The Dissertation Committee for Susan Varghese certifies that this is the approved version of the following dissertation:

Evaluating the Feasibility of a Nurse-driven Follow-up Telephone Triage Intervention to Improve Post-treatment Outcomes in Head and Neck Cancer Patients Undergoing Chemotherapy and Radiation in the Ambulatory Setting

Committee:

Sheryl L. Bishop, PhD, Chair

M. Terese Verklan, PhD

Charlotte A. Wisnewski, PhD

Pamela J. Haylock, PhD, RN, FAAN

Kelly J. Brassil, PhD, RN, AOCNS, ACNS-BC, CNL

Dean, Graduate School

Evaluating the Feasibility of a Nurse-driven Follow-up Telephone Triage Intervention to Improve Post-treatment Outcomes in Head and Neck Cancer Patients Undergoing Chemotherapy and Radiation in the Ambulatory Setting

by

Susan Varghese, MSN, ANP-C

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Dedication

I dedicate this work to all head and neck cancer patients who bravely struggle through the symptoms and side effects of cancer and its treatment effects.

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Susan Varghese, PhD
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Supervisor: Sheryl L. Bishop

Head and neck cancers (HNCs) account for 3% to 5% of all cancers in the United States. HNC remains a considerable challenge to both patients, families and family caregivers, and healthcare providers because of persistent treatment related acute and long-term effects which interfere with the patients' basic functions such as, breathing, tasting, chewing, swallowing, and speech. Most acute symptoms are experienced during the treatment and in first eight weeks after completion of chemotherapy and radiation. Since cancer treatment is increasingly delivered in outpatient settings, patients reporting treatment related symptoms by phone has become a growing trend. To date, studies demonstrate inconclusive data about the superiority of nursing telephone interventions compared to standard of care for symptom assessment in cancer patients. Studies suggest that patients feel best supported when providers are perceived to take an active interest in their symptom experience and offer advice and coaching to support symptom relief. Telephone triage programs are broadly described as a means for follow-up and monitoring the status of patients in surgical, medical, and oncologic settings. The use of proactive triage calls for symptom assessment are well-defined in the surgical oncology populations, but less so around patients undergoing anti-neoplastic therapies.

Objective: The overall purpose of this pilot study was to explore the feasibility of a proactive nurse-driven telephone triage intervention and to evaluate whether pro-active follow-up calls during the post treatment period are beneficial to HNC patients with respect to the management of symptoms and patient satisfaction, and symptom experience of patients with HNC's receiving chemoradiation therapy in the ambulatory setting.

Methods: The study design is a single group (pre-post-test) quasi-experimental, repeated measures design that examines patient outcomes related to the use of nurse initiated weekly telephone follow-ups over 8 weeks. In this design, subjects served as their own controls.

Sample /Setting: A convenience sample of 30 subjects, male and female, meeting eligibility requirements was recruited from head and neck medical and radiation oncology services at MD Anderson Cancer Center, Houston Texas.

Results: Acceptable feasibility was defined as the completion of 70% of the nurse-driven calls. The actual completion of the calls was 92.19% [95% CI = 88.09, 94.95]. The best predictor of lower symptom management needs was the number of triage calls, after controlling for the age of the patients.

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List of Abbreviations

BCN	Breast Cancer Nurse
CORe	Clinical Oncology Research Systems
EGP	Educational group program
EPIC	Expanded Prostate Cancer Index Composite
EORTC	European Organization for Research and Treatment of Cancer
HADS	Hospital anxiety and depression
HFU	Hospital-based follow-up
HNC	Head and neck cancer
MDASI	MD Anderson Symptom Inventory
NP	Nurse Practitioner
PI	Principal Investigator
PSA	Prostate specific antigen
PSQ III	Patient Satisfaction Questionnaire III
QOL	Quality of life
RAM	Roy’s Adaptation Model
RCT	Randomized Control Trial
REDCap	Research Electronic Data Capture
SPSS	Statistical Package for Social Sciences
STAI	State Trait Anxiety Inventory
TFU	Telephone-based follow-up
UTMB	University of Texas Medical Branch

Chapter 1: Introduction

This dissertation presents the findings of a single group quasi-experimental pilot study conducted to explore the feasibility of a proactive nurse-driven telephone triage intervention for patients with head and neck cancers (HNCs) receiving chemotherapy and radiation. Chapter one presents the background of the study, the study problem, the significance, theoretical framework, specific aims, and research questions.

INTRODUCTION

Worldwide, HNC accounts for more than 550,000 cases and 380,000 deaths annually (Fitzmaurice et al., 2017). In the United States, HNC accounts for 3% of new cancer diagnoses, with approximately 63,000 Americans developing HNC and 13,000 dying from the disease annually (Siegel, Miller, & Jemal, 2017). Males are affected significantly more than females, with ratios ranging from 2:1 to 4:1. HNCs present considerable challenges to patients, families and family caregivers, and healthcare providers because of persistent acute, extended, or permanent treatment related effects, which, depending on disease site, degree of involvement (stage of disease), and treatment regimen, interfere with basic functions such as respirations, taste sensations, abilities to taste, chew and swallow foods, and speech. Persons with HNCs have specific needs that are different from those of patients diagnosed with other types of cancer. Given its visible physical nature and discernable functional difficulties, patients find it difficult, if not impossible, to conceal effects of the cancer and its treatment. These patients also must adapt to changes in speech and abilities to swallow, and appreciable changes in appearance that may cause more emotional trauma than is typically seen in patients diagnosed with other cancers (Taneja, 2013). Other side effects encountered by patients are incomprehensible speech and drooling that can cause awkwardness and can lead to low-self-esteem (Taneja, 2013) and subsequent social isolation.

Traditional aggressive treatments with surgery and chemotherapy with radiation often result in psychosocial dysfunction including fear, anxiety, depression, uncertainty, issues around role changes, employment, costs of care and insurance, and other challenges that affect individuals and families. Most prevalent toxicities include dehydration, pain, weight loss, copious secretions, aspirations, mucositis, dysphagia, loss of taste, dry mouth, hoarseness of voice due laryngeal edema, nausea, vomiting, and constipation (Argiris, Karamouzis, Raben, & Ferris, 2008; Myer, Fortin, Wang, Liu, and Bairati, 2012). Argiris et al. (2008) found that swallowing capacity and quality of life tend to improve within the first year after treatment, but are also permanently altered. Other late sequelae of chemoradiation treatment involve osteoradionecrosis, dental caries (especially if oral health is not assessed and appropriate interventions applied prior to the initiation of treatment), subcutaneous fibrosis, thyroid dysfunction, hearing loss, lymphedema, pharyngeal or esophageal stenosis, and myelitis (Argiris et al., 2008; Studer et al., 2013). Persons with HNCs have a difficult time resuming normal life after treatment and often express fear of recurrence (Humphris et al., 2003; Wells, 1998a). HNC patients are a population that has been understudied and, therefore, experience needs and challenges that are underreported in the literature.

Most of the extant literature framing this study was, in fact, drawn from studies of other types of cancer as there is a dearth of research on HCN patients specifically. HNC patients have unique needs with regards to instruction and information about their cancers, potential treatment and acute toxicities, long-term and late effects, and long-term psychosocial support and guidance (de Leeuw and Larsson, 2013). Despite the ramifications of the treatment and protracted recovery period, there is a paucity of discussion about informational and support needs of HNC patients (Fang and Heckman, 2016). A survey of 280 surgical patients designed to identify concerns relating to post-operative changes in physical appearance or speech revealed the patients were generally satisfied with their healthcare providers but voiced dissatisfaction with information provided about possible scarring, disfigurement and potential adverse effects of chemotherapy and radiation on physical appearance (Fingeret et al., 2012).

BACKGROUND OF THE STUDY

Based on recommendations by The Institute of Medicine in 2001 specifying that care should be based on a continuous healing relationship between patients, families, and providers, utilizing both in-person and *telehealth communication modalities*, and anticipatory care rather than simply reactionary to patient care needs, the employment of proactive, remote follow-up modalities have been pursued. Within the field of cancer management, treatment efficacy is not measured based on survival alone because cancer and its treatment can create physical, emotional, and psychological hardship for patients. Because nearly 25% of all cancer patients develop an affective disorder within two years of diagnosis, it is important for healthcare providers to assess both quantity and quality of life (Maguire, 1995; Taneja, 2013).

Surgery and chemotherapy with radiation have documented significant and extensive impairment, including disfigurement, speech disorders, stiffening of neck, chewing and swallowing difficulty, aspiration, anxiety, depression, and dry mouth that was so severe that patients lost the ability of enjoying food (Languis et al., 1993; Lees, 1999; Mason et al., 2016; Molassiotis & Rogers, 2012; Wells, 1998a; Wilson et al., 1991). Most acute symptoms are experienced during treatment and in first eight weeks after completion of chemotherapy and radiation (Johnson et al., 1989; Vissink et al., 2003). Few of the symptoms that were reported by the patients even at their nine-month follow-up included dry mouth, dysphagia, taste changes, and skin changes. Embarrassment was common, leading to increased social segregation. Many individuals were self-conscious about eating in front of others due to noises made while eating, such as coughing and spitting food out (Patterson et al., 2015).

Cancer care has migrated to outpatient settings for various reasons, including increased cost of hospitalizing patients for cancer treatment, the availability of infusion pumps required for chemotherapy, the effectiveness of newer medicines to minimize and control the adverse effects of treatment, and the development of targeted treatments for cancer that can be administered at home. Since cancer treatment is predominantly administered in the outpatient setting, using telephones to report symptoms or address concerns has become an accepted practice for patients and caregivers. Telephone reporting differs from face-to-face evaluation in that it is usually initiated by the patient or the family member (Flannery, McAndrews, & Stein, 2013).

In the study institution, typically throughout treatment for HNCs, symptoms are addressed and managed during weekly visits with oncologists. After treatment completion, however, HNC patients normally have little or no direct interactions with their oncologists for six to eight weeks post-discharge while struggling with management of symptoms, dehydration, or commonly at least one emergency center visit. HCN patients manage care on their own while attempting to mitigate the disruption caused by surgery and chemoradiation treatment. Thus, patient needs for information and care are not always met during the post-treatment period (Fingeret et al., 2012) and patients are often inadequately prepared for post-discharge expectations. To date, standard practice is for patients to be instructed to call existing head and neck oncology triage lines for questions or concerns.

Coolbrandt et al. (2015) used a Grounded Theory approach to explore how patients who received chemotherapy dealt with treatment related adverse effects at home, and the factors that influenced the self-management of their symptoms. Their study enrolled 28 cancer patients, which included six patients diagnosed with breast cancer, who identified that the symptom experience in the home setting is both a process and very personal. The "process" included identification of the side effects and how they handled them. At times this was either a straightforward learning process or an adaptation process. The patients' symptom experiences and symptom-management approach were based on personal factors, e.g., coping skills, and environmental factors which included information resources and healthcare providers concern and attitudes about their symptoms. Patients reported they felt best supported when providers were perceived to take an active interest in their symptom experience and offered advice and coaching to support symptom relief. This study suggests that healthcare providers should be cognizant that the symptom experiences and symptom-management techniques vary in patients, and therefore professional care should be tailored to the patient's perspective.

Since chemotherapy treatments are administered predominantly in the outpatient setting, an essential part of cancer care is to encourage patients and caregivers to have an active participation in managing treatment related or disease related symptoms McCorkle et al., 2011). Many patients who are undergoing treatment for cancer tend to face impediments in self-managing their symptoms. Lack of adequate information and guidance, difficulty in processing information, accepting that symptoms are an unavoidable part of cancer and its treatment, and hesitation to contact the providers are some of the hurdles that have been identified in previous studies (Pedersen, Koktved and Nielsen, 2012; Spichiger et al., 2012; Sun et al., 2012). Studies indicate that patients tend to underreport problems that they experience (Moore et al, 2002; Wells, 1998a). Given the extent of symptoms that patients who receive treatment for cancer experience, effective symptom management should be a priority. Yet studies indicate that patients with cancer receive insufficient symptom support (Johnsen, Petersen, Pedersen, Houmann, and Groenvold, 2013) and often feel left alone to manage their symptoms (Spichiger et al., 2012). Symptoms are often a frequent and main topic of discussion between cancer patients and their providers.

Nurse-led Follow-up

The effectiveness and efficacy of employing nurse-led follow-up has gone hand-in-hand with the development of telephone follow-up case management. Moore et al. (2002) found that patients with lung cancer (Stage I-IV) showed higher scores in patient satisfaction with nurse-led telephone follow-up compared to conventional follow-up at three months. Patient satisfaction with care was generally high at three, six, and twelve months in a nurse-led follow-up intervention. At three months, 53 of 75 (78%) patients in the nurse-led group reported a preference to nurse-led follow-up contrasted with 11 of 71 (17%) patients in the conventional follow-up who favored seeing a physician only. Significantly more patients who received nurse-led care died at home rather than a hospital or hospice, i.e., 29 of 72 (40%) versus 14 of 62 (23%) (p=0.04) for the patients who received conventional follow-up. Patients enrolled in the nurse-led follow-up group were assessed monthly over the phone or in a nurse-led clinic to assess symptoms of disease progression or serious complications.

In 2003, Cox and Wilson conducted a literature review and meta-analysis to provide an overview of work to date evaluating the impact of nurse-led services and examining the cost and demand for nurse-led patient follow-up. The authors reviewed 37 articles from 1982 to 2000 that included literature reviews, discussion papers, and evaluations of nurse-led follow-up and telephone services. The review was divided into three categories: the first category examined how and why patients required follow-up after cancer treatment; the second category reviewed studies done to evaluate the effectiveness of nurse-led follow-up in cancer sites; the third category explored the practice of nurse-led telephone follow-up primarily in cancer settings. This review validated the efficacy of nurse-led follow-up measures, convenience, and efficiency. Results indicated that nurses had been instrumental in providing patient education, symptom management, and self-care guidance (Cox & Wilson, 2003). The review also highlighted the need to explore patients' perspectives so that these follow-ups can be suited to the needs of the population (Cox & Wilson, 2003). Other studies at the time indicated that patients encounter an array of long- and short-term problems, including anxiety, depression, fear of recurrence, loneliness, change in body image, effects on personal relationships, and finances (Molassiotis et al., 2000). Thus, nurse-led telephone follow-up was validated as an appropriate and economical method to meet the needs of a large population, especially provision of support and reinforcement of patient education in post-cancer treatment settings.

In a study of head and neck oncology nurse coordinators specifically, Wiederholt, Connor, Hartig, and Harari (2007) evaluated the need and the role of head and neck oncology nurse coordinators (HNONC) in providing continuity throughout the course of care for patients and maintenance of overall quality of patient-centered HNC care. The results from this qualitative study did not provide evidence to support the success of having a HNONC to advance patient care. Although the study was largely descriptive in nature, findings reflected a positive response pertaining to co-ordination of consultations, assessment of patients' needs, providing patient education, managing symptoms, and promoting outpatient support group (Wiederholt et al., 2007).

More recently, De Leeuw and Larsson (2013) examined literature on nurse-led follow-up for cancer patients in general to evaluate the current state of practice and knowledge for future research and to make changes in clinical practice. The authors noted that outcomes of nurse-led follow-up included patient satisfaction levels equal to or slightly better than traditional physician-led follow-up (de Leeuw & Larsson, 2013). The researchers suggest that nurse-led care was less costly, relating to less laboratory blood assessments and fewer radiographic studies. No change was noted in patient satisfaction with care received, even when cancer and treatment-related pain and nutritional issues were addressed by the nurse-led group but not the physician-led group. Additionally, patients' physicians were satisfied with the timeliness of information provided by nurses (de Leeuw & Larsson, 2013).

STUDY PROBLEM

For over 20 years, experts have recommended telephone counseling to provide psycho-educational support to cancer patients and survivors (Gotay & Bottomley, 1998;

Kimman et al., 2010; Mason et al., 2013; Flannery et al., 2013; Beaver et al., 2016). Telephone triage has been extensively employed to manage and support numerous patient populations known to experience chemotherapy and radiation side effects at home (Anastasia, 2002; Groves, 2005). However, demonstrating efficacy with telephone follow-up protocols has been mixed (Coolbrandt et al., 2015; Traeger et al., 2015). It has been long documented (Giardino & Wolf, 1993) that patients often downplay their symptoms and delay seeking help because they consider their symptoms to be unavoidable outcomes of disease and treatment. Patients' responses to symptoms depend on their interpretation of the meanings of symptoms and their perception of the existence of the symptom (Giardino & Wolf, 1993, p. 3). Patients tend to report what they perceive their providers want to hear as they do not want to complain or make a fuss and are hesitant to initiate a call to a hospital-based, nurse-led telephone service to address their needs (Bostron et al., 2006). In the past, this may have been exacerbated by healthcare providers making light of patients' symptoms, occasionally suggesting that they have seen much worse (Waxler, 1980). More recent studies suggest that this reluctance to seek help may be attributable to patients' lack of confidence in which side effects warrant a telephone call and reluctance to inconvenience healthcare provider (Mooney, Beck, Friedman, & Farzanfar, 2002). Later studies have found that identifying opportunities to maximize self-management through proactive symptom support may result in decreased symptom severity, enhanced quality of life for patients, and decreased demand for acute care services (McCorkle et al., 2011).

Effective symptom management is one of the vital effects of comprehensive communication between patients, their caregivers, and physicians (D'Agostino et al., 2017;

Epstein & Street, 2007; Grant & Wiegand, 2013). Despite the significance of effective communication to help manage patients' symptoms, there is a paucity of information addressing how symptom-related problems were discussed by the healthcare providers during follow-up visits (Tang et al., 2018). Patients emphasized the significance of consistent healthcare providers' follow-up throughout various periods of their treatment (Nund et al., 2014; Ottosson et al., 2013). The need for instructions involved pain management, side effects of treatment and its effect on oral intake, daily activities, and approaches to cope with these symptoms (Larsson et al., 2003; Ottosson et al., 2013). Few studies indicate that patients who interact with their healthcare providers have a better understanding of how to manage their symptoms and report the ones that are not improving with the recommended instructions (Feber, 1996; Janjan et al., 1992; Shieh et al., 1997). Cancer patients with low health literacy level have been found to have low health-related quality of life and increased anxiety and depression (Husson, Mols, Fransen, van de Poll-Franse, & Ezendam, 2015). Health care providers are the primary source of information and should modify the information to cater to the patients' information needs, level of health literacy level, and type of symptoms that are experienced by the patients (Ousseine, et al., 2018). Clear communication and support induce patient's trust, satisfaction with care, incentive to adhere to the recommended treatment plan, which in turn improves health outcome (Street, Makoul, Arora, & Epstein, 2009).

However, to date, studies yield inconclusive results about the superiority of nursing telephone-based interventions compared to standard care for symptom assessment in cancer patients (Coolbrandt et al., 2015; Traeger et al., 2015). In a recent systematic review of literature relating to patients of all diagnoses in surgical, medical, and oncologic settings, telephone triage programs are generally described as an approach to follow-up and monitor patient status (Dickinson, Hall, Sinclair, Bond, & Murchie, 2014). While some triage programs are proactively used for follow-up, most are implemented as a way for patients to contact the healthcare provider with questions or with symptoms. Some of the most common applications for patient-initiated triage calls are to report symptoms, request refills for medications, change of appointments and assistance with insurance paper work. Patients commonly describe telephone triage as a complex and unclear phone system for the callers, lacking the ability to talk to a person directly about their concerns, and causing delays in receiving a response from the provider’s team. Rutenberg and Greenberg (2012) assert that “live” calls or real time calls increase patient satisfaction and quality of care and decrease emergency department visits and perceptions of incompetence with the triage process.

SIGNIFICANCE

HNCs account for 3% to 5% of all cancers in the United States. An estimated 53,640 people develop HNC and an estimated 11,520 deaths occur annually (NCCN, 2013). Both patients and healthcare providers struggle with the management of treatment-related symptoms and toxicities during and after treatment. Patients with HNC frequently have compromised oral intake and nutritional status at the time diagnosis, even prior to initiating treatment, as the cancer alone can cause pain, trismus, difficulty chewing and swallowing, and an increase in the risk of malnutrition (Bressan et al., 2017; Jager-Wittenaar et al., 2011). Chemoradiation and surgeries for HNC aim to improve patients’ survival, local disease control and quality of life (Dechaphunkul et al., 2013; Speksnijder et al., 2010). However, these treatments can have detrimental effects on patients' oral functions and intake (Dechaphunkul et al., 2013; Kubrak et al., 2013).

The adverse effects from HNC treatments can become late effects and may become permanent. Mucositis, oral pain, dysphagia, odynophagia, xerostomia, altered taste and smell, decreased oral intake, weight loss, dehydration, thick oral secretions, nausea, vomiting, and radiation dermatitis are some of the effects that can occur during and immediately after HNC treatment (Ganzer et al., 2015; van den Berg et al., 2014). Late symptoms include dysphagia, trismus, xerostomia, dysgeusia, neck stiffness, osteoradionecrosis, dental problems, and hypothyroidism (Rutten et al., 2011; Vissink et al., 2003). These symptoms linger long after completion of treatment, often interfering with basic daily activities. Absence of patients' gratification of tasting food, pain with chewing and swallowing food, and difficulty opening the mouth, result in slow and protracted eating time, which leads to diminished satisfaction of eating and reluctance to dine with family and friends (Ehrsson et al., 2015). Patients' social interactions during meals is compromised significantly, leading to psychological and physical issues (Ganzer et al., 2015). In some cases, patients rely on enteral feeding due to inability of maintaining adequate nutritional intake with oral feeding alone (McQuestion et al., 2011).

Using nurse-driven triage calls along with computer generated calls to administer valid and reliable symptom assessment instruments may contribute to early identification and management of symptoms in patients with severe symptoms in home settings (Sikorskii et al., 2007). Such measures engage patients, the care givers, and clinicians as collaborative partners in symptom management during cancer treatment. Further, identifying opportunities to maximize self-management through proactive symptom support may result in decreased symptom exacerbation and enhanced quality of life for patients, as well as decreased demand for acute care services.

The opportunity to meld real time interactions with remote communication technology has provided additional opportunities beyond the use of telephone-only follow up that will continue to enrich patient centered practice. Telemedicine is increasingly and successfully applied in patient care, revealing new opportunities for use of proactive telephone triage and other modalities to communicate with patients treated in ambulatory settings, identify and address symptoms early, and enhance patient interactions and engagement with healthcare providers. Proactive management of symptoms may reduce emergency center visits and unplanned hospital admissions, metrics known to relate to financial hardship and distress for patients and families, strain hospital resources, and increase healthcare costs. On the horizon are possibilities for employment of newer modalities such as social media support groups, online diaries or surveys and automatic text reminders to complete self-reporting assessments.

The use of proactive triage calls for symptom assessment has been well-defined in the surgical oncology populations, but less so for patients undergoing anti-neoplastic therapies. Thus, this study sought to integrate symptom assessment within nursing-driven proactive triage calls to address a gap in the literature about the efficacy of nurse-initiated calls and their effect on symptom severity in HNC cancer patients. While such research has been conducted using reactive triage driven by patient calls, this study utilized a novel application in its use of proactive telephone triage for symptom assessment to help support patients through, and mitigate the symptom burden of, chemotherapy and radiation in the ambulatory setting. The purpose of this study was to evaluate whether weekly follow-up calls during the first eight weeks of the post-treatment period was beneficial to patients diagnosed with HNC in the context of management of symptoms and increasing patient satisfaction.

THEORETICAL FRAMEWORK

Coolbrandt et al. (2015) found that healthcare providers' attitudes towards symptoms were of utmost importance to patients. Patients wanted assurance of their caregivers' genuine concern about their symptoms and were exceedingly grateful when their professional caregivers took the initiative to discuss their symptoms. In addition to being available for discussions, healthcare professionals exhibited true interest and care about patients' concerns by promptly addressing symptoms disclosed by patients, providing advice, coaching patients, or proposing a plan for symptom relief. Moreover, the Institute of Medicine (2001) indicated that care should be based on continuous healing relationships that anticipated patient care needs rather than being simply reactive.

The evidence above supports the use of Roy's Adaptation Model (RAM) (Roy & Andrews, 1986), that underscores the role of nurses in partnering with patients to support their adaptation to a healthy state. RAM focuses on the concept of adaptation of the person and has been contributing to nursing practice, research, education, and management by providing model-based information for the past four decades (Smith & Parker, 2015). People are constantly exposed to environmental stimuli, which elicit response and adaptation. The response that is exhibited may be an adaptive or ineffective response. Adaptation refers to "the process and outcome whereby individuals as persons or in groups use conscious awareness and choice to create human and environmental integration"

(Andrews & Roy, 1986, p. 54). Adaptive responses lead to optimal health and well-being, to improved quality of life, and to death with dignity (Roy & Andrews, 1991).

Two interrelated subsystems exist in RAM. The primary, functional, or control processes subsystems consists of the regulator and cognator. The secondary subsystem, i.e., the effector, consists of the four adaptive modes of physiological needs, self-concept, role function, and interdependence (Andrews & Roy, 1986; Meleis, 1985). Nursing's unique goal is to assist a person's adaptation effort through environmental management, which results in the attainment of an optimal level of wellness (Andrews & Roy, 1986)

The nursing RAM (Roy & Andrews, 1991) guided the design of the experimental and control treatment interventions and selection of outcome variables. RAM depicts humans as biopsychosocial beings who adapt as systems to environmental stimuli. Those stimuli are classified as focal, contextual, and residual (Table 1.1). Focal stimuli are those most immediately confronting the person, contextual stimuli are other factors that contribute to the situation, and residual stimuli are other unknown factors that may influence the situation. When the factors making up residual stimuli become known, they are reclassified as focal or contextual stimuli. Adaptation occurs in four response modes: physiologic, role function, self-concept, and interdependence (Table 1.2). The physiologic mode focuses on basic needs requisite to maintaining the physical and physiologic integrity of human beings. The self-concept mode addresses individuals' conceptions of their physical and personal selves, including emotions and moods. The role function mode is concerned with individuals' performance of activities associated with the various roles they assume in society. The interdependence model deals with development and maintenance of satisfying affectional and interpersonal relationships with significant others. Within RAM, nursing interventions involve the management of stimuli, including increasing, decreasing, removing, maintaining, or otherwise altering the relevant focal or contextual stimuli.

According to RAM, the purpose of nursing is to ensure adaptation (Figure 1.1). Promoting adaptation during health and illness enhances the interaction between the environment and the human systems and thereby improving health (Ursavas et al., 2014). The nurse's role includes maneuvering the stimuli from the environment thus enabling the patient to have positive coping with his cancer and its symptoms, which leads to adaptation. The goal of nursing is to "promote adaptation for individuals and groups in the four adaptive modes, thus contributing to health, quality of life, and dying with dignity by assessing behavior and factors that influence adaptive abilities and to enhance environmental factors" (Roy, Whetsell, and Frederickson, 2009.

Table 1.1.

Types of Stimuli

Focal Stimulus	Contextual Stimulus	Residual Stimulus
Cancer diagnosis, Chemotherapy, Radiation	Age, income, health insurance, education, stage of disease, social and financial support	Pain, fatigue, loss of appetite/taste, mouth sores, dry mouth, anxiety, fear

Table 1.2.

Modes of Adaptation

Physiological	Self-concept	Role function	Interdependence
Oxygen, Nutrition Elimination, Activity and rest	A composite of beliefs that a person has about himself, body image	Social interaction with others and his role in society	Interdependence with family and support system

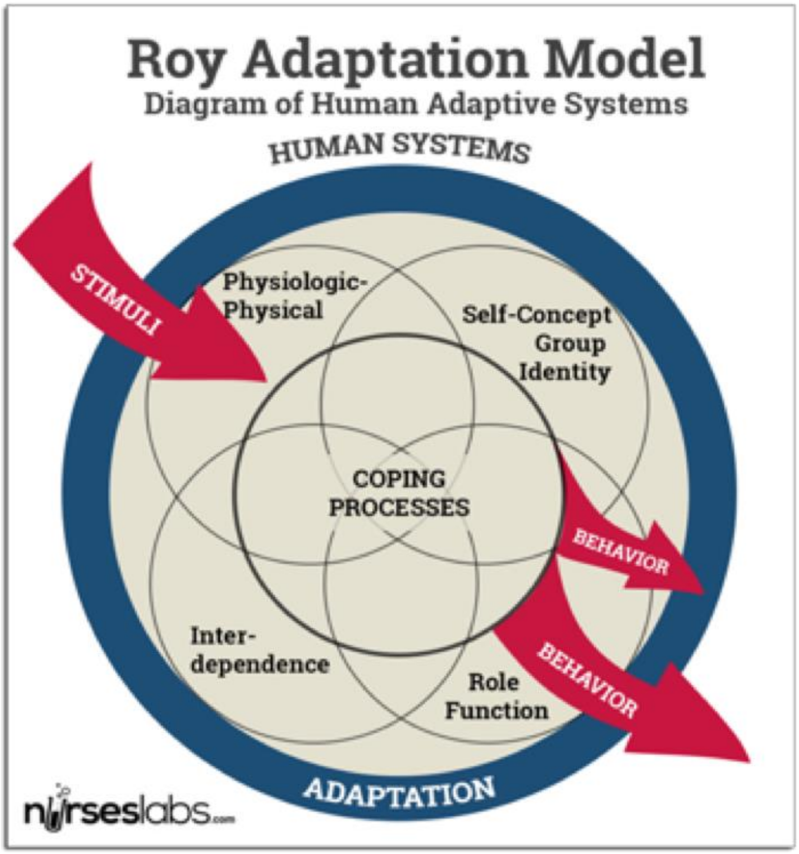


Figure 1.1. *Roy's Adaptation Model*

The study supports RAM by recognizing the various stimuli encountered by patients, assessing whether they were adapting to these new stimuli, and setting up support systems to promote adaptation.

DEFINITION OF RELEVANT TERMS

- HNCs: Cancers that occurs in the oral cavity, pharynx, oropharynx, nasopharynx, hypopharynx, larynx, paranasal sinuses, nasal cavity, and salivary glands.
- Chemotherapy: Medications that prevent cancer cells from dividing and growing, thereby killing those cells.
- Radiation: High-energy particles or waves, such as x-rays, gamma rays, electron beams, or protons, that destroy or damage cancer cells.
- Telephone triage: Trained healthcare providers speak to participants, assess their symptoms or health concerns, and offer advice.
- Provider-initiated call: Calls made by healthcare providers to assess and manage participants' problems or concerns.
- Proactive calls: Calls made by healthcare providers to assess potential problems and resolve them before participants ask for help.
- Symptom Management Support: Assessed by the number of the times the participants visited the emergency room, number of times the participants were admitted to the hospital for symptom management, and the number of times the participants called the telephone triage line for symptom support.
- Scoring Symptom Severity: The MD Anderson Symptom Inventory (MDASI) assesses the severity of the symptoms at their worst over the last 24 hours on a scale of 0 – 10 numeric rating scale, with 0 being the least and 10 being the worst.

- Symptom Burden: The grand mean of the number, severity, and interference of participants' symptoms measured with MDASI.
- Total Symptom Management Score: Sum of the number of times the participants went to the emergency room for symptom management, the number of times the participants were admitted and the number of times the participants called the triage line for symptom management.

STUDY AIMS AND RESEARCH QUESTIONS

Primary Endpoints

The primary aim of this study was to evaluate the feasibility of completing nurse-driven telephone triage calls. Completion was defined as participants answering the call and completing the assessment. The target completion rate was set at 70%. The intervention would be declared feasible if the 90% Wald confidence interval for the completion rate was completely above or equal to 70%.

Secondary Endpoints

The main secondary endpoints were symptom experience among participants receiving the telephone intervention as measured by the MDASI, patient satisfaction, number of emergency room visits, number of hospital admissions, and combined symptom support score.

SPECIFIC AIMS

The following specific aims and relevant research questions were addressed:

Specific Aim 1: To explore the frequency of emergency room visits and hospital admissions for symptom management by participants receiving weekly telephone follow-ups after completion of treatment.

Specific Aim 2: To explore the relationship between frequency and duration of weekly telephone calls, total Symptom Management Score, symptom burden (i.e., number, severity, interference), and patient satisfaction.

RQ 2.1 What is the relationship between frequency and duration of weekly telephone calls and number, severity, and interference of participants' symptoms?

RQ 2.2 What is the relationship between frequency and duration of weekly telephone calls and patient satisfaction?

RQ 2.3 What is the relationship between frequency and duration weekly telephone calls and the total Symptom Management Score?

RQ 2.4 What is the relationship between the symptom burden, total Symptom Management Score, and patient satisfaction?

Specific Aim 3: To evaluate the impact of age, gender, duration, and frequency of weekly telephone calls on patient satisfaction, total Symptom Management Score, and number and severity of symptoms.

RQ 3.1 What are the best predictors of higher patient satisfaction: age, gender, time on call, frequency of calls, or an interaction of time and frequency?

RQ 3.2 What are the best predictors of fewer symptom management needs (i.e., total Symptom Management Score): age, gender, time on call, frequency of calls, or an interaction of time and frequency?

RQ 3.3 What are the best predictors of number of symptoms: age, gender, time on call, frequency of calls, or an interaction of time and frequency?

Specific Aim 4: To explore differences between the genders and ethnic groups on symptom burden, total Symptom Management Score, and patient satisfaction at baseline and at eight weeks (across time) when controlling for frequency and duration of weekly telephone calls, if appropriate.

RQ 4.1 Are there significant differences between genders and ethnic groups on symptom burden across pre- and post-assessments (i.e., baseline, eight weeks) when controlling for frequency and duration of weekly telephone calls, if appropriate?

RQ 4.2 Are there significant differences between genders and ethnic groups on patient satisfaction at eight weeks when controlling for frequency and duration of weekly telephone calls, if appropriate?

RQ 4.3 Are there significant differences between genders and ethnic groups on total Symptom Management Score at eight weeks when controlling for frequency and duration of weekly telephone calls, if appropriate?

Chapter 2: Literature Review

INTRODUCTION

Chapter two presents a review of literature on telephone follow-up and its advantages in the healthcare setting. HNCs affect the most visible area of the body. Chemotherapy and radiation for HNC have a profound impact on the most basic activities of daily living, such as breathing, eating, and speaking. Common treatment effects from HNC cancer are pain from mouth sores, difficulty eating and speaking, dry mouth, and, at times, airway compromise. Most of these problems occur towards the end of treatment and for about eight weeks after completion, at patient discharge. During this phase, patients struggle with poor symptom management because they lack direct interactions with and support from their healthcare providers.

INTERVENTIONS

Telephone consultation about health concerns has been used for many years and is an effective and efficient way to provide treatment and care in several settings (Stierwalt et al., 1982). During treatment, HNC patients are evaluated by the healthcare team on a regular basis and taught how to manage their symptoms and side effects. Yet due to the length of the treatment and intensity of symptoms, patients become overwhelmed and are not always able to adequately control the adverse effects caused by treatment. Conducting telephone follow-ups facilitates reinforcement of teaching, evaluates the effectiveness of treatments, monitors adverse effects, provides continuity, and increases patient satisfaction (Flannery, Phillips, & Lyons et al., 2009). Flannery et al. (2009) also asserted that telephone monitoring can prevent symptoms from becoming unmanageable, and help patients avoid unnecessary and costly visits. Many patients are unsure of when to report symptoms, are reluctant to call and “bother” their health providers, or wait until symptoms are seriously unmanageable before they seek help (Mooney et al., 2002).

Seminal studies include Wells (1998a) who used Lincoln and Guba’s (1985) naturalistic inquiry method to evaluate the experience of 12 HNC patients during recovery following completion of treatment. To obtain a clear picture of the patients’ stories, the researcher utilized a diary-interview method. Wells (1998a) used multiple methods to collect data, including in-depth interviews and diaries that allowed patients to write in their own words about the treatment and their experience. The patients were given a diary at the end of their treatment and instructed to write about events and feelings that were important to them. These patients were interviewed in their homes one month after completing treatment. The diaries provided insight into their anxieties, experiences of the treatments, and new ways of adapting to changes in tasting, chewing, swallowing and speaking in the post-treatment phase. The author used symptom cards to prompt patients to discuss symptoms that they may have failed to discuss in their interviews. Wells (1998a) indicated that one of the concerns surrounding single in-depth interviews was that sensitive issues could be raised with no opportunity for follow-up. The author indicated that these patients were given her telephone number as well as the number for standard of care triage line so that they could contact their healthcare providers by telephone or by appointment as warranted.

Study findings re-emphasized that effects of HNC treatment were pronounced when the support of the oncology team was not easily attainable. Patients were hesitant to report their symptoms because they believed other patients who were receiving treatment were entitled to have their problems addressed (Wells, 1998a). Some patients were less likely to complain about their problems because they understood them to be part of the treatment. In their diaries, patients often made light of their problems because they did not want to be an annoyance or waste the time of their healthcare providers. Some patients mentioned that it may have been beneficial if their healthcare providers followed up with them after completion of treatment (Wells, 1998a) providing evidence for the subsequent emergence of provider initiated follow up efforts later. Patients' interviews and diary entries indicated the need for emotional support and symptom management during the post-radiation period (Wells, 1998a). The study was one of the first to concluded that healthcare providers should provide an integrative follow-up approach for HNC patients, including telephone contact, practical support, and interaction with local multidisciplinary team (Wells, 1998a).

In 2008, Wells et al. conducted a similar study that compared the nature and content of support received by patients during radiation treatment in a nurse-led clinic to a traditional follow-up clinic. Twenty participants followed-up with their primary consultant (medical group) and 23 patients followed-up with a nurse specialist. No significant differences between symptoms in the nurse-led and medical groups were found. The study indicated that nurse-led clinics managed pain, oral issues, and nutritional problems more efficiently, however, scores for emotional and cognitive function were higher in the medical group even though these issues were addressed in the nurse-led clinic. Some of these nonsignificant differences in the two groups may have been due to small sample size. The study did not include patients receiving chemotherapy or explore hospital admissions and delays in treatment. Wells et al. (2008) concluded that oncology-trained nurses were suitable to handle treatment related toxicities.

Psychosocial Intervention

Two early studies with newly diagnosed HNC patients were conducted by Hammerlid et al. (1999) involving psychosocial interventions in Swedish and Norwegian patients (n = 13 in therapy group, n = 34 in control group). The study examined the feasibility and utility of different supportive approaches in this population. The first study examined the effect of long-term group psychological counselling, as led by a psychologist, for patients who were newly diagnosed with HNC. Quality of life (QOL) including psychiatric morbidity was measured for one year and was compared to a control group.

Hammerlid et al.'s (1999) second study evaluated the effect of a short psychoeducational program one year after treatment for HNC patients. The purpose of the group therapy was to provide a supportive and safe environment conducive for expressing feelings of anxiety, fear, and death. Assessment of QOL was made from the time of diagnosis until one month after the intervention. The Hospital Anxiety and Depression (HADS) scale was used, which was comprised of two scales: one for depression (seven questions) and one for depression (seven questions).

The authors concluded that QOL of the intervention groups had increased as compared to the control groups, especially regarding psychiatric morbidity, social functioning, emotional functioning, and overall quality of life (Hammerlid et al., 1999). The findings revealed that one-third of participants were classified via HADS as having possible or probable cases of major mood disorder. The participants in the group scored worse at the time of diagnosis for most of the items in both questionnaires; at one-year follow-up, however, the intervention group scored higher than the control group especially regarding emotional functioning, social functional, and overall QOL.

Both studies were pilot studies with a small sample size and some issues with non-compliance for group therapy participation. The authors maintained that HNC patients could benefit from psychosocial interventions during and after their treatment (Hammerlid et al., 1999). Similar conclusions were seen in other studies that revealed anxiety and depression were exhibited in 30–40% of patients after treatment for HNC (Boulnd, 1985; Morton et al., 1984). Depression may be associated with suicide, and Boulnd (1985) attested that a large percentage of suicides was evident in HNC patients. Farberow et al. (1971) confirmed similar findings in that cancer of the tongue and pharynx accounted for approximately 20% of the total suicides in male patients.

Radiation Intervention

Languis et al. (1993) conducted a correlational descriptive study to describe perceived eating problems, general symptoms, and general health of a group of oral and pharyngeal cancer patients to promote nursing care planning. Twenty-nine patients participated in the study (n = 20 men, n = 9 women). Patients were assigned to two groups based on whether they had received radiation treatment. Thirteen patients (group 1) had not received treatment and 16 patients (group 2) received post-radiation treatment. Both subjective and objective data were obtained from self-administered instruments and medical records.

Three questionnaires were used for the study: 1) the oral pharyngeal symptom questionnaire developed for this study, 2) the health index, and 3) demographic data. The authors concluded that patients who had completed the treatment struggled more with problems such as fatigue; poor taste; dry mouth; difficulty chewing and swallowing; mouth pain; decreased oral intake; malnutrition; and weight loss. General symptoms included shoulder and back pain; worry and anxiety; dyspnea; palpitations; nausea; vomiting; diarrhea; and constipation (Languis et al., 1993). Despite having cancer and receiving treatment, most patients perceived that their general health was good. The small sample size limits the study's generalizability; however, important information regarding patients' eating problems were identified. These findings may allow nurses to assess individual patient problems and needs and to develop a follow-up plan for these patients during and after their treatment.

Breast Cancer

Beaver, Williamson, and Chalmers (2010) conducted a randomized control trial (RCT) that compared traditional hospital follow-up with telephone follow-up by specialist breast cancer nurses (BCNs). In this study, 28 patients and four specialist BCNs were interviewed. which represented a high level of patient satisfaction in the telephone arm of the study. Telephone follow-up was reported as being convenient and relaxing because the calls were conducted in home environments rather than a busy hospital outpatient department. The relative anonymity of the telephone consultations provided an opportunity for patients to explore issues that might not have been discussed in busy hospital clinics, perhaps because patients did not feel rushed (Beaver et al., 2010). The study also demonstrated that telephone follow-up facilitated individual care that may be difficult to attain in hospital settings. Despite the convenience of telephone follow-up, some patients reported missing the connection with other patients at a hospital as well as the inability "to associate a face to the voice" via telephone conversation.

In another study, Beaver et al. (2009) compared traditional hospital follow-up (n = 183) with telephone follow-up (n = 191) by specialist nurses after patients completed treatment for breast cancer. The study included 374 women who had completed primary treatment for breast cancer and who were at a low-to-moderate risk for recurrence. This equivalence trial examined whether anxiety levels were different in the two groups. Participants in the hospital group received standard hospital follow-up and the telephone group received telephone calls from BCNs at time intervals similar to the hospital follow-up group. Both groups received mammograms per hospital policy; however, the telephone group did not receive a clinical breast examination.

A telephone intervention was developed based on information needs of breast cancer patients obtained from previous studies (Beaver et al., 2009). The outcomes measured included psychological morbidity, information needs, participant satisfaction, clinical investigations ordered, and time-to-detection of recurrent disease. Study results indicated that the group randomized to the telephone follow-up were not more anxious than the hospital group. There was no difference in the clinical tests ordered, incidence of recurrence, or time to detection of recurrence between the two groups (Beaver et al., 2009). The researchers concluded that participants were satisfied with telephone follow-up and that it was applicable for women with low risk for recurrence as well as for those with decreased mobility and transportation issues.

Patient satisfaction with the information provided was not different in the two groups at study onset; however, patient satisfaction was significantly higher for the telephone follow-up than hospital follow-up at the middle and the end of the study ($p < 0.001$). When participants were asked how helpful the interventions were in addressing their queries and concerns, the telephone follow-up group responses were more positive towards the end of the study, with a greater percentage (84%) of participants responding that it was “very helpful” (Beavers et al., 2009). The researchers maintained that the telephone follow-up was conducive to meeting the needs of these participants without any untoward physical or psychological effect. In addition, telephone follow-ups decreased the workload of busy hospital clinics (Beaver et al., 2009). Various explanations exist for the higher patient satisfaction reported toward the end of the study. The telephone follow-ups were conducted by BCNs, who may have been familiar with patients from previous appointments and treatments. The participants may have developed a rapport and become more at ease in discussing their feelings and concerns with these nurses over the course of the follow-up calls. The BCNs also have the knowledge and experience to address these concerns, thereby increasing patient satisfaction.

HNC Survival

Surviving cancer, even when at an early stage, can cause divisions between the patient’s previous self, current life adjusting to the experience of having cancer, and concerns about what the future may hold (Moore, 1999). Cancer survival is complicated by the fact that patients with HNC tend to underreport their symptoms to their clinicians (Moore et al., 2004). The symptoms associated with HNC may be intermittent to severe because this area is pivotal to various functions including speaking, swallowing, mobility of the tongue, tasting, nutrition, facial appearance, and breathing (Gellrich et al., 2002).

Moore, Chamberlain, and Khuri (2004) conducted a qualitative study utilizing semi-structured open-ended interviews with 18 HNC survivors. The purpose of this study was to document why HNC patients underreport their experiences to their clinicians. Three important themes developed from the analysis: 1) fear of addiction to pain medications, 2) hopelessness, and 3) loss of meaning in life after cancer. The authors concluded that although HNC cause significant interruptions in the lives of patients, there is a tendency to underreport problems due to the fears listed above (Moore et al., 2004). The study revealed the importance of providing a safe clinical and non-judgmental space, i.e., one that would incorporate support and counselling, so the patients can communicate their fears and concerns with clinicians and other team members. The authors assert that HCN patients continue to struggle with physical and emotional pain for several years after their treatment. In addition to identifying the hindrance to open communication, future studies that combine both quantitative and qualitative methods may be beneficial to evaluate and measure actual level of pain, anxiety, depression and their impact on QOL in this patient population.

Malmstrom et al. (2016) conducted an RCT to evaluate the effect of a nurse-led, telephone-based supportive care program on QOL. The researchers received information on the number of healthcare contacts for telephone-based care compared to conventional care for patients during post-surgery for esophageal cancer. Eighty-two patients were randomized to conventional care (n = 41) and to the interventional group (n = 41). Conventional care included a follow-up visit with the surgeon; discharge instructions on diet and weight management from a nutritionist; and post-operative exercise instructions from a physiotherapist. All patients received a follow-up telephone call one week after discharge from the nutritionist and as required based on their needs. Conventional care did not include structured information and proactive contacts. Beyond conventional care, the interventional group was visited by a nurse specialized in post-operative management prior to discharge. These patients received oral and written information on self-care during the post-operative phase and thereafter. The interventional group also received proactive telephone follow-up calls from one nurse to discuss individual needs as well as discuss and address problematic areas such as nutrition, elimination, pain, and adjustment issues. Patients in this group were also referred to other caregivers as indicated.

Two instruments were used to assess overall QOL in patients with cancer and QOL in patients specifically with esophageal or esophago-gastric cancers. Patients' experience of perceived level of information provided was measured with a third instrument. Patients were asked to record the number and type of healthcare contacts they had after discharge. Calls and assessments were conducted up to six months post-discharge. No significant differences were found between the two groups for the number of healthcare contacts, general QOL, or disease-specific QOL. At the time of discharge, the intervention group scored significantly higher than the conventional group on the received and written information scale. During the six-month assessment, the intervention group was significantly more satisfied with information on self-help. The authors concluded that the intervention group was significantly more satisfied than the control group with the information received throughout the follow-up assessment, but no difference was observed between groups on QOL. The sample included patients who had extensive surgery for esophageal cancer, which severely interferes with QOL (Malmstrom et al., 2016). Given the extent of major surgery, the chances of finding improvement in QOL in this group of patients is highly unlikely via only providing information and telephone follow-up calls. In addition to providing information, the focus of the interventions should be how to support and assist patients to live as well as possible given their limitations.

Discharge Intervention

Mistiaen et al. (2007) conducted a systematic review on discharge intervention and its effectiveness in reducing post-discharge problems for a group of adult patients discharged home from an acute care setting. Discharge support interventions are methods that aim to prevent, reduce, or solve dilemmas after discharge in order to minimize readmissions; maximize rehabilitation; and enhance functional, emotional, and social health in the post-discharge phase (Mistiaen et al., 2007). These interventions may be limited to just telephone follow-ups after discharge or may involve the use of professionals who provide services at patients' homes. Researchers reported that interventions which integrated discharge planning and support were more effective in improving discharge outcomes (Mistiaen et al., 2007). The study did not find any confirmation that discharge intervention made any difference in patients' health condition after discharge or the other medical services that the patient may have used after discharge. Educational interventions aim to equip patients with adequate knowledge to manage their care after discharge. Mistiaen et al. (2007) concluded that educational interventions can be more effective when combined with a follow-up telephone call or a home visit.

Faithfull et al. (2001) conducted a randomized control trial comparing a nurse-led follow-up to conventional care to examine whether the nurse-led method improved patients' levels of distress and satisfaction. The participants included 115 men who were treated with radiation for prostate and bladder cancer. The study compared the results of toxicity, symptoms experienced, QOL, satisfaction with care, and healthcare costs between the two groups. Self-assessment questionnaires for symptoms and QOL were completed by participants during the first week of treatment and at weeks three, six, and twelve after initiation of radiation treatment. Toxicity scores were documented before treatment and at weeks one, three, six, and twelve after start of treatment. For the nurse-led intervention group (n = 58), communication was established at the beginning of treatment and continued until 12 weeks after the treatment was initiated. The nurse-led group also received telephone calls between clinic visits. Information and advice on early identification and management symptoms were provided. The conventional care group (n = 57) received a routine medical visit that lasted for 10 minutes from the beginning of treatment and continued either weekly for patients diagnosed with bladder cancer or bi-weekly for patients diagnosed with prostate cancer throughout the course of treatment.

Results indicated that although nurse-led follow-up was unable to control the magnitude of side effects or enhance quality of life, it was useful in management of symptoms. Satisfaction with nurse-led follow-ups was greater than for standard of care follow-ups (Faithful et al., 2001). Satisfaction with nurse-led intervention was higher in all items than traditional care and costs were reduced by 31%. The reason for cost-effectiveness in the nurse-led clinic may have been because nurse-led clinics are less expensive than ones led by physicians. In addition, fewer diagnostic procedures were ordered for the group compared to the control group. It was not clear whether the intervention group had telephone follow-ups or actual clinic visits beyond visits during weeks one and twelve of treatment. Although the authors attested that nurse-led clinic provided cost benefits and that patients were more satisfied with care provided, the rationale for this finding was unclear.

Chemotherapy and Radiation Therapy

Rose-Ped et al. (2002) explored the perspectives of HNC patients who had completed chemotherapy or radiation therapy. Face-to-face interviews were conducted utilizing both open- and close-ended questions. Patients' treatment experiences were examined through questions related to cancer type, treatment administered, side effects encountered, and type of supportive care received during and after treatment. 73% of patients were not admitted during the course of their radiation therapy or chemotherapy treatment. A small percentage of patients (27%) were hospitalized for adverse effects commensurate with the treatment. The most frequent side effects reported by patients were weakness, mouth sores, pain, decreased oral intake, and dry mouth (Rose-Ped et al., 2002). The patients reported that the oral mucositis and mouth pain started as early as 2.5 weeks after initiating treatment and ended up to eight weeks after treatment began.

Recuperation time varied from two to 24 weeks, with a mean of 8.7 weeks. Oral pain was found to escalate throughout the radiation therapy and lasted even after treatment was completed (Rose-Ped et al., 2002). One patient described his problem as: "When you have a sore mouth, you are thinking about it all the time. Since it is your mouth, you speak with it, drink and eat with it, but it gets difficult . . . I stopped drinking anything but water." The authors stated that it took anywhere between 1–15 months to resume normal activities, with a mean of 5 months. All patients received supportive care which included opioids, oral rinses, mouth washes, and nutritional supplements. Twenty-nine percent of patients had feeding tubes due to decreased oral intake and weight loss (Rose-Ped et al., 2002). From the patients' perspective, the enormity of the treatment-related symptoms and its effect on quality of life underscored the need for follow-up evaluation in this group of patients at least for four weeks after completion of treatment.

Wells et al. (2008) determined that oncology trained nurses were suitable to handle treatment-related toxicities. Oncology nurses can be instrumental in evaluating, educating, and managing toxicity symptoms during and after completion of treatment. Follow-up calls to assess and talk to patients may provide insight into the disruptions and losses associated with their treatment. Intervention studies are needed to identify specific interventions that may be useful for patients while they adjust to new norms and continue to live with the side effects related to their treatment.

Endometrial Cancer

Beaver et al. (2016) conducted a multi-center, randomized, non-inferiority trial with 259 women who had completed treatment for stage 1 endometrial cancer. Participants were randomly assigned to receive traditional hospital-based follow-up (HFU; n = 130) or nurse-led telephone follow-up (TFU; n = 129). The trial was based on previous studies with nurse-led TFU for breast and colorectal cancer, which had revealed that TFU was an efficient way to address patients’ psychosocial and information needs without physical or psychological impairment (Beaver et al., 2009, 2012). Primary outcomes included psychological morbidity and patient satisfaction with information that was provided; secondary outcomes were patient satisfaction with service and timeliness, quality of life, and time to detection of recurrence (Beaver et al., 2016). The State Trait Anxiety Inventory (STAI) was used to measure psychological morbidity. QOL was measured with the European Organization for Research and Treatment of Cancer’s (EORTC) QLQ-C-30. Patients randomized to HFU received standard follow-ups according to the policy of the hospital, which was comprised of three- to four-month visits for the first two years after completion of treatment, followed by six monthly and annual visits for three to five years (Beaver et al., 2016). The hospital follow-up incorporated a physical examination and history-taking to identify signs or symptoms of recurrence. Patients randomized to the TFU arm received a call from a gynecology oncology nurse specialist at time frames consistent with that of the HFU schedule.

Beaver et al. (2016) concluded that specially trained nurses can provide telephone follow-up services for patients with stage 1 endometrial cancer. The researchers noted that TFU was not inferior to HFU, and that nurse-led TFU can supplement or substitute for doctor-led HFU without increasing patient anxiety or reducing patient satisfaction regarding information and service provided. Study limitations were that many women recruited for the TFU had a number of hospital visits in the immediate post-operative period and that their responses to some of the questions may have been biased. The authors argued that some results may have been related to carryover effects from women who may have reported on the change of appointment type rather than reporting on the telephone follow-up (Beaver et al., 2016). Seventy participants who met the inclusion criteria refused participation in TFU because they were reassured with clinical examinations conducted in the HFU. The family members of these patients also preferred that the patients continue with traditional HFU.

The study report was unclear whether the TFU group received only telephone follow-up and no hospital visits, physical examinations, or radiographic imaging throughout the time that they had TFUs (Beaver et al., 2016). It was not clear how long these participants, especially those in the TFU group, received their calls, although the authors mentioned that the TFUs reflected the frequency of the scheduled hospital follow-ups. Telephone follow-ups can be instrumental in assessing patients during immediate post-operative and post-chemotherapy and radiation therapy phases. However, TFUs alone may not be advisable for long periods of time especially in cancer patients because they require intermittent physical and radiographic examinations.

Prostate Cancer

Leahy et al. (2013) conducted a non-randomized, two cohort, comparative study that enrolled 169 men with prostate cancer. Cohort 1 was the control group (traditional medical follow-up) and recruited 83 patients with low/intermediate (n = 51) and high-risk patients (n = 32). Cohort 2 was the intervention group that had 86 patients with low-to-intermediate (n = 51) and high-risk patients (n = 35). The low-intermediate risk group was comprised of men with a Prostate Specific Antigen (PSA) of ≤ 20 (Leahy et al., 2013). Regardless of patients' enrolled cohort group, high-risk patients received conventional medical follow-up. The nurse-led intervention group received six monthly telephone consultations and PSA testing. The authors' aim was to evaluate patient satisfaction with nurse-led telephone call-ups for men with low-to-intermediate risk prostate cancer, compare patient satisfaction with medical follow-ups, and examine patient self-reported distress symptoms for low-to-intermediate risk patients receiving nurse-led follow-up or traditional medical follow-up. The nurse-led consultations were performed in accordance with evidence-based algorithms developed by medical and radiation oncologists. Patient satisfaction was measured using the Satisfaction with Consultation Scale, distress was measured utilizing the Distress thermometer, and disease-related symptoms were measured by Expanded Prostate Cancer Index Composite (EPIC) (Leahy et al., 2013).

A slightly higher patient satisfaction (p = 0.051) was found with the (cohort 2, low-to-intermediate risk) nurse-led group as compared to a similar group who received traditional physician-based follow-up (cohort 1, low-to-intermediate risk) . There was no difference in distress in the two cohorts or between the risk groups in both cohorts on any of the EPIC scales. Based on study findings, the authors concluded that nurse-led follow-up was an effective and acceptable approach to deliver care for cancer patients. A study limitation was that it was a non-randomized study and it was not powered adequately to acquire significant results. Nurse-led services involve delivery of complicated interventions that require thorough knowledge of disease conditions and treatment-associated problems and adverse effects. The nurses involved in triage roles should be knowledgeable about current evidence-based practices. Information provided by the nurses should be structured on carefully developed algorithms and pathways to provide care that is safe and tailored to the needs of each patient (Leahy et al., 2013).

Patient Satisfaction

Kimman et al. (2010) examined patient satisfaction from breast cancer patients who were enrolled in an RCT to explore cost effectiveness of nurse-led telephone follow-up for breast cancer patients (n = 299) during the first 12 months after competing cancer treatment. The participants were randomized to four different arms of follow-up: 1) hospital follow-up every three months with a mammogram at 12 months; 2) nurse-led telephone follow-up every three months, plus a hospital visit with a mammogram at 12 months; 3) arm 1 plus an educational group program (EGP); and 4) arm 2 plus EGP. The authors compared the level of patient satisfaction between the nurse-led telephone follow-up groups (arms 2 and 4) and the hospital-based follow-up groups (arms 1 and 3). A total of 162 patients were randomized to the nurse-led telephone groups and 158 participants to the traditional hospital follow-up groups. The authors used data from 149 participants who were randomized to hospital follow-up and data from 150 participants in the telephone follow-up group to assess patient satisfaction (n = 299) (Kimman et al., 2010).

Traditional follow-up in Netherlands in the first year after treatment for breast cancer is at three, six, nine and 12-months post-treatment with a physician, which normally takes 10 minutes (Kimman et al., 2010). The telephone follow-up was conducted by BCNs or nurse practitioner (NPs) at three, six, and nine months. A semi-structured interview was utilized by BCNs, which included discussions about physical and psychosocial issues, treatment-related adverse effects, compliance with hormonal treatment, and general inquiry about patients' family life and return to work. The telephone follow-up lasted between 15 to 20 minutes. The authors used Ware's Patient Satisfaction Questionnaire III (PSQ III) to evaluate patient satisfaction, which was administered at baseline, and at three, six, and 12 months after treatment (Kimman et al., 2010). In the first year after treatment, patient satisfaction scores were high in both groups in all subscales of PSQ III scores at all time points. The authors indicated that compared to the hospital follow-up group, the nurse-led telephone group had no statistically significant influence on general patient satisfaction (p = 0.379), satisfaction with technical competence (p = 0.249), or satisfaction with interpersonal aspects (p = 0.662). However patient satisfaction with access of care was significantly higher in the nurse-led telephone follow-up (p = 0.015) when compared to the hospital group (Kimman et al., 2010). The study had a protocol violation whereby 20 participants in the telephone follow-up group only received one telephone consultation, which could have affected PSQ III scores.

The authors asserted that the study echoed findings from other nurse-led telephone follow-up studies (Beaver et al., 2009; Montgomery et al., 2008), and there was increasing evidence that nurse-led telephone follow-ups were acceptable and correlated with higher patient satisfaction (Kimman et al., 2010). In addition to the telephone follow-up, there was more continuity of care since the same BCN made the call as opposed to hospital-follow-up where patients alternated follow-ups between the medical oncologist, radiation oncologist, and surgeon. The authors concluded that nurse-led telephone follow-up may be feasible and suitable for breast cancer patients in the first year after completing treatment.

Adverse Effects

Few studies exist on nursing interventions implemented to minimize or alleviate side effects from HNC treatment. Larsson (2003) conducted a literature review and located numerous studies describing adverse effects resulting from radiation therapy to the head and neck area, such as skin burns, pain, mucositis, dry mouth, poor oral intake. Larsson et al. (2003) proposed that losses were experienced at different levels in daily life due to eating problems and a lack of social interaction. Gritz et al. (1999) asserted that HNC and its treatment have been found to negatively impact patients' QOL for months and years after treatment. It is evident that HNC patients need extensive support during treatment and towards the end of treatment, when the intensity of symptoms is at its peak. Sanson-Fisher et al. (2000) found studies indicating patient dissatisfaction due to insufficient available support and inadequate information provided regarding their disease, treatment, side effects, and management. Bensinger et al. (2008) determined that when treatment-related toxicities were not addressed quickly, it can lead to hospital admissions, chemotherapy dose reductions, and treatment delays.

Patient-initiated telephone calls are different from traditional face-to-face healthcare provider assessments because the former is usually initiated by patients or family members. These calls provide an opportunity to understand how often patients report their symptoms and also which symptoms patients consider to be priorities (Flannery et al., 2013). Experienced nursing assessment and care is instrumental in early identification and management of treatment related symptoms, coordination of care, and the support of patients. Studies have shown that regular nursing assessment and support, systematic oral care, and pain management can reduce symptoms (Feber, 1996; Janjan et al., 1992).

Pilot studies conducted in a radiation oncology department have found that nurse-led review and telephone follow-ups are acceptable to patients and can improve psychosocial support, communication, education, and symptom management (James et al., 1994; Sardell et al., 2000). Assessment, education, and management of symptoms may be continued even after completion of treatment using telephone monitoring. Polinsky, Fred, and Ganz (1991) initiated a social work case management telephone program for newly diagnosed patients with breast cancer. The researchers focused on educating patients; monitoring the physical and emotional effects of cancer treatment; and providing emotional support and information. The researchers found that telephone follow-ups can be cost-efficient and effective in addressing a variety of problems.

Mason et al. (2013) evaluated the outcome of a weekly NP-managed clinic for HNC patients treated with chemoradiation. The study used a retrospective chart review to compare outcomes for patients who were managed in an NP-led clinic to those who were treated prior to initiating a weekly NP clinic. One hundred fifty-one patients were nonrandomly assigned to two groups: traditional follow-up clinic and NP-led follow-up clinic. The typical number of visits during traditional treatment was three compared to six visits after the NP-led clinic was established. The study showed that the hospitalization rate was 28% in the traditional clinic group compared to 12% in the NP-led group. Rate of chemotherapy dose reductions was 48% in the traditional group and 6% in the NP-led group. Forty-six percent of patients in the traditional clinic received the full scheduled dose of chemotherapy versus 90% of the patient seen in the NP-led clinic group.

Mason et al. (2013) concluded that the weekly clinic led by NPs' symptom management reduced hospitalization rates, chemotherapy dose reductions, and increased chemotherapy culmination rates in HNC patients receiving chemoradiation. Further, these findings may be interpreted as a reduction in cost due to fewer hospital admissions (Mason et al., 2013). Future studies to compare the cost of weekly NP-led clinic visits to hospital admissions for symptom management and patient satisfaction with these clinic visits would be warranted.

Wells et al. (2008) compared the nature and content of support HNC patients received during radiation treatment in a nurse-led clinic with a traditional follow-up clinic. Twenty participants followed-up with their primary consultant and 23 followed-up with a nurse specialist. No significant differences were found between symptoms in the nurse-led group and medical group. Wells et al.'s (2008) study indicated that the nurse-led clinics had managed pain, oral issues, and nutritional problems more efficiently. Scores for emotional and cognitive function were higher in the medical-led group even though these issues were addressed in the nurse-led clinic. Some of these differences in the two groups may also have been attributable to small sample size. The study did not include patients receiving chemotherapy or explore hospital admissions and delays in treatment. Wells et al. (2008) concluded that oncology-trained nurses were suitable to handle treatment-related toxicities.

Treatment Toxicities

The various forms of HNCs, the stages of each, and toxicities associated with the primary treatment continue to pose challenges for both patients and healthcare providers. Of all cancers, HNCs may be the most distressing form because of their complex anatomy and functioning of the area. Some of the problems encountered from cancers in this area include difficulty in swallowing, pain, impaired hearing, disequilibrium, respiratory distress, altered taste, change in voice, and facial disfigurement (Semple et al., 2008). HNC patients endure immense levels of physical and emotional anguish during and after treatment (Chen et al., 2010). Treatment involves surgery, chemotherapy, and radiation therapy, which may lead to changes in appearance; physical, social, psychological difficulties; and lifestyle changes (Semple et al., 2008). Acute side effects of radiation are often at their peak at the end of treatment and may persist or even worsen over several weeks after completion of treatment (Stone et al., 2003; Wells, 1998a). Patients experience the most severe symptoms during treatment and in the first eight weeks post-treatment. Complications include pain, mucositis, difficulty swallowing, taste changes, dry mouth, and anxiety related to the likelihood of cancer recurrence. Molassiotis and Rogers (2012) explored the experience of treatment toxicities in a three- to twelve-month timeframe following treatment. The researchers found that inadequate nutritional intake due to problems related to eating was one of the main issues affecting individuals over a long-term period.

Treatment toxicities are usually defined as acute toxicities present during treatment and for a short period after termination of treatment. Late toxicities occur for a substantial period of time after termination of treatment and may become chronic (Vissink et al., 2003). These symptoms are addressed regularly during the course of treatment; upon completion of treatment, however, patients are left to manage their symptoms alone. Inadequate management of acute mucositis, decreased oral intake, and dehydration can lead to hospitalizations in the immediate post-treatment setting. Telephone counseling provided to breast and prostate cancer patients yielded better outcomes and improved QOL (Sandgren et al., 2000; Leahy et al., 2013).

Qualitative studies have examined more specific challenges, e.g., eating, lifestyle changes, of patients with HNC after treatment (Larsson et al., 2003; McQuestion et al., 2011; Molassiotis & Rogers, 2012; Semple et al., 2008). Most qualitative studies were conducted using questionnaires or interviews at two to six months following treatment. Limited research has been conducted on telephone communication initiated by healthcare providers (e.g., doctors, nurses, NPs) to assess HNC patients, especially during the first eight weeks after completion of treatment. Wells et al. (1998b) asserted that healthcare professionals were less accessible to patients after returning home upon completion of treatment. During this time there were typically no scheduled clinic appointments with healthcare providers, but this was when the symptoms were at their peak. Lack of follow-up can lead to an increase in symptoms of poor oral intake, dehydration, and an increase in emergency room visits.

The current study aimed to contribute to evaluating acute treatment related symptoms during the first eight weeks after completion of HNC treatment. Identifying and understanding these existing problems will help to develop a tool to address these problems and improve symptom management, decrease hospitalizations, and enhance patient satisfaction.

IDENTIFICATION OF GAPS IN THE LITERATURE

Clear evidence exists that HNC patients endure extensive treatment-related adverse effects both during and after treatment. Adequate information about care and management of symptoms at home are not always provided, and patients and their caregivers are often insufficiently educated for what to expect after dismissal from treatment. Patients are simply instructed to call the triage line for questions or concerns.

There is no regularly established follow-up care or agreement about the number of follow-up appointments, or the type of tests for patients treated for HNC (Liu et al., 2012; Sasaki et al., 2011). There is insufficient evidence about the justification for frequency and duration of follow-up appointments for patients after completing treatment for HNC (Kanatas, Bala, Lowe, and Rogers; 2014). Under current practice protocols, at the institution that the study was conducted, HNC patients are dismissed home after completion of their treatment with no direct face to face encounter with their oncologist for eight weeks. During this period, they struggle with poor management of symptoms, dehydration, and at least one emergency center visit. Yet few studies have examined whether telephone communication initiated by healthcare providers to HNC patients during the first eight weeks after treatment completion will help improve symptom control and avoid ER visits due to treatment-related symptoms. Thus, the purpose of the current study was to evaluate whether proactive weekly follow-up calls in the post-treatment period would be beneficial to patients for management of symptoms and increasing patient satisfaction. The purpose of this study was to address the lack of follow-up initiated by the nurse after patients completed treatment with chemotherapy and radiation, a time during which they often experienced the most intense symptoms.

The study sought to integrate symptom assessment within nursing-driven proactive triage calls to address a gap in the literature about the efficacy of proactive nurse-initiated calls and its effect on symptom severity in cancer patients. While such research had been conducted using reactive triage driven by patient-calls, we believe this study was novel in its use of proactive telephone triage for symptom.

Chapter 3: Research Design and Methods

In chapter three, the research design, methods, sample, instruments, data collection methodology, and the statistical procedures used to analyze the data are described in detail.

DESIGN

A single group, pre-post-test, quasi-experimental, repeated measures design was used to examine patient outcomes related to the use of nurse initiated weekly telephone follow-ups over eight weeks. Participants served as their own controls. Thirty subjects who met the inclusion criteria were contacted and consented by the PI.

Study participants received a call from the PI at the beginning, middle, and end of their treatment, followed by weekly telephone calls for eight weeks when they returned home after completion of their treatment. There was no evidence to support a particular frequency or number of calls that were most beneficial to patients across various cancer types. As such, variations in call frequency were based on treatment plans, standard of care practices in each clinic, as well as clinical observations of when symptom severity appeared to be most impactful as reported by patients in the ambulatory clinics.

If calls were unanswered participants were called up to three times within 72 business hours at each call interval. Call completion was documented by the PI on the triage call template. In addition, duration of each call was documented on the triage call template. Successful completion was defined as the patient being reached by phone and completing the symptom assessment questionnaire. Reasons for unsuccessful call completions were also documented.

When participants were reached, the MDASI was reviewed and completed verbally with participants to identify symptom severity. MDASI scores of 5–6 were defined as moderate severity and scores of 7 or greater were severe; therefore, a trigger score of 5 was used to identify potential symptom distress. Patient scores of 5 or greater on one or more items were addressed and supported using a standardized triage algorithm, which included referral to the participants' primary team if further symptom management was required. All symptom follow-up was documented in the participants' electronic health records.

In addition, disease specific symptoms were addressed with the participants. Any reported symptom concerns were managed using a standard algorithm for symptom management for HNC patients based upon the Oncology Nursing Society Telephone Triage guidelines (Hickey & Newton, 2012). (Appendix A). The algorithm provides alternative measures for management of symptoms that are not controlled by current methods. All symptom scores of 5 or greater were reported to the primary medical and radiation oncologist for additional recommendations.

SAMPLE AND SETTING

A convenience sample of 30 male and female participants who met eligibility requirements were recruited from Head and Neck Medical and Radiation Oncology services at MD Anderson Cancer Center. Participants who were dispositioned to receive concurrent chemotherapy with radiation were approached by the PI prior to initiating their treatment to evaluate their interest in study participation. After discussing the purpose of the study, eligible and interested participants were consented and administered baseline measures.

Setting

Participants were enrolled from ambulatory head and neck centers at MD Anderson Cancer Center. The study paralleled a simultaneous sister study conducted in the breast and sarcoma units at MD Anderson Cancer Center. The Head and Neck Center has over 7,500 annual HNC patient visits. Nearly 2,483 new patients were seen in fiscal year 2017, of which 179 were newly diagnosed and underwent first line systemic therapy. Prior to the initiation of concurrent chemoradiation therapy, potential participants who met the inclusion criteria were identified from the medical oncologists' weekly clinic list and approached by the PI during their visit with the medical oncologist. The PI explained the purpose and method of the study to participants. They were informed of the voluntary nature of participation, confidentiality, and the right to withdraw at any time without any interruption in the care provided. If the participant agreed to participate in the study, an informed consent was obtained. Demographic data were obtained from adult subjects, ranging in age between 25 to 75 years, using a demographic questionnaire, which included age in years, sex, occupation, marital status, employment, and education. A time that was convenient for participants for weekly telephone follow-up was scheduled. The PI conducted the telephone calls from a separate patient counseling room, where there were no interruptions or possibility of the conversation being overheard. Subjects were located in the privacy of their homes. Each telephone conversation lasted for approximately 10–15 minutes.

Inclusion criteria

1. Male and female HNC patients undergoing first line concurrent chemotherapy with radiation

2. Age: 25 to 75 years
3. English speaking
4. All treatment administered at the institution

Exclusion criteria

1. Patients who had previously received chemotherapy for HNC
2. Patients who had undergone previous surgery for HNC
3. Patients who were unable to verbalize
4. Patients with metastatic disease
5. Eastern Cooperative Oncology Group (ECOG) performance status 3 or greater
6. Patients younger than 25 years or older than 75 years
7. Patients who were on immunosuppressive medications
8. Patients who were on hemodialysis for renal failure

Variable List with Definitions

SYMPTOM MANAGEMENT SUPPORT

Symptom management support was assessed through several measures: 1) number of times participants presented to the MD Anderson emergency center for symptom management; 2) number of times participants were admitted to the hospital for symptom management, each of which was tracked through a review of the electronic health record; and 3) number of times participants called the standard of care triage line for symptom support, which was tracked by existing triage nurses in each center who received and documented these calls. A total Symptom Management Score was computed from the sum of these three metrics. The symptoms or concerns with which these participants presented was obtained from medical record documentation related to each of these events and descriptively reported.

WEEKLY TELEPHONE CALLS

No evidence existed to support a particular frequency or call number that was most beneficial to patients across cancer types. As such, variations in call frequency were based on treatment plans, standard of care practices in each clinic, as well as clinical observations of when symptom severity appears to be most impactful as reported by patients in the ambulatory clinics. Both numbers of attempted and completed calls per week and duration of each call were recorded. Completion was defined as patients answering calls and completing the assessment. Completed calls were the variable of analysis for frequency of call. Duration was computed at the sum of time spent across all completed calls for the twelve-week period.

SYMPTOM BURDEN

Number, severity, interference was measured by the MD Anderson Symptom Inventory (MDASI-HN) (Appendix B). Symptom frequency, severity, and interference scores were averaged together to form a grand mean across all assessments post-discharge (Appendix B).

FEASIBILITY

Acceptability feasibility was defined as the completion of 70% of nurse-driven calls.

PATIENT SATISFACTION

Patient satisfaction was the degree to which healthcare services, products, or the manner by which services were delivered were regarded by individuals as useful, effective, or beneficial. Patient satisfaction was assessed using a modified version of the Press Ganey© patient satisfaction survey (Appendix C) at the end of their treatment and when they returned for their first follow-up visit approximately eight weeks after completion of treatment after eight weeks of telephone follow-up intervention.

GENDER

Gender was defined as male or female.

AGE

Age included measures from 25 to 75 years.

ETHNICITY

Ethnicity categories included Caucasian, African-American, Hispanic, or Asian.

TREATMENT REGIMEN (TYPE OF CHEMOTHERAPY/RADIATION)

The treatment regimen was comprised of concurrent chemotherapy with radiation over 6 to 7 weeks.

INSTRUMENT

The core MDASI was a multiple-symptom measure of the severity of cancer-related symptoms and the functional interference caused by symptoms (Cleeland et al., 2000) that was sensitive to disease and treatment changes (Cleeland et al., 2004). The instrument assessed three dimensions of cancer symptoms: 1) the *severity* of 13 core MDASI symptom items: pain, fatigue, nausea, disturbed sleep, distress (emotional), shortness of breath, lack of appetite, drowsiness, dry mouth, sadness, vomiting, difficulty remembering, and numbness or tingling; 2) the degree of *interference* in six dimensions: general activity, mood, walking ability, normal work, relations with other people, and enjoyment of life; and 3) the *occurrence* of nine symptoms relevant to HNC: mucus in the mouth and throat; difficulty swallowing or chewing; choking or coughing; difficulty with voice or speech; skin pain, burning, or rash; constipation; problems with tasting food; mouth or throat sores; and problems with teeth or gums (Appendix B). The instrument took less than 5 minutes to complete, was easily understood, and was validated in the cancer population. The MDASI was also specifically validated in a large sample of patients with breast cancer (Mendoza et al., 2013). The MDASI can be administered in several formats, including traditional "paper and pencil" format, either self-administration or research-staff interview, and electronic formats such as telephone-based interactive voice response (IVR) systems, PC tablets, and web-based applications. The coefficient alpha reliabilities in past studies were 0.88, 0.83, and 0.92 for the 13 core MDASI items, the nine HNC specific items, and the six interference items, respectively (Cleeland et al., 2000; Rosenthal et al., 2007).

Scoring Symptom Severity

The MDASI assessed the severity of symptoms at their worst during the past 24 hours on a 0–10 numeric rating scale, with 0 being "not present" and 10 being "as bad as you can imagine." A component or mean score for the MDASI symptom severity scale was obtained by taking the average of the 13 items together. A prorated total score was obtained when patients scored at least seven of the 13 items using the following formula:

(Sum of items answered) x 13 / Number of items answered

Scoring Symptom Interference

The MDASI measured how much symptoms had interfered with six daily activities: *general activity, mood, work, relations with others, walking,* and *enjoyment of life*. Interference was rated on a 0–10 numerical rating scale, 0 being “did not interfere” and 10 being “interfered completely.” The mean of the interference items was used to represent overall *symptom distress*. If more than 50% (four of six items) of the items were completed on a given administration:

(Sum of items answered) x 6 / Number of items answered (McNair et al., 1992; Ware, Jr. & Sherbourne, 1992).

When calculating any subscale score, e.g., the arithmetic mean of items in the subscale, the majority of the subscale’s items must have received responses—7 out of the 13 core symptom severity items or 4 out of the 6 interference items. If the patient responded to fewer than half of the subscale’s items, then the subscale score was considered as “missing.”

Press-Ganey© Ambulatory Oncology Survey

The Press Ganey Outpatient Oncology Survey© was a 40-item survey administered to patients receiving oncology care in the ambulatory setting. The survey used a five-point Likert scale by which participants could rate their satisfaction with aspects of the care received from 1 (very poor) to 5 (very good). Outcomes from a particular organization can be benchmarked against healthcare institutions across the U.S. The results of the Ambulatory Oncology Survey were benchmarked against cancer centers within the Comprehensive Cancer Center Consortium for Quality Improvement. A subset of seven questions related to participant' personal experiences, chemotherapy, and overall experience (Appendix C) was administered to participants.

PROCEDURE

The study protocol was reviewed by the MD Anderson Psychosocial, Behavioral, and Health Services Research Committee; the MD Anderson IRB; and the UTMB IRB prior to study initiation. A daily list of patients who were scheduled to initiate concurrent chemotherapy with radiation treatment was obtained from the clinic or from the treating physicians. Eligible patients who met the pre-determined inclusion criteria were identified and approached by the PI during a clinic visit prior to initiation of treatment.

The purpose, aims of the study, and the risks associated with participation in the study were outlined in the informed consent and reviewed with potential subjects. Participants were informed of the voluntary nature of participation, confidentiality, and the right to withdraw at any time without any interruption in the care provided. Informed consent was obtained. After the participants were consented, demographic data were obtained from subjects through a demographic questionnaire (Appendix D) that included age in years, gender, ethnicity, co-morbidity, and treatment regimen. Telephone follow-up was scheduled at a time that was convenient for participants. All questions that the participants may have had were discussed and clarified. The PI was the only person conducting the telephone follow-up calls to control for rater variability. The telephone calls were made from a separate patient counseling room, where there were no interruptions or chance of the conversation being overheard. Symptom assessment questions was asked using MDASI-HN regarding problems encountered during the week, and suggestions for management of symptoms were made by the PI. Treatment recommendations and relevant referrals for physical therapy and pain management were provided by the PI, if indicated. A total of 11–12 weekly telephone follow-ups calls were made. The first 3–4 calls were made every two weeks while the patient received the treatment at the hospital; the remaining eight call were made after the participants completed the treatment and were discharged home for eight weeks to recover from the effects of their treatment. Each subject was assigned an individual identification number (ID), which was only known to the PI and professor supervising the study. All data collected were stored on the PI's personal password-protected computer located in a secure location. Data were analyzed using standard statistical methods Statistical Package for Social Sciences (SPSS) version 20.

When contacted, the PI reviewed and completed the MDASI with participants. Responses to the MDASI were reviewed to identify symptom severity. The MDASI defined scores of 5–6 as moderate severity and scores 7 or greater as severe; therefore, a trigger score of 5 was used to identify potential symptom distress. The PI addressed all symptoms with a score of 5 or greater on one or more items and supported them using a standardized triage algorithm for symptom management (Appendix A) based upon the Oncology Nursing Society Telephone Triage guidelines (Hickey & Newton, 2012). All symptom follow-up was documented in participants' electronic health records. In addition, disease specific symptoms were addressed with participants. Any reported symptom concerns were managed using a standard algorithm for symptom management specific to each study population (Appendix A), based upon the Oncology Nursing Society Telephone Triage guidelines (Hickey & Newton, 2012). The algorithm provides alternative measures for management of symptoms that are not controlled by current methods. All symptom scores of 5 or greater were reported to the primary medical and radiation oncologist for additional recommendations.

To measure patient satisfaction, a subset of the Press Ganey patient satisfaction survey (Appendix C) was administered to study participants at the midway point of their study participation and eight weeks following study completion to evaluate participants' satisfaction with their care. The modified Press Ganey Satisfaction Survey was administered in two ways to ensure completion by study participants. At the defined midpoint and study completion time points, the survey was sent electronically via the secure Research Electronic Data Capture (REDCap) program to those participants who consented to receive data from the survey electronically. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. REDCap has built-in measures to protect participants' anonymity (Harris et al., 2009). REDCap was programmed to send up to three reminders during the week the survey was to be completed. If the survey was not completed electronically, the PI contacted the participant by phone to administer the survey during the midway point of treatment and when they were seen for their first follow-up visit, eight weeks post treatment.

Participants were offered gift cards in the amount of $10 at three study time points: once at the time of enrollment after signing the consent form and completing baseline questionnaires, mid-way through treatment, and at the end of the study. The Press Ganey survey was administered at the end of eight weeks during the follow-up visit.

DATA ANALYSIS

The SPSS version 20 software was used for all data analyses. Descriptive statistics were used to determine data range, distribution, normality, and linearity of the sample. The sample characteristics were analyzed using descriptive statistics including means and percentages. If issues of heterogeneity were unresolvable, nonparametric analysis was used. Patient demographics and clinical factors (e.g., age, race, gender, ethnicity) were collected on all study participants and examined descriptively to identify potential covariates between demographic and clinical variables and response to the triage intervention. Due to small sample size, two variables (i.e., education, employment) were collapsed into fewer groupings. Employment was regrouped from four groups (i.e., unemployed, part-time, full-time, retired) to two groups (i.e., unemployed/part-time/retired; full-time) and education was re-grouped from four groups (i.e., high school, some college, completed college, graduate degree) to two groups (i.e., high school/some college, completed college/graduate degree). Significance was set at $p<.05$ for all analyses.

PRIMARY ENDPOINT

Statistical Considerations

ANALYSIS

The primary aim of the current study was to evaluate the feasibility of completing nurse- driven telephone triage calls. Completion was defined as the patient answering the call and completing the assessment, with the target completion rate set as 70%. The intervention would be declared feasible within the center if the 90% Wald confidence interval for completion rate was completely above or equal to 70%. To calculate the confidence interval, we constructed a generalized linear mixed model with only a term for intercept. This model accounted for repeated observations within participants. The antilog of the confidence interval for the intercept was the confidence interval for completion rate.

SECONDARY ENDPOINTS

The main secondary endpoints were symptom experience among participants receiving the telephone intervention as measured by the MDASI, satisfaction, number of emergency room visits, number of hospital admissions, and combined symptom support score. Information was summarized using graphical methods including box-plots and histograms, as well as summary statistics and 90% confidence intervals. The MDASI, satisfaction, emergency room visits, hospital admissions, and combined symptom support score were assessed by time points as appropriate. The data obtained aided in generating hypotheses and providing a better understanding needed to narrow the focus for a larger phase of the study.

SPECIFIC AIMS

Under practice protocols at the time of study, after completion of their treatment HNC patients were dismissed home with no direct interaction with their oncologist for eight weeks. During this time patients underwent poor management of debilitating symptoms, decreased oral intake dehydration, and at least one emergency center visit. A paucity of research had examined whether telephone communication initiated by the healthcare provider to HNC cancer patients during the first eight weeks after completion of their treatment could help improve symptom control and avoid ER visits due to treatment-related symptoms. The purpose of the current study was to evaluate whether proactive weekly follow-up calls in the post-treatment period was beneficial to the patients with respect to management of symptoms and increasing patient satisfaction.

ETHICAL CONSIDERATIONS

Ethical issues related to the study included informed consent, confidentiality of study participants, facility identification, and use of medical records. Permission to conduct the study was obtained from The University of Texas Medical Branch IRB (Appendix E) and MD Anderson Cancer Center IRB (Appendix F). Permission to use the MDASI was obtained from Dr. Charles Cleeland (Appendix G). To ensure confidentiality, the PI and an IRB-trained staff member were the only people who collected data. The purpose of the study was revealed to participants and caregivers without any form of deception. Informed consent was obtained electronically prior to data collection after participants had been informed that their participation was voluntary. The PI ensured participants that they could withdraw from the study without any interruption in their treatment or care. No digital photographs or images were taken throughout the study. The responses to the MDASI were reviewed by research team members to identify symptom severity and interference. One hundred and sixty-eight referrals were made to the primary medical or radiation oncologists for scores of 5 or greater. Of these referrals, 47 were for pain, 46 for dry mouth, 40 for decreased taste, and the remainder for mouth sores, radiation dermatitis, decreased appetite, and difficulty swallowing.

While adverse effects from participation in the study were not anticipated, it was possible that participants may have become distressed when completing surveys. Therefore, the protocol provided the option for participants reporting distress to stop study participation immediately if they felt unable to complete the surveys. These participants, as well as those who reported distress even if able to complete the surveys, would have then be referred to the primary medical team for evaluation and follow-up. Referral to the primary care team for assessment would have been documented by the PI as part of the study notes in participants' electronic health records. None of the participants withdrew from the study due to distress or any other reason.

DATA MONITORING

The protocol was monitored primarily by the PI, with reports provided to the IRB per institutional policy. All study data were kept in a locked file in the office of the PI or in a password-protected file on a secure institutional computer. No data were stored on permanent hard drives and data will be mechanically destroyed within five years after study completion. Study participants were reported, as per MD Anderson Cancer Center institutional policy, to CORe (Clinical Oncology Research Systems).

Chapter 4: Results

INTRODUCTION

The overall purpose of the pilot study was to evaluate whether follow-up calls during the post treatment period were beneficial to HNC patients with respect to management of symptoms and increasing patient satisfaction. The results are presented in 12 sections. The first section summarizes the demographic characteristics of *N*=30 participants who participated in the study. The second section addresses specific aim 1 and the subsequent 10 sections address the 10 research questions covered in the remaining specific aims.

SECTION 1: SAMPLE CHARACTERISTICS

The study was conducted over 12 months from December 20, 2016 to November 27, 2017. The overall sample consisted of a convenience sample of 30 male and female participants with HNC who were dispositioned to receive chemotherapy and radiation at MD Anderson Cancer Center.

Characteristics of Participants

Table 4.1 summarizes the demographic characteristics of the HNC participants (*N* = 30) who participated in the pilot study. The majority of the participants (*n* = 24, 80.0%) were male. They ranged in age from 39 to 71 years old (M = 58.10; SD = 9.11). The most frequent age group was 56 to 64 years (*n* = 13, 43.3%). Most of the participants (*n* = 26, 86.7%) were married. Half of the participants (*n* = 15, 50.0%) were employed full-time, while the remainder (*n* = 15, 30.0%) were employed part-time, unemployed or retired. The most frequent education levels of the participants were high school or some college (*n* =

19, 63.3%). The least frequent education levels were completed college or graduate (*n* = 11, 36.7%). The cancer stage of the vast majority of participants was defined as localized (*n* = 28, 93.3%) and remainder (*n* = 2, 8.7%) were metastatic.

SECTION 2: SPECIFIC AIM 1, SYMPTOM MANAGEMENT SUPPORT

Section two addresses specific aim 1, which was to explore the frequency of emergency room visits and hospital admissions for symptom management by participants receiving telephone follow-ups after completion of treatment. Usually the patients received chemo/radiation for about six weeks. During this time, they were followed up by the medical and radiation oncologists, dietitian, speech pathologist, and supportive care service for pain, mouth sores, poor appetite, fatigue, nausea, vomiting, difficulty swallowing, and radiation dermatitis. However, after the six weeks of treatment, the patients were discharged home for eight weeks while they recuperated from the adverse effects of the treatment. The patients returned after eight weeks for their first evaluation and CT scans by the head and neck team. The acute side effects of pain, difficulty swallowing, mouth sores, skin burn, nausea and vomiting lasted for several weeks after competition of treatment. The purpose of the study was to determine whether provider-initiated proactive follow/up telephone calls while the patients recovered were beneficial with respect to assisting with symptom management; decreased emergency room visits or hospital admissions; or improved patient satisfaction.

Table 4.1.

Demographic characteristics of participants (N = 30)

Characteristic	Category	n	%
Gender	Male	24	80.0
	Female	6	20.0
Age (Years)	≤ 55	9	30.0
	56 to 64	13	43.3
	≥ 65	8	26.7
Ethnic groups	White/Caucasian	27	90.0
	Hispanic/Latino	2	6.7
	Other	1	3.3
Marital Status	Married	26	86.7
	Divorced/Separated/Widowed	4	13. 3
Employment	Unemployed Status	3	10.0
	Part Time Employed	4	13.3
	Full Time Employed	15	60.0
	Retired	8	26.7
Highest Education Completed	High School	4	13.3
	Some college	15	15.0
	Completed college	5	5.0
	Graduate	6	6.0
Cancer stage	Localized	28	93 .3
	Metastatic	2	8.7

Figures 4.1–4.4 display frequencies of symptom management support, such as ER visits, hospital admissions, numbers and durations of calls to the triage line at each of the 12 follow-up time points. The first four calls were made during treatment starting one week after initiating treatment and then every two weeks thereafter until the six weeks of treatment were completed. Calls 5–12 were the weekly follow-up calls across the eight-

week post treatment period specifically targeted for the study. While many factors during treatment could impact symptom management support and be absent in the post treatment period such as ongoing interaction with other services such as pain management, supportive care, dietitian, medical and radiation oncologists, dentists. A comparison of during treatment and post treatment frequencies could be useful (Figure 4.1).

The total number of ER visits across the 14-week period was 17. The frequency of ER visits at each time-point ranged from 0 to 4, with the highest occurrence in the later stages during treatment. Of interest was the low number of ER visits as time progresses, suggesting that ER visits were more prevalent during and immediately after going home and diminish with time.

The total number of hospital admissions was 7 (Figure 4.2). The frequency of admissions at each time-point ranged from 0 to 2. In the case of admissions, the majority occurred during the post treatment period but at low incidence (n =1) which may reflect the same patient.

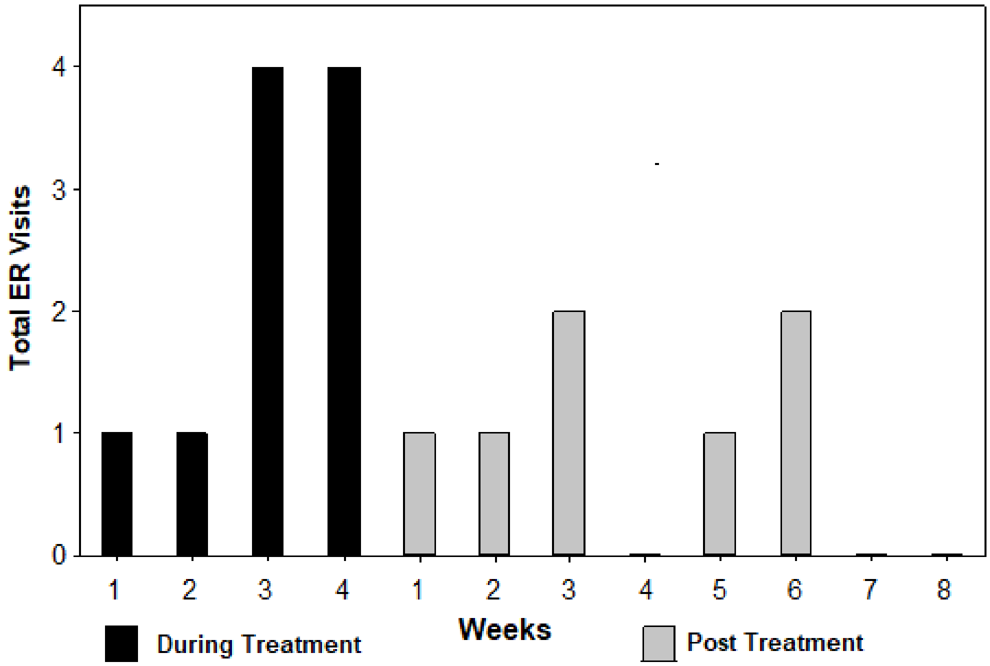


Figure 4.1. Total number of ER visits across during and post-treatment periods

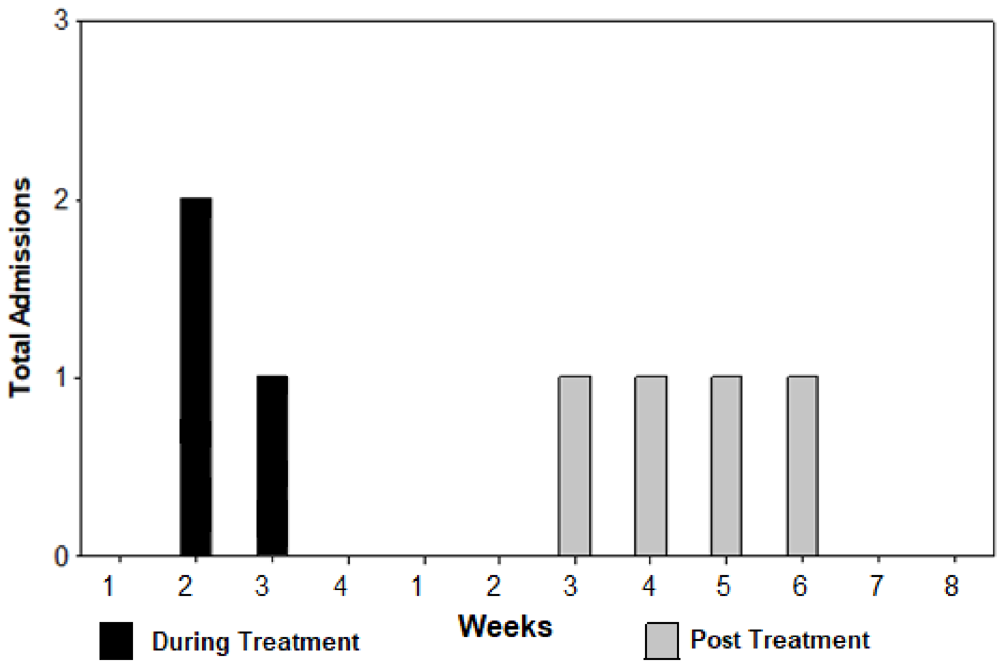


Figure 4.2. Total number of admissions across the during and post treatment periods

Acceptable feasibility was defined as the completion of 70% of the nurse-driven calls. The actual completion of the calls was 92.19% [95% CI = 88.09, 94.95). The frequency of patient-initiated triage calls at each time point ranged from 0 to 6 (Figure 4.3). The total number of patient-initiated triage calls to the standard triage call line were also documented and was 24. Of note during the final week of treatment (treatment week 4) and the first two weeks in the post treatment follow-up period (post-treatment weeks 5 and 6) there were no patient-initiated triage calls to the standard triage call line. A similar issue was evident in the last two weeks of the follow-up period (post treatment weeks 7 and 8), which was preceded by a high incidence of call responsiveness at post-treatment weeks 3, 5, and 6.

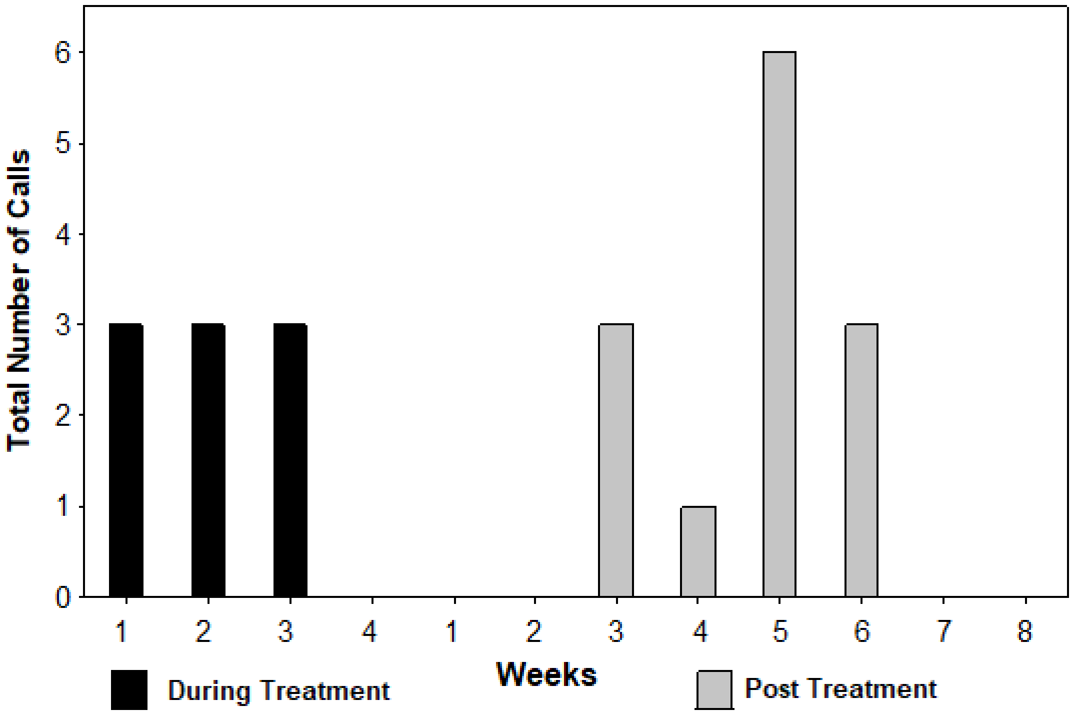


Figure 4.3. Total number of patient-initiated triage calls across the during and post treatment periods

Figure 4.4 compares the total duration of patient-initiated triage calls to the standard triage call line at each time point. The total duration of calls across the 14 weeks was 3,705 minutes. The range of duration of calls ranged from 123 to 338 minutes. With the exception of the last week of treatmentFor the weeks receiving calls, the duration of calls stayed relatively constant. The total duration of calls in weeks 1–3 during treatment ranged from 300 to 318 minutes. The total duration of calls in weeks 3–6 post-treatment ranged from 275 to 338 minutes.

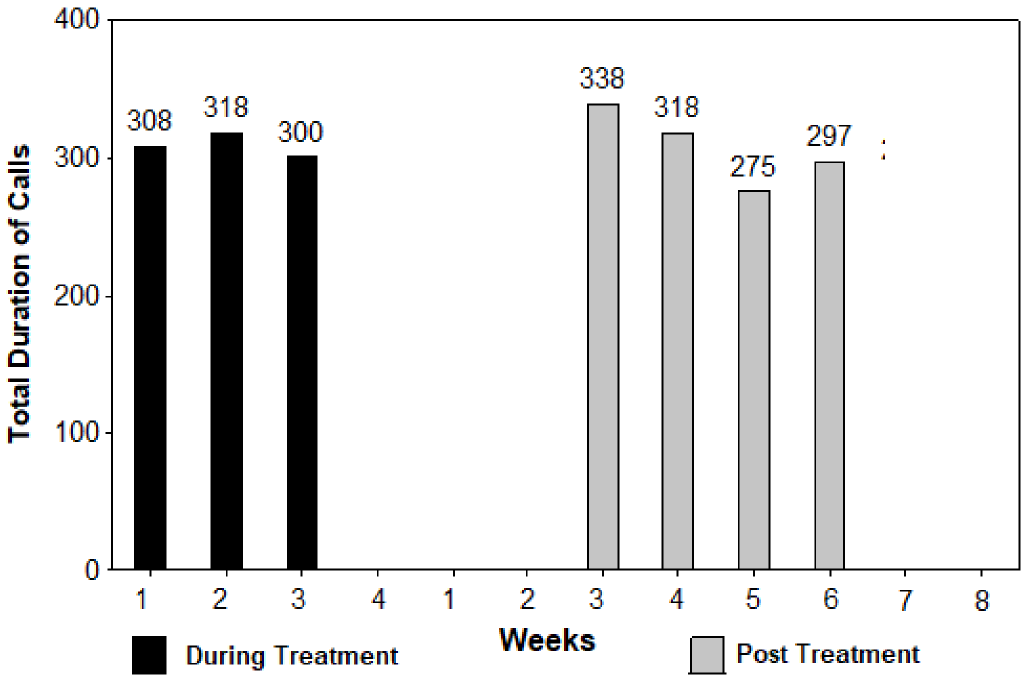


Figure 4.4. Total duration of patient-initiated triage calls across the during and post treatment periods

The following data refer only to the eight weeks post treatment period. Table 4.2 presents the descriptive statistics for the defined categories of symptom management support measured across eight weeks after treatment for *N* = 30 participants. Skewness for all variables except total ER visits was marginally significant (i.e., >+/-2.0). The median (*Mdn*) of the total number of ER visits, hospital admissions, and calls to the triage line was zero reflecting the low number of participants that required ER visits or hospitalization as well as how infrequently participants called the standard of care triage line for symptom support.

Table 4.2.

Descriptive statistics for symptom management support (N = 30 across 8 weeks post-treatment)

Symptom Management Support	Min	Max	Mdn	M	SD	Skew
Total ER visits	0	3	0	0.57	0.94	1.55
Total hospital admissions	0	2	0	0.23	0.57	2.43
Total number of calls	0	6	0	0.8	1.35	2.29
Total duration of calls	32	153	131	123.50	24.02	-2.05
Total Symptom Management Support	0	6	0	0.83	1.44	2.54

Total symptom management support was operationalized by summing across total ER visits + total hospital admissions + total number of calls. Total symptom management support had a skewed frequency distribution with a conspicuous mode (n = 17) at a score of zero, indicating that more than half of the participants (57%) had no ER visits, hospital admissions, or standard triage.

SECTION 3: SPECIFIC AIM 2, RESEARCH QUESTION 1, RELATIONSHIPS BETWEEN TELEPHONE CALLS, SYMPTOM MANAGEMENT, AND SYMPTOM BURDEN

Section 3 presents the results to explore the relationship between telephone calls (frequency and duration), total symptom management score, symptom burden (number, severity, and interference), and patient satisfaction.

Telephone Calls and Symptom Burden

Research question 2.1 was what is the relationship between frequency and duration of weekly telephone calls and number, severity, and interference of patients' symptoms? The number, severity, and interference were measured using MDASI. The symptom burden was reliably measured (Cronbach's alpha = .854).

Table 4.3 presents the descriptive statistics for the grand mean MDASI scores for number, severity, interference, and overall. There was no significant skewness and the mean and median scores were similar. The frequency distribution histograms of all MDASI scores were approximately bell shaped, reflecting normal distributions.

Table 4.3.

Descriptive statistics for MDASI scores (symptom burden)

Grand Mean MDASI Scores	Min	Max	Mdn	M	SD	Skew
Number	0.69	1.99	1.31	1.32	0.31	-0.07
Severity	0.51	1.38	1.06	1.03	0.26	-0.44
Interference	0.07	1.57	0.75	0.77	0.39	0.43
Overall	0.46	1.60	1.05	1.04	0.30	-0.16

Table 4.4 shows that there were no significant Pearson's r correlation coefficients at the .05 level between the grand mean MDASI scores and number of triage calls. The effect sizes (r^2 = .039 to .089) reflected little or no practical significance, applying the criteria of Ferguson (2009, p. 2) where $r^2 = .04$ is the absolute minimum effect size required to indicate a practically significant effect for clinical studies, whilst $r^2 = .25$ is a "moderate" effect size.

Table 4.4.

Correlations between symptom burden and number of triage calls

	Number of Triage Calls		
Grand Mean MDASI Scores	Pearson's r (N = 30)	p	r^2
Number	.198	.295	.039
Severity	.299	.108	.089
Interference	.228	.225	.051
Overall	.251	.181	.063

Table 4.5 presents the Pearson's correlation coefficients between the number, severity, interference, and overall grand mean MDASI scores and the total duration of triage calls. There were no significant correlations at the $p = .05$ level. Applying Ferguson's (2009) clinical criteria, the effect sizes ($r^2 = .027$ to $.045$) reflected little or no practical significance.

Table 4.5.

Correlations between symptom burden vs. total duration of calls

	Total Duration of Calls		
Grand Mean MDASI Scores	Pearson's r (N = 30)	p	r^2
Number	.165	.385	0.027
Severity	.213	.259	0.045
Interference	.190	.314	0.036
Overall	.197	.296	0.039

SECTION 4: SPECIFIC AIM 2, RESEARCH QUESTION 2.2, TELEPHONE CALLS AND PATIENT SATISFACTION

This section presents results addressing research question 2.2: What is the relationship between frequency and duration of weekly telephone calls and patient satisfaction? The 5-point patient satisfaction scores (ranging from 1 = very poor to 5 = very good) for seven items assessing satisfaction with personal experiences, chemotherapy, and overall clinical service were collected twice: the middle of treatment; (Cronbach's alpha = .898) and end of the treatment, eight weeks later (Cronbach's alpha = .797). Table 4.6 presents the descriptive statistics for the patient satisfaction score at baseline and the final score at the end of treatment.

There was no significant skewness and the mean and median scores were similar. The frequency distribution histograms were approximately bell shaped, reflecting normal distributions. The mean score increased from *M* = 4.57 at baseline to *M* = 4.81 at the end. A paired t-test indicated a significant difference at the .05 level between the baseline and the final score (*t* (29) = 3.20; *p* = .003) with higher satisfaction being expressed at the end of the study.

Table 4.6.

Descriptive statistics for patient satisfaction score (N = 30)

Score	Min	Max	Mdn	M	SD	Skew
Baseline Patient Satisfaction Score	3.71	5.00	4.71	4.57	0.47	-0.56
Final Patient Satisfaction Score	4.00	5.00	5.00	4.81	0.27	-1.39

Table 4.7 indicates that there were no statistically significant Pearson's *r* correlation coefficients at the.05 level between the patient satisfaction scores and the telephone calls. Ferguson's (2009) criteria for the magnitudes of effect sizes in clinical studies were applied to interpret the r^2 values where $r^2 \leq .04$ is negligible; $r^2 = .041$ is the minimum acceptable effect size to reflect practical significance, i.e., the proportion of the variance explained is large enough to be meaningful), $r^2 = .041$ to .24 is a weak effect size, reflecting limited practical significance; $r^2 = .25$ to .63 is a moderate effect size, reflecting acceptable practical significance and $r^2 \geq .64$ is a strong effect size, reflecting substantial practical significance. The r^2 values in Table 4.7 indicated that the effect sizes were of negligible or limited practical significance.

Table 4.7.

Correlations between patient satisfaction and telephone calls

	Number of Triage Calls			Total Duration of Calls		
Score	Pearson's r (N = 30)	p	r^2	Pearson's r (N = 30)	p	r^2
Baseline Patient Satisfaction	-.102	.592	.010	.201	.287	.040
Final Patient Satisfaction	-.011	.954	.000	.309	.096	.095

SECTION 5: SPECIFIC AIM 2, RESEARCH QUESTION 2.3, TELEPHONE CALLS AND SYMPTOM MANAGEMENT

This section presents the results to address research question 2.3:What is the relationship between frequency and duration weekly telephone calls and the total Symptom Management Score?

Table 4.8 indicates no significant Pearson's *r* correlations between the total symptom management scores and the number or duration of calls, with negligible effect sizes. The results indicate that higher symptom management scores were not associated with greater numbers or a greater duration of follow-up calls.

Table 4.8.

Correlations between total symptom management support and telephone calls

	Number of Triage Calls			Total Duration of Calls		
Score	Pearson's r (N = 30)	p	r^2	Pearson's r (N = 30)	p	r^2
Total Symptom Management Support	-.198	.537	.039	-.084	.794	.007

SECTION 6: SPECIFIC AIM 2, RESEARCH QUESTION 2.4, SYMPTOM BURDEN AND PATIENT SATISFACTION

Table 4.9 presents the Pearson's r correlation coefficients to address research question 2.4, which was what is the relationship between the symptom burden, total symptom management score, and patient satisfaction?

The number of symptoms, the level of interference, and the overall symptom management scores were positively correlated with the total symptom management support scores at the .05 level. However, applying Ferguson's criteria, the effect sizes (r^2 = .207 to .233) reflected limited practical significance in the context of clinical research. There were no significant correlations between symptom burden and patient satisfaction at the end of the study, with negligible effect sizes suggesting that satisfaction was determined by other factors unrelated to triage calls.

Table 4.9.

Correlations between symptom burden, total symptom management support, and patient satisfaction

	Total Symptom Management Support			Final Patient Satisfaction		
Grand Mean MDASI Scores	Pearson's r (N = 30)	p	r^2	Pearson's r (N = 30)	p	r^2
Number	.458	.011*	.210	-.088	.645	.008
Severity	.341	.091	.116	.055	.772	.003
Interference	.483	.007*	.233	.171	.366	.029
Overall	.455	.012*	.207	.059	.756	.003

Note: * Significant correlation (*p* < .05)

SECTION 7: SPECIFIC AIM 3, RESEARCH QUESTION 3.1, PREDICTORS OF PATIENT SATISFACTION

This section addresses research question 3.1: What are the best predictors of higher patient satisfaction—age, gender, time on call, frequency of calls, or an interaction of time and frequency? Table 4.10 presents the three-level hierarchical multiple linear regression model to predict Final Patient Satisfaction at the end of the treatment.

The demographic variables (age and gender) were entered in the first level to act as control variables. The number of calls and total duration of calls were entered in the second level. The interaction term (number x total duration of calls was entered in the third level. None of the predictors (other than the constants that indicated patient satisfaction when all the predictors were zero) were statistically significant (indicated by $p > .05$ for all of the unstandardized and standardized partial regression coefficients.

Table 4.11 presents the R^2 statistics, which indicated the proportion of the variance in patient satisfaction explained by the predictors at each level of the model. The R^2 statistics adjusted for the number of predictors in the model, indicated that only a small proportion (2.1% to 7.1%) of the variance was explained (Ferguson, 2009). The R^2 values did not change significantly between level 1, level 2, and level 3, as indicated by $p > .05$ for the change statistics. Therefore, none of the variables tested were predictors of patient satisfaction.

Table 4.10.

Multiple linear regression model to predict final patient satisfaction

Level	Predictors	Unstandardized Coefficients		Standardized Coefficients	t	p
		b	SE	β		
1	(Constant)	4.927	.428		11.502	<.001*
	Age	-.002	.006	-.054	-.265	.793
	Gender	-.018	.133	-.027	-.132	.896
2	(Constant)	4.605	.462		9.968	<.001*
	Age	-.005	.006	-.156	-.722	.477
	Gender	-.014	.130	-.022	-.108	.915
	Number of Calls	-.007	.039	-.035	-.178	.860
	Total Duration of Calls	.004	.002	.363	1.823	.080
3	(Constant)	4.594	.474		9.701	<.001*
	Age	-.005	.006	-.155	-.703	.489
	Gender	-.024	.139	-.037	-.174	.863
	Number of Calls	.085	.387	.429	.219	.829
	Total Duration of Calls	.004	.002	.377	1.780	.088
	Number x Total Duration of Calls	-.001	.003	-.471	-.238	.814

Note: * Significant predictor (*p* < .05).

Table 4.11.

R^2 Statistics for model to predict patient satisfaction

		Change Statistics				
Level	Adjusted R^2	R^2 Change	F	df1	df2	p
1	-.071	.003	.036	2	27	.965
2	-.021	.117	1.662	2	25	.210
3	-.061	.002	.057	1	24	.814

SECTION 8: SPECIFIC AIM 3, RESEARCH QUESTION 3.2, PREDICTORS OF TOTAL SYMPTOM MANAGEMENT

What are the best predictors of fewer symptom management needs—age, gender, time on call, frequency of calls, or an interaction of time and frequency? Table 4.12 presents the three-level hierarchical multiple linear regression model to predict the total symptom management support score across eight weeks post-treatment. The demographic variables age and gender were entered in the first level to act as control variables. The number of calls and total duration of calls were entered in the second level. The interaction term, number x total duration of calls, was entered in the third level. Although age was a significant predictor in the first level and number of calls was a significant predictor in the second level, none of the variables were significant predictors in the third model with all variables and the interaction term included. Failure for variables previously significant in the prior iterations to be retained in the final model suggests that incorporation of the interaction term was counterproductive and may have resulted in an overfitted model given the small sample size and inclusion of five variables.

Table 4.12.

Multiple linear regression model to predict total symptom management support

		Unstandardized Coefficients		Standardized Coefficients		
Level	Predictors	b	SE	β	t	p
1	(Constant)	-2.767	2.104		-1.315	.200
	Age	.065	.029	**.411**	**2.226**	**.035***
	Gender	-.143	.653	-.041	-.220	.828
2	(Constant)	-1.218	2.034		-.599	.554
	Age	.043	.028	.270	1.539	.136
	Gender	-.248	.573	-.070	-.433	.669
	Number of Calls	.550	.172	**.515**	**3.201**	**.004***
	Total Duration of Calls	-.005	.010	-.077	-.475	.639
3	(Constant)	-.876	1.974		-.444	.661
	Age	.042	.027	.264	1.559	.132
	Gender	.052	.581	.015	.090	.929
	Number of Calls	-2.145	1.613	-2.009	-1.330	.196
	Total Duration of Calls	-.009	.010	-.156	-.958	.348
	Number x Total Duration of Calls	.020	.012	2.561	1.680	.106

Note: * Significant predictor (*p* < .05).

Table 4.13 presents the R^2 statistics, which indicated the proportion of the variance in total symptom management support explained by the predictors at each level of modeling. The R^2 statistics (adjusted for the number of predictors in the model) indicated that the R^2 changed from 12.1% in level 1, to 32.7% in level 2, and 37.3% in level 3. The change statistics indicated that the addition of number of calls in level 2 significantly increased the R^2 ($p < .05$). When applying Ferguson's (2009) criteria to interpret the values of R^2, the amount of variance explained was moderate. The failure of significant improvement through addition of the interaction term in model 3 is further support for utilizing only the four core variables included in model 2.

Table 4.13.

R^2 Statistics for model to predict total symptom management score

			Change Statistics			
Level	Adjusted R^2	R^2 Change	F	df1	df2	p
1	.121	.181	2.992	2	27	.067
2	.327	.238	5.131	2	25	.014*
3	.373	.061	2.821	1	24	.106

Note: *p <.05

Thus, the best predictor of lower symptom management needs, indicated by the largest standardized regression coefficient in level 2 (β = .515), appeared to be the number of triage calls after controlling for all other predictors in the model. Total symptom management support scores increased by .550 for every increase in the number of calls, assuming that the age, gender, and duration of call was constant reflecting a positive relationship between number of calls and total management scores such that more calls were indicative of higher symptom management support scores.

SECTION 9: SPECIFIC AIM 3, RESEARCH QUESTION 3.3, PREDICTORS OF NUMBER OF SYMPTOMS

This section addresses research question 3.3: what are the best predictors of number of symptoms—age, gender, time on call, frequency of calls, or an interaction of time and frequency? Table 4.14 presents the three-level hierarchical multiple linear regression model to predict the number of symptoms across eight weeks post-treatment. The demographic variables age and gender were entered in the first level. The number of calls and total duration of calls were entered in the second level. The interaction term number x total duration of calls was entered in the third level. The age of the participants was the only significant predictor of the number of symptoms in the first level and while reduced in significance with each subsequent addition of more predictors, remained at least marginally significant in all models.

Table 4.14.

Multiple linear regression model to predict total number of symptoms

Level	Predictors	Unstandardized Coefficients		Standardized Coefficients		
		b	SE	β	t	p
1	(Constant)	.502	.455		1.103	.280
	Age	.015	.006	**.423**	**2.298**	**.030***
	Gender	-.022	.141	-.029	-.155	.878
2	(Constant)	.516	.521		.991	.331
	Age	.013	.007	**.392**	**1.896**	**.070**
	Gender	-.025	.147	-.032	-.170	.866
	Number of Calls	.017	.044	.074	.387	.702
	Total Duration of Calls	.000	.002	.023	.121	.905
3	(Constant)	.485	.531		.914	.370
	Age	.014	.007	**.394**	**1.881**	**.072**
	Gender	-.052	.156	-.068	-.333	.742
	Number of Calls	.260	.434	1.121	.599	.555
	Total Duration of Calls	.001	.003	.056	.277	.784
	Number x Total Duration of Calls	-.002	.003	-1.063	-.563	.579

Note: * Significant predictor ($p < .05$).

The R^2 statistics in Table 4.15, adjusted for the number of predictors in the model, indicated that only a small proportion (6.1%) of the variance in the number of symptoms was explained by the age of the patients age (Ferguson, 2009). The R^2 values did not change significantly between Level 1 and Level 2, or between 2 and Level 3.

Table 4.15.

R^2 change statistics for model to predict total number of symptoms

		Change Statistics				
Level	Adjusted R^2	R^2 Change	F	df1	df2	p
1	.127	.187	3.112	2	27	.061
2	.064	.006	.089	2	25	.916
3	.038	.011	.317	1	24	.579

SECTIONS 10–12: SPECIFIC AIM 4, DIFFERENCES BETWEEN GENDERS AND ETHNIC GROUPS

The following section addresses three research questions concerning the differences between genders and ethnic groups. Unfortunately, the sample sizes in each group were very small and unbalanced. The proportion of male participants (*n* = 24, 80.0%) was four times greater than the proportion of female participants (n = 6, 20.0%). The proportion of White/Caucasian participants (*n* = 27, 90.0%) was nine times greater than the proportion of Latino/Hispanic (*n* = 2, 7.7 %) and Other racial groups (*n* = 1, 3.3%). Consequently, inferential statistics to control for frequency and duration of telephone calls such as Analysis of Variance, Analysis of Covariance were highly underpowered and thus inappropriate. A simple graphical descriptive analysis was subsequently conducted, using bar charts to compare the trends between the mean scores across the groups.

SECTION 10: SPECIFIC AIM 4, RESEARCH QUESTION 4.1, DIFFERENCES BETWEEN GENDERS AND/OR ETHNIC GROUPS ON SYMPTOM BURDENS

Research question 4.1 asked: are there differences between genders and/or ethnic groups on symptom burden (number, severity and interference)? Figure 4.5 indicates that the mean number of symptoms was highest among the male Latino group followed closely by white males and then white females and lowest among the males of other races. The lack of representation by female Latinos and females from other groups seriously limits inferences from these descriptive analyses.

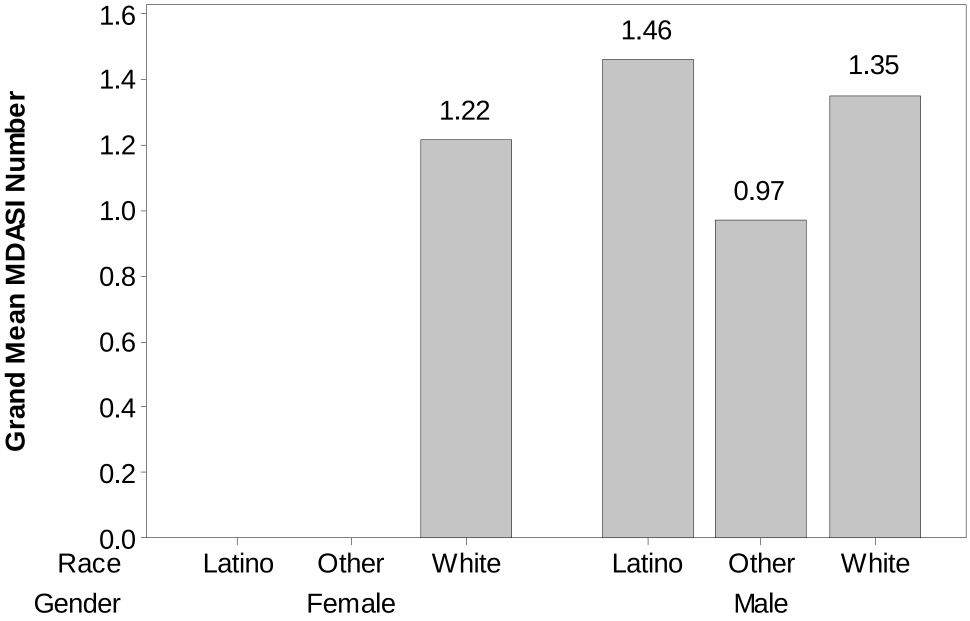


Figure 4.5. Comparison of number of symptoms by race and gender

Figure 4.6 shows that the pattern of severity of symptoms was again highest among the male Latino group followed by white males and then white females and lowest among the males of other races.

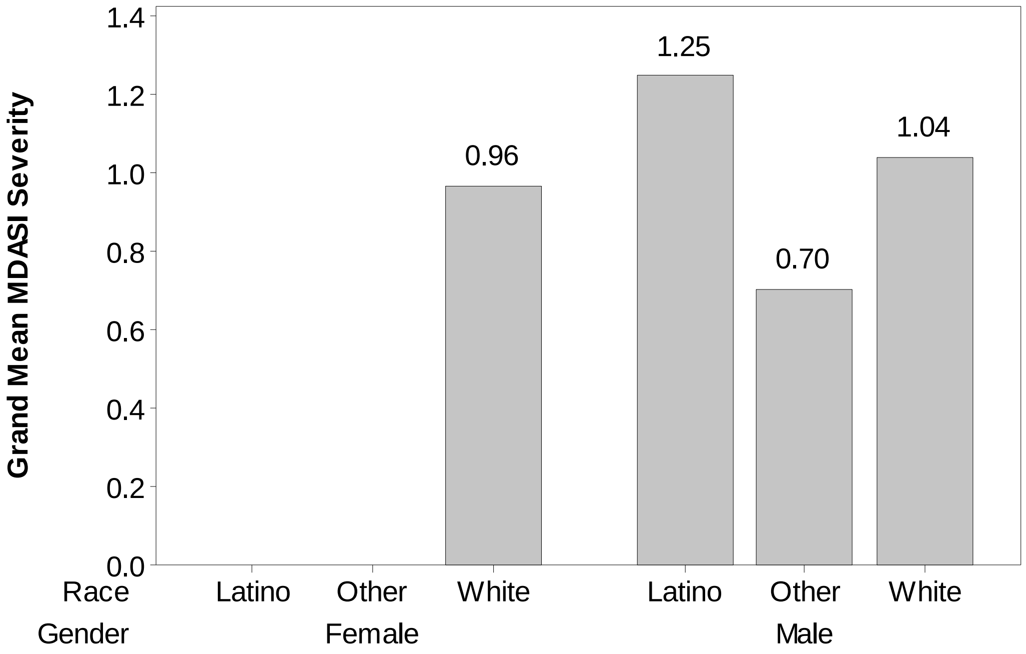


Figure 4.6. Comparison of severity of symptoms by race and gender

Figure 4.7 shows that interference was also highest among the male Latino group (*M* = 0.86) and lowest among the males of other races which was notably lower for this dimension.

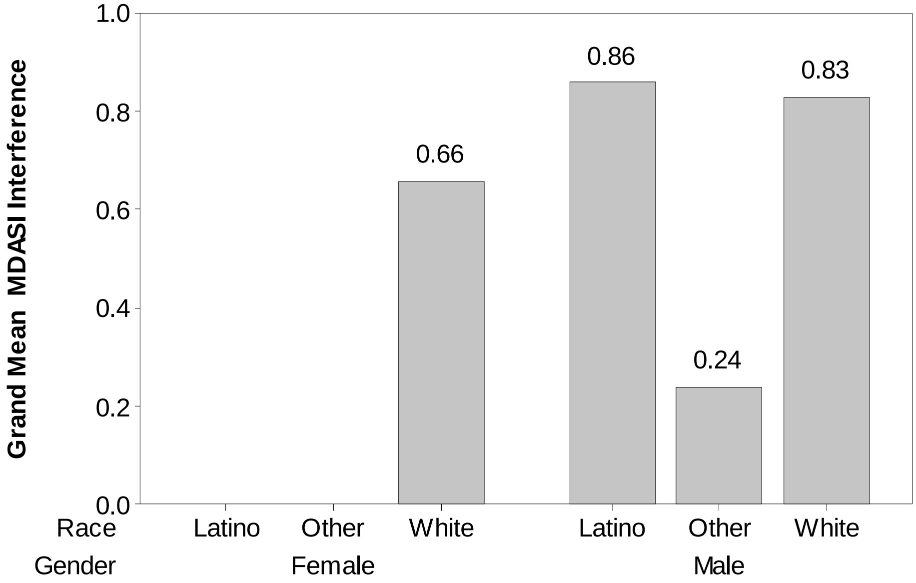


Figure 4.7. Comparison of interference by race and gender

SECTION 11: SPECIFIC AIM 4, RESEARCH QUESTION 4.2, DIFFERENCE BETWEEN GENDER AND ETHNIC GROUPS ON PATIENT SATISFACTION

Research question 4.2 was: are there differences between genders and/or ethnic groups on patient satisfaction? Figure 4.8 shows that the mean baseline patient satisfaction score was highest among the males of other races and lowest among the male Latino group. Figure 4.9 shows that the mean final patient satisfaction score eight weeks after treatment, was also highest among the males of other races and lowest among the male Latino group.

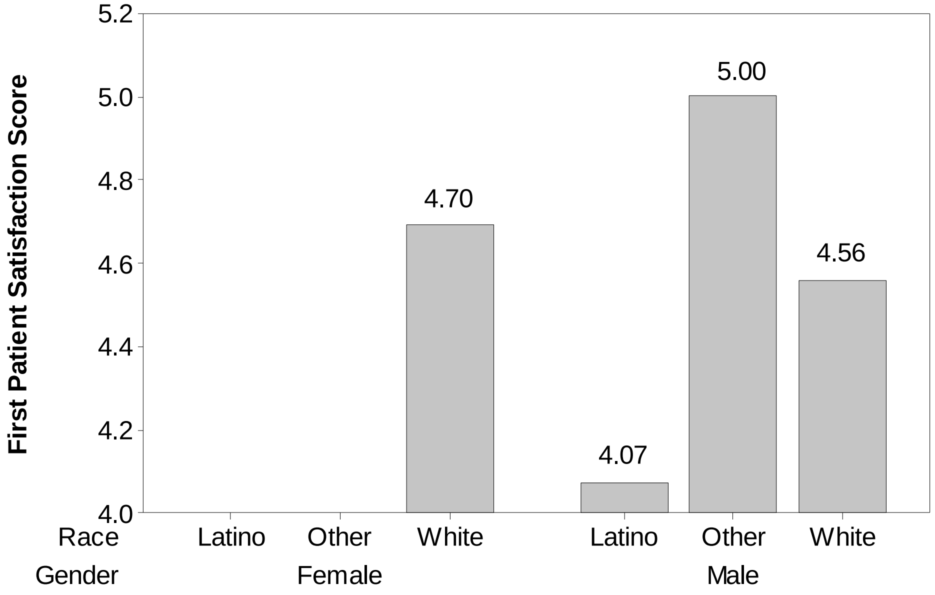


Figure 4.8. Comparison of baseline patient satisfaction score by race and gender

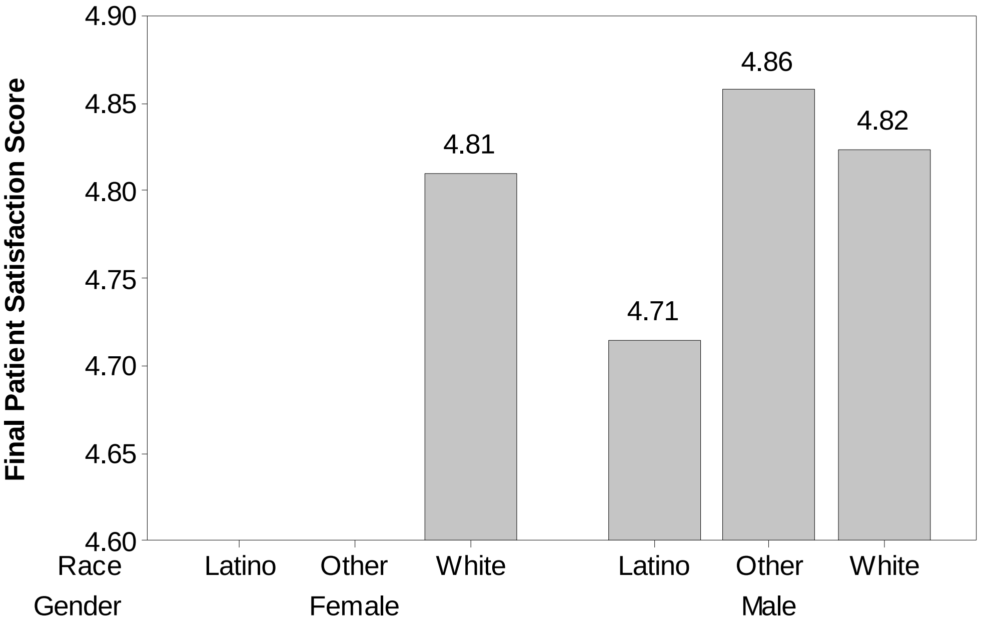


Figure 4.9. Comparison of final patient satisfaction score by race and gender

SECTION 12: SPECIFIC AIM 4, RESEARCH QUESTION 4.3: DIFFERENCE BETWEEN GENDER AND/OR ETHNIC GROUPS ON TOTAL SYMPTOM MANAGEMENT SCORES

Research question 4.3 asked: are there differences between genders and/or ethnic groups on total symptom management support? Figure 4.10 shows that the mean of the total symptom management support score was lowest among the males of other races and highest among the male White group.

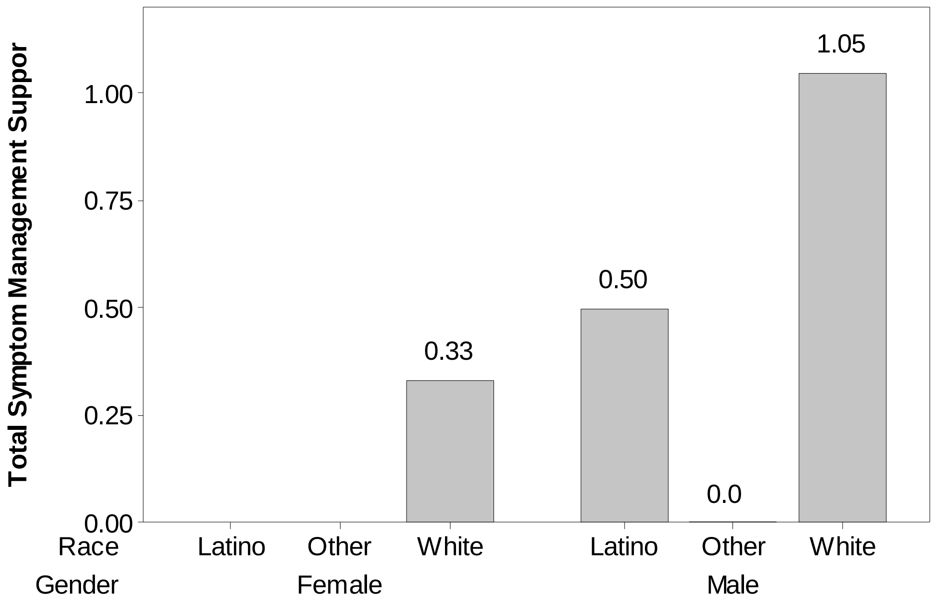


Figure 4.10. Comparison of total symptom management support by race and gender

Chapter 5: Discussion, Recommendations, and Conclusions

Chapter five consists of five sections. The first section presents a summary of the study. The second section provides a review of the methodology. The third section provides a discussion of the findings in the context of the existing literature. The fourth and fifth sections consider the implications of the findings for nursing and recommendations for future research. The chapter concludes with a discussion of the strengths and limitations of the study, followed by final conclusions.

SUMMARY

The overall purpose of this pilot study was to evaluate whether proactive follow-up calls during the post-treatment period was beneficial to HNC patients in regards to management of symptoms and patient satisfaction. Data were collected for four weeks during treatment and eight weeks after treatment. The study focused on determining whether triage calls helped patients specifically during the eight weeks after treatment, when patients were at home and managing their problems and symptoms; thus, the data analysis focused mainly on the data collected eight weeks after treatment.

The convenience sample contained a single group of *N* = 30 participants. There was no control group. The majority of the participants were male, White/Caucasian, between 56 to 64 years old, married, with a high school or some college education, and with a localized cancer stage. The frequency of emergency room visits and hospital admissions for symptom management by participants receiving telephone follow-ups after completion of treatment were described. Descriptive statistics, correlation, and regression analysis were used to address the research questions.

No statistically significant relationships were found using correlation analysis between study variables for research questions 2.1, 2.2, or 2.3. For research question 2.4, there was limited statistical evidence and weak effect sizes between the symptom burden and total symptom management support. Significant correlations were found between number of symptoms versus total symptom management support and between the overall mean MDASI scores as compared to total symptom management support. There was no statistically significant relationship between symptom burden and patient satisfaction.

The data were tested using multiple linear regression analysis to address research question 3.1. Results indicated that none of the study variables were significant contributors to patient satisfaction. Multiple linear regression analysis on research question 3.2 determined that the best predictor of lower symptom management needs, indicated by the largest significant standardized regression coefficient, was number of triage calls, after controlling for the age of the participants.

To address research question 3.3, multiple linear regression analysis indicated that younger age of the participants appeared to be the only significant predictor of fewer symptoms.

The sample size was too small to statistically test research questions 4.1, 4.2, and 4.3. Therefore, a simple graphical comparison of mean values was conducted and indicated that Latino male participants may have the greatest symptom burden, the lowest level of symptom support, and the least level of patient satisfaction. While sample distribution was too small to be generalized outside this sample for the gender x ethnic groups, the findings suggest a need for attention to gender and cultural differences in the utility of the intervention as well as needs for symptom management.

REVIEW OF METHODOLOGY

The survey methodology chosen for this study was adequate for a pilot study, otherwise known as a feasibility or vanguard study, whose primary intent is to provide results that are useful in guiding the design of more detailed future studies (Satake, 2015; Thabane et al., 2010; van Tellingen & Hundley, 2002). The validity and reliability of the survey data were ensured by administering instruments with established psychometric properties, including the MDASI to measure the construct of symptom burden. The MDASI measured the number of core symptoms based on 13 symptoms with the highest frequency in patients with various cancers, severity symptoms that assessed how severe the symptoms were in the last 24 hours, and interference symptoms that evaluated how much the symptoms interfered with the patients' lives. Patient satisfaction was assessed using a modified version of the Press Ganey patient satisfaction survey (Press Ganey Corporation, 2016). Although the survey data were assumed to be valid and reliable, the results based on this pilot study could not be generalized to provide dependable information that may be applied in future in clinical settings. Thus, data cannot be used to support evidence-based practice or make policy decisions that may ultimately affect the care, welfare, and health of HNC patients.

DISCUSSION OF RESULTS

The findings of this pilot study were broadly consistent with those of other researchers who have evaluated telephone triage programs as an approach to follow-up and monitor the status of patients in surgical, medical, and oncologic settings (Dickinson et al., 2014). Findings validated the general view that nurse-led follow-ups are accepted, convenient, and efficient (Cox & Wilson, 2003) and that triage calls are a useful way to manage and support the large number of cancer patients who experience chemotherapy and radiation side effects at home (Anastasia & Blevins, 1997; Groves, 2005).

However, the findings were unable to provide support for previous research that found clear evidence that nurse-led follow-up calls may contribute to increased patient satisfaction (de Leeuw & Larsson, 2013). This is due, in part, to the fact that patient satisfaction is a complex dynamic that is very difficult to measure accurately and precisely in practice (Berkowitz, 2016). The responses to the Press-Ganey Patient Satisfaction Survey are affected by patient characteristics such as age, sex, insurance type, encounters with specialists, and non-response bias (Tyser, Abtahi, McFadden, & Presson, 2016). Furthermore, the study was not able to find evidence for the superiority of nursing telephone interventions compared to standard of care for symptom assessment in cancer patients (Coolbrandt et al., 2015; Traeger et al., 2015). In addition, findings of this study were not able to determine the extent to which using nurse-driven triage calls contributed to early identification and management of symptoms in patients with severe symptoms in the home setting (Sikorskii et al., 2007). In both cases, the impact of the small pilot sample size limited sensitivity and analytical approaches to address comparisons, especially in Specific Aim 4. The need to collapse categories for education and employment because of underrepresentation, again driven by the small sample, was data driven and could not be anticipated prior to the study. The utilization of a larger, more robust sample in future studies will significantly mitigate these issues. The study provided information on the feasibility of proactive telephone calls during the post-treatment period to help symptom management of HNC patients, affirming that novel use of proactive telephone calls in this population will be useful in mitigating some of their symptom burden in the post-treatment period.

IMPLICATIONS FOR NURSING

The implications for nursing include the significant correlations between system burden, symptom management support, and the demographic characteristics of the patients (Table 4.9). A significant positive correlation between symptom burden and symptom management support suggests that nurses should ideally give more support to patients with a higher number of symptom needs. A significant positive correlation between age and number of symptoms (Table 4.12) reinforces the expectation that older patients may require more support than younger patients. Because the best predictor of symptom management needs appeared to be the number of triage calls after controlling for the age of the patients, the implications are that follow-up calls during the post treatment period may be beneficial to HNC patients with respect to the management of symptoms. The study provided clear evidence about the feasibility of proactive triage calls, indicating that it is imperative to have a standard protocol for nurses to make these calls proactively, and assess the patients for symptom burden and management in the post-treatment period. However, in order to truly ascertain efficacy or effectiveness of the proactive calls, the nature and extent of calls needs to be further evaluated. The extent that triage calls are aiding the management of *physical symptoms*, thereby reducing ER visits or hospital admissions depend on the nature and severity of the problems and success of the clinical management over the phone. The extent that the triage calls are addressing *psychological reassurance*, leading to reduction of ER and hospital admissions may show weaker relationship since patients experiencing severe physical symptoms will still need to utilize ER and hospital services. It will be important to understand the nature of the benefits that patients derive from this kind of intervention to effectively provide both physiological and psychological supportive care during the period following treatment.

STRENGTHS OF THE STUDY

Proactive triage calls are usually made by healthcare providers in the surgical unit to assess patients post-operatively. The strength of this pilot study was its novel use of proactive telephone triage for symptom assessment to help support HNC patients through, and mitigate the symptom burden of, chemotherapy and radiation. The study sought to integrate symptom assessment within nursing-driven proactive triage calls to address a gap in the literature for the efficacy of this modality and its effect on symptom severity in cancer patients. A strength of this pilot study was that significant statistical relationships were found that provided useful information on the feasibility of making follow-up calls during the post-treatment period to help the management of the symptoms of HNC patients.

LIMITATIONS OF THE STUDY

The most important limitation of this pilot study was the use of a non-random convenience sample with a small sample size (N = 30). Methodologists recommend that medical and healthcare researchers should ideally select a sample of random patients from the target population that is large enough to provide adequate power to conduct inferential statistics, and also to be representative of the target population in all of its essential details, e.g., age, gender, race (Omair, 2013). If patients were sampled via random sampling (e.g., systematic, stratified, cluster), then findings would have stronger external validity, meaning that they could be generalized from the sample to the target population. However, the convenience sampling method used in this study could only generate findings that were applicable to the patients within a single sample. The incidence of head and neck cancer nationally is approximately 80% in males and 20% in females, therefore a large sample size is required to have an adequate representation of each gender. The sample included 93% of the participants who had localized disease and only 7 % had metastasis to the neck based on the exclusion criteria which excluded participants with metastatic disease. Furthermore, the sample size of N = 30 was not large enough to provide sufficient statistical power to identify statistically significant differences, associations, or correlations that may have existed within the sample data (van Voorhis & Morgan, 2007; Zodpey, 2004). Coupled with some mild skewness, the limited range for many of the study variables and small sample size, use of parametric statistics (e.g., Pearson's correlations, multiple regression analysis) may have been compromised. A reanalysis using non-parametric approaches (e.g., Spearman's rank correlations) was explored and although the results did not contradict those of parametric analyses, effect sizes were marginally improved, suggesting future considerations to non-parametric approaches.

Despite its limitations, valuable descriptive information that may ultimately help to improve the care of patients can still be obtained from a simple statistical analysis of data collected in a small pilot study (Satake, 2015; van Tellingen & Hundley, 2002). Therefore, the findings of this pilot study could potentially be applied to guide and justify the design of a more extensive study in the future that will provide new information and insights about the associations between follow-up calls during the post-treatment period and the management of symptoms and satisfaction of HNC patients.

RECOMMENDATIONS FOR FUTURE RESEARCH

Having established the feasibility of employing a follow-up telephone triage for the period immediately post-treatment, the next steps would be to conduct larger, quasi-experimental studies that would have sufficient power to determine efficacy (explanatory trials) to determine whether an intervention produces the expected result under ideal circumstances or effectiveness (pragmatic trials) that measure the degree of beneficial effect under "real world" clinical settings. Since ideal conditions would be extremely difficult to construe for this population, the logical next step would be to proceed to effectiveness trials where hypotheses and study designs are formulated based on conditions of routine clinical practice and on outcomes essential for clinical decisions. Future studies will be beneficial to track the reason for failure of patients to call the triage lines during the last week of treatment and immediate post treatment weeks despite have acute symptoms. Studies to analyze MDASI scores across time may also provide insight about when the symptoms are at their peak, so that a standard protocol may be used to call the patients when they have the most severe symptoms. Patients who follow-up with their medical oncologist for symptom management, prior to their scheduled 8 weeks post-treatment follow-up should also be tracked as a covariate in triage effectiveness.

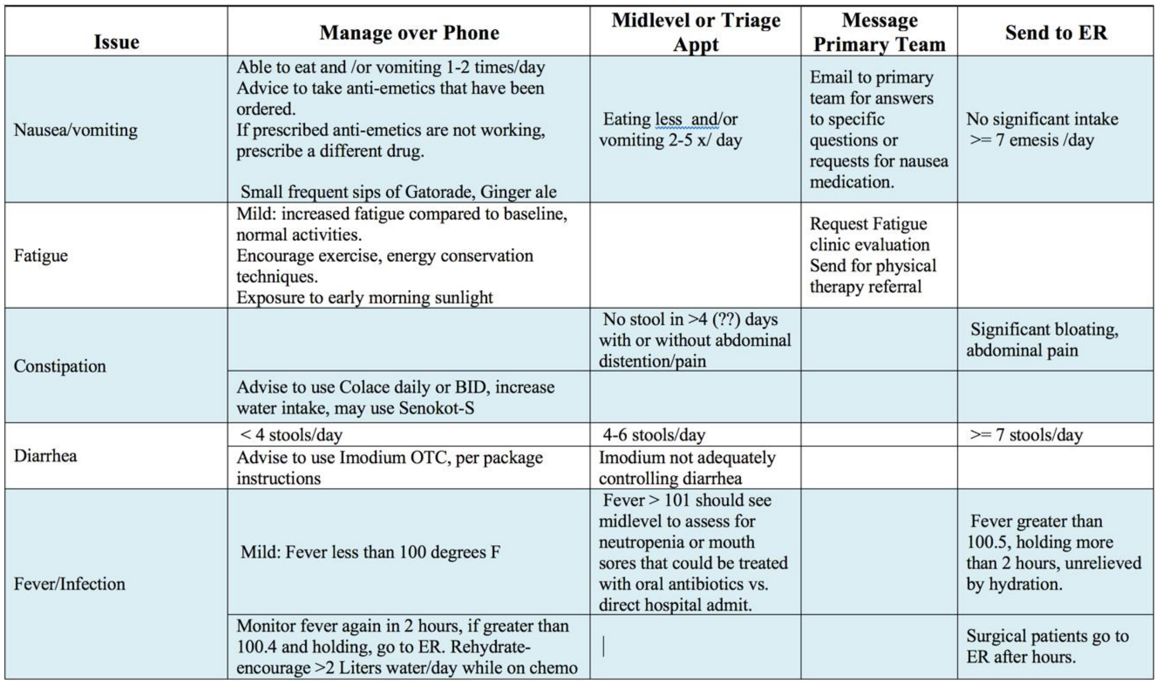
A randomized controlled trial (RCT) is the gold standard to evaluate the effects of treatments for intervention studies in medical research (Satake, 2015). A randomized controlled trial (RCT) is recommended at an appropriate point in the course of study as it is the gold standard for intervention studies in medical research (Satake, 2015). An RCT design can be used to examine the extent to which a prescribed intervention (e.g., triage calls) has a statistically and clinically significant effect on patient outcomes (e.g., symptom needs, symptom management, patient satisfaction) on two randomly assigned groups of patients suffering from a specific disease (e.g., HNC). One group is exposed to the intervention (i.e., treatment group) and one group (i.e., control group) is unexposed. Randomization is used to reduce selection bias and a control group is essential so that the effects of the intervention can be evaluated when other variables remain constant. In one such example, Malmstrom et al. (2016) conducted an RCT to determine the effect of nurse-led telephone supportive care program on patients' quality of life, information received, and number of healthcare contacts after esophageal cancer surgery. At the time of discharge, the intervention group scored significantly higher than the conventional group on the received and written information scale. During the six-month assessment, the intervention group was significantly more satisfied with information on self-help. However, several preliminary issues can be addressed with smaller studies before proceeding to an RCT using adequate sample sizes determined a priori via a power analysis. First, the issue of measurement of relevant domains should be more firmly established. Patient satisfaction was assessed using a subset of Press-Ganey items that may not have been sensitive to both physiological support needs as well as psychological support needs. As discussed previously, the differences in ‘benefit’ between these two domains could have vastly different impact on outcome variables. Therefore, a consideration of sensitive measures as well as relevant outcome variables that would reflect improvements in physiological and psychological symptom management needs should be identified and validated.

Second, the issue of tracking patient-initiated calls to the standard triage call line needs to be improved to account for the time when patients did not call in during the last week of treatment and the first two post treatment period. Characterizing the underlying reasons for lack of use of triage calls despite having high symptom burden will be crucial to protocols for the intervention in subsequent studies as well as contributing to tailored support provided through the intervention. It could identify alternative or additional modalities for follow-up, such as use of text messages, login to social media messaging, online chat rooms or online diaries that patients can record their symptoms and be reviewed by clinicians within specified time frames. At the point where these intermediary issues have been clarified, an RCT design can be used to examine the extent to which triage calls have a statistically and clinically significant effect on patient outcomes, e.g., symptom needs, symptom management, patient satisfaction, on two randomly assigned groups of patients suffering from a HNC or breast cancer. Results can then be integrated into clinical practice as part of evidence-based quality improvement in patient care for this population.

CONCLUSIONS

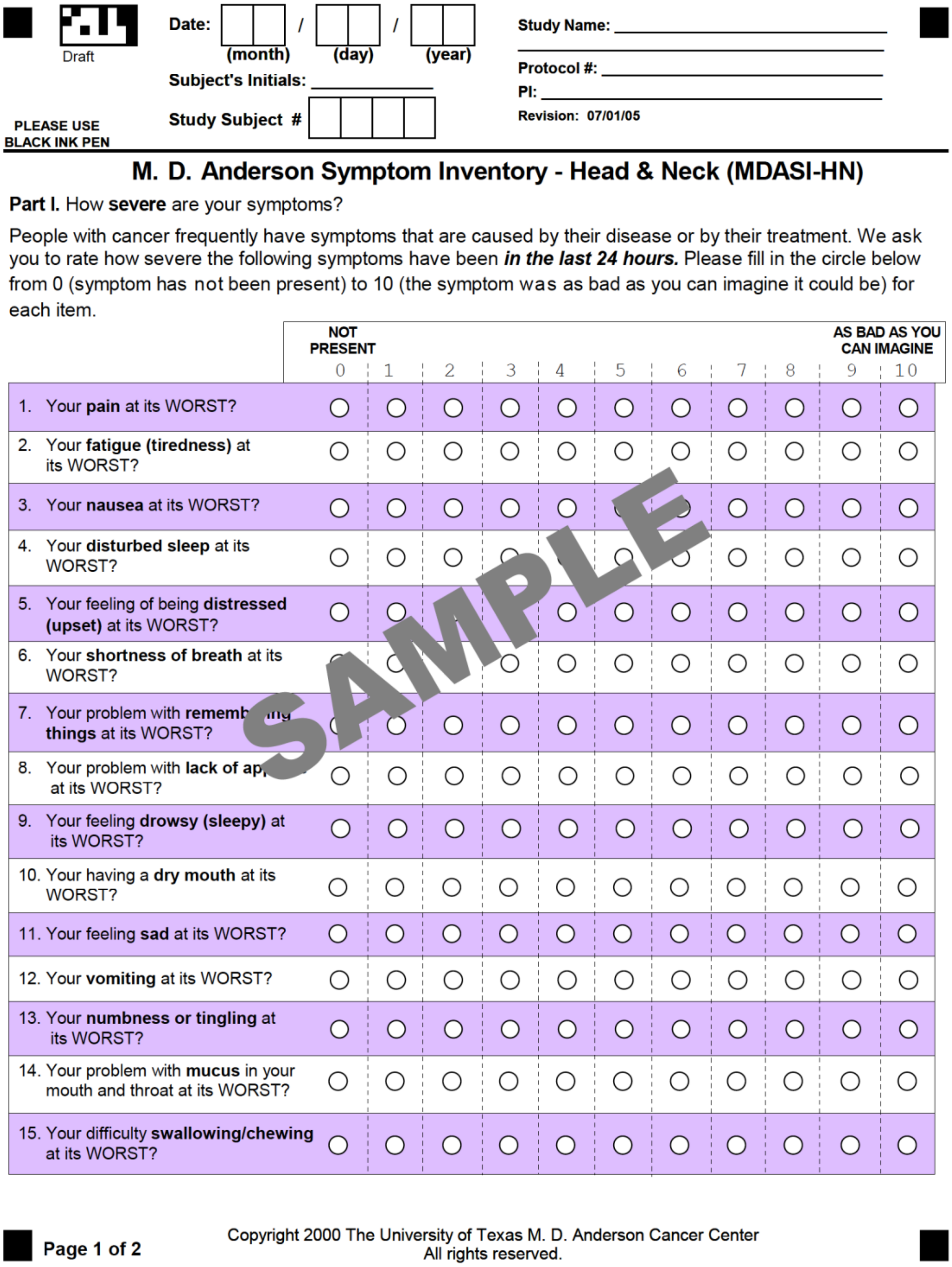
The overall purpose of the pilot study was to evaluate whether follow-up calls during the post treatment period was beneficial to HNC patients with respect to management of symptoms and increasing patient satisfaction. The study, which used a convenience sample of $N = 30$ patients, did demonstrate strong feasibility for this particular kind of intervention but did not provide evidence supporting the effectiveness or efficacy of follow-up triage calls to support evidence-based practice for all HNC patients. The limitations of this study do not devalue the appropriateness of reporting these findings, because important clinical tools typically start as ideas based on small datasets (Satake, 2015; van Tellingen & Hundley, 2002). The findings merit following-up in future studies that would address the difficulties in reaching patients during certain time frames, clarify the reasons for their unavailability, identify alternative data gathering modalities that would encourage patient utilization of the triage service and prevent loss to follow-up, and identify sensitive measures to capture both physiological and psychological benefits and appropriate outcome measures. Ultimately the goal would be to employ an RCT with more advance multivariate statistical methods to evaluate whether follow-up calls during the post-treatment period are indeed beneficial to HNC cancer patients (particularly older patients) with respect to the management of symptoms.

Appendix A: Symptom Management Algorithm



Issue	Manage over Phone	Midlevel or Triage Appt	Message Primary Team	Send to ER
Nausea/vomiting	Able to eat and /or vomiting 1-2 times/day Advice to take anti-emetics that have been ordered. If prescribed anti-emetics are not working, prescribe a different drug. Small frequent sips of Gatorade, Ginger ale	Eating less and/or vomiting 2-5 x/ day	Email to primary team for answers to specific questions or requests for nausea medication.	No significant intake >= 7 emesis /day
Fatigue	Mild: increased fatigue compared to baseline, normal activities. Encourage exercise, energy conservation techniques. Exposure to early morning sunlight		Request Fatigue clinic evaluation Send for physical therapy referral	
Constipation		No stool in >4 (??) days with or without abdominal distention/pain		Significant bloating, abdominal pain
	Advise to use Colace daily or BID, increase water intake, may use Senokot-S			
Diarrhea	< 4 stools/day	4-6 stools/day		>= 7 stools/day
	Advise to use Imodium OTC, per package instructions	Imodium not adequately controlling diarrhea		
Fever/Infection	Mild: Fever less than 100 degrees F	Fever > 101 should see midlevel to assess for neutropenia or mouth sores that could be treated with oral antibiotics vs. direct hospital admit.		Fever greater than 100.5, holding more than 2 hours, unrelieved by hydration.
	Monitor fever again in 2 hours, if greater than 100.4 and holding, go to ER. Rehydrate- encourage >2 Liters water/day while on chemo			Surgical patients go to ER after hours.

Appendix B: MDASI-HN



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Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials: ____________

Study Subject # ☐☐☐☐

PLEASE USE BLACK INK PEN

Study Name: ______________________________
____

Protocol #: ______________________________

PI: ______________________________

Revision: 07/01/05

M. D. Anderson Symptom Inventory - Head & Neck (MDASI-HN)

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptom was as bad as you can imagine it could be) for each item.

	NOT PRESENT 0	1	2	3	4	5	6	7	8	9	**AS BAD AS YOU CAN IMAGINE** 10
1. Your **pain** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
2. Your **fatigue (tiredness)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
3. Your **nausea** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
4. Your **disturbed sleep** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
5. Your feeling of being **distressed (upset)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
6. Your **shortness of breath** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
7. Your problem with **rememb[illegible]ing things** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
8. Your problem with **lack of ap[illegible]** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
9. Your feeling **drowsy (sleepy)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
10. Your having a **dry mouth** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
11. Your feeling **sad** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
12. Your **vomiting** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
13. Your **numbness or tingling** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
14. Your problem with **mucus** in your mouth and throat at its WORST?	○	○	○	○	○	○	○	○	○	○	○
15. Your difficulty **swallowing/chewing** at its WORST?	○	○	○	○	○	○	○	○	○	○	○

Page 1 of 2

Draft

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials: ____________

Study Subject # ☐☐☐☐

PLEASE USE BLACK INK PEN

Study Name: ____________

Protocol #: ____________

PI: ____________

Revision: 07/01/05

	NOT PRESENT										**AS BAD AS YOU CAN IMAGINE**
	0	1	2	3	4	5	6	7	8	9	10
16. Your **choking/coughing** (food/ liquids going down the wrong pipe) at its WORST?	○	○	○	○	○	○	○	○	○	○	○
17. Your difficulty with **voice/speech** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
18. Your **skin pain/burning/rash** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
19. Your **constipation** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
20. Your problem with **tasting food** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
21. Your **mouth/throat sores** at their WORST?	○	○	○	○	○	○	○	○	○	○	○
22. Your problem with your **teeth or gums** at its WORST?	○	○	○	○	○	○	○	○	○	○	○

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items in the last 24 hours:

	Did not interfere										**Interfered Completely**
	0	1	2	3	4	5	6	7	8	9	10
23. **General activity?**	○	○	○	○	○	○	○	○	○	○	○
24. **Mood?**	○	○	○	○	○	○	○	○	○	○	○
25. **Work (including work around the house)?**	○	○	○	○	○	○	○	○	○	○	○
26. **Relations with other people?**	○	○	○	○	○	○	○	○	○	○	○
27. **Walking?**	○	○	○	○	○	○	○	○	○	○	○
28. **Enjoyment of life?**	○	○	○	○	○	○	○	○	○	○	○

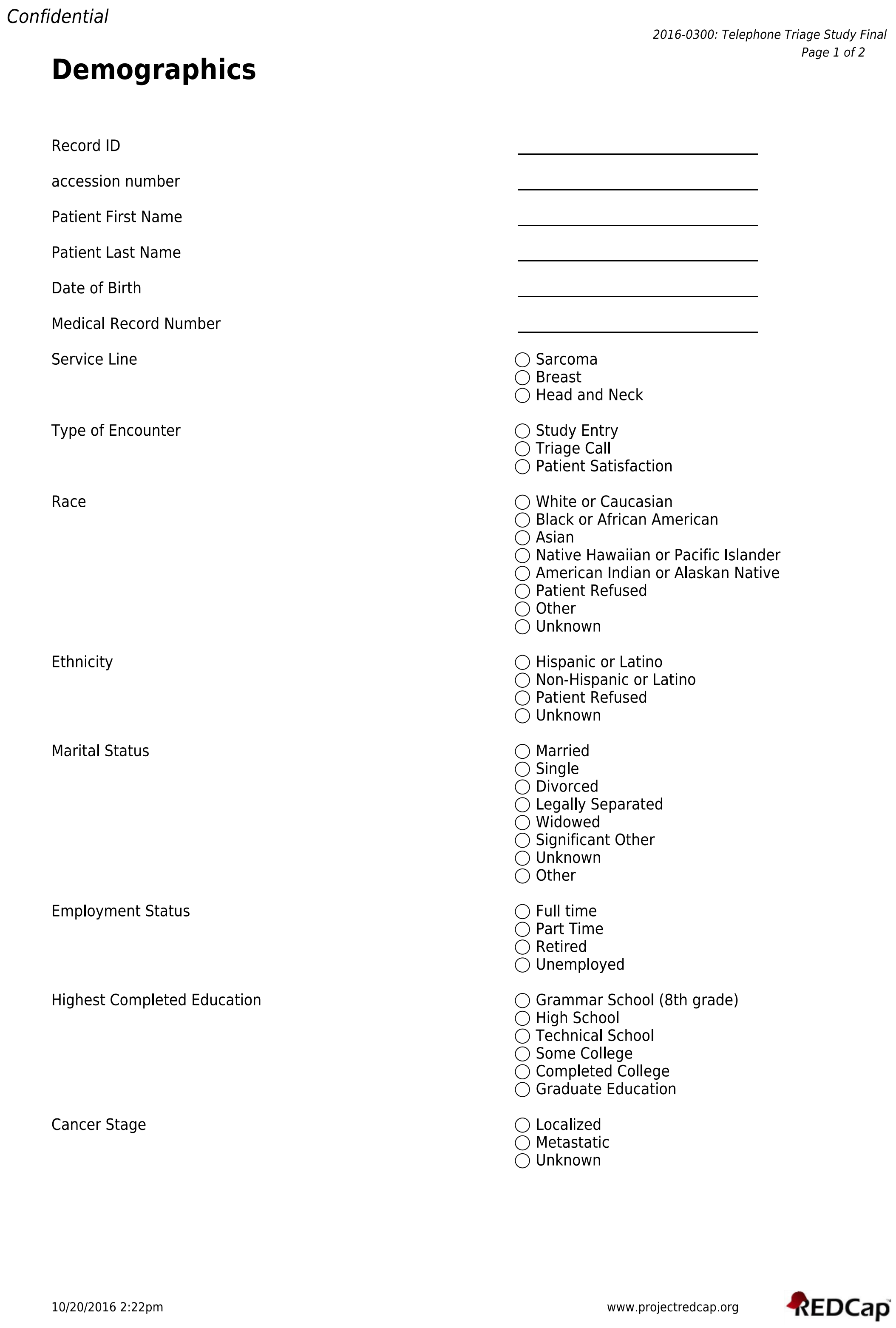
Appendix C: Patient Satisfaction Survey

Appendix C. Patient Satisfaction Survey 1

Survey Instructions: Please rate how satisfied you were with the services you received. Answer each questions completely by filling in the circle to the left of your answer.

	Very Poor (1)	Poor (2)	Fair (3)	Good (4)	Very Good (5)
1. Our helpfulness on the telephone					
2. Friendliness/courtesy of the care provider					
3. Concern the care provider showed for your questions or worries					
4. Care provider’s efforts to include you in decisions about your treatment					
5. Information the care provider gave you about medications (if any)					
6. Instructions the care provider gave you about follow-up care					
7. Our sensitivity to your needs					

Appendix D: Demographics for Telephone Triage



Confidential

2016-0300: Telephone Triage Study Final
Page 1 of 2

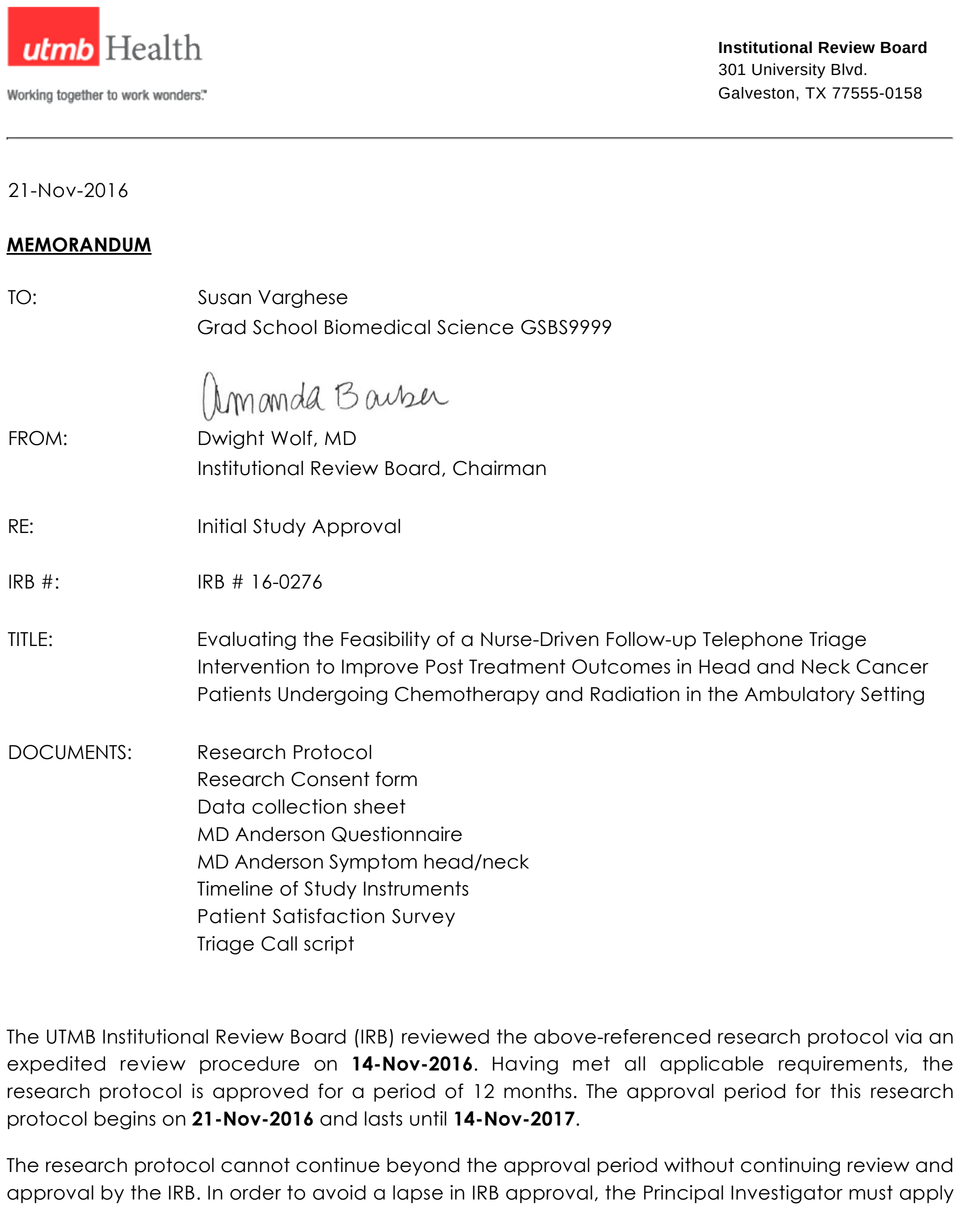
Demographics

Record ID	________________________
accession number	________________________
Patient First Name	________________________
Patient Last Name	________________________
Date of Birth	________________________
Medical Record Number	________________________
Service Line	○ Sarcoma ○ Breast ○ Head and Neck
Type of Encounter	○ Study Entry ○ Triage Call ○ Patient Satisfaction
Race	○ White or Caucasian ○ Black or African American ○ Asian ○ Native Hawaiian or Pacific Islander ○ American Indian or Alaskan Native ○ Patient Refused ○ Other ○ Unknown
Ethnicity	○ Hispanic or Latino ○ Non-Hispanic or Latino ○ Patient Refused ○ Unknown
Marital Status	○ Married ○ Single ○ Divorced ○ Legally Separated ○ Widowed ○ Significant Other ○ Unknown ○ Other
Employment Status	○ Full time ○ Part Time ○ Retired ○ Unemployed
Highest Completed Education	○ Grammar School (8th grade) ○ High School ○ Technical School ○ Some College ○ Completed College ○ Graduate Education
Cancer Stage	○ Localized ○ Metastatic ○ Unknown

10/20/2016 2:22pm www.projectredcap.org REDCap

Co-morbidities	☐ Hypertension ☐ Diabetes ☐ Coronary Artery Disease ☐ Depression ☐ Anxiety ☐ Arthritis ☐ None
Hospital Admission Since Last Call	○ Yes ○ No
Reason for Hospital Admission	__________________________________
Emergency Visit Since Last Call	○ Yes ○ No
Reason for Emergency Visit	__________________________________
Triage Call Since Last Visit	○ Yes ○ No
Reason for Triage Call	__________________________________

Appendix E: UTMB IRB Approval



utmb Health
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Institutional Review Board
301 University Blvd.
Galveston, TX 77555-0158

21-Nov-2016

MEMORANDUM

TO: Susan Varghese
Grad School Biomedical Science GSBS9999

Amanda Barber

FROM: Dwight Wolf, MD
Institutional Review Board, Chairman

RE: Initial Study Approval

IRB #: IRB # 16-0276

TITLE: Evaluating the Feasibility of a Nurse-Driven Follow-up Telephone Triage Intervention to Improve Post Treatment Outcomes in Head and Neck Cancer Patients Undergoing Chemotherapy and Radiation in the Ambulatory Setting

DOCUMENTS:
- Research Protocol
- Research Consent form
- Data collection sheet
- MD Anderson Questionnaire
- MD Anderson Symptom head/neck
- Timeline of Study Instruments
- Patient Satisfaction Survey
- Triage Call script

The UTMB Institutional Review Board (IRB) reviewed the above-referenced research protocol via an expedited review procedure on **14-Nov-2016**. Having met all applicable requirements, the research protocol is approved for a period of 12 months. The approval period for this research protocol begins on **21-Nov-2016** and lasts until **14-Nov-2017**.

The research protocol cannot continue beyond the approval period without continuing review and approval by the IRB. In order to avoid a lapse in IRB approval, the Principal Investigator must apply for continuing review of the protocol and related documents before the expiration date. A reminder will be sent to you approximately 90 days prior to the expiration date.

The approved number of subjects to be enrolled is **30.00**. The IRB considers a subject to be enrolled once s/he signs a Consent Form. If, additional subjects are needed, you first must obtain permission from the IRB to increase the approved sample size.

If you have any questions, please do not hesitate to contact the IRB office via email at IRB@utmb.edu.

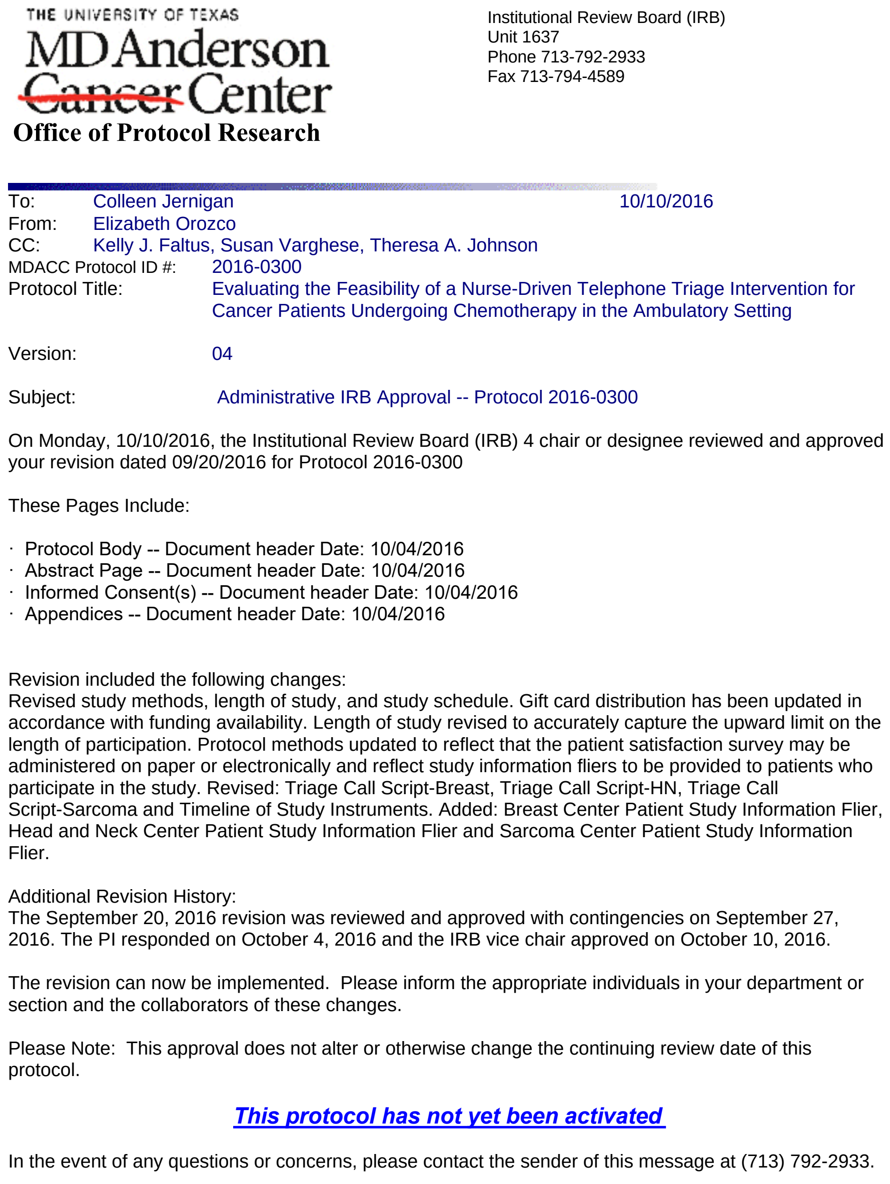
All research is being done at MD Anderson.

General Instructions

To maintain IRB approval in good standing, please observe the following requirements:

1. The research consent form(s) (if applicable) with the date of the IRB approval is available in infoED. Please use the IRB stamped consent form(s) with the current approval/expiration dates and make additional copies as they are needed.
2. All subjects must sign the consent form before undergoing any research study procedures, including screening procedures unless this requirement has been waived by the IRB. When conducting research involving children, a child assent form must be reviewed with and signed by the child (if applicable) in addition to obtaining a signed parental permission form unless these requirements are waived by the IRB. A photocopy of the signed consent form(s) should be given to each participant. The copy of the consent form(s) bearing original signature(s) should be kept with other records of this research for at least six years past the completion of the research study.
3. Obtain prior IRB approval for any modifications including addition of new recruiting materials, changes in research personnel or site location, sponsor amendments or other changes to the protocol or associated documents. Only those changes that are necessary to avoid an immediate apparent hazard to a subject may be implemented without prior IRB approval.
4. Report all adverse events, protocol violations, DSMB reports, external reports and study closures promptly to the IRB.
5. Make study records available for inspection. All research-related records and documentation may be inspected by the IRB for the purpose of ensuring compliance with UTMB policies and procedures and federal regulations governing the protection of human subjects. The IRB has authority to suspend or terminate its approval if applicable requirements are not strictly adhered to by all research study personnel.
6. When enrolling subjects who do not speak or read English, in research involving therapeutic or prophylactic interventions or invasive diagnostic procedures, a bilingual translator must be continuously available to facilitate communications between research personnel and a subject. If a bilingual translator will not always be available, it may be unsafe for an otherwise eligible candidate to participate in the research if that person does not speak and read English.
7. When enrolling the prisoner population, this study will also require approval from the Texas Department of Criminal Justice (TDCJ) Executive Services in addition to approval from the UTMB IRB. Approval from TDCJ Executive Services must be received prior to the enrollment of offenders or the acquisition or utilization of offender data. Failure to obtain approval from TDCJ Executive Services constitutes non-compliance with UTMB IRB Policies and Procedures. Instructions regarding the submission and approval process may be found at http://www.tdcj.state.tx.us/.

Appendix F: MD Anderson Cancer Center IRB Approval



THE UNIVERSITY OF TEXAS
MD Anderson
~~Cancer~~ Center
Office of Protocol Research

Institutional Review Board (IRB)
Unit 1637
Phone 713-792-2933
Fax 713-794-4589

To: Colleen Jernigan 10/10/2016
From: Elizabeth Orozco
CC: Kelly J. Faltus, Susan Varghese, Theresa A. Johnson
MDACC Protocol ID #: 2016-0300
Protocol Title: Evaluating the Feasibility of a Nurse-Driven Telephone Triage Intervention for Cancer Patients Undergoing Chemotherapy in the Ambulatory Setting

Version: 04

Subject: Administrative IRB Approval -- Protocol 2016-0300

On Monday, 10/10/2016, the Institutional Review Board (IRB) 4 chair or designee reviewed and approved your revision dated 09/20/2016 for Protocol 2016-0300

These Pages Include:

- Protocol Body -- Document header Date: 10/04/2016
- Abstract Page -- Document header Date: 10/04/2016
- Informed Consent(s) -- Document header Date: 10/04/2016
- Appendices -- Document header Date: 10/04/2016

Revision included the following changes:
Revised study methods, length of study, and study schedule. Gift card distribution has been updated in accordance with funding availability. Length of study revised to accurately capture the upward limit on the length of participation. Protocol methods updated to reflect that the patient satisfaction survey may be administered on paper or electronically and reflect study information fliers to be provided to patients who participate in the study. Revised: Triage Call Script-Breast, Triage Call Script-HN, Triage Call Script-Sarcoma and Timeline of Study Instruments. Added: Breast Center Patient Study Information Flier, Head and Neck Center Patient Study Information Flier and Sarcoma Center Patient Study Information Flier.

Additional Revision History:
The September 20, 2016 revision was reviewed and approved with contingencies on September 27, 2016. The PI responded on October 4, 2016 and the IRB vice chair approved on October 10, 2016.

The revision can now be implemented. Please inform the appropriate individuals in your department or section and the collaborators of these changes.

Please Note: This approval does not alter or otherwise change the continuing review date of this protocol.

This protocol has not yet been activated

In the event of any questions or concerns, please contact the sender of this message at (713) 792-2933.

Elizabeth Orozco 10/10/2016 10:39:04 AM

This is a representation of an electronic record that was signed and dated electronically and this page is the manifestation of the electronic signature and date:

Elizabeth Orozco
10/10/2016 10:37:55 AM
IRB 4 Chair Designee
FWA #: 00000363
OHRP IRB Registration Number: IRB 4 IRB00005015

Appendix G: Permission to use MDASI

From: Cleeland,Charles
Sent: Wednesday, March 30, 2016 4:36 PM
To: Varghese,Susan <svarghese@mdanderson.org>; symptomresearch <symptomresearch@mdanderson.org>
Subject: RE: permission to use MDASI

You can use this email as notification you have permission to use the core and HN module.

Good luck with your study.

Charlie

Charles S. Cleeland, PhD
McCullough Professor of Cancer Research
Department of Symptom Research
Division of Internal Medicine
U.T. M.D. Anderson Cancer Center, Unit 1450
1400 Pressler
Houston, Texas 77030
713:745-3470
MDAnderson ~~Cancer~~ Center
Making Cancer History®

From: Cleeland,Charles
Sent: Tuesday, May 3, 2016 4:41 PM
To: Varghese,Susan <svarghese@mdanderson.org>
Subject: RE: permission to use MDASI

References

Anastasia, P. J. (2002). Telephone triage and chemotherapy symptom management in the ambulatory care setting. *Oncology Supportive Care Quarterly, 1*(1), 40-55.

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Vita

Susan Varghese

4331 Merriweather St. Sugar Land, Texas 77478
Home: (281)-265-3713, Mobile: (281)-989-6102
Email: svarghese@mdanderson.org

EDUCATION

Doctor of Philosophy in Nursing Fall 11- Present (UTMB)
MSN/Nurse Practitioner Adult Health Fall 98-Spring 02 (Stony Brook, NY)
BSN in Nursing S.N.D.T. Women's University (1984-86), Bombay India

Licenses and Certifications

American Academy of Nurse Practitioner Certificate #A 1102273
Nurse Practitioner in Adult Health
RN: State of Texas License # 699829
Certificate of Introductory Coronary Care
BCLS Certificate-2018
EKG Certification

Activities

- Precepting student P.A's and N.P's during clinical rotations
- Nursing continuing education lectures through presentations/lectures
- Member of the APN orientation and mentorship committees.

Professional Experience

Advanced Nurse Practitioner (Thoracic & Head/Neck Cancer)
University of Texas M.D. Anderson Cancer Center Houston, TX April 2005-Present

- Collaborate with physician with diagnosis and treatment plan for lung and head/neck cancer patients.
- Educate patients and family members about diagnosis, treatment plan, and management of treatment related adverse effects.
- Order comprehensive tests to monitor patients' prognosis.
- Prescribing medications as indicated for patients' problems.
- Educate patient and family members about clinical trials available in the department.

Clinical Nurse (Intensive Care Unit/Pain Management Clinic)
University of Texas M.D. Anderson Cancer Center Houston, TX Oct 2003-April 2005

Registered Nurse (Coronary Care Unit)
North Shore University Hospital Manhasset, New York April 1996- Aug 2003

Registered Nurse (Medical/Surgical-Inpatient)
Flushing Hospital Medical Center, Flushing New York Dec 1989-March 1996

Publications

1. Adult- Gerontology Acute Care Practice Guidelines (To be published in Feb 2019)
2. Lee, W. C., Diao, L., Wang, J., Zhang, J., Roarty, E. B., Varghese, S., . . . Zhang, J. (2018). Multiregion gene expression profiling reveals heterogeneity in molecular subtypes and immunotherapy response signatures in lung cancer. Modern Pathology, 6, 947-955.

Permanent address:

Susan Varghese

4331 Merriweather St

Sugarland, Tx 77478