**UNIVERSITI PUTRA MALAYSIA**

# *EFFECTIVENESS OF INTENSIVE NUTRITION INTERVENTION ON NUTRITIONAL, SIDE-EFFECTS AND FUNCTIONAL OUTCOMES AMONG HEAD AND NECK CANCER OUTPATIENTS ON RADIOTHERAPHY*

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**FPSK(m) 2021 11**

# EFFECTIVENESS OF INTENSIVE NUTRITION INTERVENTION ON NUTRITIONAL, SIDE-EFFECTS AND FUNCTIONAL OUTCOMES AMONG HEAD AND NECK CANCER OUTPATIENTS ON RADIOTHERAPHY


**By**

**NORSHARIZA JAMHURI**


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**September 2020**

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Malnutrition is common in head and neck cancer (HNC) patients even prior to treatment. An intensive nutrition intervention (INI) might able to improve their nutritional status. However, malnutrition risk is greater among HNC outpatients due to the limited contact time with dietitian, absence of close monitoring and oral nutrition supplement (ONS) provision compared to HNC inpatients plus that there was limited research on the effectiveness of INI among HNC outpatients. Thus, this leads to significant gap in optimising the deliverance of dietitians' services in this area. An open labelled pragmatic randomised controlled trial study was conducted to ascertain the effectiveness of INI (prescription and provision of ONS, dietary consultation and frequent follow-up) vs routine care (RC) which includes dietary consultation, frequent follow up and ONS prescription only, among HNC outpatients towards nutritional, side effects and functional outcome. A total of 36 subjects were recruited from the HNC outpatients list in radiotherapy clinic at National Cancer Institute, Putrajaya, obtained from the online system and randomised into the INI and RC group using online randomiser software. Patients who already started on ONS, tube feeding and cancer treatments prior to the study period were excluded. Patient Generated Subjective Global Assessment (PG-SGA) and Head and Neck Symptoms Checklist (HSNC) were used to assess nutritional and side effect status whilst handgrip strength (HGS) was used to assess the functional status of study subjects. Parametric test was used for normally distributed data unless otherwise stated and univariate analysis was used for repetitive measurements. A modified intention to treat principle (ITT) and per protocol (PP) principle were

used for fair comparisons among treatment groups which reflects clinical effectiveness in actual practices and built confidence in study results when both analyses came into same conclusions. Changes in nutrition outcomes including weight, body mass index (BMI), fat mass (FM) and muscle mass (MM); side-effects outcome (nutrition impact symptoms (NIS) and HGS were observed and analysed. Overall median weight was 70.6±16.8kg with 52.8% overweight. Most subjects were well-nourished, yet the NIS score was 21+5 before treatment started. Significant weight loss ($p<0.001$), reduction in BMI ($p<0.001$), lower FM ($p<0.001$), reduction in MM ($p<0.001$), and higher NIS score ($p<0.001$) within subjects in both groups were observed. The provision of INI produced positive changes in handgrip strength (HGS). Improvements in HGS were reported in INI subjects. Inadequate overall intake in energy (< 25kcal/kg body weight) and protein in both groups (< 0.8gram protein/ kg body weight) compared to the recommended requirement of 30kcal/kg body weight and 1.2-gram protein/kg body weight were observed. FM reduction was significantly different ($p=0.013$) between groups. The INI group had a lower percentage of weight loss, FM loss, BMI loss and MM loss compared to the RC group. Combination of ONS prescription and provision, dietary consultation and frequent follow-up could prevent further deterioration in nutritional, side effects and functional outcomes among HNC outpatients and can be adapted in outpatient setting as standard procedures in HNC dietary care against malnutrition.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Master Sains

**KEBERKESANAN INTERVENSI PEMAKANAN INTENSIF PADA HASIL PEMAKANAN, KESAN SAMPINGAN DAN FUNGSI DI KALANGAN PESAKIT LUAR KANSER KEPALA DAN LEHER DENGAN RADIOTERAPI**

Oleh

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Malpemakanan kerap berlaku di kalangan pesakit kanser kepala dan leher (HNC) walaupun sebelum rawatan dimulakan. Intervensi pemakanan secara intensif (INI) mampu menambahbaik status pemakanan mereka. Namun begitu, risiko malpemakanan adalah lebih tinggi di kalangan pesakit luar HNC disebabkan oleh masa hubungan dengan Pegawai Dietetik yang terhad, ketiadaan pemantauan yang kerap dan pembekalan suplemen makanan tambahan (ONS) jika dibandingkan dengan pesakit dalam HNC dan terhadnya kajian tentang keberkesanan INI di kalangan pesakit luar HNC. Jadi, wujudnya satu jurang yang ketara dalam penyampaian perkhidmatan Pegawai Dietetik secara optima bagi perkhidmatan pesakit luar. Satu kajian 'open labelled' pragmatik yang terkawal secara rawak dijalankan untuk memastikan keberkesanan INI (kombinasi preskripsi dan pemberian ONS, runding cara diet (RCD) dan pemantauan yang kerap) dibandingkan dengan intervensi diet rutin (RC) termasuk RCD, pemantauan yang kerap dan preskripsi ONS sahaja di kalangan pesakit luar HNC terhadap hasil pemakanan, kesan sampingan dan fungsi. Sejumlah 36 orang subjek dipilih dari senarai pesakit luar HNC dari klinik radioterapi, Institut Kanser Negara, Putrajaya, yang diperolehi dari sistem atas talian dan dimasukkan secara rawak ke kumpulan INI dan RC menggunakan perisian dalam talian. Pesakit yang telah mengambil ONS, menggunakan tiub pemakanan dan menerima rawatan kanser sebelum tempoh kajian adalah dikecualikan. *Patient Generated Subjective Global Assessment* (PG-SGA) dan *Head and Neck Symptoms Checklist* (HSNC) digunakan untuk menilai status pemakanan dan kesan sampingan manakala kekuatan genggaman tangan (HGS) digunakan untuk menilai status fungsi subjek kajian. Ujian parametrik dan bukan parametrik digunakan untuk menganalisis data yang berkaitan dan analisis univariat digunakan untuk pengukuran berulang. Prinsip analisis intention to treat (ITT) dan per protokol (PP) digunakan untuk menyediakan perbandingan yang adil di antara

kumpulan kajian yang mencerminkan keberkesanan klinikal di dalam amalan sebenar serta membina keyakinan terhadap hasil kajian sekiranya kedua-dua prinsip analisis menunjukkan keputusan yang sama. Perubahan dalam status nutrisi termasuk berat, indeks jisim tubuh (IJT), jisim lemak (JL) dan jisim otot (JO); status kesan sampingan (simptom kesan pemakanan (NIS) dan status fungsi diperhatikan dan dianalisa. Secara keseluruhan, median berat badan adalah 70.6±16.8kg dan 52.8% pesakit luar HNC mempunyai berat badan berlebihan. Kebanyakan pesakit mempunyai status nutrisi yang baik, namun, skor NIS adalah 21+5 walaupun rawatan belum dimulakan. Kehilangan berat badan ($p<0.001$) yang signifikan, penurunan dalam IJT ($p<0.001$), JL yang lebih rendah ($p<0.001$), penurunan dalam JO ($p<0.001$) dan skor NIS yang lebih tinggi dalam kalangan subjek kajian dapat diperhatikan. Pemberian ONS menunjukkan peningkatan kekuatan HGS dalam kumpulan INI. Melalui pemerhatian, didapati pengambilan tenaga (<25 kilokalori per kg berat badan) dan protein (< 0.8gram per kg berat badan) adalah tidak mencukupi oleh subjek kajian jika dibandingkan dengan saranan keperluan sebanyak 30kkal per kg berat badan dan 1.2 gram per kg berat badan. Kehilangan JL ($p=0.013$) sahaja yang menunjukkan perubahan yang signifikan di antara kumpulan. Kumpulan INI mempunyai peratusan kehilangan berat badan, IJT, JL, dan JO yang lebih rendah berbanding dengan kumpulan RC. Gabungan preskripsi dan pemberian ONS, RCD dan susulan RCD yang lebih kerap boleh menghalang kemerosotan lebih lanjut dalam tahap pemakanan, kesan sampingan dan fungsi di kalangan pesakit luar HNC dan boleh diadaptasi dalam prosedur penjagaan pesakit luar sebagai prosedur piawai dalam penjagaan diet pesakit kanser HNC dalam menangani masalah malpemakanan.

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| ACS | American Cancer Society |
| AND | Academy of Nutrition and Dietetics |
| ASPEN | American society of Parenteral and Enteral Nutrition |
| BAPEN | British Association for Parenteral and Enteral Nutrition |
| BFM | Body Fat Mass |
| BIA | Bioelectrical Impendence Analysis |
| BMI | Body Mass Index |
| CCRT | Concurrent Chemoradiotherapy Treatment |
| CONSORT | Consolidated Standards of Reporting Trial |
| DCF | Data Collection Form |
| DV | Dependent Variables |
| ECOG | Eastern Cooperative Oncology Group |
| EMR | Electronic Medical Report |
| FM | Fat Mass |
| GBD | Global Burden of Disease |
| GLIM | Global Leadership Initiative on Malnutrition |
| Hb | Haemoglobin |
| HGS | Handgrip Strength |
| HNC | Head and Neck Cancer |
| HNSC | Head and Neck Patient Symptoms Checklist |
| HPV | Human Papillomavirus |
| ICT | Information and Communication Technology |
| IDV | Independent Variables |
| IGBT | Image Guided Brachytherapy |
| IMRT | Intensity Modulated Radiotherapy |
| INI | Intensive Nutrition Intervention |
| ITT | Intention to treat |
| LOA | Loss of Appetite |
| LOCF | Last Observation Carried Forward |
| LOS | Length of Stay |
| M | Metastasis |
| MCAR | Missing Completely at Random |
| MM | Muscle Mass |
| MNA | Mini Nutritional Assessment |
| MNCRR | Malaysian National Cancer Registry Report |
| MNT | Medical Nutrition Therapy |
| MOH | Ministry of Health |
| MST | Malnutrition Screening Tools |

| | |
|---|---|
| MUST | Malnutrition Universal Screening Tools |
| N | Nodes |
| NCCN | National Comprehensive Cancer Network |
| NCI | National Cancer Institute |
| NCP | Nutrition Care Process |
| NHMS | National Health and Morbidity Survey |
| NI | Nutrition Intervention |
| NIS | Nutrition Impact Symptoms |
| NMAR | Not Missing at Random |
| NPC | Nasopharynx Cancer |
| NRS | Nutritional Risk Screening |
| OIS | Oncology Information System |
| ONS | Oral Nutrition Supplement/Supplementation |
| OS | Overall Survival |
| PG-SGA | Patient-Generated Subjective Global Assessment |
| PIS | Patient Information Sheet |
| RC | Routine Care |
| REE | Resting Energy Expenditure |
| SCC | Squamous Cell Carcinoma |
| SCCHN | Squamous Cell Carcinoma Head and Neck Cancer |
| SD | Standard Deviation |
| SGA | Subjective global Assessment |
| SRS | Stereotactic Radiosurgery |
| T | Tumor |
| TBW | Total Body Water |
| TEE | Total Energy Expenditure |
| THIS | Total Hospital Information System |
| TMCE | Tools and Method of Competitive Engineering |
| TNM | Tumor, nodes and metastasis |
| UK | United Kingdom |
| US | United States |
| USA | United States of America |
| QoL | Quality of Life |
| WBC | White Blood Cell |
| WHO | World Health Organisation |

# CHAPTER 1

# INTRODUCTION

## 1.1 Background

In recent years, the alarming number of cancer incidences worldwide has caused a global health concern. According to the National Centre for Health Statistics, Centres for Disease Control and Prevention, United States of America, cancer has become the second leading cause of death among Americans (Siegel et al., 2019) and a leading cause of death in Malaysia (Azizah et al., 2016). Cause of death in as many as 20% of patients with cancer is associated with tumour-induced and treatment-related malnutrition and inanition (WHO, 2014). Malnutrition is common in patients with cancer and depicted with a loss of weight and muscle (Von Haehling & Anker, 2012). Alvaro Sanz et. al. (2019), reported that 76% of cancer outpatients in Spain were considered at moderate degree of malnutrition and 12% of them were severely malnourished. In a study by Gyan et al. (2017) in France among cancer patients, the prevalence of malnutrition was 39% (n=826 patients) from 2197 patients. Another study reported that 67% of subjects were malnourished before treatment, and 94% was after treatment (Mulasi et al., 2016). It was reported that 15% to 80% of cancer patients in the National Cancer Institute Malaysia were malnourished during hospital admission (Norshariza et al., 2017). A total of 58.3% of cancer outpatients suffers weight loss within three (3) months of treatment period where 36.8% had suffers weight lost >10% (Álvaro Sanz et al., 2019).

### 1.1.1 Head and neck cancer and malnutrition

Head and neck cancer (HNC) are cancer that arises in the head and neck region consist of the nasal cavity, sinuses, lips, mouth, salivary glands, throats and larynx (Figure 1). The types of cancer included in HNC categories are oral cancer (oral cavity, inner lip, tongue, the floor of mouth, gingivae and hard palate), nasopharynx cancer (NPC), oropharyngeal cancer, hypopharynx cancer, laryngeal cancer, and cancer of trachea.

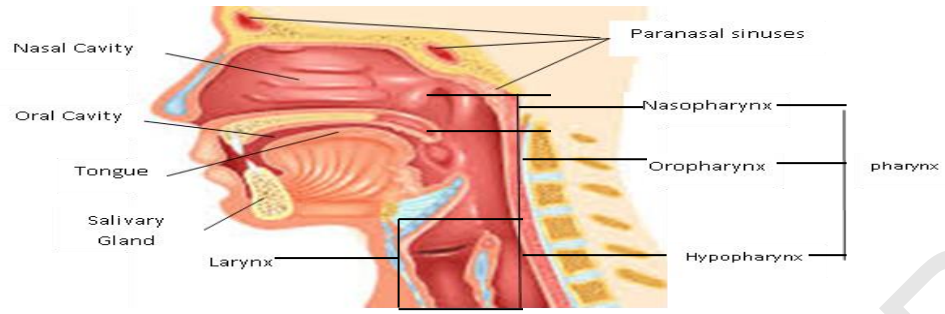


**Figure 1.1: Head and neck cancer region (image adapted from medgadget.com)**

HNC is the sixth most common malignancy in the world, accounting for around 6% of cancer cases and 1-2% of cancer deaths (ESMO, 2017). HNC is predicted for 742 270 new cases and 407 037 deaths worldwide in 2015, and it is the most common cancer in Central Asia (ESMO, 2017). NPC accounted for 4.9% of the ten most common cancer diagnosed among Malaysian population by the Malaysian National Cancer Registry Report, 2007-2011 (Azizah et al., 2016) and 4.0% of cancer cases for the period of 2012 to 2016 (Azizah et al., 2019).

HNC patients have a higher risk of malnutrition when compared to other types of cancer due to the physiological nature of the disease itself. The cancer site contributes towards difficulties in swallowing or chewing, loss of appetite, mucositis, fatigue and pain, leading to reduce oral intake. These nutrition impact symptoms (NIS) occur as a result of cancer itself and may worsen during treatment causing a further disturbance in nutrient balance, negatively influence the HNC patients beyond the acute phase of treatment (Crowder et al., 2018). NIS leads to insufficient nutrient intake thus further decreased nutrition and quality of life of HNC outpatients such as malnutrition risk, weight loss and reduced food intake (Crowder et al., 2018). Hébuterne et al. (2014) reported that malnutrition is a frequent comorbidity in HNC patients who were frequently malnourished at the time of diagnosis and prior to treatment initiation (Denaro et al., 2014). A total of 41.7% of HNC outpatients in Spain had been cachexic during treatment period and 33.3% of patients were at risk of malnutrition prior to treatment initiation (Álvaro Sanz et al., 2019). Based on Patient Generated Subjective Global Assessment (PG-SGA), 70% of HNC outpatients were identified as moderately or severely malnourished prior to treatment initiation (Mulasi et al., 2020). In HNC cases, involuntary weight loss of > 5% in 1 month; or > 1-2% per week is also considered as an indicator of malnourishment (Langius et al., 2016). From a review of more recent studies, which used a critical weight loss as parameter, estimation of the prevalence of malnutrition in specific groups of cancer patients was up to 50% in HNC patients (Langius et al., 2016). The same study also reported that significant weight loss (≥5%) was observed in 16% of HNC patient pre-treatment. In addition, HNC patients also had an increased risk of involuntary weight loss, and cumulative weight losses in these patients usually exceed 20% of pre-treatment body weight (Kubrak et al., 2013). The identification of malnutrition in routine clinical practice is based on the consensus of the Academy of Nutrition

and Dietetics (AND) or American Society of Parenteral and Enteral Nutrition (ASPEN) and includes insufficient energy intake, weight loss, loss of muscle mass, loss of subcutaneous fat, a localised or generalised fluid accumulation that may sometimes mask weight loss and diminished functional status as measured by handgrip strength (White et al., 2012). A cancer patient who has two (2) or more of the above said characteristics are considered malnourished.

Weight loss indicates inadequate dietary intake and is consistently related to nutrition impact symptoms (NIS) (de Pinho et al., 2019; Kubrak et al., 2013). Evidences suggested that almost 90% of HNC patients will eventually developed acute NIS (side effects outcomes) as a result from the cancer treatment and location (Gellrich et al., 2015). Any symptoms like dysphagia, mucositis, pain, sensory and taste alteration could compromise oral intake that may fail to resolve in the following therapy. Acute NIS refers to any symptoms happen before, during and immediately after treatment, while chronic NIS refer to any symptoms that exist beyond the completion of treatment (Crowder et al., 2018). Either way, NIS could cause deterioration of swallowing functions, thus decreased overall energy and protein intake (Ganzer et al., 2013) causing further weight loss leads to malnutrition (Leoncini et al., 2014). In addition, swallowing and chewing difficulties promotes reduction in patients' quality of life (QoL) (Gellrich et al., 2015). Therefore, acknowledging the patients' eating difficulties and challenges is crucial for maintaining optimal nutritional status preventing HNC patients from incidence of malnutrition (Bressan et al., 2017).

Recently, handgrip strength (HGS) has been used as a marker of nutritional status as muscle function reacts early towards nutritional deprivation (Norman et al., 2011) or as prognostic criteria as it was independently associated with survival, functional and quality of life in advanced cancer patients (Kilgour et al., 2013). Mendes et al., (2014), reported that a lower HGS value prior to ward admission was associated with increased risk of longer hospital stay and severe dependence. A lower HGS also had significantly lower body mass index (BMI), lower Eastern Cooperative Oncology Group (ECOG) performance scale, lower albumin and haemoglobin level, poorer functional performance, greater weakness, lower lean and fat mass, reduced appetite greater fatigue and poor QoL (Kilgour et al., 2013). In disease related malnutrition such as cancer cases, malnutrition results in decrease muscle functions where a study reported that 25.8% patients with lower HGS were malnourished (Norman et al., 2011).

Malnutrition leads to numerous adverse outcomes, including decreased quality of life, psychological stress, and decreased treatment tolerance (Hunter et al., 2020). In some patients, malnutrition can progress to cancer cachexia which is 'a multifactorial syndrome defined by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment' (Fearon et al., 2011). Its pathophysiology is characterised by a negative protein and energy balance driven by a variable combination of reduced food intake and abnormal metabolism (Fearon et al., 2011). HNC patients had a higher risk of

malnutrition prior, during and post-treatment (Gorenc et al., 2015). It is vital to identify malnutrition early and provide early nutrition intervention for patients that can improve patients' nutritional status and help them maintain body weight, lean body mass, better treatment toleration, and improve their QoL.

### 1.1.2 Role of nutrition in head and neck cancer and oncology treatment

Oncology nutrition focuses on personalised nutrition plans to help patients deal with the unique challenges of their illness and treatment plan. A patient's nutrition can be optimised to support treatment and combat symptoms and side-effects with the right dietary advice and guidance. In the United States of America (U.S), several agencies recognised the role of nutrition in oncology treatment or oncology nutrition, including the American Cancer Society (ACS), American College of Surgeons' Commission on Cancer, American Society of Clinical Oncology (limited to certain diagnoses and survivorship), ASPEN, AND, Association of Community of Cancer Centres, National Cancer Institute (NCI), National Comprehensive Cancer Network, National Institute for Health and Care Excellence, and Oncology Nursing Society (Pray, & Yaktine, 2016). Nutrition therapy is used to help cancer patients maintain healthy body weight, strength, keep body tissue healthy, and decrease side-effects during and after treatment. Oncology nutrition helps form individualised plans for patients to ensure they receive appropriate nutrition and helps them through complex dietary needs. The right foods can promote strength and overall wellness in patients. Adopting certain eating habits can also help combat common side-effects that may arise from treatments such as decreased appetite, constipation, diarrhoea, altered taste and weight loss. The overall goal of nutrition in oncology treatment is to maintain or improve the nutritional status of cancer patients. It helps tolerate the prescribed treatment as malnourished patients may not be able to tolerate and receive the cancer treatments planned for them. As HNC patients are more likely to be malnourished, they are more likely to have intolerance towards treatments and higher possibility of treatment interruptions.

#### 1.1.2.1 Role of the dietitian in nutrition oncology

Dietitians play an important role in oncology nutrition in cancer care. Oncology dietitians help cancer patients in dietary modification to optimise their health and minimise side-effect caused by cancer and its treatments while promoting good nutrition. Dietitians work individually with patients, their families and caregivers to identify which foods the patient can eat, how to develop good habits, and how making good nutritional choices enable a patient to engage in controlling their care and health actively. Oncology dietitians are qualified and capable of prescribing nutrition interventions (NI) including the evaluation of nutritional shortcomings or areas of risk, discuss planning and the setting of nutritional goals. They also give simple, practical tips and advice to help patients achieve their nutritional needs daily, and advice on ways to deal with weight loss, fatigue, and nausea brought on by illness or treatment side-effects. Dietitians also provide personalised guidelines based on the patients' biological needs and unique circumstances, plans for families or caregivers in support of

the patient's nutritional needs and prescription of recipes, lists of foods, dietary supplements, and vitamins beneficial for cancer patients (National Cancer Institute, 2019).

#### 1.1.2.2 Nutrition intervention

NI is an important step in managing cancer patients to decrease the side-effects of treatment on the patient's nutritional status, causing treatment interruption. Adequate NI or nutrition support during radiotherapy can decrease the impact of side-effects, minimise weight loss, improve the QoL and help patients in swift recovery from radiotherapy (Bossola, 2015). Kang et al. (2016) reported that early and intensive nutrition intervention (INI) appears to be beneficial in terms of minimising weight loss and further deterioration in nutritional status among 40 HNC patients receiving radiotherapy treatment. Various strategies in cancer patients, including individual dietary consultation or oral nutrition supplementation (ONS) alone or a combination of both dietary consultation and ONS. The aims of NI in patients with cancer are numerous including maintaining an acceptable weight and preventing or treating malnutrition, leading to better tolerance of treatment and its side-effects, rapid healing and recovery, reducing the risk of infection during treatment, reduced hospital readmission, in-hospital mortality and enhanced overall survival (Bossola, 2015; Hopanci Bicakli et al., 2017; Isenring, 2013; Kang et al., 2016). A systematic review and meta-analysis of oral NI in malnourished cancer patients reported that NI was associated with statistically significant improvements in weight and energy intake and better QoL compared with routine care (RC) (Baldwin et al., 2012). In the systematic review by Baldwin et al. (2012), RC is defined as no additional NI, nutrition advice and ONS, ad libitum food intake or usual care including standard booklet or standard information sheet (providing information on all aspects of treatment includes advice to eat nutritious diet plus a request to a referral to see a dietitian. A narrative review of NI among HNC patients concluded that NI should be used to improved overall intake and prevent negative outcomes (Bossola, 2015). The patients receiving NI had greater treatment completion rates and fewer unplanned hospital admissions. Those who were received NI and admitted to hospital had shorter lengths of stay (LOS) compared to the patients receiving routine care (Odelli et al., 2005).

### 1.2 Nutrition oncology in Malaysia

In Malaysia, the oncology nutrition provided for cancer inpatients in public hospitals by the Ministry of Health (MOH) includes nutrition counselling, nutrition monitoring, prescription and provision of ONS. However, due to the limited numbers of dietitians in Malaysia (with a ratio of 2 dietitians for 100,000 patients) (Kevin Davasagayam, 2019), these dietitians are often assigned to multiple wards including dedicated cancer wards and other disciplines. Higher workload, schedules and limited encounters with patients have led to less frequent monitoring sessions for NI compliance.

Another access to oncology nutrition is via outpatients' settings. In outpatients' settings, oncology nutrition services include nutrition counselling and prescription of ONS but no provision of ONS. This service is given via several methods such as by dietitian's referral to dedicated outpatient dietitians in MOH hospitals or by assigning dietitians who provide services in the scheduled oncology clinic. Yet, in most MOH hospital settings, the same inpatient dietitians are often being "pulled" to cover the outpatient's oncology clinic. Challenges in providing oncology nutrition in outpatients services are patients often see the outpatient dietitian only once and the scheduled oncology clinic often limited to a specific day of the week, which means dietitians see only those patients who come in and are referred by the dietitian on that day. Dietitians are unable to see all patients who need to be seen, which increases the risk of malnutrition among outpatients with cancer due to limited access to oncology nutrition. In addition, either in inpatients or outpatients' settings, the decision to refer a cancer patient for oncology nutrition is made by the oncologist or physicians who alone refer patients to dietitians, until they are certain that patients are in need of NI or notice signs of undernourishment are present. By this point, patients are often severely malnourished and in acute or crisis situations that are often irreversible.

The same model of good care in oncology nutrition for cancer patients was also applied in the United States (US) (Pray & Yaktine, 2016). However, chances of cancer patients to get access to oncology nutrition in inpatients settings is higher than outpatients cancer, since inpatients are always treated as urgent cases when compared to outpatients. It is more convenient for dietitians to easily implement NI for inpatients once referred since dietitians are able to monitor closely the provision of diets given to the patient, their daily food intake and compliance with ONS prescription while ensuring enough provision of ONS to boost up patients' oral intake. None of these can be done in outpatient settings due to the lack of referral, late referral to the dietitian for early NI, difficulties in monitoring patients' compliance and defaulters. Given the above, the risk of HNC outpatients developing undernutrition is higher, and there was no NI implemented until later stages when HNC patients are already malnourished.

### 1.3 Problem Statement

HNC patients undergoing radiotherapy, chemotherapy, or concurrent chemo and radiotherapy treatment (CCRT) were at risk of malnutrition due to the side-effects of the treatment (Bossola, 2015). Cancer treatment will induce the presence of NIS, such as difficulties in swallowing and chewing, which further impacts patients' oral intake (Bossola, 2015). Thus, HNC patients can show significant involuntary weight loss within a shorter period. Significant weight loss among HNC patients could cause treatment interruption, reduced treatment efficacies and reduced patient's QoL (Langius et al., 2016; Trujillo et al., 2019). Therefore, an early NI would be beneficial in helping HNC patients maintaining good health for them to cope with treatments, its side-effects, and reduced treatment interruption for better healing (Isenring, 2013). NI in

oncology nutrition involves the implementation of medical nutrition therapy (MNT) by dietitians, prescription of suitable diet according to the patient's condition and prescription of ONS in addition to the patient's oral intake when needed. Several studies demonstrated that consumption of ONS and regular diet consultation had improved outcomes of treatment, patient's QOL and increased energy and protein intake in cancer patients (Cereda et al., 2018; Isenring, 2013). However, only a few involved HNC patients in an outpatient setting.

During the treatment period, HNC patients are given options to receive treatment as inpatients or outpatients according to their preference. However, when the condition deteriorates, or the NIS worsens, they would be admitted as inpatients for close treatment. When HNC patients are treated as inpatients, NI can be administered easily. In most MOH hospitals, HNC patients were referred to dietitians for NI due to impaired oral intake related to NIS as observed by the oncologist or physician during their admission, or in a few hospitals that have implemented the 'auto-referral' policy for cancer inpatients. This policy enables dietitians to automatically see all cancer patients admitted to the ward for necessary NI implementation, especially for HNC patients. Via NI, dietitians are able to prescribe appropriate diets, closely monitor a patient's daily food intake and implement rectification of NI spontaneously if needed. Dietitians are also able to prescribed suitable ONS accordingly to patients' requirements and preferences to ensure adequate intake to improve the patient's condition and prevent further involuntary weight loss. Any adjustment needed to the ONS prescription can be made promptly with the supervision of dietitian and compliance towards ONS prescription can be closely monitored based on the provision of ONS prescribed in the ward. When the prescribed ONS finished within the estimated duration, it can be concluded that patients are following the advice given by dietitians. The patient's compliance can be counter checked during diet recall to ascertain whether the patient is aware and abides with the recommended ONS dilution prescribed by the dietitian.

Different from inpatients' setting, HNC patients who chose to be treated as outpatient usually look healthier from HNC inpatients. However, without proper nutrition screening, HNC patients are often not identified as being at risk of malnutrition, especially prior to treatment commencement. A study by Platek et al., (2015) had mentioned that an experienced oncology physician had failed to identify cancer outpatients in need of clinical nutritional care. In addition, due to the absence of nutritional screening process, only one third of gastrointestinal cancer outpatients who lost >10% of weight was referred to dietitians (Baldwin et al., 2006) and even HNC outpatients who were at higher risk to be malnourished and had been given different care from other cancer cases, thus, the need for nutritional care were still based on the referral basis (Platek et al., 2015). In summary, the lack of nutrition screening in outpatients' clinics leads to late identification of malnutrition among HNC cases. Late identification leads to late referral to the dietitian and then late NI.

Trujillo et al., (2019), concluded that there was inadequate nutrition coverage in Outpatients Cancer Care in United States of America (USA). In this national survey done in 215 cancer care centers, they found out that the ratio of registered dietitian to patients was 1:2308, where dietitians were capable to counselled and evaluate an average of 7.4±4.3 oncology patients only. A total of 53.1% of the centers do the malnutrition screening, and majority (76.8%) of centers do not bill for nutrition services which indicates significant gap in nutrition coverage or access to dietitians for oncology patients in needs of nutritional care (Trujillo et al., 2019). In another study done by Platek et al., (2015), a total of 93.8% from 32 cancer care centre rely on referral based clinical nutrition services to the cancer outpatients, which are not consistently a part of multidisciplinary care that can cause limited access to the nutritional care services if an outpatient was failed to be identified as persons who need nutritional interventions. Same situation has been observed in most of MOH hospitals. As nutrition oncology services in outpatients' settings is limited due to time constraints, current practices and limited workforce, HNC outpatients often have limited time with dietitians (sometimes only once), their daily food intake is not monitored closely, and whenever follow-up session is given to patients, they become defaulters until they are referred to dietitians when their conditions worsen.

Another barrier identified for optimal nutritional care services among outpatient was the ONS provision. Prescriptions of ONS were also given to HNC outpatients, but patients need to buy the prescribed ONS themselves or get aid from relevant authorities since the provision of ONS is not part of the standard operating procedure in outpatient dietetics practice. However, based on the MOH dietitians' experiences, it was time-consuming for HNC outpatients to receive aid for the ONS prescribed, leaving them with the only option to buy it on their own temporarily. This causes dietitians to doubt whether patients are actually buying those ONS and following the prescription precisely.

Non-compliance towards ONS intake is related to the socioeconomic status where purchasing ONS as it is expensive and could be beyond the reach of many patients. Even though dietitians gave the standard dietary advice based on the dietary guidelines to HNC outpatients together with the prescription of ONS, the certainty of patients' oral intake on ONS consumption was absent since dietitians were unable to observe ONS intake at home closely. Over-claiming or under-reporting of dietary intake is common and can sometimes be detected easily as the results show different outcomes from expectations. In addition, in many outpatient settings, sometimes these incidences cannot be detected or identified since there were no regular follow-up sessions due to the patient's limited conditions (lethargy or treatment defaulter) and medical nutrition therapy services (limited workforce). Hence, regular dietary consultation and prescription of ONS in HNC outpatients were difficult to commence due to late or no referral. Late or no NI will cause a further nutritional decline in HNC patients and promotes poor tolerance to their treatment regime. To the best of our knowledge, no published data are available on the impact of ONS with regular dietary consultation in HNC outpatients undergoing treatments.

## 1.4 Research questions

a. What is the nutritional outcome (weight, BMI, dietary intake, muscle mass (MM), fat mass (FM), and biochemical data such as albumin, haemoglobin (Hb) and white blood cell (WBC), energy and protein intake and PG-SGA score), side-effect (NIS) and functional outcome (handgrip strength) in HNC outpatients undergoing radiotherapy treatment?

b. Is there any change between INI and RC in the nutritional outcome, side-effects and functional outcomes in HNC outpatients undergoing radiotherapy treatment?

c. Is there any change of nutritional, side-effect and functional outcome within INI and RC in HNC outpatients undergoing radiotherapy treatment?

## 1.5 Significance of the study

In RC for outpatient settings, dietary consultation took place among HNC patients after the condition already worsen. Patients had already lost lots of weight, with multiple NIS and nutritional status already declined. Thus, patients became too weak resulting in treatment interruption and compromised the effectiveness of the anti-cancer treatment received by patients. The absence of a proper nutrition screening process to identify HNC patients at risk of malnutrition, despite proven evidence highlighting the importance of nutrition screening implementation for early NI in outpatients' settings, will increase the risk of malnutrition among HNC outpatients and result in a poor survival rate (Isenring et al., 2013). Automatically self-referring HNC outpatients for NI and bypassing the nutritional screening process might help HNC outpatients receive the NI necessary to achieve optimal nutritional status for better treatment tolerance. In view of the complexity of HNC cases which will impact patients' oral intake at any time of disease progression, ONS prescription is essential aid helping patients to increase their oral intake. However, the absence of ONS provision as given in inpatient settings causes difficulties in ensuring a patient's compliance due to their deteriorated condition and limited financial ability. Patients tend to modify ONS intake as they were unable to tolerate or accept the ONS consistency, taste or smell due to the disease progression. In addition, they might not consume the ONS prescribed as they could not get the ONS supply, especially for those with financial constraints. This will cause further nutrition deterioration as patients are unable to comply with NI given while waiting for aid for that purpose. Therefore, consideration of ONS provision in outpatient settings could give positive outcomes towards HNC patients' overall nutritional status. A good overall nutritional status could prevent further expected treatment side-effects. This study could be used as a baseline or aid for researchers in future intervention or policy-making for improved patient care.

### 1.5.1 General objective

To investigate the effectiveness of INI which includes regular dietary consultation with the prescription, provision and monitoring of ONS intake when compared to RC (regular dietary consultation and ONS prescription only) on nutritional, side-effects and functional outcomes in HNC outpatients.

### 1.5.2 Specific objectives

a) To determine and compare the sociodemographic, medical backgrounds, nutritional outcomes (weight, BMI, MM, FM, energy and protein intakes, biochemical data such as albumin, Hb and WBC and PG-SGA score), side effects and functional outcomes of INI and RC groups at baseline.

b) To determine and compare the nutritional outcomes (weight, BMI, MM, FM, energy and protein intakes, biochemical data such as albumin, Hb and WBC and PG-SGA score), side-effect outcomes (NIS score) and functional outcomes (in general and among gender) of INI and RC groups at the end of treatment.

c) To determine the effectiveness of INI on nutritional outcomes (weight, BMI, MM, FM, energy and protein intakes, biochemical data such as albumin, Hb and WBC and PG-SGA score), side-effect outcomes (NIS score) and functional outcome (in general and among gender) between and within INI and RC groups of HNC outpatients at the end of treatment.

## 1.6 Conceptual framework

Figure 1.2 shows the dependent (DV) and independent variables (IDV) in the current study. The DV include the sociodemographic data such as age, gender, ethnic, education level and occupation. The IDV include the nutritional outcome such as weight, BMI, muscle mass, fat mass, biochemical data such as albumin, hemoglobin and white blood cell, PG-SGA score, energy and protein intakes, the side effects outcomes represented by NIS prevalence and its severity and the functional outcome measured by handgrip strength. The difference in DV and IDV within and between each group was assessed. The difference between INI group and RC group before and after intervention approach was also evaluated.

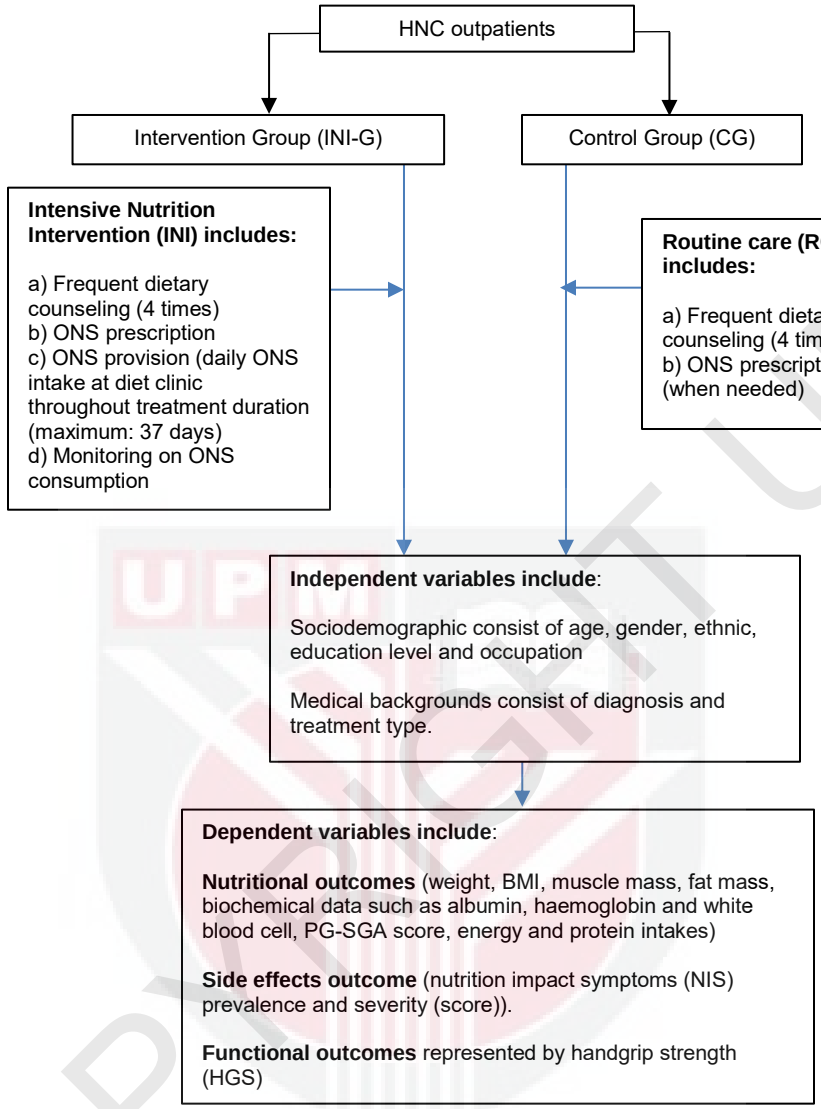


**Figure 1.2: Conceptual framework**

## 1.7 Research hypothesis

a) There is no significant difference in sociodemographic, medical background, nutritional outcome (weight, BMI, MM, FM, biochemical data such as albumin, Hb and WBC, PG-SGA score, energy and protein intakes), side effect outcomes and functional outcomes at baseline between INI vs RC group.

b) There is no significant difference in nutritional outcome (weight, BMI, MM, FM, biochemical data such as albumin, Hb and WBC, PG-SGA score,

energy and protein intakes), side effect outcomes and functional outcomes at the end of treatment in INI vs RC group.

c) There is no significant difference in functional outcome between gender in INI and RC groups at the end of treatment.

d) The INI group had significantly better nutritional outcomes (weight, BMI, MM, FM, biochemical data such as albumin, Hb and WBC, PG-SGA score, energy and protein intakes), fewer side effect and better functional outcome compared to the RC group at the end of treatment.

e) The male and female subjects in INI group had significantly better handgrip strength compared to the male and female subjects in RC groups.

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