UNIVERSITI PUTRA MALAYSIA

EFFECT OF INTENSIVE NUTRITION INTERVENTION ON NUTRITIONAL STATUS, HAND GRIP STRENGTH, AND QUALITY OF LIFE ON MALNOURISHED PRE-OPERATIVE GYNECOLOGICAL CANCER PATIENTS AT A CANCER INSTITUTE

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FPSK(m) 2021 18

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By

AINI MASITAH BINTI MOHAMMAD

Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfilment of the Requirements for the Degree of Master of Science

January 2021

Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Master of Science

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January 2021

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Recently, emerging studies conducted to explore the effect of nutrition intervention (NI) pre-operatively, however, none sample GC patients. Those studies also unable to demonstrate benefit of NI to malnourished patient and finding in those studies were not comprehensive. Adopting an open label randomised control trial, this study aimed to identify intensive nutrition intervention (INI) (individualized dietary counselling, oral nutrition supplements [ONS], telephone counselling and home visit follow-up) can improve outcomes among patients with gynecological cancer (GC) during pre-operative period. Results of this study also could help documented the urgent need of screening for risk of malnutrition during 1st visit at clinic and the need to provide continuous professional support to malnourished cancer.

Selected GC patients stage 1 to 4, planned for surgery, age >18 years old, were randomly grouped into control group (CG) (n= 35) and intervention group (IG) (n=34). Malnutrition screening tool (MST) was used as a screening tool, while the Patient-Generated Subjective Global Assessment (PG-SGA) was used as a nutrition assessment tool. IG patients received an intensive individualized dietary counselling with the supply of ONS at baseline (Day 1). This continued with telephone counselling and home visit follow-up by research dietitian (Day 3 and Day 6). Meanwhile, CG patients only received general nutritional counselling without supply of ONS. Final assessment was conducted on Day 14. The primary outcomes were weight changes measured using TANITA and dietary intake assessment using 24-hour diet recall. Secondary outcome was Quality of Life assessed using European Organization for Research and Treatment

of Cancer Quality of Life Questionnaire version 3.0 (EORTC QLQ-C30) and functional status assessed using Handgrip strength (HGS).

The mean duration of INI was 14 days. About 84% of GC patients were categorized as PG-SGA B and 16% were categorized as PG-SGA C, at baseline. At the end of treatment period, there was a significant weight changes between groups ($p<0.001$) with 0.14% weight gain in IG and 1.3% weight reduction in CG. The mean energy and protein intake of IG patients were higher compared to CG patients by 329 kcal/day and 12.2 g/day, respectively ($p<0.001$). Appetite and emotional scale (EORTC QLQ-C30 scale) significantly improve after the intervention ($p=0.001$ and $p=0.003$, respectively). Meanwhile, no significant changes observed in HGS ($p= 0.69$).

This study shows that INI that incorporated individualized dietary counselling, ONS, telephone counselling and home visit follow-up able to increase energy and protein intake of GC patients, resulting in weight gain. Thus, all GC cancer patients should be screen for risk of malnutrition upon presented to clinic and those found malnourished should be intervene by dietitian earlier by incorporating INI.

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

KESAN INTENSIF INTERVENSI PEMAKANAN TERHADAP STATUS PEMAKANAN, KEKUATAN TANGAN DAN KUALITI HIDUP KEPADA PESAKIT MALPEMAKANAN KANSER GINEKOLOGI PRA-PEMBEDAHAN DI INSTITUT KANSER

Oleh

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Kini, banyak kajian-kajian dijalankan untuk meneroka kesan intervensi pemakanan semasa pra-pembedahan, walaubagaimanapun, tiada kajian tersebut yang dijalankan terhadap pesakit kanser Ginekologi. Kajian tersebut juga, tidak menunjukkan manfaat intervensi pemakanan ke atas pesakit malpemakanan dan hasil dapatan kajian tersebut juga tidak komprehensif. Menggunakan jenis kajian kawalan rawak label terbuka, kajian ini bertujuan untuk mengenalpasti intensif intervensi pemakanan (kaunseling pemakanan individu, minuman tinggi kalori dan protein, kaunseling melalui telefon dan lawatan susulan di rumah) boleh meningkatkan hasil kajian di kalangan pesakit malpemakanan kanser Ginekologi semasa pra-pembedahan. Hasil dapatan kajian ini juga dapat mendokumentasi keperluan untuk menjalankan pemeriksaan risiko kekurangan pemakanan semasa lawatan pertama pesakit ke klinik dan keperluan untuk memberi sokongan profesional berterusan kepada pesakit malpemakanan kanser.

Pesakit kanser Ginekologi peringkat 1 hingga 4, yang akan menjalani pembedahan dan berumur > 18 tahun, dimasukkan secara rawak ke dalam kumpulan intervensi (n=34) atau kumpulan kawalan (n=35). *Malnutrition screening tool (MST)* digunakan sebagai alat saringan nutrisi, manakala *Patient-Generated Subjective Global Assessment (PG-SGA)* digunalan sebagai alat penilaian pemakanan. Pesakit dalam kumpulan intervensi menerima intensif kaunseling pemakanan individu dengan minuman tinggi kalori dan protein pada sesi perjumpaan pertama (Hari 1). Ini diteruskan dengan dengan kaunseling melalui telefon dan lawatan susulan di rumah oleh Pegawai Dietetik (Hari 3 dan Hari 6). Manakala, pesakit kumpulan kawalan menerima kaunseling umum tanpa diberi minuman tinggi kalori dan protein. Penilaian terakhir dijalankan pada hari 14. Hasil dapatan utama adalah perubahan berat badan diukur menggunakan TANITA dan pengambilan makanan dinilai dengan *24-hour diet recall*. Hasil dapatan kedua adalah kualiti hidup dinilai menggunakan *European Organization for Research and Treatment*

of Cancer Quality of Life Questionnaire version 3.0 (EORTC QLQ-C30) dan status fungsi dinilai dengan mengukur kekuatan tangan.

Durasi intensif intervensi pemakanan ini adalah 14 hari. Seramai 84% pesakit kanser Ginekologi dikategorikan sebagai PG-SGA B dan 16% dikategorikan sebagai PG-SGA C pada sesi perjumpaan pertama. Pada akhir intervensi, terdapat perubahan berat badan yang signifikasi diantara 2 kumpulan ($p<0.001$) dengan 0.14% kenaikan berat pada kumpulan intervensi dan penurunan sebanyak 1.3% berat pada kumpulan kawalan. Pengambilan tenaga dan protein pesakit kumpulan intervensi adalah tinggi berbanding kumpulan kawalan sebanyak 329 kalori/sehari dan 12.2g/sehari, masing-masing ($p<0.001$). Selera makan dan skala emosi (EORTC QLQ-C30 skala) meningkat dengan signifikasi selepas intervensi ($p=0.001$ dan $p=0.003$, masing-masing). Manakala, tiada perubahan signifikasi dilihat pada HGS ($p=0.69$).

Kajian ini menunjukkan intensif intervensi pemakanan yang menggabungkan kaunseling pemakanan individu, minuman tinggi kalori dan protein, kaunseling melalui telefon dan lawatan susulan di rumah dapat meningkatkan pengambilan kalori dan protein di kalangan pesakit kanser Ginekologi, dan seterusnya meningkatkan berat. Justeru, kesemua pesakit kanser Ginekologi perlu menjalani saringan risiko malpemakanan pada perjumpaan pertama ke klinik dan mereka yang didapati mempunyai masalah malpemakanan perlu mendapatkan intervensi pemakanan awal oleh Pegawai Dietetik dengan menggabungkan pendekatan intensif intervensi pemakanan.

ACKNOWLEDGEMENTS

First of all, from the bottom of my heart, I would like to thank my supervisor Dr Zalina Abu Zaid for her consistent support and guidance during the running of this research. I appreciate her contributions of time and ideas to make my work productive. Her valuable suggestions, comments and guidance encourage me to learn more day by day. Besides, I also would like to thank all my co-supervisors, Dr Zuriati, Dr Zulfitri and Dr Nor Baizura for their kindness.

Furthermore, very special thanks to my boss and colleagues for their understanding and kindness. Many thanks to all participants that took part in the study and enabled this research to be possible.

To conclude, I cannot forget to thank my husband, my family and friends for all the unconditional support in this very memorable experience. Thank you all.

I certify that a Thesis Examination Committee has met on 14 January 2021 to conduct the final examination of Aini Masitah binti Mohammad on her thesis entitled "Effect of Intensive Nutrition Intervention on Nutritional Status, Hand Grip Strength, and Quality of Life on Malnourished Pre-Operative Gynecological Cancer Patients at a Cancer Institute" in accordance with the Universities and University Colleges Act 1971 and the Constitution of the Universiti Putra Malaysia [P.U.(A) 106] 15 March 1998. The Committee recommends that the student be awarded the Master of Science.

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Date: 08 July 2021

Declaration by graduate student

I hereby confirm that:

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LIST OF ABBREVIATIONS

$(\Delta)^2$	Differences to be detect
BIA	Bioelectrical impedance analysis
BMI	Body Mass Index
CDC	Centers for Disease Control and Prevention
CG	Control Group
CNS	Central Nervous System
CR	Crude Incidence Rate
CRC	Colorectal cancer
EN	Enteral Nutrition
EORTC QLQ-C30	European Organization for Research and Treatment of Cancer
ESPEN	The European Society for Clinical Nutrition and Metabolism
FACT	Functional Assessment of Cancer therapy
GC	Gynecological Cancer
GI	Gastrointestinal
IDNT	International Dietetics and Nutrition Terminology
IG	Intervention Group
MDC	Multidisciplinary Clinic
MNCRR	Malaysian National Cancer Registry Report
MNT	Medical Nutrition Therapy
MRN	Medical Record Number
MST	Malnutrition Screening Tool
MUAC	Mid-upper arm circumferences
MUST	Malnutrition Universal Screening Tool
NMRR	National Medical Research Register
NPC	Nasopharyngeal Cancer
NCI	National Cancer Institute
NCR	National Cancer Registry
NI	Nutrition Intervention
ONS	Oral Nutrition Supplement
PG-SGA	Scored Patient-Generated Subjective Global Assessment
PN	Parenteral Nutrition
QOL	Quality of Life
SF 36	Short Form Health Survey
SGA	Subjective Global Assessment
TSF	Triceps Skinfold Thickness
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

1.1 Background

1.1.1 Cancer

Cancer is a significant global health concern. One in seven deaths worldwide is due to cancer (American Cancer Society, 2015). Based on Malaysian Study on Cancer Survival (MySCan, 2018), cancer is the fourth leading cause of death in Malaysia. Cancer is a disease characterized by the uncontrolled growth and spread of abnormal cells. Cancer can start almost anywhere in human body and they can spread into, or invade, nearby tissues. The latter process is called metastasizing and is a major cause of death from cancer.

There are more than 100 types of cancer which most cancers are usually named for the organs or tissues where the cancers form. Lung cancer for example, starts in cells of the lung while breast cancer starts in the cell of breast. Family history is one of the risk factors of cancer. Others, include exposure to chemical, age, tobacco, alcohol and radiation (NCI, 2020). People who are obese also have higher risk of developing certain types of cancer including endometrium cancer, breast cancer and colon cancer (NCI, 2020).

The occurrence of cancer is increasing because of the growth and aging of the population, especially in economically developed countries (American Cancer Society, 2015; Global cancer statistics, 2015). Besides, the reason of increasing in number of new cases are due to increasing prevalence of established risk factors such as smoking, overweight, physical inactivity, and changing reproductive patterns associated with urbanization and economic development (Global cancer statistics, 2015).

1.1.2 Gynecological Cancer

Gynecological Cancer (GC) is cancers that affect woman's reproductive system. GC account for a significant amount of morbidity and mortality in the world (Wijeratne et al., 2018). GC consist of ovarian cancer, uterine cancer, vaginal cancer, cervical cancer, and vulvar cancer (CDC, 2019). Other types of GC include fallopian tube cancer and placenta cancer.

In 2006, it is reported that 19% of the 5.1 million new cases in women cancer is GC, worldwide (Sankaranarayanan, 2006). The number of GC cases increase to 20% of the 14.1 million new cases by year 2012, worldwide (International Agency for Research on Cancer) (Barman et al., 2017). Cervical cancer, which one of the type of GC was the most common diagnosed cancer in women in year 2012, with an estimated 527 600 new cases globally. It also top four cause of death in women worldwide (American Cancer Society, 2015). Cervical cancer becomes the fourth most commonly diagnosed cancer in women with highest incidence rates were in Central and South America and sub-Saharan Africa (American Cancer Society, 2015).

Besides cervical cancer, ovarian cancer also reported highest incidence among women, where, 238,700 estimated new cases of ovarian cancer reported in 2012 worldwide with 58% of new cases occurred in developing countries (Reid, Permuth and Sellers, 2017). Other type of GC namely uterine cancer (endometrial cancer) also reported high prevalence among women worldwide with 382 069 new cases in 2018 (Zhang et al., 2019). Meanwhile, less common type of GC which is vulvar cancer also reported increase prevalence with 6500 new cases in 2018 (American Cancer Society, 2018).

As for Malaysian population, cervical and ovarian cancer, are in ten most common cancers in year 2012- 2016 (MNCRR, 2019). Cervical cancer was the third most common cancer in women while ovarian cancer was the fourth common cancer in women registered at National Cancer Registry (NCR, 2018). Meanwhile, the National Cancer Incidence reported that endometrial cancer contributed 4.1% cases involving women in 2007 (Wan-Nor-Asyikeen et al., 2016). When compared among the major races, highest incidence rate (CR per 100,000) for cervical cancer is among Chinese population (8.3), followed by Indian (5.6) and Malay (4.1) whereas incidence of ovarian cancer highest among Malay (5.9), followed by Chinese (5.4) and Indian (5.4) (MNCRR, 2019). More than 50% of patients at the point of first diagnosis were already at stage 3 and 4 (MNCRR, 2019).

1.1.3 Treatment of Cancer – Surgery

Surgery is one of the treatments for GC patients and following surgery, certain patients might require radiation or chemotherapy or combination of both. Surgery for GC usually involves removal of the tumor and may also include removal of the cervix, uterus, ovaries and other pelvic organs. Patients going for surgery, is frequently require the intake of additional nutrition (Nho et al., 2014). Nutrition requirements for surgery are higher, if compared to the normal requirements, in order to support speedy recovery. Surgical stress response that characterizes by increased cardiac output and oxygen consumption and mobilization of energy reserved highlights the importance of nutrition body reserve. However, most of the cancer patients do unable to achieve even 50% energy requirement before operation. A study conducted in National Cancer Institute (NCI) between 2014 to 2015, found that female patients were only able to achieve 59% of their energy requirement before treatment started (Norshariza et al., 2017).

The success of surgery does not depend exclusively on technical surgical skills but also on metabolic intervention therapy, taking into account the ability of patient to carry a metabolic load and to provide appropriate nutrition support. Hence, in elective surgery it has been shown that preoperative intervention reduces the stress of surgery by minimize catabolism and support anabolism throughout surgical treatment and allow patients to recover substantially better and faster (Gillis & Carli, 2015).

Besides, study indicated that these preoperative interventions particularly needed in malnourished cancer patients that going for surgery (for long term outcome) (Kabata et al, 2015). Identifying nutritionally deficient patients allows preoperative intervention to optimize their nutritional status (Gupta & Gan, 2016). According to ESPEN Guidelines, in order to optimize the mildly malnourished patient, short term (7-10 days) nutritional conditioning has to be considered and longer periods (10-14 days) of nutritional conditioning are necessary for severely malnourished patients.

Finally, understanding that surgical pathways are designed with a different aim in mind (improve patient care and satisfaction), thus patients that went for elective surgery rarely being offered a preoperative optimization package. Besides, cancer patients have limited time from the time they take to consider and decide for surgery to the actual surgical date, make it even difficult to initiate these preoperative interventions (Malcolm et al.). Thus, limited study explores successfulness of intervention during these preoperative periods. Hence, our study able to add to the literature by contributing scientific evidence about effect of nutritional intervention during preoperative period among malnourished GC patients.

1.2 Malnutrition in Cancer Patients

Malnutrition is defined as an 'inadequate intake of protein and/or energy over prolonged periods of time resulting in loss of fat stores and/or muscle wasting including starvation-related malnutrition, chronic disease-related malnutrition, and acute disease or injury-related malnutrition' (IDNT, 2010). However, malnutrition among cancer patient occur due to metabolic changes in the patients with cancer itself. The term commonly used to describe this are cancer related malnutrition. Metabolic changes in the cancer patients caused by the tumor or by the cancer therapy which later alter the ability of body to utilize nutrients (Baracos, 2018). These metabolic changes (inflammation, excess catabolism, futile cycling and anabolic resistance) imposed cancer patients with risk of malnutrition as mentioned above.

Malnutrition is common among cancer patients however, what even worse is that many are unrecognized by the healthcare professionals (Somanchi, Tao, & Mullin, 2011). It is reported that the prevalence of malnutrition in patients with cancer ranges from 20% to more than 70% in worldwide studies, (Arends et al., 2017) and approximately 50% of these patients are not identified as having malnutrition problems (Somanchi et al., 2011). Recent published study conducted in National Cancer Institute (NCI) between 2014 to 2015, show that 43.5% of the patients were

malnourished upon admission based on the Subjective Global Assessment (SGA) scores (Norshariza et al., 2017).

Although malnutrition prevalence in cancer patients commonly reported in patients with colon, nasopharyngeal (NPC) and gastric cancer (Norshariza et al., 2017; Nho, Kim & Kwon, 2014; Ncolini et al., 2013), the reported prevalence of malnutrition among GC varies (Nho, et al., 2014; Fuchs-Tarlovsky, Alvarez-Altamirano, Turquie-Sacal, Alvarez-Flores, Hernandez-Steller, 2013). A significant proportion of patients with GC patients were found to have malnutrition (Nho et al., 2014; Laky et al., 2007), and patients with ovarian cancer were particularly at risk (Nho et al., 2014; Fuchs-Tarlovsky et al., 2013). Recent study by Obermair and collegues (2017), reported that the prevalence of malnutrition among GC patients were higher in developing countries where between 62% and 88% of patients presented with malnutrition at diagnosis (Obermair, Simunovic, Isenring & Janda, 2017).

1.2.1 Impact of Malnutrition in Patient Undergoing Surgery

The detrimental outcome of cancer patients having malnutrition reported in many studies. Malnutrition in cancer patients affects the quality of life (QOL) of the patients, increase risk of functional impairment, delayed wound healing and depletion of muscle (Ravasco, 2019; Fuchs-Tarlovsky et al., 2013). In patients requiring surgery, malnutrition in cancer patient is associated with increased risk of postoperative complications, increase length of hospital stay (LOS) and greater risk of mortality (Gillis & Wischmeyer, 2019).

Studies indicates that malnutrition is a modifiable risk factor surgery (Zhong, Kang & Shu, 2015; Burden, Todd, Hill & Lal, 2012). As malnourished cancer patients associated with greater risk of complication post surgery, implementing preoperative intervention significantly associated with improving clinical outcomes in malnourished cancer patients (Gillis & Wischmeyer, 2019).

In addition, in order to provide preoperative intervention, appropriate malnutrition screening in the hospital setting should be carried out. Nutritional screening not only, should be performed on all patients on admission to the hospital, but also for the outpatients during appointment with outpatient clinic (Barton, 2012). The aim of nutritional screening is to provide an indication of the nutritional status of the patients and to assess whether those patients' nutritional needs are being met, thereby identifying patients who are at risk of, or experiencing, nutritional deficits before progression to malnutrition (Reber et. al, 2019). Later, those identified as malnourished, or at risk of malnutrition following nutritional screening, should be referred for a complete nutritional assessment by a dietitian which is believe as an essential step in the global management of cancer patients (Nicolini et al., 2013).

1.3 Nutritional Pre-habilitation

Recently, the term of "Pre-habilitation" has been introduced with aim to optimize nutrient stores and metabolic reserve preoperatively and provide an adequate buffer to compensate for the catabolic response of critical illness or surgery (Figure 1.1). Later, emerging studies conduct to explore the impact of nutrition-only outcome of pre-habilitation. Gillis et al., 2018, in the study, found that nutrition is a key component of pre-habilitation interventions. Nutritional pre-habilitation is an approach that optimizes the patient's nutritional status before major elective surgery especially for those patients with high risk preoperative conditioning.

It has been shown that nutritional pre-habilitation improves energy and protein intake of patients in the treatment group (Burden et al., 2017; Manasek et al., 2016). In these studies, patients in the treatment group received dietary counselling and oral nutrition supplements (ONS). However, the colorectal cancer (CRC) patients in both studies, failed to maintain or improve their weight pre-operatively and were unable to manage more than 75% compliance towards the prescribed ONS. Furthermore, the provision of ONS varied individually in these studies; thus, which suggesting potential bias.

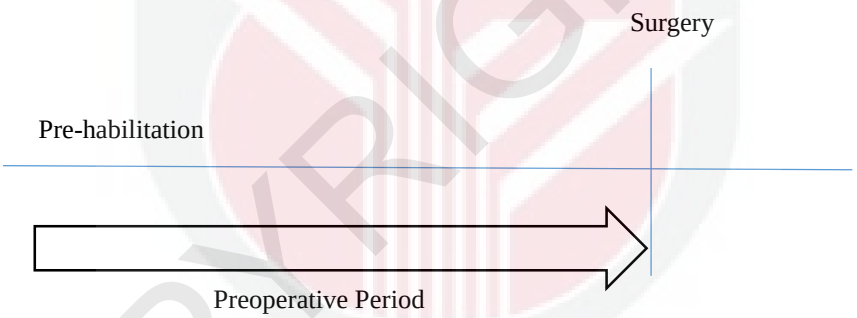

Figure 1.1: Pre-habilitation Assessment and interventions designed to improve outcomes are beginning with the preoperative period (pre-habilitation) (Source: Gillis et al.,2018)

1.4 Early and Intensive Nutrition Intervention

Meanwhile, it has been agreed that early identification play an important part in overall nutrition intervention. Early identification allows for early intervention (commence at time of diagnosis) and early intervention is necessary to improve nutritional outcome (Richards et al., 2020). Study conducted by Hanna and colleagues (2018) proven that early and intensive nutritional intervention (INI), which incorporated individualised dietary counselling, provision of ONS, and regular follow-up, were found to improve nutritional status and QOL among upper gastrointestinal

and head and neck cancer (HNC) patients undergoing radiotherapy (Hanna et al, 2018). Early nutrition intervention important in optimizing patient's nutritional status so that their bodies can receive optimal effects of their cancer treatment (ESPEN, 2017).

However, 32% patients were not referred to a dietitian for immediate nutritional assessment even though met the screening criteria (Baldwin, Spiro, Ahern & Emery, 2012). It is state that staff in the outpatient department overlook patients who need the proper nutritional intervention. Again, patient was mostly identified as at risk of malnutrition or having malnutrition during hospital admission (Baldwin et al., 2012).

Recent study by William & Wischmeyer (2017), reveals significant deficiencies in nutritional screening and intervention in US and European colorectal and oncologic surgical patients with only 1% in five US hospitals currently utilizing a formal nutrition screening process. This finding contradict with data that claimed 83% of surgeons in US support preoperative nutrition optimization to reduce perioperative complications. Only 20% of US oncologic surgery patients receive any nutritional supplements in preoperative setting.

INI which include individualize dietary counselling, provision of ONS and regular follow-up shown to exhibit greater energy and protein intake compared to standard group (Uster et al., 2013; Isenring et al., 2013). Meanwhile, Furness et al. (2014) in the study demonstrated that early intervention with intensively planned dietetic contact able to enhance oral intake and show higher global QOL as well as better functional and symptom scores.

Dietitians play an important role in nutrition intervention, particularly on their role of providing dietary counselling. As stated in ESPEN Guideline (2017), where, in order to optimize nutrient intake among malnourished cancer patients, individualized dietary counselling is crucial (Ravasco, 2019). Research have proven effectiveness of dietary counseling in nutritional status outcome. An intervention study conducted in CRC patients found that individualized dietary counseling is effective in increase patients' nutritional intake, nutritional status and also QOL (Zalina et al., 2016). Besides, another study performed in oncology outpatients whose receiving radiotherapy to gastrointestinal and HNC, conclude individualized dietary counseling beneficial in minimizing weight, declining in nutritional status, and QOL (Bossola, 2015; Isenring et al., 2004). Finally, study in patients with CRC and gastric cancer (Furness et al., 2014) has shown that nutritional counseling given early which is start at time of diagnosis result in fewer weight loss. However, the effects of individualized dietary counselling among GC patients pre-operatively have been underexplored.

Nutrition requirement for surgery is higher if compared with normal requirement in order to support speedy recovery for cancer patients. However, most of the cancer patients do unable to achieve even 50% of the energy requirements before operation, resulting in further depletion of their nutritional status (Menon et al., 2014). This will

cause further depletion of nutritional status of patient. Thus, ONS is typically proposed to provide option or alternative for these patients to acquire the recommended nutrient intake (ESPEN, 2017). ONS play an important part in management of malnourished cancer patients. Provision of ONS show positive outcome on nutritional status, QOL and functional status in gastrointestinal (GI) and HNC outpatient receiving radiotherapy (Isenring, Capra, & Bauer, 2014). A study by Yamamoto et al. (2017) documented provision of ONS pre-operatively among gastric cancer patients results in higher energy and protein intake. Another study conducted among colon cancer patients (Manasek et al., 2016), also reported higher energy and protein intake after provision of ONS pre-operatively. However, to our knowledge, the effectiveness of the provision of ONS preoperatively among GC patients, especially those with nutritional risk, was not explored, which highlighted the need to explore the effects of the provision of ONS preoperatively among malnourished GC patients in this study.

Again early screening, detection of patients with risk of malnutrition allow for an early patient tailored nutritional intervention before operation should be carried out to reduce or even reverse the poor nutritional status in cancer patient before operation and promoting rapid recovery after operation. Meanwhile since many cancer patients were malnourished and presented with poor appetite and weight loss, hence, they required INI to optimize nutritional status preoperatively.

1.5 Adherence towards Nutrition Intervention

The adherence of patient to dietary advice is crucial as well in diet management. Goals of diet management is to achieve with patients' cooperation and adherence on diet advice. A systematic review by Hubbard et al. (2012), suggested that good adherence can be achieved if patients received extra care and more visit and encouragements. Efforts to improve compliances on ONS intake is crucial as to maximize the clinical and cost-effectiveness of ONS in management of malnutrition.

Study of Morey et al. (2009) showed that telephone counseling and home-visit are helpful in increasing patients' adherence on dietary advice. Telephone counselling was revealed to be important in providing social support and self-efficacy, while the suggested time required for each telephone call counselling session was around 15 to 30 minutes only. It is more time-consuming for patients if they are required to travel to the clinic (for their appointment). During each telephone call the counselor worked with the participant to monitor progress, provide reinforcement, explore strategies in overcoming barriers, field questions, direct participants to appropriate resources, and establish future goals. Automated telephone messages which provided additional and intermittent reinforcement also shown positive outcome on diet adherence among patients. Considering that greater adherence to the prescribed ONS and dietary advice serve as a critical component for a successful nutrition intervention, the best pathway of interventions (e.g. face-to-face counselling, ONS, and telephone counselling as follow-up) that can improve nutritional outcome should be critically explored in order to improve the current practices, especially in managing cases that involve malnourished cancer patients.

Even though, multiple interventions have demonstrated a positive effect on dietary adherence compared to a control group, it is unknown of the optimal combination of interventions to enhance adherence to ONS prescribed and dietary advice for malnourished GC patient. Which known that GC patient often experience early satiety.

1.6 Problem Statement

The present practice in NCI, patient who has been scheduled for surgery will be admitted to the ward only 2 to 3 days prior to the operation date. Even they usually were not been referred to dietitian to assess their nutritional status and intervene malnutrition pre-operatively during their visit at clinic. Patients were only seen by dietitian during their admission to the ward. Apparently, patients who are been referred to dietitian due of their poor oral intake. However, these GC patients were already in the state of malnourished prior to the surgery. Even though these patients have been intervened by the dietitian, is not enough to optimize their nutritional status. Cancer patients are less likely able to be nutritionally built up as recommended by ESPEN 2017 in short period (Laky, Janda, Kondalsamy-Chennakesavan, Cleghorn, Obermair, 2010). Besides, most of the time, surgery treatment needs to be delayed due to the nutritional status of these patient is not optimized for surgery.

Traditionally, the focus was during post operative phase and rarely or limited studies focus on pre-operative phase. Later, more studies start to explore the effect of pre-operative intervention but limited on the use of parentarel nutrition (PN) and enteral nutrition intervention (Burden et al., 2012; Elia et al., 2006). Recently, more studies explore the impact of dietary counseling and ONS during pre-operative phase (Gillies et al., 2018; Gillis et al., 2016; Manasek et al., 2016). Those studies show higher energy and protein intake and smaller decrease in weight (Gillis et al., 2018; Kabata et al., 2015). However, to our best knowledge, none sample GC patients and outcome effect on malnourished (mostly mixed baseline nutritional status) patient unknown (Steenhagen et al., 2019). Additionally, those studies failed to demonstrate and discuss any benefit of nutrition intervention (NI) on functional status and quality of life (Gillies et al., 2018; Smedley et al., 2004). Thus, future study need to determine the optimal NI to improve nutritional status among malnourished cancer patients pre-operatively. As the prevalence of GC cases in Malaysia rising, a careful attention required on the malnutrition occurrence among those GC patients and appropriate intervention should be given. We believed that there is need of comprehensive study of understand and investigate the effect of INI (individualized dietary counseling, ONS and regular follow-up (telephone and home visit)) in management of malnourished cancer patient in pre-operative phase.

Besides, even though compliance malnourished patients with ONS prescribed and dietary advice was documented before but gap regarding role of dietitian (particularly) in reinforce or encourage compliance need to be further study. The benefit of individualized dietary counselling and provision of ONS among HNC and GI patients

had shown improvement in nutritional status and QOL. However, the effects of individualized dietary counselling among GC patients and beneficial of provision ONS among malnourished GC patients, especially during preoperative phase have been underexplored. Meanwhile, the most importance component of any intervention are patients' adherence towards dietary advices. Therefore, further research needed in order to find good practices that benefit the patients' the most.

As summary, published studies reported the high prevalence of pre-operative malnutrition among GC patients and NI are recommended to improve outcome in those malnourished cancer patients. Recently, emerging studies conducted to explore the effect of NI pre-operatively, however, none sample GC patient. Meanwhile, those studies unable to demonstrate benefit of NI to malnourished patient, additionally, finding in those studies were not comprehensive.

The increasing interest in surgical preoperative intervention for surgical cancer patients stems for growing, however limited, evidence that such intervention pathway can improve outcomes. The aims of current study was to determine if early and INI approaches, compared control group can improve nutritional, functional status and QOL in GC Outpatients. Besides, INI proposed in the study was to provide continuous professional support to malnourished cancer. The obtained results of this study documented the significance of screening for risk of malnutrition in the early clinic visit and involving a research dietitian to provide nutrition intervention as early as possible.

1.7 Objectives

1.7.1 General Objective

To determine the effect commencing of early and INI on nutritional, functional status and QOL among malnourished GC outpatient as compared to a control group in NCI.

1.7.2 Specific Objectives

1. To determine and compare nutritional status (anthropometric, biochemical, dietary intake, malnutrition), functional status and QOL between control group and intervention group of GC patients.
2. To compare the effect of intensive nutrition intervention on nutritional, functional outcome and QOL from baseline to pre-operatively between control group and intervention group of GC patients in NCI.

1.8 Research Hypotheses

1. There is a significant difference in nutritional, functional status and QOL between IG and CG.
2. There is a better nutritional, functional status and QOL outcomes for those that receives the intensive nutrition intervention than those in control group.

1.9 Research Questions

What is the effect of providing intensive nutrition intervention among malnourished GC patients during pre-operative phase?

1.10 Conceptual Framework

Intensive nutrition intervention that include individualized dietary counseling, provision of ONS and follow-up by phone and home visit, among malnourished GC patients will improve nutritional status, QOL and functional status (Figure 1.2).

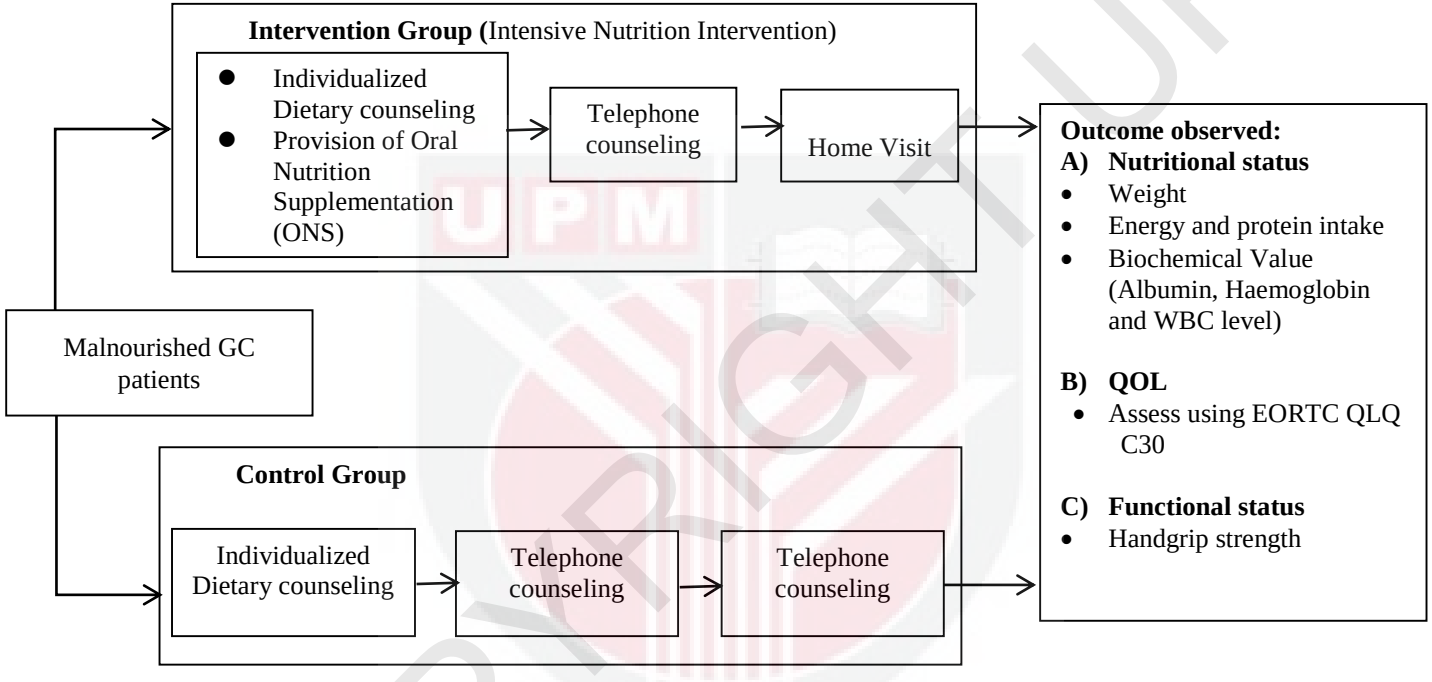

Figure 1.2: Conceptual framework

1.11 Significance of Study

Malnutrition imposed negative health outcome for GC cancer patients prior of treatment. For GC patients that requiring surgery, malnutrition is associated with reduced QOL, morbidity and mortality. Nutrition pre-habilitation that aimed to improve nutritional outcome of cancer patients has been extensively studied recently. The idea is to capitalize time during preoperative phase to improve patients' nutritional status especially those with risk of malnutrition or malnourished.

However, past studies were not able to demonstrate weight changes among patients preoperatively and none of these studies sampled malnourished GC patients, particularly within the local settings. Therefore, the current study aimed to improve the weight and energy and protein intake of GC patients during the preoperative phase and identify effective strategies that improve their nutritional outcomes. Our study which not only aim to improve patients' nutritional status during preoperative phase but also identifying pathway that could improve their functional and QOL especially among GC outpatient.

Results of this study also could help documented the urgent need of screening for risk of malnutrition during 1st visit at clinic and the need of dietitian in involvement to provide nutrition intervention as early as possible. Dietitians play an important role in nutrition intervention, particularly on their role of providing dietary counselling. Thus, in patients with risk of malnutrition, it is important to ensure these patients were intervening earlier.

Besides, further research on multidisciplinary approach is needed in order to find good practices that benefit the patients' the most. Multidisciplinary approached not only improved QOL but also has resulted in better care of cancer patients based on study conducted in United States of America (Abdulrahman, 2011). Besides, the management of cancer patients are more consistent with the implementation of multidisciplinary approach, which was the common problems before the implementation take place. Hence, in this study, we could understand better the effectiveness of multidisciplinary (surgeon, dietitian, staff nurse) approach in management of GC patients, especially in current institute.

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