

INFORMATION AND ITS IMPORTANCE IN HEAD AND NECK CANCER CARE

VIOLET D'SOUZA

BDS, MSc

FACULTY OF DENTISTRY

MCGILL UNIVERSITY

MONTREAL

April 2013

The thesis submitted to

the Faculty of Graduate and Postdoctoral Studies of McGill University

in partial fulfillment of the degree of doctor of philosophy in dental science and research.

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Acknowledgements

Without the contributions of the following people, this dissertation would not have been possible. It is to them I owe my deepest gratitude.

Dr. Paul Allison took me as a student and provided me with remarkable supervision which helped me succeed. It has been an honor to be his student. I appreciate the time he spent and the patience he had in guiding me in various ways.

I like to thank Dr. Carmen Loiselle, Dr. Linda Edgar and Dr. Gerry Humphris for providing professional advices in initialing and planning this project. I sincerely thank every single member of the Oral Health and Society for their support and encouragement, especially Dr. Belinda Nicolau, Dr. Mary Ellen McDonald, Dr. Alissa Levine and Dr. Richard Hovey for their professional advice and unconditional support.

I like to acknowledge all the participants for their contribution by giving us their precious time and effort. My sincerest gratitude goes to the head and neck cancer care teams at the McGill University Hospital Center and at the Jewish General Hospital.

My sincere thanks go to my parents, Francis and Lily, sisters (Clara, Greta and Savita), brother (Wilson), in-laws, nieces and nephews. My special thanks go to my husband Franklin and two children, Nathan and Joshua for their constant unconditional support and encouragement. I am grateful to all friends for being there and helped me succeed.

Preface

Declaration of contribution of co-authors of manuscripts contained in this thesis

Manuscript 1: An investigation of the effect of tailored information on symptoms of anxiety and depression in Head and Neck Cancer patients; Manuscript 2: Do multimedia based information services increase knowledge and satisfaction in head and neck cancer patients?; Manuscript 3: Information Provision in Head and Neck Cancer Care – a qualitative study. All three articles report the results of the research project presented in this thesis. The original concept of the research protocol, data collection and analysis, and preparation of first drafts of manuscripts were done by Violet D’Souza (the student). Among the co-authors, Dr. Paul Allison contributed as a supervisor in planning the study, preparation of the research protocol, the data collection, data analysis and modifying and reviewing the draft texts. Dr. Anthony Zeitouni and Elizabeth Blouin were responsible for developing the test intervention and its delivery. Dr. Katia Muller contributed in data analysis and interpretation of the data presented in article 1 and 2. Dr. Erin Watson contributed in data collection and data analysis presented in manuscript 3. Lastly, Dr. Jose Correa and Dr. Gerry Humphris contributed to this project through their professional advice on the statistical analyses presented in article 1 and 2.

ABSTRACT –English

Head and Neck (H&N) cancers are a diverse group of malignant tumors arising in the mouth, nose, pharynx and larynx. They are the 8th most common cancers in the world. Individuals who receive a diagnosis of these cancers often have enormous unmet informational needs. In spite of a large quantity of literature advocating the necessity to move from “one size fits all” to a tailored approach while providing information to cancer patients, the majority of hospitals provide information in an ad hoc manner. The primary aim of this study was to investigate the impacts of a multimedia based tailored information service on H&N cancer patients' anxiety, depression, satisfaction and cancer knowledge ratings. Our secondary aim was to describe and compare the experiences of H&N cancer patients' receiving information concerning their cancer and treatment at two hospitals with different approaches to deliver information. We used an embedded mixed methods research design within a non-randomized controlled trial within which we nested a qualitative study to address the aforementioned secondary aims. The project was conducted with stage III and IV H&N cancer patients at the participating hospitals. Ethical approval was obtained from the Institutional Review Board and the Research Ethics Boards of the participating hospitals. The test hospital delivered the Multimode Comprehensive Tailored Information Package (MCTIP) and the control hospital received the normal care. A total of 103 individuals with H&N cancer took part in the quantitative study, out of which 96 participants completed baseline and all follow up evaluations. In the qualitative study, a subsample of 11 participants of the main study and 2 Nurse Pivots took part. Quantitative and qualitative data were collected concurrently. Our study findings show that the participants who received the test intervention experienced significantly lower levels of anxiety, had higher levels of cancer

knowledge, were better satisfied with the information they received and had a good information provision experience in comparison to the subjects who received the normal care. Therefore, we conclude that MCTIP is a potentially beneficial adjuvant in H&N cancer care.

RÉSUMÉ-Français

Les cancers de la tête et du cou (T & C), constituent un groupe hétérogène de tumeurs malignes qui se présentent dans la bouche, le nez, le pharynx et le larynx. Ils sont les huitièmes cancers les plus fréquents dans le monde. Les personnes qui reçoivent le diagnostic d'un de ces cancers ont souvent de grands besoins d'information qui ne sont pas comblés. En dépit d'une grande quantité d'écrits prônant la nécessité de passer d'une approche « à solution unique » vers une approche sur mesure tout en fournissant des informations aux patients atteints de cancer, la majorité des hôpitaux fournissent des informations de manière ad hoc. L'objectif principal de cette étude était d'étudier les effets d'un ensemble complet d'information sur mesure multimode (ECIMM) sur l'anxiété, la dépression, la satisfaction à l'égard des soins reçus et la connaissance du cancer chez les patients atteints de cancer T & C. Notre objectif secondaire était de décrire et de comparer les expériences des patients atteints de cancer T & C qui reçoivent des informations sur leur cancer et leur traitement à ceux de deux hôpitaux ayant des approches différentes de diffuser l'information. Nous avons utilisé des méthodes de recherche mixtes intégrées conçues dans un essai non randomisé contrôlé dans lesquelles nous avons imbriqué une étude qualitative pour répondre aux objectifs secondaires mentionnés précédemment. L'ensemble du projet a été mené auprès des patients atteints de cancer T & C de stade III et IV dans les hôpitaux participants. L'étude a reçu l'approbation éthique du Comité de protection des personnes et des comités d'éthiques locaux des hôpitaux participants. Un total de 103 personnes atteintes de cancer du T & C ont pris part à l'étude quantitative, à laquelle 96 participants ont reçu une évaluation au tout début de l'étude et des évaluations de suivi. Un sous-échantillon de 11 participants de l'étude principale et de 2 infirmières pivots y ont pris part à l'étude qualitative. Les données

quantitatives et qualitatives ont été recueillies en même temps. Les résultats de notre étude montrent que les participants qui ont bénéficié de l'intervention ont connu des niveaux significativement inférieurs d'anxiété, des niveaux supérieurs de connaissances sur le cancer, sont davantage satisfaits de l'information qu'ils ont reçue et ont eu une bonne expérience pour ce qui fut de recevoir de l'information, si on les compare aux sujets qui ont reçu les soins normaux. Par conséquent, nous concluons que le ECIMM est un adjuvant potentiellement bénéfique pour les soins contre le cancer T & C.

1. INTRODUCTION

1.1 Background

Head and Neck (H&N) cancers are a diverse group of malignant tumors arising in the mouth, nose, pharynx and larynx (1). They include cancers of the nasal cavities, paranasal cavities, oral cavity, nasopharynx, oropharynx, hypopharynx and larynx. H&N cancers are the 8th most common cancers in the world affecting over 500,000 people around the world and over 4000 Canadians annually (2, 3). These cancers are more prevalent in men over the age of 50 (4, 5).

H&N cancers usually begin in the squamous cells that line the moist, mucosal surfaces inside the mouth, the nose, and the throat. They may also begin in the salivary glands, but salivary gland cancers are relatively uncommon (6). Sometimes, the cancer cells may be found in the lymph nodes of the upper part of the neck only and such cancers are known as unknown primary (7).

Even though survival rates for many cancers have increased, the survival rate for people with H&N cancers has largely remained unchanged during the last 3 decades (4). The 5- year survival rate for H&N cancer patients is about 35-50% (8). Survival mainly depends on cancer stage and other factors such as age of the patients, cancer site, recurrence and the type of treatments given (8).

The most important risk factors for H&N cancers are alcohol and tobacco use and this includes smokeless tobacco, chewing or smoking tobacco. These risk factors are commonly related to cancers of the oral cavity, pharynx, and larynx (9-11). At least 75 percent of H&N

cancers are caused by tobacco and alcohol use (12). People who use both tobacco and alcohol are at greater risk of developing these cancers than people who use either tobacco or alcohol alone (5, 12, 13). However, tobacco and alcohol use are not risk factors for cancer of the salivary glands. In addition to the alcohol and tobacco use, the other risk factors for these cancers are certain dietary habits (14), poor oral health, low socioeconomic conditions (15, 16) and infections with Human Papilloma Virus (HPV) (17, 18). Oropharyngeal cancers are often associated with HPV infections (19).

Cancer staging describes the extent of a cancer, especially whether the disease has spread from the original site to other parts of the body. Staging is important in cancer diagnosis because it assists the physician with determining the progression of a disease in order to choose an appropriate method of treatment and to accurately assess a prognosis. TNM is the most widely used system for cancer staging. This staging describes the extent of the primary tumor (T), the absence or presence of spread to nearby lymph nodes (N) and the absence or the presence of distant spread metastasis (M). The specific TNM status of each patient is then tabulated to give a numerical status of Stage I, II, III, IV. Specific subdivisions often exist for each stage and they are generally denoted with an a, b or c status. In general, early-stage disease is denoted as Stage I or II disease, and advanced-stage disease as Stage III or IV disease (20).

Generally, H&N cancers are treated with surgery, radiation therapy, chemotherapy, targeted therapy, or combinations of treatments. The treatments of these cancers are extremely aggressive and can be more debilitating in comparison to the treatments of other cancers, particularly as the treatments affect organs that are so important to human functioning, such as the face, mouth, tongue, throat and larynx.

H&N cancers are often associated with esthetic and functional impairments. They include facial disfigurement, blindness, speech defects, inability to speak, difficulty in eating, difficulty in swallowing, dry mouth, hearing loss, pain and more (21-24). When compared with other cancer patients, people with H&N cancers often face complex prolonged illness, extreme side effects of the treatments and experience high levels of anxiety and depression and pain (23, 25, 26).

Although a large majority of individuals who receive a cancer diagnosis are not familiar with the cancer and its management, they are required to make serious decisions about their treatment shortly after their diagnosis. To make such decisions, it is necessary that they have a good understanding of their cancer and its treatment. Studies have reported that H&N cancer patients often have high informational needs and often these needs remain unmet (27-29).

1.2 An overview of information provision in health care practices

An emphasis on informed consent in medical practice and related research initially emerged in the last half of the twentieth century and has remained as a foundation principle in medical ethics (30, 31). The purpose of bringing “Informed consent policy” more strongly into health care practice was to educate the patients about their illness and treatment options (32). Given the required information, a patient should be able to understand what they are about to experience in their treatment, including possible side effects and the possibility that things could go wrong and that the treatment may not be successful. Patients going through the consent process and indeed the whole treatment and follow-up process should be in a position to make the required decisions about their treatments based on their own values (33). In the current era, even though legislation

concerning information delivery varies from country to country, obtaining informed consent is a common practice in most countries. And, the obligation to obtain informed consent rests solely on the health care professionals who carry out the treatments or investigative procedures (33). And regrettably, the majority of the time, informed decision-making has been replaced by a ritual of reading and signing the various forms.

Studies report that physicians are the main sources of information for cancer patients (34-36). It is expected that physicians will provide the needed information to their patients. If the physicians provide information to their patients in an interactive or personalized manner, it would enhance the communication between them and their patients. To do this, often, physicians may face many practical obstacles. Some physicians may lack the time and others may lack the motivation or skill (37). And if physicians are willing and ready to undertake this responsibility of providing personalized interactions, patients may lack the required literacy to understand what physicians are saying (38-40).

1.3 The importance of communication between the patients and the physicians

Patient-centered care involves integrating patient preferences and values in order to guide patients in making treatment decisions and improving their communication with their care providers (41). When an individual receives a cancer diagnosis he/she is more likely to interpret or seek explanations for his/her symptoms (42, 43). In such situations, communication plays an important role. The majority of newly diagnosed cancer patients wish to discuss questions concerning their cancer with their health care professionals (34, 44). If appropriate communication is maintained in cancer care, it may lessen patients' confusion and anxiety, and

increase their satisfaction (45-47). Communication is very important to maintain a hopeful attitude, especially in patients with poor prognoses (48). Furthermore, inadequate communication may escalate uncertainty and suspicion (49).

1.4 Informational needs in cancer care

People who receive a cancer diagnosis are often in an uncertain and vulnerable position. They experience a significant need for information and report difficulty in understanding what is happening to them (27, 28, 50). They prefer to receive straightforward information whether good or bad, even though their reactions and preferences may vary from person to person (51). Often they have questions about treatment choices, side effects and their management, psychological well-being, and daily concerns. Cancer patients often convey their questions through verbal cues, such as direct or indirect questions or statements (52, 53).

Informational needs are not restricted to cancer patients alone. When a person receives a cancer diagnosis, his/her family members also face a serious need for information. Although, patients and their family members share a number of common needs, their informational needs are not necessarily identical in content and quantity (54). In a family environment, when one person receives a cancer diagnosis, the other members of family take the care giving role immediately with no extra training on cancer. It is not uncommon that family members look for information (55, 56). When these informational needs are not met adequately, it may lead to various consequences (see section 1.6).

1.5 The benefits of Information

Providing information to patients is one of the most important factors in supportive cancer care (57, 58). Studies have reported that providing comprehensive information to cancer patients leads to improved health competency, a better sense of control over cancer, better symptom management and lower levels of anxiety (59-62). Patients whose informational needs were met showed better psychological adjustment, had lower levels of distress and were better satisfied with their medical consultations than those patients whose informational needs were not met (63-65). In addition, information provision has been shown to bring many other positive outcomes such as increasing cancer knowledge, improving the quality of life of patients and adherence to cancer treatments (35, 36, 62, 65-71). Furthermore, when information is provided to patients, communication channels may open up in the family. This may help patients' family members learn and cope with their relative's cancer, prepare them to meet the challenges involved with cancer and its treatment and also improve their ability to provide the needed care to their family member with cancer (56, 72).

1.6 The consequences of unmet informational needs in cancer care

Patients whose informational needs are unmet and those who are dissatisfied with information they receive may have worse psychological outcomes in the long term (73). Empirical data indicate that lack of information is associated with post-treatment uncertainty and psychological distress (74). Beyond this, there are a number of consequences related to inadequate information provision in cancer care and these are described in the following sections.

1.6.1 Psychiatric morbidity in H&N cancer patients

The H&N region is a vital area with respect to expression of feelings, communication and social interactions (75). Any defects or deformations caused by these cancers or their treatments are difficult to mask or cover. Receiving a cancer diagnosis in this region brings added uncertainties, concerns, fears and high levels of anxiety (23, 25). Additionally, patients with these cancers often find it difficult to understand their medical care plans. As a result, feelings of anger, confusion and other negative emotions are commonly seen (45). The greater the informational needs in H&N cancer patients, the greater the anxiety they feel (76). Anxiety together with fatigue, treatment side effects and impaired communication can further disrupt a person's social life and negatively affect his/her self-esteem and confidence (77, 78).

People with H&N cancer often suffer from serious bouts of illness, debility and numerous physical and psychological challenges (46, 75, 79, 80). Often, they are in a state of shock and experience high levels of distress (81-85). Although prevalence estimates vary widely, evidence suggest that 30-50 % of H&N cancer patients experience psychiatric morbidity such as anxiety and depression (46, 75, 79, 80, 86, 87). This can persist for months or even years following successful treatment (88, 89). Anxiety and depression are often associated with serious functional impairment, reduced quality of life (90, 91), high levels of health care service use and rising costs borne by patients, or the insurance companies or the publicly funded health care agencies (92). Studies have reported that suicide rates are high among H&N cancer patients (93, 94).

Anxiety is often seen as a prodromal stage, or as a predictor of depression. In other words, anxiety usually precedes depression, increasing the risk for depression about threefold and stands out as a powerful causal risk factor for depression (95-98). Therefore, addressing and treating patients' anxiety is extremely important in cancer care.

1.6.2 Psychiatric morbidity in families of the patients

Cancer is a chronic disease and it needs long term care and monitoring. A diagnosis of cancer can affect the entire family in various ways (psychiatric morbidity, fear, lost hours of work, financial problems etc) (99, 100). When an individual receives a cancer diagnosis, his/her family members are left to provide them with specialized care with no professional training on cancer. Studies have reported that family caregivers perceive “care-giving” as a burden and often experience high levels of distress (101-103). This can affect their work performance and physical functioning, making it difficult for them to provide the needed care to their loved ones (104, 105). A large number of studies have reported that family caregivers of cancer patients experience high levels of anxiety and depression and even more so when the cancer is advanced (72, 106-112).

1.6.3 Effects on the conjugal relationship

In couples where one is diagnosed with cancer, partners are important sources of support (113, 114). A strong sense of coherence seems to have a protective role in the development of distress in cancer patients as well as in their partners (115, 116). When one member of a couple develops cancer, the other member may experience high levels of anxiety and distress, and it can affect their quality of life (117-119). Partners commonly face adjustment difficulties leading to

problems related to the financial issues, employment, intimacy, mutual support and cohesion, and greater marital conflicts (120-122). When there is a conflict in the relationship, it may escalate the stress, thereby decreasing the available support for each other (123). This may lead to withdrawal of the needed support for the ill spouse at the most needed time (100). Additionally, the demands of an ill spouse can be so stressful that they may exhaust the energy of the partner and the support that existed prior to the illness may end (100, 119).

1.6.4 Dissatisfaction, misunderstanding and confusion

Patients are required to make important decisions concerning their treatment soon after their diagnosis. To make such decisions with inadequate knowledge may lead to anger, confusion and high levels of anxiety (124, 125). Studies have shown that unmet informational needs seem to interfere with cancer patients' treatment decisions (125). Patients whose informational needs are not met are less likely to adhere to their treatment, experience poorer quality of life, and are less satisfied with the treatment they receive (62, 126).

1.7 Searching for information

Cancer patients experience an enormous need for information and a number of studies have reported information seeking behavior in them (127-131). Even though this information seeking behavior continues from the time of diagnosis, through treatment to follow-up and survivorship, informational needs are highest between diagnosis and the initiation of treatment (28, 129, 132). In this internet era, seeking information on the internet is extremely popular among cancer patients, especially, when they do not receive the needed information (133, 134). Even though

some websites provide clear information, searching on the internet is time consuming, may be scary, often generic and not tailored to their needs (125, 127, 135).

1.8 Frequently faced challenges in information provision

Effective communication is a fundamental principle to the practice of clinical medicine. However, providing information to patients is a complex process involving more than just giving them information. There could be a number of barriers to information provision for patients and they include: i) lack of resources, particularly time; ii) inability to understand patients' needs and expectations; iii) lack of communication skills (both patients and their health care providers); and iv) language, literacy and health literacy barriers (40, 136, 137). Additionally, clinicians may fail to understand their patients' informational needs and their cues (138, 139). It seems that health care providers often under-estimate the informational needs of cancer patients, and give information only to those who actively seek it (140, 141). Or there could be misunderstandings in the communication between patients and their doctors. There often seems to be a serious mismatch between patients' questions and doctors' ability to comprehend them. It has been reported that clinicians seem to focus on specific details of treatments while patients want information about the impacts of their treatments (142).

Low health literacy is an important barrier in health care practices. Often, health care providers overestimate or underestimate patients' health literacy levels while communicating with them (40). It is important to acknowledge that Canada has a serious health literacy problem with more than half of working age adults (11.7 million) and 88% of adults over the age of 65 (3.1 million) have less than adequate health literacy (143). Health literacy tends to decline with

age and as a consequence, the gap between more and less educated people tends to become more pronounced as they age. A low level of health literacy is a barrier to the effective use of patient self-management and may increase the health care cost. If these individuals are provided with tailored information intervention, it may improve their health literacy and self management and reduce the health care cost (144).

1.9 Current information provision practices and their drawbacks

Generally, doctors provide information to their patients even though involvement of the nurse navigators in providing information is on the rise (34, 145, 146). In spite of the literature emphasizing the need to move to tailored information delivery approach, a majority of hospital staff still provide information verbally in an ad hoc manner and patients have no control over the flow of information they receive (147, 148). Cancer involves complex terminologies and it is not uncommon that patients find it difficult to comprehend whatever is said to them. In such situations, if the information is given verbally and only once, he/she may not be able to retain all of it, and some of the most important and beneficial information may be lost to them (149). As a result, patients proceed towards their cancer ablative therapies with fear and anxiety. This is more pronounced if the patients have lower levels of education (150-152).

Patients' expectations vary and this leads to some patients being under-informed while others are overwhelmed. As a result, patients face extreme difficulties while making decisions about their treatments. It is not uncommon that patients may not know the advantages and disadvantages of their decisions, even after receiving too much information. Too much information seems to distract patients from the most important issues and may escalate their

anxiety (153-155). Unfortunately, too often, the process of informed consent has become a standardized and inflexible custom of complying with the ethico-legal duty to inform all patients in a generic manner (156). There is an absolute need to improve the communication between patients and their health care providers.

1.10 Propositions to improve information provision

Studies have been advocating the urgent need for tailored information provision for patients, especially to patients with debilitating illnesses such as cancer. It is necessary to move from a “one size fits all” to a tailored approach (35, 142, 157, 158). A large number of innovative information delivery approaches have been tried with patients with many illnesses including cancers. There is no single best method for information delivery, because patients’ expectations and preferences vary. A method that works with one population may not work in another population. Therefore, it is important that cancer care facilities understand the existence of this problem and develop innovative and flexible methods to deliver information to their patients.

Various types of interventions have been used to provide information for cancer patients and popular ones are written information in the form of booklets or pamphlets, audio tapes of their consultation with their physicians and multimedia based approaches (151, 159-164). These methods of providing information seem to be superior to providing information verbally (161, 162, 164). They seem to help patients retain what was said by their doctors and be helpful by decreasing their anxiety and increasing their satisfaction with care. Studies conducted in cancer patients using written information have demonstrated many beneficial outcomes such as enhanced information recall (164, 165), higher levels of satisfaction (165) and improved

psychological adjustment to cancer (140). However, written information has its own disadvantages such as being too generic, or containing complex terminologies that are difficult to understand, and often not tailored to meet the needs of the individuals (132, 152).

Some hospitals have started using multimedia programs (MMP) to deliver information to their patients. MMPs can combine text, sound, graphics, video and interactivity to reinforce and complement one another to facilitate learning. MMPs can be easily and quickly updated to incorporate new information. They can provide the benefits of patient education without increasing staff costs or time, and are capable of being accessed at home via the Internet or CD or DVD. Studies have shown that multimedia programs as health education tools have reported positive results in increasing patients' knowledge, satisfaction, information-seeking and participation (163, 166-170). Development of multimedia programs based on patient preferences enhance education, learning, and, ultimately, quality of patient care (171). Multimedia technology offers many advantages to meet the informational needs of patients (170, 172)

In conclusion, an enormous need exists for information to be tailored to the needs of individuals and maintain appropriate standards (67, 132, 173). The importance of providing individualized information has been supported by The National Cancer Alliance, which points out that information given to patients is often inadequate for their needs (174). Today, helpline educators must extensively assess the different needs and problems within target patient groups, and follow this assessment with the provision of tailored information (175). Other than the aforementioned aspects, patients also have other needs, such as psychosocial and financial, that can be addressed.

2. THEORETICAL FRAMEWORK FOR THE PROPOSED WORK

This study was based on the interactional model developed by Loiselle CG (176), which predicts the relative contribution of the information interventions on specific outcomes such as anxiety, depression, satisfaction, quality of life and health care service utilization by cancer patients. According to this model, personal and contextual resources modulate patients' psychosocial adjustments to illness. Additionally, this model also hypothesizes potential interaction effects between these two (personal and contextual) resources. Instead of the IT intervention, in our study, we used a multimedia based tailored information tool to provide information to patients.

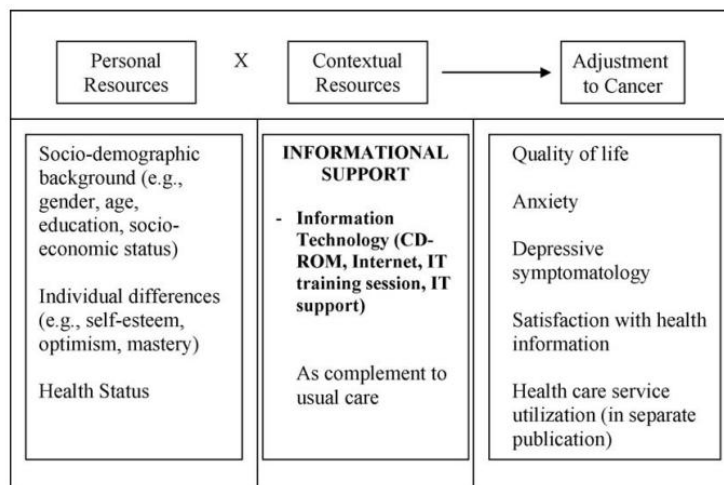


Figure1. Interactional model of psychosocial adjustment to cancer and the role of IT-based informational support (176).

3. STUDY RATIONALE

The Head and Neck (H&N) region is a very important anatomical site in relation to various forms of communications and social interactions. Patients who receive a diagnosis of cancer in this region are in a position of extreme uncertainty and vulnerability, usually leading to

significant psychological challenges. Shortly after their diagnosis, they are required to make important decisions about their treatments. In order to make such decisions, they should have a comprehensive understanding of their illness and treatment options. Often, they report difficulty in understanding what is happening to them and express a desire to understand their illness and the treatment options better. Unfortunately, a majority of the time, these informational needs go unmet.

In spite of a large number of studies emphasizing the need for tailored information services in cancer care, most H&N cancer care facilities provide information in an ad hoc manner, mainly verbally and sometimes complemented with written information, booklets or pamphlets. The major deficiency of verbal information provision is failure to recall what was said by their physicians. Furthermore, although written information can be beneficial, often it is too generic and not tailored to individuals' needs. Thus, in spite of providing information to patients, their informational needs often remain unmet.

Understanding the needs of the H&N patients, the H&N cancer team at the McGill University Hospital Center (MUHC) developed a multimedia based tailored information tool. This tool has been introduced for routine use in all patients with stage 3 and 4 cancer in the H&N region at the MUHC, but its impacts had not been tested scientifically. Therefore, we tested this information package by comparing its effects on anxiety and depression ratings and knowledge and satisfaction, when compared with standard care at another hospital in the same city.

4. STUDY OBJECTIVES

- 1 To investigate if multimodal, tailored information on H&N cancer leads to changes in the levels of anxiety and depression in H&N patients when it is given soon after diagnosis.
- 2 To investigate if multimodal, tailored information increases knowledge and satisfaction in H&N cancer patients when it is given soon after diagnosis.
- 3 To describe and compare the experiences of H&N cancer patients' receiving information concerning their cancer and treatment at two hospitals with different approaches to delivering information for H&N cancer patients.

5. HYPOTHESIS

The provision of comprehensive information about H&N cancer and its treatment significantly decreases anxiety and depression, and results in an increase in the level of knowledge about cancer and satisfaction with knowledge in H&N cancer patients.

6. METHODS

6.1 Study design

We used a mixed method research approach, which is a combination of quantitative and qualitative research approaches and provides better understanding of the research problems than either approach alone. Among the mixed method research designs, we chose a variant of an “Embedded mixed method research design” (177), which is also known as “concurrent nested mixed method design” (Figure 2). This design allows both qualitative and quantitative studies to be conducted in one phase, allowing the integration of a small qualitative study within the full

clinical trial design (see below) by prioritizing quantitative experimental methodology with a subservient qualitative data set to provide a supportive, secondary role (177). This design is intended to answer different research questions; therefore, the two data sets (quantitative and qualitative) were not converged, but were reported separately.

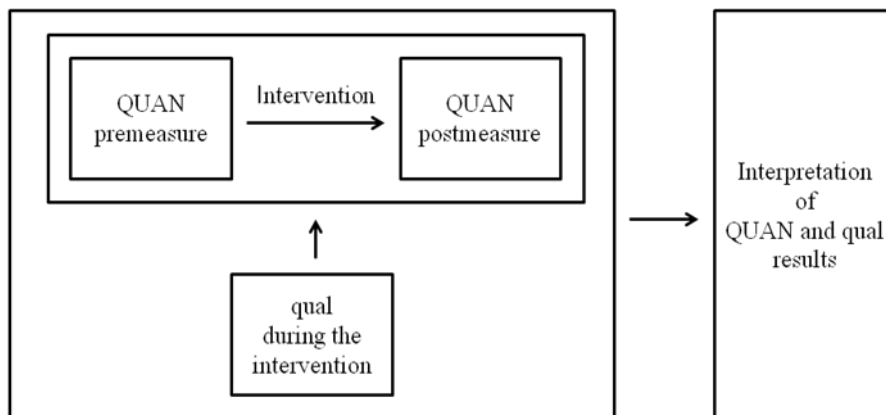


Figure 2. Embedded design model (177)

Unlike this model, the QUAN premeasure (quantitative baseline data) were collected after providing the test intervention in this study – see explanation in section 6.9.

For the quantitative element of this mixed methods project, we used a non-randomized controlled study design. The project was conducted at two participating academic hospitals in Montreal. The MUHC (test hospital) delivered the Multimedia Comprehensive Tailored Information Package (MCTIP), while the Jewish General Hospital (JGH), the control hospital, delivered the normal care control intervention. The MCTIP was available to all stage III and IV H&N cancer patients being treated at the test hospital and it had become the normal care for that hospital prior to the initiation of our research project. To be in accordance with the Belmont

principle of beneficence, it was unethical to withdraw the test intervention from those already being offered it and therefore, we did not choose a randomized design, which would have been the most appropriate design methodologically, given the goals.

6.2 Study setting

This mixed method study was conducted at McGill University and two participating academic hospitals in Montreal, namely the McGill University Hospital Center (MUHC) and the Jewish General Hospital (JGH). Ethical approval was obtained from the Institutional Review Board of McGill University and the Research Ethics offices of the participating hospitals prior to the initiation of the study.

6.3 Study subjects

6.3.1 Quantitative

Participants of the quantitative study were patients with stage III and IV cancer in the H&N region taking their cancer treatment at the participating hospitals.

6.3.2 Qualitative

Participants for this qualitative study were a subsample of the main study participants and two H&N oncology Nurse Pivots (NP) at the two hospitals.

6.4 Sample size

6.4.1 Quantitative study

The sample size was calculated based on data extracted from the literature shown below (84, 99, 109, 178-180), using assumptions of 80% statistical power and a two-sided significance level of

5% (see table 1). Considering the upper-most limit to demonstrate a difference of 2 points in mean anxiety scores of the HADS, 47 subjects were required in each arm at the primary outcome point, 6 months following diagnosis of the cancer. Anticipating an attrition rate of 25%, we had a target of 65 participants per arm, so that there would be 47 participants left in each arm at 6 months.

Table 1. Anxiety data from the literature

	Anxiety (HADS) Mean(SD)	Difference in mean anxiety	n (sample size/arm)	2n (Total sample size)
H&N cancer, UK Llewellyn CD et al. 2007	6.5 (4.9)	2	47	94
Oral cancer, UK Llewellyn CD et al. 2006	5.21 (4.21)	2	35	70
H&N cancer, India Pandey M et al. 2007	5.21 (4.21)	2	35	69
All cancers, Canada Sellick SM. 2007	6.76 (4.31)	2	36	73
GIT cancer, Iran Tavoli A et al. 2007	7.6 (4.5)	2	40	79
H&N cancer, Switzerland Jenewein J. 2008	4.5 (3.0)	2	35	70
H&N cancer, Canada Allison PJ et al. 2004	5.8 (3.2)	2	20	40

6.4.2 Qualitative study

For this qualitative project, we included two NPs, in addition to the patient participants. We recruited patient participants at both centres until the content of the generated themes became saturated (181, 182).

6.5 Inclusion and exclusion criteria for the study participants

6.5.1 Inclusion criteria

As mentioned earlier, the qualitative study sample (the patient participants) was a subsample of the main quantitative study. Therefore, our inclusion criteria were the same for both quantitative and qualitative studies and are described as follows. Potential participants were included only if they were newly diagnosed patients with stage III or IV primary or recurrent cancer in the H&N region, 18 years of age or older, spoke either English or French, and if they were cognitively and physically capable of participating and completing self-report questionnaires.

6.5.2 Exclusion criteria

In both quantitative and qualitative studies, we excluded the potential participants if they had begun their cancer treatment and those who had any history or diagnosis of any cognitive disorders.

6.6 Interventions (Test and control)

6.6.1 Test Intervention

The Multimode Comprehensive Tailored Information Package (MCTIP) is a multimedia tool with audiovisual aids that was developed by the H&N cancer team at the McGill University Health Center (MUHC). The MCTIP has 5 parts and is available in English and French.

1. Patient booklet – this contains general information about cancer, terminologies used in cancer care, information about the medical team and the different diagnostic procedures.

2. Interactive computer booth – patients may observe and interact with computer software developed to tailor the information for that patient. It gives site, stage and treatment specific cancer and treatment information, which can be printed and taken home.
3. Computer animation – a short animation to describe cancer, its spread, staging and a few specific surgical procedures.
4. DVD – a take-home DVD that provides a guided tour showing steps in cancer treatment, and importantly, allows family members to take part in information gathering.
5. Database – this permits the storing of information about a patient in an easily understandable format and enables the provision of a copy to the patient as well as access for the multidisciplinary team so that everyone is discussing the same information.

The NP in the H&N cancer care department at the test center delivered the information using the MCTIP and all other resources available at the hospital and this took about 1.5 – 2 hours. Besides providing information, patients’ questions and concerns were explored, and as part of the intervention, patients’ distress levels were assessed using the Distress Thermometer. For the “database module” the NP had to gather a lot of personal information from the patients concerning their personal needs and life situation and it took longer time. Together with this patients’ distress levels were assessed and appropriate psychosocial referrals were subsequently made.

6.6.2 Control intervention (Normal care)

The control hospital delivered information in the routine manner. There were no specific information resources available for the H&N cancer patients at the control center. The control

intervention was delivered by the NP in an ad hoc manner, with some patients meeting the NP and others not. Those meeting the NP spent from 15-45 minutes with her. The NP provided verbal information, often complemented by pamphlets from the Canadian Cancer Society. Patients' concerns were explored and appropriate referrals were made.

6.7 Recruitment

6.7.1 Quantitative study

On average, the time between cancer diagnosis and the initiation of cancer treatment ranged from 0- 2 months. During this time, cancer patients normally undergo various diagnostic and necessary adjuvant procedures related to their cancer treatment. And this is the time that normally they receive information. By attending the outpatient clinic review and tumor board meetings at both hospitals, the researchers working in this project identified the potential participants. These identified potential participants were approached by phone and were informed of the study. If they agreed to participate, appointments were scheduled for their interviews for the baseline data collection at the hospitals or at their homes.

6.7.2 Qualitative study

Participants from our main study (quantitative) were approached by phone and this qualitative investigation was explained to them. If they agreed to participate, appointments were scheduled at the hospitals or at their homes. Participants were recruited at different phases of cancer care (prior to and following the completion of their cancer therapy).

6.8 Data collection

6.8.1 Quantitative study

6.8.1.1 Quantitative data collection procedure

At both test and control hospital sites, subjects received their cancer diagnosis and then immediately received the interventions (test and normal care). It was not feasible or appropriate to separate the diagnosis from the initiation of information provision. Therefore the baseline data at both sites were collected following the initial information provision and prior to their cancer treatment. Subjects were then followed up at 3 and 6 month intervals as shown in Figure 3. All baseline and the majority of follow-up data were collected in face-to-face interviews using the aforementioned questionnaires. However, some data were collected by phone or by mail. All participants signed an informed consent prior to their participation. A total of 165 patients were identified at both hospitals and of them 17 patients did not meet the eligibility criteria. Of the remaining 148 patients, a total of 105 (71% of those eligible) patients participated in the study.

6.8.1.2 Variables collected

6.8.1.2.1 Exposure variables

- Socio-demographic: age, gender, educational level, employment status and living situation
- Clinical: type of cancer, stage of the cancer, type of cancer ablative treatment
- Social : family support
- Behavioral: alcohol use, smoking status, history of narcotic use

6.8.1.2.2 Outcome variables

- Anxiety
- Depression
- Satisfaction level
- Knowledge change

6.8.1.3 Instruments used

The following questionnaires were used in the Study.

1. The Hospital Anxiety and Depression Scale (HADS) (See Appendix)

HADS is a validated instrument to assess psychological distress in patients (183, 184) and has been used in multiple studies to assess the levels of anxiety and depression in H&N cancer patients (75, 180, 185, 186). It measures anxiety and depression with two subscales with scores ranging from 0-21: scores of 0-7 indicate no anxiety or depression; scores of 8–10 indicate borderline anxiety or depression; and scores >10 indicate clinical anxiety or depression.

2 Satisfaction with Cancer Information Profile (SCIP) (See Appendix)

This instrument can be used in both research and routine clinical practice to assess whether a patient's information needs have been met. The SCIP consists of 2 subscales (187).

Subscale 1: Satisfaction With the Amount and Content of Information. This subscale consists of 14 items relating to the quantity and content of the information. A subscale score is obtained by summing the scores for each item. Total scores range from 0 to 14, with high

scores indicating a high degree of satisfaction with the amount and content of the information received.

Subscale 2: Satisfaction With the Form and Timing of the Information Received. This section contains 7 items (items 15–21), each rated on a 5-item response scale from “very satisfied” to “very dissatisfied”. The responses are summed to give the overall score for satisfaction with the form and timing of information. Scores range from 7 to 35, with higher scores indicating higher levels of satisfaction.

The SCIP was not available in French language. Therefore, we translated the SCIP into French according to the “Guidelines for Translating Surveys in Cross-Cultural Research” by two bilingual translators (188). First, the SCIP was translated from English to French language by the first bilingual translator. Then the second bilingual translator translated it back to English. And then both versions were compared and the French version adjusted as necessary.

3 Cancer Knowledge questionnaire (See Appendix)

This questionnaire was developed for this study to evaluate the patients’ knowledge about H&N cancers and their treatment. The questions were based on the information intervention being tested in this study. It has 20 multiple choice questions, with some questions having more than one correct answer leading to maximum score of 25. First, this questionnaire was developed in English language and then we translated it into French by a bilingual translator. Then, a second bilingual translator translated it back into English and both versions were compared (188).

- 4 A questionnaire on socio-demographic status and relevant clinical and behavioral factors
(See Appendix)

This questionnaire included subjects' demographic characteristics, clinical diagnosis and staging, and behavioral information such as smoking and alcohol histories were obtained at baseline.

6.8.2 Qualitative study

6.8.2.1 Qualitative data collection procedure

Once recruited, data were collected by semi-structured interviews with subjects at both test and control hospitals, and through shadowing the NPs and audio taping the information delivery sessions at both centers. Additionally, both NPs were interviewed through semi-structured interviews at both hospitals. Most of the data were collected at the respective hospitals, except one interview with a patient participant, which was done over the phone. All interviews were audio taped. The interviews ranged from 25 to 90 minutes long. Field notes were taken while shadowing the NPs.

6.8.2.2 Content of the qualitative data

The qualitative data contained detailed information concerning how the patients gathered information during their cancer journey, how the information was delivered to them at the hospitals, the timing of the information reception, the quality, quantity and the details of the information they received, and lastly their experiences concerning the information delivery at the hospitals where they were taking treatment.

6.9 Study timeline

The study involved initial planning of the study, writing the protocol, gathering and developing the required questionnaires, obtaining official translations of the questionnaires into the target language, obtaining ethical approval, data collection, data analysis and writing the thesis and the manuscripts. The data were collected according to the schedule presented in Figure 3. It took a total of 31 months to collect the complete data for the quantitative study.

As mentioned earlier, both quantitative and qualitative data were collected concurrently. The study time line is presented in Figure 3.

6.9.1 Quantitative

A total of 31 months were spent this quantitative project, which included recruiting and data collection at baseline and follow-ups at 3 and 6 months later.

Time 0 (baseline): here the subjects entered the study and were evaluated for the first time using the socio-demographic questionnaire, HADS, SCIP and the Cancer Knowledge Questionnaire.

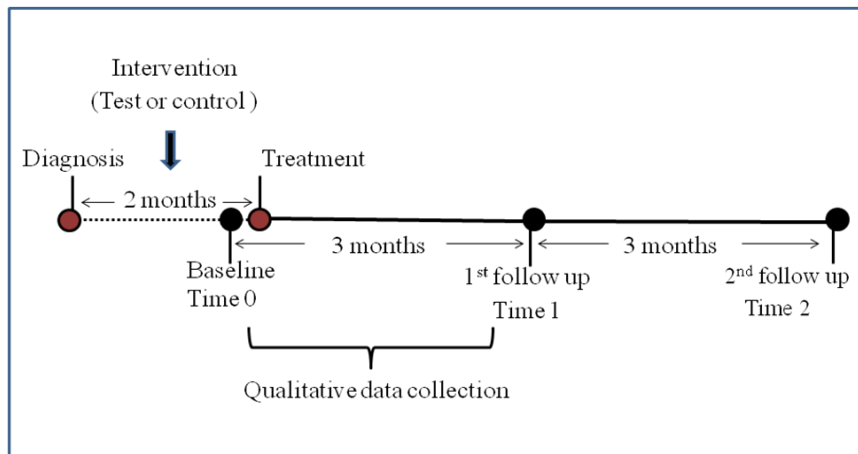
Time 1 (1st follow up, 3 months from baseline, +/- 1 week): here subjects were evaluated for the second time using the HADS, SCIP and the Cancer Knowledge Questionnaire.

Time 2 (2nd follow up, 6 months from baseline, +/- 1 week): here subjects were evaluated using the HADS, SCIP and the Cancer Knowledge Questionnaire.

6.9.2 Qualitative

It took a total of 6 months to have the complete qualitative data collection.

Figure 3: Study timeline



6.10 Data analyses (quantitative and qualitative)

6.10.1 Quantitative

This study tested the hypothesis that providing information decreases anxiety and depression and increases knowledge and satisfaction in H&N cancer patients. All the statistical analyses were carried out using the Statistical Package for Social Sciences (SPSS) version 20. The significance level was set at $p < 0.05$ (two tailed). Before performing any analysis addressing any particular aims, we analyzed the characteristics of the sample to document the similarities and the differences in the make-up of the test and control groups. These analyses of differences in demographic, clinical and behavioral variables were performed using t-test or chi-square test according to the normality or not of data distribution.

HADS data analysis

Our first aim was to investigate if multimodal, tailored information on H&N cancer leads to changes in the levels of anxiety and depression in H&N patients when it is given soon after diagnosis. To answer this question, first, we calculated the mean and standard deviations for anxiety and depression ratings separately for the test and control groups at the baseline and two follow-up evaluation points. Then, to investigate the potential impact of the intervention on anxiety and depression ratings of the test and control groups at the three time points, we used two types of analyses. 1) We used linear mixed model analysis for anxiety and depression separately with Time (T0, T1, and T2) as a within-subject factor and Group (test vs control) as a between-subject factor while controlling for the following covariates: age, gender, language background, employment status, educational level, living situation and if they had any person to count on during their cancer journey. 2) A secondary analysis was performed categorizing mean anxiety and depression ratings using well recognized cut-off points as described earlier. These analyses of different proportions in each anxiety and depression category in test and control groups were performed using chi square tests.

The SCIP and Cancer Knowledge data analysis

The second aim of this study was to investigate if multimodal, tailored information increases knowledge and satisfaction in H&N cancer patients when it is given soon after diagnosis. To answer this aim, we analyzed the SCIP and Cancer Knowledge data separately as follows.

SCIP

First, we calculated the mean scores for both subscales of the SCIP separately for both test and control groups at the baseline and two follow-up evaluation points. Then, to investigate the potential impact of the intervention on the satisfaction ratings of the participants, we performed linear mixed model analyses for both subscales of SCIP separately using the variable Time (T0, T1 and T2) as a within-subject factor and the variable Group (Test vs Control) as a between-subject factor. In these analyses, we controlled for the following covariates: age, gender, language background, employment status, educational level, living situation and if they had any person to count on during their cancer journey.

In addition to these tests, since, the SCIP was newly translated into French language, we tested for its internal consistency by calculating the Cronbach's α . First, Cronbach's α was calculated for the whole sample at three time points and then for French and English speaking participants separately at three time points (Figure 3). Finally, to see if satisfaction ratings were consistent across the 2 SCIP subscales, both SCIP subscales were tested for inter-correlation.

Cancer Knowledge data

First, mean cancer knowledge ratings were calculated for both test and control groups at the baseline and two follow-up evaluation points. Then, a linear mixed model test was performed to evaluate the potential impact of the intervention on the cancer knowledge ratings of both test and control groups. In this analysis, we used the variable Time (T0, T1 and T2) as a within-subject factor and the variable Group (Test vs Control) as a between-subject factor and controlled for the

following covariates: age, gender, language background, employment status, educational level, living situation and if they had any person to count on during their cancer journey.

Since, this questionnaire was newly developed for this study, we tested for its internal constancy by calculating Cronbach's α . First, we calculated Cronbach's α for the whole study sample at three time points and then for French and English speaking participants separately at three time points. Finally, using Pearson's correlation coefficients, we investigated if there is a relationship between satisfaction and cancer knowledge ratings of the individuals.

6.10.2 Qualitative data analysis

All interviews and field notes were transcribed verbatim, read, coded and continuously analyzed from the outset of the data collection. The detailed analysis and interpretation of the codes helped us develop the categories. Even though the generated codes and categories became repetitious after 8 interviews, we included another three participants to re-examine and confirm the emerging themes. We terminated the sampling after 11 interviews as the categories were saturated (181, 182). Data were analyzed by repeatedly reading the interview transcripts, through use of the coding system, by in-depth analysis of the categories and interpretation of the themes (181). Coding was done independently by two researchers and then compared to ensure the accuracy and congruence of the themes identified. In case of disagreement, a discussion was held to reach consensus (189). Main points and topics were identified and emerging themes were used in developing categories. Care was taken to guard the anonymity of subjects.

7. RESULTS

The results for each study objective are presented as manuscripts prepared based on data analysis from this project.

Our first objective was to investigate if tailored information provision decreases symptoms of anxiety and depression in late stage Head and Neck (H&N) cancer patients. Results of this investigation have been presented in the manuscript titled “An investigation of the effect of tailored information on symptoms of anxiety and depression in Head and Neck Cancer care”.

Manuscript 1. D'Souza V, Blouin E, Zeitouni A, Muller K, Allison PJ. An investigation of the effect of tailored information on symptoms of anxiety and depression in Head and Neck cancer patients. *Oral Oncol.* 2013 Jan 4.

Abstract

Objective: To investigate if tailored information provision decreases symptoms of anxiety and depression in late stage Head and Neck (H&N) cancer patients. **Methods:** This non-randomized, controlled trial was conducted with Stage III or IV H&N cancer patients. Subjects were recruited at two academic health centres in Montreal. At the test centre, subjects received the Multimode Comprehensive Tailored Information Package (MCTIP), while at the control centre, they received normal information provision. Participants were evaluated using the Hospital Anxiety and Depression Scale (HADS) at baseline and 3 and 6 month later. Data were analyzed using descriptive statistics then T tests and chi square tests to compare group differences and finally mixed model analysis to test differences in outcome variables. **Results:** A total of 103 subjects were recruited and of them 96 (47 tests and 49 controls) participants completed baseline, 3 and 6

month evaluations. The test group experienced lower levels of anxiety ($p = 0.001$) and depression ($p = 0.089$) than the control group. **Conclusion:** The subjects receiving tailored information had lower levels of anxiety than their counterparts. In addition, depression showed a reduction in the expected direction in the test group. Practice implications: Our results need to be further confirmed using a randomized approach in different samples but they suggest benefits for stage III and IV H&N cancer patients receiving tailored, multi-modal information concerning their cancer.

Key words: Multimedia tailored information, Head and Neck cancers, psychosocial oncology, anxiety and depression,

1. Introduction

Head and Neck (H&N) cancers are a group of malignant tumours arising in the mouth, nose, pharynx and larynx.¹ Collectively, they are the 8th most common cancer in the world and the incidence is increasing.² People who receive a diagnosis of cancer are often in a state of shock and experience high levels of distress.^{3, 4} Recognising and treating symptoms of distress is extremely important in these patients as it may hamper their adjustment to cancer and its treatment.

People with H&N cancer can often experience extremely severe side effects of the disease and its treatment in comparison to patients with other cancers. The difficulties experienced by people diagnosed with H&N cancer patients may range from facial disfigurement to speech defects, difficulties in eating, altered taste and smell perceptions, sore mouth, inability to open the mouth, difficulty in swallowing, hearing loss, breathing and more.⁵⁻⁸ In addition to these problems, they often experience challenging emotional and psychological symptoms as these cancers are located close to anatomical features that are very important for various forms of communication and social interactions. Although prevalence estimates vary widely, evidence suggests that 30-50 % of the patients with H&N cancers experience anxiety and depression⁹⁻¹⁴ and this can persist for months or even years following successful treatment.^{15, 16} These disorders are often associated with serious functional impairment, reduced quality of life^{17, 18} high levels of health care service use and rising costs borne by the patients.¹⁹

One avenue that has been explored to try to reduce stress, anxiety and other psycho-emotional morbidity is information provision.^{20, 21} Existing research clearly demonstrates that

lack of information is a source of anxiety and depression.^{22, 23} Many studies have pointed out the importance of information in cancer care and have made recommendations to provide the needed information, particularly in a form tailored to the needs of individual patients.²⁴⁻²⁸ Patient education and providing information are gaining popularity in supportive cancer care for their positive outcomes in managing side effects, such as improved adherence to treatment, lowered levels of anxiety and depression, improved emotional well-being, satisfaction with care and much more.²⁹ Research has shown that people take on proactive roles when they learn and receive information about their health, especially, if they obtain information that is tailored to their needs using multiple modalities.^{30, 31} Furthermore, information seems to reduce distress and enhance patients' sense of control and this in turn relieves anxiety.³¹ Despite these observations, traditionally, information is given to patients verbally, in an ad hoc manner and through generic pamphlets.

In recent years, the use of multimedia to provide information to patients is expanding in health care facilities to provide information to patients. A number of studies have examined the benefits of information in cancer patients using information technology.³²⁻³⁴ Even though a few studies have used information interventions in H&N cancer care,^{29, 35, 36} none have used multimedia based tailored information interventions.

Given these observations, we aimed to prospectively investigate levels of anxiety and depression in H&N cancer patients receiving multi-modal, tailored information concerning their cancer soon after its diagnosis, when compared with a similar group receiving routine information about their cancer. We hypothesized that those H&N cancer patients who receive

tailored information about their cancer experience lower levels of anxiety and depression compared with H&N patients who receive usual care.

2. Methods

Study design

A non-randomised, controlled study design was used with all subjects at one site receiving the test intervention and all subjects at the second site receiving the control intervention. This non-randomised approach was taken because the test intervention was already in place and being used at one hospital site before the study started so it would have been unethical to use a randomisation approach, which would have resulted in some subjects at the test site not receiving the intervention. Also, there would have been a very strong possibility of contamination if both test and control interventions had been used at both hospital sites. This study was approved by the Institutional Review Board (IRB) and the Local Ethics Offices of participating institutions.

Sample

The sample size estimate was based on data from the literature, with an assumption of 80% statistical power and a two-sided significance level of 5%. It was estimated that to demonstrate a difference of 2 points in mean anxiety scores as part of the Hospital Anxiety and Depression Scale (HADS), 47 subjects in each arm of the study would be required at the primary outcome point 6 months following diagnosis of the cancer. Inclusion criteria for the participants were: 1) newly diagnosed patients with stage III or IV primary or recurrent cancer in the H&N region; 2) 18 years of age or older; 3) spoke either English or French; and 4) cognitively and physically capable of participating and completing self-report questionnaires. Potential participants were

excluded if they had a history or a diagnosis of any cognitive disorders, and if they had already begun their cancer treatment.

Subject recruitment and data collection

Potentially eligible participants were identified from outpatient clinic reviews and from tumour board discussions. Patients were informed of the study and approached by phone. If they agreed to participate, appointments were scheduled for their interviews for the baseline data collection at the hospitals or at their homes. At both Test and Control hospital sites, subjects received their cancer diagnosis and then immediately received the interventions (test and normal care). It was not feasible or appropriate to separate the diagnosis from the initiation of information provision. Therefore the baseline data at both sites were collected following the information provision and prior to their cancer treatment and were then followed up at 3 and 6 month intervals as shown in the Figure 1. All baseline and the majority of follow-up data were collected in face-to-face interviews. However, some data were collected by phone or by mail. All participants signed an informed consent prior to their participation. A total of 165 patients were identified at both hospitals and of them 21 patients did not meet the eligibility criteria. Of the remaining 144 patients, a total of 103 (71% of those eligible) patients participated in the study.

The test intervention

The Multimode Comprehensive Tailored Information Package (MCTIP) is a multimedia tool with audiovisual aids that was developed by the H&N cancer team at the McGill University Health Center (MUHC). The MCTIP has 5 parts and is available in English and French.

1. Patient booklet – this contains general information about H&N cancer, terminologies used in H&N cancer care, information about the medical team and the different diagnostic and adjuvant procedures used in H&N cancer care.
2. Interactive computer booth – patients may observe and interact with computer software developed to tailor the information for that patient. It gives site, stage and treatment specific cancer and treatment information, which can be printed and taken home.
3. Computer animation – a short animation to describe cancer, its spread, staging and a few specific surgical procedures.
4. DVD – a take-home DVD that provides a guided tour showing steps involved in H&N cancer care. It contains information which can help the H&N cancer patients while preparing themselves towards their treatment. It was aimed to educate H&N cancer patients on various diagnostic and adjuvant procedures that H&N cancer patients need to undergo as part of their cancer care. Important ones are radiation mask, Percutaneous Endoscopic Gastrostomy (PEG), importance of practice speech and swallowing, nutritional facts, and more. Importantly, allows family members to take part in information gathering.
5. Database – This data base is designed to input patient`s information such as his/her cancer diagnosis, staging, recommended treatment, medication in use, available family or social support, financial situation, any referrals made. This software permits the storing of information in an easily understandable format and enables the provision of a copy to the patient as well as access for the multidisciplinary team so that everyone is discussing the same information.

Patients' stress levels were routinely screened using the Distress Thermometer³⁷ and the results were used as part of the assessment of whether further psychosocial support is required for patients. However, it is important to note that the data generated by these assessments were not part of the research project and so could not be analysed.

The Nurse Pivot (NP) involved in H&N cancer care at the Test hospital delivered the Test intervention. The Test intervention was delivered along with all other resources available at the hospital and this took about 1.5 – 2 hours. Besides providing information, patients' questions and concerns were explored, their distress levels were assessed (as mentioned above) and appropriate psychosocial referrals were subsequently made based on patients' needs and life situation.

The control intervention (Normal care)

The Control center delivered information in the routine manner. There were no specific information resources available for the H&N cancer patients at the control center. The control intervention was delivered by the NP in an ad hoc manner, with some patients meeting the NP and others not. Those meeting the NP spent from 15-45 minutes with her. The NP provided verbal information, often complemented by pamphlets from the Canadian Cancer Society. Patients' concerns were explored and appropriate referrals were made.

Outcome measurement

Outcomes evaluation was performed using the Hospital Anxiety and Depression Scale (HADS). HADS is a validated instrument to assess psychological distress in patients^{38, 39} and has been used in multiple studies to assess the levels of anxiety and depression in H&N cancer patients.^{13,}

^{29, 36, 40} It measures anxiety and depression using two subscales, each with scores ranging from 0-21: scores of 0-7 indicate no anxiety or depression; scores of 8-10 indicate borderline anxiety or depression; and scores >10 indicate clinical anxiety or depression.⁴¹

In addition to evaluation of outcomes, subjects' demographic characteristics, clinical diagnosis and staging, and behavioural information such as smoking and alcohol histories were obtained at baseline.

Data analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 20. Analyses were performed for all participants with available data at baseline. The significance level was set at $P < 0.05$ (two tailed). Differences in demographic, clinical and behavioral variables were analyzed using a t-test for continuous variables and chi-square of Fisher's Exact test for categorical variables, depending on the distribution of categories. Mean scores for the outcomes were calculated at three time-points. As the outcomes were normally distributed, we used parametric tests to investigate the impact of the intervention on the outcomes. First, we used linear mixed model analysis with Time (T0, T1, and T2) as a within-subject factor and Group (Control vs. Test) as a between-subject factor controlling for covariates (age, gender, language background, employment status, educational level, living situation and if they had any person to count on during their cancer journey). While the primary analysis was performed with continuous HADS scores as outcomes, a secondary analysis was also performed categorizing anxiety and depression scales using well recognized cut-off points as described above. Analysis

of different proportions in each anxiety and depression category in Test and Control groups was performed using chi square tests.

3. Results

A total of 103 (50 Test and 53 Control) subjects participated in this study. Of these, 96 (47 test and 49 control) completed all three (Time 0, Time 1 and Time 2) evaluations. The general characteristics of both groups at baseline are shown below in Table 1. Test and control groups exhibited similar general characteristics except for language ($p = 0.006$) and education level ($p = 0.014$).

Anxiety

Mean anxiety ratings were higher in the Control group than the Test group and are presented in Table 2 and Fig 2 a. The results of the mixed model analysis showed that the anxiety ratings of the Test and Control groups were significantly different from each other ($p = 0.001$). Even though there was no main effect of Time ($p = 0.122$), there was a significant interaction effect of Group by Time ($p = .025$), indicating that anxiety levels in the two groups varied differently over time.

When controlling for covariates in the mixed model analysis, anxiety showed a significant association with employment status ($p=0.04$). Participants who were unemployed had higher levels of anxiety than participants who were employed or retired.

Depression

Mean depression ratings for the Test group and control group are presented in Table 2 and Fig 2b. The mean depression ratings over time were constantly lower for the Test group subjects than the Control group subjects ($p = 0.089$). This difference was not statistically significant indicating there was no main effect of Group. However, there was a main effect of Time showing that depression ratings increased for both Test and Control groups with time ($p=0.001$). The variation of depression levels experienced by both groups with time was similar, indicating there was no interaction effect of Group by Time ($p = 0.214$).

When controlling for covariates, depression was significantly associated with age ($p=0.04$) and employment status ($p = 0.02$), indicating that younger and unemployed subjects had higher levels of depression.

In our secondary analysis, anxiety and depression scores were categorized into three categories as mentioned earlier. The results of this analysis are presented in Fig. 2a.

Low levels of anxiety: At baseline, almost equal numbers Test and Control group participants reported low levels of anxiety. As the time progressed from baseline 3 and 6 months, significantly higher number of Test subjects reported low levels of anxiety when compared with the Control group subjects (0.003).

Borderline levels of anxiety: At baseline, a slightly higher number of Test participants experienced borderline levels of anxiety than that of the Control group. By 3 months, the number of Test subjects with borderline levels of anxiety diminished slightly and almost equal number of Test and Control group participants experienced borderline anxiety levels. At 6 months, the

number of Test subjects with borderline levels of anxiety diminished further, while the number of Control subjects with borderline levels of anxiety increased.

Clinical levels of anxiety: As the time progressed from baseline to 3 and 6 months, the number of Test group subjects who experienced clinical levels of anxiety decreased gradually. At all 3 time-points, fewer Test group subjects experienced clinical levels of anxiety in comparison with the Control group. The number of Control group subjects with clinical levels of anxiety increased to a highest point at 3 months and then started to decline at 6 months. The difference in the number of people who experienced clinical levels of anxiety at 3 and 6 months is statistically significant ($p = 0.014$, $P = 0.005$ respectively).

With respect to ratings of depression, the numbers of subjects with clinical depression in the Test group remained stable throughout the study (Fig. 2b) However, the number of subjects with clinical depression in the Control group approximately doubled between the baseline and 3 month evaluations, then returned to the same numbers as the test group at the 6 month evaluation. The difference between the numbers of subjects who had clinical depression in the Test and Control group at 3 months was statistically significant ($p = 0.05$).

4. Discussion

This is the first study that has investigated the impact of multimode, tailored information on anxiety and depression ratings in H&N cancer patients. Within the limits of the study design, the results of this investigation suggest that the test intervention did have a significant impact on anxiety ratings. The effects on depression were less clear with some evaluations showing significant impact while the other evaluation showing borderline impact.

Studies conducted with cancer patients have reported that information helps patients by lowering their anxiety, distress and depression.⁴²⁻⁴⁶ Despite this evidence, there is a paucity of literature on educational interventions in H&N cancer patient population.^{29, 47} Therefore comparison with the existent literature is limited. To date, the majority of the studies conducted with H&N cancer patients used psychosocial or psycho-educational interventions to improve their psychiatric symptoms.^{29, 36, 40, 48, 49} There are only a few published studies that have used information interventions in H&N cancer patients.^{29, 50, 51} Among them, only one study investigated the impact of information on anxiety in this population and their results are similar to our study findings with respect to anxiety.²⁹

Even though our study was a non-randomized clinical trial, the general characteristics of both the Test and Control groups were similar except for the language and educational status. Interestingly, both these differences did not affect the outcomes. What affected the outcomes was employment status, with unemployed subjects experiencing higher levels of anxiety and depression than the subjects who were either employed or retired. Secondly, depression was significantly associated with age, indicating that the younger subjects were more depressed than the older subjects. And this type of association between age and psychiatric symptoms in cancer patients has been documented elsewhere.⁵²⁻⁵⁴

Our results showed that both the depression ratings and the number of people who had clinical depression increased in both groups at 3 months when compared to the baseline and this phenomenon has been observed earlier.^{55, 56} Our first follow-up time point was a crucial time in H&N cancer care because at that time patients experience maximum side effects as they would have just completed their cancer treatment. Difficulties with speech, eating, swallowing and

severe dry mouth, sleep dysfunction, fatigue and unrelieved pain, despite pain management, are common during this time, especially in patients who received radiation treatment.⁵⁶⁻⁵⁸ These symptoms are known to be associated with high levels of anxiety and depression in cancer patients.^{56, 57, 59-62} What is interesting here is the number of Control group subjects who had clinical depression at three months was more than 2 times that of the Test group subjects, although it needs to remember that absolute numbers in this small sample were not large. It is possible that the MCTIP helped the Test subjects in managing the side effects.

A number of limitations in our study methods should be kept in mind while interpreting the results. First of all, our study was not randomized, which is the ideal design to test an intervention. As previously explained, we had no choice to use this design for ethical reasons. Nevertheless, one must recognize the possibility of systematic bias in the nature of the sample and in factors that may have affected the results either at baseline or during the progress of the study. Furthermore, the compliance of subjects with the test and control interventions and referrals to other psychosocial services were not assessed and could have been systematically different. Indeed, one may argue that the Test and Control groups are not comparable. The analysis we performed demonstrated that the subjects recruited at the two sites were similar for most variables. However, there were a few differences including the proportion of people who spoke English or French as well as their educational status. In such a small sample, these findings are important and suggest that there could be fundamental differences in the nature of the patients being treated at the two sites. It is important to acknowledge the possible affects these differences may have had on our results. However, in our analysis we did not find the outcomes were associated with language or education status.

Another important limitation of this study is the timing of baseline data collection. Ideally, baseline data should be collected prior to the intervention. In this study, because of the difficulty of separating diagnosis and the initiation of information provision, our baseline data were collected after the intervention was provided.

It is also important to realize that we used ‘normal care’ as the comparison/control group rather than a placebo control. In theory, the improvement in the intervention group might have resulted from the additional time with the person who provided the information rather than the specific intervention. Or it might have been the test hospital and the care being very different from the control hospital. It is not possible for us to claim the effect was only because of the intervention. Lastly, even though we had the statistical power to see anxiety differences between the groups, our sample was too small to explore more complex interactions between covariates.

On the other hand, while we have to recognize these limitations in the study design, a major strength of our study is the good adherence of the study subjects and very low drop-out rates in both Test and Control groups, which is particularly exceptional in research with H&N cancer patients. In our Test group, all three subjects who dropped-out did so due to death. While in the Control group, the four subjects who dropped-out refused to respond to the follow up calls. Secondly, we used the HADS, which is a well validated and widely used outcome indicator that enables comparisons with the results of many other similar studies. Nevertheless, it is important to recognise that although the HADS is widely used in research as an indicator of levels of anxiety and depression symptoms, it is not a diagnostic tool for these conditions and so appropriate follow-up and diagnosis is required for good quality care.

Our findings indicate that subjects who received the MCTIP experienced significantly lower levels of anxiety than the Control group. Even though the hypotheses were only partially supported, our findings do provide preliminary evidence that a tailored information provision intervention using different modes can be supportive in H&N cancer care. Therefore, we conclude that informational interventions are a promising adjuvant in H&N cancer care in preventing psychiatric morbidity. However, it needs to be noted that this intervention takes significant resources in terms of time of personnel and some material costs, so future research needs to consider this in a cost-benefit analysis as well.

Tailored, multi-modal information delivery seems to benefit stage III and IV H&N cancer patients compared to a normal ad hoc approach to information provision. Patients' informational needs and expectations vary widely. Therefore, it is important to explore the extent or the severity of their informational needs. It is also very important to explore the potential barriers of the health care teams in delivering the needed information to their patients.

Conflict of interest statement

We have nothing to declare.

Funding

This work was partially supported by Faculty of Dentistry-McGill University, Le Réseau de Recherche en Santé Buccodentaire et Osseuse (RSBO), CIHR Strategic Training Initiative in Health Research Program, Alpha Omega Trust.

Acknowledgement

We acknowledge the Head and Neck cancer teams at the McGill University Health Center and the Jewish General Hospital and the generous participation and the precious time of the Head and Neck cancer patients. Lastly, we like to thank Dr. Carmen Loiselle, Dr. Linda Edgar, Dr. Gerry Humphris and Dr. Jose Correa for their professional advices.

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Appendix

Table 1.

General characteristics of the participants

Groups	Test (n =50) n (%)	Control (n=53) n (%)	p (2- tailed)
Age			
Mean $\pm$ SD	57.9 $\pm$ 11.1	61.7 $\pm$ 14.6	
Range	39 - 83	19 - 87	0.15
Gender			
Male	35 (70)	42 (79.2)	0.28
Female	15 (30)	11 (20.8)	
Language			
English	28 (56)	43 (81.1)	0.006
French	22 (44)	10 (18.9)	
Employment			
Working	20 (40)	30 (56.6)	0.078
Retired	25 (50)	15 (28.3)	
Unemployed	5 (10)	8 (15.1)	
Living			
Alone	9 (18)	13 (24.5)	0.477
With family	41 (82)	40 (75.5)	
Education			
High school or below	26 (52)	15 (28.3)	0.014
College or University	24 (48)	38 (71.7)	
Treatment			
Surgery	9 (18)	6 (11.3)	0.182
Chemotherapy and radiation	36 (72)	35 (66)	
Combination	5 (10)	2 (22.6)	
Person you counted on the most			
Partner	21 (42)	25 (47.2)	0.248
Family or a friend	24 (48)	18 (34)	
None	5 (10)	10 (18.9)	

Table 2

Means and standard deviations for outcomes for Test and control groups

Outcomes		Patients (n = 103, test=50, control= 53)				
by group	Baseline Mean (SD)	3 months Mean (SD)	6 months Mean (SD)	<i>p</i> -Value by Group	<i>p</i> -Value by Time	<i>p</i> -Value Time/Group
Anxiety						
Test	8.6 (3.8)	8.15 (3.7)	6.9 (3.9)	0.001	0.122	0.025
Control	8.9 (4.9)	9.84 (5.0)	9.5 (4.7)			
Depression						
Test	6.0 (4.4)	7.9 (4.1)	7.1(4.4)	0.089	0.001	0.214
Control	6.5 (5.1)	9.9 (4.5)	8.7(4.8)			

Figure.1. The time line for data collection points

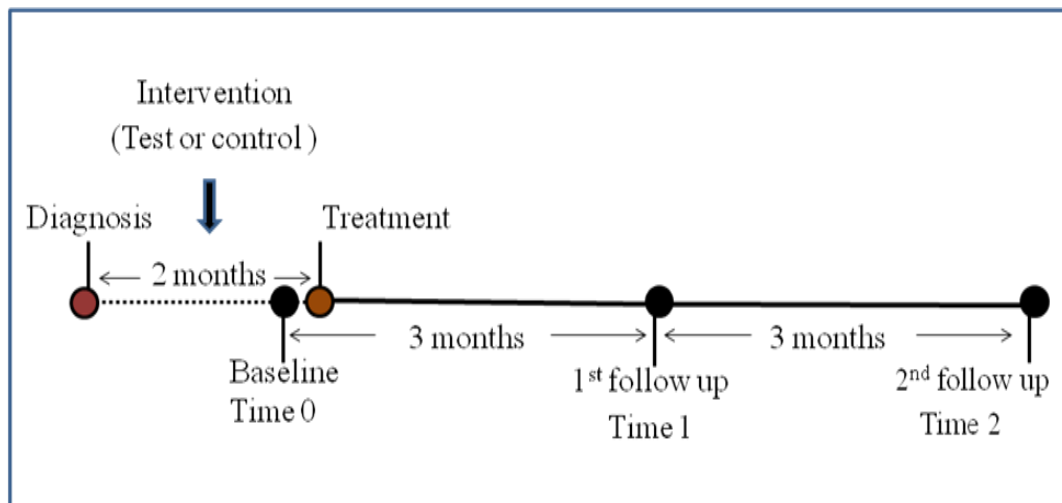


Figure 2 (a & b). Anxiety and depression ratings in test and control groups at baseline (T0), 3months (T1) and 6 months (T2).

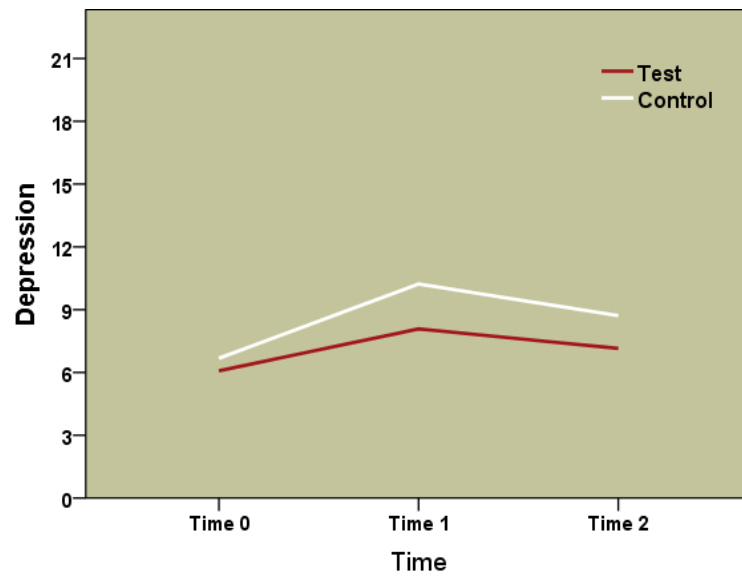
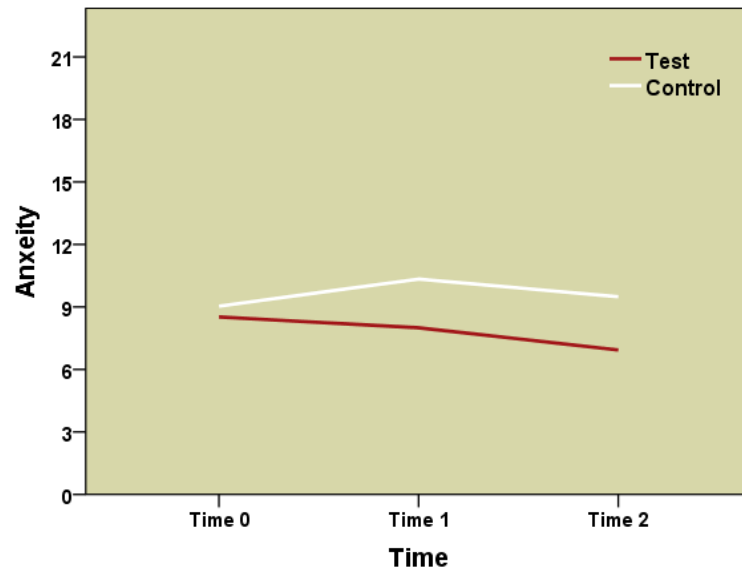
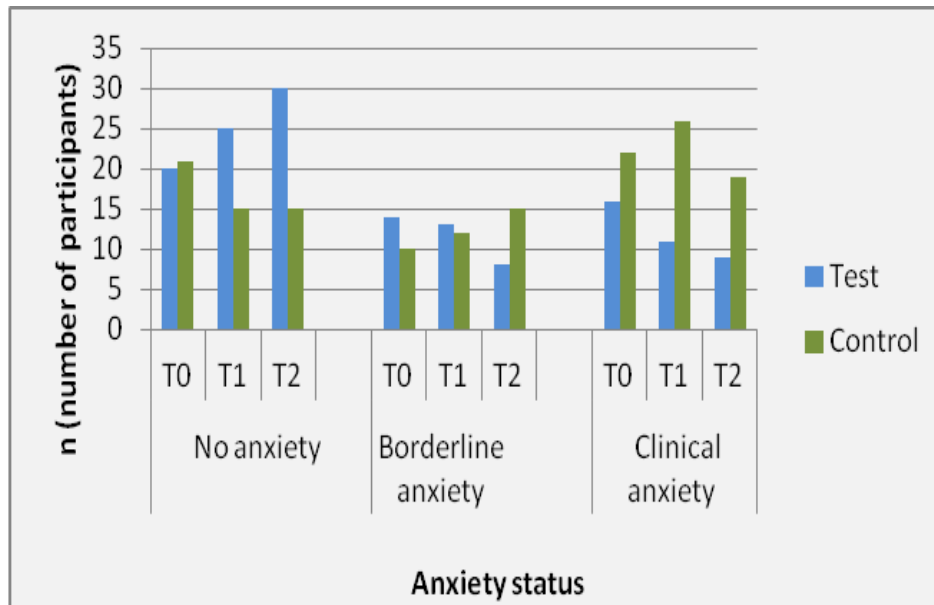
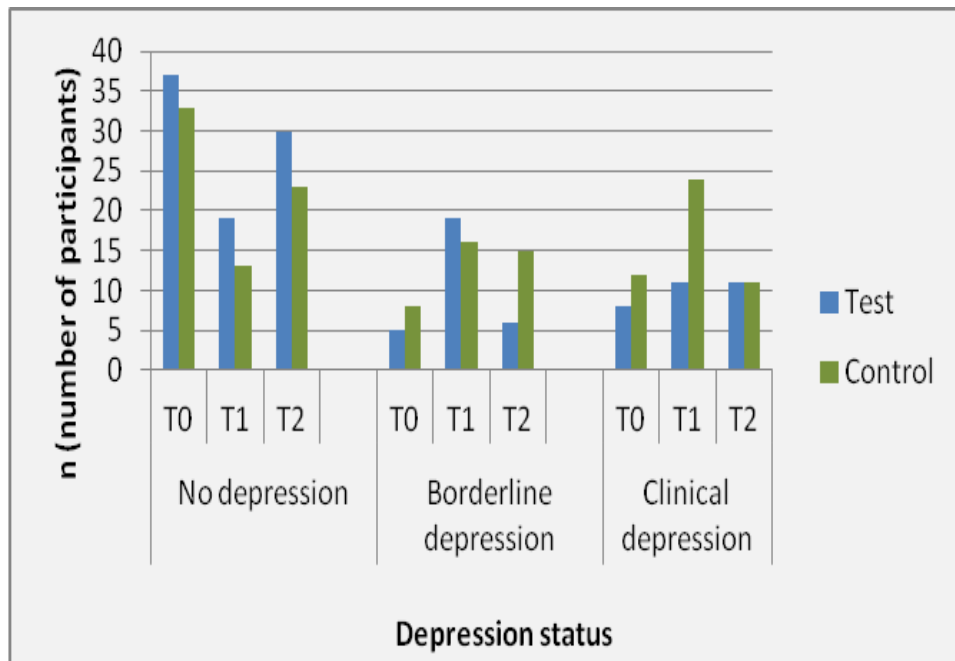


Figure 3 (a & b). Anxiety and depression ratings in test and control groups categorized at classic cut off points: No anxiety or depression (0-7), Borderline anxiety or depression (8-10) and Clinical anxiety or depression (11-21).

a)



b)



7.2 Objective 2

Our second objective in this project was to investigate the impact of the Multimode Comprehensive Tailored Information Package (MCTIP) on H&N cancer patient's cancer knowledge and satisfaction. The results of this investigation are presented in the manuscript titled "Do multimedia based information services increase knowledge and satisfaction in head and neck cancer patients?"

Manuscript 2: Do multimedia based information services increase knowledge and satisfaction in head and neck cancer patients?

D'Souza V, Blouin E, Zeitouni A, Muller K, Allison P. J – submitted to Patient Oral Oncology

Abstract

Objectives: To investigate the impact of a Multimode Comprehensive Tailored Information Package (MCTIP) on Head and Neck (H&N) cancer patients' knowledge and satisfaction.

Methods: A non-randomized controlled trial was conducted at two participating hospitals. One hospital delivered the test intervention and the second hospital provided normal care. The study was approved by local ethical committees. Patients with Stage III and IV cancer in the H&N region were recruited between their diagnosis and treatment. All participants were evaluated at baseline, 3 and 6 months later using the Satisfaction with Cancer Information Profile (SCIP) and a Cancer Knowledge questionnaire. Data were analyzed using descriptive statistics, T tests, chi square tests and finally linear mixed model analyses to test the potential impact of the intervention. **Results:** A total of 103 subjects participated in this study. The Test group reported higher levels of Cancer Knowledge and Satisfaction at all time points ($p < 0.001$ with all

comparisons) compared to the Control group. **Conclusion:** Our results suggest that there are benefits for subjects who receive a tailored, multimedia-based information intervention compared to normal ad hoc information delivery in terms of knowledge gained and satisfaction. Implications: Exploring patients' informational needs is necessary before planning information services to them.

Key words: Cancer, information intervention, multimedia, satisfaction, knowledge

1 Introduction

Head and Neck (H&N) cancers are the 8th most common cancers in the world and more prevalent in individuals over the age of 50 (1). The H&N area is so closely related to expression of feelings and communication and therefore receiving a diagnosis of cancer in this region is extremely devastating and frightening (2).

Cancer patients experience an enormous need for information, especially early in their treatment course (3, 4), and providing them with necessary information is important (5, 6). Information, not only prepares the patients for their treatment, it can also improve their treatment adherence, promote psychological well-being, improve their coping abilities, promote recovery and increase their satisfaction with care (7-11). Those patients who are satisfied with the information they receive, have a better quality of life and lower levels of anxiety and depression (12) on the other hand lack of information is associated with post-treatment uncertainty and psychological distress (13, 14).

The majority of the health care facilities provide information to their patients verbally or through information pamphlets (15). If the information is given verbally, patients tend to forget due to the shock of their diagnosis with cancer (16, 17). Even though written information can be helpful, it is not specific and not tailored to patients' needs. Besides, there seems to exist a large discrepancy between the average patients' reading and comprehension abilities and the literacy levels needed to understand the information provided to them (18, 19). This is more common among patients who have lower educational levels, poor language comprehension, poor eye sight

and the elderly (18, 20, 21). Often health care providers underestimate the informational needs of cancer patients, and give information only to those who actively seek it (22, 23).

Even though unmet informational needs are common among cancer patients (3, 4), there are patients who face information overload and time constraints (24). Cancer patients prefer to receive information in different formats that can be accessible from home (3, 25). Various approaches to provide information to cancer patients have been tried and multimedia approaches are among them (26, 27). Use of multimedia has the potential to enhance understanding without adverse psychological outcomes and it can increase patients' satisfaction (28, 29). However, these kinds of multimedia approaches have not been investigated in H&N cancer care. Given these observations, we aimed to investigate if multimodal, tailored information reduces levels of anxiety and depression and increases knowledge and satisfaction in H&N cancer patients when it is given soon after their diagnosis. This paper focuses on the knowledge and satisfaction outcomes. We hypothesized that multi-modal tailored information increases knowledge and satisfaction in H&N cancer patients when compared with H&N patients who receive usual care. In a previous paper, we reported anxiety and depression rating outcomes among the study subjects (30). In these analyses, we found that the test group had reduced anxiety ratings compared to the control group and that depression ratings were also lower in the test group although the difference was not necessarily significant (30).

2 Patients and Methods

This study was conducted at two academic hospitals in Montreal. The test intervention, the Multimode Comprehensive Tailored Information Package (MCTIP) was delivered at one

hospital site, and the second hospital delivered normal care. The test intervention was available to all stage III and IV H&N cancer patients at the test hospital before this research project was initiated. In such a situation, it would have been unethical to use a randomized approach, leading to some subjects at the test site not receiving the existing service (the test intervention). To be in accordance with the Belmont principle of beneficence, we chose a non-randomised experimental design. This study was approved by the IRB and the Local Ethics Offices of the participating hospitals.

The sample size was estimated for our main study, based on data from the literature, with an assumption of 80% statistical power and a two-sided significance level of 5% (30). According to this estimation, 47 subjects per arm were required to demonstrate a difference in 2 points in mean anxiety scores between the Test and Control groups at the primary outcomes point (6 months) following the cancer diagnosis. The satisfaction and knowledge change outcomes reported in this paper were the secondary outcomes in the main study.

Newly diagnosed patients with stage III or IV cancers in the H&N region, who were 18 years or older and who spoke either English or French were included in the study. Those patients who had already begun their cancer treatment and those who had a history or a diagnosis of any cognitive disorders were excluded. Subjects were recruited between diagnosis and the initiation of their cancer treatment. All subjects who participated in this study signed a written informed consent.

Subject Recruitment and Data Collection Procedures

Potentially eligible participants were identified from outpatient clinic reviews and from tumor board discussions. Patients were approached by phone and were informed of the study. If they agreed to participate, appointments were scheduled for interviews to collect baseline data at the hospitals or at their homes. At both test and control hospital sites, subjects received their cancer diagnosis and then immediately started to receive information. Therefore, it was not feasible or appropriate to separate the diagnosis from the initiation of information provision. Therefore baseline data at both sites were collected following diagnosis and initiation of information provision and prior to their cancer treatment. Subjects were then followed up at 3 and 6 month intervals as shown in the Figure 1. A total of 144 eligible patients were identified at both hospitals, out of them a total of 103 (71% of those eligible) participated in the study. Of these 103 participants, 94 were followed up at the primary outcome point.

Test intervention

The Multimode Comprehensive Tailored Information Package (MCTIP) is a multimedia based information tool that was developed by the H&N cancer team at the McGill University Health Center (MUHC). The MCTIP has 5 parts and is available in English and French.

1. Patient booklet – this contains general information about H&N cancer, terminologies used in H&N cancer care, information about the medical team and the different diagnostic procedures and adjuvant procedures using in H&N cancer care.

2. Interactive computer booth – patients may observe and interact with computer software developed to tailor the information for that patient. It gives site, stage and treatment specific cancer and treatment information, which can be printed and taken home.
3. Computer animation – a short animation to describe cancer, its spread, staging and a few specific surgical procedures.
4. DVD – a take-home DVD that provides a guided tour showing steps in H&N cancer care. It contains information on various diagnostic and adjuvant procedures that H&N cancer patients need to undergo as part of their cancer care.
5. Data base – This is a software that permits the storing of patients' information in an easily understandable format and enables the provision of a copy to the patient as well as access for the multidisciplinary team so that everyone is discussing the same information.

The Nurse Pivot (NP) in the H&N cancer care department at the test centre delivered the information using the MCTIP and all other resources available at the hospital. This initial information delivery session took about 1.5 – 2 hours. In addition, patients' questions and concerns were explored, distress levels were assessed and appropriate psychosocial referrals were made based on patients' needs.

Control intervention (normal care)

There were no specific information resources available for the H&N cancer patients at the control hospital other than the information pamphlets from the Canadian Cancer Society. The control intervention was delivered by a different NP at the control hospital in an ad hoc manner, with some patients meeting the NP and others not. Those meeting the NP spent from 15-45

minutes with her. The NP provided information verbally and this was often complemented by pamphlets from the Canadian Cancer Society. Patients' concerns were explored and appropriate referrals were made.

Data collected

All participants at both centers were evaluated using the Satisfaction with Cancer Information Profile (SCIP) (31) and an H&N Cancer Knowledge Questionnaire. Additionally, patients' demographic characteristics, clinical diagnosis and staging and behavioral information such as smoking and alcohol histories were obtained at baseline.

1. Satisfaction with Cancer Information Profile (SCIP)

This instrument is validated to measure the level of satisfaction with information provision in H&N cancer patients (32). The SCIP consists of 2 subscales. Since, the SCIP did not have a French version, it was translated into French using the classic forward-backward translation technique (33).

Subscale 1: Satisfaction With the Amount and Content of Information. This subscale consists of 14 items relating to the quantity and content of the information. A subscale score is obtained by summing the scores for each item. Total scores range from 0 to 14, with high scores indicating a high degree of satisfaction with the amount and content of the information received.

Subscale 2: Satisfaction With the Form and Timing of the Information Received. This section contains 7 items (items 15–21), each rated on a 5-item response scale from “very satisfied” to “very dissatisfied”. The responses are summed to give the overall satisfaction score with the

form and timing of information. Scores range from 7 to 35, with higher scores indicating higher levels of satisfaction.

2. Cancer Knowledge questionnaire

This questionnaire (see appendix) was developed to test patients' knowledge about their cancer and its management. The questions were focused about the cancer, its spread, etiology, treatment modalities and side effects. It was developed in English and then translated into French language using the classic forward-backward translation technique (33). It has 20 multiple choice questions with some questions having the possibility of choosing more than one answer. Scores were generated by simply adding the total correct responses to a maximum score of 25.

Data analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 20. Analyses were performed for all participants with available data at baseline. The significance level was set at $P < 0.05$ (two tailed). Differences in demographic, clinical and behavioral variables were analyzed using a t-test for continuous variables or chi-square of Fisher's Exact test for categorical variables, depending on the distribution of categories.

Mean Satisfaction (SCIP subscale A and B) and Cancer Knowledge ratings were calculated at baseline and two follow-up evaluation points for the Test and Control groups separately. As the outcomes were normally distributed, linear mixed model analysis were performed to investigate the potential impact of the intervention on Satisfaction and Cancer Knowledge ratings of the participants using the variable Time (T0, T1 and T2) as a within-subject factor and the variable Group (Test vs Control) as a between-subject factor, controlling

for the following covariates: age, gender, language background, employment status, educational level, living situation, type of cancer treatment and if they had any person to count on during their cancer journey.

Since the SCIP had been newly translated into French language, additional analyses were performed to evaluate its validity in the context of this study: 1) First, Cronbach's alpha was calculated for the whole study population at three time points and then for the French and English participants separately at three time points (Figure 3); 2) Then Pearson's correlation coefficients were calculated to assess the level of correlation between subscales A and B. The Cancer Knowledge questionnaire was newly developed for this study and to evaluate its validity in the context of this study, Cronbach's alpha was calculated for the whole study population at three time points and then for the French and English participants separately at three time points.

Finally, using Pearson's correlations, the relationship between Satisfaction and Cancer Knowledge ratings was investigated.

3 Results

A total of 103 subjects participated in this study. Of these, 96 (47 test and 49 control) participants completed all three (Time 0, Time 1 and Time 2) evaluations. The general characteristics of the sample are presented in Table 1. Test and Control groups exhibited similar general characteristics except for language use ($p = 0.006$) and educational level ($p = 0.014$). The mean (SD) ages for the Test and Control groups were 57.9 (± 11.1) and 61.7 (± 14.6) years respectively.

The SCIP subscale A

The mean ratings of the SCIP subscale A are presented in Table 2. The Test group had higher levels of satisfaction than the control group at all time points (T0, T1 and T2). The Test groups' satisfaction levels increased steadily over the 6 month follow up, while only a little variation was observed in the Control group. The results of the linear mixed model analysis showed a main effect of Group ($p < 0.001$) indicating satisfaction levels were significantly different between the Test and Control groups. The satisfaction ratings of both groups varied differently with time indicating an interaction effect between Time and Group ($p = 0.009$).

When controlling for covariates, the type of cancer treatment they received/were to receive was associated with the satisfaction ($p = 0.05$) indicating that subjects who received chemotherapy and radiation were better satisfied than subjects who received other treatments.

The SCIP subscale B

The mean ratings of subscale B (Table 2) show that the Test group subjects were better satisfied than the Control group subjects at all time points (T0, T1 and T2). The satisfaction levels of the Test group increased steadily over the 6 month period while only a slight variation was observed in the Control group. The results of the linear mixed model analysis showed a significant main effect of Group ($p < 0.001$) indicating that the satisfaction ratings were significantly different between Test and Control groups. Even though the satisfaction ratings significantly changed with Time ($p = 0.04$) and the trajectory of the change followed different paths indicating an interaction effect between the Group and Time ($p = 0.014$). While controlling for covariates in this analysis, the SCIP subscale B was not associated with any covariates.

Cancer Knowledge

The mean Cancer Knowledge ratings (Table 2) showed that the Test group subjects had a higher level of cancer knowledge than the Control group subjects at all time points (T0, T1 and T2). There was a significant main effect of Group ($p < 0.001$) indicating that the cancer knowledge differed significantly between both the Test and Control groups. There was an effect of Time ($p < 0.001$) showing that the cancer knowledge changed (increased) as both groups gained knowledge over the 6 month period. It is interesting that the knowledge gains in both groups were similar and therefore, there was no interaction effect between the Time and Group ($p = 0.76$).

While controlling for covariates, cancer knowledge showed significant associations with living situation ($p= 0.001$), employment status ($p=0.016$), educational level ($p=0.03$), type of treatment ($p=0.008$) and age ($p=0.021$). Those participants living alone had a higher level of cancer knowledge than those living with family or their partners. Participants who were employed or retired had a higher level of cancer knowledge than those who were unemployed. Those subjects who had a higher level of education had a higher level of cancer knowledge than those who had a lower level of education. Lastly, we observed that older participants had a lower level of cancer knowledge than the younger subjects.

Reliability test

The results of the reliability test for the SCIP and Cancer Knowledge questionnaires are presented in the Table 3. These tests demonstrated high internal consistencies for both the SCIP and Cancer Knowledge questionnaires with Cronbach's α ranging from 0.76 - 0.9 when tested

across the whole study population and then separately for English and French participants. The analysis of correlations between SCIP subscales A and B showed significant correlations with moderate-to-good magnitudes at baseline, 3 and 6 months with $r = 0.53$ ($p < .001$), $r = 0.71$ ($p < .001$) and $r = 0.68$ ($p < .001$) respectively. This indicates that both SCIP subscales A and B were moderately-to-well correlated with each other.

Finally, the analysis of correlation between the SCIP and the cancer knowledge ratings showed that the SCIP subscale A was significantly and positively correlated with Cancer Knowledge at 3 months ($r = 0.35$, $p < 0.001$) and 6 months ($r = 0.32$, $p = 0.001$); and Satisfaction B was positively correlated with Cancer Knowledge at baseline, 3 and 6 months ($r = 0.3$, $p = 0.005$; $r = 0.4$, $p < 0.001$; and $r = 0.4$, $p < 0.001$ respectively) indicating that those who had higher cancer knowledge were better satisfied with the information they received.

4 Discussion

Determining H&N cancer patients' satisfaction and knowledge levels are important in planning supportive services in H&N cancer care. In this study, we investigated the impact of multimedia-based, tailored information on H&N cancer patients' cancer knowledge and satisfaction. This is the first study conducted with H&N cancer patients using a multimedia based information intervention. Our study results show that the Test subjects had higher levels of cancer knowledge and were better satisfied than Control subjects suggesting that the test intervention had a significant impact on the satisfaction and cancer knowledge of the H&N cancer patients. These results further strengthen other results in this study showing that H&N cancer patients' anxiety and depression ratings were lower in the Test group compared to the Control group (30).

Information interventions have been used and evaluated in various health care settings including cancer care facilities. There are not many studies that have used information interventions in H&N cancer care. Even though a few studies used information interventions in the form of pamphlets and booklets, and demonstrated positive outcomes (30, 34-36), none of them have focused on knowledge outcomes. Therefore, cross comparison with other studies is limited.

Our results suggest that MCTIP is an information tool that can overcome the limitations that are faced by the booklets and pamphlets often used in “normal care”. The MCTIP is tailored to patients’ needs, and uses different delivery formats and audiovisuals that can improve information retention and is provided by trained personnel in a devoted session allowing them to communicate with the patient. The MCTIP thus reduces the possibility of over burdening the patients with a lot of information. Our control hospital delivered information verbally and through information pamphlets and the outcomes we observed in that group were inferior when compared with the Test group.

The Test group had a higher level of satisfaction and knowledge as early as baseline, even though it was not significantly different at that time. The test intervention was initiated before the baseline data collection and this may have led to the baseline differences between the groups. Both groups gained knowledge as they moved from the time of diagnosis to treatment and post-treatment periods. The repeated consultations they have had with health care professionals during their treatment, as well as their firsthand experiences might have helped them in their knowledge gain in both groups.

Our descriptive statistical tests showed that the Test group had a significantly lower level of education than the Control group subjects. Based on this, one could assume that the Test group subjects would have a lower level of knowledge than the Control group subjects. However, it was not so. On the contrary, the Test group subjects had a higher level of cancer knowledge. The only possible explanation we have is the test intervention made this difference.

Our study results showed that cancer knowledge was significantly associated with living situation, employment situation, educational level, type of treatment and age. These findings are in line with many other studies conducted with patients with chronic illness including cancers using information intervention (26, 37-43). Cancer knowledge was associated with living conditions, with people living alone having a higher level of cancer knowledge than the participants who lived with family or their partners. People who were working or retired had a higher level of cancer knowledge than those who were unemployed and this observation has been reported in other studies too (41, 43). Those participants who received chemotherapy with radiation for their cancer had a higher level of cancer knowledge than those who had surgery or radiation alone. The subjects who received surgery alone did not receive information on chemotherapy or radiation. But the subjects who received chemotherapy and radiation received information on both chemotherapy and radiation. In addition, they also experienced the two treatments and their side effects. Over all they had a higher level of exposure to information than those who received just one kind of treatment. Lastly, our results showed knowledge was significantly associated with age, with younger people having a higher level of knowledge than older people and this finding is seen in other studies as well (43).

The SCIP was translated into French and was used in this study. The results of our reliability test showed good internal consistencies for both SCIP subscales A and B suggesting that it is a reliable tool to evaluate satisfaction both in English and French languages. In addition to this, the results of the inter-correlation test conducted between the SCIP subscales A and B suggest that the SCIP is a valid instrument to measure H&N cancer patients' satisfaction although the magnitudes of the correlation coefficients were moderate. These results are in line with the work done to validate this instrument previously (31). Even though the Cancer Knowledge questionnaire was newly developed for our study and has not been validated earlier, it was able to capture the H&N cancer patients' knowledge levels in a comprehensive way. The reliability test showed good internal consistencies (Cronbach's alpha 0.76 -0.81) suggesting that this instrument is reliable in addition to having face validity to evaluate H&N cancer patient's knowledge. Lastly, our results showed that SCIP and cancer knowledge were positively and significantly correlated at a moderate level indicating that those who had higher cancer knowledge expressed greater satisfaction although the magnitude was moderate.

There are a number of limitations to be kept in mind while interpreting the results. Firstly, the study was not randomized, which is the ideal design to test an intervention. As previously explained, we had no choice to use this design for ethical reasons. Another methodological limitation was that baseline data were collected after the initiation of the intervention. Ideally, baseline data should be collected prior to the intervention. Because of the difficulty of separating diagnosis and the initiation of information provision, our baseline data were collected after the intervention was provided. The final limitation was the use of a 'normal care' comparison group rather than a placebo control. In theory, the improvement in the

intervention group might have resulted from the additional time with the person who provided the information rather than the specific intervention. While we recognize these limitations, a major strength of our study is the good adherence of the study subjects and very low drop-out rates in both Test and Control groups, which is particularly exceptional in research with H&N cancer patients. In our Test group, all three subjects we lost were due to death. While in the Control group, the four subjects who dropped-out refused to respond to the follow up calls.

Our findings indicate that the subjects who received the MCTIP were better satisfied with the information they received and had higher levels of cancer knowledge than the subjects who received the normal care. The findings reported in this paper complement those reported in a previous paper, in which Test subjects had lower anxiety and depression ratings, as well as having higher cancer knowledge and satisfaction scores as reported here. Our findings provide preliminary evidence that an information intervention using different modes is feasible and such an intervention is a beneficial adjuvant in H&N cancer care.

Tailored information services using different formats are very important in cancer care as they bring in many positive outcomes. Patients' informational needs and expectations vary widely. Therefore, it is important to understand the patients' expectations and informational needs and provide information accordingly. It is also important to explore if these kinds of information sources lessen the burden of the health care providers in information delivery.

Conflict of interest

We have nothing to declare.

Funding

This work was partially supported by Faculty of Dentistry-McGill University, Le Réseau de Recherche en Santé Buccodentaire et Osseuse (RSBO), CIHR Strategic Training Initiative in Health Research Program, Alpha Omega Trust.

Acknowledgement

We acknowledge the Head and Neck cancer teams at the McGill University Health Center and the Jewish General Hospital and the generous participation and the precious time of the Head and Neck cancer patients. Lastly, we like to thank Dr. Carmen Loiselle, Dr. Linda Edgar, Dr. Gerry Humphris and Dr. Jose Correa for their professional advices.

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Appendix

Table 1.

General characteristics of the participants

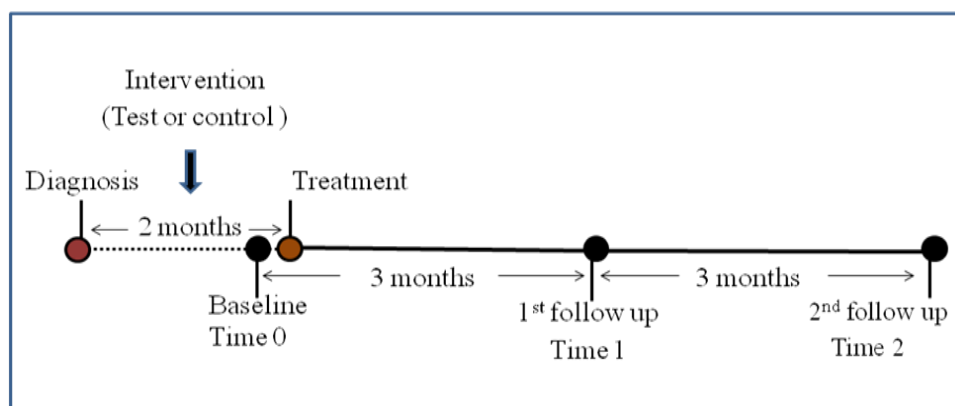
Groups	Test (n =50) n (%)	Control (n=53) n (%)	p (2- tailed)
Age			
Mean $\pm$ SD	57.9 $\pm$ 11.1	61.7 $\pm$ 14.6	
Range	39 - 83	19 - 87	0.15
Gender			
Male	35 (70)	42 (79.2)	0.28
Female	15 (30)	11 (20.8)	
Language			
English	28 (56)	43 (81.1)	0.006
French	22 (44)	10 (18.9)	
Employment			
Working	20 (40)	30 (56.6)	0.078
Retired	25 (50)	15 (28.3)	
Unemployed	5 (10)	8 (15.1)	
Living			
Alone	9 (18)	13 (24.5)	0.477
With family	41 (82)	40 (75.5)	
Education			
High school or below	26 (52)	15 (28.3)	0.014
College or University	24 (48)	38 (71.7)	
Treatment			
Surgery	9 (18)	6 (11.3)	0.182
Chemotherapy and radiation	36 (72)	35 (66)	
Combination	5 (10)	2 (22.6)	
Person you counted on the most			
Partner	21 (42)	25 (47.2)	0.248
Family or a friend	24 (48)	18 (34)	
None	5 (10)	10 (18.9)	

NB: Differences in continuous variables were evaluated using a t-test. Differences in categorical variables were evaluated using a chi square test, except where cells had low numbers (below 10), when a Fisher's Exact test was used.

Table 2. Means and standard deviations for outcomes for Test and control groups

Patients n = 96, test 47, control 49						
Outcomes by groups	Baseline Mean (SD)	3 months Mean (SD)	6 months Mean (SD)	<i>p</i> Value by Group	<i>p</i> Value by Time	<i>p</i> Value Time/Group
Satisfaction A (Satisfaction with the amount and content of information)						
Test	10.8(3.7)	11.8(3.0)	12.2(2.9)	< 0.001	< 0.76	0.009
Control	9.4(3.4)	8.3(3.5)	8.6(3.8)			
Satisfaction B (Satisfaction with the form and timing of the information received)						
Test	29.7(3.5)	30.5(4.5)	30.9(3.7)	< 0.001	0.04	0.014
Control	26.8(4.6)	24.9(4.5)	26.4(4.3)			
Cancer Knowledge						
Test	19.1(4.0)	21.7(3.4)	22.4(3.3)	< 0.001	< 0.001	0.76
Control	17.3(4.9)	18.6(3.9)	19.5(3.4)			

Figure.1. The time line for data collection points



Knowledge Questionnaire

We would like to ask you about the information you have received about head and neck cancer and your treatment. Kindly choose and **circle** the appropriate answer/s what you feel is right based on the information provided to you. If required, **you are allowed to choose more than one answers for the questions.**

1. Cancer is an uncontrolled growth of cells or tissues.
 - A. True
 - B. False
 - C. I don't know
2. Cancers have the ability to spread.
 - A. True
 - B. False
 - C. I don't know
3. Cancers can spread to the adjacent (neighboring) areas.
 - A. True
 - B. False
 - C. I don't know
4. Cancers can spread through the blood.
 - A. True
 - B. False
 - C. I don't know
5. Cancers can spread to the bones.
 - A. True
 - B. False
 - C. I don't know
6. Even though, cancers generally grow fast, there are cancers that grow slow.
 - A. True
 - B. False
 - C. I don't know
7. Cancer is also known as:
 - A. Benign tumor

- B. Malignant tumor
 - C. Neither benign nor malignant
 - D. I don't know
8. Which of the followings habits are strongly associated with cancers in the head and neck region:
- A. Smoking
 - B. Routinely taking sleep medications
 - C. Routinely taking pain killers
 - D. I don't know
9. Which of the following categories of people are more likely to develop head and neck cancer:
- A. People who consume large quantities of alcohol.
 - B. People who consume large quantities of fatty food.
 - C. People who eat large quantities of meat.
 - D. I don't know
10. Chose the correct statement:
- A. Cancers always comes back once treated.
 - B. Once treated, cancers never come back.
 - C. Cancers may come back even after treatment.
 - D. I don't know
11. Cancer staging explains:
- A. When the cancer started.
 - B. The size and spread of the cancer at diagnosis.
 - C. What type of cancer it is.
 - D. I don't know
12. Which of the following methods do you think are used to treat head and neck cancers?
- A. Surgery
 - B. Radiotherapy (X-ray treatment)
 - C. Chemotherapy
 - D. Surgery, radiotherapy and chemotherapy.
 - E. I don't know
13. Most of the time, more than one type of cancer treatments are given to treat head and neck cancer.
- A. True
 - B. False
 - C. I don't know

14. Radiotherapy in the head and neck region can lead to
- A. Dry mouth
 - B. Vomiting
 - C. Hearing loss
 - D. I don't know
15. Radiotherapy in the head and neck region can cause
- A. Burning sensation in the mouth
 - B. Difficulty in swallowing
 - C. Loss of taste
 - D. All of the above mentioned choices
 - E. I don't know
16. One of the common side effects of radiotherapy is vomiting.
- A. True
 - B. False
 - C. I don't know
17. All head and neck cancer patients lose hair, irrespective of the type of treatment they received.
- A. True
 - B. False
 - C. I don't know
18. Radiotherapy (X-ray treatment) in the head and neck region increases the risk for teeth cavities.
- A. True
 - B. False
 - C. I don't know
19. Chemotherapy has very few side effects and is the preferred treatment of choice for cancer.
- A. True
 - B. False
 - C. I don't know
20. Chemotherapy
- A. Does not kill any cells in the body
 - B. Kills only cancer cells in the body
 - C. Kills cancer cells and the normal cells of the body.
 - D. I don't know

7.3 Objective 3

Our third objective in this project was to describe and compare the experiences of Head and Neck (H&N) cancer patient subjects receiving a new tailored, multimodal information delivery intervention with those receiving normal information deliveries. The findings of this investigation are presented in the manuscript presented below.

Manuscript 3: Information Provision in Head and Neck Cancer Care – a qualitative study

D'Souza V, Blouin E, Zeitouni A, Allison PJ - Submitted to Journal of Journal of Psychosocial Oncology.

Acknowledgements

This work was partially supported by Faculty of Dentistry-McGill University, Le Réseau de Recherche en Santé Buccodentaire et Osseuse (RSBO), CIHR Strategic Training Initiative in Health Research Program, Alpha Omega Trust. We acknowledge the Head and Neck cancer teams at the McGill University Health Center and the Jewish General Hospital and the generous participation and the precious time of the Head and Neck cancer patients. Lastly, we like to thank Dr. Carmen Loiselle, Dr. Linda Edgar, Dr. Gerry Humphris and Dr. Richard Hovey for their professional advices.

Abstract

The intention of this study was to describe and compare the experiences of Head and Neck (H&N) cancer patient subjects receiving a new tailored, multimodal information delivery intervention with those receiving normal information deliveries. In this qualitative study, a total of 11 H&N patients and two Nurse Pivots participated. Data were gathered by semi-structured interviews with the participants and by observing information provided at both centers. Our findings show that subjects who received the tailored information had a good information provision experience, while peers who received the normal care approach expressed dissatisfaction with their information provision experience.

Keywords: Tailored information, multimedia information, head and neck cancer patients, psychosocial oncology.

Introduction

Head and Neck (H&N) cancers are a group of cancers arising in the lips, mouth, salivary glands, throat, larynx, nasal cavity or sinuses (Dobrossy, 2005). They are the 8th most common cancers in the world, and are more prevalent in men over the age of 50 (Ferlay et al., 2010).

Diagnosis of cancer is known to cause sentiments of anxiety, susceptibility and helplessness related to the uncertain clinical course and the treatments that provide no guarantees of cure (Llewellyn, McGurk, & Weinman, 2007). H&N cancer patients often suffer from a wider array of psychosocial problems than the majority of other cancer patients since the H&N region is closely associated with communication and socialization. Although receiving a diagnosis of cancer is inevitably distressing, appropriate communication between health care providers and patients is known to alleviate some elements of the traumatic nature of this experience (Simpson et al., 1991; van Dulmen, 2011). Studies show that providing comprehensive and relevant information can assist the patients by preparing them and enhancing their ability to manage their illness. On the other hand inadequate information may increase stress and lead to mistrust and or miscommunication (Arora, 2003; Tattersall, Butow, & Clayton, 2002; Vardy & Tannock, 2004).

In spite of the literature showing the importance of information provision in cancer care, the informational needs of H&N cancer patients often remain unmet (Mesters, van den Borne, De Boer, & Pruyn, 2001; Ragaccio, Lombardo, & Garrone, 2007; Yap & Davis, 2008). When these informational needs are not adequately met at the hospitals, patients often look for information on the Internet. Even though there are some websites that provide clear and exhaustive information on cancer, searching for the needed information on the web is frustrating,

scary and time-consuming (Andreassen, Randers, Naslund, Stockeld, & Mattiasson, 2005; Evrard, Guertin, Remacle, Jamart, & Leveque, 2009). Furthermore, past studies have shown that obtaining cancer-related information from the internet does not replace face-to face encounters with health professionals (Basch, Thaler, Shi, Yakren, & Schrag, 2004; James et al., 2007).

Patients' informational needs often differ from person to person and they convey them through verbal cues, such as direct or indirect questions or statements (Butow, Brown, Cogar, Tattersall, & Dunn, 2002; Street, 1991). It is imperative that health care providers recognize and understand the unique needs of these patients' in order to furnish them with the appropriate information. It is also necessary that health care providers possess resources to provide information to their patients in the most comprehensive manner. As other related studies suggested, information provision should move from a "one-size-fits-all" to a tailored approach that considers the unique needs, beliefs, values, and emotions of different patients (Fujimori & Uchitomi, 2009; Knobf, 2007; Rodin et al., 2009; van Dulmen, 2011; Wen & Gustafson, 2004). Communicating in a purposeful way, while respecting patients' values and feelings, should become the standard of care in health care practices especially, when the disease management strategies are complex and multiple, as is in H&N cancer (van Dulmen, 2011).

Even though, empirical evidence shows that tailored information provision can yield better outcomes in cancer care, the majority of cancer care facilities provide information in an ad hoc manner (Chelf et al., 2001; Rutten, Arora, Bakos, Aziz, & Rowland, 2005; Wiljer & Catton, 2003). Consequently, very little research has been done with patients living with H&N cancer especially concerning the information dissemination. We therefore designed a study to investigate the potential benefits of a Multimode Comprehensive Tailored Information Package

(MCTIP) provided for people diagnosed with stage III or IV cancers in the H&N region at two academic hospitals in Montreal. This report describes the results of a qualitative project nested within the main study. We used the theory “interpretive phenomenology” that combines psychological, interpretive and ideographic components (Heidegger, 1962). This theory helps in gaining insight into how a given person can make sense of a given phenomenon in a given context. The intention of this study was to describe and compare the experiences of H&N cancer patients’ receiving information concerning their cancer and treatment at two hospitals with different approaches to delivering information for H&N cancer patients: at one hospital the MCTIP; and at the other a normal care approach.

Methods

Study design

This descriptive qualitative study is part of a larger non-randomized, controlled trial examining the impacts of a MCTIP provided to H&N cancer patients shortly after their diagnosis and then on an on-going basis as required. The study was conducted at two academic hospitals in Montreal after obtaining ethical approval from the McGill University Institutional Review Board and the Research Ethics Offices of the participating hospitals. The test intervention (MCTIP) was delivered at one hospital, while normal information delivery practices (the control intervention) were used at the second hospital. The inclusion criteria for the main study were: 1) patients with stage III and IV primary cancer in the H&N region; 2) patients 18 years of age or older; and 3) patients able to communicate in English or French. Patients who had a diagnosis or a history of any cognitive disorders were excluded. Subjects in the main study were recruited shortly after

diagnosis of their cancer. Baseline data were collected on recruitment and then 3 and 6 months later.

Participants

Participants for the qualitative project reported in this paper were a subsample of the main study sample. This subsample comprised participants recruited at different phases of the main study, including participants recruited prior to and following the completion of their cancer therapy. This purposeful sample of participants was recruited like this to ensure data were collected from subjects at different phases of cancer therapy and information provision. Participants for this qualitative project were recruited until the content of the information generated during data collection reached saturation point.

Test information provision intervention

MCTIP is a multimedia based tool with audiovisual aids that was developed by the H&N cancer team at the McGill University Health Center (MUHC). The MCTIP has 5 parts and is available in English and French. This test intervention was delivered formally in a devoted session by the Nurse Pivot (NP – this role is as a coordinator for and communicator of all elements of cancer care for patients so they have a “one-stop” source of coordination of care and provision of information) involved at the test center. The intervention comprised:

1. A booklet - containing general information about cancer, terminologies used in cancer care, information about the medical team and the different diagnostic procedures.

2. An interactive computer booth – patients observe and interact with computer software developed to tailor the information for that patient. It gives site-specific cancer disease and treatment information, which can be printed and taken home.
3. A computer animation – a short animation to demonstrate cancer, its spread, staging and a few specific surgical procedures.
4. A DVD – this is a guided tour that shows up-coming steps in cancer treatment, enables patients to review information provided in consultations and importantly, it allows family members to take part.
5. A Database – this allows storing all information about a patient in a readily understandable format. A copy is given to the patient and the multidisciplinary team accesses and uses it to plan therapy.

Standard care for information provision (control intervention)

The control hospital delivered “normal information provision”. There were no specific information resources available for the H&N cancer patients at the control center other than the information pamphlets from the Canadian Cancer Society. The control intervention was delivered by the NP based at that hospital (i.e. a different NP to the individual at the test hospital site) in an ad hoc manner, mainly verbally and often complemented by pamphlets from the Canadian Cancer Society.

Data collection

Participants already recruited in the main project were approached by phone to request participation in this qualitative study and those agreeing to participate had interviews set up at

the respective hospitals where they were registered for their cancer care. Data were collected by a research assistant through semi-structured interviews with the participants at both test and control centers, and through shadowing the NPs and audio taping the information delivery sessions at both centers. Finally, data were collected from both NPs through semi-structured interviews at both centers. Most of the data were collected at the respective hospitals, except one interview with a participant, which was done over the phone. All interviews were audio taped. The interviews ranged from 25 to 90 minutes long and in addition, field notes were also taken.

The questions used in the interviews were structured in a way that required that two of the participants were NPs and the remainder patients. The interviews were structured in a manner to enable exploration and better understanding of how the information was delivered and the participants' perceptions of the benefits of the information delivery at both hospitals. Interview questions were designed get deeper insight into understanding how the participants acquired information during their cancer journey, the timing of information reception, the time spent on information provision, the quality, quantity, details and understandability of the information and subjects' perception of the information provision. After each interview, the data were transcribed, coded, and the emerging themes were used in generating questions for subsequent interviews (Corbin & Strauss, 2008). Additionally, participants who were patients were asked to speak freely about their experience at the hospital and their opinions regarding information reception from the time of their cancer diagnosis.

Data analyses

All interviews and field notes were transcribed verbatim. Transcripts were read and coded from the outset of the data collection independently by two researchers and then compared to ensure the accuracy and congruence of the codes identified. In case of disagreement, a discussion was held between the two to reach consensus (Miles & Humberman, 1994). A detailed analysis and interpretation of the codes helped in developing categories. Even though the generated codes, categories and themes became repetitious after 8 interviews, three more participants were recruited to re-examine and confirm the emerging themes. Sampling was terminated after 11 interviews as the categories were saturated (Glaser, 1978; Strauss & Corbin, 1990). Care was taken to guard the anonymity of subjects.

Results

A total of 11patient participants (5 at the test hospital and 6 at the control hospital) with stage III and IV cancer in the H&N region and 2 NPs participated in this study at both test and control centers. Three main themes emerged from the interviews with the participants and we have organized them by categories as follows.

1. Information delivery

The participants recruited at the test site received most of the disease and treatment related information from their doctors and other professionals involved in their cancer care such as dentists, nutritionist, speech therapist and nurses. In addition to this, the test participants also received a 1.5-2 hour long, devoted session with the NP. The NP used the MCTIP as the main

source for information provision and also used other information available at the hospital such as information pamphlets through the Canadian Cancer Society. Additionally, as part of the information delivery process, participants' psychosocial distress was evaluated using a distress thermometer and appropriate referrals were made as needed for e.g. psychological, social or welfare interventions.

Participants recruited at the control site also received cancer and treatment related information mainly from their doctors and other professionals involved in their cancer care e.g. dentists, nutritionists, speech therapist and nurses. Some participants had the opportunity to meet with the NP briefly in the out-patient clinics while they were waiting to see their doctors and some did not have this opportunity. Those who met with the NP had the opportunity to be followed up by the NP. Meeting with the NP was solely based on the availability of the NP at the out-patient clinic and was not systematic. Some participants scheduled appointments to see the NP at another time, and this meeting generally lasted 15 - 45 minutes. The information they received at the control center was mainly verbal in nature, and based on the experience and knowledge of the NP, rather than from a standardized source. This was complemented by pamphlets from the Canadian Cancer Society. One participant mentioned browsing the internet to find information when he/she did not obtain the answers to his/her question at the hospital.

2. The NP perspective

At the test center, a large majority of the participants were referred to the NP soon after their diagnosis, if not, at least prior to their commencement of their treatment. The NP at the test center said that:

“The role of the nurse pivot is really to be the personal resource for the patient and the family so I am really like the resource person for the patient and the family. Of course I deal with the surgeon, the oncologist, the radio-oncologist, dentistry, PEG (Percutaneous Endoscopic Gastrostomy tube, also known as the feeling tube), physician, radiologist, nutritionist, speech pathologist, social worker, psychology, psycho-oncology on the other side.... So I am really like the hospital person. For mostly everyone... it’s a good thing, and [the doctors] are very involved with me, and they really refer me mostly to everyone”.

It was not the same case at the control hospital. The patients were not routinely referred to the NP. Some did not meet the NP until they began their treatment, and some never met the NP. The NP at the control center explained that:

“I feel that if I meet them [patients] early, and we get that link, that they use me more....I give booklets on chemotherapy, radiotherapy, everything that I can hand them, they take. That’s why it’s important if I meet them early, I mean then at least I can give them that. It may only be like, generic, from the Canadian Cancer Society, but... if they read it then it may get them thinking “Oh I should ask those questions.” Whereas when they get into the treatment, I mean its ok, I meet them, but they just don’t get that little initial time where I sit, I listen to... you know they sit, they cry. Just to be able to acknowledge that they have this terrible disease and that someone is willing to sit with them and realize that it has impacted them”.

3. The patients' perspective

From the patient's perspective, three major comparative themes emerged from the data: the timing of the information being provided; the importance of a general overview; and the value of using different modes in information provision. The findings regarding each of these themes are described below.

3a. Timing of the information provision

We found that the timing of information provision is crucial for patient participants. A participant recruited at the test center explained that their experience at the hospital would not have been the same had they not received this first encounter.

Participant 1: I found it excellent that she [the NP] took us in hand right away after the announcement [of the diagnosis] because otherwise I don't think we would... we would not have been ok. She really... she reassured us, told us what was going on, she reassured us... If we didn't have that we would have left the hospital with our hearts in our stomachs, no one would have told us anything other than the fact that there was a cancer....Yes [it is essential to meet her the day that you get the diagnosis] ...I am certain... imagine leaving the room with the doctor with no one to meet with after... no I think that for myself and my husband it was magnificent. I encourage the hospital to continue that with their patients.

At the control center, those participants who met with the NP immediately following their diagnosis emphasized the importance of being able to speak with someone prior to commencing their treatment. They reported the positive affect it had on their anxiety level and that it allowed

them to go forward with their treatment. Had this research participant not met with the NP, she/he either would have been unprepared to start the treatment or would have anxiously undergone chemotherapy without any opportunity to discuss the treatment and would not have known what to expect.

Participant 6: Once I finished having the panic attack then I kind of settled down then... my biggest concern was what the chemo involved because I was diagnosed and then the next day I was gonna have chemo and I was thinking "This is moving too fast". So... it was nice of [the pivot nurse] she explained it.... And she explained everything to me about as to what would happen, how, how things work. So it kind of helped 'cause I calmed down a bit so I was ready for it the next day. I didn't have a problem with it.

And those participants at the control center who did not meet with the NP felt that they had no one to call to update their status and provide them with valuable information as to what is going on behind the scenes. As a result, they reported feeling anxious and uncertain about the care they were going to receive in the weeks following their diagnosis.

Participant 7: When I first saw the doctor, he told me not to worry, that everybody here would take care and I would know as things were progressing. At one point, nothing was happening. I wasn't sure what was going on. I didn't get any phone calls. I didn't get any information. I finally got a phone call from the ahh radio-oncologist...the secretary for [the radio-oncologist] to meet him on Wednesday. A few Wednesdays ago, so when I got there I asked him a whole bunch of questions because I wasn't sure. I was very nervous.

Participant 8: “I didn’t know where I was going, I didn’t know what to expect...when I see the next Doctor at 11:30, I don’t know what he’s...I don’t even know why I’m going to see him! So..... I’m still, I’m still walking around with a question mark in my face, but not as much as before”.

3b. Importance of a general overview

Although participants at the test center stated that their doctors gave them an overview about their cancer and its treatment, they greatly appreciated the general overview provided by the NP using different modes to explain to them about their cancer and what would come next. They appreciated the use of audiovisuals and their role in simplifying the information that they had already received from their doctors. Additionally, good quality information concerning the nature of the treatment made them think beyond the diagnosis and helped in preparing them for the treatment.

Participant 2: “She [the NP] was really helpful in the sense that she gave us an overview of what to expect, basically what’s going to happen, who would be there to support, basically set up the team concept, and that of course she was the nucleus of that, if there was a problem we call her... she is really good.”

Participant 4: “It’s reassuring because we know where we are going. I can tell you that we did not get any pleasure from watching it (the DVD), because it’s not things that you like to do as a person, but on the other hand to know what is coming... that is... it gives you a very good idea. It is essential, I think, for the patient. Because when we arrived for

appointments, the MRI, the PEG tube, we had the impression that we had already done it. In our head we already knew where we were going.”

At the control center, those participants who met with the NP felt that they had someone in the hospital who works on their behalf and they had someone to call in case they had questions.

Participant 6: “Well, she (the NP) told me exactly step by step as to what would happen like with the chemo she even said you won’t be sick in front of people, you won’t do this. Basically you will get tired and that’s what I mean. I kinda passed out a few times like, I fell asleep because I was tired but that’s about it. That’s the only thing that happened everything else was fine. So because she explained it there was not going to be something dramatic it calmed me down so I was able to take, do the chemo I had no problem with it”.

And the participants who did not meet with the NP claimed that they received pieces of information from their physicians, but still did not know what to expect.

Participant 8: Every time the doctor is changed you know my questions are all lost because if I had one doctor then they gonna totally know that’s what I am going through. Every time I come here I am totally lost and I have to start my story all from the beginning and... when you are like sick, with sickness, probably you are lost of your consciousness...you don’t know what to ask and not what to ask, whom to ask, is there someone I can call ? There is lots of questions”.

Participant 10: “I’m questioning in the sense that, did I get all the info or not? Like...I don’t know, I don’t know...like, the doctor gave me some information, but did he give me everything? I don’t know.” If you know, it makes it easier for a person to decide what to do. And how, you know, so feelings get involved a lot, emotions get involved, so if you know details then you are not as anxious, or no anxiety comes up if you know, if you are well informed about it”.

Some participants at the control center mentioned that they did receive an overview from their doctors and were concerned that they may not have received all the necessary information they needed to know. They did not have any one to fall back on for further information provision and expressed the need to have someone they could be referred to, who has enough time to provide information that they need.

3c. Different modes used in information delivery

The test intervention tool with different modes of information delivery was appreciated by the test participants. They expressed their satisfaction with the MCTIP and said that it had all the information that they needed to know. The simplified, multi-modal form of explanation allowed them to understand more about their cancer, its treatment and its impacts. Several major reasons for the value of the DVD, in particular, were cited. In addition to the general overview described above, it provided the patient with detailed information regarding the treatments they were to receive. Finally, it also gave them a chance to come up with questions regarding what they saw, long before they had to meet with the entire medical team.

Participant 3: “Out of everything that she [the NP] told us, we retained different things. We took the news in our own fashion. So [the NP] knows that she can’t tell us everything at once, but to have it at the house to watch calmly, two or three times...and then we could talk about it at the house, for sure we would not have done that without the DVD. Understand? So that DVD, it reassured us, helped us feel calmer. When we got to the house and the shock had passed, we watched the DVD and we saw everything in a different light.”

Participant 4: “The results [of the CT Scan] were very, very, very vague. The doctor told me about my bone and that the jaw was implicated in the cancer, but in the written information there was no information about that. It did not have the possibility, the probability. But the NP showed us the animation on the screen of the computer, here is the cancer that it is in the bone of the jaw. Ah, ok. I understand.”

Participant 5: “It helped and I can say that it was good to have it at home to watch when we were a little bit... less aggravated. It [the DVD] was good, but because of it we were able to ask more questions about everything we saw, to question whether we have to do this... We asked a lot of questions about what we saw on it. It helped have the possibility to think, and think of these questions, and to ask these questions. To ask questions which are very pertinent at that moment.”

Participants at the control center said that they would like to receive information to take home and go through at their own pace. They said that this would prepare them for their meetings with their doctors and allow them to generate a list of questions in advance, based on

what they read or see. They felt that not having this kind of information provision in advance hindered their ability to absorb the verbal information being presented to them at their appointments. Even those who met with the NP shortly after their diagnosis said that they did not retain all that was said. In general, control participants reported feeling lost without having a clear idea of the steps leading to their treatment.

Participant 9: If you know, it makes it easier for a person to decide what to do. And how, you know, so feelings get involved a lot, emotions get involved, so if you know details then you are not as anxious, or no anxiety comes up if you know, if you are well informed about it”.

Participant 10: “If it’s something that I’ve already had a little information on, I can absorb it better. But if it’s something totally new I need to draw back, analyze with questions. But when I come back with questions sometimes they’re [the doctors] there, sometimes they’re not there.”

When the participants at the control center were asked how they would prefer to receive the information, if in any particular format or if they had any suggestions to improve the information provision, almost all of them found having some audiovisual aids in the form of booklets, or CDs would be a good idea. They said:

Participant 6: “That [a DVD or CD etc.] would be great for sure because then you would have some idea of what to expect”. “Oh well it would work well because it would be easier for me to get to know more stuff instead of me searching for it but then I could do my own questions...and search and stuff like that so... yeah it would make sense. But I

dunno how they would do the booklet 'cause everybody has different types of cancer so they would have to be specific as to overall cancer what they would do and then you would still have to do research for the type you have, you know.”

Participant 8:“Every cancer patient ... must be taking home a booklet, or CD or DVD about what the doctors say about the cancer, so I can listen or watch the information and when I watch the DVD... next time I may know”... I feel that’s good idea, yeah.”

Discussion

This study was conducted to describe and compare the experiences of H&N cancer patients receiving information concerning their cancer and treatment at two hospitals with different approaches to information delivery. Our study provides evidence that multimedia based intervention is a tool that is strongly appreciated by H&N cancer patients. We believe that the standard of care which provides information verbally in an ad hoc manner; in other words, using pamphlets is a missed opportunity to maximize the needed information in cancer care settings.

Our results showed that our test group participants received the needed information on time. The information they received was clear, understandable and the different formats used in the MCTIP helped them in understanding what was said to them by their doctors. In addition, they had something to take home to read or listen to at their own pace. They were provided with the opportunity to share it with their family members. The information helped them and their family members in preparing them towards their cancer treatment and the various steps involved in their cancer care. On the contrary, the information the control group participants received was too generic and did not contain a lot of the details that they needed. Most of the information was

verbal, of which they did not retain much, and they did not have anything to review when they went home. Most of them went ahead with their treatment with no clear idea about the various steps involved in their treatment. Some searched the internet for more information. Their overall experience with information delivery was negative and they expressed dissatisfaction about the information they received.

A Number of studies have been conducted with cancer patients, some investigating the cancer patients' needs while the others focusing on psychosocial outcomes (Fang et al., 2012; Janiszewska et al., 2008; Krupat, Fancey, & Cleary, 2000; Newell, Ziegler, Stafford, & Lewin, 2004). Those studies that explored the H&N cancer patients' needs have reported that H&N cancer patients' informational requirements remain unmet and have recommended tailored information provision to them (Fujimori & Uchitomi, 2009; Knobf, 2007; Rodin, et al., 2009; van Dulmen, 2011; Wen & Gustafson, 2004). Interestingly, the findings reported in the previous studies concerning the unmet informational needs in cancer patients are similar to the findings we observed in our control group participants (Krupat, et al., 2000; Newell, et al., 2004; Pollock, Cox, Howard, Wilson, & Moghaddam, 2008). It is interesting that many of the so called unmet informational needs of H&N cancer patients were met for our test group participants. To our knowledge, there is just one published study that has used a multimedia based tailored intervention for only two H&N cancer patients and their findings are similar to the observations of our test group participants (Atack, Luke, & Chien, 2008).

The MCTIP is indeed a privileged opportunity for patients to participate in an individualized information session where they could receive the most needed information using different modes. Even though the information was sometimes repetitive the systematic way of

delivering it, different formats and the audio visuals used made a difference. It ameliorated their understanding about what was said to them by their doctors. Information that may have appeared complex and vaguely understood initially was simplified and comprehended through the MCTIP. Overall, the test participants felt they had a fairly good understanding of the key elements and various necessary procedures involved in their cancer care. Having something to take home, read or watch at their own pace was beneficial to the people who received it. It helped them in preparing themselves for their next appointments. The test participants knew who they were meeting with and why. Additionally, the MCTIP gave the test subjects the opportunity to share information with their family members at home. It also helped the family members in understanding and preparing for various phases they needed to pass in their loved ones' cancer journey. It gave them an opening to come up the questions they could ask in their next appointment with their cancer care team. However, these observations were not clearly visible at the control hospital.

On the contrary, the participants recruited at the control centre did not understand well the general overview that their doctors had given to them. As a result some of them searched the internet for the needed information and most of them attended their appointment with no clear idea as to who they were seeing and why.

It was interesting to learn that the MCTIP has helped in establishing the role of the NP at the test center allowing the NP to provide information to H&N cancer patients at the most needed time. The existence of this role is important for patients to communicate with the health care team without becoming lost in the complex hospital and cancer care services. Surprisingly, the MCTIP had an effect on the way patients were referred by their physicians to the NP and

therefore had an effect on the timing of information provision. It is of interest to note that this phenomenon was first observed by the researchers and later substantiated in interviews with the NP at both locations. The MCTIP addressed the perceived informational needs of the subjects.

In summary, written information alone is not beneficial in bringing positive outcomes in H&N cancer patients. But, if the information is tailored and delivered using multiple formats, it can bring positive experiences as our test group reported. Our test intervention addressed the recommendation made by many other authors and the national Cancer Alliance concerning the need for tailored information in cancer care (Llewellyn, et al., 2007; Mesters, et al., 2001; Rodin, et al., 2009; Weinman, 1990).

Limitations

It is important to note that this study reflects the perceptions and experiences of specific individuals and it is possible that our observations may not be applicable to all other cancer care facilities. Furthermore, the patients who agreed to become a part of the study do not represent all members of the H&N cancer patient population. However, we found both samples had consistent findings with little variation in their responses, supporting our assertion that the data collection techniques used in this study reached saturation. No new information was to be gleaned by further interviews.

Another important limitation was that we used a non-randomized design. Since the MCTIP was in use to deliver information to H&N cancer patients at the test hospital prior to the initiation of our study, it was ethically inappropriate to withdraw its benefits. On the contrary,

this limitation served beneficial to us as there was less chance for contamination between the test and control participants.

Conclusion

Our findings show that participants who received the multimedia based tailored information had a good information provision experience, while peers who received the normal care approach expressed dissatisfaction with their information provision experience. The use of different modes is useful in simplifying the complex information about cancer and its treatment without compromising the quality and quantity. Therefore, it is a potentially beneficial adjuvant in H&N cancer care.

Competing interests

There are no potential competing interests related to this study.

Author's contribution

Collection and assembly of data: Erin Watson, Violet D'Souza and Paul Allison.

Data analysis and interpretation: Erin Watson, Violet D'Souza and Paul Allison.

Manuscript writing: Violet D'Souza, Erin Watson and Paul Allison.

Manuscript review: Paul Allison, Anthony Zeitouni and Elizabeth Blouin.

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8 DISCUSSION

8.1 Summary of the thesis

The overall aim of this dissertation work was to investigate the impact of a multimedia based tailored information tool on H&N cancer patients. Even though studies conducted in cancer care claim the benefits of information with respect to anxiety, depression, satisfaction and knowledge change, very little research exists in H&N cancer care. Given this, we aimed to investigate if multimodal, tailored information on H&N cancer leads to changes in the level of anxiety and depression in H&N patients when it is given soon after diagnosis. Our study results showed that those people who received the test intervention experienced significantly lower levels of anxiety than those who did not receive it. The impact on depression was less clear with some forms of analysis showing significant reductions while the other forms showing borderline significant reductions. In addition, there were benefits for the test group compared to the control group in terms of cancer knowledge and satisfaction. Our qualitative project further demonstrated the benefits of the test intervention, providing explanations as to why subjects liked this intervention and how control subjects were often frustrated with the normal care.

The interactional model claims that the contextual resources may interact with the personal resources and modulate the individuals' adjustment to health treat. We observed that our study outcomes (lower levels of anxiety, depression, higher levels of cancer knowledge and satisfaction) were better for the participants with higher personal resources such as higher levels of education, younger age and being employed. At the same time, those participants with poorer personal resources (being old, retired, unemployed, lower levels of education) had poorer

outcomes. The personal resources of the individuals might have acted as significant buffers in their adjustment to cancer and this finding has been reported earlier (190). In this study, the MCTIP acted as the contextual resource. Based on our study findings, we can say that our study supports the interactional model, and strengthens the claim that contextual resources together with personal resources do modulate psychosocial adjustment to illness (176).

Studies report that anxiety is highest between the time of diagnosis and treatment (27, 35, 191). In our study (article 1), anxiety levels of the test participants started to decline at the 3-month follow-up, whereas they increased during the same period for the control group. Unlike anxiety, the depression ratings increased over time for both groups. In our study, highest levels of depression were seen at 3 months and this could be because the H&N cancer treatments are aggressive and extremely debilitating and that is the time that they experience lots of side effects (192). And these side effects are known to cause anxiety and depression in cancer patients (193-198).

Our second analysis (Article 2) showed that the test group of participants had higher levels of cancer knowledge and were better satisfied with the information than the control group. This is interesting because, our study was non-randomized and our control group patient subjects had significantly higher levels of education than the test group subjects. Based on this, one could hypothesize that the control group subjects would have higher levels of knowledge, but this was not the case. The test group had better cancer knowledge than the control group following the test and control interventions. This suggests that the tailored information was associated with higher levels of knowledge among test group subjects. Satisfaction and knowledge were positively and significantly correlated showing that those who had higher levels of knowledge

were better satisfied. The reliability tests performed for the Cancer Knowledge questionnaire demonstrated high internal consistency showing that the Cancer Knowledge questionnaire we developed is a reliable tool to measure H&N cancer patients' cancer knowledge when used in both English and French languages. Similarly, the reliability tests performed for the SCIP showed that it has good internal consistency and is a reliable tool to measure cancer patients' satisfaction level with the information they receive, when used in English or French languages.

Our third analysis (Article 3) showed that the information the test group received was clear and had sufficiently varied formats of information to render it understandable. The information helped test subjects in preparing for their cancer treatment through for instance, being able to prepare for next consultations with various questions. Also, test subjects had the opportunity to take some forms of information home and share it with their families. The use of different modes was useful in simplifying the complex information about cancer and its treatment without compromising the quality and quantity. However, the information the control group received was too generic and did not contain appropriate details. Most of the information was verbal, of which subjects did not retain much, and they did not have anything to review when they went home. As a result, some of them searched the internet for more information. In summary, the subjects who received the multimedia based tailored information had a good information provision experience, while peers who received the normal care approach expressed dissatisfaction with their information provision experience.

Navigating the health care system during cancer diagnosis is difficult for those who are most familiar with it, and for people with lower health literacy skills it is extremely overwhelming.

As stated earlier, health literacy is low in Canada. Our test group participants had lower levels of education and their health literacy might therefore have been lower than that of the control group participants who had comparatively higher levels of education. The information given to the test group participants was tailored to their disease, treatment options and its management and was given based on their needs and expected levels of health literacy. Not every participant was given exhaustive amounts of information, but just what they needed at that particular time point. At the same time, if someone wanted more information, it was provided. This was done so as not to over burden the patients. The tailored information service might have contributed towards their cancer literacy as has been claimed in earlier work (144).

Studies report the role of the NP and their association with positive outcomes in cancer patients (145, 146). Based on these claims, one may think that the positive outcomes we observed in our test group were related to the involvement of the NP at the test center. We want to remind the readers that in our study, both hospitals had NPs even though the expectations of their roles and challenges were different. Our observations through the qualitative study helped us understand the roles of the NPs and their association with the participants at both centers. At the test hospital, the role of the NP was well established for patient navigation. The test hospital had this new tool, the MCTIP with different modules. For one of the 5 modules, the database, it was necessary for the NP to gather patients' personal information from the patients and this was time consuming. This justifies the NP at the test hospital spending a longer time with each patient. We also observed that the physicians used this opportunity to refer their patients to the NP and therefore, all patients had the opportunity to meet with her. It was also clear that the information given in the MCTIP was repetition of what the doctors had already said. But,

patients found this service (The MCTIP) was helpful as there were audiovisuals, they could watch it at home and at their own pace. It improved their ability to understand what the doctors had told them during their consultations.

The control hospital had different challenges. The NP at the control hospital, besides her role as the NP, had other responsibilities such as administering the chemotherapy to in-patients, which took a significant part of her time, making her less or even not available to all patients. This explains our finding that some patients had the opportunity to meet with her while the others did not. Secondly, the NP at the control hospital provided the information verbally or through general information pamphlets. There were no additional or special resources available at this hospital and therefore the physicians did not have a strong reason to refer their patients to her.

It is interesting that we did not find any difference between the (test and control) NPs concerning their willingness to provide information and support to their patients. Another important thing we observed was once the patients started their cancer treatment, it was unlikely that they went back to the NPs, as they were cared by the nurses from the clinics where they were taking their treatments. This was same for both test and control hospitals. The NPs did not stay in the participants' lives once they began their cancer treatment. The outcomes at 3 and 6 months were better only for the test participants even when the NPs role did not exist in their cancer care at that time point. Lastly, the MCTIP was designed to be used by patients with minimal help from the hospital personnel. However, it was observed that patients never took the information on their own until they were referred to the NP.

Our mixed method research design helped us understand many areas that would have not been clear or else. The qualitative observations together with the patients' perceptions complemented our quantitative study results and helped us in understanding the results of this clinical trial better. If we had not chosen this method research design, we might have missed out some very important findings and thus it would have been difficult for us to interpret our study findings clearly. Through the quantitative part, we were able to see a positive association between the intervention and the outcomes, but without the qualitative element, we would not have been able to explain how different both these centers were in terms of information provision, the NPs' involvement and the time spent on information provision, all of which may have affected the findings. By adding the qualitative part, we are able to learn that the test group seemed to have longer information sessions and what the patients' perceptions were and how important these information and discussion sessions were. The qualitative element to our study gave us an opportunity to explore both test and control center experiences closely and we would have missed this if we had not chosen mixed methods research.

8.2 Methodological considerations

A number of limitations in our study methods should be kept in mind while interpreting the results. First of all, our study was non-randomized, and this non-randomized design is not the ideal design to test an intervention. As previously explained, we had no choice to use this design for ethical reasons. Another important limitation of this study is the timing of baseline data collection. Ideally, baseline data should be collected prior to the intervention. In this study, because of the difficulty of separating diagnosis and the initiation of information provision, our baseline data were collected after the initiation of the intervention. It is also important to realize

that we used ‘normal care’ as the comparison/control group rather than a placebo control. In theory, the improvement in the intervention group might have resulted from the additional time with the person who provided the information rather than the specific intervention. Or it might have been the test hospital and the care being very different from the control hospital. It is not possible for us to claim the effect was only because of the intervention. Lastly, another limitation concerned the cancer knowledge questionnaire, which was newly developed for this study. Its development was based on the information available in the MCTIP considering all treatment modalities, all types of cancer and the management of side effects. Those who had access to the MCTIP (the test group) might have found all the answers to the questions found in this questionnaire in the intervention material. The instrument had good internal consistency in our study and demonstrated differences in the expected direction but this limited validation need to be considered in interpreting the results.

On the other hand, while we have to recognize these limitations in the study design, a major strength of our study is the good adherence of the study subjects and very low drop-out rates in both test and control groups. In our test group, all three subjects dropped-out due to death. While in the control group, the four subjects who dropped-out refused to respond to the follow up calls. Secondly, we used the HADS which is a well validated and widely used outcome indicator that enables comparisons with the results of many other similar studies. And finally, a major strength of our project was the mixed methods design, which enabled qualitative data to help corroborate and explain data we gathered using the quantitative phase of the project.

8.3 Conclusion

This study was conducted in order to investigate and explore the impacts of a multimedia based tailored information intervention in H&N cancer patients for the first time. The study results provided the following main conclusions:

Our hypothesis was partially supported by showing the subjects who received the multimodal, tailored information:

1. experienced significantly lowers levels of anxiety than the subjects who received normal care.
2. had higher levels of cancer knowledge and were better satisfied with the information they received than the subjects who received the normal care.
3. had a good information provision experience, while peers who received the normal care approach expressed dissatisfaction with their information provision experience. The use of different modes is useful in simplifying the complex information about cancer and its treatment without compromising the quality and quantity.

In conclusion, our study demonstrated an association between receiving the multimedia based tailored information and lowered levels of symptoms of anxiety and depression, plus higher levels of satisfaction and cancer knowledge. In addition, the qualitative element of the project revealed reports of good quality experiences among subjects receiving the test intervention, while subjects receiving the control intervention reported important levels of dissatisfaction and unmet information needs.”

8.4 Original contribution of the work

This research project is original. To our best knowledge, this is the first study that investigated the impact of a multimedia based information intervention on H&N cancer patients. A mixed methods approach chosen, helping us better understand the areas that would have been otherwise understated using either quantitative or qualitative research methods alone. Our qualitative findings helped us better explain and validate our quantitative study findings. This study was conducted during the most critical time in the cancer trajectory, starting from the initial time after diagnosis, continuing during the treatment and post treatment period. Through this study, we were able to demonstrate the impact of the information intervention in a longitudinal model.

8.5 Implications for future work

Even though our results show positive outcomes, this kind of study needs to be replicated with a randomized controlled trial designs. Before providing information patients, it is important to explore the extent or the severity of the informational needs of individual patients on regular basis. This would help the health care providers to better understand the patients' needs and provide them with needed informational support. It is also very important to explore the potential barriers of the health care teams in delivering the needed information to their patients.

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APPENDICES

10.1 Quantitative questionnaires

Socio-demographic, clinical and behavioral Information

Telephone number 1: _____

Best time to be contacted _____

Telephone number 2: _____

Best time to be contacted _____

E- mail _____

Are you immediately available Yes ☐ No ☐

If no, when ? _____

Socio-demographic information

1. Language English ☐ French ☐

2. Gender Male ☐ Female ☐

3. Age _____ Years

4. Living arrangement

Living alone ----- ☐ With partner ----- ☐

With family----- ☐ Communal accommodation --- ☐

5. Principal occupation

Retired ----- ☐

Employed –working ----- ☐

Employed – on sick leave ☐

Unemployed ----- ☐

Home maker ----- ☐

6. Maximum level of education

Primary school ----- ☐

High school ----- ☐

College ----- ☐

University ----- ☐

Cancer related questions – completed by the research assistant

1. Cancer site

Cancer of the lip -- ☐

If other----- ☐

Oral cavity ----- ☐

specify _____

Larynx ----- ☐

Pharynx ----- ☐

Unknown ----- ☐

2. Cancer staging

T ----

M ----

N ----

Over all

3. Treatment modality

Surgery ----- ☐

Radiation ----- ☐

Chemotherapy-- ☐

Combinations ☐

4. Smoking

Do you smoke tobacco now? Yes ☐ No ☐

If yes,

Manufactured cigarettes --- ☐

Hand rolled cigarettes----- ☐

Both ----- ☐

How many /day _____

5. Drinking

How often you consume/consumed alcoholic drink

More than once/day ----- ☐

Never ----- ☐

Daily or almost daily----- ☐

If you drink alcohol,

Once a week ----- ☐

What kind _____

Once a month----- ☐

Quantity _____

6. History of narcotic (abused) drug use

Are you currently using narcotics?

Yes ---- ☐

If yes, what kind_____

No ----- ☐

Dosage_____

If yes, is it through prescription by your doctor?

Yes ----- ☐

No ----- ☐

If no, what kind _____

How often_____

Hospital Anxiety and Depression Scale (HADS)

To be completed by the participant

Please choose one phrase for each question that best applies to you, right now

1. I feel tense or “wound up” :
 - a) Most of the time
 - b) A lot of the time
 - c) From time to time, occasionally
 - d) Not at all
2. I get a sort of frightened feeling as if something awful is going to happen
 - a) Very definitely and quite badly
 - b) Yes, but not too badly
 - c) A little, but doesn't worry me
 - d) Not at all
3. Worrying thoughts go through my mind
 - a) A great deal of the time
 - b) A lot of the time
 - c) From time to time, but not too often
 - d) Occasionally
4. I can sit at ease and feel relaxed
 - a) Definitely
 - b) Usually
 - c) Not often
 - d) Not at all
5. I get a sort of frightened feeling like “butterflies” in the stomach
 - a) Not at all
 - b) Occasionally
 - c) Quite often
 - d) Very often
6. I feel restless as if I have to be on the move
 - a) Very much indeed
 - b) Quite a lot
 - c) Not very much
 - d) Not at all

7. I get sudden feeling of panic
 - a) Very often indeed
 - b) Quite often
 - c) Not very often
 - d) Not at all
8. I still enjoy the things I used to enjoy
 - a) Definitely as much
 - b) Not quite so much
 - c) Only a little
 - d) Hardly at all
9. I can laugh and see the funny side of things
 - a) As much as I always could
 - b) Not quite so much now
 - c) Definitely not so much now
 - d) Not at all
10. I feel cheerful
 - a) Not at all
 - b) Not often
 - c) Sometimes
 - d) Most of the time
11. I feel as if I am slowed down
 - a) Nearly all the time
 - b) Very often
 - c) Sometimes
 - d) Not at all
12. I have lost interest in my appearance
 - a) Definitely
 - b) I don't take as much care as I should
 - c) I may not take quite as much care
 - d) I take just as much care ever
13. I look forward with enjoyment to things
 - a) As much ever
 - b) Rather less than I used to
 - c) Definitely less than I used to
 - d) Hardly at all

14. I can enjoy a good book, radio or TV program

- a) Often
- b) Sometimes
- c) Not often
- d) Very seldom

Satisfaction with Cancer Information Profile

We would like to ask you about the information you have received about your treatment for cancer. First, please circle the appropriate answer regarding whether you have received any information about the following aspects of your treatment and, second, rate the amount you have received (if applicable). If you are having or have had more than 1 type of treatment please give your overall feeling about the information you have received.”

A. Satisfaction with the amount and content of information

1. Whether the treatment has any unwanted side effects
 - A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
2. What the risks of your experiencing side effects are
 - A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
3. What the risks of your experiencing complications are
 - A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
4. What you should do if you experience unwanted side effects
 - A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
5. Whether your treatment interferes with other medicines you may be taking
 - A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
6. How you may expect to feel immediately after treatment
 - A. Too much

- B. About right
 - C. Too little
 - D. None wanted
7. The effects of your treatment on your ability to work
- A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
8. Who to ask/where to go for possible financial support
- A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
9. Whether you may need further treatment in the future
- A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
10. The effect of treatment on your appearance
- A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
11. The effect of treatment on functioning (daily activities)
- A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
12. How long you expect recovery to take
- A. Too much
 - B. About right
 - C. Too little
 - D. None wanted
13. How your treatment may impact on your quality of life over the next year
- A. Too much
 - B. About right

- C. Too little
- D. None wanted

14. Patient support groups for you and your partner

- A. Too much
- B. About right
- C. Too little
- D. None wanted

B. Satisfaction with the form and timing of information

1. The usefulness of the information to you

- A. Very satisfied
- B. Satisfied
- C. Neither
- D. Dissatisfied
- E. Very dissatisfied

2. The usefulness of the information to your partner/family

- A. Very satisfied
- B. Satisfied
- C. Neither
- D. Dissatisfied
- E. Very dissatisfied

3. The amount of written information supplied

- A. Very satisfied
- B. Satisfied
- C. Neither
- D. Dissatisfied
- E. Very dissatisfied

4. The amount of verbal information supplied

- A. Very satisfied
- B. Satisfied
- C. Neither
- D. Dissatisfied
- E. Very dissatisfied

5. The timing at which you received information

- A. Very satisfied
- B. Satisfied
- C. Neither

- D. Dissatisfied
 - E. Very dissatisfied
6. The details of the information given to you
- A. Very satisfied
 - B. Satisfied
 - C. Neither
 - D. Dissatisfied
 - E. Very dissatisfied
7. How understandable the information was to you
- A. Very satisfied
 - B. Satisfied
 - C. Neither
 - D. Dissatisfied
 - E. Very dissatisfied

Cancer Knowledge Questionnaire

We would like to ask you about the information you have received about head and neck cancer and your treatment. Kindly choose and **circle** the appropriate answer/s what you feel is right based on the information provided to you. If required, **you are allowed to choose more than one answers for the questions.**

- 1 Cancer is an uncontrolled growth of cells or tissues.
 - A. True
 - B. False
 - C. I don't know
- 2 Cancers have the ability to spread.
 - A. True
 - B. False
 - C. I don't know
- 3 Cancers can spread to the adjacent (neighboring) areas.
 - A. True
 - B. False
 - C. I don't know
- 4 Cancers can spread through the blood.
 - A. True
 - B. False
 - C. I don't know
- 4 Cancers can spread to the bones.
 - A. True
 - B. False
 - C. I don't know
- 6 Even though, cancers generally grow fast, there are cancers that grow slow.
 - A. True
 - B. False
 - C. I don't know
- 7 Cancer is also known as:
 - A. Benign tumor
 - B. Malignant tumor
 - C. Neither benign nor malignant
 - D. I don't know

- 8 Which of the followings habits are strongly associated with cancers in the head and neck region:
- A. Smoking
 - B. Routinely taking sleep medications
 - C. Routinely taking pain killers
 - D. I don't know
- 9 Which of the following categories of people are more likely to develop head and neck cancer:
- A. People who consume large quantities of alcohol.
 - B. People who consume large quantities of fatty food.
 - C. People who eat large quantities of meat.
 - D. I don't know
- 10 Choose the correct statement:
- A. Cancers always comes back once treated.
 - B. Once treated, cancers never come back.
 - C. Cancers may come back even after treatment.
 - D. I don't know
- 11 Cancer staging explains:
- A. When the cancer started.
 - B. The size and spread of the cancer at diagnosis.
 - C. What type of cancer it is.
 - D. I don't know
- 12 Which of the following methods do you think are used to treat head and neck cancers?
- A. Surgery
 - B. Radiotherapy (X-ray treatment)
 - C. Chemotherapy
 - D. Surgery, radiotherapy and chemotherapy.
 - E. I don't know
- 13 Most of the time, more than one type of cancer treatments are given to treat head and neck cancer.
- A. True
 - B. False
 - C. I don't know
- 14 Radiotherapy in the head and neck region can lead to
- A. Dry mouth
 - B. Vomiting
 - C. Hearing loss

- D. I don't know
- 15 Radiotherapy in the head and neck region can cause
- A. Burning sensation in the mouth
 - B. Difficulty in swallowing
 - C. Loss of taste
 - D. All of the above mentioned choices
 - E. I don't know
- 16 One of the common side effects of radiotherapy is vomiting.
- A. True
 - B. False
 - C. I don't know
- 17 All head and neck cancer patients lose hair, irrespective of the type of treatment they received.
- A. True
 - B. False
 - C. I don't know
- 18 Radiotherapy (X-ray treatment) in the head and neck region increases the risk for teeth cavities.
- A. True
 - B. False
 - C. I don't know
- 19 Chemotherapy has very few side effects and is the preferred treatment of choice for cancer.
- A. True
 - B. False
 - C. I don't know
- 20 Chemotherapy
- A. Does not kill any cells in the body
 - B. Kills only cancer cells in the body
 - C. Kills cancer cells and the normal cells of the body
 - D. I don't know

Qualitative Interview guide

1. Who was their main source of information?
2. How the participants acquired information during their cancer journey?
3. Where was information provided and how?
4. If any particular modes were used to deliver information?
5. Was there a particular person allotted to provide information to them? If so who?.
6. When was information given to them? How long after their diagnosis? What ere the settings, and how long it took?
7. What were the contents of the information they received?
8. What were their perceptions about the understandability of the information given, the vocabulary, and language use? In what forms information was given?
9. Were their informational needs met? If not how do they plan to obtain further information?
10. Is there a person whom do they count on for information?
11. Did they look through any sources, in and out of the hospital?

10.2 Consent form

**Montreal General Hospital
Royal Victoria Hospital
Jewish General Hospital
Head and Neck Department**

CONSENT FORM

**Anxiety and depression in head and neck cancer patients and partners:
A clinical trial examining the effectiveness of the
Multimode Comprehensive Tailored
Information Package (MCTIP)**

Dr. Paul Allison, McGill University

1. Purpose of the study

We are inviting you to participate in this study because you or your partner has recently been diagnosed with head and neck cancer. The purpose of this study is to assess the impact of providing information to patients and their partners.

2. Expected procedure

Your participation will take 6-7 months from the time you consent. You will be asked to fill out 5 short questionnaires concerning your background, your current feelings, your understanding about cancer and its treatment, and your satisfaction level about the information you receive.

For this purpose, the research assistant will meet with you 3 times as follows :

1. within 2 weeks after you agree to participate in the study and prior to your treatment
2. at 3 months following the initial interview

3. at 6 months following the initial interview

In addition, your meetings or telephonic consultations with the Pivot Nurse may be audio taped to permit quality assurance of their contents.

3. Potential risks

Your participation will involve approximately 2 to 2.5 hours for the whole study including all three interviews. Biological tests (blood) or physical evaluations of any kind are not involved in this study. Your participating in this study does not involve any potential risks. You may or may not experience emotional responses to the information acquired through the information delivery system.

4. Potential benefits

You may or may not receive any direct benefits from this study. However, this study may help us to provide better care for all head and neck cancer patients in the future.

5. Alternatives

There are many resources in the hospital and in the community, both professional and commonly accessible that can provide assistance to people with head and neck cancer. We will also provide you with information on resources and expertise that are available to people with head and neck cancer.”

6. Voluntary participation/withdrawal

Your participation is completely voluntary. Although you are encouraged to answer all the questions in the questionnaires, you are not obliged to do so. You are free to refuse to participate

or to withdraw your consent at any time and your care and medical treatment will not be affected in any way.

7. Confidentiality

All information obtained from you and about you during this research will be treated confidentially within the limits of the law. The information collected will remain strictly confidential stored in lockable filing cabinets in a secure room accessible to only Dr. Allison, the principal investigator and the members of the research team including Dr. D'Souza, the PhD student involved in the study. In addition, the Institutional Review Board of the Faculty of Medicine will have access to the study data for quality assurance purposes. These data will only be used for the "Anxiety and depression in head and neck cancer patients" project. These research data will be stored for a minimum of 5 years following the completion of the study according to the University policy, and later will be destroyed in an appropriate manner. The published results will be presented in a way that insures confidentiality and anonymity.

8. Information

If you have any questions regarding your rights as a research volunteer, you can contact the MUHC ombudsman for questions regarding participant's rights at the following number (514) 934-1934 ext. 48036. You can obtain more information about this project at any time during the course of this study by contacting the principal investigator of this research project, Dr. Paul Allison at 514 398 6758.

Consent agreement

Signature page

By signing this consent form, I agree that:

1. I have read the above and my questions were answered to my satisfaction.
2. The study and this form have been explained to me by _____
(name of the research assistant) who has responded satisfactorily to my questions.
3. My participation is voluntary, and I can withdraw from the study at any time without giving reasons, and without affecting my health care now or later.
4. I do not give up any of my legal rights by signing this consent form.
5. I agree to participate in this study.

Patient's signature

Date

Name of the Patient

Telephone number

Name of the researcher

Telephone number

Researcher's signature

Date

There are three copies of this consent form: one is for you,
one is for our records, and the third one is for the hospital.