Coping and Psychological Distress among Head and Neck Cancer Patients

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Table of Contents

Abstract

Objectives: To identify correlates of psychological distress and to investigate how coping skills, anxiety and depression are related in a group of head and neck cancer patients 6-12 months after their diagnosis. Methods: We evaluated in 107 head and neck cancer patients their anxiety and depression levels using the Hospital Anxiety and Depression Scale, and their coping strategies using the Ways of Coping Checklist. Results: There were statistically significant associations between gender and anxiety level, and between living arrangements, cancer site, time since treatment, tumor stage and depressive symptoms. Results also showed that patients used a variety of coping strategies. Different coping strategies were used in subjects with high versus those with low levels of anxiety or depressive symptoms. Conclusion: Data show several correlates of psychological distress in head and neck cancer patients. They also suggest that coping strategies of these patients vary according to their level of psychological distress.

Résumé

Objectifs: Identifier les corrélats de détresse psychologique d'un groupe de patients atteints de cancer de la tête et du cou 6 à 12 mois après diagnostic, et investiguer l'interaction entre les capacités à faire face à la maladie, l'anxiété et la dépression. Méthodes: Nous avons évalué 107 patients en utilisant l'Echelle de Dépression et d'Anxiété de l'Hôpital, et la Liste de Vérification de Stratégies Face à la Maladie. Résultats: Des associations sont présentes entre le genre et l'anxiété du patient, les conditions de vie, la position du cancer, la durée du traitement, le stade de la tumeur, et les symptômes de dépression. Les patients ont utilisé une variété de stratégies pour faire face à la maladie ; celles des patients à forte anxiété étant différentes de celles des patients dépressifs. Conclusion: Les données montrent plusieurs corrélats de détresse psychologique qui varient selon leur niveau de détresse psychologique.

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Chapter I: Introduction

Worldwide, head and neck cancer accounts for 5% of all malignancies (1). With the advances in the medical field patients are living longer and thus forced to face the challenges associated with the life-threatening disease and its treatments.

Head and neck cancer and its associated treatments have a multidimensional influence on patients' life. They can cause patients to endure facial disfigurement that is usually visible and difficult to hide, altering the appearance and body image (2;3). In addition, head and neck cancer can affect vital functions like eating, breathing and talking (4;5). Such manifestations can result in considerable disability that can lead to fear from society, rejection and loss of communication; compromising patients' social and personal relationships (6). As a consequence of these physical and psychological difficulties, patients' quality of life and well-being can be adversely affected.

In the last two decades, attention to psychological issues has been increasing and the concept of health related quality of life is being studied in response to the World Health Organisation's definition of health (state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity) (7). Accordingly, many researchers have explored different issues of quality of life relative to cancer patients in an attempt to obtain more insight into survivors' well-being. This lead to research focusing on psychological problems related to the cancer experience and investigating possible treatments and interventions.

It has been shown that the psychological effects of head and neck cancer are similar to those of cancer in general, and even more intense due to the importance of the facial region. Up to 46% of head and neck cancer patients encounter significant emotional distress throughout the course of their disease (8). This high prevalence of psychological distress reflects the complexity of their condition. Moreover, the burden can include partners and family members (9;10). These consequences if left untreated can have a drastic effect on a patient's life; jeopardizing their survival and possibly driving them to suicide (11).

The association of psychological distress and head and neck cancer signify the importance of early detection and intervention for those patients. In response to this issue, numerous studies focused on enhancing the detection of psychological distress and identifying patients at high risk to alert clinicians to those patients. Despite considerable research in this matter it remains uncertain which factors predispose to distress. Additionally, very few studies in head and neck cancer explored patients' experiences and adaptation with their disease which could provide imperative knowledge to assist in dealing with the affected individuals. This lead us to conduct a cross-sectional study among head and neck cancer patients 6-12 months after their diagnosis to identify patients at risk of developing anxiety and depression and to better understand their coping mechanism.

Chapter II: Literature review

2.1 Head and Neck Caner Epidemiology

Head and neck cancer most commonly refers to cancers of lip, salivary glands, tongue, floor of the mouth, oropharynx, nasopharynx and larynx. More than 90% of head and cancers are squamous cell carcinomas arising from the mucosa, or lining, of the upper aerodigestive tract (12).

The incidence and mortality of head and neck cancer varies throughout the world. In the year 2000, head and neck cancer was ranked the eighth leading cause of cancer death worldwide (1). In 2002, there were around 643,869 cases of head and neck cancer around the world and 351,740 deaths (13). In Canada it was estimated that there will be 4350 new cases in 2007 and around 1610 deaths (14). Head and neck cancer is more common in males; it represents about 4% of the incidence of all cancers in males and 2% of all cancers in females. It affects mainly older age group populations with increased incidence in the 6th and the 7th decade (14-20).

Five-year survival rates for head and neck cancer refers to the percentage of people who live at least 5 years after their head and neck cancer is first diagnosed. Using Quebec data (21), Table 1 represents the anatomic sites and gender differences in survival rates among head and neck cancer patients during the period 1984-1994. It can be seen that there is no particular trend in survival rates over time and that women had a higher survival rates in most of the sites.

Table1-Five-year survival rates for head and neck cancer in Quebec between 1984-1994[a]

Anatomic site	**Interval**							
	1984-1986		1987-1989		1990-1992		1993-1994	
	Men	Women	Men	Women	Men	Women	Men	Women
Lip	68	84	66	89	69	82	69	85
Tongue	32	53	30	47	37	45	37	52
Salivary glands	52	70	54	67	53	59	54	74
Gingiva	43	45	45	42	32	46	33	68
Floor of the mouth	34	61	44	48	39	53	40	52
Other parts of the mouth	33	51	35	59	32	48	35	57
Oropharynx	38	49	33	48	36	39	36	63
Rhinopharynx	42	38	31	38	36	44	35	51
Hypopharynx	25	27	23	21	26	27	25	29
Oral cavity	29	25	31	26	19	46	29	28
Larynx	55	62	55	60	55	62	58	67

[a] Data taken from Louchini R, Beaupre M (21)

The primary treatment for head and neck cancer includes surgery, radiation therapy and chemotherapy. The treatment choice depends on several factors such as the tumor stage, accessibility and the expected post treatment function. These treatments can be associated with significant and distressing side effects such as facial disfigurement, difficulty in speech, eating and breathing (20).

2.2 Psychological issues associated with head and neck cancer

A diagnosis of head and neck cancer forces the affected patients to face not only a life threatening disease, but also possible facial disfigurement and impaired essential functions such as impaired eating, breathing and talking.

Disfigurement in head and neck cancer patients can arise from the cancer itself or its associated treatments. Most patients fear this disfigurement because of the importance of the face and the role it plays in communication and self confidence. The visibility of the face also adds additional burden to the disfigured head and neck cancer patient. Previous research illustrated those concerns in the affected patients. In a study by Chaturvedi et al, 50 oral and laryngeal cancer patients were investigated to understand their concerns about their disease. The analysis revealed that patients' main concerns were about the future, finances, subjective physical evaluation and communication. Regarding disfigurement, 52% of oral cancer patients reported their concerns about their appearance while 24% of laryngeal cancer patients reported similar concerns (22). In another study by Millsopp et al with 278 oral and oropharyngeal cancer patients; 41% of the patients reported their concern about the disfigurement that can result from the cancer treatments (23).

Furthermore in a cohort study in 1999, patients with head and neck cancer demonstrated high levels of anxiety after facial surgery due to their anticipation of disfigurement (3).

The nature and extent of functional disability associated with head and neck cancer depends largely on the site of the tumor and the treatment approach used (24-26). Accordingly many head and neck cancer patients may suffer from various degrees of difficulty in swallowing, chewing, taste and speech. Nguyen et al in 2006 evaluated the severity of dysphagia in 110 head and neck cancer patients. They found that severe rates of dysphagia, observed on the modified barium swallow test, were present in 33% of patients receiving chemoradiation and in 21% of patients receiving postoperative radiation (27). Additionally, Chua et al in a retrospective study of 40 head and neck cancer patients found that physical disfigurement, dysphagia and jaw dysfunction were the most common functional impairments among the patients (28). In the United States, a cohort study evaluated quality of life in patients with laryngeal and oropharyngeal cancer. Although most patients reported fair overall quality of life, the results show that those patients had problems with swallowing, chewing and taste after their treatment with chemoradiation (29). Another prospective study in the United Kingdom examined weight loss in head and neck cancer patients. Fifty seven percent of the 100 patients included in the study had lost weight due to different nutritional problems. The main causative factors as reported by patients were dry mouth, wearing dentures, sore mouth and difficulty in mastication and swallowing of food (30).

Furthermore, a number of studies investigated the long- term survivors of head and neck cancer. Beeken et al reported in their retrospective study the persistent side effects in head and neck cancer patients at a mean of 3.5 years post treatment; 80% of these patients were still complaining of dry mouth problems. Patients also reported complaints about longer time to eat meals, inability to eat in public and taste change (31). In 2006, a five year follow up for 89 patients with pharyngeal carcinoma revealed that some of the treatments side effects like dry mouth and teeth problems still persisted in those patients (32).

Another important issue distressing head and neck cancer patients is the problem of facing society and continuing their usual daily life. Many of these patients may become disabled and experience changes to their work status or even have to quit their jobs. This was demonstrated in a study by Taylor et al to assess disability in head and neck cancer patients (33). They found that 52% of the 384 participants who were working prior to their cancer diagnosis were disabled by their cancer treatment. They also found significant associations between disability and chemotherapy, neck dissection status, pain scores and time since most recent diagnosis. Moreover, some patients avoid their social activities like social eating due to the presence of feeding tube or other eating difficulties which can influence their social relationships (4;5). As a consequence, head and neck cancer patients tend to be more vulnerable to isolation and their social life deteriorates. This was demonstrated in a study by Chaturvedi et al in which they found that 54% of the head and neck cancer patients in their study reported worry about their social communication and 34% expressed concerns about their jobs (22).

As a result of the disruptions to aspects of daily life like family, work and friendships; considerable psychological distress is likely to occur in head and neck cancer patients. This may affect the patients' psychological wellbeing and can result in depression. It is reported that up to 46% of the head and neck cancer patients suffer from depression (8;34;35). This high prevalence of depression may be explained by the reduced satisfaction with life in head and neck cancer patients. Bjordal et al in 1995 compared 204 long-term head and neck cancer survivors with 766 matched controls and found that cancer patients had significantly lower satisfaction with life and physical health (36).

The presence of anxiety and depression in head and neck cancer patients presents a threat not only to the affected patients but to their partners as well; therefore can distress the whole family. Verdonck de Leeuw et al explored in 41 patients-spouse pairs the effect of head and neck cancer on spouses of treated patients. Using the HAD scale to assess psychological distress; they found that 20% of spouses and 27% of patients were psychologically distressed (9).

In some extreme cases of depression associated with head and neck cancer patients may commit suicide. This was shown in a retrospective study of 241 head and neck cancer patients where they found 1.2% of the patients had committed suicide (11). In another retrospective study, Kendal W.S investigated the suicide risk among different types of cancer patients. The results showed that male head and neck cancer patients were in the high risk group to commit suicide (37).

2.3 Predictors of anxiety and depression

In an attempt to alleviate the psychological distress associated with head and neck cancer and help clinicians to recognize patients at risk of developing anxiety and depression, several studies focused on identifying psychosocial variables and physical symptoms most strongly associated with psychological distress.

Many studies have identified different sociodemographic and clinical variables as predictors for anxiety and depression in head and neck cancer patients. In the United Kingdom, a study among 18 patients who have been treated for head and neck cancer, demonstrated that younger patients were more likely to have high anxiety and depression than other patients (38). In a cross-sectional study, Reisine et al examined the association between sociodemographic risk indicators and depression among 167 oral cancer and 234 oral epithelial dysplasia cases. Their analysis revealed that participants who were younger, unemployed and had poor social support were more likely to have clinical depression (39). Furthermore in 2000, De Leeuw et al studied the influence of pretreatment variables to predict depression in 155 head and neck cancer patients 6 and 12 months after their treatment. Physical symptoms, depressive symptoms, emotional support, extent of the social network and avoidance coping correctly predicted depression in 81 % of the patients 6 months and 67% of the patients 12 months after treatment (40). In 2001, De Leeuw et al in another prospective study examined 197 head and neck cancer patients to determine which pre-treatment factors can predict depression up to three years after treatment. They identified eight pre-treatment variables that could be used to correctly predict depression in 84% of the patients. These variables included advanced cancer, more tumor-related physical symptoms, female gender, presence of pretreatment depression, lack of appraisal support, less received emotional support, lack of formal social network and less openness to discuss cancer in the family (41).

Other studies investigated the association between quality of life and psychological distress. In a recent cross sectional study with 43 nasopharyngeal cancer patients, Lue et al examined the association between quality of life measured by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and psychological distress. Their findings show that emotional and physical functioning were significant correlates for anxiety and that emotional and social functioning were significant correlates for depression (42). Additionally, a cohort study with 153 head and neck cancer patients revealed that high depressive symptoms at baseline predicted poor quality of life after treatment (43).

It has been shown that only 15-40 % of cancer patients who are in need for psychological intervention are actually referred to counselling (44;45). This was further explained in a study that investigated oncologists' ability to recognize patients with psychological distress. The study reported that oncologists identified only 11 of 30 patients who were severely distressed. An alarming finding in this study, was oncologists failure to recognize distress mostly in patients with head and neck cancer (67%) and lung cancer (68%) (46).

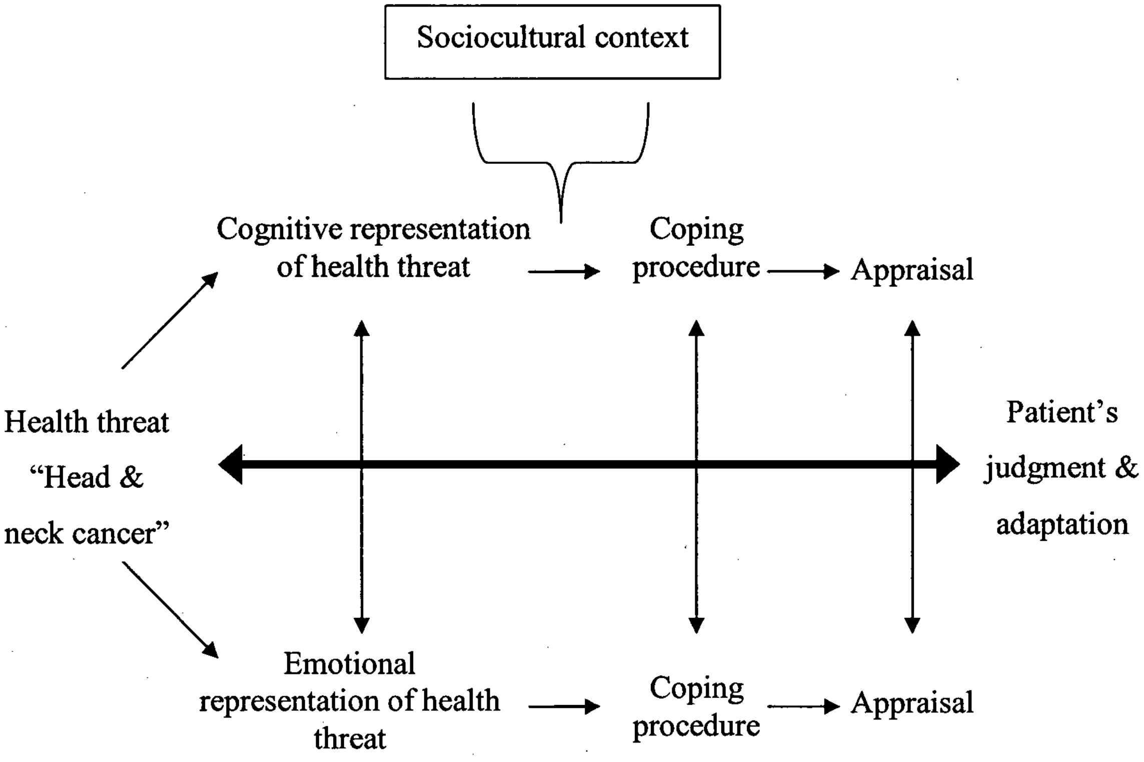
According to the previous findings, evidence suggests that there are some associations between anxiety and depression and patients' sociodemographic and clinical characteristics. These predictors should be used to screen patients for risk of psychological distress so that appropriate management and treatment can be done.

2.4 Coping and adaptation

For the purpose of this study we adopted Lazarus and Folkman definition of coping which is "constantly changing cognitive and behavioural efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person". In their theoretical framework of coping, Lazarus and Folkman explained how coping provides two principal functions. First, dealing with the problem that is causing the distress (problem-focused coping) and second, adjusting the emotional response to the problem (emotion-focused coping) (47).

To better understand coping with head and neck cancer we used the framework of the self-regulation model to illustrate how patients react and manage specific health threat (Figure 1). The model demonstrates how a stimulus, which in this case is the head and neck cancer threat to patient's health, generate two processes; one creating the cognitive representation of the threat, which includes patient's beliefs about their disease and treatment, with its coping procedures and evaluative processes and the other emotional process, which includes the affective reactions to the disease, the coping procedures and appraisal for management of emotion. Together the two processes represent the selfregulative system. Representations (both cognitive and emotional) are affected by self and social context (48;49) .

Figure 1- The self regulation model. Adapted from Leventhal et al (48;49)



Coping has been studied among different cancer patients and is related to several outcomes (50). However, coping was extensively studied in breast cancer patients. Several studies have related patients' psychological distress to coping. It has been shown that women who cope through emotional expression had lower psychological distress (51). Stanton et al followed 117 women prospectively before breast biopsy, after diagnosis and after surgery for those who had cancer diagnosis. Their analysis revealed that those women who had high prebiopsy distress used more cognitive avoidance coping (52). In 1996, Classen et al studied the association between coping styles and adjustment to cancer in 101 women with metastatic or recurrent breast cancer. Their findings showed that emotional control coping was positively associated with emotional distress, while fighting spirit coping was negatively associated with emotional distress (53). Additionally, a prospective study in 80 breast cancer women reported a significant association between high anxiety and depression symptoms and problem-focused and emotion- focused disengagement coping (54).

Other studies related coping to patients' survival. Greer et al found in their 15-year prospective study among breast cancer patients that "those patients who used fighting spirit or denial response were significantly more likely to be alive and free of recurrence" (55;56). In addition, a cohort study with 578 breast cancer patients reported that women with high scores on the helpless and hopelessness category of the Mental Adjustment to Cancer scale (MAC) at baseline have a high risk of relapse or death at 5 year follow up. The same study also shows significant association between high depressive symptoms and decreased survival (57).

These previous studies indicate that cancer patients use different coping strategies to adapt with their disease. In addition, it was shown that coping can be associated with patients' psychological distress, quality of life and survival. However, relative to other types of cancer little is known about coping with head and neck cancer. Sherman et al examined 120 patients with advanced head and neck cancer at different phases of their illness and found that patients who are receiving or just finished their treatment used denial, behavioural disengagement, suppression of competing activities and emotional ventilation coping strategies more than other types coping. They also reported that denial, behavioral disengagement, emotional ventilation were associated with more distress (58). Hassanein et al in 2001, examined the association between coping and patients' functional status in 68 patients with oral cancer. There was a negative association between ineffective coping strategies and patient's activity, recreation and chewing measured by the University of Washington Quality of Life Questionnaire (UW-QoL) (59).

The relation between coping and quality of life has also been investigated in head and neck cancer patients. In 2005, a prospective study in 35 head and neck cancer patients illustrated significant association between emotion-oriented coping measured by the Coping Inventory for Stressful Situation (CISS) and quality of life (60). Using the Jalowiec Coping Scale (JCS), He et al also reported a positive association between quality of life and positive emotion-focused coping styles (optimistic and palliative) and a negative association between quality of life and negative emotion-focused coping styles (evasive, fatalistic and emotive) in 98 Chinese nasopharyngeal cancer patients (61).

Although recently the psychological adaptation and coping of patients with head and neck cancer has gained research attention, still further research is needed to confirm these findings and to further explore coping strategies and their association with patients' psychological status.

2.5 Aims and Hypothesis

Aims

1. To identify correlates of psychological distress among a group of head and neck cancer patients 6-12 months after their cancer diagnosis.
2. To investigate how coping skills and anxiety/depression are related in those head and neck cancer patients.

Hypothesis

Head and neck cancer patients with low levels of anxiety or depression use different coping skills compared to those with high levels of anxiety or depression 6-12 months following the diagnosis of their cancer.

Chapter III: Methods

3.1 Study Design

The data collected in this study were cross sectional in nature and the baseline data from a large randomized control trial (RCT). The randomized control trial investigates the effect of a psychosocial intervention (Nucare) to reduce psychological distress in people with head and neck cancer and who have high levels psychological distress. Participants were randomized into test or control group using a block randomization technique. Participants in the test group received the experimental intervention (Nucare); consisting of 2-3 sessions with a trained therapist, and those in the control group received an attention placebo consisting of 1-3 meeting with the same therapist as the test group to discuss cancer related issues of the subject's choice. The required sample size for the RCT was 250 participants and the analysis for our study was done from the first 107 patients at baseline.

3.2 Study Sample

Patients were included if they met the following criteria: 1) were diagnosed with a primary cancer of the head and neck region (ICD-9 140-149 and 161; lip, salivary glands, tongue, floor of mouth, other mouth, oropharynx, nasopharynx, other pharynx and larynx); 2) had completed cancer therapy with curative intent for that cancer; 3) were diagnosed 6-12 months previously; 4) were able to understand and complete either French or English questionnaires; 5) had signed a consent form. Patients were excluded if they:

1) were undergoing palliative or terminal care only; 2) had a previous history of malignant disease affecting other parts of their body; 3) had a diagnosis of depression and were currently receiving anti-depressive therapy.

3.3 Sample size

For sample size justification we used 80% power and an alpha of 0.05. The standard deviation for the *Ways of Coping Checklist* domains scores varied in the literature with different patients population (62-64). The sample size calculation is based on the hypothesis that head and neck cancer patients with low levels of anxiety or depression use different coping skills compared to those with high levels of anxiety or depression 6-12 months following the diagnosis of their cancer. We proposed several different standard deviations and mean differences from previous studies in the literature that used the HAD scale in head and neck cancer patients to predict the required sample size that will enable us to detect significant difference between the groups of patients with low anxiety/depression versus those with high anxiety/depression in the study. Table 2 summarizes sample sizes enabling the detection of various differences.

Table 2 - Summary of proposed sample sizes

Outcomes [a]	Standard Deviation	Difference in means [b]	N per group [c]	N total [d]
Seek social support coping	4.9	1.5	84	168
	4.25	1.5	63	126

	3.90	1.5	53	106
Wishful thinking coping	6.00	1.5	125	250
	4.50	1.5	71	142
	4.00	1.5	56	112
Avoidance coping	4.90	1.5	84	168
	4.00	1.5	56	112
	3.50	1.5	43	86
Seek social support coping	4.25	1.5	63	126
	4.25	2	35	70
	4.25	2.5	23	46
Wishful thinking coping	4.50	1.5	71	142
	4.50	2	40	80
	4.50	2.5	25	50
Avoidance coping	4.90	1.5	84	168
	4.90	2	47	94
	4.90	2.5	30	60

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[a] Some domains of coping according to the *Ways of coping Checklist*

[b] Difference in mean scores between high and low anxiety/depression groups.

[c] Number required per group + [d] for whole study sample to detect differences shown in "mean difference" column.

3.4 Recruitment

Study subjects were recruited while they attended the out-patient head and neck cancer clinics of the Jewish General Hospital (JGH), L'hopital Notre Dame (HND), Royal Victoria Hospital (RVH) and the Montreal General Hospital (MGH) in Montréal. The physicians responsible for the patients' cancer management introduced the study to the patients. Research assistants (RA) at each of the recruitment sites then provided a complete explanation and gave a consent form to patients who agreed to participate. After signing the consent, RAs collected data from patients through interviews and self assessment questionnaires.

3.5 Variables and measures

3.5.1 Demographic and clinical data

Demographic measures consisted of language, gender, age, living arrangement, occupation and education [Appendix # 1]. Living arrangements were classified as living alone, living with partner, living with other family or communal accommodation. Occupation was classified as retired, employed-working, employed-on sick leave, unemployed or homemaker. Education was categorized into not graduated from high school, high school graduate, college or university. Language was classified as either French or English. We collected information about these demographic measures because as noted earlier [section 2.3] many studies have proposed sociodemographic factors as predictors for anxiety and depression in head and neck cancer patients and the relationship between these factors and anxiety and depression have been also analysed in previous research.

Cancer-related information included tumor site and stage, time since diagnosis, comorbidity, treatment modality and time since end of treatment. Tumor site was categorized as cancer of lip, oral cavity, larynx, pharynx, unknown or other and tumor stage was classified as stage I, II, III or IV. Treatment modality was classified as surgery only, radiotherapy only, chemotherapy only, surgery and radiotherapy, surgery and chemotherapy, chemotherapy and radiotherapy or surgery, radiotherapy and chemotherapy. Comorbidity was defined as either present or absent according to patients' response to the questionnaire and not collected from patients' records.

3.5.2 Measures

Psychological distress was assessed using the *Hospital Anxiety and Depression* scale *(HAD)*. This self –assessment scale was developed by Zigmond and Snaith in 1983; it is designed to detect the presence and severity of mood disorder likely to be found in non-psychiatric hospital out-patients. The scale discriminates between anxiety and depression and it has the advantage of not including any questions related to physical symptoms of psychological distress (e.g. headache or weight loss) which could give false results if they were due to other medical illness. The HAD scale includes two subscales; anxiety and depression. Each subscale consists of seven items and every item is rated on a four- point Likert scale from 0-3 with a higher score indicating more frequent or more severe symptoms. Item scores for each subscale are summed so the possible scores range from 0 to 21 for each subscale. A score of 0 to 7 indicates non-case, a score of 8 to 10 represents possible case and a score of >10 indicates a probable case of depression or clinical anxiety (65). For this study we used a cut-off point of 8 to dichotomize the scale. Patients who score less than eight on either scale are considered to have low anxiety or depression and those who score ≥8 on either scale are considered to have high anxiety or depression. We used the cut off point of 8 according to Zigmond and Snaith recommendation in their HAD scale development study to detect all possible cases of anxiety and depression (65). This cut-off is validated and commonly used in the literature to detect all possible cases of anxiety and depression (66-68)

The HAD scale was designed and widely used as a screening instrument because it is a brief self assessment tool. In 2002, Bjelland et al reviewed 747 papers that used the HAD scale and confirmed its ability as a screening tool for detecting anxiety and depression (69).

The validity and reliability of the HAD scale has been studied in different countries and languages (70-72), as well as among different patient populations (73-76). Herrmann C. in 1997, examined the validity and reliability of the HAD scale by reviewing about 200 published studies in different countries and different medical settings and concluded that

"HADS is reliable and valid instrument for assessing anxiety and depression in medical patients" (68).

Furthermore, several studies compared the ability of the HAD scale to detect anxiety and depression with other self-assessment scales such as the General Health Questionnaire, the Irritability-Depression-Anxiety scale and the Rotterdam Symptom Checklist. The HAD scale performed well in detecting the presence of anxiety and depression and showed acceptable sensitivity and specificity in comparison to the other scales (76-80).

For this study we used both the English and French versions of the HAD scale because the participants in the study speak either English or French [Appendix # 2]. The validity and reliability of both versions were confirmed in several previous studies. The English version of the HAD scale has been shown to have good internal consistency and criterion validity (78;79). Johnston et al reported in their study that Cronbach's α for the anxiety subscale was 0.89 and for the depression subscale was 0.82 for breast patients receiving radiotherapy in their population (73). In Canada, in 1998 Savard et al evaluated the psychometric properties of the French version of the HAD scale. They reported that the "French Canadian version was found to be equivalent to the original English version" and demonstrated that the measure was a reliable and valid instrument to detect anxiety and depression among HIV- infected patients. They reported a Cronbach's α of 0.89 for each of the anxiety and depression subscales (71).

Coping skills were assessed using the *Ways of Coping Checklist (WOCC)*. This scale was originally reported by Folkman and Lazarus (47). It aims to assess coping as an adaptational outcome in relation to a stressful encounter. The original WOCC was a 68-item list that was classified on the basis of problem- focused or emotion- focused ways of coping (81).

In this study coping was assessed with a revised version of the Ways of Coping Checklist. The revised version is a 42 –item scale describing responses to a stressful situation. The response to each statement is rated on a 4-point scale response (0=not used, 1= used somewhat, 2= used quite a bit, 3= used a great deal) instead of the yes-no format in the original scale. The revised WOCC measures five coping strategies, namely, problem-focused, seek social support, blamed self, wishful thinking and avoidance coping. Scores are calculated by summing the ratings for each coping strategy to describe the extent of use of each of those strategies, wherein higher score indicates more use of the strategy. Scores range from 0-45 for problem-focused coping, from 0-18 for seek social support coping, from 0-9 for blamed self coping, from 0-24 for wishful thinking coping and from 0-30 for avoidance coping. For the purpose of comparison we standardized each coping strategy score on a scale from 0-100 to enable comparison between rates of use of different coping strategies (62;82).

We used the English and French versions of the WOCC to assess coping skills in this study [Appendix # 3]. In 1985, Vitaliano et al, examined the psychometric properties of the revised English WOCC and reported that "the revised scale had respectable internal consistency reliabilities, and construct and criterion-related validity". They found that among the medical student sample the mean Cronbach's α was 0.81 for the original scale versus 0.82 for the revised version (62). Another study in France validated the French version of the WOCC and demonstrated its validity (83).

3.6 Statistical analysis

Simple descriptive statistics were used to analyze the sociodemographic and clinical data (frequencies and percentages). For analytic purposes some of the variables were grouped into categories. We categorized age into four groups according to quartiles, living arrangements were dichotomized into either living alone or living with others and occupation was grouped according to theoretical sense into three categories: employed on sick leave or unemployed, homemaker or retired and employed working. Cancer sites were grouped into larynx, pharynx and oral cavity or other. Treatment modalities were grouped according to similar means into four categories: chemotherapy and radiotherapy, radiotherapy only, surgery only or surgery and radiotherapy and surgery, radiotherapy and chemotherapy. TNM stages were dichotomized into either early or late stage.

To address our first aim; to identify correlates of psychological distress among a group of head and neck cancer patients 6-12 months after their cancer diagnosis, the following variables were considered as the independent variables: demographic characteristics (gender, age, living arrangement, occupation, education and language) and clinical characteristics (tumor site, tumor stage, comorbidity, time since diagnosis, treatment modality and time since end of treatment). Anxiety and depression were considered the dependent variables and were examined in two different ways; as a binary variable using the cut-off point of 8 [see section 3.5.2] and as a continuous variable. When anxiety and depression were treated as a continuous variable, we used both parametric and non-parametric approaches to test the associations since the distribution of both anxiety and depression data were not perfectly normal and not very skewed (for anxiety the skewness value =0.85 and kurtosis =0.33 and for depression the skewness value was 1.39 and kurtosis= 2.79). When the HAD scale was treated as a binary scale, we used Chi-square tests to determine the associations between the different independent variables and anxiety and depression. When the HAD scale was considered normally distributed, we used Student *t*-test to determine the associations between anxiety and depression and the binary independent variables (gender, living arrangements, language, comorbidity, TNM stage, time since treatment and time since diagnosis). We also used ANOVA to determine the associations between the dependent variable (anxiety and depression) and the categorical independent variables (age, occupation, maximum level of education attained, cancer site and treatment modality). When HADS was considered non-normally distributed, we used Mann-Whitney U and Kruskal Wallis tests to verify the associations. Mann-Whitney U was used with the binary independent variables and Kruskal Wallis was used when the independent variables were categorical.

For multivariate analysis, multiple logistic regression was used to examine correlates of psychological distress among the sample. The dependent variable was considered the dichotomized anxiety and depression scores. The independent variables were entered manually in a stepwise process and were included in the model based on their statistical significance in the bivariate analysis (*P*-value < 0.05).

To address our second aim, to describe how coping skills are related to anxiety and depression, we considered the different coping strategies as the dependent variable and the dichotomized HAD scale as the independent variable. Student *t*-test was used to examine the association. Coping strategies were considered as a continuous normal scale because we standardized each coping strategy on a scale from 0-100.

The data were analyzed using the Statistical Package for the Social Sciences (SPSS). For all tests, *P*-value less than 0.05 were considered statistically significant.

3.7 Ethical Considerations

The study reported in this thesis uses data collected as part of a large randomized controlled trial study. Ethics committee approval was provided by the Institutional Review Board of McGill faculty of Medicine and by the review board of each of the four hospitals that the patients were recruited from. [Appendix # 4]

Each Patient was approached by a research assistant to explain the purpose of the study. Patients were told that their participation is voluntary and their decision to participate will not affect their medical care. Patients were also assured that the information they provide will be confidential. Participants who agreed to participate and were eligible signed a consent form which was available in both English and French language [Appendix # 5].

Patients HADS scores were provided to treating physicians so that they could manage the distress symptoms as they thought appropriate.

Chapter IV: Results

4.1 Descriptive characteristics of the sample

Table 3 presents the sociodemographic and clinical characteristics of the 107 patients included in the study. The mean age of patients was 60.6 years and the majority was male (75.7%). Among the participants, 48.6% were homemaker or retired and most of the patients were living with another person (76.6%). The most common cancer sites were the pharynx (37.4%) followed by the oral cavity (36.4 %) and the larynx (24.3%). Almost half of the patients presented with TNM stage IV (54.2%). Treatment modality varied among the participants of whom (21.5%) were treated with Chemotherapy, radiotherapy and surgery, (25.2%) were treated with chemotherapy and radiotherapy, (19.6%) were treated with radiotherapy only and (29%) were treated with surgery only or surgery and radiotherapy.

Table 3- Demographic and clinical characteristics of the patients (N= 107)

	Number of cases (%)	Mean	SD
Gender			
Female	26 (24.3)		
Male	81 (75.7)		
Age groups, years			
<53	26 (24.3)	60.6	11.3
54-60	31 (29.0)		
61-69	25 (23.4)		
> 70	23 (21.5)		

Living arrangements	
Alone	25 (23.4)
With other	82 (76.6)
Principal occupation	
Employed-On sick leave/Unemployed	35 (32.7)
Employed-Working	20 (18.7)
Homemaker/Retired	52 (48.6)
Maximum level of education attained	
Did not graduate from high school	33 (30.8)
High school graduate	23 (21.5)
College /CEGEP	19 (17.8)
University	29 (27.1)
Language	
English	26 (24.3)
French	81 (75.7)
Cancer site	
Larynx	26 (24.3)
Oral cavity/Other	39 (36.4)
Pharynx	40 (37.4)
TNM stage	
I	20 (18.7)
II	11 (10.3)
III	14 (13.1)
IV	58 (54.2)
Treatment modality	
All three	23 (21.5)
Chemotherapy + Radiotherapy	27 (25.2)
Radiotherapy only	21 (19.6)
Surgery only/Surgery + Radiotherapy	31 (29.0)

Comorbidity			
Presence	54 (50.5)		
Absence	52 (48.6)		
Time since treatment [a]			
Up to 24 weeks	60 (56.1)	22.3	9.3
More than 24 weeks	41 (38.3)		
Time since diagnosis [b]			
Up to 8 months	53 (49.5)	8.7	2.5
More than 8 months	53 (49.5)		

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[a] Time since treatment varied among the participants from 3-42 weeks

[b] Time since diagnosis varied among the participants from 6-24 months

4.2 Univariate analysis

4.2.1 Prevalence of psychological distress

The mean scores for anxiety and depression subscales of the patients are presented in Table 4. Among the participants the mean anxiety rating was 5.1 and the mean depression rating was 4.1. We defined positive cases by scores of 8 or greater on either the anxiety or the depression subscales. There were twenty six patients (24.3%) with high levels of anxiety and sixteen patients (15%) with high depressive symptoms.

Table 4- Prevalence of distress

	Mean (SD)	Range	Positive cases [a] (%)	Negative cases [b] (%)
Anxiety score	5.1 (3.9)	0-17	26 (24.3)	81 (75.7)
Depression score	4.1 (3.7)	0-18	16 (15)	91 (85)

[a] Positive cases represent cases with score ≥8 on either anxiety or depression subscale

[b] Negative cases represent cases with score <8 on either anxiety or depression subscale

N.B. Possible HADS score can range from 0-21 for each subscale

4.2.2 Coping

Table 5 lists means and standard deviations for each of the five coping strategies. Each strategy score can range from 0-100 with higher scores indicating more use of the strategy. Patients used a variety of coping strategies with "Problem focused" coping strategy being used most frequently (mean 42.8) and "blamed self" coping strategy being the least used (mean 17.4).

Table 5- Means and Standard of deviations for coping strategies

	Mean (SD)	Range
Problem focused	42.8 (21.7)	0 - 86.7
Seek social support	39.7 (27.3)	0 - 100
Blamed self	17.4 (24.5)	0 - 100
Wishful thinking	31.6 (23.8)	0 - 91.7
Avoidance	24.8 (16.3)	0 - 90

N.B. Possible WOCC score for each strategy can range from 0-100

4.3 Bivariate analysis

4.3.1 HAD Scale (Binary)

When analysis was done to examine the associations between the independent variables and the dichotomized HAD scale, we found higher proportion of female having high anxiety than male (*P*=0.053, Chi-square=3.75, df=1). We also found borderline difference in proportion of patients according to cancer site (*P*=0.096, Chi-square=4.68, df=2) with higher proportion for oral cancer patients having high anxiety. This was similar to what we found in regard to treatment modality (*P*=0.090, Chi-square=6.5, df=3); with higher proportion of patients who were treated with surgery only or surgery and radiotherapy having high anxiety. In regard to depression, we found higher proportion of patients who live alone having high depressive symptoms than those who live with other person (*P*<0.001, Chi-square=16.09, df=1). In addition, there were higher proportion of patients with laryngeal cancer having high depressive symptoms (*P*=0.33, Chi-square=6.81, df=2, while time since treatment had borderline significant finding (*P*=0.078, Chi-square=3.1, df=1); with those treated up to 24 weeks having higher levels of depressive symptoms (Table 6).

Table 6- Prevalence of HAD scale (Binary) among the participants (N= 107)

	Number of cases	High Anxiety(%)	^{a}*P*-value	High Depression(%)	^{a}*P*-value
Gender					
Female	26	10 (38.5)	0.053	3 (11.5)	0.575
Male	81	16 (19.8)		13 (16.0)	
Age groups, years					
<53	26	7 (26.9)	0.437	4 (15.4)	0.973
54-60	31	10 (32.3)		4 (12.9)	
61-69	25	4 (16.0)		4 (16.0)	
>70	23	4 (17.4)		4 (17.4)	
Living arrangements					
Alone	25	7 (28.0)	0.622	10 (40.0)	0.000
With other	82	19 (23.2)		6 (7.3)	
Principal occupation					
Employed-On sick leave/Unemployed	35	10 (28.6)	0.522	5 (14.3)	0.314
Employed-Working	20	3 (15)		1 (5.0)	
Homemaker/Retired	52	13 (25)		10 (19.2)	

Maximum level of education attained					
Did not graduate from high school	33	6 (18.2)	0.437	8 (24.2)	0.226
High school graduate	23	8 (34.8)		2 (8.7)	
College/CEGEP	19	6 (31.6)		1 (5.3)	
University	29	6 (20.7)		5 (17.2)	
Language					
English	26	7 (26.9)	0.720	4 (15.4)	0.943
French	81	19 (23.5)		12 (14.8)	
Cancer site					
Larynx	26	6 (23.1)	0.096	8 (30.8)	0.033
Oral cavity/Other	39	14 (35.9)		3 (7.7)	
Pharynx	40	6 (15)		5 (12.5)	
TNM stage					
Early	31	9 (29.0)	0.561	3 (9.7)	0.282
Late	72	17 (23.6)		13 (18.1)	
Treatment modality					
All three	23	7 (30.4)	0.090	3 (13)	0.175
Chemotherapy + Radiotherapy	27	4 (14.8)		4 (14.8)	
Radiotherapy only	21	2 (9.5)		6 (28.6)	
Surgery only/Surgery + Radiotherapy	31	11 (35.5)		2 (6.5)	
Co-morbidity					
Presence	54	11 (20.4)	0.427	8 (14.8)	0.935
Absence	52	14 (26.9)		8 (15.4)	
Time since treatment					
Up to 24 weeks	60	17 (28.3)	0.313	12 (20.0)	0.078
More than 24 weeks	41	8 (19.5)		3 (7.3)	
Time since diagnosis					
Up to 8 months	53	15 (28.3)	0.367	10 (18.9)	0.278
More than 8 months	53	11 (20.8)		6 (11.3)	

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[a] Based on Chi-square tests

4.3.2 HAD Scale (continuous normal distribution)

When the HAD scale was considered as continuous normally distributed variable, the mean anxiety score of males and females were significantly different (*P*=0.047, t=2.01, df=105) with more females having higher mean anxiety scores. As for depression, the difference in mean scores of early and late TNM stage were borderline significant (*P*=0.097, t=-1.68, df=101) while mean scores of living arrangements (*P*<0.001, t=4.51, df=105), occupation (*P*=0.037, F=3.39, df=2) and time since treatment (*P*=0.045, t=2.03, df=99) all demonstrated significant difference of depressive symptoms (Table 7).

Table 7- Prevalence of HAD scale (Continuous-normal distribution) among the participants (N= 107)

	Number	Mean anxiety (SD)	*P*-value	Mean depression (SD)	*P*-value
Gender					
Female	26	6.4 (4.5)	[a]0.047	3.7 (3.5)	[a] 0.552
Male	81	4.7 (3.6)		4.2 (3.7)	
Age groups, years					
<53 years	26	5.4 (3.8)	[b] 0.328	3.9 (3.4)	[b] 0.596
54-60 years	31	6.0 (4.0)		4.4 (3.8)	
61-69 years	25	4.3 (4.4)		3.4 (4.2)	
> 70 years	23	4.4 (3.1)		4.7 (3.2)	
Living arrangements					
Alone	25	5.5 (4.6)	[a] 0.590	6.7 (5.3)	[a] 0.000
With other	82	5.0 (3.7)		3.3 (2.5)	

Principal occupation					
Employed-On sick leave/Unemployed	35	5.5 (3.8)	[b] 0.579	4.9 (3.8)	[b] 0.037
Employed-Working	20	4.4 (3.6)		2.3 (2.8)	
Homemaker/Retired	52	5.2 (4.0)		4.2 (3.6)	
Maximum level of education attained					
Did not graduate from high school	33	4.3 (4.1)	[b] 0.215	4.9 (5.0)	[b] 0.373
High school graduate	23	6.1 (3.5)		4.1 (2.7)	
College/CEGEP	19	6.2 (4.2)		3.1 (2.3)	
University	29	4.8 (3.6)		4.0 (3.1)	
Language					
English	26	5.5 (4.4)	[a] 0.599	4.5 (4.0)	[a] 0.451
French	81	5.0 (3.7)		3.9 (3.5)	
Cancer site					
Larynx	26	5.3 (3.7)	[b] 0.402	5.0 (4.7)	[b] 0.302
Oral cavity/Other	39	5.7 (4.7)		3.5 (3.0)	
Pharynx	40	4.5 (3.2)		4.1 (3.6)	
TNM stage					
Early	31	5.7 (4.4)	[a] 0.396	3.3 (3.9)	[a] 0.097
Late	72	5 (3.7)		4.6 (3.5)	
Treatment modality					
All three	23	5.1 (3.8)	[b] 0.262	4.4 (4.0)	[b] 0.290
Chemotherapy + Radiotherapy	27	4.4 (3.3)		4.1 (2.4)	
Radiotherapy only	21	4.5 (3.8)		5.1 (5.0)	
Surgery only/Surgery + Radiotherapy	31	6.2 (4.5)		3.1 (3.4)	
Co-morbidity					
Presence	54	5.0 (3.9)	[a] 0.781	4.1 (3.6)	[a] 0.976
Absence	52	5.2 (3.9)		4.1 (3.8)	
Time since treatment					
Up to 24 weeks	60	5.6 (3.8)	[a] 0.118	4.7 (4.1)	[a] 0.045
More than 24 weeks	41	4.4 (3.7)		3.2 (2.9)	

Time since diagnosis					
Up to 8 months	53	5.7 (4.3)	[a] 0.140	4.5 (3.7)	[a] 0.269
More than 8 months	53	4.6 (3.3)		3.7 (3.6)	

[a] Based on *t*-test

[b] Based on ANOVA test

4.3.3 HAD Scale (Continuous-non normal distribution)

When we considered the HAD scale as continuous non-normally distributed dependent variable, the difference in mean anxiety score of female and male was borderline significant (*P*=0.090). Similarly, the difference in mean anxiety score of time since treatment was also borderline significant (*P*=0.084). On the other hand, the mean depressive symptoms scores of living arrangements (*P*=0.003), occupation (*P*=0.013) and TNM stage (*P*=0.025) were significantly different. Whereas the difference in mean depressive symptoms scores of time since treatments was borderline significant (*P*=0.063) (Table 8).

Table 8-Prevalence of HAD scale (Continuous-non normal) among the participants (N= 107)

	Number	Mean anxiety (SD)	*P*-value	Mean depression (SD)	*P*-value
Gender					
Female	26	6.4 (4.5)	[a]0.090	3.7 (3.5)	[a]0.499
Male	81	4.7 (3.6)		4.2 (3.7)	
Age groups, years					
<53	26	5.4 (3.8)	[b]0.211	3.9 (3.4)	[b]0.233
54-60	31	6.0 (4.0)		4.4 (3.8)	
61-69	25	4.3 (4.4)		3.4 (4.2)	
>70	23	4.4 (3.1)		4.7 (3.2)	
Living arrangements					
Alone	25	5.5 (4.6)	[a]0.880	6.7 (5.3)	[a]0.003
With other	82	5.0 (3.7)		3.3 (2.5)	
Principal occupation					
Employed-On sick leave/Unemployed	35	5.5 (3.8)	[b]0.515	4.9 (3.8)	[b]0.013
Employed-Working	20	4.4 (3.6)		2.3 (2.8)	
Homemaker/Retired	52	5.2 (4.0)		4.2 (3.6)	
Maximum level of education attained					
Did not graduate from high school	33	4.3 (4.1)	[b] 0.115	4.9 (5.0)	[b] 0.716
High school graduate	23	6.1 (3.5)		4.1 (2.7)	
College/CEGEP	19	6.2 (4.2)		3.1 (2.3)	
University	29	4.8 (3.6)		4.0 (3.1)	
Language					
English	26	5.5 (4.4)	[a]0.821	4.5 (4.0)	[a]0.488
French	81	5.0 (3.7)		3.9 (3.5)	

Cancer site					
Larynx	26	5.3 (3.7)	[b]0.623	5.0 (4.7)	[b]0.579
Oral cavity/Other	39	5.7 (4.7)		3.5 (3.0)	
Pharynx	40	4.5 (3.2)		4.1 (3.6)	
TNM stage					
Early	31	5.7 (4.4)	[a] 0.532	3.3 (3.9)	[a] 0.025
Late	72	5 (3.4)		4.6 (3.5)	
Treatment modality					
All three	23	5.1 (3.8)	[b]0.378	4.4 (4.0)	[b]0.260
Chemotherapy + Radiotherapy	27	4.4 (3.3)		4.1 (2.4)	
Radiotherapy only	21	4.5 (3.8)		5.1 (5.0)	
Surgery only/Surgery + Radiotherapy	31	6.2 (4.5)		3.1 (3.4)	
Co-morbidity					
Presence	54	5.0 (3.9)	[a]0.787	4.1 (3.6)	[a]0.899
Absence	52	5.2 (3.9)		4.1 (3.8)	
Time since treatment					
Up to 24 weeks	60	5.6 (3.8)	[a]0.084	4.7 (4.1)	[a]0.063
More than 24 weeks	41	4.4 (3.7)		3.2 (2.9)	
Time since diagnosis					
Up to 8 months	53	5.7 (4.3)	[a]0.259	4.5 (3.7)	[a]0.180
More than 8 months	53	4.6 (3.3)		3.7 (3.6)	

---

[a] Based on Mann-Whitney U test

[b] Based on Kruskal Wallis test

4.3.4 Coping strategies and anxiety/depression

Analyses were performed to determine the associations between different coping strategies and anxiety and depression. Table 9 displays the associations between the different coping strategies and anxiety. We found statistically significant difference between anxiety mean scores and “seek social support” (*P*=0.037), “blamed self” (*P*=0.023) “Wishful thinking” (*P*<0.001) and “avoidance” (*P*<0.001) coping strategies. In addition, we found statistically significant difference between depressive symptoms mean scores and “blamed self” (*P*=0.003), “wishful thinking” (*P*<0.001) and “avoidance” (*P*<0.001) coping strategies (Table 10).

Table 9- Statistical associations between different coping strategies and anxiety

	Low anxiety mean	High anxiety mean	[a] *P*-value
Problem focused	42.7	43.2	0.923
Seek social support	36.6	49.4	0.037
Blamed self	14.4	26.9	0.023
Wishful thinking	27	45.8	0.000
Avoidance	21.7	34.5	0.000

[a] Based on *t*-test

Table10- Statistical associations between different coping strategies and depression

	Low depression mean	High depression mean	[a] *P*-value
Problem focused	43.7	37.8	0.317
Seek social support	39.6	40.3	0.923
Blamed self	14.5	34	0.003
Wishful thinking	28.2	51	0.000
Avoidance	21.6	42.7	0.000

[a] Based on *t*-test

4.4 Multivariate analysis

Multivariate regression analysis was done to determine which variables would predict anxiety and depression. Table 11 shows the results of the multiple logistic regression model for anxiety. The dichotomized anxiety subscale was considered the dependent variable and gender was the independent variable, while controlling for age. There was an association between gender and anxiety (P=0.047) and that was the only predictive variable for anxiety.

Table11 –Multiple Logistic Regression analysis of predictive factors of anxiety

Variable	[a] OR $_{adj}$	95% Confidence Interval	*P*-value
Gender			
Female [b]	1		
Male	0.367	0.14 – 0.99	0.047

[a] Odds ratio adjusted for gender as well as age

[b] Reference category

We also performed logistic regression analysis for depression. The dichotomized depression subscale was entered in the model as the dependent variable. The independent variables selected were living arrangements, cancer site (oral cavity or larynx *vs.* pharynx), time since treatment and TNM stage, while controlling for age and gender. Logistic regression revealed that living arrangements ($P<0.001$), cancer site ($P=0.01$), time since treatment ($P=0.04$) and TNM stage ($P=0.04$) were significantly related to depression. Table 12 presents the results of the logistic regression models.

Table 12- Multiple Logistic Regression analysis of predictive factors of depression

Variable	[a] OR $_{adj}$	95% Confidence Interval	*P*-value
Living arrangements			
Alone [b]	1		
With others	0.04	0.01 – 0.23	*P*<0.001
Cancer site			
Pharynx [b]	1		0.01
Larynx	27.56	2.95 - 257.68	*P*<0.01
Oral cavity/Other	2.2	0.29 - 16.39	0.44
Time since treatment			
Up to 8 months [b]	1		
More than 8 months	0.14	0.02 - 0.9	0.04
TNM stage			
Early [b]	1		
Late	13.37	1.15 – 154.86	0.04

[a] Odds ratio adjusted for the variables in the table as well as age and gender

[b] Reference category

[c] Note: only variables with significant associations are shown in the table. Other variables that were included in the model but their association were not significant are not shown.

Chapter V: Discussion

The aims of our study were to identify correlates of psychological distress among a group of head and neck cancer patients 6-12 months after their diagnosis and to investigate how coping skills and anxiety and depression are related in those head and neck cancer patients.

Our data analysis revealed significant associations between anxiety and depression and different sociodemographic and clinical variables. In addition, we were able to find significant differences in coping strategies between patients with high anxiety or depression and those with low anxiety or depression.

5.1 Psychological distress

In our study 24.3% patients had high levels of anxiety and 15% had high levels of depressive symptoms. This prevalence of psychological distress is similar to what has been shown in the literature among head and neck cancer patients. In a prospective study by Telfer et al, using the HAD scale to screen for anxiety and depression in 40 head and neck cancer patients, 33% of the patients had high anxiety while 15% were depressed (84). In a more recent study using the HAD scale to evaluate patients' psychological status, Hassanein et al reported that 16% of the patients included in their study were anxious and 19% were depressed (85). However, these findings are considerably higher than what Pandey et al found among 123 head and neck cancer patients; they reported that 12% of the participants had high anxiety and 10% had high depressive symptoms

(86). Voogt et al also reported lower prevalence of anxiety and depression compared to our findings. Their results indicated that among the 105 advanced different cancer patients; 8% had high anxiety and 13% had high depressive symptoms measured by the HAD scale (87).

The variations in prevalence of psychological distress among different studies are likely to be due to several issues. First, the role of cancer site in affecting patients' psychological status can be a major factor owing to different prevalence of anxiety and depression in cancer patients. It has been shown that according to the cancer site; patients can experience different levels of psychological distress (34). Second, variations can be due to different samples with different levels of psychological distress in various studies. Finally, the use of different instruments to assess anxiety and depression can also yield different results. This could possibly be due to the sensitivity and specificity for each scale to detect the levels of anxiety and depression and to the method of using the scale. In regard to the HAD scale, some studies use the overall score to indicate patient's anxiety and depression; others use it to evaluate anxiety and depression separately. Additionally, the issue of identifying the cut-off point in the scale which as well can account for different results. For our study we used the HAD scale with the cut-off point of 8 according to the original authors recommendations [see section 3.5.2].

5.2 predictors of anxiety and depression

5.2.1 Anxiety symptoms

Anxiety in cancer patients most frequently arises from patients' fear of metastasis, unpredictability about the future, fear of physical suffering and the loss of control over their own body (87). We found that females had higher levels of anxiety symptoms than males. This finding is consistent with other studies among head and neck cancer patients. In 1989, Espie et al investigated the relationship between demographic characteristics and psychological distress in 41 head and neck cancer patients who had received major intra-oral surgery. Their results indicated that female and younger patients had higher anxiety symptoms measured by the HAD scale than male and older patients (88). Hammerlid et al studied 357 head and neck cancer patients prospectively and found that women had significantly higher levels of anxiety at diagnosis as well as at one year follow-up than men. Similar finding was reported in regard to age, where younger patients were significantly more anxious than older patients (67). In another prospective study to assess fear of recurrence among orofacial cancer patients; females had also high levels of anxiety compared to males at 3 months following treatment (89).

This gender difference was shown in studies among different cancer patients as well. In Sydney, Pascoe et al, administered the HAD scale to 504 mixed cancer patients and found that female gender and restricted activity levels were significantly associated with anxiety (90). Consistent with previous reports, Bredart et al also found that among 190 mixed cancer patients; women had higher levels of anxiety and depression than men (91). To better understand gender difference in perceptions about cancer, McQueen et al examined 939 men and 1,580 women from the 2003 Health Information National Trends Survey (HINTS) to evaluate the risk and worry of participants for gender specific (breast/prostate) and colon cancers. They revealed that "women reported more cancer worry and men reported greater comparative risk for developing cancers" (92).

5.2.2 Depressive symptoms

Depression which is a treatable condition is common in cancer patients in general (93-95). It has been shown that depression in cancer patients can predict reduced quality of life and short survival and may even be associated with risk of mortality (96-98).

Our data analysis shows that living arrangements, cancer site, time since treatment and TNM stage were significantly associated with level of depressive symptoms. We found that patients who live alone had higher levels of depressive symptoms compared to those who live with another person. This supports the findings of Kugaya et al in their study of 107 head and neck cancer patients to predict factors of psychological distress. They found that living alone significantly predicted psychological distress (99). Although this association between living alone and depression can be related to patients' isolation, less communication and even less social support, there are few data to explain this association. Some studies related marital status to depression but not living alone in particular (100).

Patients with laryngeal cancer had higher levels of depressive symptoms compared to other cancer sites. Further explanation of this association can be clarified by Hammerlid et al a prospective study of 57 patients with laryngeal carcinoma to demonstrate the effects of tumor and treatments on those patients. The main complaints reported by the patients were dyspnoea and problems in communication such as hoarseness, talking to other people and talking on the phone (101).

In the multivariate analysis we reported that time since treatment and advanced disease stage were associated with depression. Those patients who were assessed for psychological distress less than 24 weeks following their treatment had higher depressive symptoms than those who were evaluated afterwards. The longer time enhance patients' ability to adjust and adapt with their disease and better accustom to their daily life. However, this finding does not support the work of Espie et al. They found no significant association between time elapsed since patient's treatment and their psychological distress (88).

Regarding the tumor stage, patients with advanced stage (III and IV) had higher depressive symptoms than those with early stage (I and II). These findings are in agreement with previous studies in head and neck cancer patients. Kugaya et al in 1999, studied 99 head and neck cancer patients to identify correlates of depression and reported that advanced disease stage was significantly associated with depressed mood (100). In Norway, another study with 79 male head and neck cancer patients confirmed similar association between tumor stage and depression (98). Advanced tumours are likely to be treated more aggressively, and thus commonly combinations of treatments are used for those patients. As a result, worse physical symptoms, longer treatments and treatment related side effects are expected which can justify our findings. This was pointed out in Hammerlid et al descriptive study with 357 head and neck cancer patients. Their results indicated that the more advanced the tumor stage; the lower is the health related quality of life (102).

5.3 Coping

The results of our study indicate that head and neck cancer patients used different types of coping strategies and that problem focused coping was used the most by patients. This is related to what List et al reported in their study of 79 head and neck cancer patients. They also found that patients used a wide range of coping strategies but social support seeking was the strategy used most frequently by patients; it represented about 25% of the total coping efforts (103). In addition, a descriptive correlational study among 183 different cancer patients, revealed that among the different coping styles measured by the Jalowiec Coping Scale (JCS); optimistic, confrontive and evasive coping styles were most often used by the patients (104).

There were significant associations between coping strategies and psychological distress in our results. We found that those patients with high anxiety used more of seek social support, blamed self, wishful thinking and avoidance coping strategies and those who had high depressive symptoms used more blamed self, wishful thinking and avoidance coping strategies. Similar associations are shown in the literature but the major difficulty in relating these findings is the different methods and instruments used to assess coping in various studies. Despite these difficulties, our results are parallel with that of Hassanein et al in 2005. They investigated the relation between anxiety, depression and coping mechanisms in 68 patients with oral cancer following their treatment. Using the Mental Adjustment to Cancer Questionnaire (MAC-Q) to assess coping among their participants; their results indicated that there was a significant association between ineffective coping style (described as the sum of the scores of helplessness/hopelessness, anxious preoccupation and fatalism coping) and both anxiety and depression (85).

Our results also support findings of studies with mixed cancer population. Miller et al examined 75 patients diagnosed with different types of cancer to describe the relationship between coping styles and psychological distress. Their analysis shows that among the coping strategies used by patients; Escape-avoidance coping was the only strategy that predicted distress (63).

Similar associations between psychological distress and coping have also been demonstrated in breast cancer patients. Carver et al in 1993, using the Coping Orientation to Problems Experienced questionnaire (COPE), examined which coping styles prospectively predicted distress in breast cancer patients. They found that acceptance type of coping was a significant predictor of psychological distress; thereby patients with higher acceptance presurgery had lower levels of postsurgical psychological distress (105). In another prospective study using the COPE questionnaire to evaluate coping among 72 Greek women diagnosed with breast cancer, it was shown that using acceptance and humor style of coping negatively associated with distress level presurgery, post surgery and 3 months follow-up. In contrast, the use of denial and emotional expression were positively related to distress post surgery and 3 months follow-up (106).

5.4 Limitations

A number of limitations exist in our study. First, the cross-sectional design which prevents any conclusions on whether correlates of anxiety and depression identified in our sample increased patients vulnerability to psychological distress or were consequences of that distress. A Similar limitation also exists in terms of coping strategies; we can not determine if coping strategies used by patients' were adaptational to their psychological condition or whether the reverse was true. In addition, changes overtime in anxiety, depression and coping can not be evaluated. Further longitudinal studies are needed to evaluate patients over time.

Second, our sample size is relatively small. However, sample size calculation showed that with a mean difference of 1.5, our sample size would enable us to detect statistically significant findings between high and low anxiety/depression groups of patients [section 3.3]. This was further shown by our findings; we found significant statistical associations between anxiety and depression and the different coping strategies used by patients. In addition, our findings demonstrated similar prevalence of psychological distress to previous studies.

Third, the issue of generalizability of the results; our sample was convenience sample of head and neck cancer patients visiting several hospitals in Montreal. Therefore, our results can not be generalized to other populations and settings and further research with more representative sample is needed.

Finally, the measures and statistical approach used to analyse the data in our study have some limitations. We assessed anxiety and depression using the HAD scale which was extensively validated in different languages and settings. In contrast, we used WOCC to assess coping which has been validated less frequently and very few studies validated the French version of that scale. For the statistical analysis we used multiple approaches to analyse the data. We considered the HAD scores in several ways; as a binary and continuous normal and non normal distributed variable. However, similar results were obtained from the different approaches.

Despite these limitations, we were able to identify significant associations in our data. This emphasizes the need for future studies to be conducted with more representative sample in different patient population to investigate if similar associations between different coping strategies and psychological distress can be reported to confirm our findings.

Chapter VI: Conclusion

This study confirms many others that have reported psychological distress in head and neck cancer patients. Our data also suggests several correlates of psychological distress in head and neck cancer patients. We report that females had higher anxiety symptoms than males. We also found that participants who live alone, have laryngeal cancer, have advanced disease stage or longer time since treatment had higher depressive symptoms. Knowledge about patients' characteristics at high risk can help clinicians to identify those patients and thus provide appropriate managements. Additionally, we demonstrated the usefulness of the HAD scale as a screening instrument to detect anxiety and depression among head and neck cancer patients. These data highlight the need for including simple screening instruments in the medical settings to recognize patients at risk of psychological distress.

Our findings also suggest that coping strategies in head and neck cancer patients vary according to patients' level of psychological distress. Subjects with high levels of symptoms of anxiety were more likely to use "seek social support", "blamed self", "wishful thinking" and "avoidance" coping strategies. Subjects with high depressive symptoms were more likely to use "blamed self", "wishful thinking" and "avoidance" coping strategies. These findings highlight the need for further research to explore the association between patients' coping strategies and their sociodemographic and clinical characteristics. Furthermore, it suggests the need for early psychological interventions for head and neck cancer patients to meet their needs and help them to learn how to live and cope with their disease for better psychological status.

We recommend that this study be considered as a descriptive study for head and neck caner patients to direct future research. Further studies are needed to confirm the relation between anxiety, depression and coping in head and neck cancer patients.

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Appendices

Appendix # 1

Sociodemographic and Clinical Variables

Section C: Socio-demographic information – SDI - *completed by interviewer*

1. Language: English 1 ☐ French 2 ☐
2. Gender: Male 1 ☐ Female 2 ☐
3. Age: yrs

4. Living arrangements:

    Alone ☐ 1
    With partner ☐ 2
    With other family ☐ 3
    Communal accommodation ☐ 4

5. Principal occupation:

    Retired ☐ 1
    Employed – Working ☐ 2
    Employed - On sick leave ☐ 3
    Unemployed ☐ 4
    Homemaker ☐ 5

6. Maximum level of education attained:

    Did not graduate from high school ☐ 1
    High school graduate ☐ 2
    College/CEGEP ☐ 3
    University ☐ 4

<u>Section D: Cancer related information</u> (CRI) - ***completed by research assistant <u>from medical file</u>***

1. Previous cancer ☐ Yes If YES: ☐ No
    - 1-1- Type of cancer: Date of diagnosis:
    - 1-2- Type of cancer: Date of diagnosis:
    - 1-3- Type of cancer: Date of diagnosis:

2. Cancer site:
    - lip ☐ 1
    - oral cavity ☐ 2
    - larynx ☐ 3
    - pharynx ☐ 4
    - unknown ☐ 5
    - other ☐ 6(specify) 1.1:

3. Initial TNM stage: Overall stage: Unknown: 2.1:

4. T: Unknown: ☐
5. N: Unknown: ☐
6. M: Unknown: ☐

6. Stage I and II = Early ☐
   Stage III, IV and Unknown = Late ☐

7. Date of initial diagnosis: /dd / MONTH /yyyy

8. Time since diagnosis: months

9. Treatment modality:
    - Surgery Only ☐ 1
    - Radiotherapy Only ☐ 2
    - Chemotherapy only ☐ 3
    - Surgery + Radiotherapy ☐ 4
    - Surgery + Chemotherapy ☐ 5
    - Chemotherapy + Radiotherapy ☐ 6
    - All three ☐ 7

10. Time elapsed since end of treatment : weeks

<u>Section E: Health related information</u> – HRI - *completed by interviewer*

1. Co-morbidity (excluding depression and anxiety): Yes ☐ If yes, specify No ☐

1.1. ……*Condition 1:*

1.1.1 ……..Pharmacological treatment: Yes ☐ No ☐

1.1.1.1. ………………If yes, specify:

1.1.2. ………..Other treatment: Yes ☐ No ☐

1.1.2.1. ………………If yes, specify:

1.2. …….*Condition 2*:

1.2.1. ……….Pharmacological treatment: Yes ☐ No ☐

1.2.1.1………………If yes, specify:

1.2.2. ………..Other treatment: Yes ☐ No ☐

1.2.2.1………………If yes, specify:

2. History of treatment for clinical depression: Yes ☐ No ☐

2.1. Presently being treated for depression? Yes ☐ No ☐ **If no, go to Q3**

2.1.1. ………Pharmacological treatment: Yes ☐ No ☐

2.1.2. ………Other treatment: Yes ☐ No ☐

2.1.2.1………………If yes, specify:

3. History of treatment for clinical anxiety: Yes ☐ No ☐

3.1. Presently being treated for anxiety? Yes ☐ No ☐ **If no, go to Section F**

3.1.1. ………Pharmacological treatment: Yes ☐ No ☐

3.1.2. ………Other treatment: Yes ☐ No ☐

3.1.2.1. ………………If yes, specify:

Appendix # 2

Hospital Anxiety and Depression Scale (HAD)

Section L: HADS – *completed by the subject*

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

1. (A) 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 Score: ______________

2. (D) 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 Score: ______________

3. (A) I get a sort of frightened feeling as if something awful is about to happen:

   a) ☐ Very definitely and quite badly
   b) ☐ Yes, but not too badly
   c) ☐ A little, but it doesn't worry me
   d) ☐ Not at all Score: ______________

4. (D) 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 Score: ______________

5. (A) 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 Score: ____________

6. (D) I feel cheerful:

a) ☐ Not at all
b) ☐ Not often
c) ☐ Sometimes
d) ☐ Most of the time Score: ____________

7. (A) I can sit at ease and feel relaxed:

a) ☐ Definitely
b) ☐ Usually
c) ☐ Not often
d) ☐ Not at all Score: ____________

8. (D) I feel as if I am slowed down:
a) ☐ Nearly all the time
b) ☐ Very often
c) ☐ Sometimes
d) ☐ Not at all Score: ____________

9. (A) I get a sort of frightened feeling like "butterflies" in the stomach:

a) ☐ Not at all
b) ☐ Occasionally
c) ☐ Quite often
d) ☐ Very often Score: ______________

10. (D) 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 as ever Score: ______________

11. (A) 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 Score: ______________

12. (D) I look forward with enjoyment to things:

a) ☐ As much as ever
b) ☐ Rather less than I used to
c) ☐ Definitely less than I used to
d) ☐ Hardly at all Score: ______________

13. (A)I get sudden feelings of panic:

a) ☐ Very often indeed
b) ☐ Quite often
c) ☐ Not very often
d) ☐ Not at all

Score: ______________

14. (D) I can enjoy a good book or radio or TV program:

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

Score: ______________

To be completed by interviewer:

15. Overall (A) score: ______________

16. Overall (D) score: ______________

17. Overall HADS score: ______________

18. Greater than 10 on both scales: Yes$_1$ ☐ No$_2$ ☐

Appendix # 3

The Ways of Coping Checklist (WOCC)

<u>Section H: WOCC</u> – ***completed by subject***

When people experience stress in their lives, they usually try to manage it by trying out different ways of coping. The next set of items is on the ways of coping you may have used in trying to manage your problems with cancer in the past month. Please mark how often you have used each of the following coping strategies **to deal with your cancer in <u>the past month</u>**.

		Not used	**Used somewhat**	**Used quite a bit**	**Used a great deal**
1.	Bargain or compromised to get something positive from the situation.	0	1	2	3
2.	Concentrated on something good that could come out of the whole thing.	0	1	2	3
3.	Tried not to burn my bridges behind me, but left things open somewhat.	0	1	2	3
4.	Changed or grew as a person in good way.	0	1	2	3
5.	Made a plan of action and followed it.	0	1	2	3
6.	Accepted the next best thing to what I wanted	0	1	2	3
7.	Came out of the experience better than When I went in.	0	1	2	3
8.	Tried not to act too hastily or follow my own hunch.	0	1	2	3
9.	Changed something so things would turn out all right.	0	1	2	3
10.	Just took things one step at a time.	0	1	2	3
11.	I know what had to be done, so I doubled my efforts and tried harder to make things work.	0	1	2	3
12.	Came up with a couple of different solutions to the problem.	0	1	2	3
13.	Accept my strong feelings, but didn't let them interfere with other things too much.	0	1	2	3
14.	Changed something about myself so I could deal with the	0	1	2	3

		Not used	Used somewhat	Used quite a bit	Used a great deal
	situation better.				
15.	Stood my ground and fought for what I wanted.	0	1	2	3
16.	Talked to someone to find out about the situation.	0	1	2	3
17.	Accepted sympathy and understanding from someone.	0	1	2	3
18.	Got professional help and did what they recommended.	0	1	2	3
19.	Talked to someone who could do something about the problem.	0	1	2	3
20.	Asked someone I respected for advice and followed it.	0	1	2	3
21.	Talked to someone about how I was feeling.	0	1	2	3
22.	Blamed yourself.	0	1	2	3
23.	Criticized or lectured yourself.	0	1	2	3
24.	Realized you brought the problem on yourself.	0	1	2	3
25.	Hoped a miracle would happen.	0	1	2	3
26.	Wished I was a stronger person – more optimistic and forceful.	0	1	2	3
27.	Wished that I could change what had happened.	0	1	2	3
28.	Wished I could change the way that I felt.	0	1	2	3
29.	Daydreamed or imagined a better time or place than the one I was in.	0	1	2	3
30.	Had fantasies or wishes about how things might turn out.	0	1	2	3
31.	Thought about fantastic or unreal things (like perfect revenge or finding a million dollars) that made me feel better.	0	1	2	3
32.	Wished the situation would go away or somehow be finished.	0	1	2	3

		Not used	Used somewhat	Used quite a bit	Used a great deal
33.	Went on as if nothing had happened.	0	1	2	3
34.	Felt bad that I couldn't avoid the problem.	0	1	2	3
35.	Kept my feelings to myself.	0	1	2	3
36.	Slept more than usual.	0	1	2	3
37.	Got mad at the people or things that caused the problem.	0	1	2	3
38.	Tried to forget the whole thing.	0	1	2	3
39.	Tried to make myself feel better by eating, drinking, smoking, taking medications.	0	1	2	3
40.	Avoided being with people in general.	0	1	2	3
41.	Kept others from knowing how bad things were.	0	1	2	3
42.	Refused to believe it had happened.	0	1	2	3

Appendix # 4

Ethical Approval

Appendix # 5

Consent Form

Montreal General Hospital / Royal Victoria Hospital
Head and Neck department
Dr Karen Kost (MGH)
Dr Anthony Zeitouni (RVH)

CONSENT FORM

A randomized controlled trial of the effectiveness of coping strategies interventions for people with head and neck cancer

- Dr Paul Allison, McGill University -

Purpose of the study:

Previous research suggests that people who have recently been diagnosed with cancer and who subsequently have high levels of stress could benefit from learning new coping skills. These previous studies suggest that, through a variety of ways, people with cancer can be helped to cope with the disease and this may lead to a reduction in emotional stress and a faster return to a usual lifestyle.

With these observations in mind, the research team would like to compare the possible benefits of two interventions (treatments) to see which one produces the greatest benefits in terms of reduced emotional stress and a better quality of life. We are inviting you to participate in this study because you have recently been diagnosed and treated for a cancer in the head and neck region and as such you are the sort of person who may benefit from the treatments we are testing.

Expected procedures:

If you agree to participate in this study, your participation will take approximately 14 months from the time you consent to the last time we will see you to collect data from you. If you agree to participate this is what will happen:

1. <u>Your current level of emotional stress:</u>
Firstly, we will ask you to complete a short questionnaire, the results of which will indicate to us the levels of stress and anxiety you are currently feeling. *If your score is low*, this indicates that you will probably feel no benefit from the treatments we are testing because your level of stress is low and so you do not need any treatment. We will inform you of this and you will not be offered the test treatments.

However, *if your score is high*, this indicates that your level of stress is relatively high and it is possible that you may benefit from receiving a test treatment. We will therefore inform the physician treating you for your cancer of this high score and we will invite you to participate in the rest of the study. If you agree, this will happen:

2. Randomization:

This is a procedure that selects participants randomly (purely by chance) into two different groups. With it, you have a 50% chance of being allocated to one of two groups. Once the randomization process is done, the research assistant will tell you which group you have been randomized to and explain what happens to people in each group. It is important to understand that the research assistant has no control over which group you are randomized to and that you will not be permitted to change groups.

If you are assigned to group A, an experienced counsellor will call you and schedule to meet with you. Together, you will go through a series of exercises set out in a workbook and accompanying audio material that will be yours to keep. This involves 2 or 3 sessions of about 2 hours each, provided over the course of approximately 1 month at times that are convenient for you. In addition, you will be seen several times by the research assistant to answer some questionnaires as described in section 3, below. Parts of the one-to-one sessions may be observed directly by investigators in the research team or audiotape recorded. The purpose of this procedure is to monitor the counsellors' performance and provide them with an evaluation. No participant will be specifically identified. These tapes will be reviewed by the research team only, and subsequently erased.

If you are assigned to group B, an experienced counsellor will call you and schedule to meet with you. The counsellor will discuss your cancer, your cancer treatment and how well you are feeling in your emotional and social life. You will be invited to discuss the issues you wish to talk about and that you think will be helpful. You will be given the opportunity to meet the counsellor up to three times over the course of approximately 1 month. In addition, you will be seen several times by the research assistant to answer some questionnaires as described in section 3, below. Parts of the sessions may be observed directly by investigators in the research team or audiotape recorded. The purpose of this procedure is to monitor the counsellors' performance and provide them with an evaluation. No participant will be specifically identified. These tapes will be reviewed by the research team only, and subsequently erased.

For both interventions, you will be permitted to invite one person of your choice, to join you in the sessions with the counsellor. You may have no more than one person and you are free to choose to have no person with you.

3. Filling out questionnaires:

Regardless of whether you are assigned to group A or to group B, you will be asked to fill out some short questionnaires. The questions are about how you are coping with your life. They are not used to evaluate you, rather, they are used to evaluate the program that we are testing. To do this, a research assistant will meet with you 5 times – once, a few days after you agree to participate, a second time around 8 weeks later, and then about 4 months, 8 months and 14 months after your first visit with the assistant. The first visit should take about 30 minutes and the following ones only about 15 minutes or less to do.

Potential risks and /or benefits:

You will be required to give a total of approximately 3 to 7 hours of your time within the next 14 months. Although it is unlikely, it is possible that you may find some of the questions related to how you are presently coping somewhat stressful or surprising. There is no blood test or other physical evaluation involved in this study. On the other hand, it is possible that you could feel some benefits following either of the test treatments we are proposing.

Alternatives:

There are many resources in the hospital and the community, both professional and non-professional that offer help to people with cancer. We will give you a list of resources where you can get such support.

Confidentiality:

In order to participate in this research project, it is necessary for the research staff to review your medical records as they relate to the study. You will be assigned a code to protect your identity from being revealed. Any information collected about you will be held in strict confidence, stored in a locked filing cabinet and will be destroyed three years after we have completed the whole study. The investigators in this research project intend to use results to write scientific papers or to present them at conferences. As all data are recorded and reported in an anonymous form, your identity will never be revealed.

Information:

If you have any questions regarding your rights as a research volunteer, contact your hospital's Ombudsman at (514) 934-1934 extension 35655. You may 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) 398-7203 ext. 00045.

Your rights as a volunteer:

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. Your care and medical treatment will not be affected in any way.

Compensation:

If you are required to come to the hospital for filling out questionnaires as described above, you will be given 20$ to help pay for transport and parking costs for EACH visit.

CONSENT AGREEMENT

Signature:

By signing this consent form, I agree that:

1. The study and this form have been explained to be by __________________ *(name of research assistant)*, who has responded satisfactorily to my questions.
2. My participation is voluntary. My withdrawal from the study will not lead to any loss of services.
3. If I have a high level of stress, my physician will be informed and I will be asked to participate in the study and will be randomly allocated to one of two test treatments.
4. I have a 50% chance of being allocated to either of the two test treatments and I understand the implications of each situation in terms of timing and procedures.
5. I give permission for my sessions with a counsellor to be audiotape recorded.
6. A copy of the present form will be given to me and another one will be kept in a file created for the study.

____

Participant's signature	Date	Full name, in block letters

____

Witness' signature	Date	Full name, in block letters