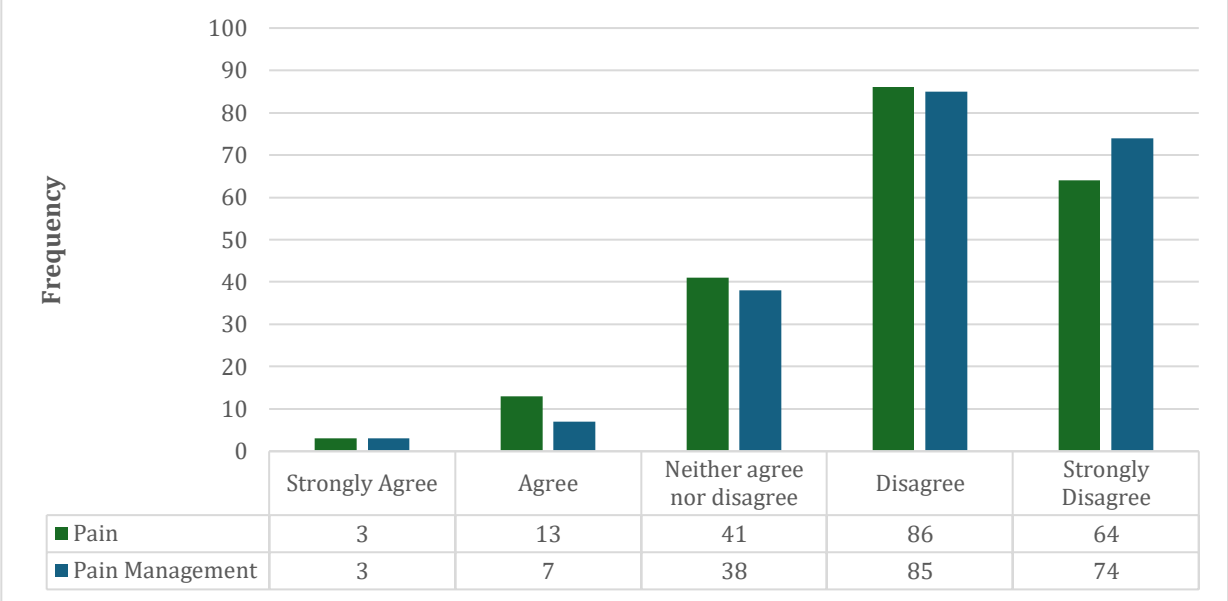


Figure 19. *Speech-language pathologists' opinion on adequacy of education on pain and pain management*



	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree
Pain	3	13	41	86	64
Pain Management	3	7	38	85	74

4.1.3 Impact of Pain on Patients (RQ 1.2)

Research question 1.2 addresses perceptions regarding patient experiences with pain. Responses to four survey questions (6, 7, 12, and 13) were analyzed regarding specific medical populations and SLP diagnoses of clients/patients they see who have pain and what impact pain has on evaluations, treatment, or patient progress. The frequency counts from the content analysis of medical populations seen clinically by the SLPs who have pain are in Table 5. Overall, neurologic and oncologic populations were most frequently identified by SLPs as having pain. Within oncologic populations, HNC was reported most (64.5%), followed by "cancer" generally (36.8%). For the question regarding which categories of speech-language pathology diagnoses were associated with pain, survey responses were cast into the ASHA Big 9 categories (Table 6). Swallowing (55.6%), voice and resonance (33.8%) and language disorders (aphasia; 27.1%) were most frequently identified. Of note, respondents did provide some answers for the medical population question that were SLP diagnoses (e.g., dysarthria) or that were based on some other parameters (e.g., "adults", "schools"). This also occurred for the question about SLP diagnosis. For both questions, these are reported in the respective Tables 5 and 6.

Table 5. *Medical populations seen by speech-language pathologists.* Frequency counts and percentages will exceed 207 and 100% as respondents could report multiple diagnostic categories.

n=207

	Category	Example Response	Frequency (%)
Medical Population	Neurology	TBI[1], CVA[2], PD[3]	89 (43)
	Oncology	HNC[4], general, GI[5]	76 (36.7)
	Miscellaneous	Multiple comorbidities, chronic pain, fall, infectious disease, sickle cell	48 (23.2)
	Surgical	Post-op, amputation	35 (16.9)
	Orthopedics	Arthritis, ACDF[6], degenerative joint disease	23 (11.1)
	Trauma	MVA[7], facial trauma	16 (7.7)
	Pulmonary/Respiratory	COPD[8], trach/vent, post-Extubation	10 (4.8)
	Congenital/Developmental	CP[9], developmental delay	8 (3.9)
	Gastroenterology	GERD[10], LPR[11]	8 (3.9)
	Otolaryngology	Vocal nodules	3 (1.5)
	Spinal Cord Injury	SCI[12]	3 (1.5)
	Psychology	Emotional, grief, shame	2 (1)
	Cardiology	Heart attack	2 (1)
Other	Age-based	Adults, geriatrics, peds	65 (31.4)
	SLP Dx	Dysphagia, dysphonia	34 (16.4)
	Quantity	All, most, none	32 (15.5)
	Setting-based	Acute, IPR, SNF, schools	30 (14.5)
	Invalid	"not sure" or N/A	12 (5.8)

[1]Traumatic brain injury
[2]Cerebrovascular accident
[3]Parkinson's Disease
[4]Head and Neck Cancer
[5]Gastrointestinal
[6]Anterior cervical discectomy and fusion
[7]Motor vehicle accident
[8]Chronic obstructive pulmonary disease
[9]Cerebral Palsy
[10]Gastroesophageal reflux disease
[11]Laryngopharyngeal reflux
[12]Spinal cord injury

Table 6. *Speech-language pathology diagnostic categories that have associated pain as reported by SLPs.* Frequency counts and percentages will exceed 207 and 100% as respondents could report multiple diagnostic categories.

n=207

	Category	Example response	Frequency (%)
ASHA Big 9 (SLP Diagnosis)	Swallowing	Dysphagia, odynophagia	115 (55.6)
	Voice and Resonance	Dysphonia, MTD[1]	70 (33.8)
	Language	Aphasia	56 (27)
	Articulation	Dysarthria	39 (18.8)
	Cognition	"Cognitive-communication impairment"	31 (15)
	Fluency	Stuttering	2 (1)
	Hearing	"Children who perceive sounds as painful"	1 (0.5)
	Social Communication	Behavioral/social	1 (0.5)
	Communication Modalities		0
Other	Medical Population	TBI[2], CVA[3], HNC[4]	75 (36.2)
	Quantity	All	14 (6.8)
	Invalid	"I'm not sure if you're asking if the pain is associated with that diagnosis"	6 (2.9)
	Age-based	Peds	2 (1)
	Setting-based	Acute	2 (1)

[1]Muscle tension dysphonia
[2]Traumatic brain injury
[3]Cerebrovascular accident
[4]Head and Neck Cancer

Seventy percent of SLPs (n=145) reported that patients' pain has impacted their ability to complete evaluations and treatment (Figure 20) and 77.3% (n=160) indicated pain affects their patient's therapeutic progress (Figure 21). The 160 respondents who indicated that pain did impede therapeutic progress were asked what percentage of their caseload were affected. Responses varied widely from 0 to 100%, with an overall mean of 28.5% (*SD*=21.8) (Figure 22).

Figure 20. *Impact of pain on speech-language pathologist's completion of evaluations and treatment*

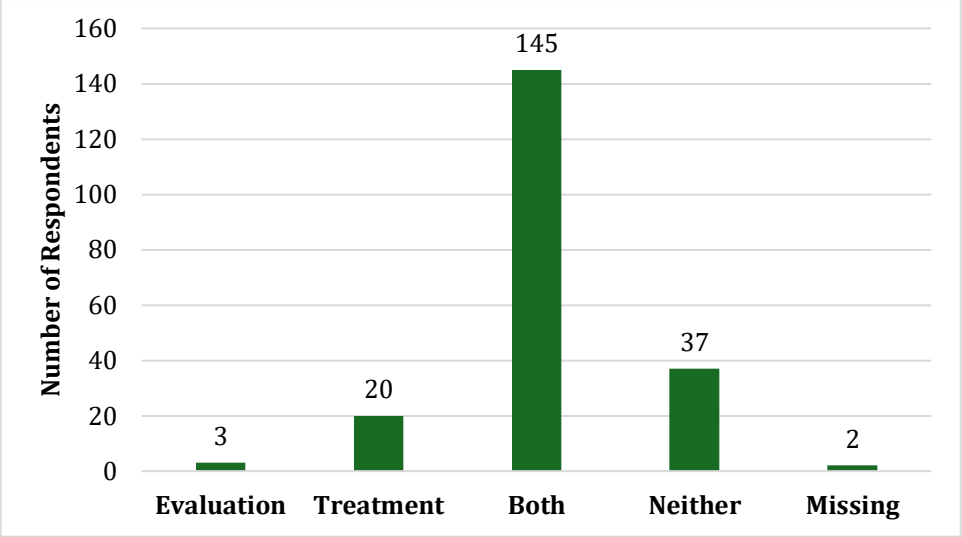


Figure 21. *Impact of pain on patient progress in speech-language therapy*

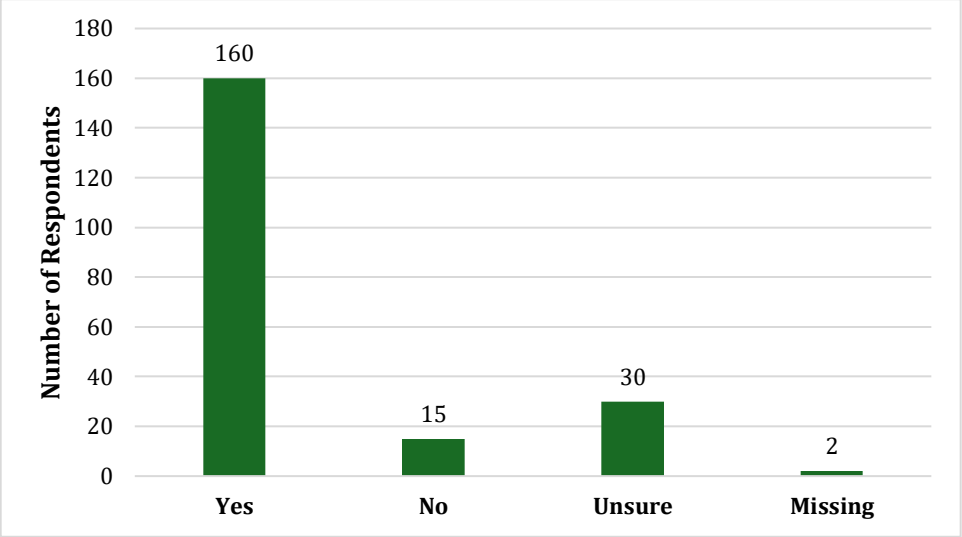
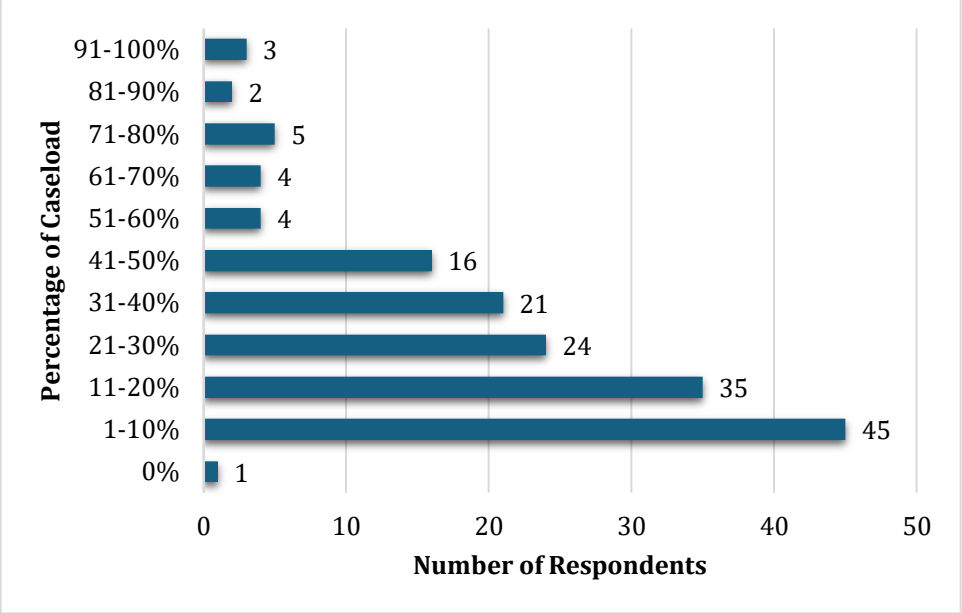


Figure 22. *Percentage of speech-language pathologist's caseload impacted by pain*



4.1.4 Use of Pain Management Techniques (RQ 1.3)

Research question RQ1.3 addressed SLPs' use of pain management techniques (survey item 14), confidence in helping to manage pain (survey item 14c), and their willingness to use novel pain management techniques (survey question 15c). About 45% (n=93) of respondents reported that they used pain management techniques with their patients. A wide range of techniques were reported including repositioning, breathing techniques, massage, stretching, visualization, mindfulness, and distraction, among others. Of those that do implement pain management strategies, 18.5% were very confident and 50% were somewhat confident in their use (Table 7). There were no respondents who selected "not confident" and only 10.9% reported feeling somewhat not confident indicating that those individuals using PM techniques tend to feel confident in their use.

Nearly 86% of the SLPs agreed (47.8%) or strongly agreed (37.7%) that they would be willing to implement novel pain management techniques (Table 7). A Chi-square test of

Independence was completed as secondary analysis to examine the relation between SLP willingness to adopt novel therapeutic techniques as a function of both age and years of clinical experience, respectively. Individuals who responded with "prefer not to answer" for the age question were excluded from the analysis. The relationship between SLP willingness to implement pain management and age was not significant ($\chi^2(16, N = 201) = 19.67$, $p = .236$) (Figure 23). Similarly, the relation between SLP willingness and years of clinical experience was also not significant ($\chi^2(28, N = 205) = 39.36$, $p = .075$) (Figure 24).

Table 7. *Pain management (PM) implementation by speech-language pathologists*

		Frequency (%)
Implementation of PM		n=207
	Yes	93 (44.9)
	No	114 (55.1)
Confidence in Using PM		n=92
	Very confident	17 (18.5)
	Somewhat confident	46 (50)
	Neither	19 (20.7)
	Somewhat not confident	10 (10.9)
	Not confident	0 (0.0)
	Missing	1 (1.1)
Willingness to Implement New PM		n=207
	Strongly Agree	78 (37.7)
	Agree	99 (47.8)
	Neither Agree nor Disagree	21 (10.1)
	Disagree	4 (1.9)
	Strongly Disagree	4 (1.9)
	Missing	1 (0.5)

Figure 23. Speech-language pathologist's *willingness to implement novel pain management techniques by age categories*

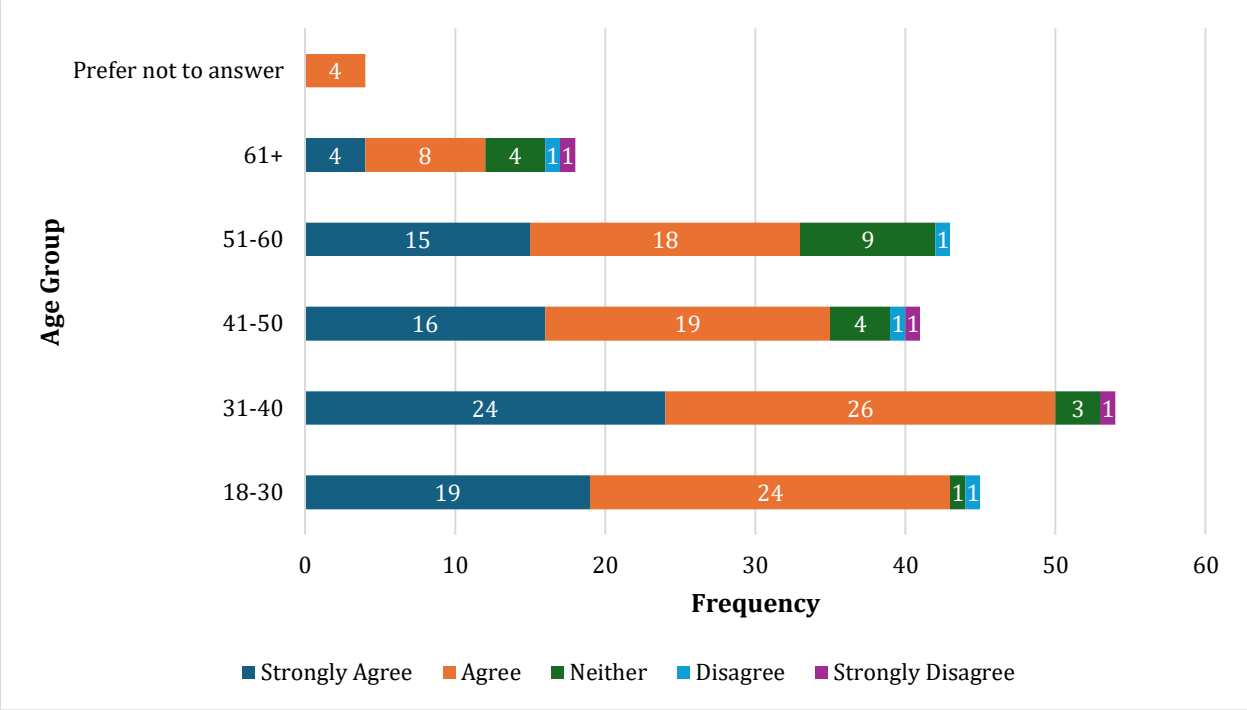
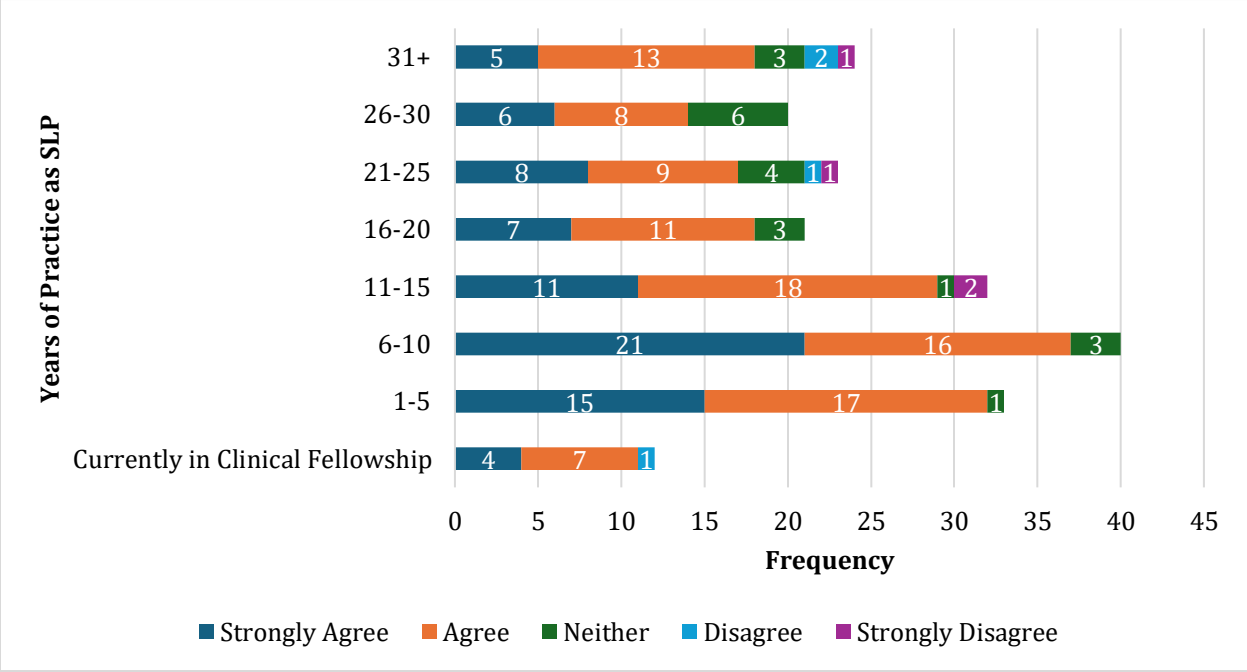


Figure 24. Speech-language pathologist's *willingness to implement novel pain management techniques by years of practice*



4.2 Study 2 – Comparative Cross-Sectional Study: Adults without HNC

As a reference, Table 8 provides the associated research questions and hypotheses for specific aim 2. Additionally, the survey measures utilized and specific questions or subscales that were analyzed are detailed.

Table 8. *Study two research questions, hypotheses, and specific survey questions utilized for analysis.*

Research Questions & Hypotheses	Measure	Subscale or Question
RQ 2.1: Does the usability of VR in adults without HNC differ between active and passive experiences? H2.1.1: Individuals will have higher satisfaction levels in the active experience. H2.1.2: Adults without HNC will report the same level of learnability between active and passive experiences.	VEQ	Emotion subscale (Satisfaction)
		Skill subscale (Learnability)
	Post VR Survey - Q6	Could you engage in the VR application again without instruction? (Learnability)
RQ 2.2: Does the level of acceptability of VR use expressed by adults without HNC vary depending on which VR application is used, active versus passive? H2.2.1: There will be increased engagement levels in the active experience. H.2.2.2: The level of adoption of VR will be the same in both groups.	VEQ	Immersion subscale (engagement)
		Presence subscale (engagement)
		Technology adoption subscale (adoption)
	Post VR Survey - Q7	Would you engage in the VR application again? (adoption)
RQ 2.3: What are the negative side-effects of VR use among adults without HNC? Does this differ between active and passive experiences? H2.3: Adults without HNC are expected to report some cybersickness and other VR side effects. There will be an increase in reported side effects in those in the active VR.	VEQ	Experience Consequence subscale (negative side effects)

4.2.1 Group Demographics

Information on participant demographics is provided in Table 9. The aVR group had a mean age of 48.9 (SD=18.3; range 22-77); the pVR group had a mean age of 52.1 (SD=19.6; range 24-89). There was no difference between the two groups in terms of age ($t(28)=.461$,

p=.646). All identified as either male or female with no participants selecting transgender, non-binary, or *prefer not to answer*. The distribution of males and females between the VR groups did not differ (χ^2(1, N=30) =.46, *p*=.536). Both groups were predominantly White/Caucasian (87% and 80% for the aVR and pVR groups, respectively). The distribution of education level also did not differ between the aVR and pVR groups (χ^2(4, N=30)=.97, *p*=.483; Figure 25). Lastly, the two groups did not differ in terms of their self-reported history of VR use (χ^2(1, N=30)=1.43, *p*=.232). Summary information about overall medical history of the two groups is in Table 10.

Table 9. *Study two demographic and technology use information.* aVR = active virtual reality; pVR = passive virtual reality

Demographic Variable	**aVR Group** (n=15)	**pVR Group** (n=15)	**Total** (n=30)
Gender			
Female	6	8	14
Male	9	7	16
Race or Ethnicity			
American Indian or Alaskan Native	0	0	0
Asian	0	0	0
Black or African American	0	1	1
Hispanic or Latino/a	1	0	1
Middle Eastern or North African (MENA)	0	2	2
Native Hawaiian or Pacific Islander	0	0	0
White/Caucasian	13	12	25
Multiple/Other	1	0	1
Prefer not to answer	0	0	0
History of VR use			
Yes	6	3	9
No	9	12	21
Experience with smart device applications			
Yes	12	14	26
No	3	1	4
Experience with video games controllers			
Yes	12	8	20
No	3	7	10
Comfort level with technology			
Very comfortable	3	3	6
Somewhat comfortable	6	7	13
Indifferent	0	1	1
Somewhat uncomfortable	3	1	4
Very uncomfortable	3	3	6

Figure 25. *Distribution of participant education level.* aVR = active virtual reality; pVR = passive virtual reality

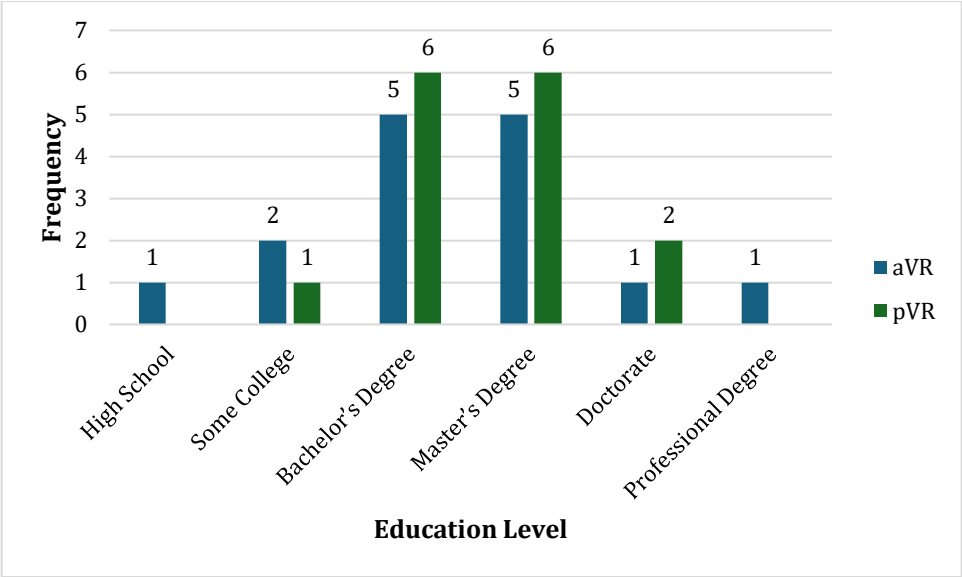


Table 10. *Participant medical history.* aVR = active virtual reality; pVR = passive virtual reality; COPD = chronic obstructive pulmonary disease

	aVR Group (n=15)	**pVR Group** (n=15)	**Total** (n=30)
Diagnosis			
Alcohol/Drug problem	0	0	0
Anxiety	4	4	8
Asthma	2	1	3
Dementia	0	0	0
Depression	1	3	4
Cancer Type*	1	4	5
Coronary artery disease	0	0	0
Congestive heart failure	0	0	0
Emphysema/COPD	1	0	1
Heart-attack	0	0	0
Cardiac – Pacemaker or Defibrillator	0	0	0
High blood pressure	3	5	8
Migraines	0	3	3
Neuropathy	1	0	1
Osteoporosis	1	0	1
Stroke	0	0	0
Seizure	0	0	0
Physical/mental health disorder	0	0	0
Neurological disease (i.e. Parkinson's, etc.)	0	0	0
Other**	3	1	4
Prefer not to answer	0	0	0

*Lymphoma (1), Skin (3), Cervical (1)

**Hand tremor (2), Arthritis (2)

4.2.2 Usability of VR (RQ 2.1)

4.2.2.1 Satisfaction with VR

Satisfaction with VR is reflected in the *Emotion* subscale of the VEQ. Descriptive statistics for the VEQ subscales by VR group are in Table 11. The Mann Whitney U test to assess whether this subscale differed between groups was not statistically significant (U=98.5, n=30, p=.567). The *Emotion* subscale scores when combined were mostly in the

high range of the scale. See Figure 26 for distribution of VEQ subscale scores for the two groups. Figure 27 displays the combined subscale scores for *Emotion* across the sample.

Table 11. Study two *descriptive statistics for all VEQ subscales.* aVR = active virtual reality; pVR = passive virtual reality; IQR = interquartile range

		Median	Range	Minimum	Maximum	IQR
aVR (n=15)	Immersion	2.8	8.6	1.2	9.8	3
	Presence	2.78	8	1.22	9.22	1.89
	Emotion	3.91	3.81	2.55	6.36	1.54
	Skill	2.33	5.83	1.17	7	2.17
	Technology Adoption	3.14	5.14	1	6.14	2.71
	Experience Consequence	9	4	6	10	2.5
pVR (n=15)	Immersion	2.8	5.2	1.6	6.8	2.8
	Presence	2.89	5	2	7	1.45
	Emotion	3.36	3.09	2.09	5.18	1.54
	Skill	2.83	5.17	1	6.17	1.67
	Technology Adoption	3.29	7.14	1.29	8.43	3
	Experience Consequence	9.5	4.62	5.38	10	2.25

Figure 26. *Box and whisker plot of VEQ subscale score for Emotion.* Lower scores are desired. aVR = active virtual reality; pVR = passive virtual reality

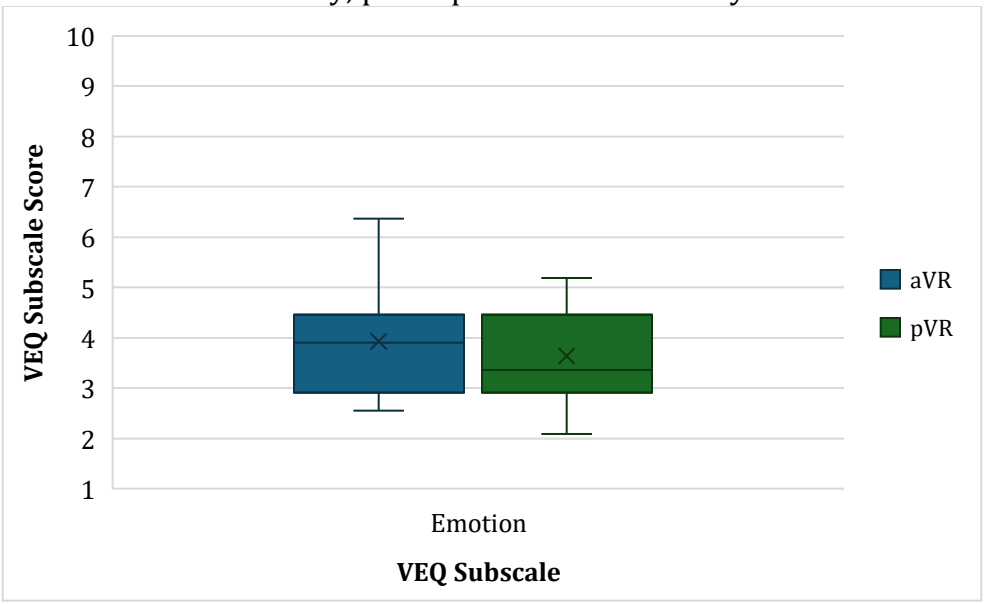
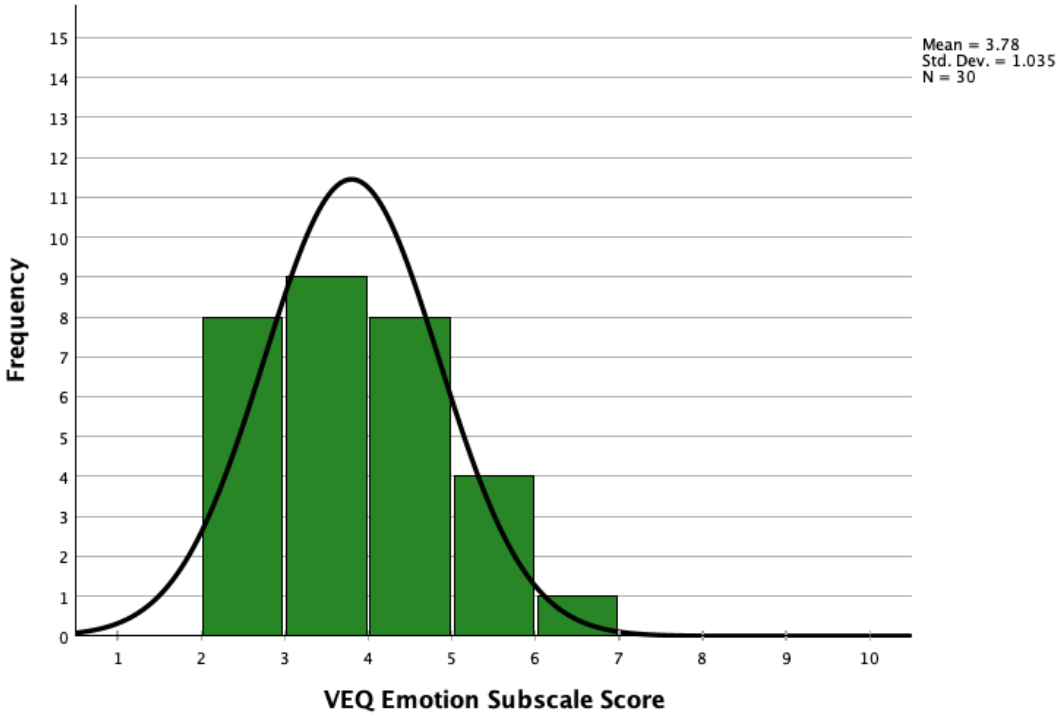


Figure 27. *Histogram of VEQ Emotion subscale across all participants*



4.2.2.2 Learnability of VR

The *Skill* subscale from the VEQ, as well as a single question from the post-VR survey (Question 6, [Q6]) were used as measures of *Learnability* of VR, or ease of use, which is another element of overall usability. A Mann-Whitney U Test was completed to determine differences between the aVR and pVR groups. Results demonstrated that *Skill* did not differ between groups (U=96.0, n=30, *p*=.733); see Figure 28 for distribution of scores between groups. When combined, participant ratings indicated a mid-high range of *Skill* with values in the lower portion of the scale (lower scores are desired; Figure 29). Results from Q6, a question prompting participants on their ability to engage with VR again unassisted, were positive with 80% of aVR participants and 85.7% of pVR participants reporting "yes" (Table 12). A Mann-Whitney U Test was completed with the data from Q6 to determine if there were differences between the groups; there were no differences (U=99.0, n=30,

p=.421). These results combined with those from RQ 2.1 result in overall high scores of usability across groups.

Figure 28. *Box and whisker plot of VEQ Skill subscale score.* Lower scores are desired. aVR = active virtual reality; pVR = passive virtual reality

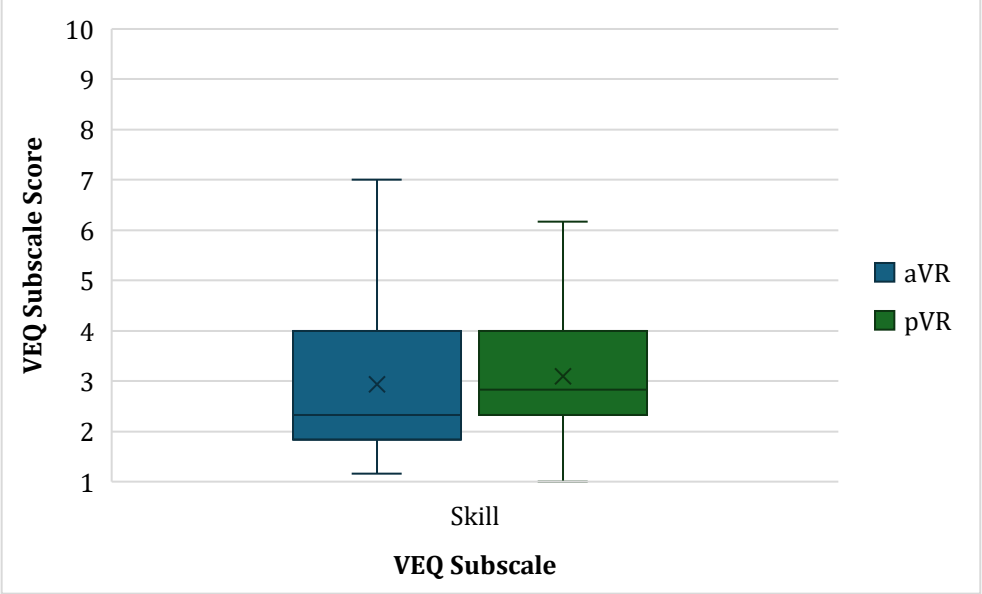


Figure 29. *Histogram of VEQ Skill subscale across all participants*

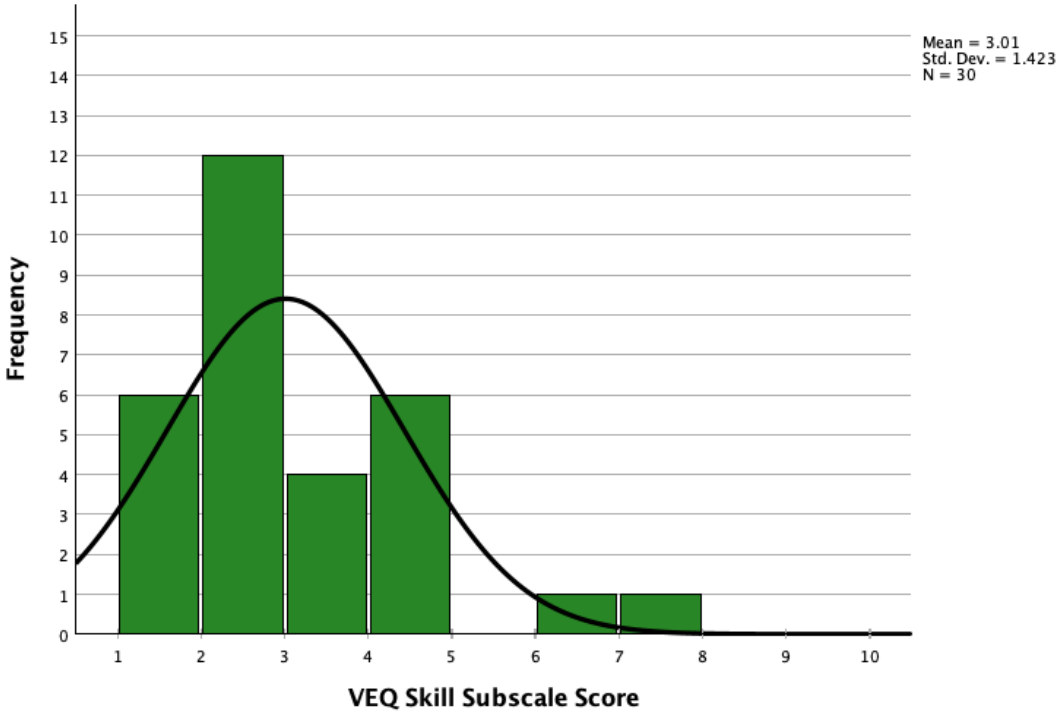


Table 12. *Question 6 data from post-VR survey*

Could you engage in the VR application again without instruction?		
	aVR (n=15)	**pVR** (n=14)
Yes	12	12
No	3	2

4.2.3 Acceptability of VR (RQ2.2)

4.2.3.1 Engagement with VR

Two subscales from the VEQ reflect VR *Engagement*, namely the *Immersion* and *Presence* subscales. A Mann-Whitney U Test was performed to evaluate whether *Immersion* differed between the aVR and pVR groups. The results indicated that *Immersion* did not differ as a function of VR group membership (U=111.5, n=30, p=.967). Likewise, the two groups did not differ on the *Presence* subscale (U=104.5, n=30, p=.744). Taken together, there was not a difference in *Engagement* between the aVR and pVR groups. Combining the two groups together for the *Immersion* subscale, the participants' ratings indicated a mid-high level of immersion as indicated by scores in the lower end of the scale (i.e., lower scores are desired). The combined groups demonstrated high levels of *Presence* (i.e., scores in the lower portion of the range). Figure 30 displays the VEQ subscale scores for the groups. Additionally, Figures 31 & 32 demonstrate the distribution of combined scores across the VEQ subscales of *Immersion* and *Presence*, respectively.

Figure 30. *Box and whisker plot of VEQ subscale scores for Immersion & Presence.* Lower scores are desired. aVR = active virtual reality; pVR = passive virtual reality

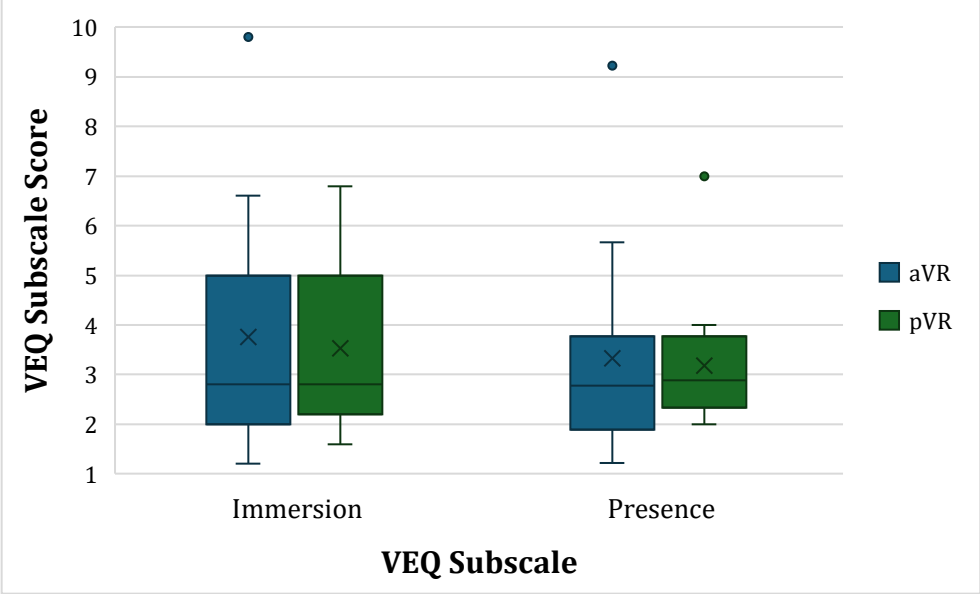


Figure 31. *Histogram of VEQ Immersion subscale across all participants*

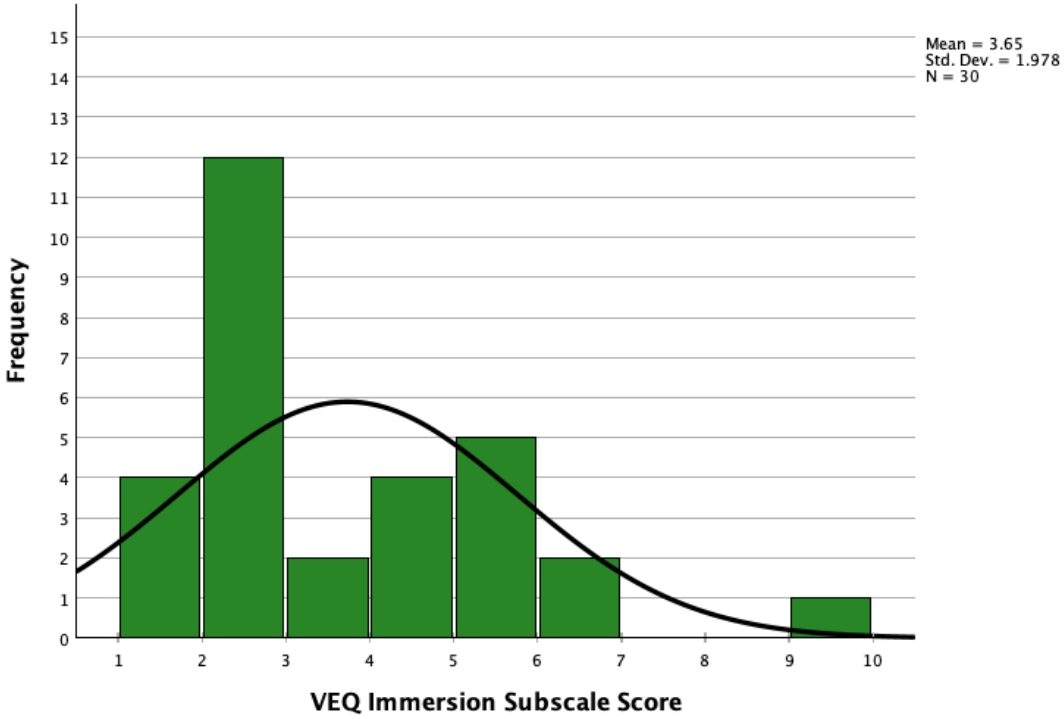
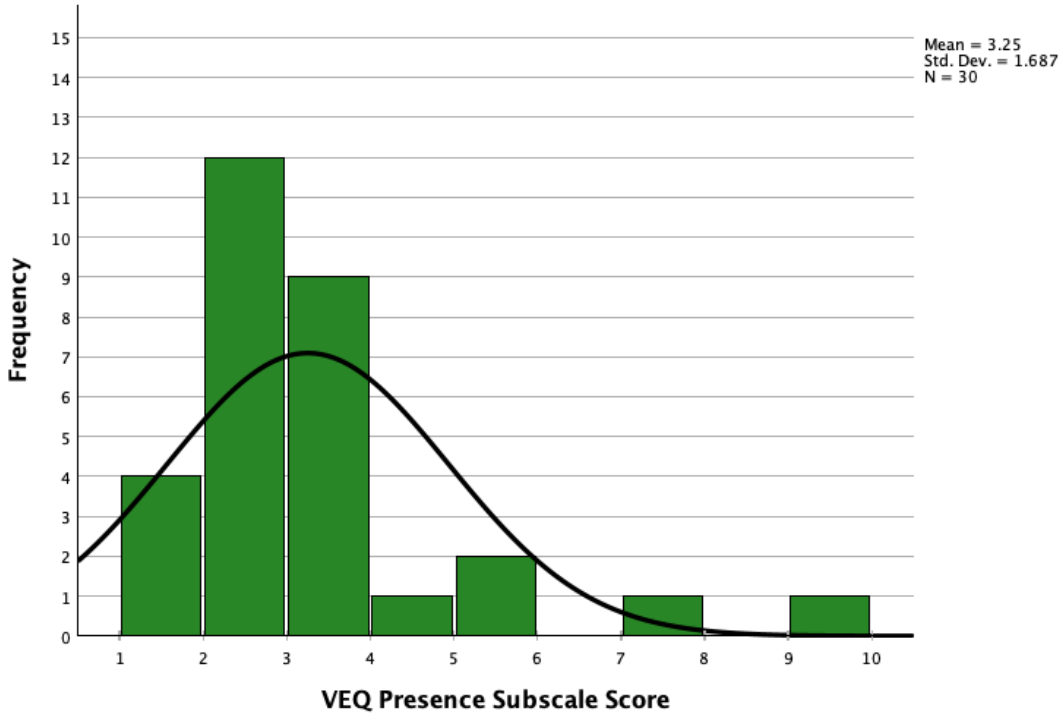


Figure 32. *Histogram of VEQ Presence subscale across all participants*



4.2.3.2 Adoption of VR

Both the *Technology Adoption* subscale from the VEQ and Question 7 [Q7] from the post-VR survey were utilized to assess *Adoption* of VR. A Mann-Whitney U Test was completed to see if the aVR group differed from the pVR group on the *Technology Adoption* subscale. There was no difference between groups (U=100.0, n=30, *p*=.162). Figure 33 displays the distribution of scores between groups. As a combined group, the participant scores indicate a mid-high level of *Technology Adoption* (again, lower scores on the subscale indicate higher technology adoption; Figure 34). The results from Q7, a question eliciting information on desire to engage with VR again, also indicate a high level of acceptability across groups with 86.7% of the aVR group and 93% of the pVR group reporting "yes" (Table 11). A Mann-Whitney U Test for responses on Q7 indicated no difference between the aVR and pVR groups (U=105, n=30, *p*=.550).

Figure 33. *Box and whisker plot of VEQ Technology Adoption subscale score.* Lower scores are desired. aVR = active virtual reality; pVR = passive virtual reality

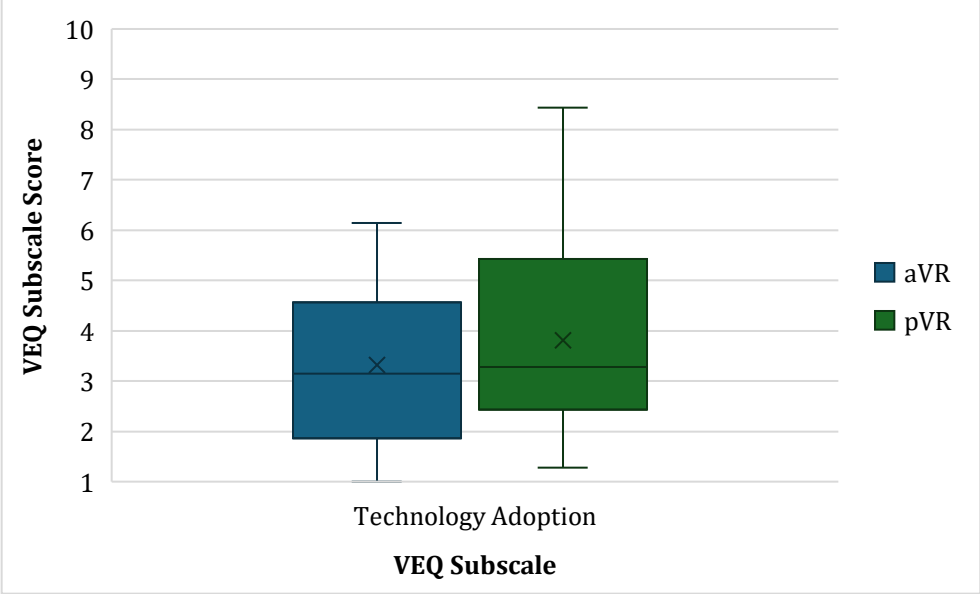


Figure 34. *Histogram of VEQ Technology Adoption subscale across all participants*

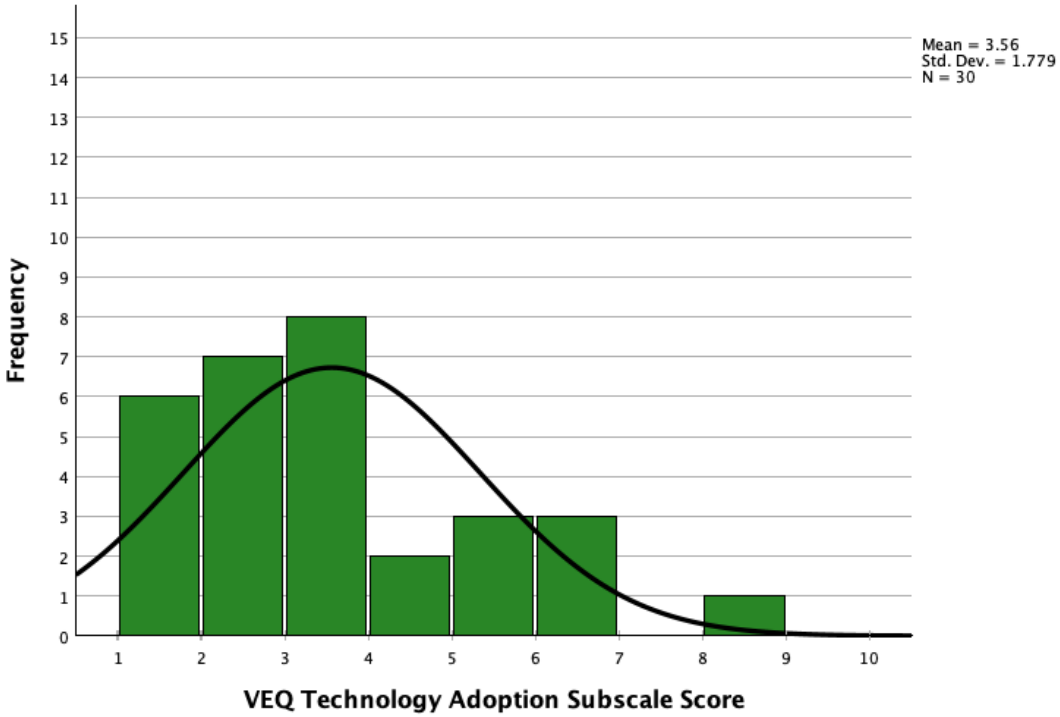


Table 13. *Question 7 data from post-VR survey*

Would you engage in the VR application again?		
	aVR (n=15)	**pVR** (n=15)
Yes	13	14
No	2	1

4.2.4 Negative Consequences of VR Use (RQ 2.3)

The final VEQ subscale of interest was *Experience Consequence* which was used to determine the presence of negative side effects related to VR. A Mann-Whitney U Test revealed no differences between the aVR and pVR groups on this subscale (U=106.5, n=30, *p*=.806). The distribution of scores between groups is provided in Figure 35; as noted, higher scores for this particular subscale are desired. When assessed as a combined group, the participants had an overall low level of *Experience Consequence* indicating low incidence of negative side effects (Figure 36). The individual negative side effects assessed in the *Experience Consequence* subscale are depicted in a box-and-whisker plot in Figure 37. Median values for all side effects in both groups ranged from approximately 8-10, although the ranges and some outlying data indicate the variability in impact.

Figure 35. *Box and whisker plot of VEQ Experience Consequence subscale score.* High scores are desired. aVR = active virtual reality; pVR = passive virtual reality

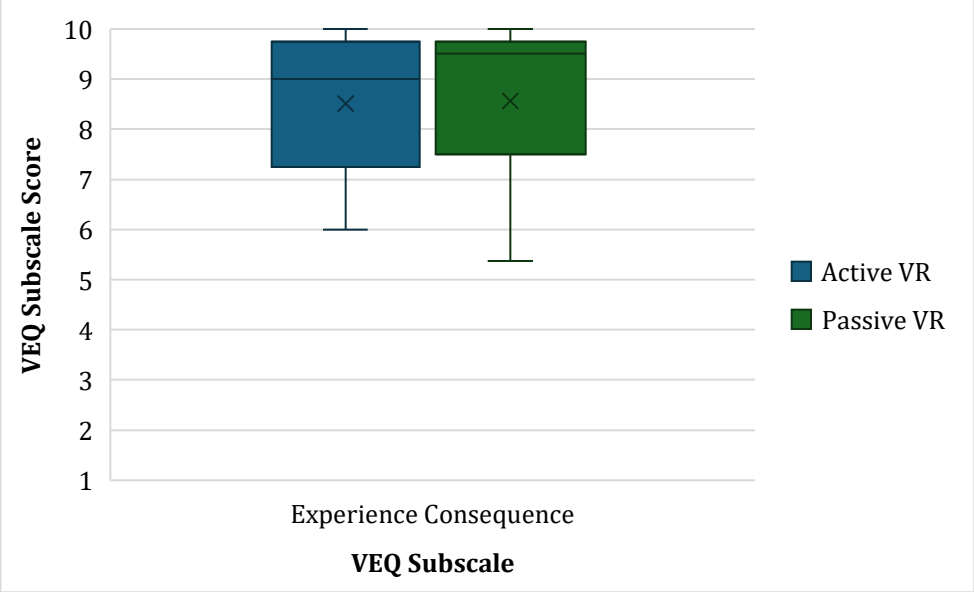


Figure 36. *Histogram of VEQ Experience Consequence subscale across all participants*

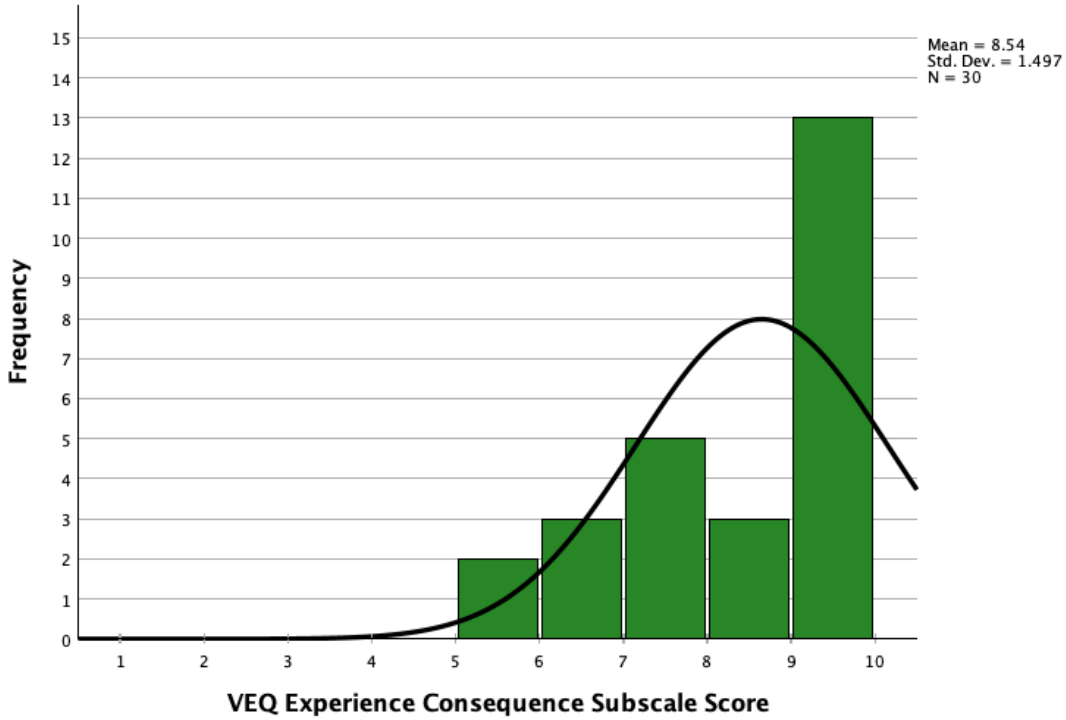
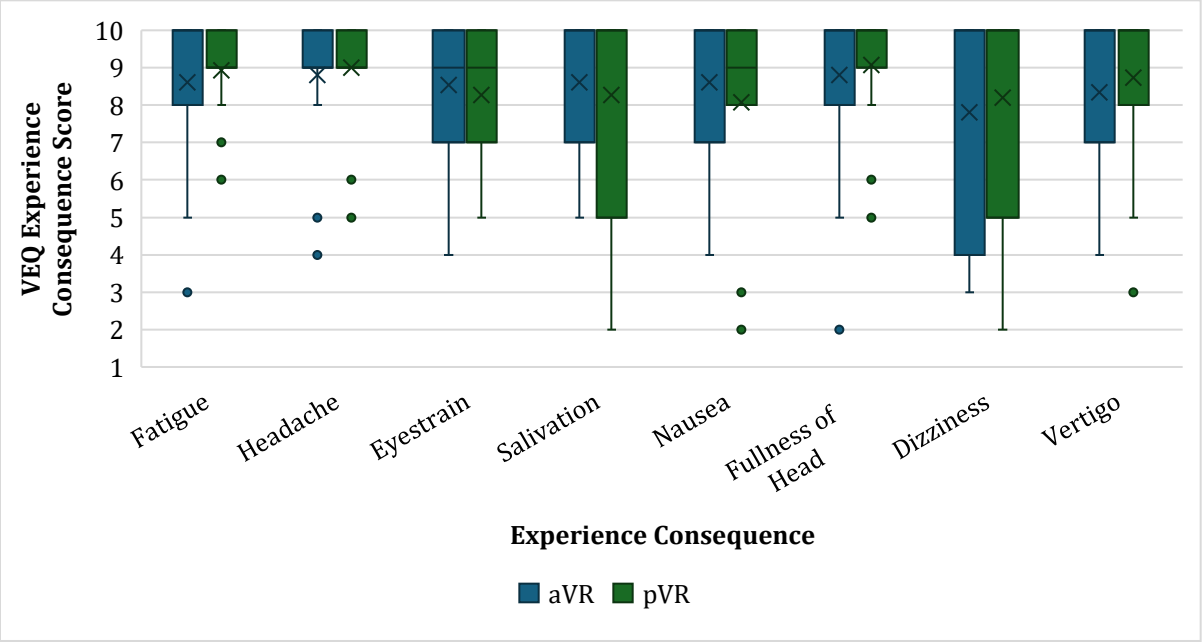


Figure 37. *Box and whisker plot of specific negative side effects addressed in the VEQ Experience Consequence subscale.* Higher scores indicate lower negative side effects. aVR = active virtual reality; pVR = passive virtual reality



4.2.5 Secondary Analysis

As part of this pilot study, a secondary research question was explored regarding the strength of the relationship between interoception and the UX in VR. This analysis focused on the *Not-distracting* subscale of the MAIA-2 and each of the VEQ subscales (e.g., *Immersion, Presence, Emotion, Skill, Technology Adoption, and Experience Consequence)*. A Spearman's correlation was conducted to evaluate the relationship between the *Not-distracting* subscale and the subscales of the VEQ. Correlation coefficients ranged from r_s=-.315 to r_s=.067 (Table 14). There was a moderate negative correlation between the *Not-distracting* subscale and VEQ-*Technology Adoption*, and small negative correlations between the *Not-distracting* subscale and VEQ-*Presence* and *Emotion,* however there were no statistically significant correlations with any of the VEQ subscales.

Additionally, the VEQ subscales were analyzed for relationships within the VEQ itself. Amongst the VEQ subscales, multiple Spearman's Correlations were completed, approximately half were statistically significant (Table 15). There were strong positive correlations between *Presence* and *Immersion*, *Presence* and *Skill*, *Immersion* and *Emotion*, and *Emotion* and *Technology Adoption.* There were moderate positive correlations between *Presence* and *Emotion*, *Presence* and *Technology Adoption*, *Immersion* and *Skill*, and *Emotion and Skill*. There was a moderate negative correlation between *Skill* and *Experience Consequence* and *Experience Consequence and Presence*.

Table 14. *Spearman's rank-order correlation coefficients for the VEQ subscales and Not-distracting subscale of MAIA-2*

VEQ Subscale	r_s	p
Immersion	.067	.726
Presence	-.109	.566
Emotion	-.139	.464
Skill	-.009	.963
Technology Adoption	-.315	.090
Experience Consequence	.047	.805

Table 15. *Spearman's rank-order correlation coefficients (r_s) for the VEQ subscales.* Shading indicates a strong correlation.

Variables	Presence	Immersion	Emotion	Skill	Technology Adoption
Presence	—				
Immersion	.623**	—			
Emotion	.495**	.626**	—		
Skill	.504**	0.345	.391*	—	
Technology Adoption	.395*	0.182	.528**	0.293	—
Experience Consequence	–.301	–.174	–.238	–.383*	0.014
* p < .05 ** p < .01					

Multiple Mann-Whitney U Tests were completed to determine if there were differences in any of the VEQ subscale scores based on participant gender (again, an alpha level of .05

was shared across this set of tests using the Holm-Bonferroni correction). None of the statistical tests were significant (*Emotion*; U=70.0, n=30, *p*=.081; *Skill*: U=104.5, n=30, *p*=.755; *Immersion*: U=86.5, n=30, *p*=.288; *Presence*: U=94.5, n=30, *p*=.466; *Technology Adoption*: U=72.5, n=30, *p*=.100; *Experience Consequence*: U=92.5, n=30, *p*=.416). These data are displayed in Figure 38.

Kruskal-Wallis H Tests were performed to assess differences between VEQ subscale scores as a function of age group (decades). There were no differences in VEQ subscales based on age (*Emotion*: H(6)=5.59, *p*=.471; *Skill*: H(6)=6.17, *p*=.404; *Immersion*: H(6)=3.02, *p*=.807; *Presence*: H(6)=5.65, *p*=.463; *Technology Adoption*: H(6)=4.50, *p*=.610; *Experience Consequence*: H(6)=7.41, *p*=.285). Distribution of the VEQ subscale scores across age groups are provided in Figures 39-44.

Figure 38. *Box and whisker plot of VEQ subscale scores based on gender*. Lower scores desired for all subscales except *Experience Consequence* where high scores indicate lower presence of side effects.

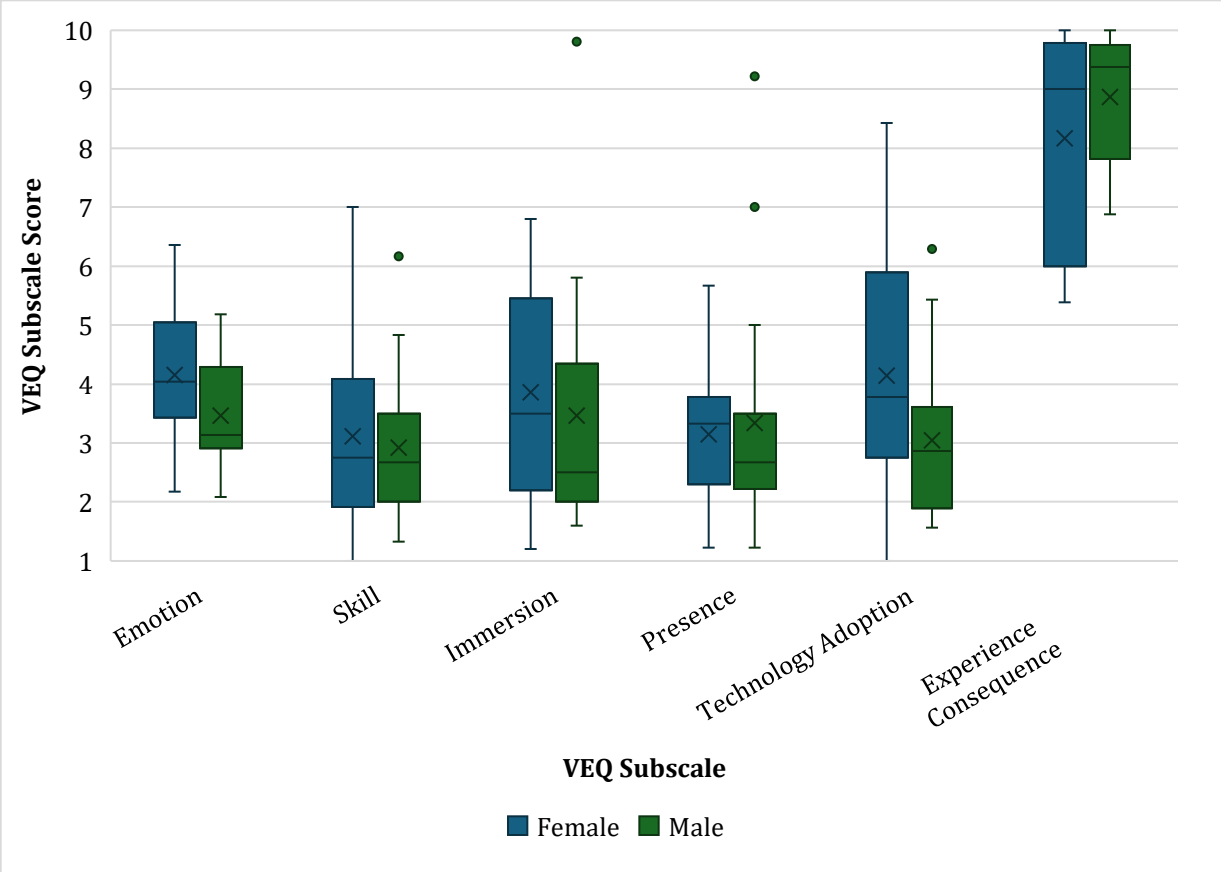


Figure 39. *Box and whisker plot of VEQ Emotion subscale scores based on age group*

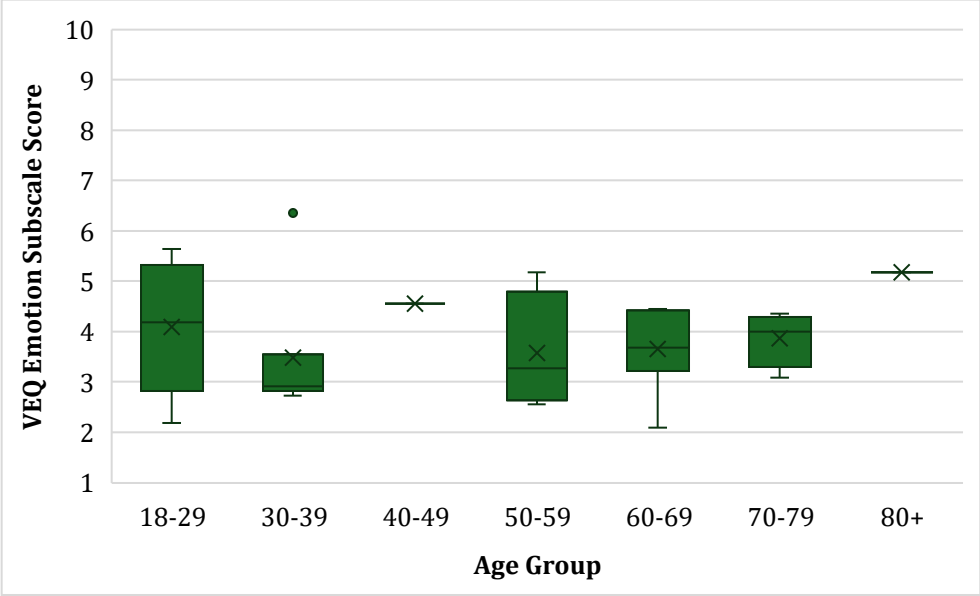


Figure 40. *Box and whisker plot of VEQ Skill subscale scores based on age group*

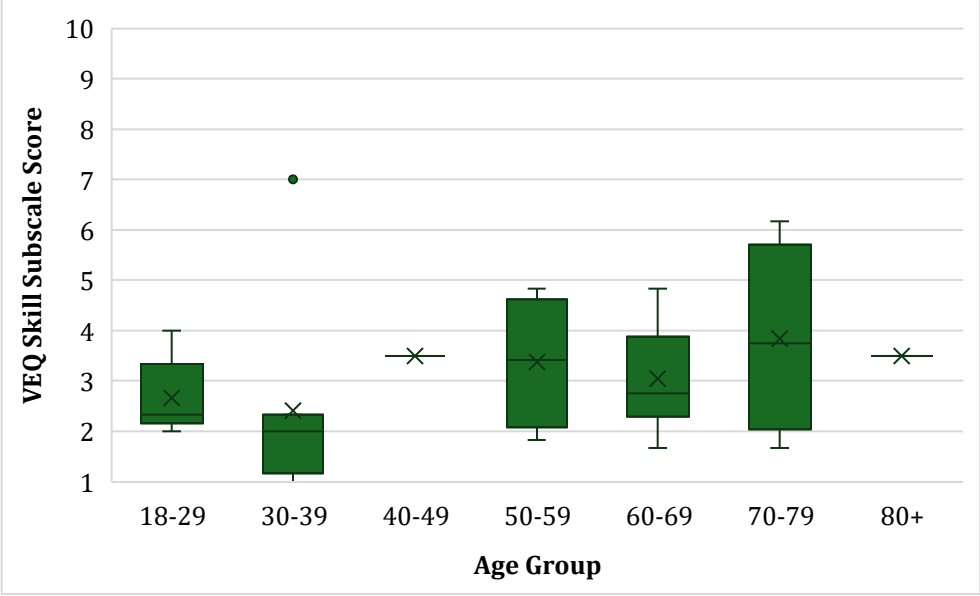


Figure 41. *Box and whisker plot of VEQ Immersion subscale scores based on age group*

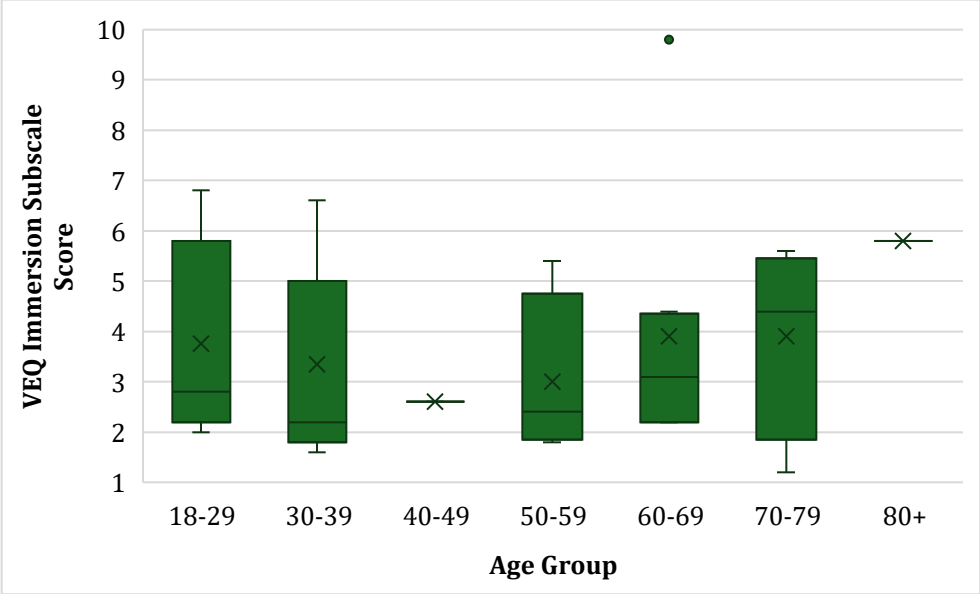


Figure 42. *Box and whisker plot of VEQ Presence subscale scores based on age group*

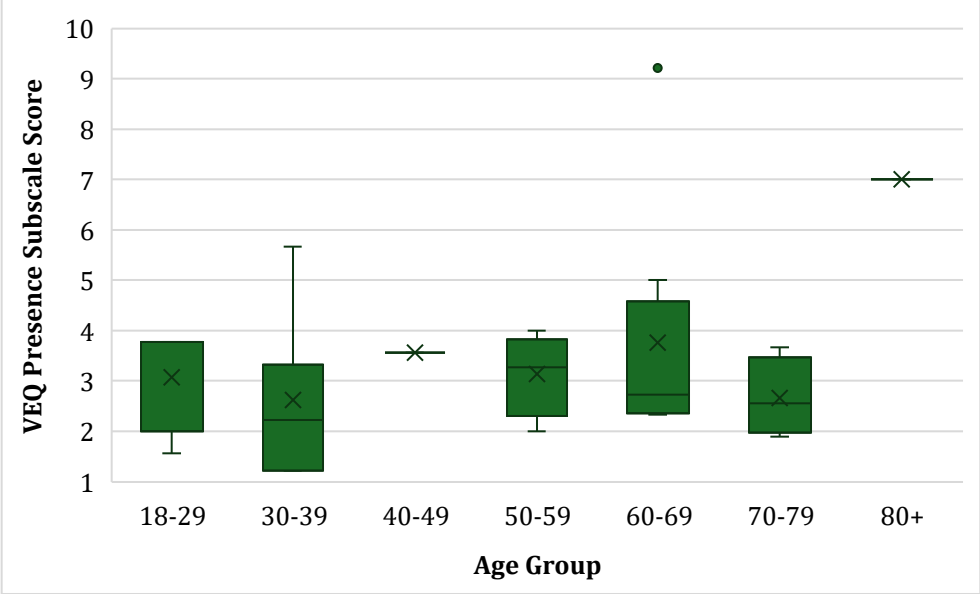


Figure 43. *Box and whisker plot of VEQ Technology Adoption subscale scores based on age group*

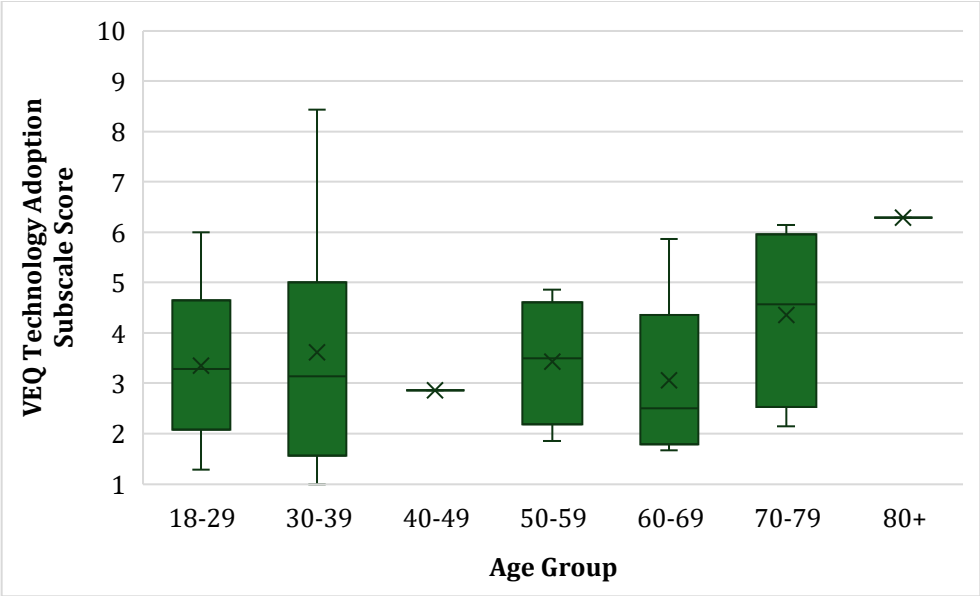
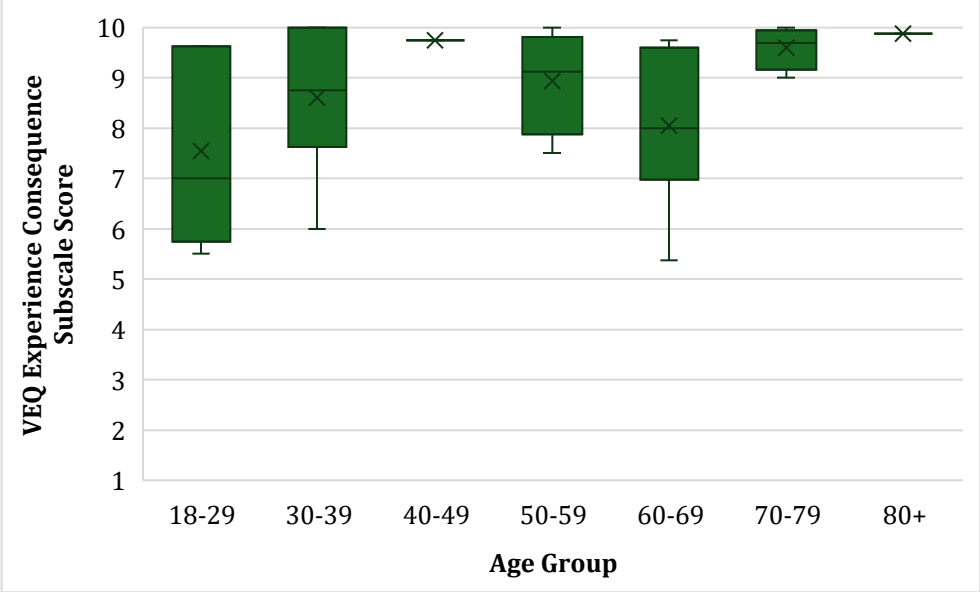


Figure 44. *Box and whisker plot of VEQ Experience Consequence subscale scores based on age group*



4.3 Study 3 – Early Phase Interventional Study: HNC Population

As a reference, Table 16 provides the associated research questions and hypotheses for specific aim 3. Additionally, the survey measures utilized and specific questions or subscales that were analyzed are detailed.

Table 16. *Study three research questions, hypotheses, and specific survey questions utilized for analysis.*

Research Questions & Hypotheses	Measure	Subscale
RQ 3.1: Does the usability of VR in HNC patients differ between active and passive VR experiences? Of interest is whether this changes over the course of XRT? H3.1.1: Patients with HNC in the active experience will report increased satisfaction. H3.1.2: There will be similar learnability between the passive and active groups. H3.1.3: Usability of VR in patients with HNC will increase over time across both active and passive VR experiences	VEQ	Emotion subscale (satisfaction)
		Skill subscale (learnability)
RQ 3.2: Does the level of VR acceptability expressed by HNC patients differ between active and passive VR experiences? Does this change over time? H3.2.1: Patients with HNC will have increased engagement levels in the active experience. H3.2.2: There will be no differences in level of VR adoption between groups. H3.2.3: Furthermore, the level of reported acceptability will increase over time	VEQ	Immersion subscale (engagement)
		Presence subscale (engagement)
		Technology adoption subscale (adoption)
RQ 3.3: What are the negative side effects of VR use in HNC patients? Does it change over the course of XRT? H3.3.1: Negative side effects reported will be consistent with cybersickness H3.3.2: Reported side effects will worsen over time in concordance with XRT	VEQ	Experience Consequence subscale (negative side effects)
	ESAS	NRS-N

Table 16. (Cont'd)

RQ 3.4: Is there a difference between patients with HNC and adults without HNC in terms of experience in VR? H3.4.1: Individuals will report similar usability levels compared to an age and gender control group. H.3.4.2: Levels of acceptability will be the same between HNC and control groups. H.3.4.3: Adults with HNC are expected to report cybersickness and other negative side effects of VR at rates higher than what is found in age and gender matched adults without HNC.	VEQ	Skill subscale (learnability)
		Emotion subscale (satisfaction)
		Technology adoption subscale (adoption)
		Immersion subscale (engagement)
		Presence subscale (engagement)
		Experience Consequence subscale (negative side effects)
RQ 3.5: Does use of VR have carryover effect that impacts swallowing-related pain (odynophagia)? H3.5: VR use will result in lower perceived pain during swallowing.	ESAS	NPR-S (Swallow-related pain)

4.3.1 Demographics, Medical History, and Cancer Treatment

Patient demographic information is provided in Table 17. The aVR group had a mean age of 62.8 (SD=5.7; range 57-72); the pVR group had a mean age of 66.8 (SD=6.2; range 61-74). There was no difference between the two groups in terms of age ($t(8)=-1.06$, $p=.319$). All patients identified as either male or female with no participants selecting transgender, non-binary, or *prefer not to answer*. The distribution of males and females between the VR groups did differ as all females were randomized to the pVR group. Both groups were predominantly White/Caucasian (80% and 60% for the aVR and pVR groups, respectively). There was a wide distribution of education levels across the sample as a whole ranging from some high school up through a Master's degree.

Table 18 details patient information related to cancer diagnostics and staging, oncologic treatment, and XRT dosages. Cancer staging in the aVR group ranged from Stage I to III and the pVR group ranged from Stage 0-IV. Location of primary tumor was more diverse in the

aVR group (larynx (20% of patients), oropharynx (40%), other (40%)) with the pVR group being localized to cancers in either the larynx (40% of patients) or oropharynx (60%). Two individuals, one in each group, required a tracheostomy during treatment; with the individual in the aVR group receiving it prior to starting XRT and the one in the pVR group requiring placement during week 2. The majority of the aVR group members (80%) had concurrent chemotherapy but only 40% of those in the pVR group required both interventions. Eighty percent of each group received the standard 70 Gy over 35 XRT sessions. For data collection, the individuals were seen at three time points, pre-XRT (timepoint A), mid-XRT (timepoint B), and post-XRT (timepoint C). These time points varied per patient based on XRT schedule and dosage (Table 19). On average, individuals in the aVR group were seen on days 2, 18, and 31 with corresponding radiation dosage averages of 5.5 Gy, 36 Gy, and 65.33 Gy, respectively. The pVR group was seen, on average, on days 2, 21, and 31 with average radiation dosages of 4.1 Gy, 42.35 Gy, and 65 Gy, respectively. Nine of the ten patients completed all VR sessions. One patient in the aVR group deferred the final session due to severe fatigue.

Table 17. *Patient demographic information and virtual reality group assignment.* aVR = active virtual reality; pVR = passive virtual reality

VR Group	Patient	Age	Gender	Race	Education
Active (n=5)	1	64	Male	White/ Caucasian	Associate's Degree (2)
	4	57	Male	White/ Caucasian	High School
	6	60	Male	Black or African American	Some College
	8	61	Male	White/ Caucasian	Bachelor's Degree
	9	72	Male	White/ Caucasian	Some College
Passive (n=5)	2	74	Male	White/ Caucasian	(missing data)
	3	61	Male	White/ Caucasian	Master's Degree
	5	63	Female	Black or African American	High School
	7	73	Male	White/ Caucasian	Bachelor's Degree
	10	63	Female	Black or African American	Some High School

Table 18. *Patient medical, cancer, and treatment-related information.* aVR = active virtual reality; pVR = passive virtual reality; SCC = squamous cell carcinoma; TNM = tumor, node, metastasis; XRT = radiation treatment, Gy = Gray; PMV = Passy Muir Valve; s/p = status post

	Patient	Cancer Stage	TNM	Oncologic Treatment	Dose	Tracheostomy Status	PMHx
aVR	1	Stage I SCC of the larynx (glottis)	T1bN0M0	XRT	63 Gy in 28 Fractions		UC[1]
	4	Stage I p16+ SCC of unknown primary	T0N1M0	XRT +Chemo	70 Gy in 35 Fractions		
	6	Stage I p16+ SCC of the oropharynx (base of tongue)	T2N1M0	XRT +Chemo	70 Gy in 35 Fractions		CKD[2], neuropathy
	8	Stage III p16+ SCC pyriform	T3N0M0	XRT +Chemo	70 Gy in 35 Fractions		GERD[3], Barrett's esophagus
	9	Stage II p16+ oropharynx (base of tongue)	T3N1M0	XRT +Chemo	70 Gy in 35 Fractions	Pre-XRT (PMV use)	
pVR	2	Stage II sarcomatoid SCC of the larynx (supraglottis)	T2N0M0	XRT	70 Gy in 35 Fractions		Afib[4], COPD[5], MI[6] s/p PCI[7]
	3	Stage III p16+ SCC of the oropharynx (base of tongue)	T4N2M0	XRT +Chemo	70 Gy in 35 Fractions	Week 2 (PMV use)	
	5	Stage 0 SCC of larynx (glottis)	TisN0M0	XRT	63 Gy in 28 Fractions		
	7	Stage II p16+ SCC of oropharynx (tonsil)	T3N1M0	XRT +Chemo	70 Gy in 35 Fractions		
	10	State I SCC p16+ of oropharynx (tonsil)	T2N1M0	XRT	70 Gy in 35 Fractions		

[1]Ulcerative colitis
[2]Chronic kidney disease
[3]Gastroesophageal reflux disease
[4]Atrial fibrillation
[5]Chronic obstructive pulmonary disease
[6]Myocardial infarction
[7]Percutaneous coronary intervention

Table 19. *Patient radiation day and dosage corresponding with virtual reality sessions.* aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment; Gy = Gray; X = missing data for this session

	Patient	Radiation Day				Radiation Dose (Gy)		
		Pre-XRT	Mid-XRT	Post-XRT		Pre-XRT	Mid-XRT	Post-XRT
aVR	1	Simulation	17	27		0	38.25	60.75
	4	5	17	32		10	34	64
	6	4	16	31		8	32	62
	8	Simulation	19	X		0	38	X
	9	2	20	35		4	40	70
pVR	2	2	20	32		4	40	64
	3	6	21	32		12	42	64
	5	2	23	27		4.5	51.75	60.75
	7	Simulation	19	34		0	38	68
	10	Simulation	20	32		0	40	64

Information on patient swallowing ability, cognitive communication, and diet levels throughout XRT were extracted from their electronic medical records. Dysphagia diagnoses were obtained from baseline videofluoroscopic swallow study reports, cognitive functioning from standardized assessments given by a psychologist pre-XRT, and diet levels via Functional Oral Intake Scale (FOIS; <5 = significant decrease or alteration in oral intake; see Appendix K for details) scores documented in treatment notes. This information is provided in Tables 20 and 21. Patients in the aVR group had dysphagia diagnoses at baseline ranging from functional oropharyngeal swallowing to mild oropharyngeal dysphagia (40% functional, 60% mild). The pVR group was more severe with individuals having diagnoses ranging from functional oropharyngeal swallowing to moderate dysphagia (40% functional, 20% mild, 40% combination of mild and moderate). Additional speech-language pathology diagnoses present at baseline were dysphonia in the aVR group and dysphonia, dysarthria, and trismus in the pVR group. Average scores on the Mann

Assessment of Swallowing Ability – Cancer (MASA-C; <178 indicates clinically significant dysphagia) for the aVR and pVR groups were 197.4 and 193.8, respectively. Montreal Cognitive Assessment (MoCA; <26 = cognitive impairment) score averages were 26.75 for the aVR group and 25.75 for the pVR group (these were calculated out of n=4 given one patient in the aVR group was provided the visually impaired version [MoCA-BLIND] due to session being via telehealth and one score was missing in the pVR group).

Average FOIS scores across the three timepoints for the aVR group were 6.6, 5.4 , and 4.5. The pVR group average FOIS scores were 6.6 at pre-XRT, 5.2 at mid-XRT, and 4.4 for the last session. Three individuals in the aVR group required a feeding tube with one receiving a PEG prophylactically before XRT, one requiring a PEG during week 6, and the third getting a Dobhoff (DHT) 2-weeks post completion of XRT. The pVR group had two individuals that required feedings tubes, one a PEG during week 2 and the other a DHT during week 6.

Table 20. *Patient information on swallowing and cognitive communication.* aVR = active virtual reality; pVR = passive virtual reality; SLP = speech-language pathology; MASA-C = Mann Assessment of Swallowing Ability–Cancer, MoCA = Montreal Cognitive Assessment; XRT = radiation treatment; DHT = Dobhoff tube; PEG = percutaneous endoscopic gastrostomy; VFSS = videofluoroscopic swallow study

	Patient	SLP Diagnosis	MASA-C	MoCA	Feeding Tube Status
aVR	1	Functional oropharyngeal swallow Dysphonia	200/200	27/30	
	4	Functional oropharyngeal swallow	200/200	29/30	2 weeks Post-XRT (DHT)
	6	Mild pharyngeal dysphagia	200/200	20/22 (MoCA-BLIND)	
	8	Mild oropharyngeal dysphagia Dysphonia	193/200	26/30	Week 6 (PEG)
	9	Mild oropharyngeal dysphagia Dysphonia	194/200	25/30	Pre-XRT (PEG)
pVR	2	Functional oropharyngeal swallow	200/200		
	3	Mild oral and moderate pharyngeal dysphagia Flaccid dysarthria	187/200	27/30	Week 2 (PEG)
	5	Functional oropharyngeal swallow Dysphonia	192/200	26/30	
	7	Moderate oral and mild pharyngeal dysphagia Flaccid dysarthria Trismus	190/200	28/30	Week 6 (DHT)
	10	Mild oropharyngeal dysphagia	200/200 (calculated based on VFSS note)	22/30	

Table 21. *Patient Functional Oral Intake Scale (FOIS) scores across radiation treatment.* aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment; X = no data for this session

	Patient	FOIS Score		
		Pre-XRT	**Mid-XRT**	**End-XRT**
aVR	1	7	7	7
	4	7	6	4
	6	7	5	4
	8	6	6	X
	9	6	3	3
pVR	2	7	7	6
	3	5	3	1
	5	7	5	7
	7	7	6	3
	10	7	5	5

4.3.2 Usability of VR (RQ 3.1)

4.3.2.1 Satisfaction with VR

The *Emotion* subscale from the VEQ was utilized as an indicator of *Satisfaction* with VR. Of note, analyses were performed to determine differences between the two VR groups, aVR and pVR, at each of the three time points (A: Pre-XRT, B: Mid-XRT, and C: Post-XRT). Descriptive statistics for the VEQ subscales at the three timepoints are provided in Tables 22-24. A Mann-Whitney U Test was completed to assess differences between groups at the three time points. There were no differences between groups at any time point (A: U=11.0, n=10, p=.841; B:U=7.5, n=10, p=.310; C: U=8.0, n=10, p=.730). The *Emotion* subscale scores combined were also in the mid-high range of the scale, (Figure 45). Since there were no differences between groups at any of the time points, a combined group was used for the Friedman Test. A Friedman Test was conducted to assess differences across time. Results revealed no differences ($\chi^2(2)=.53$, p=.767). *Emotion* subscale scores over time are displayed in Figure 46.

Table 22. *Descriptive statistics for VEQ subscales for Pre-XRT (timepoint A).* aVR = active virtual reality; pVR = passive virtual reality; IQR = interquartile range

		Median	Range	Minimum	Maximum	IQR
aVR (n=5)	Immersion	3.6	7.8	1.4	9.2	5.7
	Presence	2.5	7.13	1.5	8.63	4.37
	Emotion	3.55	3.45	3	6.45	1.91
	Skill	3.17	8.0	1.17	9.17	5.25
	Technology Adoption	4.71	3.29	2.57	5.86	2.5
	Experience Consequence	9.25	2.37	7.63	10	1.99
pVR (n=5)	Immersion	2.2	6.8	1	7.8	4.2
	Presence	3.88	5.13	1	6.13	3.51
	Emotion	4.27	3.09	2.09	5.18	2.14
	Skill	4.33	4.33	1	5.33	3.16
	Technology Adoption	3.57	2.71	2.29	5	1.64
	Experience Consequence	8.63	5.25	4.75	10	3.5

Table 23. *Descriptive statistics for VEQ subscales for Mid-XRT (timepoint B).* aVR = active virtual reality; pVR = passive virtual reality; IQR = interquartile range

		Median	Range	Minimum	Maximum	IQR
aVR (n=5)	Immersion	2	1.6	1.4	3	1
	Presence	2.13	1.5	1.38	2.88	1.07
	Emotion	3	1.63	2.73	4.36	1
	Skill	2	3	1	4	1.92
	Technology Adoption	2.71	5.57	1	6.57	3.22
	Experience Consequence	9.13	1.5	8	9.5	1.32
pVR (n=5)	Immersion	2.8	6	1	7	3.7
	Presence	2.88	3.5	1	4.5	2.38
	Emotion	4.18	3.64	2.09	5.73	2.05
	Skill	3.67	5	1	6	3.34
	Technology Adoption	2.71	4	1.86	5.86	3.36
	Experience Consequence	8.25	4.12	5.13	9.25	2.5

Table 24. *Descriptive statistics for VEQ subscales for Post-XRT (timepoint C).* aVR = active virtual reality; pVR = passive virtual reality; IQR = interquartile range

		Median	Range	Minimum	Maximum	IQR
aVR (n=5)	Immersion	2	2.4	1.2	3.6	3
	Presence	2.07	1.13	1.75	2.88	1.89
	Emotion	3.55	3.18	2.82	6	1.54
	Skill	2.5	5.83	2	7.83	2.17
	Technology Adoption	2.36	3.14	2	5.14	2.71
	Experience Consequence	8.88	2	7.88	9.88	2.5
pVR (n=5)	Immersion	3.2	6.6	1	7.6	1
	Presence	3	4.5	1	5.5	1
	Emotion	4.27	4.54	1.82	6.36	1.82
	Skill	3	6.33	1	7.33	1
	Technology Adoption	3.57	4.86	1	5.86	1
	Experience Consequence	8.25	4	6	10	6

Figure 45. *Study three box and whisker plot of VEQ Emotion subscale score across timepoints.* Lower scores are desired. aVR = active virtual reality; pVR = passive virtual reality

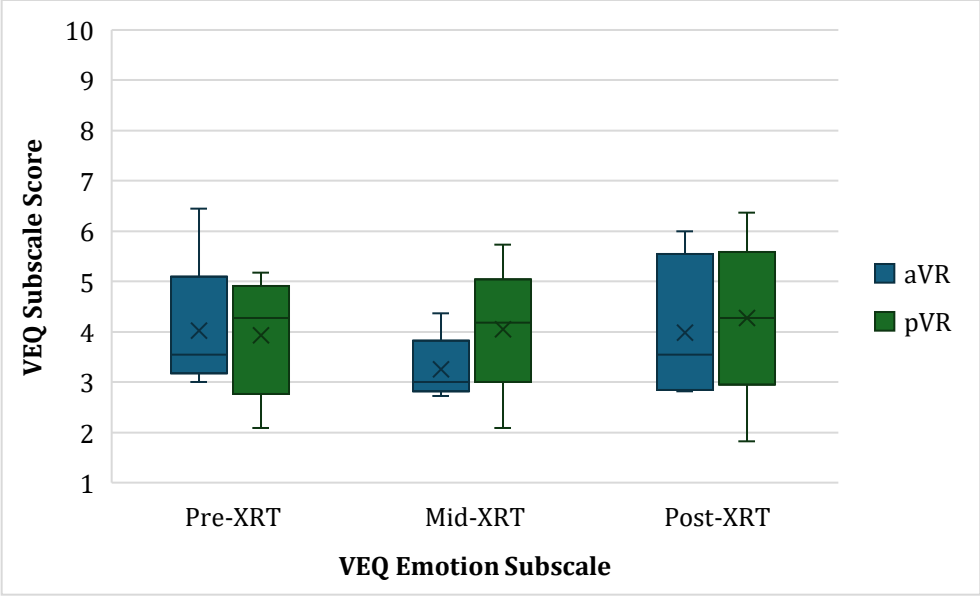
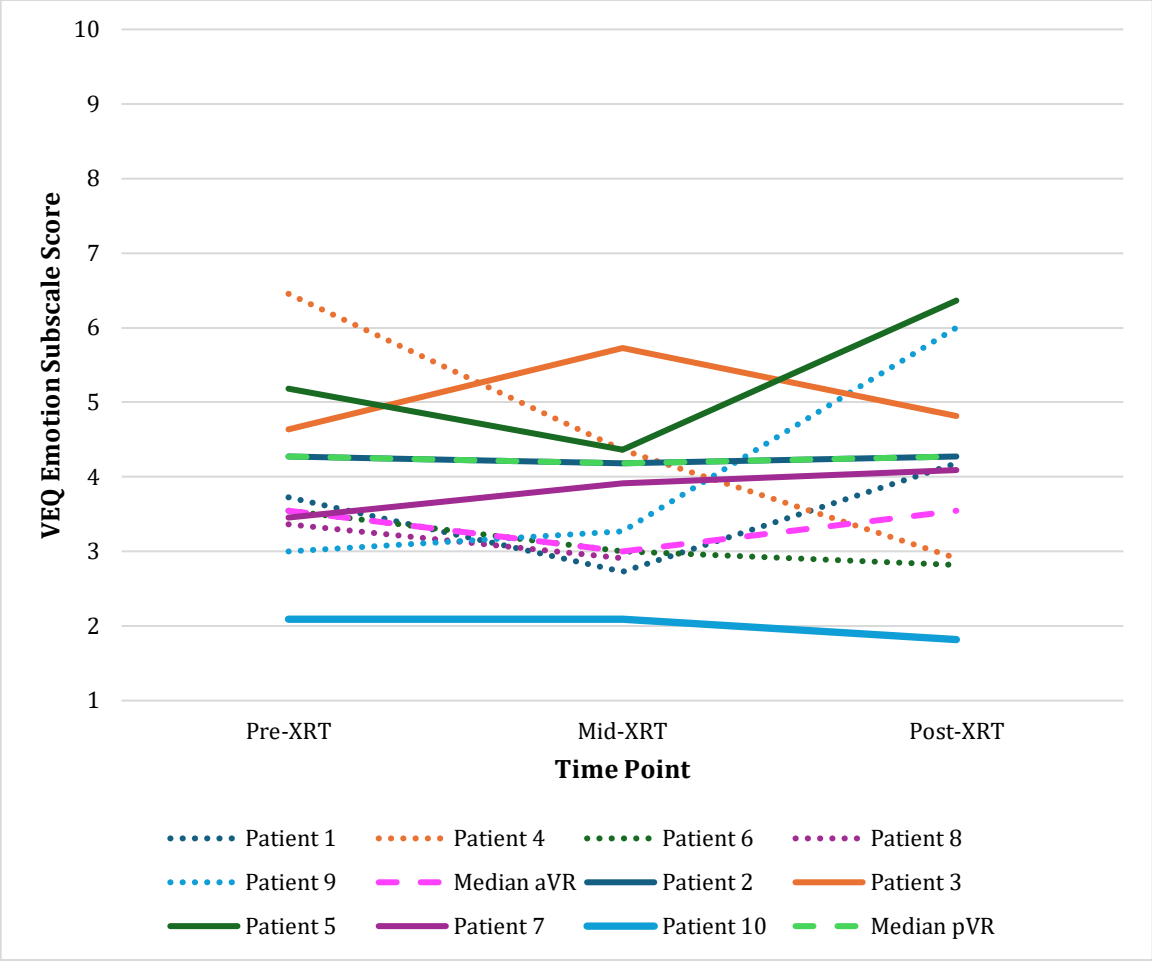


Figure 46. *VEQ Emotion subscale scores plotted over time.* Lower scores are desired. Dotted lines represent the aVR group and solid lines represent the pVR group. Dashed lines indicate group medians. aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment



4.3.2.2 Learnability of VR

In order to determine the *Learnability* of VR in individuals, the VEQ *Skill* subscale scores were analyzed. A Mann-Whitney U Test was performed to determine if any differences arose between groups at each of the three time points. Results revealed no significance between groups at any time point for *Skill* (A: U=12.5, n=10, p=1.000; B: U=6.5, n=10, p=.222; C: U=9.5, n=10, p=.905). When combined, patient scores indicated mid-high range of *Skill* with values in the lower portion of the scale (i.e., lower scores are desired). See

Figure 47 for the distribution of patient *Skill* scores between groups, as well as Figure 48 for scores plotted across the three time points. With no differences between groups across time points, a combined group was again used for the Friedman Test assessing differences across the time points. Results again revealed no differences ($\chi^2(2)=3.47$, $p=.177$). These results combined with those for satisfaction demonstrate overall high scores of usability across both VR groups.

Figure 47. *Study three box and whisker plot of VEQ Skill subscale score across timepoints.* Lower scores are desired. aVR = active virtual reality; pVR = passive virtual reality

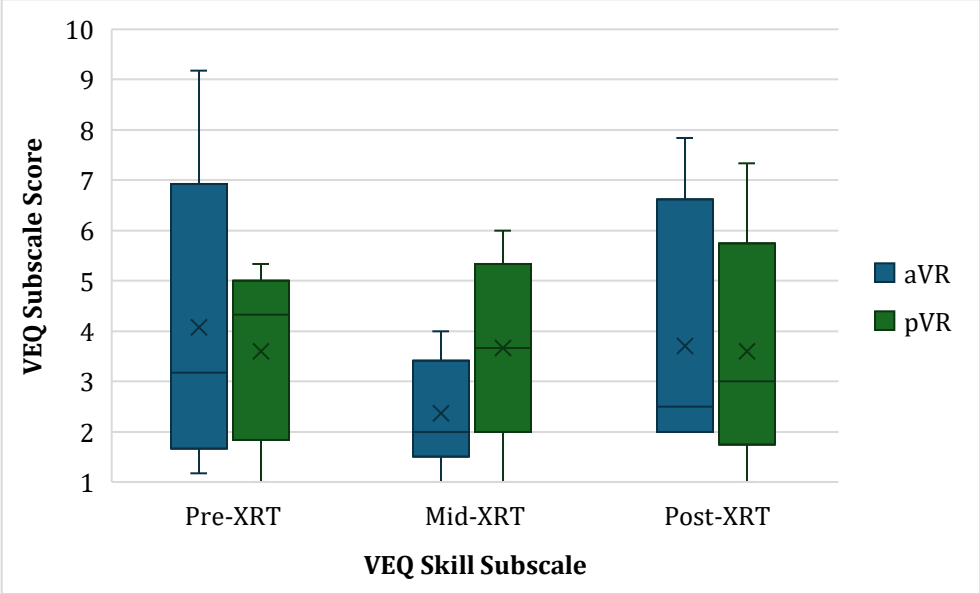
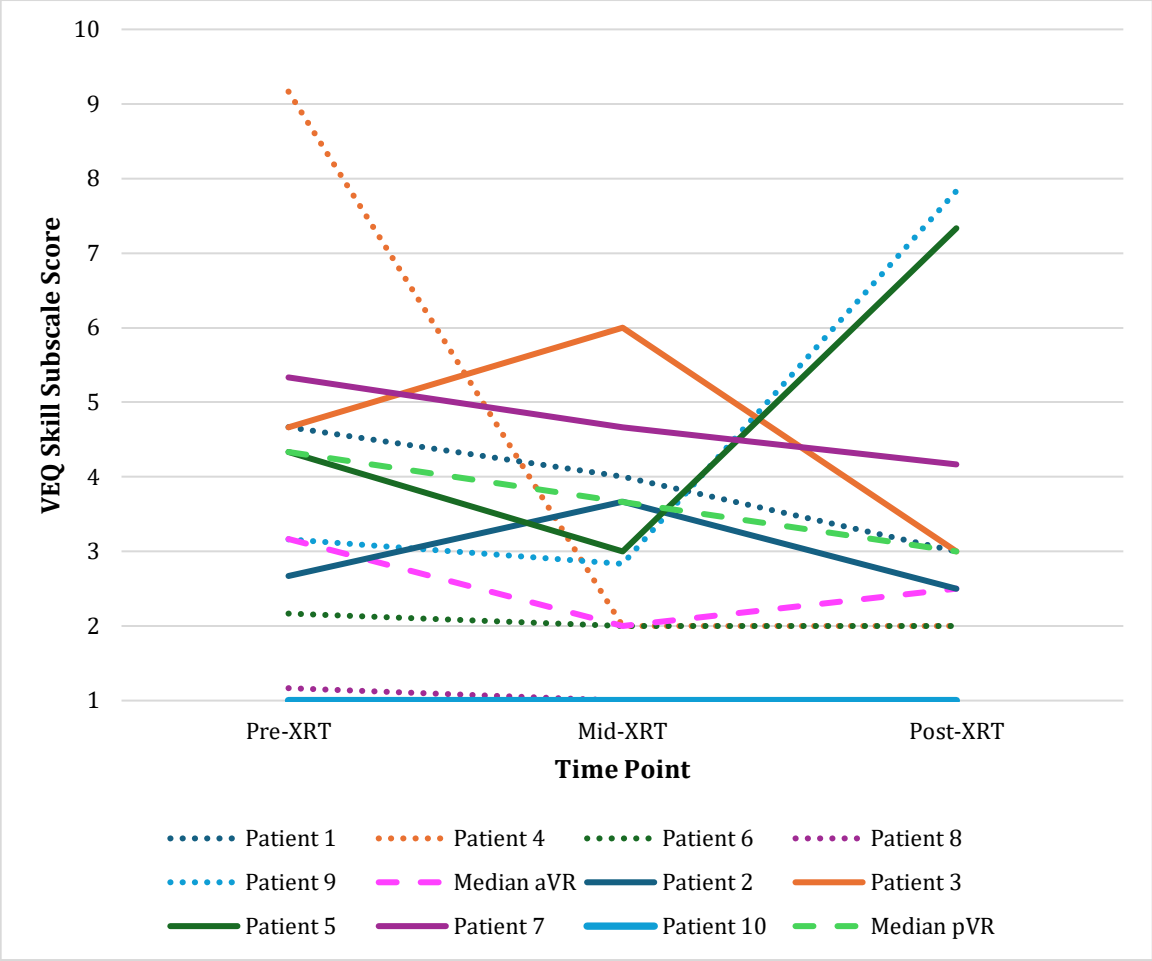


Figure 48. *VEQ Skill subscale scores plotted over time.* Lower scores are desired. Dotted lines represent the aVR group and solid lines represent the pVR group. Dashed lines indicate group medians. aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment



4.3.3 Acceptability of VR (RQ 3.2)

4.3.3.1 Engagement with VR

Similar to study two, the VEQ subscales of *Immersion* and *Presence* were used to measure VR *Engagement*. A Mann-Whitney U test was performed to determine whether *Immersion* differed between the two groups. Results revealed *Immersion* did not differ based on VR group membership at any of the three timepoints (A: U=11.0, n=10, p=.841; B:U=7.0, n=10, p=.310; C: U=7.0, n=10, p=.556). Likewise, there were no differences

between groups across the three timepoints for the *Presence* subscale (A: U=12.0, n=10, p=1.000; B:U=9.5, n=10, p=.548; C: U=5.0, n=10, p=.286). Looking at the sample as a whole, the two groups' ratings indicated a mid-high level of immersion (i.e., lower scores are desired and were selected) (Figure 49). Similarly, the combined groups reported mid-high levels of *Presence* (Figure 50). Given no differences in scores between groups at the three timepoints, a combined group was used for the Friedman Tests which were used to determine if there were changes in these subscales across the three timepoints. Results indicated no significant differences across time for *Immersion* ($\chi^2(2)$=.19 p=.908) or for *Presence* ($\chi^2(2)$=1.70, p=.417). Individual scores on the *Immersion* and *Presence* subscales are plotted across time in Figures 51 and 52, respectively.

Figure 49. *Study three box and whisker plot of VEQ subscale scores for Immersion across timepoints.* Lower scores are desired. aVR = active virtual reality; pVR = passive virtual reality

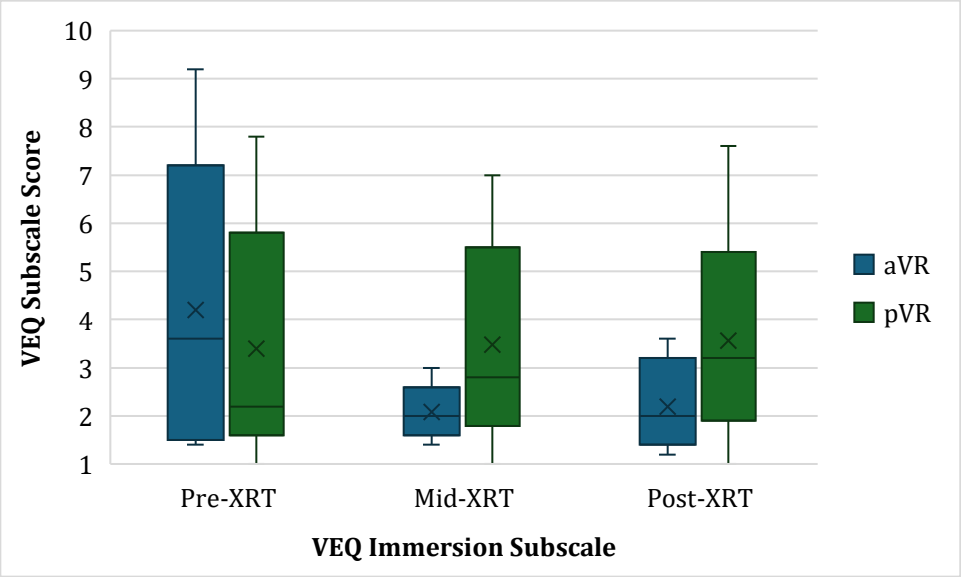


Figure 50. *Study three box and whisker plot of VEQ subscale scores for Presence across timepoints.* Lower scores are desired. aVR = active virtual reality; pVR = passive virtual reality

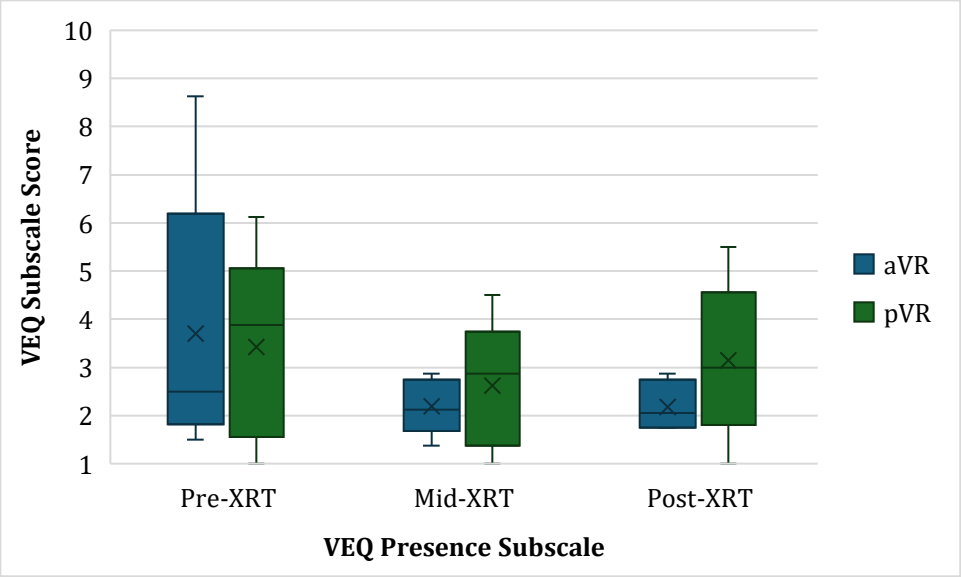


Figure 51. *VEQ Immersion subscale scores plotted over time.* Lower scores are desired. Dotted lines represent the aVR group and solid lines represent the pVR group. Dashed lines indicate group medians. aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment

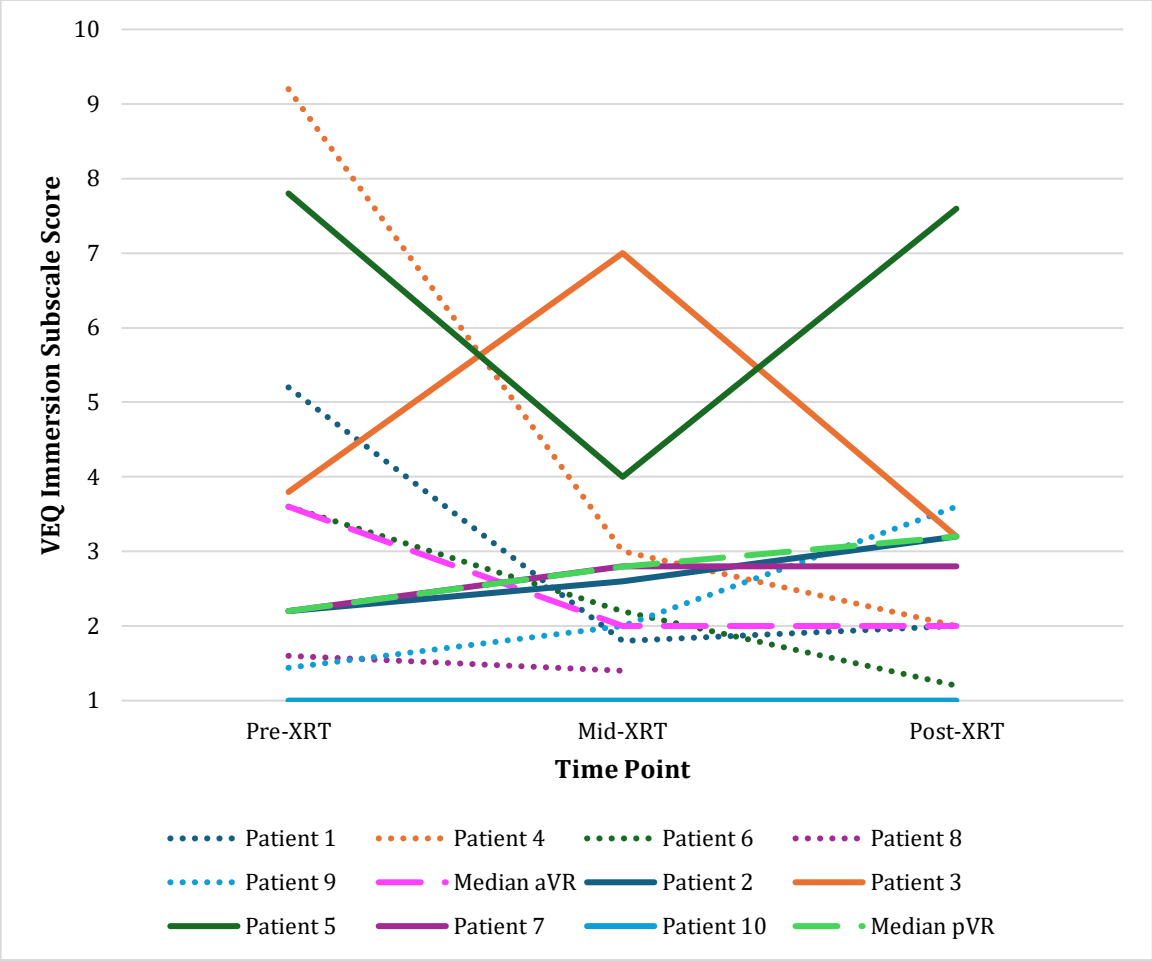
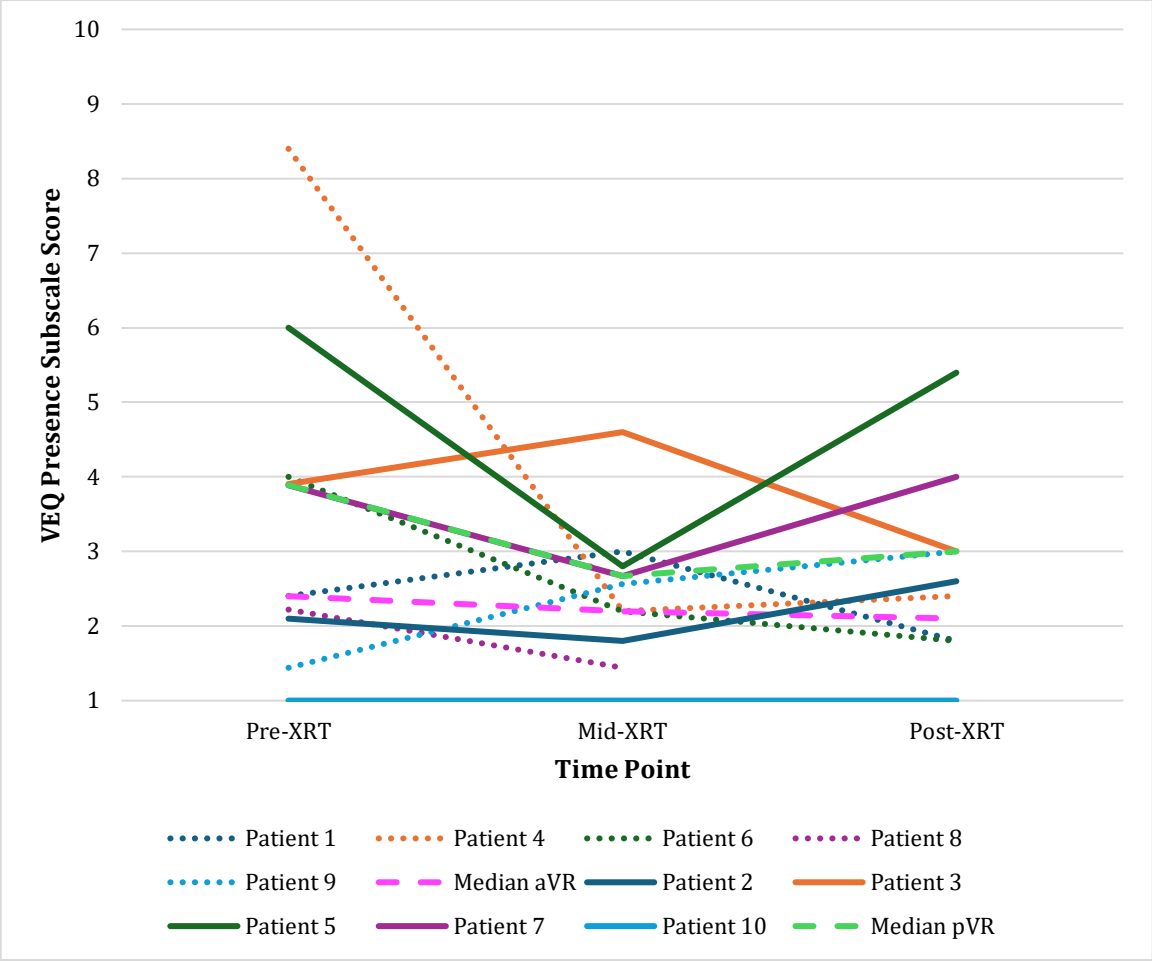


Figure 52. *VEQ Presence subscale scores plotted over time.* Lower scores are desired. Dotted lines represent the aVR group and solid lines represent the pVR group. Dashed lines indicate group medians. aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment



4.3.3.2 Adoption of VR

The VEQ *Technology Adoption* subscale was used as a measure of VR acceptability. To determine if differences occurred between aVR and pVR groups at the three time points, Mann-Whitney U Tests were completed. There were no differences between groups at any of the time points (A: U=9.0, n=10, p=.548; B: U=12.5, n=10, p=1.000; C: U=7.0, n=10, p=.556). When combining groups, scores revealed overall mid-high levels of *Technology Adoption*, (again, lower scores on the subscale indicate higher technology adoption; Figure

53). A Friedman Test (with aVR and pVR groups combined) revealed no differences in *Technology Adoption* across the three time points ($\chi^2(2)=.44$, $p=.804$). Figure 54 depicts patient scores over time.

Figure 53. *Study three box and whisker plot of VEQ Technology Adoption subscale score across timepoints.* Lower scores are desired. aVR = active virtual reality; pVR = passive virtual reality

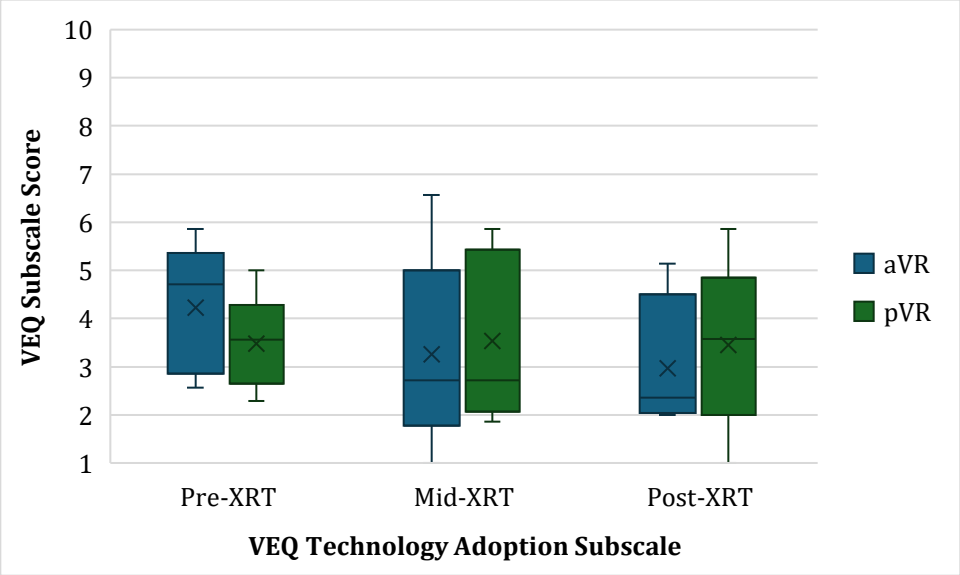
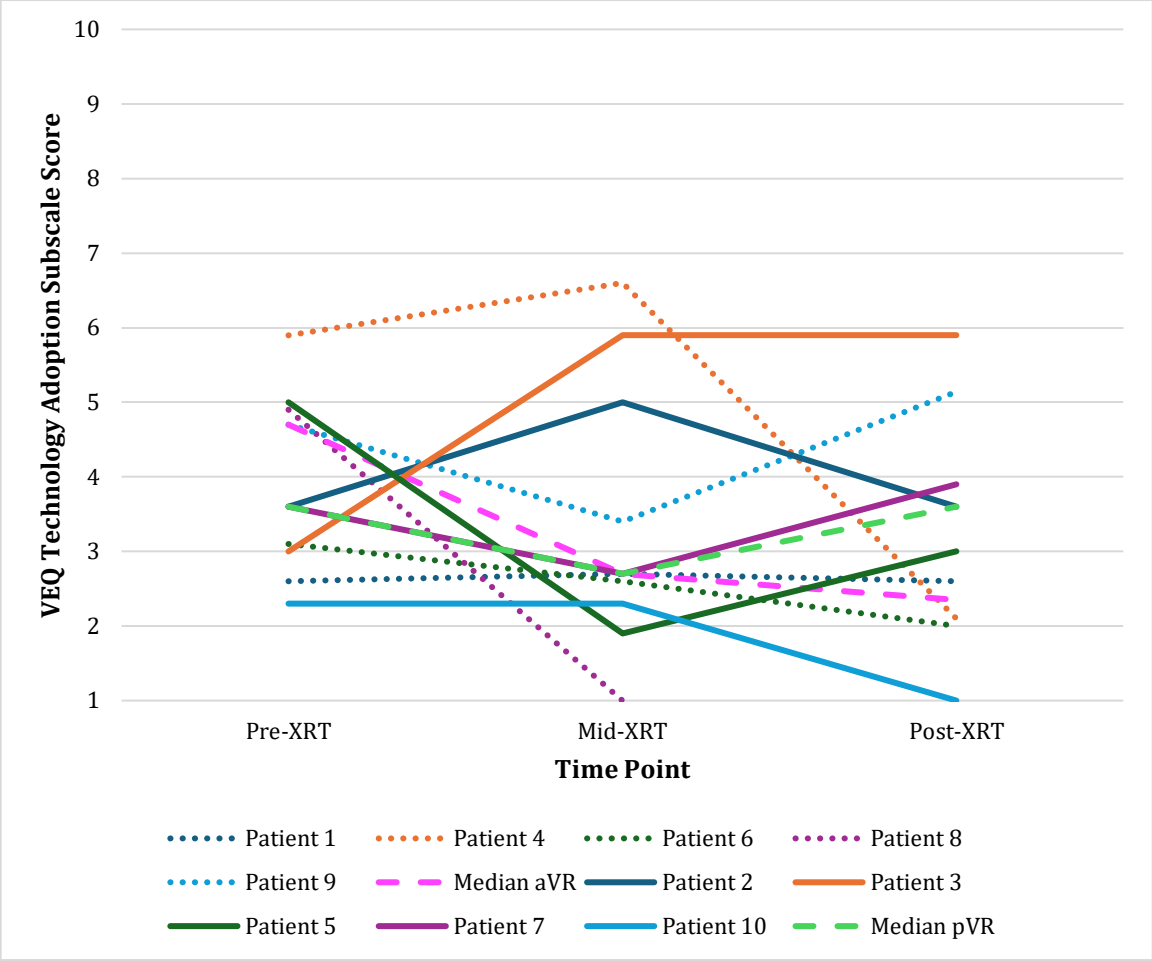


Figure 54. *VEQ Technology Adoption subscale scores plotted over time.* Lower scores are desired. Dotted lines represent the aVR group and solid lines represent the pVR group. Dashed lines indicate group medians. aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment



4.3.4 Negative Consequences of VR Use (RQ 3.3)

Two measures were used to determine the presence of negative side effects due to VR use, the VEQ *Experience Consequence* subscale and the within session change scores from pre- to post-VR nausea ratings (Numeric Rating Scale-Nausea [NRS-N]). A Mann-Whitney U Test was performed to determine differences across VR groups at each time point. Results indicated no significant differences in the *Experience Consequence* subscale scores (A: U=10.0, n=10, p=.597; B: U=7.5, n=10, p=.295; C: U=9.0, n=10, p=.806). Looking at the

scores of both groups, patients largely presented with minimal negative consequences, or low level of side effects as indicated by the high scores (i.e., high scores are desired for this particular subscale), see Figure 55. The combined group scores were used for the Friedman Test given that there were no differences between groups across the three timepoints. A Friedman Test was performed to assess changes over time in *Experience Consequence* scores and revealed no differences ($\chi^2(2)=1.12$ $p=.572$). The patient scores are plotted over time in Figure 56. Individual negative side effects assessed in the *Experience Consequence* subscale were further analyzed (Figure 57). Median values in both groups ranged from 7-10 indicating low levels of *Experience Consequence* (higher scores desired as it indicates lower occurrence of negative side effects). Of note, the "increased salivation" side effect had the most impact on patients in both the aVR and pVR groups. Following this, fatigue had the lowest median value for the aVR group and headache for the pVR group (same median value as increased salivation).

The NRS-N scores were collected from participants both pre- and post-VR use within a data collection session. Change scores were calculated and utilized for analysis. A Mann-Whitney U Test revealed no differences between aVR and pVR groups across the three time points (A: U=10.0, n=10, $p=.317$; B: U=10.0, n=10, $p=.317$; C: U=8.0, n=10, $p=.371$). A Friedman test was completed to look at changes over time. Again, these results were insignificant ($\chi^2(2)=1.00$ $p=.607$). This indicates that nausea rates stayed consistent in both groups across XRT. Of note, 7 of 10 participants never reported having nausea at any of the data collection times. The three who did report nausea included 2 in the aVR and 1 in the pVR group; in all three cases, the NRS-N decreased from pre- to post-VR with changes from 2 to 1, 8 to 0 (i.e., clinically meaningful change), and 3 to 0 (i.e., clinically meaningful

change). Overall, results thus demonstrate that both groups maintained similar levels of usability, acceptability, and negative side effects throughout radiation treatments.

Figure 55. *Study three box and whisker plot of VEQ Experience Consequence subscale score across timepoints.* Higher scores are desired. aVR = active virtual reality; pVR = passive virtual reality

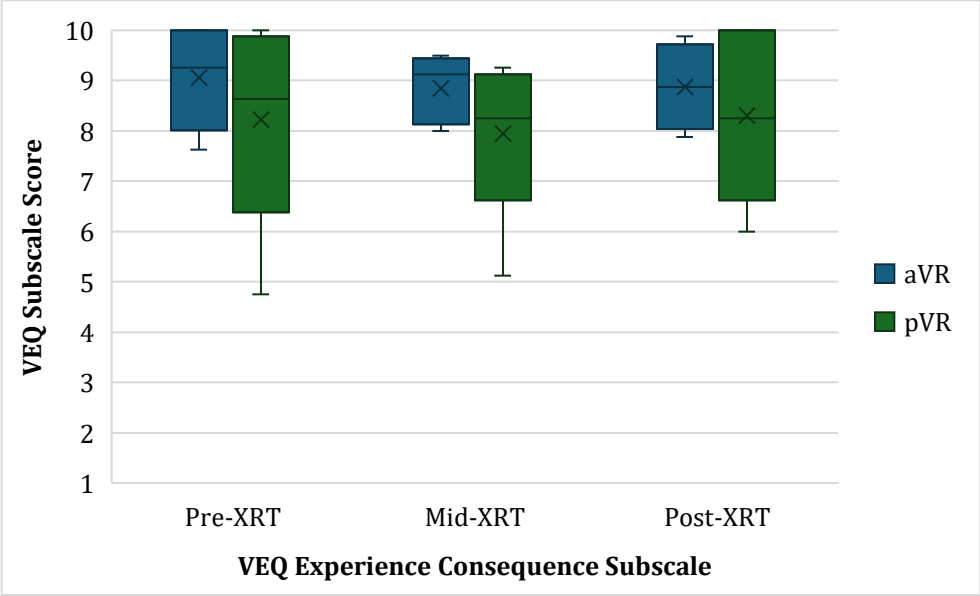


Figure 56. *VEQ Experience Consequence subscale scores plotted over time.* Higher scores are desired. Dotted lines represent the aVR group and solid lines represent the pVR group. Dashed lines indicate group medians. aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment

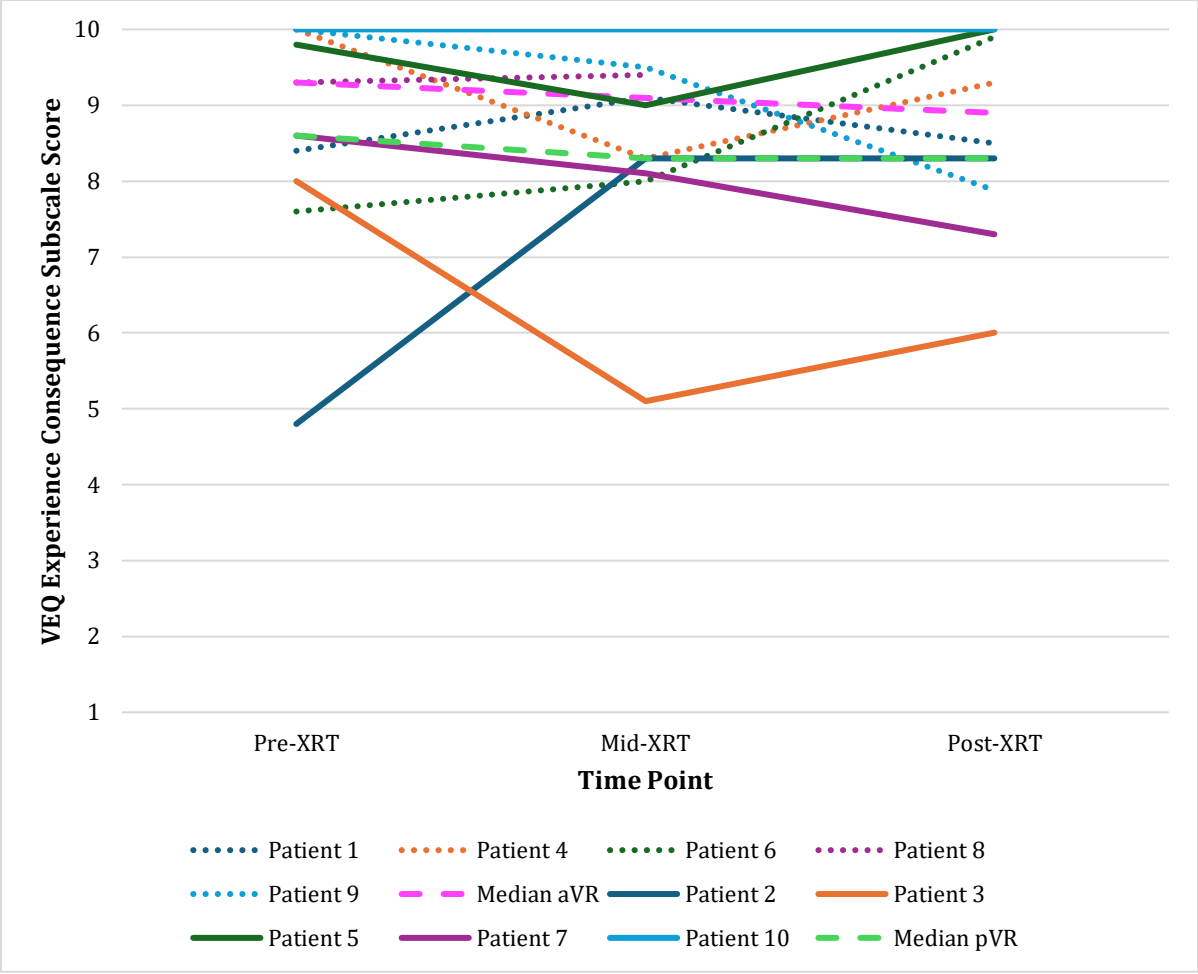
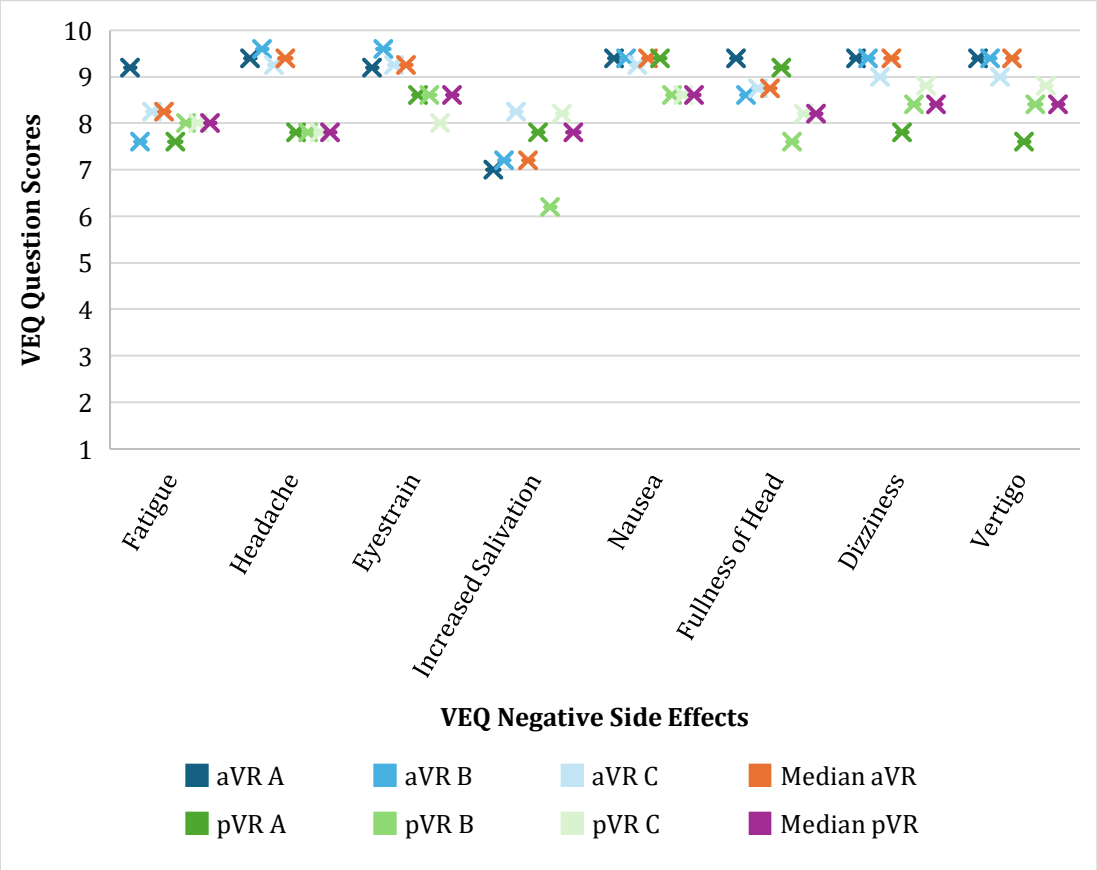


Figure 57. *Scatter plot of averages of specific negative side effects from VEQ Experience Consequence subscale.* Higher scores are desired. Blue represents the aVR group over the three timepoints (A, B, and C). Green represents the pVR group. aVR = active virtual reality; pVR = passive virtual reality



4.3.5 VR User Experience: Head & Neck Cancer versus Non-Head & Neck Cancer (RQ3.4)

Comparative analyses between the HNC patients (timepoint A) and a subgroup of age and gender matched controls from experiment two were also conducted. A Mann-Whitney U Test was performed with each of the VEQ subscales to determine differences between the groups (i.e., control and HNC). Results were insignificant across all subscales indicating there were no differences between the control group and the patients with HNC (*Emotion*; U=41.0, n=20, *p*=.496; *Skill*: U=45.5, n=20, *p*=.733; *Immersion*: U=40.0, n=20, *p*=.477; *Presence*: U=48.0, n=20, *p*=.880; *Technology Adoption*: U=31.5, n=20, *p*=.162;

Experience Consequence: U=41.5, n=20, *p*=.529). Distribution of the group differences across the VEQ subscales are displayed in Figures 58-63. These are further broken down by VR experience in Appendix L.

Figure 58. *Box and whisker plot of VEQ Emotion subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

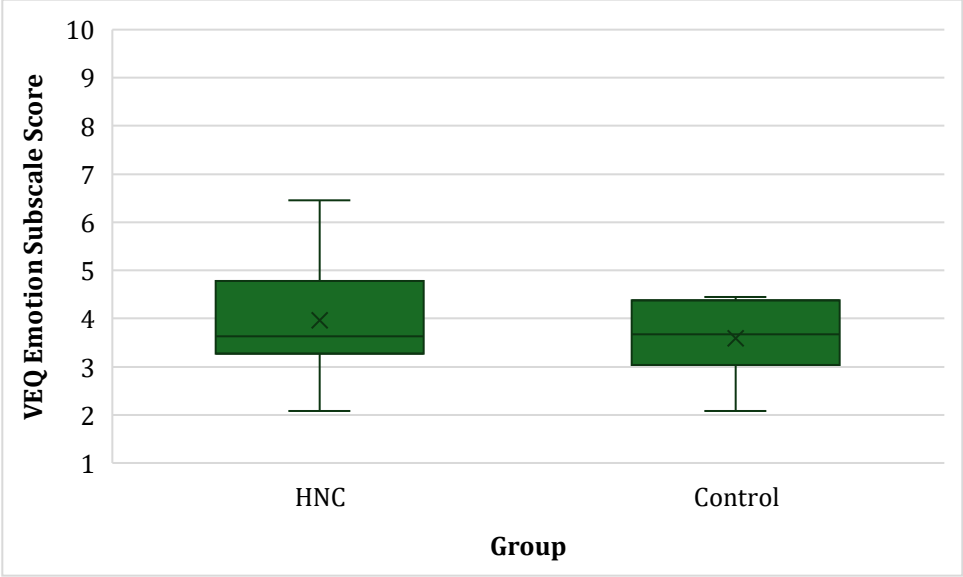


Figure 59. *Box and whisker plot of VEQ Skill subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

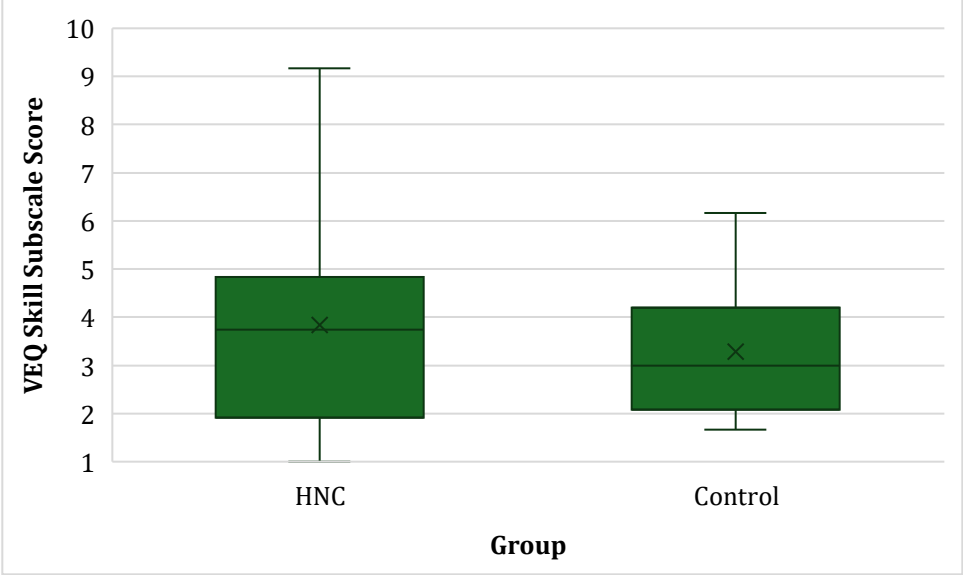


Figure 60. *Box and whisker plot of VEQ Immersion subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

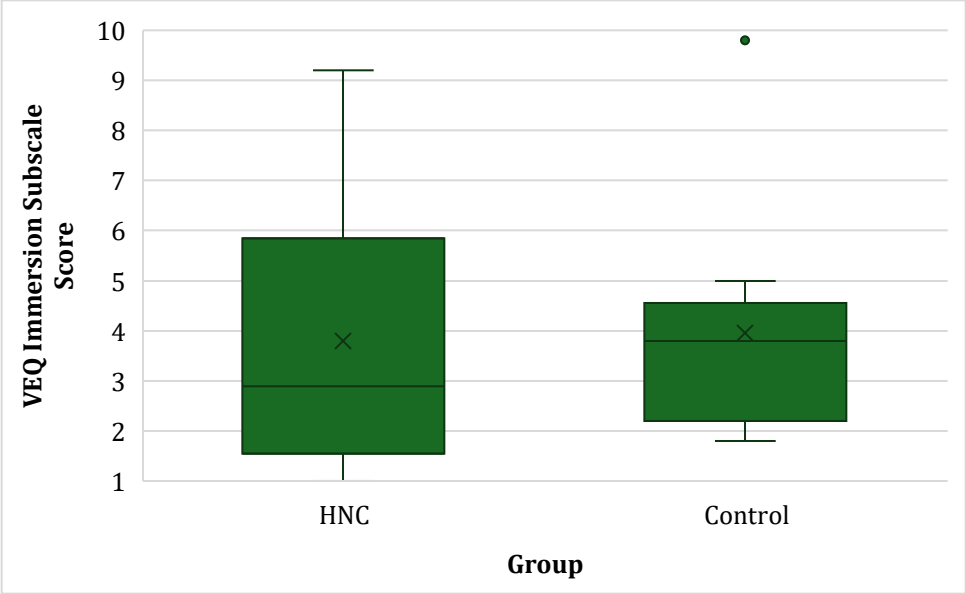


Figure 61. *Box and whisker plot of VEQ Presence subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

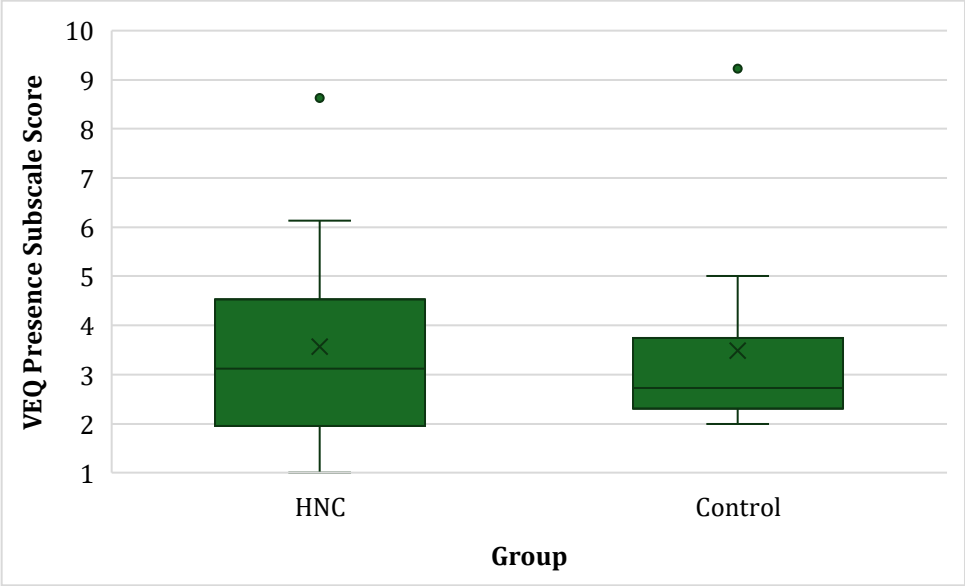


Figure 62. *Box and whisker plot of VEQ Technology Adoption subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

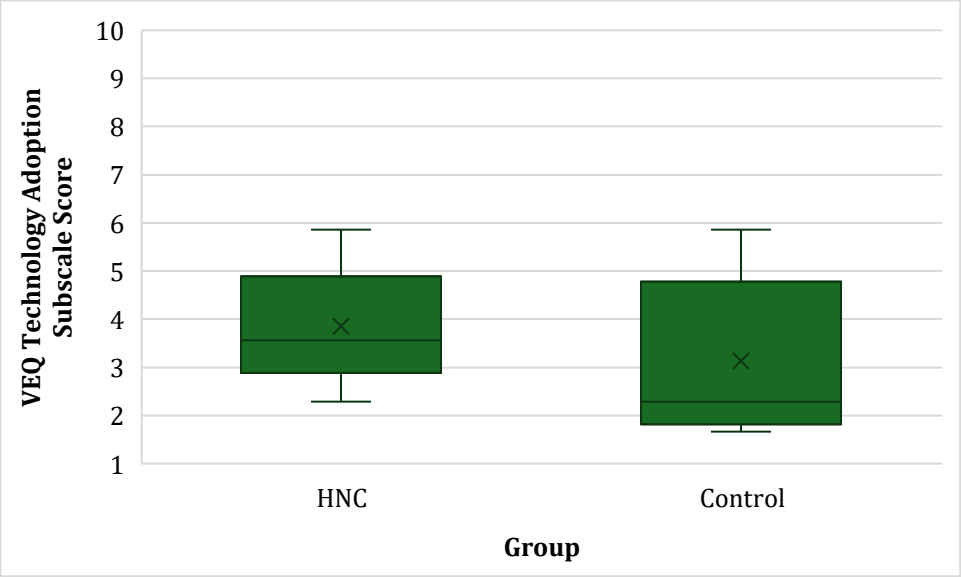
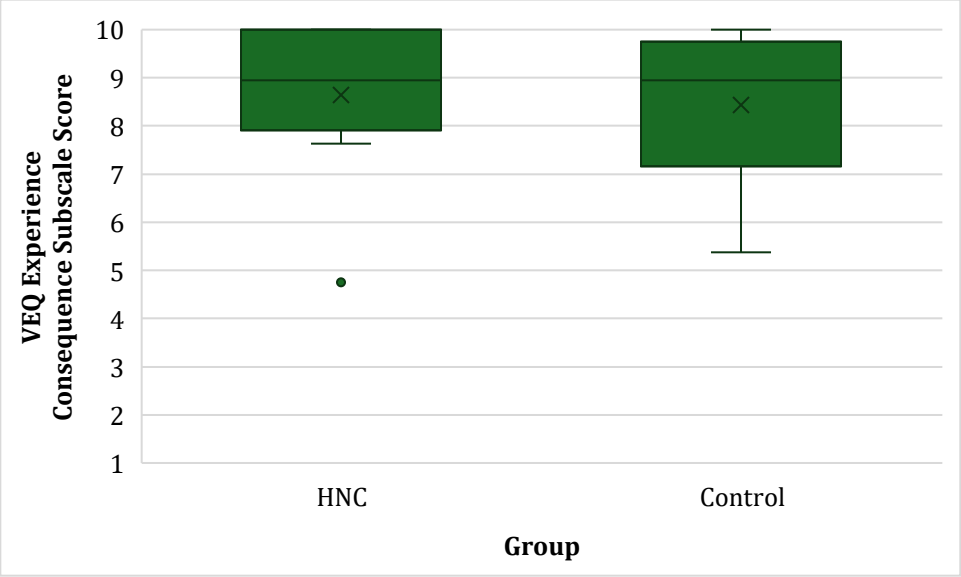


Figure 63. *Box and whisker plot of VEQ Experience consequence subscale scores based on group.* Higher scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality



4.3.6 Impact of VR on Swallowing-related Pain in Head & Neck Cancer Patients (RQ 3.5)

Similar to the NRS-N, patients provided pre- and post-VR levels of swallowing-related pain at each timepoint via a Numeric Pain Rating-Swallowing scale (NPR-S). Change scores for a given timepoint were calculated and utilized for analysis. A series of three Mann-Whitney U Tests was completed to determine whether there were differences in NPR-S change scores between the aVR and the pVR groups. There was a statistically significant difference at Post-XRT (U=2.0, n=10, p=.030). The pVR group had a greater change in scores (Table 25). There was no difference between aVR and pVR change scores in the NPR-S at Pre-XRT (A: U=10.0, n=10, p=.317). At Mid-XRT, the difference in change scores approached significance (B: U=4.0, n=10, p=.054) and in this case, there was greater reduction in swallowing-related pain in the aVR group.

Pre-VR, post-VR, and change scores for the NPR-S are provided in Table 25. A pain change of +/- 2 points is generally considered clinically significant (Mao et al., 2022). Several patterns are noted in the NPR-S ratings. As anticipated, the percentage of participants who had pre-VR pain at each timepoint increased in the Pre-, Mid-, and Post-XRT periods from 40% to 70% to 80%, respectively. There was a total of 29 pre-VR ratings (patient 8 declined participation in Post-XRT) and 19 of these ratings (66%) had some level of pain prior to the VR experience. Of these, 10 (52%) registered a reduction in pain immediately after their VR session, and among these, 7 (70%) had a clinically meaningful reduction in swallowing-related pain.

In the Pre-XRT phase, three of the four patients with pain >0 were in the pVR group (ratings of 2, 2, 10) and one was in aVR group (rating of 6). One participant who was in the pVR group registered a 1-point reduction in swallow-related pain right after the VR

session. At Mid-XRT, among the seven patients with pain >0, five (71%) registered a swallowing-related pain reduction and all were clinically meaningful changes (ranging from 2-4, median = 2). At Post-XRT, eight of nine patients (89%) had baseline pain >0. Of these eight, four (50%) registered a swallowing pain reduction (range 1-2, median=1.5) with two of them reaching the threshold of a clinically meaningful change; all were from the pVR group. Of note, one participant in the pVR group reported swallowing pain being at a level 10, and they did so for all three pre-VR time points. Descriptive statistics for NPR-S are provided in Table 26. See Figure 64 for swallowing-related pain levels plotted over time.

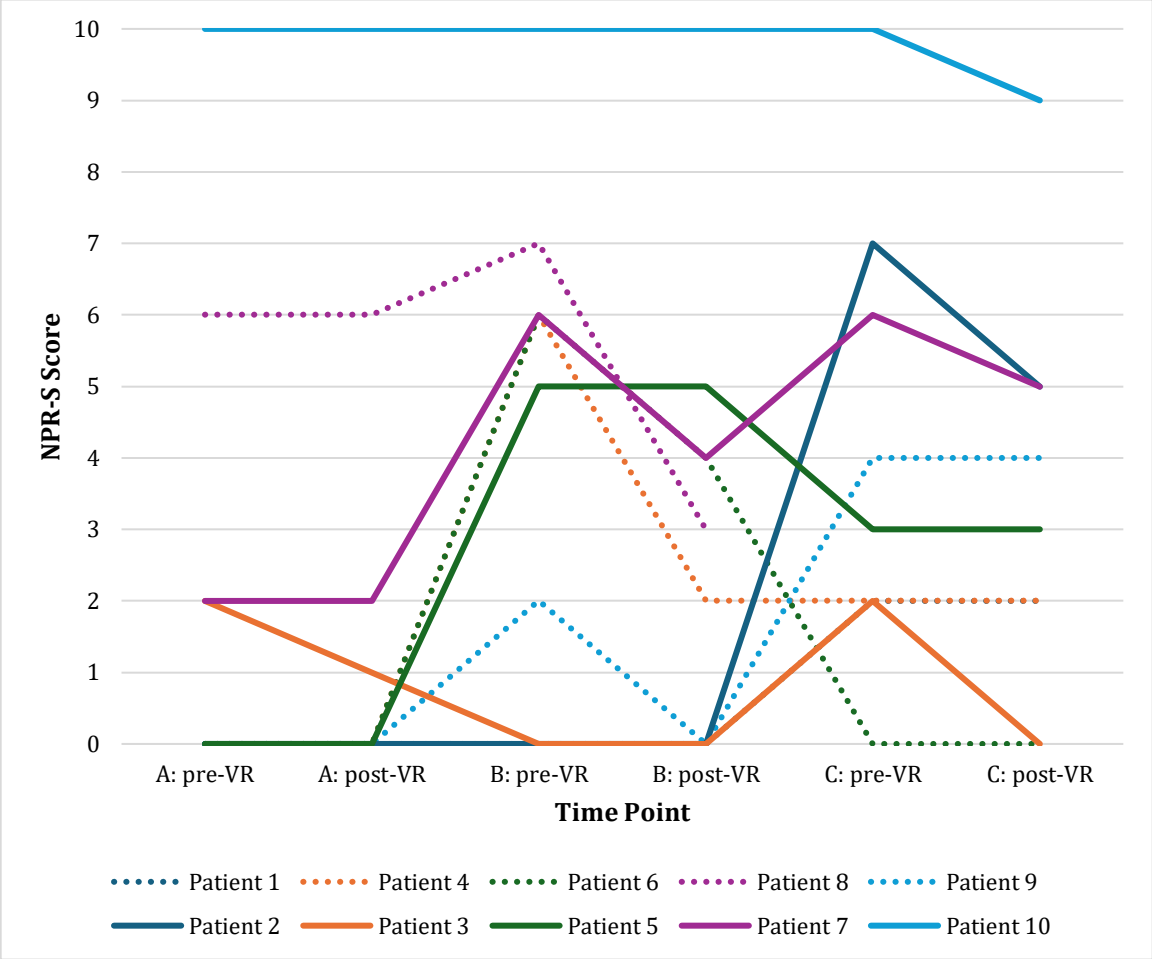
Table 25. *Patient reported NPR-S pain levels across timepoints.* Yellow highlighting indicates a change occurred from pre- to post-VR. Grey indicates that there was no change in pain level meaning pain persisted after VR. Bold and italicized indicates a clinically meaningful change in scores (2 or more). aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment; IQR = interquartile range; X = missing data for this session

		Pre-XRT (A)			**Mid-XRT (B)**			**Post-XRT (C)**		
	Patient	T1 (Pre)	T1 (Post)	T1 (Change)	T2 (Pre)	T2 (Post)	T2 (Change)	T3 (Pre)	T3 (Post)	T3 (Change)
aVR	1	0	0	0	0	0	0	2	2	0
	4	0	0	0	6	2	***4***	2	2	0
	6	0	0	0	6	4	***2***	0	0	0
	8	6	6	0	7	3	***4***	X		
	9	0	0	0	2	0	***2***	4	4	0
pVR	2	0	0	0	0	0	0	7	5	***2***
	3	2	1	1	0	0	0	2	0	***2***
	5	0	0	0	5	5	0	3	3	0
	7	2	2	0	6	4	***2***	6	5	1
	10	10	10	0	10	10	0	10	9	1
				*All in pVR			*All clinically meaningful			*All in pVR

Table 26. *Descriptive statistics for NPR-S scores.* aVR = active virtual reality; pVR = passive virtual reality; IQR = interquartile range

	Time Point		Median	Mean	Range	Minimum	Maximum	IQR
aVR (n=5)	A	Pre-VR	0	1.2	6	0	6	0
		Post-VR	0	1.2	6	0	6	0
	B	Pre-VR	6	4.2	7	0	7	4
		Post-VR	2	1.8	4	0	4	3
	C	Pre-VR	2	2	4	0	4	1
		Post-VR	2	2	4	0	4	1
pVR (n=5)	A	Pre-VR	2	2.8	10	0	10	2
		Post-VR	1	2.6	1	0	1	2
	B	Pre-VR	5	4.2	10	0	10	6
		Post-VR	4	3.8	2	0	2	5
	C	Pre-VR	6	5.6	9	0	9	4
		Post-VR	5	4.4	2	0	2	2

Figure 64. *Swallowing-related pain scores plotted over time*. Dotted lines represent the aVR group and solid lines represent the pVR group. Time points A, B, and C correspond to Pre-XRT, Mid-XRT, and Post-XRT respectively. aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment



4.3.7 Secondary Analysis

In addition to the primary research questions for this feasibility study, a secondary research question was explored specifically looking at the impact of VR on general pain levels. This analysis was done in parallel to the swallowing-related pain, i.e., within session pre- and post-VR pain ratings (Numeric Pain Rating-General [NPR-G]. Change scores were calculated and used for analysis. Three Mann-Whitney U Tests, one per timepoint, were applied to assess differences in general pain between the aVR and the pVR groups. None of

these tests were statistically significant (A: U=2.5, n=10, *p*=.180; B: U=12.5, n=10, *p*=1.000; C: U=8.0, n=10, *p*=.606).

All NPR-G pre- and post-VR scores as well as the change scores are in Table 27. Of the 29 total sessions (10 Pre-, 10 Mid-, and 9 Post-XRT), 19 (66%) had pre-VR exposure general pain >0. Among these, 15 (79%) had reductions, 3 (16%) had no change, and 1 (5%) had a 1-point increase in general pain after the VR experience. Additionally, one other participant who had 0 pain at baseline reported a 1-point increase post-VR. Among the 15 who reported pain reduction post-VR, 8 (53%) had clinically meaningful change (ranging from 2-8, median = 2). In pre-XRT, four patients had reductions, and all were in the pVR group; two of these reductions (50%) were clinically meaningful. At Mid-XRT, three of six changes in pain were considered clinically meaningful (2 in aVR and 1 in pVR). There were two participants at this timepoint that had a 1-point increase in NPR-G rating. In the final session, 80% of the pVR had a reduction in NPR-G with 50% of those changes being clinically meaningful. The aVR group had 75% of patients with reduced levels or general pain (1 of 3 was a clinically meaningful change).

In general, there was overlap between participants who reported swallowing-related pain and those reporting general pain, although this was not exact. Additionally, the magnitude of the pain ratings and the changes in these ratings frequently differed within the same participant. Of note, is patient 10 in the pVR group who had an 8 point reduction in general pain at the mid-XRT phase and a clinically meaningful 3-point reduction at post-XRT but did not have a parallel decrease in swallowing-related pain. Descriptive statistics for the NPR-G scores are in Table 28. See Figure 65 for general pain levels plotted over time.

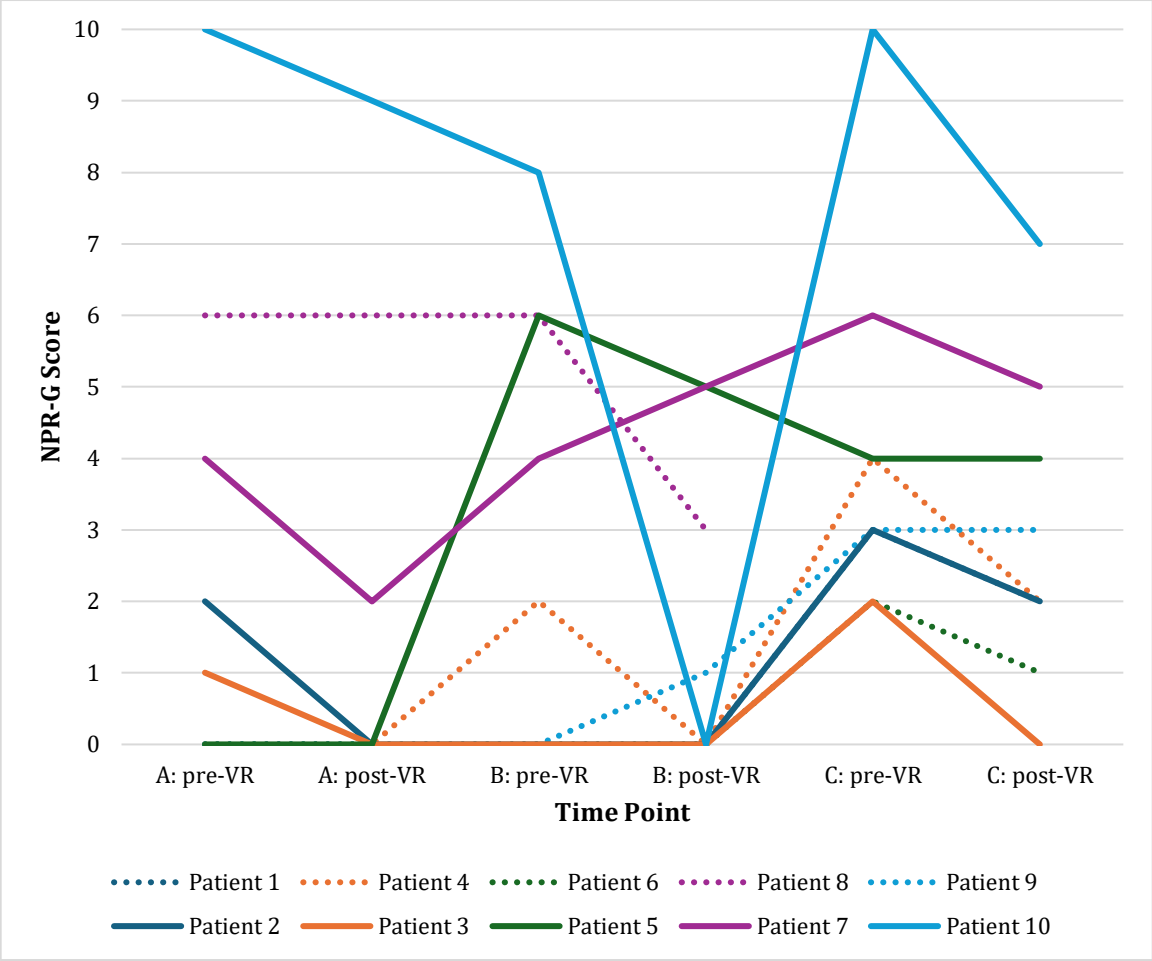
Table 27. *Patient-reported NPR-G pain levels across timepoints.* Yellow highlighting indicates a change occurred from pre- to post-VR. Grey indicates that there was no change in pain level meaning pain persisted after VR. Bold and italicized indicates a clinically meaningful change in scores (2 or more). aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment

	Patient	Pre-XRT (A)			Mid-XRT (B)			Post-XRT (C)		
		T1 (Pre)	T1 (Post)	T1 (Change)	T2 (Pre)	T2 (Post)	T2 (Change)	T3 (Pre)	T3 (Post)	T3 (Change)
aVR	1	0	0	0	0	0	0	3	2	1
	4	0	0	0	2	0	***2***	4	2	***2***
	6	0	0	0	0	0	0	2	1	1
	8	6	6	0	6	3	***3***	X		
	9	0	0	0	0	1	-1	*3*	*3*	0
pVR	2	2	0	***2***	0	0	0	3	2	1
	3	1	0	1	0	0	0	2	0	***2***
	5	0	0	0	6	5	1	*4*	*4*	0
	7	4	2	***2***	4	5	-1	6	5	1
	10	10	9	1	8	0	***8***	10	7	***3***
				* all in pVR						

Table 28. *Descriptive statistics for NPR-G scores.* aVR = active virtual reality; pVR = passive virtual reality; IQR = interquartile range

	Time Point		Median	Mean	Range	Minimum	Maximum	IQR
aVR (n=5)	A	Pre-VR	0	1.2	6	0	6	0
		Post-VR	0	1.2	6	0	6	0
	B	Pre-VR	0	1.6	6	0	6	2
		Post-VR	0	0.8	3	0	3	1
	C	Pre-VR	3	3	2	2	4	0.5
		Post-VR	2	2	2	1	3	0.5
pVR (n=5)	A	Pre-VR	2	3.4	10	0	10	3
		Post-VR	0	2.2	9	0	9	2
	B	Pre-VR	4	3.6	8	0	8	6
		Post-VR	0	2	5	0	5	5
	C	Pre-VR	4	5	8	2	10	3
		Post-VR	4	3.6	7	0	7	3

Figure 65. *General pain scores plotted over time*. Dotted lines represent the aVR group and solid lines represent the pVR group. Time points A, B, and C correspond to Pre-XRT, Mid-XRT, and Post-XRT respectively. aVR = active virtual reality; pVR = passive virtual reality; XRT = radiation treatment



4.3.8 Use of Surface Electromyography

Collection of sEMG was planned as a secondary measure in Study 3 to evaluate potential changes in pre- and post-VR sEMG swallow amplitudes and swallow counts. This was attempted with all patients, however, there were multiple issues that precluded use of this data. The issues included difficulty adhering the device to skin due to facial hair (i.e., patients are unable to shave during XRT), oily skin surface (i.e., on the recommendation of care providers, patients frequently use Aquaphor® ointment to combat skin side effects

from XRT), and reduced skin integrity (i.e., breakdown, open wounds). There also appeared to be some problems with the sEMG signal detection that may have been due to tissue issues such as edema and developing fibrosis. Because there was significant missing data, no analysis was attempted. Anecdotally, a few patients for whom sEMG could be collected expressed enthusiasm and motivation to use the device as a biofeedback tool although it was not implemented as such in this study.

CHAPTER 5. DISCUSSION

Three studies were completed that provide foundational information addressing the use of VR in dysphagia therapy with HNC patients undergoing XRT. Study one provides important knowledge about SLP's perceptions about pain and PM as it relates to their education and training, current clinical practices, and the impact pain has on patients. These results are important for understanding how SLPs currently are involved in PM and their openness to using a novel non-medical and non-pharmacological approach such as VR. Study two was a prospective cohort study that evaluated the UX of adults without HNC in VR. This study was important for two reasons. First, there is a paucity of information about UX in adults, particularly those matching the typical age range of HNC patients. VR has the potential to cause negative consequences such as dizziness, nausea, and eyestrain, among others. Because HNC patients undergoing XRT +/- chemotherapy may experience similar side effects from their cancer treatment, it was important to assess the extent to which the planned VR intervention is tolerated by individuals without HNC. Study two allowed insight into usability, acceptability and occurrence of negative side effects in a non-HNC group. The second reason for study two was to gather data from a non-HNC group so that comparison of UX with the patients in study three could be completed. Study three recruited patients with HNC for an early phase interventional study to assess feasibility of VR use during XRT with a specific focus on UX and possible negative side effects. The results of this study are important to inform design of larger scale trials of VR during dysphagia therapy in HNC patients undergoing XRT. Study three also gathered preliminary data on the impact of VR on the patient's perception of pain. Across studies two and three, participants were divided into two groups with one being active VR (more physical and

cognitive engagement required) and the other passive VR (limited physical and cognitive engagement required) to gather preliminary data about whether type of VR influences UX.

The main findings from these studies are the following. First, SLPs have limited education and training in pain and PM despite having caseloads that are impacted by patient reported pain, but are willing to implement novel PM techniques. Second, adults without HNC have positive UX in VR with minimal side effects in both active and passive environments. Lastly, UX of VR in individuals with HNC is positive with limited presence of side effects. This was consistent across the active and passive VR experiences and over the course of XRT. Virtual reality use resulted in clinically meaningful pain reduction for several HNC patients. These findings are discussed in more detail below.

5.1 Speech-Language Pathologists' Perceptions about Pain and Pain Management

The perception of pain is highly subjective with factors such as prior experiences, beliefs, and individual coping styles having potential to moderate or amplify an individual's pain level, making subsequent pain management challenging (Zoffness, 2022). Pain has been studied extensively in the medical and psychology literature, however in the field of speech-language pathology such studies are scarce. Within dysphagia research specifically, pain has been studied as it relates to adherence to dysphagia therapy where it has been identified as a barrier for HNC patients during XRT (Shinn et al., 2013; Starmer et al., 2023; Zhu et al., 2022). Overall, there is not a general understanding of how PM strategies are integrated into SLP clinical work.

Findings from study one begin to address this gap in the literature. Before discussing the findings, it is important to note that survey respondents largely reflected the demographics of the SLP profession in terms of age, gender distribution and self-identified

race and ethnicity (ASHA, 2024). Most respondents reported practicing in settings where patient reported pain might be expected such as a hospital or an outpatient clinic. A broad recruitment strategy was employed that did not specifically target SLPs in only medical settings. However, it may be that some SLPs self-selected out of completing the survey because they might have less experience with individuals who have pain.

5.1.1 Education and Training

The hypothesis that SLPs will report having limited education and training on pain and PM was supported. Approximately 75% of respondents indicated they had inadequate education/training. Less than ten individuals reported having training on pain or PM in their undergraduate or graduate studies. This is not surprising as there are no explicit requirements for instruction in either pain or PM for programs to receive academic accreditation (Council on Academic Accreditation in Audiology and Speech-Language Pathology [CAA], 2019) or for individuals to obtain clinical certification (Council for Clinical Certification in Audiology and Speech-Language Pathology [CFCC], 2020). These findings are consistent with other therapeutic discipline programs such as physical therapy (PT) and occupational therapy (OT) as currently in the United States (US) neither are required to provide formal training on pain or PM (Accreditation Council for Occupational Therapy Education, n.d.; Commission on Accreditation in Physical Therapy Education, n.d.).

Globally, however there are differing trends for the fields of PT, OT, and SLP. The only countries requiring pain to be formally integrated within curriculum are the United Kingdom (PT only) (Health and Care Professions Council, 2017) and Australia (PT and OT) (Australian Occupational Therapy Association, 2020; Australian Physiotherapy Association, n.d.). Other countries such as Canada and New Zealand are similar to the US in that they

place “emphasis” on the importance of pain education, but do not formally incorporate it within their curricula (New Zealand Speech-language Therapists’ Association, n.d.; Speech-Language & Audiology Canada, 2019). Overall, these findings are intriguing as there have been multiple interdisciplinary pushes for standardized pain curriculum due to both health care provider interest in obtaining further training in PM, and the uncertainty of pain education amongst fellow members of the interdisciplinary team (McKinnon et al., 2020; Norton et al., 2025). Some groups have even established formal core competencies and models to help guide health professional programs with implementation of pain education (Fishman et al., 2013; Watt-Watson et al., 2004; Watt-Watson et al., 2017).

Although the SLP survey data indicate a perception that training about pain and PM is inadequate, most indicated they received some training. The majority reported receiving informal rather than formal education and training. On the job opportunities such as a journal club or discussion with colleagues were noted. Some participants referenced “medical grand rounds” or “self-educate by reading books.” Others cited personal experiences (e.g. “husband has a SCI” or “personal chronic pain problems”) as a source of experience/training regarding pain and PM. A large majority reported a combination of informal opportunities. Formal education/training was also reported with continuing education (CE) courses being the primary mechanism. This took various forms ranging from a single lecture to entire, multi-day conferences and training programs. A few respondents reported that they completed CE training in pain and PM for licensure requirements. Currently, Michigan (MI) is the only state that requires pain and/or symptom management continuing education for SLP license renewal every two years (Michigan Department of Licensing and Regulatory Affairs, n.d.-c). Similarly, MI is also the

only state that requires pain management CE for PT licensure renewal (Michigan Department of Licensing and Regulatory Affairs, n.d.-b). Occupational therapists, however, are required to obtain CE in pain in both Michigan and Oregon (Michigan Department of Licensing and Regulatory Affairs, n.d.-a; Oregon Occupational Therapy Licensing Board, n.d.). This is again an interesting finding as pain-related organizations and centers, such as the Center on Advanced Palliative Care, have clinical training recommendations for SLPs in regard to pain and PM (Center to Advance Palliative Care, n.d.).

5.1.2 Patient Experiences with Pain and Clinical Implications

It was hypothesized that SLPs would identify individuals with voice and/or swallowing problems as patients who frequently report pain; this was supported by the results. Over 50% of SLPs identified dysphagic patients as a population having pain. This was an expectation as pain associated with dysphagia, or odynophagia, is well documented in the literature. Odynophagia has been reported in patients post-extubation (El-Boghdadly et al., 2016), in those with Guillan-Barre (Kazandjian & Dikeman, 2012), and in patients with HNC (Zebralla et al., 2021), to name a few. Additionally, common gastroesophageal disorders, like GERD, can be associated with painful swallowing (Clarrett & Hachem, 2018). Similar to dysphagia, the occurrence of pain as a symptom of voice disorders, or odynophonia, has been well established in the literature. For example. research has reported painful voice to occur in individuals with fibromyalgia (Hamdan et al., 2024), COVID-19 (Tohidast et al., 2024), and in those who are frequent voice users such as teachers (Dantas et al., 2024), singers (Kwok & Eslick, 2019), and voice actors (Reid et al., 2024). Additionally, pain in both populations (swallowing and voice) is not always localized to the oropharynx and larynx but could be more general such as neck/shoulder

pain or even a headache (Almeida et al., 2020; White & Bell, 2003). The relatively large proportion of respondents (27%) who identified "language" as an SLP diagnostic category associated with patient pain was somewhat unexpected. This may be due, however, to SLP caseloads having large numbers of stroke patients and the literature indicates a high prevalence of pain in patients with aphasia ranging from 43.8%-87.5% (de Vries et al., 2016).

The hypothesis that pain interferes with therapeutic progress was supported. The majority of the SLPs (81%) reported that their ability to complete evaluations and/or treatment have been impacted by patient's pain. Of these respondents, 18% reported that greater than 50% of their caseload was impacted by pain. Specifically related to treatment, over 75% indicated that they have had patients for whom pain limited speech-language therapy progress. These findings align directly with the current dysphagia literature for HNC. Pain is a well know barrier to adherence to dysphagia therapy during XRT (Baudelet et al., 2023; Shinn et al., 2013). Another thought to consider is how pain impacts cognitive functioning, and thus the effect it might have on patient performance during evaluations. The literature is robust with examples of individuals with pain demonstrating lower scores in areas such as memory, attention, and executive functioning (Moore, et al.; Moriarty et al., 2017; Wiech et al., 2008). It is important to note, however, that the survey in this study did not ask about specific ways in which pain interfered with evaluation and/or treatment. Future work utilizing other methodologies such as in depth interviewing will be needed to better understand the various ways that pain interferes with both evaluation and treatment.

Interestingly, the sample of SLPs surveyed had a wide range in the age of their caseloads (e.g., adults, pediatrics, both) suggesting that SLPs seeing pediatric populations were also navigating pain and its impact on their patients. Specifically, of the individuals who reported working only in school settings, over half reported that pain had an impact on their evaluations, treatment, or both. Additionally, 35% of those SLPs stated that pain impacted student therapeutic progress. These numbers were similar in SLPs who reported having a caseload that was 75% or more pediatric (54% reported impact on clinical practice and 37% reported impact on therapeutic progress). This was an unexpected yet important discovery as children can be overlooked in discussions about pain, especially in settings such as schools where pain might be affecting academic endurance and performance (Groenewald et al., 2020; Mathews, 2011).

5.1.3 Utilization of PM Techniques

The hypothesis that SLPs would report limited confidence in management of pain was refuted, but the hypothesis that SLPs are open to implementing PM techniques into therapeutic practice was supported. Despite a large portion of individuals reporting the impact of pain on their patients' progress (78%), less than half of respondents are utilizing PM techniques. A positive however, is that those SLPs who did report using PM techniques, were more often than not confident in their use; of further interest is that there were no SLPs who reported being "not confident" in use of their PM techniques. Speech-language pathologists were largely positive in their willingness to use novel PM techniques. Other health professionals demonstrate the same positive interest in use of new technologies, such as VR, as they see the potential clinical utility with patients – with some even stating it could be a useful tool for rehabilitative therapy (Shiner et al., 2024). These findings could

be explained by the Diffusion of Innovation (DoI) Theory in which adoption of a new practice like VR is influenced by a variety of concepts such as innovation, communication channels, time, and social systems (Rogers, 2003). The idea or practice must offer a relative advantage or observable result before being widely adopted. Oftentimes the initial adopters of new innovations are those who are adventurous or risk-takers, or in the case with technology it may be those who are already experienced with the technology, like VR (Schreiter et al., 2025). With the majority of survey respondents falling into generations that grew up with or were exposed at younger ages to technology, it was hypothesized that younger individuals would be more accepting of novel, innovative PM techniques. This would have been consistent with literature that younger individuals are more willing to attempt new things, especially technology in the workplace (Morris & Venkatesh, 2000). However, neither age nor years of clinical practice had had a strong relationship with willingness to trial new PM strategies with patients. The communication channel and social system constructs within the DoI Theory might also explain these results as SLPs have a smaller community in which they communicate updates to the field and across a variety of platforms (i.e., online discussions in ASHA SIGs, the ASHA leader, etc.).

5.1.4 Conclusions and Implications of Survey of SLPs Perceptions about Pain and Pain Management

The overall goal of this study was to gauge the current state of the field of speech-language pathology in terms of educational and clinical experiences with pain and pain management, as well as to determine SLPs' willingness to implement novel PM strategies. The survey revealed that a large majority of SLP respondents feel they did not receive enough training about pain and PM although most received some, with informal learning

opportunities reported more frequently than formal ones. The results highlight a clear need for pain curriculum to be incorporated at a systemic level due to the high frequency of impact on caseloads across the lifespan and the ASHA Big 9. Results from this study strengthen the literature supporting the need for comprehensive, interdisciplinary, and standard pain and PM training competencies and guidelines (McKinnon et al., 2020; Norton et al., 2025). When trained adequately, SLPs are confident in use of PM strategies and can employ these to not only improve evaluation and treatment sessions, but patient therapeutic progress (Kouijzer et al., 2023). Additionally, this study provided evidence of SLPs' willingness to use novel PM techniques further indicating the high likelihood that SLPs would accept implementation of VR for PM with their patients.

5.2 User Experience of Virtual Reality in Adults without Head and Neck Cancer

Virtual reality has been used in several populations such as cancer, burn, and mental health (Hartshorn et al., 2022; Lan et al., 2023; Riches et al., 2023) for various reasons ranging from entertainment to education and healthcare (de Lurdes Calisto & Sarkar, 2024; Iqbal et al., 2024; Kshetri & Dwivedi, 2024;). User experience is a tool to analyze subjective experiences of effectiveness and satisfaction of VR, the emotions elicited, and unintended negative consequences that arise (Marques et al., 2021). Despite the presence of literature related to UX of VR in specific patient populations such as burn (Armstrong et al., 2023) and cancer (Trevino et al., 2022), there is limited evidence about the general adult population. Additionally, there is no evidence about potential differences in UX in active versus passive VR. Study two provides initial data comparing adult UX in active and passive VR environments from participants ranging from their 20's to almost 90 years of age. Scaling up data collection in the coming years ultimately will provide a useful data set for

VR game development in general. For the purposes of this research, a subset of the adult participants in study two were selected as age and gender matched controls for study three, in addition to providing insight about UX in the adult population.

5.2.1 Usability of VR in Adults without Head & Neck Cancer

The concepts of *Satisfaction* and *Learnability* are reflective of VR usability, or how pleasant and easy it is to use the technology (Nielsen, 2012). The hypothesis that individuals will have higher levels of *Satisfaction* in the active experience was not supported as there were no differences between the VR groups on the VEQ *Emotion* subscale. This was a positive finding as satisfaction is based on the emotional response that a user has after interacting with a product or technology (Hassenzahl, 2008). The occurrence of similar satisfaction levels may be due to the fact that there is not one specific feature that has been found to be the sole determinant of application (i.e., game) success (Phan et al., 2016). For example, some individuals find originality, graphics, and universal appeal to be the key to success (Chalker, 2008) whereas others find decision making, game mechanics, and easy-to-understand game rules to be top priority (Shelley, 2001). Additionally, satisfaction centers around the user's needs, expectations, and existing experiences (Zahidi et al., 2014). For 70% of individuals in study two, this was their first experience with VR. It was presented as a low stakes way to try a new technology. The absolute ratings indicated that users had an overall positive emotional response to the VR experience, or a high level of *Satisfaction* in both groups further demonstrated by exclamations such as "this is actually really cool" (Participant 29, pVR) or "this is low key soothing!" (Participant 22, aVR).

Learnability, including error in use of VR, was determined by the VEQ *Skill* subscale. The hypothesis that *Learnability* would not differ between VR experiences was supported by the results. This may again be due to the fact that the majority of participants had never used VR and thus they were starting at a similar baseline for learning. Additionally, the literature supports that individuals who have higher digital literacy have increased intuition for use based on their prior experiences (Pott et al., 2023). In the case of study two, 87% of the participants reported using applications on smart phones, two thirds of the sample have played video games that utilize hand controllers, and 63% indicated they were generally comfortable with technology. Study findings could also be attributed to the level of interaction, or specific game mechanics, required with each of the applications. Both *Puzzling Places* and *Nature Treks* were fairly simple (i.e., only used one mechanic such as point and click, etc.), slow paced, and did not require any significant action or complex decision making. Again, absolute ratings of *Learnability* were high. Participants offered commentary that represented the learning process such as "Oh! I can do this?" (Participant 25, pVR) or "I want you here, no go away." (Participant 24, aVR). The majority of participants reported that they could engage in VR again without instruction. This finding is notable as many participants did require verbal reminders on how to use the controllers, with some even commenting on their discomfort such as "my thumbs are kinda small, it's hard to use" (Participant 14, aVR), in addition to comments on how to interact with the application such as "I think I'm stuck again" (Participant 19, pVR).

Overall, usability levels were high across both active and passive VR groups indicating type of VR experience did not impact levels of *Satisfaction* or *Learnability*. This is a positive finding with beneficial implications. Having the same levels of usability between groups is

favorable as it suggests that users are not limited in the type of VR experience they might be able to learn and interact with, thus expanding the potential for incorporating different types of applications with participants in future work.

5.2.2 Acceptability of VR in Adults without Head and Neck Cancer

Like usability, acceptability is determined by a variety of factors (Alexandre et al., 2018); those important to this research, however, were the components of *Engagement* and *Adoption*. The hypothesis that there will be increased *Engagement* levels in the active experience was not supported; there were no differences between aVR and pVR groups. The VEQ subscales of *Immersion* and *Presence* were used as these are generally considered to be an indication of a person's engagement. Findings may reflect the fact that both the aVR and pVR applications provided multisensory (audio and visual), enhanced immersion components such as field of view and level of detail (Oprean & Balakrishnan, 2020). One participant noted the auditory stimuli, stating "I like all the sounds and everything, except this fly right by my ear!" (Participant 23, aVR). Presence, or the subjective feelings of users in the VR environment, was likely impacted by the ability of users to block indicators of the real world by attending to both aVR and pVR experiences (Wirth et al., 2007). Similar to findings about usability, the high levels of engagement could be related to the novelty factor eliciting a sense of curiosity (Chirico et al., 2016). The role of fun and play have been well established in the literature as methods of improving and sustaining engagement, especially when it comes to learning (Bisson & Luckner, 1996; Martin, 2012) which further connects the UX components of usability and acceptability. As indicated by the absolute ratings for both *Immersion* and *Presence*, participants had high levels of *Engagement* across both aVR and pVR groups. This demonstrates the potential for using a variety of

applications within VR and for various reasons, with one participant even noting that the experience "beats watching TV, that' for sure" (Participant 17, aVR).

The VEQ *Technology Adoption* subscale was used as an indicator of *Adoption*. The hypothesis that there would be no difference between active and passive VR experiences was supported. Absolute ratings demonstrated an overall high level of *Technology Adoption* across the sample. The Technology Acceptance Model (TAM) provides some rationale for these findings. Adoption consists of two primary factors which influence an individual's acceptance of a technology, namely perceived ease of use and perceived usefulness (Davis, 1989). The underlying concept of the TAM is that the more a user perceives the technology to enhance their performance, and the less effort it requires for use, the higher the level of technology acceptance. Again, in this study participants were provided with a low stakes opportunity to experience a new technology, one that anecdotally many commented having curiosity about. With the use of screen casting, the researcher was able to effectively and efficiently intervene with the participant if they were having difficulty which may have led to higher perceived ease of use. Also, of interest to note is that most participants had some type of degree in higher education (i.e., Bachelor's, Master's, etc.) which can contribute to acceptance of new technologies, especially when it pertains to healthcare (Lee et al., 2022). Nearly all participants said that they would engage with VR again, thus implying a positive experience, with one participant stating, "I wish I could experience this with my son too!" (Participant 20, pVR).

Acceptability levels were high for both aVR and pVR groups demonstrating that type of VR experience had no effect on *Engagement* or *Adoption*. The broad acceptance of this technology is encouraging. The lack of differences between the VR groups suggest that

individuals would be willing to interact with a variety of VR experiences, or applications, in future study.

5.2.3 Negative Side Effects

The hypothesis that participants would experience some cybersickness related side effects (e.g., eye strain, nausea, dizziness, fatigue) was supported, although these tended to be mild. The hypothesis that adults in the aVR group would experience more side effects than those in the pVR was not supported, as indicated by the VEQ *Negative Consequence* subscale. It is not uncommon to have adverse symptoms from VR, especially during initial experiences, due to disruptions in integration of the vestibular, visual, and proprioceptive input received (Chang et al., 2020). Recall that in this study, 70% of participants had no prior VR use and the study itself consisted of a single session of VR activity. In some studies, prevalence and severity of side effects increased with prolonged exposure (Kennedy et al., 2000; Risi & Palmisano, 2019; Serge & Moss, 2015; Stanney et al., 2003), whereas others have found that symptoms generally decreased due to an adaptation effect (Rebenitsch & Owen, 2016; Tyrrell et al., 2018; Zielasko, 2021). The side effect with the strongest impact was dizziness in active VR and nausea in passive VR. This is consistent with the literature assessing healthy adults in that disorientation (dizziness) is often the most commonly reported adverse event followed by nausea (Simón-Vicente et al., 2024). However, other literature, which focused on students or recent graduates, and related to use of VR in education and training, reported oculomotor disturbances (i.e., eyestrain) to be reported most followed by disorientation. Of note is that both of these reviews reported that the cybersickness literature currently centers on younger adults, ages 18-30, which thus introduces age as a consideration; both age and gender as factors related to VR UX are

addressed further below. In summary, with limited side effects in either VR experience, future research with adults can confidently implement a wide range of VR applications that are similar to *Puzzling Places* and *Nature Treks*.

5.2.4 Impact of Age and Gender on UX

There was no relationship between age or gender, respectively, with any of the UX components analyzed regarding usability, acceptability, or occurrence of negative side effects. An important clarification to note is that for the purpose of this research, the term "age" is in reference to adults (i.e., 18+) only as there is a wealth of literature and potentially different guidelines or findings for children and adolescents with VR use. A large portion of the literature related to age and UX with technology discusses the concept of the digital divide – or the phenomenon that refers to disparities in access and use of information communication technology (Lythreatis et al., 2022). The thought is that older adults did not grow up as digital natives and thus they have had to adapt to the new technologies as they aged, often navigating non-intuitive skillsets, computer anxiety, and technophobia (Ballano et al., 2014; Elena-Bucea, 2021) subsequently leading to reduced technology acceptance. However, most studies that detail this reduction in technology acceptance tend to use models, such as TAM, that do not account for biophysical decline or psychosocial factors (i.e., social isolation and fear of illness) prevalent in older individuals (Chen & Chan, 2011; Schroeder et al., 2023) which may impact their acceptance rates. Additionally, these studies fail to consider potential barriers to UX such as older adults' concerns of privacy, lack of training, cost, and limited perception of "need" (Yusif et al., 2016) and subsequent facilitators such as providing individualized content within the technology (e.g., VR) and maximizing its use for facilitating socialization with friends and

family (Roberts et al., 2019). Surprisingly, literature on VR use in older adults has demonstrated positive findings with reported high levels of ease of use and overall acceptance than other technologies historically (i.e., internet, computers, video games) (Heart & Kalderon , 2013; Hosseini et al., 2024). Additionally, in alignment with many models of technology acceptance, attitudes toward VR have been found to increase with repeated exposures (Huygelier et al., 2019). Relative to cybersickness, the literature is consistent with the current study in that older individuals do not report increased levels of side effects compared to younger individuals (Winter et al., 2021). In fact, some studies have found older adults to have less cybersickness than their younger counterparts (Cossio et al., 2025; Simón-Vicente et al., 2024).

In reference to gender, there have been notable differences reported in the literature between males and females in terms of UX in VR. Some prior research has indicated more cybersickness in females as a result of factors such as postural stability, the female hormone cycle, migraine susceptibility, and state and trait anxiety to name a few (Golding et al., 2005; Granziera et al., 2006; Munafo et al., 2017; Stanney et al., 2020). However, others have indicated that once a factor is mediated, cybersickness effects related to gender dissipate; for example, ensuring the VR display is fit properly to a person's interpupillary distance (females have smaller distance between pupils of the eyes) (Gordon et al., 2014). Further, studies have found higher levels of immersion and presence in men with VR experiences (Felnhofer et al., 2012; Kallioniemi, 2017).

The current study results contribute to the body of VR literature supporting VR use across the adult age span and across genders. This suggests that there is no ideal user for VR, thus it is a suitable technology for use by all adults. However, the lack of statistically

significant differences in VR usability, acceptability and negative side effects could also simply reflect a lack of statistical power in the current study.

5.2.5 Relationship of UX with Interoception

In addition to UX, the relationship between interoception and the presence of negative side effects was investigated. Of specific interest was assessment of the relationship between an individuals' tendency to distract themselves from bodily discomfort and the presence of negative side effects. For the full participant group, there was a range of small to medium negative correlations between the two thus indicating that a person who is more likely to distract themselves is not necessarily less likely to experience negative side effects. These findings are limited and a more comprehensive measure of interoception might be warranted to garner better insight into the strength of the relationship and the possibility of screening individuals prior to VR to determine potential negative side effects that may occur, or their ability to distract themselves from such effects. However, there may be other potential characteristics that are more important predictors of negative side effects. Research has already investigated both anxiety and well-being and similarly found no association with cybersickness (Rmadi et al., 2023). Additionally, it may be the case that enhancing other UX components within the VR experience, such as *Presence*, could reduce the occurrence of cybersickness. This study found moderate negative correlations between *Experience Consequence* and both *Skill,* and *Presence* indicating that increasing *Engagement* or *Learnability* within the VR experience may reduce negative side effects.

5.2.6 Conclusions and Implications of UX of VR in Adults without HNC

The aim of this study was to determine the usability, acceptability, and potential negative side effects of VR use in adults without head and neck cancer. There were no significant differences between active and passive VR experiences across all elements of UX (*Satisfaction, Learnability, Engagement,* and *Adoption*) indicating that both VR experiences are appropriate for use in adults. While there were some negative side effects, these were limited and in-line with what has been reported in the current literature. Looking toward study 3, and future work, more engaging VR is associated with better outcomes in studies regarding exercise (Mouatt et al., 2020) and learning (Lønne et al., 2023). Additionally, adherence rates to treatment also improve with higher levels of engagement in VR experiences (Cikajlo & Peterlin Potisk, 2019; Doré et al., 2023). Determining that both types of VR experiences were engaging experiences for users provides the foundational assurance necessary for use of either active or passive VR in future work, especially with clinical populations.

5.3 User Experience of VR in Patients with Head and Neck Cancer

There is existing literature supporting VR use for PM in individuals with cancer, especially in the breast and pediatric cancer populations (e.g., Cheng et al., 2022; Zhang et al., 2022a). Even though there are only a few studies looking at use of VR as a PM technique for HNC, promising results have been reported (Chitlange & Yadav, 2023; Pandrangi et al., 2022). The third study in this dissertation contributes to the early and growing knowledge base about potential use of VR in HNC patients. This feasibility study enrolled participants with a variety of HNCs who were undergoing XRT (both with and without concurrent CT)

to determine the potential for use of VR technology. Demographics for the participants were in alignment with expectations from other HNC studies with regard to age and gender (Karanth et al., 2023). There were a larger proportion of participants in this specific sample that identified as Black/African American compared to other studies which may be due to the urban location of the health system used for participant recruitment.

5.3.1 Usability of VR in Patients with Head and Neck Cancer

Similar to study two, the primary measures of interest were the UX domains of usability, acceptability, and negative side effects which were compared across the two VR experiences, active and passive. In addition, study three compared these measures over time as XRT progressed. The VEQ subscales of *Emotion* and *Skill* were again used to analyze usability, specifically *Satisfaction* and *Learnability*, respectively. The hypothesis that there will be increased satisfaction in the active experience was not supported. However, the hypothesis that patients will have similar levels of learnability between groups was supported. Neither *Satisfaction* nor *Learnability* differed between the two VR groups. An additional hypothesis was that usability would increase over time in both active and passive groups. This hypothesis was not supported as ratings reflecting the subcomponents of usability (*Satisfaction* and *Learnability*) did not differ across the Pre-, Mid-, and Post-XRT timepoints.

Although most patients started with and maintained high levels of usability throughout their XRT, it is important to consider how to best support those who did not. Fairly limited training and practice with the VR technology was provided and only in the first session. In subsequent sessions the researcher provided verbal or tactile cues when necessary if the patient requested, or if they clearly were in need of direction. Additional instruction and

practice with the VR technology basics may be needed with some patients as it has been found individualizing or implementing different components of training have improved satisfaction ratings across diverse populations (Chau et al., 2021). Anecdotal participant comments from some support such a need as evidenced by Patient 7 (pVR, Mid-XRT session) who stated, "last time I felt like I knew what I was doing better" and Patient 5 (pVR) mentioned "I would like this a lot more if I knew how to work the controllers" after the Post-XRT session. Of note, however, is that only 2 patients per aVR and pVR groups had worse *Emotion* ratings from Pre-XRT to Post-XRT and only 1 patient in each group had worse ratings in *Learnability* across the timepoints. The rest of the groups either remained consistent or improved over time. This is supported by current literature as repeated exposure to VR, or having prior experience with the technology, improves overall usability (Rubio-López et al., 2025).

The finding that usability did not differ between the aVR and pVR game deserves mention. An active VR environment was projected to be more usable based on *Satisfaction* because the literature supports a positive correlation between satisfaction levels and task completion, or accomplishment (Gabriel et al., 2011); this is further supported by the self-determination theory in which feeling effective in one's activities leads to increased intrinsic satisfaction (Nikiforow & Wagener, 2021). The lack of differences between aVR and pVR in this study may have been due to the aVR application not being "active" enough – *Puzzling Places* is fairly calm and uses simple game mechanics (i.e., point and click) that were similarly used in *Nature Treks VR*. Additionally, the pVR application may have not been "passive" enough as individuals did have the opportunity to move within the environment and interact with the scenery rather than solely observing. There also may

have been underestimation of the extent to which individuals, especially a HNC population, appreciated a less active VR experience, such as the nature scene. Experiencing nature, whether real or simulated, historically has had a positive impact on individuals' emotional state (Chirico & Gaggioli, 2019; Vitale & Bonaiuto, 2021) and thus this could have proven to be equally emotive for patients navigating the stressors of oncologic treatment (Emami et al., 2018). It may simply be that patients with HNC may find active and passive VR experiences equally usable. If that is the case and VR is eventually adopted as a pain mitigation strategy for HNC patients undergoing XRT, clinicians may have flexibility to tailor the selection of a specific VR game to align with each individual's interests. This would be ideal because personalizing the VR experience has been found to have higher levels of satisfaction resulting in successful distraction from cancer-related pain (Groninger et al., 2025; Malik et al., 2024).

5.3.2 Acceptability of VR in Patients with Head and Neck Cancer

Three hypotheses were offered regarding acceptability of VR which was measured by levels of *Engagement* and *Adoption*. First, patients with HNC in the active VR group were expected to have increased *Engagement* in comparison to the passive VR group, as determined by the VEQ subscales of *Immersion* and *Presence*. This was not the case as neither *Immersion* nor *Presence* differed between aVR and pVR at any XRT timepoint. *Engagement* levels were mid-high throughout XRT for both groups with only 1 patient in the aVR group having worse presence scores between Pre- to Post-XRT sessions, and immersion scores worsening between timepoints for 1 in the aVR group and 2 in the pVR group. Similar to *Satisfaction*, the literature supports the idea that when an individual is interacting with an active VR environment, engagement levels are typically increased when

compared to those in passive environments (Gutierrez-Maldonado et al., 2011; Sekhavat & Motalebi, 2018). The absence of differences in *Engagement* between aVR and pVR groups could be due to reasons previously mentioned such as somewhat similar pace and activity levels within the two VR applications. Additionally, it could be due to the fact that none of the patients had used VR previously. With the novel use of an immersive technology in a largely risk-free, low stakes environment, VR use likely evoked a "childlike" excitement when being immersed in the environment and engaging with the games (Pullen, 2016; Schutte, 2019). This is supported by Patient 6's (aVR, Pre-XRT session) exclamation of "I feel like Iron Man, like Tony Stark, I like this!" Engagement within the VR environment was unanimously positive across patients and across time points, with Patient 10 (pVR) reporting that the VR "almost makes you kinda feel the rain, I feel it on my fingers!" during the Mid-XRT session.

A second hypothesis was that there would be no difference between the aVR and pVR HNC groups in terms of *Adoption* of the technology. This was supported by the results which indicated no statistically significant differences in *Adoption* at any of the three XRT data collection sessions, as evidenced by the VEQ *Technology Adoption* subscale. Results may be due to previously mentioned concepts like that of VR novelty and simplistic game mechanics. Additionally, it could be related to the perception that the VR experience would be of benefit or use to the patient, in alignment with the TAM (Davis, 1989). Cancer patients are often willing to participate in clinical trials and new technologies not only for personal benefit, but also for altruistic reasons (Moorcraft et al., 2016). A final facilitator to technology acceptance worth mentioning is having supportive and knowledgeable healthcare professionals who endorse the technology (Hung et al., 2023). The current work

was not only supported and encouraged by the patients' radiation oncologist but facilitated by a speech-language pathologist that was well versed in both the XRT-related side effects that occur and the VR technology. *Adoption* ratings were in the mid-high range for both groups and largely improved, or remained consistent, between Pre-XRT and Post-XRT time points (although 1 patient in the pVR group had a worse score from Pre- to Post-XRT sessions). This finding is important as it demonstrates individuals with HNC are accepting of implementation of a novel technology within their oncologic intervention care plan.

The third hypothesis was that levels of acceptability, would increase across the three XRT timepoints. However, there was no change in any of the three scales reflecting acceptability (i.e., *Immersion, Presence,* and *Technology Adoption*). As previously mentioned, all scales had relatively high levels to begin with, but mindfulness is required to optimize these levels of acceptability if VR is to be considered as a complementary therapy approach to enhance dysphagia therapy in this patient population. The limited changes over time may be related to the small number of sessions of use (e.g., three). The Unified Theory of Acceptance and Use of Technology (UTAUT) model supports this as it suggests that repeated exposure to a technology can improve factors such as performance and effort expectancy, as well as social influence and facilitating conditions thus leading to higher acceptance (Venkatesh et al., 2003).

One method for improving acceptance over time, also supported by the UTAUT model, is by incorporating personalization within the technology (Jones et al., 2022). The role of personalization is well established in UX, especially when related to technology acceptance (Pardini et al., 2022). The two patients that reported having passion for, or specific enjoyment of either puzzles or nature as baseline interests prior to the study were noted to

have higher, if not the highest technology adoption score at each of the time points and made commentary such as “ooh this is so pretty, look at that Zebra! Where can I get one! [in reference to the headset]” (Patient 10, pVR) or “I just want to finish that puzzle! [while leaning away from the researcher when told the VR time had ended]” (Patient 1, aVR).

5.3.3 Negative Side Effects

Being an early phase interventional study, a primary focus of interest was evaluating whether VR caused new toxicities in patients or exacerbated known side effects from oncologic interventions such as nausea and dizziness. It was hypothesized that participants would have some side effects, and that they would worsen over time in concordance with their XRT. The first part of this hypothesis – that the HNC patients would experience some cybersickness – was confirmed. The second portion – that the side effects would worsen over time – was not. The reported side effects in both of the VR groups were consistent with expected cybersickness side effects (i.e., headache, nausea, etc.).

Even though most patients experienced at least one side effect, the magnitude of the symptoms tended to be fairly limited as reflected in the individual patient data for the VEQ *Experience Consequence* subscale at the three XRT timepoints. Looking at *Experience Consequence* plotted across XRT demonstrates that 76% of the scores remained at an 8-10 (recall that higher scores are desired on this subscale) and the median subscale values per VR group at each XRT timepoint also were above 8. The fact that negative side effects were fairly limited and that they did not increase across the course of XRT, is a positive outcome. This finding suggests that the chosen VR games do not create substantial issues with cybersickness even as XRT Gy dose and associated XRT side effects increase. While this remains to be confirmed in future work – and while there will always be the need for

vigilance with individual HNC patients – the findings show that VR may be utilized without substantial expectation of creating or exacerbating negative symptoms such as nausea.

Inspection of each potential negative side effect in isolation revealed that both groups reported "increase in salivation" to have the most notable occurrence. This was an unexpected, but positive, finding as these are individuals who often experience xerostomia (King et al., 2016; Sroussi et al., 2017). There is some literature, specifically related to various cybersickness scales that have been used historically (i.e., the Simulator Sickness Questionnaire (SSQ) ; Kennedy et al., 1993), that supports this notion that time spent in VR could potentially increase salivation (Simón-Vicente, et al., 2024). However, this is the first set of information demonstrating that it might happen for some patients undergoing XRT who could actually benefit from what is typically considered a negative effect.

Following salivation, the side effects reported most were headache in the passive group and fatigue in the active group. Higher fatigue scores in the aVR group could be explained through the lens of cognitive load theory in which learning is affected by the amount of mental effort being placed on working memory (Makransky & Lilleholt, 2018; Sweller, 1988). Working memory has limited capacity and thus if too many tasks are requiring attention at a single time, performance and engagement levels may decrease (Sweller, 1988). Presumably headaches that were reported by some HNC patients relate to oculomotor factors. For example, individuals have varying interpupillary distance which may lead to improper fit of the headset (Gordon et al., 2014). Additionally, the vergence-accommodation conflict (VAC) may be responsible (Hoffman et al., 2008). In the real world, our eyes adjust vergence (simultaneous movement of both eyes) and accommodation (focus) simultaneously to account for depth perception (Masson et al., 1997). However,

once in VR there is a conflict that arises in these adjustments as VR often presents images that require convergence of vision at varying depths while the focus remains fixed on a single plane (Dymczyk et al., 2024; Vienne et al., 2014). This mismatch has been found to cause both headache and eyestrain. These oculomotor factors are not population specific and have been found broadly across adults.

Nausea is a potential negative side effect of VR that researchers need to be aware of, particularly in HNC patients receiving CT who frequently experience this (Martini et al., 2018; McKenzie et al., 2019). Nausea can impact oral intake as well (Farrell et al., 2013). Surprisingly, only three participants throughout the study reported having nausea at the time of their VR sessions. Even more surprising was that all three had clinically meaningful reductions in reported nausea following their time in VR, with two reducing it completely. An anecdotal comment regarding side effects post-VR was Patient 1 (aVR) stating, "I don't have any nausea, but my heartburn is gone!" demonstrating yet another potential symptom that was postiviely impacted by VR use. With the limited presence of side effects between groups and across sessions, VR presents as a feasible and safe technology to use within the HNC population.

5.3.4 VR User Experience: Head and Neck Cancer versus Non-Head and Neck Cancer

An additional goal of this early phase interventional study was to compare the UX of patients with HNC to age and gender matched adults without HNC. The hypothesis was that the two groups will have similar usability and acceptability, but patients with HNC will report an increased level of negative side effects. This hypothesis was partially supported in that there were no differences between groups for any of the VEQ subscales that reflect usability (e.g., *Emotion* & *Skill*) or acceptability (e.g. *Immersion*, *Presence*, *Technology*

Adoption). Recall that this analysis was based on UX ratings at a moment in time for each group. For the non-HNC patients, there was only one data collection session. For the HNC patients, the data gathered at their Pre-XRT session were used. At this point in time, four patients had not started XRT and the other six had 4-10 Gy of radiation, an amount that is not expected to have significant physical effects. The intent was to assess potential differences at a moment in time prior to onset of XRT side effects, effectively evaluating whether the HNC itself, including potential psychological and physiological impacts, causes the UX in VR to be different from those without HNC. The null finding is considered to be a positive outcome. It suggests that if VR is eventually implemented for pain mitigation in the HNC population undergoing XRT that there may not be the need to provide additional supports for a positive UX beyond what is needed for adults in general.

Although both groups had fairly high usability and acceptability, and the two groups did not differ, it will be important to learn how to optimize the experience further. This is particularly true for the HNC population for whom VR use is being targeted. The median values for the various VEQ subscales for the HNC patients indicated that as a group they had a positive experience. However, there were individuals in this group with scores indicating a neutral or negative experience. Learning why that occurred and then determining effective means of creating a more positive UX will be important considerations for future studies. Personalization of the VR experience is a theme consistent in current literature as a means to improve UX in VR. With cancer patients, VR content related to home, natural environments, childhood, and family or friends has been suggested (Groninger et al., 2025).

The second part of the hypothesis, that the HNC group would report negative side effects of VR at a higher rate, was not supported by the results. Remarkably, there was not a difference in the VEQ *Experience Consequence* subscale between groups. Although the hypothesis was not supported, the finding is quite positive because it demonstrates that having HNC may not create additional impacts for HNC patients, at least at the start of their XRT. Recall too that HNC patients also did not have differences in the VEQ *Experience Consequence* subscale across their radiation treatment. This may be indicative of their overall cancer experience having less side effects, or simply that the sample of individuals would have had limited cybersickness even prior to their cancer diagnosis. Additionally, correlations between pre-existing nausea and dizziness prior to VR use and severity of cybersickness have been identified in cancer populations. Since the majority of patients with HNC in this study had minimal if any nausea pre-VR, this could provide an explanation for the limited presence of negative side effects (Chuan et al., 2023). Taken together, the absence of differences in UX and limited occurrence of negative side effects between individuals with and without HNC is significant. Findings indicate that VR is a suitable technology to implement with the HNC population with limited need for supplemental support.

5.3.5 Impact of VR on Head & Neck Cancer Patient Reported Pain

Both swallowing-related and general pain were explored in this study. Similar to nausea, pain is a common complaint of HNC patients (Havard et al., 2021) and it can have an impact on adherence to swallowing exercises during XRT (Baudelet et al., 2023; Shinn et al. 2013). The hypothesis that VR use would result in lower perceived pain during swallowing was supported by the study. There were identifiable differences in swallowing-

related pain change scores for the aVR group between Pre-XRT and Mid-XRT. This is not surprising as approximately halfway through treatment is when side effects related to XRT, as well CT, tend to increase (Gangopadhyay et al., 2015; Rocha et al., 2022). As such, at that Mid- point of XRT might be the first or best opportunity for a pain-reduction effect from an intervention be possible or noticeable.

In the aVR group, the pre-VR ratings on the NPR-S at the Pre-XRT time were at 0 for all but one patient whose pain was already at a 6; at the Mid-XRT data collection, four out of five had pre-VR pain ratings (including the person with a 6 in the Pre- session whose pain increased to 7 at Mid-XRT). This demonstrates the expected increase in swallowing related pain in the middle of XRT for the aVR group. At Mid-XRT, all four of these aVR participants had clinically meaningful reductions in swallowing-related pain. This is supported by participant comments like “I don't feel myself swallowing when I'm doing this" (Patient 4, aVR, Mid-XRT session) and “[swallowing] it’s a little easier now actually" (Patient 8, aVR, Mid-XRT session). A similar increase in swallowing-related pain reduction for the pVR group at the Mid- compared to the Pre-XRT was not present. This finding is supported by the literature as increased reduction of pain is associated with use of active VR (Dreesmann et al., 2022; Mosso Vázquez et al., 2019). This finding could also be due to the overall pain profiles of the groups. For example, Patient 10 (pVR) had a pre-VR pain level of 10 (the highest scale point) at every session, and it was only reduced in the Post-XRT session by one; this indicates that maybe there was not much that VR could have done to impact their score. Additionally, 2 of the 5 patients (40%) in the pVR group had no pain reported pre-VR and thus there was no potential for VR to reduce pain that isn’t present. Given that pain in patients with HNC may occur prior to the start of oncologic interventions, it could also be

the case that these individuals had already commenced a pharmacologic pain management regimen that was successful in mitigating their pain (Macfarlane et al., 2012; Mirabile et al., 2016).

Swallow-related pain was the only measure for which it seemed to matter whether a person was in the active versus passive VR experience. Interestingly, all swallow-related pain reductions observed in the final session were isolated to the passive experience. This could be due to the fact that individuals at the end of treatment are more fatigued and thus pVR reduced the overall cognitive load (Sweller, 1988; Vogel et al., 2022). However, this goes against evidence from other populations, such as burn patients, for whom the active experience was noted to be more beneficial in pain management (Armstrong et al., 2023; Xiang et al., 2021). Ultimately, it is encouraging that individuals found benefit in the passive experience as this would likely be an easier VR environment in which to implement dysphagia therapy where it may be important to not substantially increase cognitive demands from VR when a patient is attempting to complete swallow exercises. As detailed in the Results (4.3.6), there were multiple clinically meaningful reductions in swallowing-related pain (i.e., a change of 2 points or more) (Mao et al., 2022). It is noteworthy that when considering all data collection time points for aVR and pVR patients combined, there was a reduction in swallowing-related pain post-VR for 53% of the recording sessions in which there was pain reported prior to starting the VR session. The majority of reductions (70%) were clinically meaningful.

General pain ratings did not demonstrate a statistically significant reduction in either VR group at Pre-, Mid-, or Post-XRT. However, there were multiple occurrences of clinically meaningful reductions in general pain (Mao et al., 2022). Pain levels were reduced post-VR

in 75% of the sessions in which patients reported a pre-VR pain level above zero with approximately 53% of those being considered clinically meaningful reductions. These findings are consistent with extant literature which establishes VR use to be an effective method for pain reduction (Maddox et al., 2023; Wiederhold et al., 2014b). Intriguingly, all patients had a reduction in either general pain or swallow-related pain as a result of VR in at least one of their sessions. Of further interest is that all pain reductions (general and swallowing) observed during the baseline session occurred in individuals in the pVR group, yet this was not the case at later sessions.

The findings related to impact of VR on pain in patients with HNC are significant. Virtual reality seems to have some effect on mitigating pain in this population, which can be very beneficial for patients and providers alike. Determining that VR can be used as a complementary method of non-pharmacologic pain management in this population has only positive implications for future work as it confirms the potential for its use in other avenues of cancer care, such as dysphagia therapy.

5.3.6 Conclusions and Implications of UX of VR in Patients with HNC

This study sought to determine the feasibility of use of VR with the HNC population, specifically looking at usability, acceptability, and potential toxicities that may occur. The absence of significance in UX components across both VR experience (active versus passive) and time (throughout the course of XRT) is positive as it demonstrates a clinical benefit to its implementation. In looking for methods to optimize UX in patients, both increased training (Chau et al., 2021) and personalization of the VR experience emerged as key potential facilitators to VR use (Groninger et al., 2025; Malik et al., 2024). With reported cybersickness comparable to that of an age and gender matched control group, it

indicates that VR has no additional impact on patients with HNC and thus may be considered a safe technology for use, and one with the potential to unexpectedly impact side effects of oncologic intervention. Given the significance of impact of VR use on pain reduction, this research lays the foundation for using VR as a CIM technique for PM with HNC patients during XRT in future work.

5.4 Limitations and Future Work

There are limitations to the three studies that need to be acknowledged. Study 1 was an online survey design which creates some inherent limitations. First is the risk of nonresponse bias. That is, those who choose not to respond to the recruitment invitation and those who started the survey but did not complete it might differ meaningfully from those who completed the survey. For example, some may have read the opening few questions that addressed the types of education and training they may have had regarding pain and pain management and those who had not had much may have been inclined to end their participation. There also were some question design limitations that permitted respondents to reply to a question with off-target responses. For example, the questions asking about the types of medical diagnoses and SLP diagnoses with associated pain that the SLPs encounter clinically was constructed in a way that allowed for medical and SLP diagnoses to be used for either question. Additionally, most of the questions were multiple choice or multiple select and open-ended questions were limited in number to limit the survey completion time thereby encouraging more SLP respondents and more complete surveys. Future work will need to consider other methodologies such as in depth interviewing in order to gain richer insights about issues such as how evaluation and treatment are impacted by pain.

The primary limitation of study two was the overall sample size. Related to this was the need to split the participants into two groups given the interest in this study and study 3 to consider UX as a function of active versus passive VR. The intention is to grow the enrollment in study 2 in the coming years. Surprisingly, there is not a normative data set for UX in adults that could serve as a frame of reference or grounding of the results in study 2. It will be important to continue to build this UX database with a larger number of participants and ensure inclusion of a more expansive age range as well as greater inclusion of non-White/Caucasians. Although the current work included participants ranging from the 20s to the late 80s, there was not equal distribution on the age continuum (i.e., only one participant in 40s and three in 50s). For study two, there was an element of targeted recruitment that emphasized enrollment of enough people in their early 60s and older in order to provide age and gender matching for the HNC patients in study 3. An additional limitation of study two was that it required only one session of VR. Prior experience using VR is likely to influence measures of UX. Future studies of older adults placed into repeated VR exposures will be needed to assess changes as a function of time.

Study 3 was designed as an early interventional feasibility study where the primary goals are generally focused on whether the intervention can be delivered in the way that it is intended, and if it can be done in a manner that is safe and tolerable (Kunselman, 2024; National Center for Complementary and Integrative Health, n.d.; Pfledderer et al., 2024). Such studies typically enroll a limited number of patients, particularly when there is higher suspicion of potential negative side effects from the novel intervention (American Cancer Society, n.d.; Cancer Research UK, n.d.). Therefore, recruitment was intentionally limited for this initial application of VR to assess user experience. However, this means that the

study is not statistically powered to detect efficacy. The primary focus was to investigate items such as recruitment and retention, assess whether the protocol could be implemented as planned, track protocol completion, and assess user experience – including potential negative side effects. There were some difficulties in recruitment as the research study site is also involved in nationwide clinical trials, with similar inclusion criteria, which take priority. However, every patient who expressed interest in the study initially consented to participation. Retention rates for this study were at 100%, however one patient was unable to complete the post-XRT session due to severe side effects requiring hospital admission (97% completion rate of sessions). Overall, the protocol was implemented as planned without modification. Because the study is underpowered, there is an increased risk of Type II errors. Also important to note is that for this research the traditional .05 significance level was utilized for all analyses. Some may argue that given the feasibility nature of the study, a more generous alpha, such as .10, could have been used. In addition to the focus on feasibility, early clinical indicators of the effects of VR (i.e., clinically meaningful changes in swallowing and general pain perception) were included. When attention shifts to evaluating efficacy of VR as a pain mitigation approach to increased dysphagia therapy adherence during XRT, larger participant pools will be needed. Within these larger studies, continued collection of UX data should be done to refute or confirm the preliminary results reported here.

The current study did not address important issues about the ability of patients to complete recommended dysphagia therapy exercises while also being in VR. Additionally, future work will need to consider issues such as how often and for how long patients are placed in VR during their course of XRT in order to optimize its effects. One area of

improvement that was recognized in this study is the need for more initial VR training specific to the games being implemented rather than reliance on the standardized VR training (Meta First Steps application) provided in the Pre-XRT data collection session.

Consideration should also be given to using other tools for gathering UX information, either in addition to or in replacement of some used in study 3. For example, there is now an ESAS version tailored for use with patients who have cancer (Watson et al., 2024). The VEQ could also be shortened to focus on certain subscales of interest. This survey is lengthy which led to some patient reports of fatigue during completion, and the metrics for answers were at times confusing (i.e., the scale boundaries switch midway) prompting frequent clarification requests. Future work also will need to focus on identifying characteristics inherent to the patient that might predict who will benefit from VR and what type of VR experience might be best. The addition of interoception (which was not part of study 3) or coping measures could be of benefit, but other measure such as trait characteristics could also be considered for investigation. Inclusion of such measures would allow more depth assessment of the relationships between coping, interoception, distraction, and VR. Discovering a relational impact between these patient characteristics and VR could eventually help in making clinical decisions about VR use on a more individualized basis. Most importantly in terms of future work will be assessment of the efficacy of VR to reduce pain during dysphagia therapy with the goal of improving swallow outcomes, Figure 66 provides a conceptual model of this process.

Figure 66. *Conceptual model of anticipated benefit of VR integration into dysphagia therapy.*

CHAPTER 6. CONCLUSIONS

It is well established that adherence to dysphagia therapy in patients with HNC undergoing XRT is low due to barriers including fatigue, reduced motivation, and pain (Shinn et al., 2013; Rowe et al., 2023; Wall et al., 2017, Xhu et al., 2022). This dissertation research sought to determine foundational understanding of VR application to the HNC population in such a way that it might be applied to dysphagia therapy for pain mitigation in future work. Through a series of studies, it was determined that both the health care professionals that provide dysphagia therapy, namely SLPs, and the patients with HNC are willing to use novel technology in oncologic treatment, such as VR. Additionally, VR was established as a usable, acceptable, and safe technology with positive impact on patient reported pain. These results are promising as they demonstrate not only the clinical utility for VR use to mitigate pain, but also that use of VR has limited negative consequences, or side effects, associated with its use.

Study one focused on the perceptions and experiences that SLPs have had related to education, training, and clinical implementation of pain management with their patients. SLPs broadly have limited education requirements as they relate to both pain and PM. This is concerning as the majority have caseloads that are impacted by patient/client reported pain, whether that be during evaluations, treatment, or when documenting therapeutic progress. Despite limited training on pain management, SLPs expressed overwhelming support for implementation of new PM techniques, like VR. This is a valuable outcome as SLPs are primarily responsible for dysphagia therapy. The willingness of SLPs to implement VR into dysphagia therapy with patients undergoing XRT, or their acceptance of the process, is the first step in determining the feasibility of a novel PM technique.

The second study assessed UX, specifically usability, acceptability, and the occurrence of negative side effects, of VR in adults without HNC. This cross-sectional comparison revealed no differences between active or passive VR experiences, which is significant. In discovering that the type of VR experience has no impact on the UX of the player, it indicates that VR is a universal technology with potential for use in a wide range of ages and populations. Further in recognizing that VR provides an engaging and largely positive experience, it provides assurance that this technology could be suitable as a mechanism for mitigation of pain.

In study three, all research questions were answered with clinically relevant data. First, it was determined that the UX of VR in patients with HNC did not differ between VR experiences. Of utmost significance is that there were no exacerbations of oncologic intervention side effects, such as nausea; in fact, there were unexpected reductions in symptoms in some patients. With similar clinical significance is the finding that UX remained consistent over the course of XRT as the Gy dose accumulated and negative side effects from the oncologic treatment increased (i.e., as reflected in clinical measures related to swallowing, for example, extracted from the medical record). When compared to age and gender matched controls, there were no differences implicating that no additional supports will be necessary to use this technology within the HNC population. Lastly, VR use positively impacted both swallowing-related and general pain levels thus providing the possibility of a non-pharmacologic method of pain reduction in the HNC population. This study provided insight into recruitment and retention, and ultimately whether this protocol could be implemented as planned without adverse effects of VR use.

This is the first study that looks directly at UX in HNC patients undergoing XRT and the findings are encouraging. The resulting data not only provide the foundations to initiate VR use with larger samples, but indicate the potential for use as a means of non-pharmacologic PM for patients with HNC during dysphagia therapy.

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APPENDIX A. Michigan State University IRB Exemption Letter

MICHIGAN STATE UNIVERSITY

EXEMPT DETERMINATION
Revised Common Rule

June 17, 2024

To: Jeffrey Searl

Re: **MSU Study ID**: STUDY00010876
Principal Investigator: Jeffrey Searl
Category: Exempt 2(ii)
Exempt Determination Date: 6/17/2024
Limited IRB Review: Not Required.

Title: Investigating Pain: The Speech-Language Pathologist's Perspective
This study has been determined to be exempt under 45 CFR 46.104(d) 2(ii).
Reportable Events: If issues should arise during the conduct of the research, such as unanticipated problems that may involve risks to subjects or others, or any problem that may

Office of Regulatory Affairs
Human Research Protection Program

4000 Collins Road
Suite 136
Lansing, MI 48910

517-355-2180
Fax: 517-432-4503
Email: irb@msu.edu
www.hrpp.msu.edu

Principal Investigator (PI) Responsibilities: The PI assumes the responsibilities for the protection of human subjects in this study as outlined in Human Research Protection Program (HRPP) Manual Section 8-1, Exemptions.

Continuing Review: Exempt studies do not need to be renewed.

Modifications: In general, investigators are not required to submit changes to the Michigan State University (MSU) Institutional Review Board (IRB) once a research study is designated as exempt as long as those changes do not affect the exempt category or criteria for exempt determination (changing from exempt status to expedited or full review, changing exempt category) or that may substantially change the focus of the research study such as a change in hypothesis or study design. See HRPP Manual Section 8-1, Exemptions, for examples. If the study is modified to add additional sites for the research, please note that you may not begin the research at those sites until you receive the appropriate approvals/permissions from the sites.
Please contact the HRPP office if you have any questions about whether a change must be submitted for IRB review and approval.

New Funding: If new external funding is obtained for an active study that had been determined exempt, a new initial IRB submission will be required, with limited exceptions. If you are unsure if a new initial IRB submission is required, contact the HRPP office. IRB review of the new submission must be completed before new funds can be spent on human research activities, as the new funding source may have additional or different requirements.

increase the risk to the human subjects and change the category of review, notify the IRB office promptly. Any complaints from participants that may change the level of review from exempt to expedited or full review must be reported to the IRB. Please report new information through the study's workspace and contact the IRB office with any urgent events. Please visit the Human Research Protection Program (HRPP) website to obtain more information, including reporting timelines.

Personnel Changes: After determination of the exempt status, the PI is responsible for maintaining records of personnel changes and appropriate training.

The PI is not required to notify the IRB of personnel changes on exempt research. However, he or she may wish to submit personnel changes to the IRB for recordkeeping purposes (e.g. communication with the Graduate School) and may submit such requests by submitting a Modification request. If there is a change in PI, the new PI must confirm acceptance of the PI Assurance form and the previous PI must submit the Supplemental Form to Change the Principal Investigator with the Modification request (available at hrpp.msu.edu).

Closure: Investigators are not required to notify the IRB when the research study can be closed. However, the PI can choose to notify the IRB when the study can be closed and is especially recommended when the PI leaves the university. Closure indicates that research activities with human subjects are no longer ongoing, have stopped, and are complete. Human research activities are complete when investigators are no longer obtaining information or biospecimens about a living person through interaction or intervention with the individual, obtaining identifiable private information or identifiable biospecimens about a living person, and/or using, studying, analyzing, or generating identifiable private information or identifiable biospecimens about a living person.

For More Information: See HRPP Manual, including Section 8-1, Exemptions (available at hrpp.msu.edu).

Contact Information: If we can be of further assistance or if you have questions, please contact us at 517-355-2180 or via email at IRB@msu.edu. Please visit hrpp.msu.edu to access the HRPP Manual, templates, etc.

Exemption Category. The full regulatory text from 45 CFR 46.104(d) for the exempt research categories is included below. [1234]

Exempt 1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exempt 2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

Exempt 3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Exempt 4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ``health care operations'' or ``research'' as those terms are defined at 45 CFR 164.501 or for ``public health activities and purposes'' as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Exempt 5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Exempt 6. Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempt 7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for

potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

Exempt 8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

[1]Exempt categories (1), (2), (3), (4), (5), (7), and (8) cannot be applied to activities that are FDA regulated.

[2] Each of the exemptions at this section may be applied to research subject to subpart B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) if the conditions of the exemption are met.

[3] The exemptions at this section do not apply to research subject to subpart C (Additional Protections for Research Involving Prisoners), except for research aimed at involving a broader subject population that only incidentally includes prisoners.

[4] Exemptions (1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D (Additional Protections for Children Involved as Subjects in Research) if the conditions of the exemption are met. Exempt (2)(i) and (ii) only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Exempt (2)(iii) may not be applied to research subject to subpart D.

APPENDIX B. Pain Survey Questions

Q1 **Michigan State University - Informed Consent to Participate in Research**

You are being asked to participate in a research study titled "Investigating Pain: The Speech-Language Pathologist's Perspective". The purpose of the study is to gather information on speech-language pathologists' (SLPs) perceptions of pain related to their education and training, its potential impact on treatment sessions and patient progress, and their opinions on use of alternative techniques for pain management. You will be asked to answer a variety of questions about your understanding of pain generally, any education or training you have had related to pain and/or its management, as well as any experiences you have had in which pain may have impacted your sessions with your patients.

The survey will take about 5-10 minutes. Your participation is voluntary. You can skip any question you do not wish to answer or withdraw before survey submission. You must be 18 or older and currently practicing as a Speech-Language Pathologist (SLP) or Speech-Language Pathology Clinical Fellow (SLP-CF) to participate. You indicate that you voluntarily agree to participate in this research study by submitting the survey. If you have any questions, please contact Kathryn Genoa-Obradovich at genoakat@msu.edu.

I consent. (1)

I do not consent. (2)

Display This Question: If Q1 = I do not consent.

Q1a Thank you for your time and consideration of taking our survey. Have a wonderful day!

Q2 Have you had any education/training on **pain**? Select all that apply.

Yes - formal (i.e., academic coursework, CEU, etc.) (4)

Yes - informal (i.e. journal club, on the job, etc.) (5)

No (6)

I'm not sure (7)

Display This Question: If Q2 = Yes - formal (i.e., academic coursework, CEU, etc.)

Q2a In what formal setting(s)? Select all that apply.

Undergraduate studies (1)

Graduate studies (master's level - M.A./M.S.) (2)

Graduate studies (doctoral level - Ph.D.) (3)

Continuing education course (4)

Other: (5) _____

Display This Question: If Q2 = Yes - formal (i.e., academic coursework, CEU, etc.)

Q2b Please describe the education/training you received. (i.e., an entire course vs. single lecture, comprehensive coverage vs. a single topic on pain such as "odynophagia") _____

Display This Question: If Q2 = Yes - informal (i.e. journal club, on the job, etc.)

Q2c In what informal setting(s)? Select all that apply.

On the job (1)

Journal club/read an article (2)

Discussion with colleagues (3)

Other: (4) _____

Q3 Have you had any education/training on **pain management**? Select all that apply.

Yes - formal (i.e., academic coursework, CEU, etc.) (4)

Yes - informal (i.e. journal club, on the job, etc.) (5)

No (6)

I'm not sure (7)

Display This Question: If Q3 = Yes - formal (i.e., academic coursework, CEU, etc.)

Q3a In what formal setting(s)? Select all that apply.

Undergraduate (1)

Graduate studies (master's level - M.A./M.S.) (2)

Graduate studies (doctoral level - Ph.D.) (3)

Continuing education course (4)

Other: (5) _____

Display This Question: If Q3 = Yes - formal (i.e., academic coursework, CEU, etc.)

Q3b Please describe the education/training you received. (i.e., an entire course vs. single lecture, comprehensive coverage vs. a singular technique such as "progressive relaxation").
_____

Display This Question: If Q3 = Yes - informal (i.e. journal club, on the job, etc.)

Q3c In what informal setting(s)? Select all that apply.

On the job (1)

Journal club/read an article (2)

Discussion with colleagues (3)

Other: (4) _____

Q4 What words come to mind when you hear the word **pain**?_____

Q5 How would you **define** pain to a client/patient?_____

Q6 Which **medical populations** that you see, if any, have pain?_____

Q7 Do any of the patients/clients you see with **SLP diagnoses** have pain? (e.g., articulation, dysphagia, aphasia, dysphonia, etc.) If yes, please list which diagnoses.

Yes (4) _____

No (5)

Q8 Do you participate on any type of an interdisciplinary team?

Yes (1)

No (2)

Display This Question: If Q8 = Yes

Q8a Which members on your interdisciplinary team are involved with **pain management**? Select all that apply.

Primary care physician (1)

Specialty physician: (2) _____

Advanced practice provider (3)

Nurse (4)

Speech language pathologist (5)

Allied health professionals (PT, OT, etc.) (6)

Other: (7) _____

Q9 What types of **pain management techniques** are most used by your patients? Select all that apply.

Medications - Opioids (1)

Medications - Other (i.e., anti-inflammatory, topical, etc.) (2)

Physical therapies (i.e., massage, stretching, exercises, hot/cold packs, etc.) (3)

Psychological therapies (i.e., cognitive behavioral therapy, guided imagery/relaxation, biofeedback, etc.) (4)

Mind and body techniques (i.e., meditation, acupuncture, lifestyle changes, etc.) (5)

Injections/Surgery (i.e., steroids, ablations, etc.) (6)

Other: (7) _____

Q10 Do you think SLPs should be involved in **management of pain**?

Yes/Always (1)

Almost always (2)

Most of the time (3)

Some of the time (4)

Almost never (5)

No/Never (6)

Q11 Do you ever ask clients/patients about pain?

Yes (1)

No (2)

Display This Question: If Q11 = Yes

Q11a When do you usually ask about pain? Select all that apply.

During the evaluation only (1)
At the first treatment session (2)
At the evaluation and last treatment session (3)
In every treatment session (4)
If another medical provider reports the patient is experiencing pain or requests that I ask the patient about it (5)
If the client/patient directly mentions pain (6)
Physical pain indicators are present (i.e., wincing, etc.) (7)
Other: (8) _____

Display This Question: If Q11 = Yes

Q11b How do you ask clients/patients about pain? Select all that apply.

Informally - casual conversation (1)
During a type of physical evaluation (i.e., oral motor evaluation) (2)
Formally - with tool/measure (3)

Display This Question: If Q11b = Formally - with tool/measure

Q11c What tools or measures do you utilize? _____

Q12 Does patient-reported pain ever impact your ability to complete evaluations or treatment? Select all that apply.

Evaluation (1)

Treatment (2)

Both (3)

Neither (4)

Q13 Does patient-reported pain ever impact their therapeutic progress?

Yes (1)
No (2)

I'm not sure (3)

Display This Question: If Q13 = Yes

Q13a What percentage of your caseload has pain that impacts their therapeutic progress?

0 10 20 30 40 50 60 70 80 90 100

% ()

Q14 Do you implement pain management techniques with patients?

Yes (1)
No (2)

Display This Question: If Q14 = Yes

Q14a What pain management techniques do you use? _____

Display This Question: If Q14 = Yes

Q14b Do you use certain pain management techniques with specific patient populations? If yes, please explain. _____

Display This Question: If Q14 = Yes

Q14c Rate how confident you are in using pain management techniques.

1 - Very confident (1)
2 - Somewhat confident (2)

3 - Neither (3)

4 - Somewhat not confident (4)

5 - Not confident at all (5)

Q15 Rate your level of agreement with the following statements:
Q15a I feel SLPs are provided enough education/training on **pain**.

Strongly Agree (1)

Agree (4)

Neither agree nor disagree (5)

Disagree (6)

Strongly Disagree (7)

Q15b I feel SLPs are provided enough education/training on **pain management**.

Strongly Agree (1)

Agree (2)

Neither agree nor disagree (3)

Disagree (4)

Strongly Disagree (5)

Q15c If provided appropriate education/training, I would be willing to implement **novel** pain management techniques into my practice with clients/patients.

Strongly Agree (1)

Agree (2)

Neither agree nor disagree. (3)

Disagree (4)

Strongly Disagree (5)

Q16 What is your age group?

18-25 (1)

26-30 (2)

31-35 (3)

36-40 (4)

41-45 (5)

46-50 (6)

51-55 (7)

56-60 (8)

61+ (9)

Prefer not to answer (10)

Q17 Which of the following gender do you most identify with?

Male (1)

Female (2)

Transgender (3)

Non-binary (4)

Prefer not to answer (5)

Q18 In which country did you complete your SLP school/training?_____

Q19 In which country do you currently practice?_____

Q20 Which race or ethnicity best describes you?

American Indian or Alaskan Native (1)

Asian (2)

Black or African American (3)

Hispanic or Latino/a (4)

Middle Eastern or North African (MENA) (6)

Native Hawaiian or Pacific Islander (7)

White/Caucasian (8)

Multiple/Other (Please specify.) (10) _____

Prefer not to answer (11)

Q21 How many years have you been practicing as an SLP?
Currently in clinical fellowship (1)

1-5 (2)

6-10 (3)

11-15 (4)

16-20 (5)

21-25 (6)

26-30 (7)

31+ (8)

Q22 What area/setting(s) do you practice in? Select all that apply.
Birth to three (0-3) (1)

Schools (2)

College/university (3)

General medical, VA, LTACH, or university hospital (4)

Home health (5)

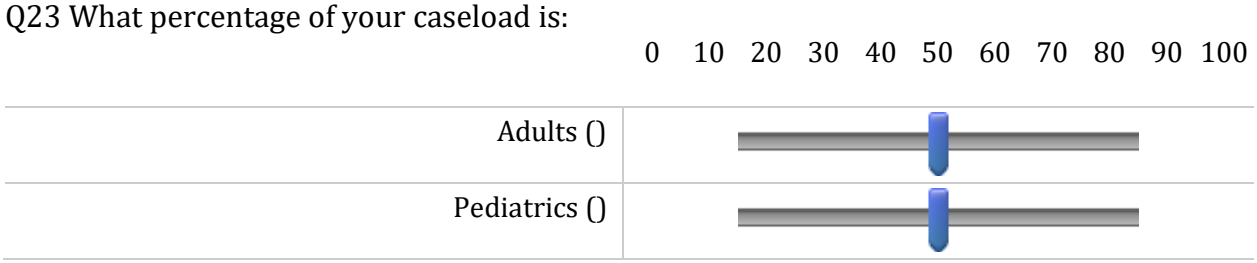
Outpatient clinic/office (6)

Rehabilitation facility (7)

Skilled nursing facility (8)

Private practice (9)
Other: (10) _____

Q23 What percentage of your caseload is:



Q24 What ASHA Big 9 Areas do you serve? Select all that apply.

Articulation (1)

Fluency (2)

Voice and resonance (including respiration and phonation) (3)

Receptive and expressive language (4)

Hearing (including the impact on speech and language) (5)

Swallowing (oral, pharyngeal, esophageal, and related functions, including oral function for feeding; oral function for feeding; orofacial myofunction (6)

Cognitive aspects of communication (attention, memory, sequencing, problem-solving, executive functioning) (7)

Social aspects of communication (challenging behavior, ineffective social skills, lack of communication opportunities) (8)

Communication modalities (including oral, manual, augmentative and alternative communication techniques, and assistive technologies) (9)

APPENDIX C. Michigan State University IRB Approval Letter

MICHIGAN STATE UNIVERSITY

Initial Study APPROVAL
Revised Common Rule

November 19, 2024
To: Jeffrey Searl

Re: **MSU Study ID:** STUDY00010999
IRB: Biomedical and Health Institutional Review Board
Principal Investigator: Jeffrey Searl
Category: Expedited 6, 7
Submission: Initial Study STUDY00010999
Submission Approval Date: 11/19/2024
Effective Date: 11/19/2024
Study Expiration Date: None; however modification and closure submissions are required (see below).

Title: Adult User Experience in Virtual Reality
This submission has been approved by the Michigan State University (MSU) BIRB.

Office of Regulatory Affairs
Human Research Protection Program

4000 Collins Road
Suite 136
Lansing, MI 48910

517-355-2180
Fax: 517-432-4503
Email: irb@msu.edu
www.hrpp.msu.edu

The submission was reviewed by the Institutional Review Board (IRB) through the Non-Committee Review procedure. The IRB has found that this study protects the rights and welfare of human subjects and meets the requirements of MSU's Federal Federal Wide Assurance (FWA00004556) and the federal regulations for the protection of human subjects in research (e.g., 2018 45 CFR 46, 21 CFR 50, 56, other applicable regulations).

How to Access Final Documents

To access the study's final materials, including those approved by the IRB such as consent forms, recruitment materials, and the approved protocol, if applicable, please log into the Click™ Research Compliance System, open the study's workspace, and view the "Documents" tab. To obtain consent form(s) stamped with the IRB watermark, select the "Final" PDF version of your consent form(s) as applicable in the "Documents" tab. Please note that the consent form(s) stamped with the IRB watermark must typically be used.

Expiration of IRB Approval: The IRB approval for this study does not have an expiration date. Therefore, continuing review submissions to extend an approval period for this study are not required. **Modification and closure submissions are still required (see below).**

Modifications: Any proposed change or modification with certain limited exceptions discussed below must be reviewed and approved by the IRB prior to implementation of the change. Please submit a Modification request to have the changes reviewed.

New Funding: If new external funding is obtained to support this study, a Modification request must be submitted for IRB review and approval before new funds can be spent on human research activities, as the new funding source may have additional or different requirements.
Immediate Change to Eliminate a Hazard: When an immediate change in a research protocol is necessary to eliminate a hazard to subjects, the proposed change need not be reviewed by the IRB prior to its implementation. In such situations, however, investigators must report the change in protocol to the IRB immediately thereafter.
Reportable Events: Certain events require reporting to the IRB. These include:

- Potential unanticipated problems that may involve risks to subjects or others
- Potential noncompliance
- Subject complaints
- Protocol deviations or violations
- Unapproved change in protocol to eliminate a hazard to subjects
- Premature suspension or termination of research
- Audit or inspection by a federal or state agency
- New potential conflict of interest of a study team member
- Written reports of study monitors
- Emergency use of investigational drugs or devices
- Any activities or circumstances that affect the rights and welfare of research subjects
- Any information that could increase the risk to subjects

Please report new information through the study's workspace and contact the IRB office with any urgent events. Please visit the Human Research Protection Program (HRPP) website to obtain more information, including reporting timelines.
Personnel Changes: Key study personnel must be listed on the MSU IRB application for expedited and full board studies and any changes to key study personnel must to be submitted as modifications. Although only key study personnel need to be listed on a non-exempt application, all other individuals engaged in human subject research activities must receive and maintain current human subject training, must disclose conflict of interest, and are subject to MSU HRPP requirements. It is the responsibility of the Principal Investigator (PI) to maintain oversight over all study personnel and to assure and to maintain appropriate tracking that these requirements are met (e.g. documentation of training completion, conflict of interest). When non-MSU personnel are engaged in human research, there are additional requirements. See HRPP Manual Section 4-10, Designation as Key Project Personnel on Non-Exempt IRB Projects for more information.
Prisoner Research: If a human subject involved in ongoing research becomes a prisoner during the course of the study and the relevant research proposal was not reviewed and approved by the IRB in accordance with the requirements for research involving prisoners under subpart C of 45 CFR part 46, the investigator must promptly notify the IRB.
Site Visits: The MSU HRPP Compliance office conducts post approval site visits for certain IRB approved studies. If the study is selected for a site visit, you will be contacted by the HRPP Compliance office to schedule the site visit.

For Studies that Involve Consent, Parental Permission, or Assent Form(s):

Use of IRB Approved Form: Investigators must use the form(s) approved by the IRB and must typically use the form with the IRB watermark.

Copy Provided to Subjects: A copy of the form(s) must be provided to the individual signing the form. In some instances, that individual must be provided with a copy of the signed form (e.g. studies following ICH-GCP E6 requirements). Assent forms should be provided as required by the IRB.

Record Retention: All records relating to the research must be appropriately managed and retained. This includes records under the investigator's control, such as the informed consent document. Investigators must retain copies of signed forms or oral consent records (e.g., logs). Investigators must retain all pages of the form, not just the signature page. Investigators may not attempt to de-identify the form; it must be retained with all original information. The PI must maintain these records for a minimum of three years after the IRB has closed the research and a longer retention period may be required by law, contract, funding agency, university requirement or other requirements for certain studies, such as those that are sponsored or FDA regulated research. See HRPP Manual Section 4-7-A, Recordkeeping for Investigators, for more information.

Closure: If the research activities no longer involve human subjects, please submit a Continuing Review request, through which study closure may be requested. Closure indicates that research activities with human subjects are no longer ongoing, have stopped, and are complete. Human research activities are complete when investigators are no longer obtaining information or biospecimens about a living person through interaction or intervention with the individual, obtaining identifiable private information or identifiable biospecimens about a living person, and/or using, studying, analyzing, or generating identifiable private information or identifiable biospecimens about a living person.

For More Information: See the HRPP Manual (available at hrpp.msu.edu).

Contact Information: If we can be of further assistance or if you have questions, please contact us at 517-355-2180 or via email at IRB@msu.edu. Please visit hrpp.msu.edu to access the HRPP Manual, templates, etc.

Expedited Category. Please see the appropriate research category below for the full regulatory text.

Expedited 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Expedited 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3

ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Expedited 3. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
Expedited 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
Expedited 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
Expedited 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
Expedited 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
Expedited 8. Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or **(b)** where no subjects have been enrolled and no additional risks have been identified; or
(c) where the remaining research activities are limited to data analysis.
Expedited 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

APPENDIX D. UX of VR in Adults: Pre-VR Survey

UX for VR in Adults: Pre-Survey

1. What is your age? _____

2. Which of the following gender do you most identify with?
   Male
   Female
   Transgender
   Non-binary
   Prefer not to answer

3. Which race or ethnicity best describes you?
   American Indian or Alaskan Native
   Asian
   Black or African American
   Hispanic or Latino/a
   Middle Eastern or North African (MENA)
   Native Hawaiian or Pacific Islander
   White/Caucasian
   Multiple/Other (Please specify.) _____
   Prefer not to answer

4. What is your highest level of education completed?
   Highschool
   GED
   Some college
   Associates degree
   Bachelor's degree
   Master's degree
   Professional degree (MD, DDS, DVM, etc.)
   Doctoral degree
   Other _____
   Prefer not to answer

5. Please list past or present medical history (circle all that apply).

Alcohol/Drug problem	High blood pressure
Anxiety	Migraines
Asthma	Neuropathy
Dementia	Osteoporosis
Depression	Stroke
Cancer Type _____	Seizure
Coronary artery disease	Physical/mental health disorder _____
Congestive heart failure	Neurological disease (i.e. Parkinson's, etc.) _____
Emphysema/COPD	
Heart-attack	Other _____
Cardiac – Pacemaker or Defibrillator	Prefer not to answer

APPENDIX E. Multidimensional Assessment of Interoceptive Awareness Version 2

Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life.

	Circle one number on each line					
	Never					**Always**
1. When I am tense I notice where the tension is located in my body.	0	1	2	3	4	5
2. I notice when I am uncomfortable in my body.	0	1	2	3	4	5
3. I notice where in my body I am comfortable.	0	1	2	3	4	5
4. I notice changes in my breathing, such as whether it slows down or speeds up.	0	1	2	3	4	5
5. I ignore physical tension or discomfort until they become more severe.	0	1	2	3	4	5
6. I distract myself from sensations of discomfort.	0	1	2	3	4	5
7. When I feel pain or discomfort, I try to power through it.	0	1	2	3	4	5
8. I try to ignore pain	0	1	2	3	4	5
9. I push feelings of discomfort away by focusing on something	0	1	2	3	4	5
10. When I feel unpleasant body sensations, I occupy myself with something else so I don't have to feel them.	0	1	2	3	4	5
11. When I feel physical pain, I become upset.	0	1	2	3	4	5
12. I start to worry that something is wrong if I feel any discomfort.	0	1	2	3	4	5
13. I can notice an unpleasant body sensation without worrying about it.	0	1	2	3	4	5
14. I can stay calm and not worry when I have feelings of discomfort or pain.	0	1	2	3	4	5

15. When I am in discomfort or pain I can't get it out of my mind	0	1	2	3	4	5
16. I can pay attention to my breath without being distracted by things happening around me.	0	1	2	3	4	5
17. I can maintain awareness of my inner bodily sensations even when there is a lot going on around me.	0	1	2	3	4	5
18. When I am in conversation with someone, I can pay attention to my posture.	0	1	2	3	4	5

How often does each statement apply to you generally in daily life? Circle one number on each line

		Never				Always
19. I can return awareness to my body if I am distracted.	0	1	2	3	4	5
20. I can refocus my attention from thinking to sensing my body.	0	1	2	3	4	5
21. I can maintain awareness of my whole body even when a part of me is in pain or discomfort.	0	1	2	3	4	5
22. I am able to consciously focus on my body as a whole.	0	1	2	3	4	5
23. I notice how my body changes when I am angry.	0	1	2	3	4	5
24. When something is wrong in my life I can feel it in my body.	0	1	2	3	4	5
25. I notice that my body feels different after a peaceful experience.	0	1	2	3	4	5
26. I notice that my breathing becomes free and easy when I feel comfortable.	0	1	2	3	4	5
27. I notice how my body changes when I feel happy / joyful.	0	1	2	3	4	5
28. When I feel overwhelmed I can find a calm place inside.	0	1	2	3	4	5

29. When I bring awareness to my body I feel a sense of calm.	0	1	2	3	4	5
30. I can use my breath to reduce tension.	0	1	2	3	4	5
31. When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	0	1	2	3	4	5
32. I listen for information from my body about my emotional state.	0	1	2	3	4	5
33. When I am upset, I take time to explore how my body feels.	0	1	2	3	4	5
34. I listen to my body to inform me about what to do.	0	1	2	3	4	5
35. I am at home in my body.	0	1	2	3	4	5
36. I feel my body is a safe place.	0	1	2	3	4	5
37. I trust my body sensations.	0	1	2	3	4	5

APPENDIX F. UX of VR in Adults: Post-VR Survey

UX for VR in Adults: Post-Survey

1. What application/game did you play?
   Puzzling Places
   Nature Treks

2. Have you used VR previously?
   Yes
   No
   If Yes, please explain context and frequency. _____

3. Do you utilize applications on a smart device such as a phone or tablet? (examples: mail, games, social media, etc.)
   Yes
   No

4. Have you ever played video games that utilize controllers?
   Yes
   No
   If yes, please explain which system and how often. (i.e., PlayStation, Xbox; weekly, once, etc.) _____

5. How much time did you feel like you were in VR for?
   Too long
   Too short
   Just right
   Unsure

6. Could you engage in the VR application again without instruction?
   Yes
   No
   Prefer not to answer

7. Would you engage in the VR application again?
   Yes
   No
   Prefer not to answer

8. What do you wish you knew when you first started the VR application?

9. What is your general comfort level with technology?
   1 Very uncomfortable
   2 Somewhat uncomfortable
   3 Indifferent
   4 Somewhat comfortable
   5 Very comfortable

APPENDIX G. Virtual Experience Questionnaire

(Previously the User eXperience in Immersive Virtual Environment, UXIVE)

1.	My interactions with the virtual environment seemed natural.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
2.	The visual aspects of the virtual environment involved me.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
3.	The devices (hand controllers) which controlled my movement in the virtual environment seemed natural								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
4.	I could actively survey the virtual environment using vision.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
5.	The sense of moving around inside the virtual environment was compelling.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
6.	I could examine objects closely.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
7.	I could examine objects from multiple viewpoints.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
8.	I was involved in the virtual environment experience.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
9.	I felt proficient in moving and interacting with the virtual environment at the end of the experience.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
10.	I could concentrate on the assigned tasks rather than on the devices (e.g., headset, controllers).								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
11.	I correctly identified sounds produced by the virtual environment.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
12.	I correctly localized sounds produced by the virtual environment.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
13.	I felt stimulated by the virtual environment.								
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
14.	I became so involved in the virtual environment that I was not aware of things happening around me.								
	1	2	3	4	5	6	7	8	9	10

	Strongly agree Strongly disagree
15.	I became so involved in the virtual environment that it is as if I was inside the game rather than manipulating the controllers and watching a screen. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
16.	I felt physically fit in the environment. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
17.	I became so involved in the virtual environment that I lost track of all time. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
18.	I felt I could perfectly control my actions. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
19.	At each step , I knew what to do. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
20.	I felt I controlled the situation. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
21.	Time seemed to flow differently than usual. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
22.	Time seemed to speed up. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
23.	I was losing sense of time. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
24.	I was not worried about what other people would think of me. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
25.	I felt I was experiencing an exciting moment. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
26.	This experience gave me a great sense of well-being. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
27.	When I mention the experience in the virtual environment, I feel emotions I would like to share. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
28.	I enjoyed being in this virtual environment. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
29.	It was so exciting that I could stay in the virtual environment for hours. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree

30.	I enjoyed the experience so much that I feel energized.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
31.	I felt nervous in the virtual environment.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
32.	I felt like distracting myself tin order to reduce my anxiety.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
33.	I found my mind wandering while I was in the virtual environment.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
34.	The interaction devices (headset, controllers) bored me to death.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
35.	When my actions were going well, it gave me a rush.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
36.	While using the interaction devices (headset, controllers), I felt like time was dragging.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
37.	I enjoyed the challenge of learning the virtual reality interaction devices (headset, controllers).									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
38.	I enjoyed dealing with the interaction devices (headset, controllers).									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
39.	I felt confident selecting objects in the virtual environment.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
40.	I felt confident moving the cross hair/pointer around the virtual environment.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
41.	I felt confident using the controllers to move around the virtual environment.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
42.	I feel confident understanding the terms/words relating to the interaction devices (headset, controllers).									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
43.	I feel confident learning advanced skills within a specific virtual reality software using the Oculus headset.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree
44.	I feel confident describing the functions of the devices (headset, controllers) of a virtual reality environment.									
	1 Strongly agree	2	3	4	5	6	7	8	9	10 Strongly disagree

[Scale anchors change for items below]										
45.	Personally, I would say the virtual environment is . . .									
	1	2	3	4	5	6	7	8	9	10
	Impractical									Practical
46.	Personally, I would say the virtual environment is . . .									
	1	2	3	4	5	6	7	8	9	10
	Confusing									Clear
47.	Personally, I would say the virtual environment is . . .									
	1	2	3	4	5	6	7	8	9	10
	Unruly									Manageable
48.	Personally, I would say the virtual environment is . . .									
	1	2	3	4	5	6	7	8	9	10
	Lame									Exciting
49.	Personally, I would say the virtual environment is . . .									
	1	2	3	4	5	6	7	8	9	10
	Amateurish									Professional
50.	Personally, I would say the virtual environment is . . .									
	1	2	3	4	5	6	7	8	9	10
	Gaudy									Classy
51.	Personally, I would say the virtual environment is . . .									
	1	2	3	4	5	6	7	8	9	10
	Unpresentable									Presentable
52.	Personally, I would say the virtual environment is . . .									
	1	2	3	4	5	6	7	8	9	10
	Ugly									Beautiful
53.	Personally, I would say the virtual environment is . . .									
	1	2	3	4	5	6	7	8	9	10
	Disagreeable									Likeable
[Scale shifts to Strongly agree to Strongly disagree for items below]										
54.	I suffered from <u>fatigue</u> during my interaction with the virtual environment.									
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
55.	I suffered from <u>headache</u> during my interaction with the virtual environment.									
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
56.	I suffered from <u>eyestrain</u> during my interaction with the virtual environment.									
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
57.	I felt an increase of my salivation during my interaction with the virtual environment.									
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
58.	I suffered from <u>nausea</u> during my interaction with the virtual environment.									
	1	2	3	4	5	6	7	8	9	10
	Strongly agree									Strongly disagree
59.	I suffered from <u>“fullness of the head”</u> during my interaction with the virtual environment.									
	1	2	3	4	5	6	7	8	9	10

	Strongly agree Strongly disagree
60.	I suffered from dizziness with my eyes open during my interaction with the virtual environment. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
61.	I suffered from vertigo during my interaction with the virtual environment. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
62.	If I use the same virtual environment again, my interaction with the environment would be clear and understandable for me. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
63.	It would be easy for me to become skillful at using the virtual environment. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
64.	Learning to operate the virtual environment would be easy for me. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
65.	Using the interaction devices (headset, controllers) is a bad idea. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
66.	The interaction devices (headset, controllers) would make work more interesting. 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
67.	I would like to work with the interaction devices (headset, controllers). 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
68.	I have the resources necessary to use the interaction devices (headset, controllers). 1 2 3 4 5 6 7 8 9 10 Strongly agree Strongly disagree
69.	In your opinion, what were the positive points about your experience?
70.	In your opinion, what were the negative points about your experience?
71.	Do you have suggestions to improve this virtual reality environment?

APPENDIX H. Henry Ford IRB Approval Letter

Research Administration
Henry Ford Health System
1 Ford Place – 2F
Detroit, MI 48202-2689
(313) 874-4464 Office

(313) 874-4288 Fax

EXPEDITED INITIAL APPROVAL LETTER

To: Farzan Siddiqui, M.D.
Radiation Oncology

From: Jonathan K Ehrman, Ph.D.

Date: December 06, 2024

IRB No.: 17573

Title: Feasibility of Virtual Reality Use to Increase Adherence to Dysphagia Therapy in Head and Neck Cancer Patients

Approval Period: December 4, 2024 – December 3, 2025

Your study was reviewed and approved by the Expedited IRB Committee via Expedited Review on **BAD** No approval period defined.. The IRB determined the Expedited Review Category for this study is: Expedited Category 4, 5, and 6

The IRB determined that the Criteria for IRB **approval** is met pursuant to 45 CFR 46.111 and if applicable, 21 CFR 56.111. The Expedited IRB Committee approved and stamped informed consent/assent form(s) must be used when enrolling subjects.
This study is approved for the enrollment of 20. An Amendment Form must be submitted, reviewed, and approved prior to exceeding the number of approved subjects.
The Expedited IRB Committee approved and stamped informed Consent/Assent form(s) must be used when enrolling subjects.
The following documents have been approved:

- 17573 - HF_UX HNC_ Data Collection Sheet.xlsx (Data Collection Forms)
- 17573 - Meta Oculus 2 Safety and Warranty Guide.pdf (Device Manual)
- 17573 - Muliti-T_IFU-Medical-Instructions-for-Use.pdf (Device Manual)
- FORM B_Mobili-T.pdf (Form B)
- FORM B_Oculus.pdf (Form B)
- Protocol_HNCVR_Vz1_9.27.24_clean3 .pdf (Protocol)
- Stamped Combined Informed Consent and HIPAA_HNCVR_Vz19.27.24_clean4.pdf (Consent Form)

- Stamped ESASr.pdf (Survey)
- Stamped MPQ.pdf (Survey)
- Stamped UXIVE.pdf (Survey)

This research proposal involving human subjects is subject to Continuing Review requirements pursuant to 45 CFR 46.109 and if applicable, 21 CFR 56.109 and must be submitted for Continuation annually.

This study will expire on December 3, 2025.

Therefore, a Continuation or Final Report for this proposal is due within sixty (60) days prior to expiration of the research study. The Principal Investigator is ultimately responsible for timely submissions of continuation and final reports.

In addition, the IRB requires that any research study initially approved on or after January 21, 2019, that is subject to the Revised Common Rule, meets the definition of a clinical trial, and is supported or regulated by a Federal department or agency, must ensure that one IRB-approved informed consent form used to enroll subjects is posted on a publicly available Federal Web site after the clinical trial is closed to recruitment, and no later than sixty (60) days after the last study visit by any subject, pursuant to 45 CFR 46.116(h).

Any revisions to the protocol must be submitted for review and approved by the IRB prior to implementation. The IRB is expected to review all documents and activities that bear directly on the rights and welfare of participants of research. Any unanticipated problems involving risks to subjects or others, non-compliance or subject complaints must be submitted to the IRB Office. This protocol will be presented as an informational item at a subsequent IRB meeting.

Please contact the IRB Administration Office at IRBQuestions@hfhs.org or IRBquestions@hfhs.org if you have any questions or concerns.

APPENDIX I. Edmonton Symptom Assessment System-Revised

Alberta Health Services

Affix patient label within this box

Edmonton Symptom Assessment System Revised (ESAS-r)

Please circle the number that best describes how you feel NOW:

No Pain	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Pain
No Tiredness *(Tiredness = lack of energy)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Tiredness
No Drowsiness *(Drowsiness = feeling sleepy)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Drowsiness
No Nausea	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Nausea
No Lack of Appetite	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Lack of Appetitie
No Shortness of Breath	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Shortness of Breath
No Depression *(Depression = feeling sad)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Depression
No Anxiety *(Anxiety = feeling nervous)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Anxiety
Best Wellbeing *(Wellbeing = how you feel overall)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Wellbeing
No _____ Other Problem *(For example constipation)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible _____

APPENDIX J. Study One Demographic and Clinical Practice Raw Values

Table 29: *Study One Demographic and Clinical Practice Information*

Demographic Variable	Raw Number or n (%)
Age	
18-30	45 (21.7)
31-40	54 (26.1)
41-50	41 (19.8)
51-60	43 (20.8)
61+	19 (9.2)
Prefer not to answer	5 (2.4)
Gender	
Female	191 (92.3)
Male	12 (5.8)
Transgender	1 (0.5)
Non-binary	1 (0.5)
Prefer not to answer	2 (1.0)
Race or Ethnicity	
American Indian or Alaskan Native	0
Asian	10 (4.8)
Black or African American	2 (1.0)
Hispanic or Latino/a	7 (3.4)
Middle Eastern or North African (MENA)	1 (0.5)
Native Hawaiian or Pacific Islander	0
White/Caucasian	170 (82.1)
Multiple/Other	10 (4.8)
Prefer not to answer	6 (2.9)
Missing	1 (0.5)
Years Practicing as SLP	
Currently in clinical fellowship	12 (5.8)
1-5	33 (15.9)
6-10	40 (19.3)
11-15	32 (15.5)
16-20	21 (10.1)
21-25	23 (11.1)
26-30	20 (9.7)
31+	25 (12.1)
Missing	1 (0.5)

Table 29: (Cont'd)

Practice Settings	
College/university	27 (6.8)
General medical/ hospital	82 (20.8)
Skilled nursing facility	35 (8.9)
Home health	21 (5.3)
Private practice	29 (7.3)
Schools	37 (9.4)
Outpatient clinic/office	85 (21.5)
Birth to three (0-3)	24 (6.1)
Rehabilitation facility	39 (9.9)
Other	16 (4.1)
# of Settings Worked	
1	96 (46.4)
2	59 (28.5)
3	36 (17.4)
>4	16 (7.8)
Caseload Information	
Adult	102 (49.3)
Pediatrics	31 (15)
Mixed	70 (33.8)
Missing	4 (1.9)

APPENDIX K. Functional Oral Intake Scale (FOIS)

Level	Oral Intake
	Tube-dependent
1	No oral intake
2	Tube-dependent with minimal/inconsistent oral intake
3	Tube supplements with consistent oral intake
	Total oral intake
4	Total oral intake of a single consistency
5	Total oral intake of multiple consistencies requiring special preparation
6	Total oral intake of multiple consistencies without special preparation, but with specific restrictions
7	Total oral diet without restrictions

APPENDIX L. Study Three Boxplots for HNC and Controls Across VR Experiences

Figure 67. *Box and whisker plot of VEQ Emotion subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

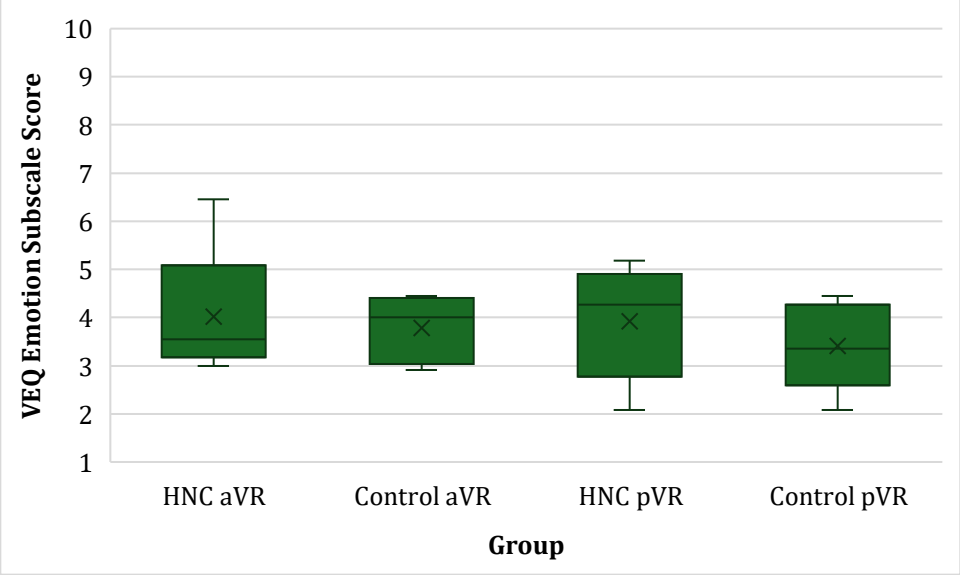


Figure 68. *Box and whisker plot of VEQ Skill subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

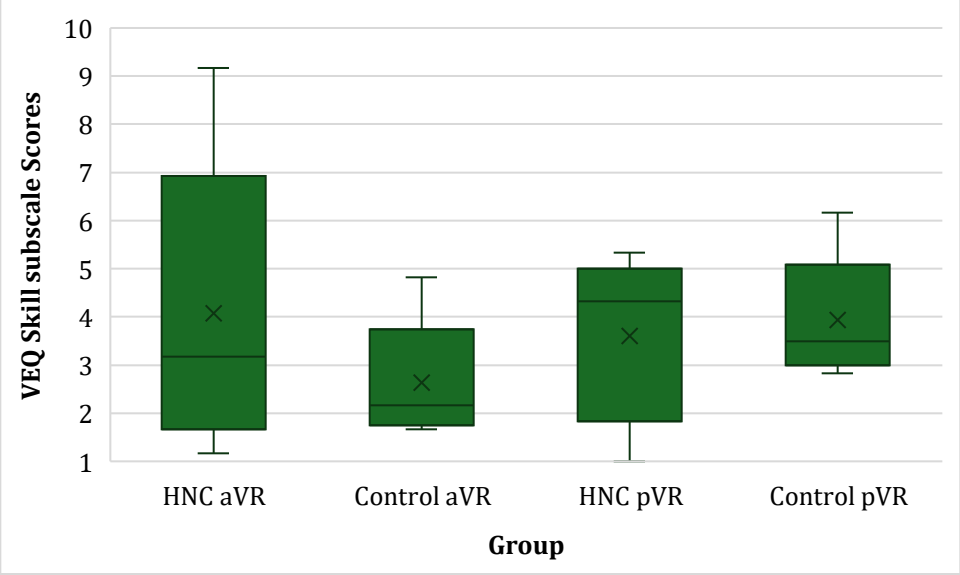


Figure 69. *Box and whisker plot of VEQ Immersion subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

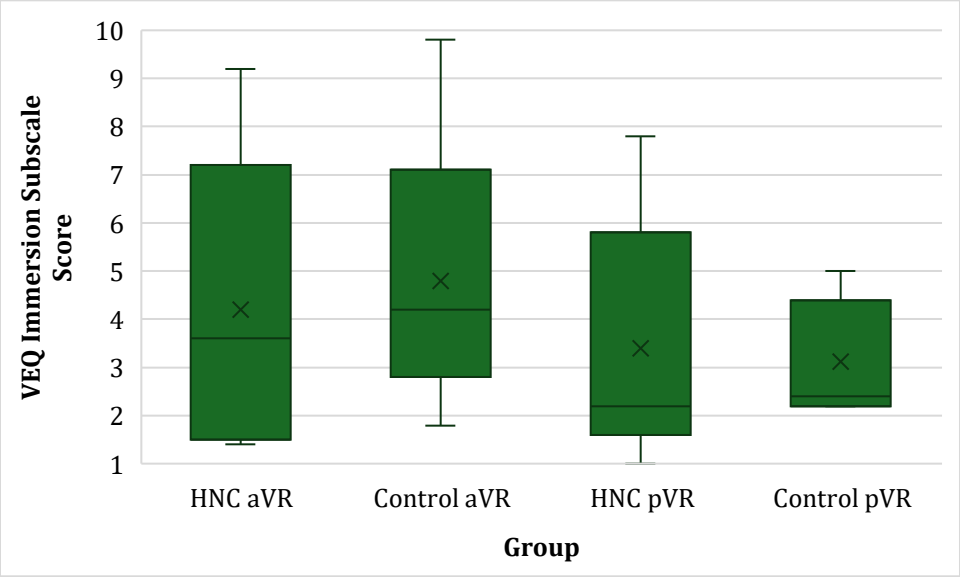


Figure 70. *Box and whisker plot of VEQ Presence subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

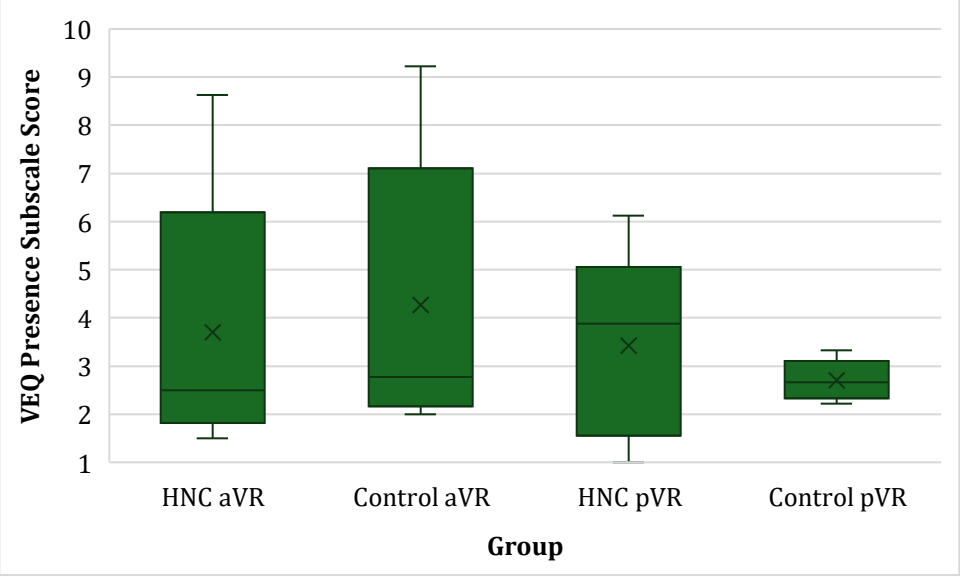


Figure 71. *Box and whisker plot of VEQ Technology Adoption subscale scores based on group.* Lower scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality

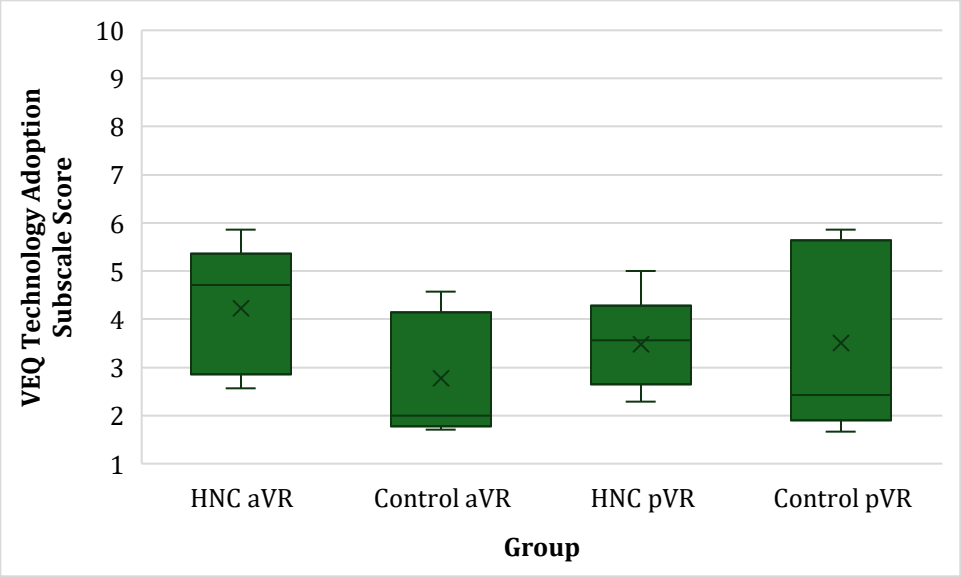


Figure 72. *Box and whisker plot of VEQ Experience consequence subscale scores based on group.* Higher scores are desired. HNC = head and neck cancer; aVR = active virtual reality; pVR = passive virtual reality